AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

1–28–94
Vol. 59 No. 19

federal register

Friday
January 28, 1994

United States
Government
Printing Office
SUPERINTENDENT
OF DOCUMENTS
Washington, DC 20402

OFFICIAL BUSINESS
Penalty for private use, $300

SECOND CLASS NEWSPAPER

Postage and Fees Paid
U.S. Government Printing Office
(ISSN 0097–6326)

1–28–94
Vol. 59 No. 19
Pages 3981–4232

federal register

Friday
January 28, 1994

Briefings on How To Use the Federal Register
For information on briefings in Washington, DC, see announcement on the inside cover of this issue.

FEDERAL REGISTER Published daily, Monday through Friday, (not published on Saturdays, Sundays, or on official holidays), by the Office of the Federal Register, National Archives and Records Administration, Washington, DC 20408, under the Federal Register Act (49 Stat. 500, as amended; 44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). Distribution is made only by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

The **Federal Register** provides a uniform system for making available to the public regulations and legal notices issued by Federal agencies. These include Presidential proclamations and Executive Orders and Federal agency documents having general applicability and legal effect, documents required to be published by act of Congress and other Federal agency documents of public interest. Documents are on file for public inspection in the Office of the Federal Register the day before they are published, unless earlier filing is requested by the issuing agency.

The seal of the National Archives and Records Administration authenticates this issue of the **Federal Register** as the official serial publication established under the Federal Register Act. 44 U.S.C. 1507 provides that the contents of the **Federal Register** shall be judicially noticed.

The **Federal Register** is published in paper and 24x microfiche format. The annual subscription price for the **Federal Register** paper edition is $444, or $490 for a combined **Federal Register**, Federal Register Index and List of CFR Sections Affected (LSA) subscription; the microfiche edition of the **Federal Register** including the Federal Register Index and LSA is $403. Six month subscriptions are available for one-half the annual rate. The charge for individual copies in paper form is $6.00 for each issue, or $6.00 for each group of pages as actually bound; or $1.50 for each issue in microfiche form. All prices include regular domestic postage and handling. International customers please add 25% for foreign handling. Remit check or money order, made payable to the Superintendent of Documents, or charge to your GPO Deposit Account, VISA or MasterCard. Mail to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954.

There are no restrictions on the republication of material appearing in the **Federal Register.**

How To Cite This Publication: Use the volume number and the page number. Example: 59 FR 12345.

SUBSCRIPTIONS AND COPIES

PUBLIC

Subscriptions:

Paper or fiche	202–783–3238
Assistance with public subscriptions	512–2303

Single copies/back copies:

Paper or fiche	783–3238
Assistance with public single copies	512–2457

FEDERAL AGENCIES

Subscriptions:

Paper or fiche	523–5243
Assistance with Federal agency subscriptions	523–5243

For other telephone numbers, see the Reader Aids section at the end of this issue.

THE FEDERAL REGISTER
WHAT IT IS AND HOW TO USE IT

FOR: Any person who uses the Federal Register and Code of Federal Regulations.

WHO: The Office of the Federal Register.

WHAT: Free public briefings (approximately 3 hours) to present:

1. The regulatory process, with a focus on the Federal Register system and the public's role in the development of regulations.
2. The relationship between the Federal Register and Code of Federal Regulations.
3. The important elements of typical Federal Register documents.
4. An introduction to the finding aids of the FR/CFR system.

WHY: To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

WASHINGTON, DC
(TWO BRIEFINGS)

WHEN: February 17 at 9:00 am and 1:30 pm
WHERE: Office of the Federal Register, 7th Floor Conference Room, 800 North Capitol Street NW, Washington, DC (3 blocks north of Union Station Metro)
RESERVATIONS: 202–523–4538

Printed on recycled paper containing 100% post consumer waste

Contents

Federal Register

Vol. 59, No. 19

Friday, January 28, 1994

Agricultural Marketing Service
See Packers and Stockyards Administration
PROPOSED RULES
Watermelon research and promotion plan, 4013–4014

Agriculture Department
See Agricultural Marketing Service
See Forest Service
See Packers and Stockyards Administration
See Rural Electrification Administration
RULES
Meat import limitations:
Australia and New Zealand, 3981–3982

Air Force Department
NOTICES
Meetings:
Scientific Advisory Board, 4047

Army Department
See Engineers Corps
NOTICES
Environmental statements; availability, etc.:
Base realignments and closures—
Sacramento Army Depot, CA, 4046
Meetings:
Armed Forces Epidemiological Board, 4047

Arts and Humanities, National Foundation
See National Foundation on the Arts and the Humanities

Blind or Severely Disabled, Committee for Purchase From People Who Are
See Committee for Purchase From People Who Are Blind or Severely Disabled

Centers for Disease Control and Prevention
NOTICES
Grants and cooperative agreements; availability, etc.:
National/regional minority organizations HIV/STD prevention, immunization, and TB projects, 4083–4084

Children and Families Administration
NOTICES
Agency information collection activities under OMB review, 4075–4076
Grants and cooperative agreements; availability, etc.:
Planned secondary resettlement program, 4076
Runaway and homeless youth program, 4076–4080

Commerce Department
See International Trade Administration
See Minority Business Development Agency
See National Institute of Standards and Technology
See National Oceanic and Atmospheric Administration

Committee for Purchase From People Who Are Blind or Severely Disabled
NOTICES
Procurement list; additions and deletions, 4042–4044

Committee for the Implementation of Textile Agreements
NOTICES
Cotton, wool, and man-made textiles:
Bangladesh, 4039
Brazil, 4039–4040
Indonesia, 4040
Sri Lanka, 4040–4041
Export visa requirements; certification, waivers, etc.:
Costa Rica, 4041–4042

Commodity Futures Trading Commission
NOTICES
Contract market proposals:
Chicago Mercantile Exchange et al.—
Common banking and settlement system, 4044–4045

Congressional Budget Office
NOTICES
Balanced Budget and Emergency Deficit Control Reaffirmation Act (Gramm-Rudman-Hollings):
Sequestration preview report for 1995 FY transmittal to Congress and OMB, 4232

Defense Department
See Air Force Department
See Army Department
See Engineers Corps
See Navy Department
NOTICES
Garnishment of Federal civilian employees wages for commercial pay for debt, 4046–4047
Meetings:
Defense Intelligence Agency Scientific Advisory Board, 4045–4046

Drug Enforcement Administration
NOTICES
Applications, hearings, determinations, etc.:
San Diego Academy of Justice, 4101–4102
Santos, Miquel A., M.D., 4102–4103
Shah, Jayen C., M.D., 4103–4104

Education Department
RULES
Postsecondary education:
State student incentive grant program, 4220–4223

Employment and Training Administration
NOTICES
Environmental statements; availability, etc.:
Detroit Job Corps Center, MI, 4104–4106
Grants and cooperative agreements; availability, etc.:
Job Training Partnership Act—
Migrant and seasonal farmworker programs, 4106–4112

Employment Standards Administration
NOTICES
Minimum wages for Federal and federally-assisted construction; general wage determination decisions, 4113

Energy Department
See Federal Energy Regulatory Commission

NOTICES
Environmental statements; availability, etc.:
Hanford Site, WA; tank waste remediation system and storage of high-level radioactive waste, 4052–4058
Floodplain and wetlands protection; environmental review determinations; availability, etc.:
Oak Ridge, TN, 4058
Meetings:
Clean coal international technology transfer program, 4058
National Coal Council, 4059
Natural gas exportation and importation:
Amoco Energy Trading Corp., 4059
Kimball Energy Corp., 4059
Tenaska Gas Co. et al., 4059–4060
Wisconsin Gas Co., 4060

Engineers Corps
RULES
Danger zones and restricted areas:
Pacific Ocean offshore Camp Pendleton, CA, 4226
NOTICES
Recreation user fees, 4047–4049

Environmental Protection Agency
RULES
Air quality implementation plans; approval and promulgation; various States:
Colorado, 4003–4004
Illinois, 4001–4003
PROPOSED RULES
Air quality implementation plans; approval and promulgation; various States:
Minnesota, 4016–4019
Water pollution; effluent guidelines for point source categories:
Metal products and machinery, 4019
NOTICES
Air pollutants, hazardous; national emission standards:
Radionuclide emissions from facilities licensed by Nuclear Regulatory Commission and Federal facilities not operated by Energy Department, 4228–4229
Air quality; prevention of significant deterioration (PSD):
Permit determinations, etc.—
Region X, 4064–4065
Drinking water:
Public water supply supervision program—
Florida, 4065
Environmental leadership program; establishment, 4066–4067
Environmental statements; availability, etc.:
Agency statements—
Comment availability, 4065–4066
Weekly receipts, 4065
Technology innovation strategy and environmental technology initiative program plan; documents availability, 4067–4069
Toxic and hazardous substances control:
Chemical testing—
Data receipt, 4069

Equal Employment Opportunity Commission
NOTICES
Meetings; Sunshine Act, 4138

Executive Office of the President
See Trade Representative, Office of United States

Federal Aviation Administration
RULES
Airspace:
Airspace overlying waters between 3 and 12 nautical miles from U.S. coast; warning areas establishment; correction, 3990
Airworthiness directives:
McDonnell Douglas, 3988–3990
Airworthiness standards:
Special conditions—
Agusta model A109C helicopter, 3988
Omnibus Transportation Employee Testing Act of 1991:
Anti-drug program for personnel engaged in specified aviation activities; correction, 3990
PROPOSED RULES
Airworthiness standards:
Special conditions—
Pratt & Whitney models PW4073, PW4084, and PW4088 turbofan engines; correction, 4140
NOTICES
Airport noise compatibility program:
Noise exposure map—
Kissimmee Municipal Airport, FL, 4132–4134
Exemption petitions; summary and disposition, 4134
Meetings:
Aviation Rulemaking Advisory Committee, 4134
Informal airspace meetings—
Texas, 4134–4135

Federal Communications Commission
RULES
Radio stations; table of assignments:
Florida, 4007
Illinois, 4007–4008
Minnesota, 4007
New York, 4008–4009
Ohio, 4008
Washington, 4008
PROPOSED RULES
Radio stations; table of assignments:
North Carolina, 4020
NOTICES
Agency information collection activities under OMB review, 4069–4070

Federal Emergency Management Agency
RULES
Flood insurance; communities eligible for sale:
Indiana et al., 4004–4007

Federal Energy Regulatory Commission
NOTICES
Applications, hearings, determinations, etc.:
ANR Pipeline Co., 4060
CNG Transmission Corp., 4060
Great Lakes Gas Transmission Limited Partnership 4060–4061
Kentucky West Virginia Gas Co., 4061
KN Interstate Gas Transmission Co., 4061
Koch Gateway Pipeline Co., 4061
Mojave Pipeline Co., 4062
Northwest Pipeline Corp., 4062
Panhandle Eastern Pipe Line Co., 4062
Texas Eastern Transmission Corp., 4062–4063
Transcontinental Gas Pipe Line Corp., 4063–4064
Trunkline Gas Co., 4064
Valero Transmission, L.P., 4064

Federal Maritime Commission
NOTICES
Agreements filed, etc., 4070–4071
Casualty and nonperformance certificates:
Commodore Cruise Line, Inc., 4071
Commodore Cruise Line, Inc., et al., 4071
Neckermann Und Reisen, 4071
Regency Cruises Inc. et al., 4071

Federal Mine Safety and Health Review Commission
NOTICES
Meetings; Sunshine Act, 4138

Federal Reserve System
NOTICES
Meetings; Sunshine Act, 4138
Applications, hearings, determinations, etc.:
Arvest Bank Group, Inc., et al., 4071–4072
First Bancorporation of Ohio et al., 4072
First Rainsville Bancshares, Inc., et al., 4072–4073
First Union Corp. et al., 4073
Mahaska Investment Co. et al., 4073–4074
Pointe Financial Corp. et al., 4074
Smith, Wiley William, et al., 4074

Financial Management Service
See Fiscal Service

Fiscal Service
NOTICES
Interest rates:
Renegotiation Board and prompt payment rates, 4135

Fish and Wildlife Service
NOTICES
Meetings:
Endangered Species of Wild Fauna and Flora International Trade Convention, 4096–4099

Food and Drug Administration
RULES
Color additives:
D&C Violet No. 2, 3998
Human drugs:
Cold, cough, allergy, bronchodilator, and antiasthmatic products (OTC)—
Antihistamine products; monograph amendment, 4216–4218
Dandruff, seborrheic dermatitis, and psoriasis products (OTC); monograph amendment, 4000–4001
Labeling policy (OTC); interchangeable words; monograph requirement, 3998–4000
PROPOSED RULES
Hazard Analysis Critical Control Point (HACCP) principles:
Fish and fishery products, safe processing and importing; procedures, 4142–4214
Human drugs:
Wart remover products (OTC); monograph amendment, 4015–4016
NOTICES
Biological products:
Export applications—
UBI HIV 1/2 PHA (passive hemagglutination assay), 4084–4085
Committees; establishment, renewal, termination, etc.:
Special Studies Relating to Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants Advisory Committee, 4085
Food Code; 1993 recommendations of PHS and FDA; availability, 4085–4086

Forest Service
NOTICES
Resource management plans, etc.:
Wallowa/Grande Ronde River, OR and WA, 4094–4095

General Accounting Office
NOTICES
Meetings:
Government Auditing Standards Advisory Council, 4074–4075

General Services Administration
NOTICES
Environmental statements; availability, etc.:
Highgate Springs, VT; border station, 4075

Health and Human Services Department
See Centers for Disease Control and Prevention
See Children and Families Administration
See Food and Drug Administration
See Health Resources and Services Administration
See Public Health Service
See Social Security Administration
NOTICES
Federal claims; interest rates on overdue debts, 4075

Health Resources and Services Administration
See Public Health Service
NOTICES
Grants and cooperative agreements; availability, etc.:
Human immunodeficiency virus (HIV)—
Children, adolescents, and families demonstration program, 4086–4089

Housing and Urban Development Department
NOTICES
Grants and cooperative agreements; availability, etc.:
Facilities to assist homeless—
Excess and surplus Federal property, 4090
Mortgage and loan insurance programs:
Debenture interest rates, 4091–4092
Mortgagee Review Board; administrative actions, 4090–4091

Interior Department
See Fish and Wildlife Service
See Land Management Bureau
See National Park Service

Internal Revenue Service
RULES
Excise taxes:
Gasoline and diesel fuel registration requirements; correction, 4140
Income taxes:
Property contributed to partnership; allocations reflecting built-in gain or loss; correction, 4140

International Trade Administration
NOTICES
Antidumping:
Stainless steel wire rods from—
Brazil, 4021–4022
France, 4022–4023
Welded stainless steel pipe from—
Malaysia, 4023–4029

Export trade certificates of review, 4029–4030
Applications, hearings, determinations, etc.:
Fordham University et al., 4030

International Trade Commission
NOTICES
Import investigations:
Multibrand infrared remote control transmitters, 4100–4101

Interstate Commerce Commission
NOTICES
Motor carriers:
Compensated intercorporate hauling operations, 4101
Railroad operation, acquisition, construction, etc.:
West Central Ohio Port Authority, 4101

Justice Department
See Drug Enforcement Administration

Labor Department
See Employment and Training Administration
See Employment Standards Administration
See Mine Safety and Health Administration
See Pension and Welfare Benefits Administration

Land Management Bureau
NOTICES
Environmental statements; availability, etc.:
Butte District, MT; predator management, 4092
Oil and gas leases:
Wyoming, 4092–4093
Realty actions; sales, leases, etc.:
Idaho, 4093–4094
Resource management plans, etc.:
Wallowa/Grande Ronde River, OR and WA, 4094–4095
Survey plat filings:
Arizona, 4095–4096
Withdrawal and reservation of lands:
New Mexico, 4096

Mine Safety and Health Administration
NOTICES
Safety standard petitions:
Martinka Coal Co. et al., 4113–4114

Mine Safety and Health Federal Review Commission
See Federal Mine Safety and Health Review Commission

Minority Business Development Agency
NOTICES
Business development center program applications:
Arkansas, 4030
Louisiana, 4031

National Foundation on the Arts and the Humanities
NOTICES
Meetings:
Arts in Education Advisory Panel, 4117
Arts National Council, 4119–4120
Challenge and Advancement Advisory Panel, 4117–4118
Expansion Arts Advisory Panel, 4118
Literature Advisory Panel, 4118–4119
Media Arts Advisory Panel, 4119

National Institute of Standards and Technology
NOTICES
Information processing standards, Federal:
Government Open Systems Interconnection Profile (GOSIP), 4031–4032
Open Document Architecture (ODA) Raster Document Application Profile (DAP), 4032–4034
Portable operating system interface (POSIX), 4034–4037
Laboratory Accreditation Program, National Voluntary:
Electric motors energy efficiency testing program, 4037–4038

National Oceanic and Atmospheric Administration
RULES
Fishery conservation and management:
Bering Sea and Aleutian Islands groundfish, 4009–4012
NOTICES
Permits:
Endangered and threatened species, 4038

National Park Service
NOTICES
Environmental statements; availability, etc.:
Natchez Trace Parkway, MS, 4099
Meetings:
Jimmy Carter National Historic Site Advisory Commission, 4099
Salt River Bay National Historical Park and Ecological Preserve at St. Croix, VI Commission, 4099–4100

National Science Foundation
NOTICES
Meetings:
DOE/USGS/NSF Continental Scientific Drilling Council, 4120
Geosciences Advisory Committee, 4120
Organization, functions, and authority delegations:
Agency relocation to Arlington, VA, 4120

Navy Department
NOTICES
Environmental statements; availability, etc.:
Base realignments and closures—
Long Beach Naval Hospital, CA, 4049–4050
Naval Shipyard, Puget Sound, WA; Pier D area dredging, 4050
Portsmouth Naval Shipyard, ME, et al.; short-term naval spent fuel storage, 4051–4052

Nuclear Regulatory Commission
NOTICES
Meetings:
Reactor Safeguards Advisory Committee, 4120–4121
Organization, functions, and authority delegations:
Local public document room relocation and establishment—
University of California at Los Angeles Research Reactor; West Los Angeles Regional Library, CA; closing, 4121
Applications, hearings, determinations, etc.:
Indiana University School of Medicine, 4123–4125
Pacific Gas & Electric Co., 4121–4123

Office of United States Trade Representative
See Trade Representative, Office of United States

Packers and Stockyards Administration
NOTICES
Central filing system; State certifications:
Oklahoma, 4021
Stockyards; posting and deposting:
Bagley Livestock Exchange, Inc., MN, et al., 4021

Pension and Welfare Benefits Administration
NOTICES
Employee benefit plans; prohibited transaction exemptions:
Grant, Frederick J., M.D., A.P.C., et al., 4114–4117

Personnel Management Office
NOTICES
Meetings:
Federal Prevailing Rate Advisory Committee, 4125–4126

Postal Service
NOTICES
Meetings; Sunshine Act, 4138–4139

Public Health Service
See Centers for Disease Control and Prevention
See Food and Drug Administration
See Health Resources and Services Administration
NOTICES
President's Council on Physical Fitness and Sports; Great American Workout participation opportunity, 4089–4090

Railroad Retirement Board
RULES
Railroad Retirement Act:
Representative payment; selection, payment, responsibilities, and monitoring, 3990–3996
Railroad Unemployment Insurance Act:
Normal and extended benefits; duration, 3996–3998

Rural Electrification Administration
RULES
Electric loans:
Operational controls exemptions, 3982–3988

Securities and Exchange Commission
NOTICES
Self-regulatory organizations; proposed rule changes:
American Stock Exchange, Inc., 4126–4127
Chicago Stock Exchange, Inc., 4127–4128
Midwest Stock Exchange, Inc., 4128–4130
Applications, hearings, determinations, etc.:
Public utility holding company filings, 4130–4131

Social Security Administration
NOTICES
Social security rulings:
Equal Access to Justice Act; timely filing for attorney fees, 4080–4083

State Department
NOTICES
Privacy Act:
Systems of records, 4131–4132

Textile Agreements Implementation Committee
See Committee for the Implementation of Textile Agreements

Trade Representative, Office of United States
NOTICES
Intellectual property rights protection, countries denying; policies and practices:
Brazil, 4135–4136

Transportation Department
See Federal Aviation Administration

Treasury Department
See Fiscal Service
See Internal Revenue Service

Veterans Affairs Department
NOTICES
Agency information collection activities under OMB review
Amounts on deposit for deceased veterans; application, 4136
Individualized tutorial assistance; enrollment certification and application, 4136–4137
Notice of default, 4136
Committees; establishment, renewal, termination, etc.:
Environmental Hazards Advisory Committee, 4137

Separate Parts In This Issue

Part II
Department of Health and Human Services, Food and Drug Administration, 4142–4214

Part III
Department of Health and Human Services, Food and Drug Administration, 4216–4218

Part IV
Department of Education, 4220–4223

Part V
Department of Defense, Corps of Engineers, 4226

Part VI
Environmental Protection Agency, 4228–4229

Part VII
Congressional Budget Office, 4232

Reader Aids
Additional information, including a list of public laws, telephone numbers, and finding aids, appears in the Reader Aids section at the end of this issue.

Electronic Bulletin Board
Free **Electronic Bulletin Board** service for Public Law numbers and **Federal Register** finding aids is available on 202–275–1538 or 275–0920.

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

7 CFR
16.....3981
1710.....3982
1717.....3982
Proposed Rules:
1210.....4013

14 CFR
27.....3988
39.....3988
73.....3990
121.....3990
Proposed Rules:
33.....4140

20 CFR
266.....3990
336.....3996

21 CFR
74.....3998
310.....4216
330.....3998
341.....4216
358.....4000
369.....4216
Proposed Rules:
123.....4142
358.....4015
1240.....4142

26 CFR
1.....4140
40.....4140
48.....4140
602.....4140

33 CFR
334.....4226

34 CFR
692.....4220

40 CFR
52 (2 documents).....4001, 4003
Proposed Rules:
52.....4016
438.....4019

44 CFR
64.....4004

47 CFR
73 (6 documents).....4007, 4008
Proposed Rules:
73.....4020

50 CFR
675 (2 documents).....4009

Rules and Regulations

Federal Register
Vol. 59, No. 19
Friday, January 28, 1994

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF AGRICULTURE

Office of the Secretary

7 CFR Part 16

Restriction on Importation of Meat From Australia and New Zealand

AGENCY: Office of the Secretary, USDA.
ACTION: Final rule.

SUMMARY: This rule amends the regulations entitled "Section 204 Import Regulations" to carry out the voluntary restraint agreements concerning the level of 1994 meat imports from Australia and New Zealand entered into by those countries with the United States pursuant to section 204 of the Agricultural Act of 1956, as amended.

EFFECTIVE DATE: January 28, 1994. See **SUPPLEMENTARY INFORMATION** for applicability dates.

FOR FURTHER INFORMATION CONTACT: Gerald Harvey, (202) 720–8031, Dairy, Livestock and Poultry Division, Foreign Agricultural Service, USDA, room 6616 South Building, Washington, DC 20250.

SUPPLEMENTARY INFORMATION: Pursuant to the authority of section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854), and Executive Order 11539, as amended, the Office of the United States Trade Representative has negotiated agreements with the Governments of Australia and New Zealand whereby those countries have voluntarily agreed to limit the quantity of certain meats exported to the United States during calendar year 1994. The Secretary of Agriculture, with the concurrence of the Secretary of State and the United States Trade Representative, is authorized to carry out such agreements and to implement such action.

Presently, 7 CFR part 16, subpart A entitled "Section 204 Import Regulations" contains provisions governing the entry or withdrawal from warehouse of certain meats imported from Australia and New Zealand during calendar year 1993. This rule amends subpart A to delete the provisions relating to Australia and New Zealand for calendar year 1993 which no longer are in effect and inserts new provisions to carry out the voluntary agreements entered into by Australia and New Zealand with the United States for calendar year 1994.

The definition of meat in the regulations encompasses the Harmonized Tariff Schedules of the United States (HTS) items which are the subject of the voluntary agreements with Australia and New Zealand. In order to prevent circumvention of the import limitations, the definition also includes meat that would fall within such definition but for processing in Foreign-Trade Zones, territories, or possessions of the United States. In addition, the regulations impose transshipment restrictions which prevent the entry or withdrawal from warehouse for consumption of meat from Australia and New Zealand unless exported from those countries as direct shipments or on through bills of lading or, if processed in Foreign-Trade Zones, territories or possessions of the United States, shipped as direct shipments or on through bills of lading from such areas.

Applicability Date

Meat released under the provisions of sections 448(b) and 484(a)(1)(A) of the Tariff Act of 1930 (19 U.S.C. 1448(b) (immediate delivery), and 19 U.S.C. 1484(a)(1)(A) (entry)), prior to January 28, 1994, shall not be denied entry.

This action has been determined to involve foreign affairs functions of the United States. Therefore, this regulation falls within the foreign affairs exception to Executive Order 12291 and the provisions of 5 U.S.C. 553 with respect to proposed rulemaking. Further, the provisions of the Regulatory Flexibility Act do not apply to this rule since the proposed rulemaking provisions of 5 U.S.C. 553 do not apply.

List of Subjects in 7 CFR Part 16

Imports, Meat and meat products.

Accordingly, the regulations at 7 CFR part 16, subpart A entitled "Section 204 Import Regulations" are amended to read as follows:

PART 16—LIMITATION ON IMPORTS OF MEAT

1. The authority citation for part 16 is revised to read as follows:

Authority: 19 U.S.C. 2253 note, 7 U.S.C. 1854, and E.O. 11539 (35 FR 10733), as amended by E.O. 12188 (45 FR 989).

2. Section 16.4 is revised to read as follows:

§ 16.4 Transshipment restrictions.

During calendar year 1994, no meat of Australian or New Zealand origin may be entered or withdrawn from warehouse for consumption in the United States unless (a) it is exported into the Customs Territory of the United States as a direct shipment or on a through bill of lading from the country of origin or, (b) if processed in Foreign-Trade Zones, territories, or possessions of the United States, it is exported into the Customs Territory of the United States as a direct shipment on a through bill of lading from the Foreign-Trade Zone, territory or possession of the United States in which it was processed.

3. Section 16.5 is revised to read as follows:

§ 16.5 Quantiative restrictions.

(a) *Import from Australia.* During calendar year 1994, no more than 664.9 million pounds of meat in Harmonized Tariff Schedule of the United States subheadings 0201.10.00, 0201.20.40, 0201.20.60, 0201.30.40, 0201.30.60, 0202.10.00, 0202.20.40, 0202.20.60, 0202.30.40, 0202.30.60, 0204.21.00, 0204.22.40, 0204.23.40, 0204.41.00, 0204.42.40, 0204.43.40, or 0204.50.00 may be entered or withdrawn from warehouse for consumption in the United States, whether shipped directly or indirectly from Australia to the United States.

(b) *Imports from New Zealand.* During calendar year 1994, no more than 406.6 million pounds of meat exported from New Zealand in the form in which it would fall within the definition of meat in Harmonized Tariff Schedule of the United States subheadings 0201.10.00, 0201.20.40, 0201.20.60, 0201.30.40, 0201.30.60, 0202.10.00, 0202.20.40, 0202.20.60, 0202.30.40, 0202.30.60, 0204.21.00, 0204.22.40, 0204.23.40, 0204.41.00, 0204.42.40, 0204.43.40, or 0204.50.00 may be entered or withdrawn from warehouse for consumption in the United States,

whether shipped directly or indirectly from New Zealand to the United States.

Issued at Washington, DC this 18th day of January 1994.

Mike Espy,

Secretary of Agriculture.

[FR Doc. 94–1903 Filed 1–27–94; 8:45 am]

BILLING CODE 3410–10–M

Rural Electrification Administration

7 CFR Parts 1710 and 1717

Exemptions of REA Operational Controls

AGENCY: Rural Electrification Administration, USDA.

ACTION: Interim rule with request for comments.

SUMMARY: Pursuant to recent amendment of section 306E of the Rural Electrification Act, the Rural Electrification Administration (REA) hereby amends its regulations governing policies and requirements with respect to controls and approvals of borrower operations and the granting of lien accommodations and subordinations. These changes apply to electric borrowers whose net worth exceeds 110 percent of the outstanding balance of loans made or guaranteed to them by REA.

DATES: This rule is effective on January 28, 1994. Written comments must be received by REA or carry a postmark or equivalent by April 28, 1994.

ADDRESSES: Written comments should be addressed to Mr. F. Lamont Heppe, Jr., Deputy Director, Program Support Staff, U.S. Department of Agriculture, Rural Electrification Administration, room 2234–S, 14th Street and Independence Avenue, SW., Washington, DC 20250–1500. REA requires a signed original and 3 copies of all comments (7 CFR 1700.30 (e)). Comments will be available for public inspection during regular business hours (7 CFR 1.27(b)).

FOR FURTHER INFORMATION CONTACT: Mr. Alex Cockey, Deputy Assistant Administrator—Electric, U.S. Department of Agriculture, Rural Electrification Administration, room 4037–S, 14th Street & Independence Avenue SW., Washington, DC 20250–1500. Telephone: 202–720–9547.

SUPPLEMENTARY INFORMATION: This regulatory action is issued in conformance with Executive Order 12866, Regulatory Planning and Review. The Administrator of REA has determined that the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) does not apply to this rule. The Administrator of REA has determined that this rule will not significantly affect the quality of the human environment as defined by the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*). Therefore, this action does not require an environmental impact statement or assessment. This rule is excluded from the scope of Executive Order 12372, Intergovernmental Consultation, which may require consultation with State and local officials. A Notice of Final Rule titled Department Programs and Activities Excluded from Executive Order 12372 (50 FR 47034) exempts REA electric loans and loan guarantees from coverage under this Order. This rule has been reviewed under Executive Order 12778, Civil Justice Reform. This rule: (1) Will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule; (2) Will not have any retroactive effect; and (3) Will not require administrative proceedings before any parties may file suit challenging the provisions of this rule.

The program described by this rule is listed in the Catalog of Federal Domestic Assistance Programs under number 10.850 Rural Electrification Loans and Loan Guarantees. This catalog is available on a subscription basis from the Superintendent of Documents, the United States Government Printing Office, Washington, DC 20402–9325.

Information Collection and Recordkeeping Requirements

The existing recordkeeping and reporting burdens contained in this rule were approved by the Office of Management and Budget (OMB) pursuant to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*), under control numbers 0572–0017, 0572–0032, and 0572–0103.

Send questions or comments regarding these burdens or any other aspect of these collections of information, including suggestions for reducing the burden, to the Office of Information and Regulatory Affairs, Office of Management and Budget, room 3201, NEOB, Washington, DC 20503. Attention: Desk Officer for USDA.

Background

Section 306E of the Rural Electrification Act of 1936 (RE Act) was amended on December 17, 1993, by Public Law 103–201. As amended, the section directs the Administrator to issue interim final regulations to minimize approval rights, requirements, restrictions, and prohibitions imposed on the operations of electric borrowers whose net worth exceeds 110 percent of the outstanding loans made or guaranteed to the borrower by REA. The section also directs the Administrator, when requested by a private lender providing financing for capital investments by such borrowers, to offer, without delay, to share the government's lien on the borrowers' systems or subordinate the government's lien on the property financed by the private lender.

In issuing the regulations, the Administrator is authorized to establish requirements, guided by the practices of private lenders with respect to similar credit risks, to ensure that the security for loans made or guaranteed by REA is reasonably adequate. REA understands this to mean that it may consider the practices of private lenders in general, and not just those that have lent or are currently lending to REA borrowers. If the regulations are not issued within 180 days of enactment of section 306E, the Administrator may not, until the regulations are issued, require prior approval of, or establish any requirement, restriction, or prohibition, with respect to the operations of any electric borrower that meets the 110 percent ratio. Nothing in section 306E limits the authority of the Administrator to establish terms and conditions on the use of funds from loans made or guaranteed by REA, or to take other actions specifically authorized by law.

Section 1710.7 added by this rule addresses the application of section 306E of the RE Act to REA operational controls that apply in general to REA borrowers or specifically to REA loans and loan guarantees. The application of section 306E to lien accommodations and subordinations is set forth in new sections 7 CFR 1717.860 and 1717.904.

Section 1710.7—Exemptions of REA Operational Controls Under Section 306E of the RE Act

This section sets forth the policy established by section 306E of the RE Act regarding REA operational controls applied to borrowers that meet the 110 percent net worth ratio; the procedures for determining whether a borrower meets the 110 percent ratio; and the specific operational controls that are or are not exempted for such borrowers.

Borrowers' net worth to REA debt ratios will be determined each year based on data as of December 31, and borrowers will be notified in writing of their respective ratios by May 1 of each year. If a borrower's net worth falls below 110 percent or if the borrower defaults on any requirement of its mortgage, loan contract, or any other agreement with REA that has not been

exempted by REA, REA may reimpose exempted operational controls by informing the borrower in writing.

In calculating net worth, deferred current period expenses properly recordable in accounts 182.2 and 182.3 will be subtracted from total margins and equities. This is the same procedure followed in 7 CFR part 1717, subpart R to determine whether a borrower has sufficient net worth to qualify for advance approval of a lien accommodation. It is intended to prevent net worth from being overstated by the amount of deferred current period expenses. The accounting data used will be based on REA's system of accounts set forth in 7 CFR part 1767. Since sinking fund depreciation is not approved under part 1767, net worth for borrowers using sinking fund depreciation will be calculated as if the borrower had been using straight line depreciation.

Paragraph (c) of § 1710.7 lists 13 operational controls contained in the REA mortgage or loan contract that are exempted for borrowers that meet the 110 percent ratio. These include, for example: The requirement that extensions and additions to the borrower's electric system financed by the borrower's own funds be included in an REA-approved construction work plan; requirements on contract bidding procedures if no REA loan funds are involved; REA approval of construction, engineering, and architectural contracts, and the use of REA standard forms of contracts if no REA loan funds are involved; higher maximum limits on plant additions that may be made without REA approval if no REA loan funds are involved; higher maximum limits on the sale of electric power and energy to ultimate consumers without REA approval; higher maximum limits on the voluntary sale, lease or transfer of any capital asset, without REA approval, in exchange for fair market value; and REA approval of the selection of a borrower's manager, provided that the borrower is not in default.

Two of the 13 exempted operational controls are also exempted for all other borrowers. These are the requirement to obtain REA approval of the purchase of data processing equipment and system control equipment (except when REA loan funds are used), and the requirement that distribution borrowers notify REA in writing of proposed changes in electric rates 90 days prior to the effective date of such rates. The required notification period has been changed to 30 days.

Although the rule exempts REA approval of the selection of a manager for borrowers that meet the 110 percent test and are not in default, REA wishes to emphasize again the critical importance of the selection of fully qualified and capable managers. It is the most important of a board of director's responsibilities. REA will shortly be issuing new guidelines on manager selection.

For the convenience of the public, paragraph (d) of § 1710.7 lists examples of the operational controls and requirements that are not exempted. The controls and requirements not exempted fall into two categories: (1) Requirements and operational controls that are necessary to ensure that the security for loans made or guaranteed by REA is reasonably adequate and that the loans will be repaid, or to accomplish other fundamental purposes of the RE Act, and (2) requirements imposed on REA or on borrowers by law.

The nonexempted controls and requirements include, for example, area coverage requirements; following REA construction standards and listed materials; certain borrowers having to maintain a power requirements study on an ongoing basis; the maintenance of minimum levels for the Times Interest Earned Ratio and Debt Service Coverage ratio; REA approval of certain retirements of capital credits; controls on borrower investments; certain borrowers having to maintain an equity development plan; requirements on maintenance and repair of the mortgaged property; and REA accounting and auditing requirements. These requirements and controls are believed to be reasonable in comparison with requirements imposed by private lenders on customers presenting similar credit risks.

Paragraph (e) of § 1710.7 authorizes REA to reinstate exempted controls and requirements if the borrower is in default on any requirement of its mortgage, loan contract with REA, or any other agreement with REA that has not been exempted. REA will notify the borrower in writing of the reinstatement, and it will remain in effect until REA determines that it is no longer needed to help ensure loan security.

Paragraph (f) is intended to make it clear that if controls are reinstated because the borrower defaults or its net worth drops below 110 percent of outstanding REA debt, the controls and approval rights will apply to all applicable subsequent actions by the borrower, including REA approval of amendments to contracts entered into by the borrower while it was exempt from controls.

Section 1717.860—Lien Accommodations and Subordinations Under Section 306E of the RE Act

Section 1717.860 promulgates the requirements of section 306E of the RE Act as they relate to lien accommodations and subordinations. In determining which borrowers qualify under the 110 percent net worth to REA debt criterion, the same calculations and procedures are used as in § 1710.7, except that the determination is made at the time of an application for a lien accommodation or subordination and there is no annual notice to borrowers.

Paragraph (c) of § 1717.860 establishes that REA will expeditiously approve a lien accommodation or subordination for financing of capital investments by borrowers that meet the 110 percent test, if the borrower is in compliance with all requirements of its mortgage, loan contract with REA, and any other agreement with REA that have not been exempted pursuant to REA regulations, and if the security, including assurance of repayment, of loans made or guaranteed by REA will remain reasonably adequate. The paragraph also lists the information that must be included in the application for the lien accommodation or subordination.

Paragraph (d) of § 1717.860 expands the circumstances under which a lien subordination may be obtained for investments in rural development and other non-electric utility endeavors in the case of borrowers that meet the 110 percent test. It provides that a borrower that meets the 110 percent test is eligible for a lien subordination on the specific assets financed by a loan made directly to the borrower for rural development or other non-electric utility purposes, provided that the outstanding balance of all such loans lien subordinated under paragraph (d), after taking into consideration the effect of the new loan, does not exceed 15 percent of the borrower's net worth and the security, including assurance of repayment, of loans made or guaranteed by REA will remain reasonably adequate after granting the lien subordination. While the rule grants this additional latitude to borrowers that meet the 110 percent test, REA continues to urge all borrowers to use separate subsidiaries when making investments in rural development or other non-electric utility endeavors.

Investments lien subordinated under paragraph (d) will be included among those investments subject to the 15 percent of total utility plant limitation set forth in 7 CFR 1717.654(b)(1), and granting of the lien subordination will not constitute approval of the

investment under 7 CFR part 1717 subpart N.

Paragraph (e) of § 1717.860 exempts borrowers that meet the 110 percent test from the requirement of § 1717.856(d) that they submit an equity development plan with their application for a lien accommodation or subordination if the ratio of their equity to total assets is below a specified level.

Finally, paragraphs (a)(1)(ii) and (b)(1)(ii)(A) of § 1717.852 are amended to make it clear that programs of demand side management and energy conservation, and on-grid and off-grid renewable energy systems are eligible for lien accommodations and subordinations.

Section 1717.904—Exemptions Pursuant to Section 306E of the RE Act

This new section establishes policies and procedures, consistent with those in § 1710.7 and 1717.860, for lien accommodations for supplemental concurrent loans made to borrowers that meet the 110 percent test.

For the reasons stated, 7 CFR chapter XVII, parts 1710 and 1717 are amended as follows:

PART 1710—GENERAL AND PRE-LOAN POLICIES AND PROCEDURES COMMON TO INSURED AND GUARANTEED ELECTRIC LOANS

1. The authority citation for part 1710 continues to read as follows:

Authority: 7 U.S.C. 901–950b; Delegation of Authority by the Secretary of Agriculture, 7 CFR 2.23; Delegation of Authority by the Under Secretary for Small Community and Rural Development, 7 CFR 2.72, unless otherwise noted.

2. Subpart A of part 1710 is amended by adding the following section to read as follows:

§ 1710.7 Exemptions of REA operational controls under section 306E of the RE Act.

(a) *General policy.* (1) Section 306E of the RE Act directs the Administrator to issue interim final regulations to minimize approval rights, requirements, restrictions, and prohibitions imposed on the operations of electric borrowers whose net worth exceeds 110 percent of the outstanding loans made or guaranteed to the borrower by REA. The section also directs the Administrator, when requested by a private lender providing financing for capital investments by such borrowers, to offer, without delay, to share the government's lien on the borrowers' systems or subordinate the government's lien on the property financed by the private lender.

(2) In issuing the regulations, the Administrator is authorized to establish requirements, guided by the practices of private lenders with respect to similar credit risks, to ensure that the security, including the assurance of repayment, for loans made or guaranteed by REA will remain reasonably adequate. If the regulations are not issued within 180 days of enactment of section 306E, the Administrator may not, until the regulations are issued, require prior approval of, or establish any requirement, restriction, or prohibition, with respect to the operations of any electric borrower that meets the 110 percent ratio.

(3) Nothing in section 306E limits the authority of the Administrator to establish terms and conditions on the use of funds from loans made or guaranteed by REA, to establish loan feasibility criteria and other requirements for the approval of REA loans or loan guarantees, such as those set forth in this part, or to take any other action specifically authorized by law.

(4) This section addresses the application of section 306E of the RE Act to REA operational controls and other requirements that apply in general to REA borrowers. The application of section 306E to lien accommodations and subordinations is set forth in 7 CFR 1717.860 and 1717.904.

(5) The exemptions granted by this section, 7 CFR 1717.860, and 7 CFR 1717.904 apply only to REA controls and approval rights. They do not affect the controls and approval rights of other co-mortgagees under the REA mortgage.

(b) *Determination of ratio.* The following principles and procedures will apply to the calculation of net worth as a ratio, expressed as a percent, to the outstanding balance of all loans made or guaranteed to the borrower by REA, hereinafter called the borrower's "net worth to REA debt ratio", or simply "the ratio":

(1) For purposes of determining whether a borrower is exempt from approvals, requirements, restrictions, or prohibitions imposed by REA with respect to borrower operations, i.e., "operational controls," the ratio normally will be based on data as of December 31. Net worth will be based on the year-end financial and statistical reports submitted by borrowers to REA, and outstanding loans made or guaranteed by REA will be based on REA's records. The financial and statistical reports (Form 7 for distribution borrowers and Form 12a for power supply borrowers) are subject to REA review and revision, and they must comply with REA's system of accounts and accounting principles set forth in 7 CFR part 1767. Since sinking fund depreciation is not approved under part 1767, net worth for borrowers using sinking fund depreciation will be calculated as if the borrower had been using straight line depreciation;

(2) Net worth will be calculated by taking total margins and equities (Line 33 of Part C of REA Form 7 for distribution borrowers, or Line 34 of Section B of REA Form 12a for power supply borrowers) and subtracting assets properly recordable in account 182.2, Unrecovered Plant and Regulatory Study Costs, and account 182.3, Other Regulatory Assets, as defined in 7 CFR part 1767; and

(3) By no later than May 1 of each year, REA will notify each borrower in writing of its ratio as of December 31 of the preceding year. If a borrower's net worth to REA debt ratio exceeds 110 percent based on the year-end data, the borrower will be exempt from the operational controls exempted under paragraph (c) of this section until subsequently notified in writing by REA that it is no longer exempt.

(c) *Borrower operations exempted from REA controls.* Borrowers who are notified by REA in writing that their net worth to REA debt ratio exceeds 110 percent are exempted from the operational controls of the REA mortgage and loan contract listed in this paragraph. These controls, which are implemented through REA regulations and other documents, are as follows:

(1) Requirement that extensions or additions to the borrower's electric utility system financed by the borrower's own funds, as defined in 7 CFR 1717.652, be included in an REA-approved construction work plan. This exemption does not apply to extensions or additions financed by loans made or guaranteed by REA or by loans for which REA has granted a lien accommodation or subordination;

(2) Requirements on contract bidding procedures, as set forth in § 1710.120 and other REA regulations, except when the construction is funded directly or through reimbursements from loans made or guaranteed by REA;

(3) REA approval of construction contracts and engineering and architectural service contracts, and use of REA standard forms of contracts, as set forth in § 1710.120 and other REA regulations, except when the construction is funded directly or through reimbursements from loans made or guaranteed by REA. To be eligible for exemption of REA approval rights, here and elsewhere in this paragraph (c), the contracts must not contain any provisions that prohibit or restrict the assignment of the contracts to the government upon the exercise by REA of its remedies under security

instruments securing loans made or guaranteed by REA. Throughout this section, REA approval of contracts also includes REA approval of contract amendments and renewals;

(4) REA approval of the borrower's use of general funds, as defined as "own funds" in 7 CFR 1717.652, for plant extensions or additions or other investments in the borrower's electric utility system, provided that the funds will not be reimbursed with funds from a loan made or guaranteed by REA, and:

(i) The plant addition will not provide direct service to any ultimate consumer having an anticipated or contract kilowatt-hour (kWh) or maximum kilowatt (kW) demand in any year that exceeds 25 percent of the borrower's total kWh sales or maximum kW demand recorded during the previous calendar year; or

(ii) If the investment is for the addition or substantial reconstruction of generation capacity, the borrower is a power supply borrower and the addition or substantial reconstruction of capacity will not exceed 25 megawatts. The exemption under this paragraph (ii) does not apply to distribution borrowers;

(5) REA approval of contracts for the sale of electric power and energy to ultimate consumers except when the kWh sales or maximum kW demand covered by the contract is for an amount in any year that exceeds 25 percent of the borrower's total kWh sales or maximum kW demand during the previous calendar year;

(6) REA approval of power purchase contracts with suppliers that do not receive financial assistance from REA, provided that the contract is for a period of not more than 1 year and the kWh amount of energy or maximum kW capacity to be purchased under the contract does not exceed 25 percent of the total kWh amount of energy purchased and/or generated by the borrower, or maximum kW demand of the borrower, during the previous calendar year;

(7) REA approval of transmission, interconnection, and power pooling contracts that cover a period of one year or less;

(8) REA approval of contracts for the operation and management and/or maintenance of a borrower's system, provided that the contract does not cover all or substantially all of the borrower's system;

(9) REA approval of the voluntary sale, lease or transfer by the borrower of any capital asset in exchange for fair market value if:

(i) The borrower is not in default under its mortgage, loan contract with REA, or any other agreement with REA. (As used in this section, the term default includes defaults declared by the mortgagee as well as events that have occurred and are continuing, which, with notice or lapse of time and notice, would become events of default.);

(ii) The proceeds of such sale, lease or transfer are applied as required by the REA mortgage;

(iii) The value of the capital asset is less than 5 percent of net utility plant and the aggregate value of capital assets sold, leased or transferred in any 12-month period is less than 10 percent of net utility plant; and

(iv) If the borrower has an REA-approved wholesale power contract with a power supply borrower (seller), the circumstances of the sale, lease or transfer of capital assets conform with the conditions in such contract under which the seller may not withhold its consent to the sale, lease or transfer. The exemption of REA approval rights under this paragraph (c)(9) applies only to voluntary sales, leases, and transfers, and does not affect REA's right under section 7 of the RE Act to approve other dispositions of property by the borrower;

(10) REA approval of the selection of a borrower's manager, provided that the borrower is not in default under its mortgage, loan contract with REA, or any other agreement with REA. Nothing herein shall limit the right of REA under the mortgage to request termination of the employment of a manager in the event of a default by the borrower;

(11) REA approval, as set forth in the loan contract, of a borrower's selection of a bank in which funds of the borrower are or will be deposited, provided that the borrower is not in default under its mortgage, loan contract with REA, or any other agreement with REA. The requirement that such bank must be a member of the Federal Deposit Insurance Corporation is not exempted;

(12) REA approval of the purchase of data processing equipment and system control equipment, except when funds for the equipment, including reimbursements, derive from loans made or guaranteed by REA. This exemption, as well as that set forth in paragraph (c)(13) of this section, also applies to all other borrowers, i.e., those that do not meet the 110 percent equity ratio; and

(13) Requirement that distribution borrowers notify REA in writing of proposed changes in electric rates 90 days prior to the effective date of such rates. Instead, the required notification period shall be 30 days.

(d) *REA requirements and operational controls not exempted.* All requirements and operational controls contained in the REA mortgage and loan contract, or otherwise imposed on borrowers pursuant to statute or regulation, that are not specifically listed in paragraph (c) of this section are not exempted and shall continue to apply according to their terms. Examples of such requirements and controls not exempted are listed in this paragraph for the convenience of the public. This list is not exhaustive, and the absence of a requirement or control from this list in no way means that the requirement or control has been exempted:

(1) Requirements and operational controls contained in the REA mortgage or loan contract that are necessary to ensure that the security for loans made or guaranteed by REA is reasonably adequate and that the loans will be repaid, or to accomplish other fundamental purposes of the RE Act. Some of these also represent terms and conditions with respect to the use by borrowers of the proceeds of loans made or guaranteed by REA. Together, these controls include, but are not limited to, the following:

(i) Area coverage requirements set forth in the loan contract and in § 1710.103;

(ii) Requirement that certain borrowers maintain, on an ongoing basis, a power requirements study and a power requirements study work plan, as set forth in § 1710.201 and § 1710.202;

(iii) Requirement that borrowers follow REA construction standards and use REA accepted materials, as set forth in 7 CFR 1710.41, 7 CFR 1710.45, and 7 CFR part 1728;

(iv) Requirement that borrowers maintain, on an ongoing basis, a long-range engineering plan and a construction work plan, as set forth in § 1710.250(b);

(v) Requirement that borrowers set rates for electric service sufficient to maintain certain levels for the Times Interest Earned Ratio and Debt Service Coverage ratio, as set forth in § 1710.114;

(vi) Requirement that certain borrowers maintain an equity development plan, as set forth in § 1710.116;

(vii) REA approval of retirements of capital credits in excess of amounts specifically authorized in the mortgage;

(viii) REA approval of borrower investments, loans, guarantees, and other obligations under 7 CFR Part 1717, subpart N;

(ix) REA requirements on accounting, auditing, irregularities, financial

reporting, and access to books and records;

(x) Requirement that borrowers record the mortgage and mortgage amendments;

(xi) Requirement that the mortgagor maintain and preserve the priority lien of the mortgage and defend title to the mortgaged property;

(xii) Requirements on maintenance and repair of the mortgaged property;

(xiii) Requirements on insurance of the mortgaged property; and

(xiv) REA approval of borrower mergers and consolidations; and

(2) Requirements imposed on borrowers pursuant to statute or regulation and not specifically exempted by paragraph (c) of this section. See, for example, §§ 1710.122 through 1710.127.

(e) *Rescission of exemptions if borrower defaults.* If a borrower is in default with respect to any requirement of its mortgage, loan contract with REA, or any other agreement with REA that has not been exempted pursuant to paragraph (c) of this section or other REA regulations, upon written notice to the borrower REA may rescind all or any part of the exemptions granted pursuant to said regulations. The reinstated requirements and controls will remain in effect until REA determines that they are no longer needed to help ensure that the security, including the assurance of repayment, for loans made or guaranteed by REA will remain reasonably adequate.

(f) *Reinstated controls.* If REA controls are reinstated because the borrower defaults or its net worth falls below 110 percent of REA debt, such controls and approval rights will apply to all applicable subsequent actions of the borrower, including without limitation the amendment of contracts that the borrower entered into while eligible for an exemption under this section.

PART 1717—POST-LOAN POLICIES AND PROCEDURES COMMON TO INSURED AND GUARANTEED ELECTRIC LOANS

3. The authority citation for part 1717 continues to read as follows:

Authority: 7 U.S.C. 901–950b; Delegation of Authority by the Secretary of Agriculture, 7 CFR 2.23; Delegation of Authority by the Under Secretary for Small Community and Rural Development, 7 CFR 2.72, unless otherwise noted.

§ 1717.85 [Amended]

4. Section 1717.851 is amended by adding the following new definition:

* * * * *

Capital investment. For the purposes of § 1717.860, capital investment means an original investment in an asset that is intended for long-term continued use or possession and, for accounting purposes, is normally depreciated or depleted as it is used. For example, such assets may include land, facilities, equipment, buildings, mineral deposits, patents, trademarks, and franchises. Original investments do not include refinancings or refundings.

* * * * *

§ 1717.852 [Amended]

5. Section 1717.852 is amended in the second sentence of paragraph (a)(1)(ii) by removing the word "and" after "coal handling facilities," and by adding after the words "for generation" the following words: ", programs of demand side management and energy conservation, and on-grid and off-grid renewable energy systems;".

6. Section 1717.852 is further amended by revising paragraph (b)(1)(ii)(A) to read as follows:

§ 1717.852 Financing purposes.

* * * * *

(b) * * *

(1) * * *

(ii) * * *

(A) Renewable energy systems and REA-approved programs of demand side management and energy conservation; and

* * * * *

7. New § 1717.860 is added to read as follows:

§ 1717.860 Lien accommodations and subordinations under section 306E of the RE Act.

(a) *General.* Under section 306E of the RE Act, when requested by a private lender providing financing for capital investments by a borrower whose net worth exceeds 110 percent of the outstanding principal balance of all loans made or guaranteed to the borrower by REA, the Administrator will, without delay, offer to share the government's lien on the borrower's system or subordinate the government's lien on the property financed by the private lender, provided that the security, including the assurance of repayment, for loans made or guaranteed by REA will remain reasonably adequate. To qualify for a lien accommodation or subordination under this section, the investment must be an original capital investment, i.e., not a refinancing or refunding. (See § 1717.851 for the definition of capital investment.)

(b) *Determination of net worth to REA debt ratio.* (1) In the case of applications for a lien accommodation, a borrower's net worth will be based on the borrower's most recent financial and statistical report, the data in which shall not be more than 60 days old at the time the application is received by REA, and the outstanding debt owed to or guaranteed by REA will be based on latest REA records available. The financial and statistical reports (Form 7 for distribution borrowers and Form 12a for power supply borrowers) are subject to REA review and revision, and they must comply with REA's system of accounts and accounting principles set forth in 7 CFR part 1767. Since sinking fund depreciation is not approved under part 1767, net worth for borrowers using sinking fund depreciation will be calculated as if the borrower had been using straight line depreciation.

(2) Net worth shall be calculated by taking total margins and equities (Line 33 of Part C of REA Form 7 for distribution borrowers, or Line 34 of Section B of REA Form 12a for power supply borrowers) and subtracting assets properly recordable in account 182.2, Unrecovered Plant and Regulatory Study Costs, and account 182.3, Other Regulatory Assets, as defined in 7 CFR part 1767.

(c) *Application requirements and process.* (1) If a borrower's net worth to REA debt ratio exceeds 110 percent, as determined by REA, and the borrower is in compliance with all requirements of its mortgage, loan agreement with REA, and any other agreement with REA that have not been exempted in writing by REA, if requested REA will expeditiously approve a lien accommodation or subordination for 100 percent private financing of capital investments, provided that the security, including the assurance of repayment, for loans made or guaranteed by REA will remain reasonably adequate. REA's approval will be conditioned upon execution and delivery by the borrower of a security instrument satisfactory to REA, if required, and such additional information, documents, and opinions of counsel as REA may require.

(2) The application must include the following:

(i) A resolution of the borrower's board of directors requesting the lien accommodation and including the amount and maturity of the proposed loan, a general description of the facilities or other purposes to be financed, the name and address of the lender, and an attached term sheet summarizing the terms and conditions of the proposed loan;

(ii) A certification by an authorized official of the borrower that the borrower is in compliance with all requirements of its mortgage, loan agreement with REA, and any other

agreement with REA that have not been exempted in writing by REA;

(iii) The borrower's financial and statistical report, the data in which shall not be more than 60 days old when the complete application is received by REA;

(iv) Draft copy of any new mortgage or mortgage amendment (supplement) required by REA or the lender, unless REA has notified the borrower that it wishes to prepare these documents itself;

(v) A copy of the loan agreement, loan note, bond or other financing instrument, unless REA has notified the borrower that these documents need not be submitted. These documents will not be subject to REA approval, but may be reviewed to determine whether they contain any provisions that would result in the security, including assurance of repayment, for loans made or guaranteed by REA no longer being reasonably adequate;

(vi) The following certifications and reports required by law:

(A) The certification by the project architect for any buildings to be constructed, as required by 7 CFR 1717.850(i);

(B) A certification by an authorized official of the borrower that flood hazard insurance will be obtained for the full value of any buildings, or other facilities susceptible to damage if flooded, that will be located in a flood hazard area;

(C) Form AD–1047, Certification Regarding Debarment, Suspension, and Other Responsibility Matters—Primary Covered Transactions, as required by 7 CFR part 3017;

(D) A report by the borrower stating whether or not it is delinquent on any Federal debt, and if delinquent, the amount and age of the delinquency and the reasons therefor; and a certification, if not previously provided, that the borrower has been informed of the Government's collection options; and

(E) The written acknowledgement from a registered engineer or architect regarding compliance with seismic provisions of applicable model codes for any buildings to be constructed, as required by 7 CFR 1792.104. All other elements of an application listed in § 1717.855, § 1717.856, and § 1717.858(c) not listed in this paragraph (c) are exempted.

(3) Applications from distribution borrowers are submitted to the general field representative (GFR), while applications from power supply borrowers are submitted to the REA Power Supply Division, or its successor, in Washington, DC. When an application is satisfactory to the GFR, it will be sent promptly to the Washington office. If Washington office staff determine that an application is incomplete, the borrower will be promptly notified in writing about the deficiencies. When the application is complete, and if the security, including assurance of repayment, of loans made or guaranteed by REA will remain reasonably adequate after granting the lien accommodation or subordination, the borrower and the lender will be promptly notified in writing that the lien accommodation or subornation has been approved, subject to the conditions cited in paragraph (c)(1) of this section.

(d) *Rural development and other non-electric utility investments.* Although REA recommends the use of separate subsidiaries as set forth in § 1717.858, if requested by a borrower that meets the 110 percent equity test and all other applicable requirements of this section, REA will provide a lien subordination on the specific assets financed in the case of loans made directly to the borrower for rural development and other non-electric utility purposes, provided that the outstanding balance of all such loans lien subordinated under this paragraph (d), after taking into consideration the effect of the new loan, does not exceed 15 percent of the borrower's net worth and the security, including assurance of repayment, of loans made or guaranteed by REA will remain reasonably adequate after granting the lien subordination. Investments lien subordinated under this paragraph shall be included among those investments subject to the 15 percent of total utility plant limitation set forth in 7 CFR 1717.654(b)(1), and granting of the lien subordination will not constitute approval of the investment under 7 CFR Part 1717, subpart N.

(e) *Equity development plans.* Borrowers that qualify for a lien accommodation or lien subordination under this section are exempt from the requirement set forth in § 1717.856(d) that they submit an equity development plan as part of their application. This exemption applies only to applications for a lien accommodation or subordination, and does not exempt borrowers from the requirements of 7 CFR 1710.116 applicable to applications for a loan or loan guarantee from REA.

(f) *Requirements and controls not exempted.* All requirements and limitations imposed with respect to lien accommodations and subordinations by this subpart R that are not specifically exempted by this section are not exempted and shall continue to apply according to their terms.

8. New § 1717.904 is added to read as follows:

§ 1717.904 Exemptions pursuant to section 306E of the RE Act.

(a) *General policy.* If a borrower's net worth to REA debt ratio exceeds 110 percent, as determined by REA, and the borrower is in compliance with all requirements of its mortgage, loan agreement with REA, and any other agreement with REA that have not been exempted in writing by REA, REA will expeditiously approve a lien accommodation for a concurrent supplemental loan if requested in writing by the borrower, provided that the security, including assurance of repayment, of loans made or guaranteed by REA will remain reasonably adequate. REA's approval will be conditioned upon execution and delivery by the borrower of a security instrument satisfactory to REA, if required, and such additional information, documents, and opinions of counsel as REA may require.

(b) *Determination of net worth to REA debt ratio.* A borrower's ratio of net worth to REA debt will be determined as set forth in § 1717.860(b).

(c) *Requirements and controls exempted.* The applicable requirements and controls exempted by 7 CFR 1710.7(c) are also exempted with respect to concurrent supplemental loans.

(d) *Requirements and controls not exempted.* All requirements and controls applicable to concurrent supplemental financing set forth in this subpart and other REA regulations that are not specifically exempted by 7 CFR 1710.7(c) are not exempted and shall continue to apply according to their terms. These include, but are not limited to:

(1) The applicable requirements listed in 7 CFR 1710.7(d); and

(2) The requirements set forth in § 1717.901(a) when a borrower requests early approval of a lien accommodation.

(e) *Procedures.* If a borrower meets the requirements of this section, upon receipt of a complete application REA will promptly notify the borrower and lender in writing that the lien accommodation has been approved subject to the conditions set forth in paragraph (a) of this section.

Dated: January 21, 1994.

Bob J. Nash,

Under Secretary, Small Community and Rural Development.

[FR Doc. 94–1987 Filed 1–27–94; 8:45 am]

BILLING CODE 3410–15–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 27

[Docket No. 93–ASW–5; Special Condition 27–ASW–2]

Special Condition: Agusta Aerospace Corporation (Agusta) Model A109C Helicopter, Electronic Flight Instrument System

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final special condition.

SUMMARY: This special condition is issued for the Agusta Model A109C helicopter. This helicopter will have a novel or unusual design feature associated with the Electronic Flight Instrument System. This special condition contains additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that provided by the applicable airworthiness standards.

EFFECTIVE DATE: January 28, 1994.

FOR FURTHER INFORMATION CONTACT: Mr. Robert McCallister, FAA, Rotorcraft Directorate, Policy and Procedures Group, Fort Worth, Texas 76193–0112; telephone (817) 222–5121.

SUPPLEMENTARY INFORMATION:

Background

On July 21, 1993, Agusta Aerospace Corporation, Philadelphia, Pennsylvania, applied for a Supplemental Type Certificate for installation of an Electronic Flight Instrument System in the Agusta Model A109C helicopter. This model is a 7 passenger, 2 engine, 5,997 pound normal category helicopter.

Type Certification Basis

The certification basis established for the Agusta Model A109C helicopter includes: Federal Aviation Regulation (FAR) § 21.29; part 27 effective February 1, 1965, Amendments 27–1 through 27–8; FAR part 29 dated February 1, 1965, paragraph 29.903(b), for Category "A" engine isolation; and equivalent safety in lieu of compliance shown for: FAR 27.1189 (regarding shut-off means); FAR 27.927(c) as amended by Amendment 27–12; and Airworthiness Criteria for Helicopter Instrument Flight, eligible for day and night Instrument Flight Rules (IFR) operations, with one or two pilots, when Agusta Kit No. 109–0810–22, Revision E or later approved revision, is incorporated, and the helicopter is operated in accordance with the Model A109C Rotorcraft Flight Manual.

If the Administrator finds that the applicable airworthiness regulations do not contain adequate or appropriate safety standards for this helicopter because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16 to establish a level of safety equivalent to that established in the regulations.

Special conditions, as appropriate, are issued in accordance with FAR § 11.49 after public notice, as required by §§ 11.28 and 11.29(b), and become part of the type certification basis in accordance with § 21.101(b)(2) for changes to the type certificates.

Novel or Unusual Design Feature

The Agusta Model A109C helicopter was identified as incorporating one or possibly more electrical, electronic, or combination of electrical electronic (electrical/electronic) systems that will be performing functions critical to the continued safe flight and landing of the helicopter. The Electronic Flight Instrument System performs the attitude display function. The display of attitude, altitude, and airspeed to the pilot is critical to the continued safe flight and landing of the helicopter for IFR operations in Instrument Meteorological Conditions.

If it is determined that these helicopters will incorporate other electrical/electronic systems performing critical functions, those systems also will be required to comply with the requirements of this special condition.

Discussion of Comments

Notice of Proposed Special Condition No. SC–93–5–SW was published in the **Federal Register** on November 17, 1993, (58 FR 60569). No comments were received. Therefore, the special condition is adopted as proposed.

Conclusion

This action affects only certain unusual or novel design features on one model of helicopter. It is not a rule of general applicability and affects only the applicant who applied to the FAA for approval of these features on the affected helicopter.

List of Subjects in 14 CFR Part 27

Aircraft, Air transportation, Aviation safety, Rotorcraft, Safety.

PART 27—[AMENDED]

The authority citation for this special condition is as follows:

Authority: 49 U.S.C. 1344, 1348(c), 1352, 1354(a), 1355, 1421 through 1431, 1502, 1651(b)(2); 42 U.S.C. 1857f–10, 4321 et seq.; E.O. 11514; 49 U.S.C. 106(g).

The Special Condition

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special condition is issued as part of the type certification basis for the Agusta Model A109C helicopter: *Protection for Electrical and Electronic Systems From High Intensity Radiated Fields.*

Each system that performs critical functions must be designed and installed to ensure that the operation and operational capabilities of these critical functions are not adversely affected when the helicopter is exposed to high intensity radiated fields external to the helicopter.

Issued in Fort Worth, Texas, on January 19, 1994.

Sanida McRae,

Acting Manager, Rotorcraft Directorate Aircraft Certification Service.

[FR Doc. 94–1927 Filed 1–27–94; 8:45 am]

BILLING CODE 4910–13–M

14 CFR Part 39

[Docket No. 93–NM–67–AD; Amendment 39–8805; AD 94–02–07]

Airworthiness Directives; McDonnell Douglas Model MD–11 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain McDonnell Douglas Model MD–11 series airplanes, that requires replacing the anti-skid control unit. This amendment is prompted by three reports of failure of the center landing gear drag link, after which the center landing gear swung aft and struck the fuselage. The actions specified by this AD are intended to prevent failure of the center landing gear drag link, which could result in extensive damage to the fuselage structure.

DATES: Effective February 28, 1994. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of February 28, 1994.

ADDRESSES: The service information referenced in this AD may be obtained from McDonnell Douglas Corporation, P.O. Box 1771, Long Beach, California 90801–1771, Attention: Business Unit Manager, Technical Publications—Technical Administrative Support, C1–L5B. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate,

Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Transport Airplane Directorate, Los Angeles Aircraft Certification Office, 3229 East Spring Street, Long Beach, California; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Andrew Gfrerer, Aerospace Engineer, Systems and Equipment Branch, ANM–131L, FAA, Transport Airplane Directorate, Los Angeles Aircraft Certification Office, 3229 East Spring Street, Long Beach, California 90806–2425; telephone (310) 988–5338; fax (310) 988–5210.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations to include an airworthiness directive (AD) that is applicable to certain McDonnell Douglas Model MD–11 series airplanes was published in the **Federal Register** on July 16, 1993 (58 FR 38321). That action proposed to require replacing the anti-skid control unit.

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the comments received.

One commenter supports the proposal.

One commenter suggests that the proposed AD action is inappropriate for two reasons:

1. Drag link failures occur only with the use of autobraking. Therefore, if only manual brakes are used, there should be no requirement to modify the anti-skid control unit.

2. Failure of the center landing gear drag link does not pose sufficient risk to the airframe to warrant AD action.

The FAA does not concur with the commenter's suggestion that this AD action is not warranted. As for the commenter's Item 1, the FAA points out that there has been at least one case of failure of the center gear with the application of manual brakes prior to touchdown of the nose gear wheel. By replacing the Part Number (P/N) 6005304–1 control unit with the P/N 6005304–2 unit (as required by this AD), center gear braking is inhibited both manually and through the use of autobrakes until nose gear touchdown.

As for the commenter's Item 2, the FAA notes that there have been at least three in-service failures of center landing gear drag links that have caused significant structural damage to the airplane. In each occurrence, the failed drag link allowed the center landing gear to swing aft and strike the fuselage. Additionally, there are numerous other possible scenarios involving similar failures that could result in damage to the hydraulic and electrical systems of the airplane. The center landing gear is also needed to properly distribute the airplane's weight for heavy weight landings. For these reasons, the FAA considers that failure of the center landing gear drag link does present an unsafe condition sufficient to warrant mandated corrective action. The appropriate vehicle for mandating such corrective action is the airworthiness directive.

Two commenters request that the proposed compliance time of 9 months be extended to 12 months. The manufacturer has indicated that the fleet of affected Model MD–11's could not be retrofitted within 9 months, given the current schedule of modifying the subject part on a rotatable basis and the capacity of the manufacturer to modify the control units. The FAA concurs with the commenter's request. Extending the compliance time an additional 3 months will not adversely affect safety and will allow the affected fleet to be modified in an orderly manner, thereby minimizing the costs associated with special airplane scheduling. Paragraph (a) of the final rule has been revised to specify a compliance time of 12 months.

One commenter requests that the wording of references to the anti-skid control unit be clarified. The preamble to the notice referred to "the anti-skid control unit for the center landing gear;" however, this control unit controls all of the landing gears, not just the center landing gear. The FAA agrees that clarification of this point is needed and, where appropriate, has changed the wording in this final rule accordingly.

After careful review of the available data, including the comments noted above, the FAA has determined that air safety and the public interest require the adoption of the rule with the changes previously described. The FAA has determined that these changes will neither increase the economic burden on any operator nor increase the scope of the AD.

There are approximately 86 McDonnell Douglas Model MD–11 series airplanes of the affected design in the worldwide fleet. The FAA estimates that 32 airplanes of U.S. registry will be affected by this AD, that it will take approximately 1 work hour per airplane to accomplish the required actions, and that the average labor rate is $55 per work hour. Required parts will be provided by the manufacturer at no cost to the operator. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be $1,760, or $55 per airplane. This total cost figure assumes that no operator has yet accomplished the requirements of this AD.

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) Is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption ADDRESSES.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends 14 CFR part 39 of the Federal Aviation Regulations as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. App. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

94–02–07 McDonnell Douglas: Amendment 39–8805. Docket 93–NM–67–AD.

Applicability: Model MD–11 series airplanes, as listed in McDonnell Douglas MD–11 Service Bulletin 32–30, dated March 3, 1993; certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent potential failure of the center gear drag link, which could lead to extensive

damage to the fuselage structure, accomplish the following:

(a) Within 12 months after the effective date of this AD, replace the anti-skid control unit, part number 6005304–1, with a new anti-skid control unit, part number 6005304–2, in accordance with McDonnell Douglas MD–11 Service Bulletin 32–30, dated March 3, 1993.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Los Angeles Certification Office (ACO), FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Los Angeles ACO.

Note: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Los Angeles ACO.

(c) Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate the airplane to a location where the requirements of this AD can be accomplished.

(d) The replacement shall be done in accordance with McDonnell Douglas MD–11 Service Bulletin 32–30, dated March 3, 1993. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from McDonnell Douglas Corporation, P.O. Box 1771, Long Beach, California 90801–1771, Attention: Business Unit Manager, Technical Publications—Technical Administrative Support, C1–L5B. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Transport Airplane Directorate, Los Angeles Aircraft Certification Office, 3229 East Spring Street, Long Beach, California; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(e) This amendment becomes effective on February 28, 1994.

Issued in Renton, Washington, on January 14, 1994.

John J. Hickey,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 94–1465 Filed 1–27–94; 8:45 am]

BILLING CODE 4910–13–U

14 CFR Part 73

[Docket No. 25767; Special Federal Aviation Regulation (SFAR) No. 53–3]

Establishment of Warning Areas in the Airspace Overlying the Waters Between 3 and 12 Nautical Miles From the United States Coast

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: This document corrects an error to the Final Rule, on "Establishment of Warning Areas in the Airspace Overlying the Waters Between 3 and 12 Nautical Miles From the United States Coast", which was published on Wednesday, December 29, 1993 (58 FR 69128). The Amendment No. was omitted.

FOR FURTHER INFORMATION CONTACT:

Melodie De Marr, Air Traffic Rules and Regulations, ATP–230, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591, telephone (202) 267–8783.

SUPPLEMENTARY INFORMATION: FR Doc. 93–31858, which was published on December 29, 1993, (58 FR 69128), in the Heading next to the "Docket No. 25767", please insert "Amendment No. 73–7".

Joseph A. Conte,

Regulations Division, Office of Chief Counsel.

[FR Doc. 94–1929 Filed 1–27–94; 8:45 am]

BILLING CODE 4910–13–M

14 CFR Part 121

[Docket No. 25148]

Antidrug Program for Personnel Engaged in Specific Aviation Activities

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: This document corrects an error to the Final Rule, on "Antidrug Program for Personnel Engaged in Specific Aviation Activities", which was published on Thursday, December 23, 1993 (58 FR 68198). The Amendment No. was omitted.

FOR FURTHER INFORMATION CONTACT:

Carol Keenan, Office of Aviation Medicine, Drug Abatement Division (AAM–800), Federal Aviation Administration, 400 Seventh Street, SW., Washington, DC 20590, telephone (202) 366–6710.

SUPPLEMENTARY INFORMATION: FR Doc. 93–30930, which was published on December 23, 1993, (58 FR 68198), in the Heading next to the "Docket No. 25148", please insert "Amendment No. 121–235".

Donald P. Byrne,

Manager, Regulations Division, Office of Chief Counsel.

[FR Doc. 94–1931 Filed 1–27–94; 8:45 am]

BILLING CODE 4910–13–M

RAILROAD RETIREMENT BOARD

20 CFR Part 266

RIN 3220–AA83

Representative Payment

AGENCY: Railroad Retirement Board.

ACTION: Final rule.

SUMMARY: The Railroad Retirement Board (Board) revises part 266 in order to provide more detailed guidelines regarding the selection, payment, responsibilities, and monitoring of representative payees. The title of part 266 is also changed from "Incompetence" to "Representative Payment" which better describes the contents of part 266. These revisions are being made to improve the administration of the Board's representative payee program.

EFFECTIVE DATE: January 28, 1994.

ADDRESSES: Secretary to the Board, Railroad Retirement Board, 844 Rush Street, Chicago, Illinois 60611.

FOR FURTHER INFORMATION CONTACT:

Thomas W. Sadler, Assistant General Counsel, Railroad Retirement Board, 844 Rush Street, Chicago, Illinois 60611 (312) 751–4513; TDD (312) 751–4701.

SUPPLEMENTARY INFORMATION: The Railroad Retirement Act of 1974 (45 U.S.C. 231 *et seq.*) provides a system of retirement and disability benefits for railroad employees, their spouses, children, and survivors who meet certain eligibility requirements under that Act. Section 12 of the Act (45 U.S.C. 231k) contains the same provisions as section 19 of the Railroad Retirement Act of 1937, the predecessor of the present Act, regarding the competence of an annuitant and the Board's authority in cases where an annuitant is incompetent. Under these provisions, any claimant or annuitant is presumed to be competent until the Board receives written notice to the contrary. If a claimant or annuitant is incompetent, the Board may make payments to, or conduct transactions with, any legally appointed guardian on behalf of the claimant or annuitant. Furthermore, section 12(a) expressly authorizes the Board to make payments, or conduct transactions, directly with the claimant or annuitant, or with any other person on his or her behalf, even though he or she is an incompetent for whom a guardian is acting. The provisions of section 12 are applicable to benefits claimed or paid under any Act administered in whole or in part by the Board, including any claim for or payment of social security benefits administered by the Board pursuant to

section 7(b)(2) of the Railroad Retirement Act (45 U.S.C. 231f(b)(2)).

There has been growing concern in the Congress to assure that surrogate decision making services, including representative-payee services, are provided in a uniform, high quality manner which maximizes the potential of every individual for self-reliance and independence.

Since the Board is currently in the process of a comprehensive review, revision, and amendment of its regulations, part 266 is revised at this time to address concerns that adequate safeguards be provided where payment of an annuity under the Railroad Retirement Act is made to a representative payee rather than directly to the annuitant. Thus, the revised part 266 expands, as well as revises, the present regulation.

A brief summary of the disposition of the various section of the present part 266 under the proposed regulation is set forth below.

The present § 266.1 simply sets forth the statutory provisions of section 12 of the Railroad Retirement Act (RRA) (45 U.S.C. 231k), and because of this redundancy, is removed.

The present § 266.2 has been incorporated into § 266.1(b) of the revised regulation. The new § 266.1 sets forth an introduction, consisting of an explanation of representative payment and the law and policy used to determine whether to make representative payment.

The present § 266.3 has been incorporated into § 266.3(a) of the revised regulation. The new § 266.3 sets forth information which the Board will consider in determining whether to make representative payment.

The present § 266.4 has been redesignated as § 266.12. New § 266.4 sets forth what information the Board will use in selecting a representative payee.

Paragraphs (a) and (b) of the present § 266.5 have been redesignated as § 266.2, and the term "beneficiary" has been removed and the term "annuitant" has been added in its place throughout the new part 266. New § 266.5 describes the order of preference the Board will generally use in selecting representative payees.

The present § 266.6 has been incorporated into the new § 266.9(a). The new § 266.9 sets forth general responsibilities of a representative payee.

The present §§ 266.7, 266.9, 266.10, and 266.11 have been revised and incorporated into a single section, § 266.10, which details how a representative payee is to use benefit payments.

The present § 266.8, "Conservation and investment of benefit payments," has been revised and incorporated into the new § 266.11.

Sections §§ 266.6, 266.7, and 266.8 are new. Section 266.6 provides that a representative payee applicant must provide the Board with the information listed in § 266.4 and will generally be required to undergo a face-to-face interview with a field representative of the Board.

Section § 266.7 provides that the representative payee make an accounting to the Board for the use of benefits he or she receives as payee and sets forth what information will satisfy the requirement of an accounting.

Section § 266.8 provides that an annuitant may challenge the appointment or selection of a representative payee. However, an individual who requests to be made a representative payee for an annuitant has no standing to challenge the Board's refusal to make the appointment.

The present § 266.12 has been revised and incorporated into the new § 266.7(c) described above. Section § 266.12, as noted earlier, is the redesignated § 266.4.

The present § 266.13 has been redesignated as the new § 266.15. Sections §§ 266.13 and 266.14 are new. The former section describes when the Board will terminate an individual's status as a representative payee and appoint a new one. The latter section describes what evidence an annuitant must provide to the Board to terminate representative payments and thereby receive benefits directly.

The Board published this regulation as a proposed rule on March 10, 1993 (58 FR 13225), requesting comments by April 9, 1993. A number of comments were received.

One commenter suggested that a paragraph be added to § 266.4 (Information considered in selecting a representative payee) to provide that a creditor who provides goods and services to the annuitant should not be able to serve as a representative payee unless such creditor is a relative, legal guardian, or connected with a licensed or certified care facility. The Board agrees with this comment and a new paragraph (i) is added to § 266.4 to reflect this proposal.

One commenter suggested that § 266.6 be modified to require a face-to-face interview with the payee-applicant rather than a discretionary interview as was proposed in that section. In the Board's experience a mandatory interview with the payee-applicant is not always necessary. In many cases the payee-applicant is a court appointed legal guardian or conservator or is a licensed care facility. However, the Board will modify its internal procedures to provide that where the payee-applicant is not interviewed, the Board employee responsible for developing the application for representative payment shall document in writing why no interview was done.

In the same vein, another commenter suggested that the regulation provide for a mandatory interview with the annuitant when a payee is proposed and that the Board seek suggestions from the annuitant as to whom would make an appropriate payee. As in the case of payee-applicant, the Board has found that a requirement to interview the annuitant in each and every case where a representative-payee is required is not necessary. In many cases, the reason for the appointment of a representative payee is that the annuitant is no longer sentient or capable of significant communication. Of course, in these cases a requirement for an interview would serve no purpose. Rather than adopt a mandatory requirement for an interview with the annuitant, the Board is of the opinion that the better approach is the one referred to above with respect to the payee-applicant interview; namely, that the annuitant will be interviewed and his or her recommendations sought whenever possible. Where the annuitant is not interviewed, the Board employee responsible for developing the application for representative-payee must document the basis for not conducting the interview. The Board's internal operating procedures will be modified to reflect this change.

A comment was also received with respect to §§ 266.7 (b) and (c). Under these sections where the representative payee fails to provide the Board with an accounting of his or her expenditures or fails to provide other information, the Board may suspend payment to the payee and then the payments are held in trust by the Board until a new representative payee is found or payments are reinstated to the present payee. One commenter was concerned that the regulation did not provide that if a new representative payee is not found, or payment to the present representative payee reinstated, within 30 days, that payments were not required to be made to the annuitant. The commenter pointed out that such a provision is provided for in the Social Security Act with respect to its representative payee program. See 42 U.S.C. 204(j)(2)(D). In the Board's experience the vast majority of

annuitants for whom representative payees are appointed are not competent to handle their finances. When payment to a representative payee is suspended pending appointment of a new payee, the Board seeks to appoint a new payee with the utmost speed. However, this process may take longer than 30 days because, as the commenter pointed out, there is indeed a shortage of individuals willing to act as representative payees. On the other hand, making payments to an individual who cannot manage his or her own affairs would not be in the best interest of the annuitant. Consequently, the Board has modified § 266.7 by adding a new paragraph (d) which provides that where payment to a representative payee is suspended to appoint a new representative payee, such payment must be reinstated within 30 days unless the annuitant is an unemancipated minor under age 18, or is judged by the Board to be incapable of handling his benefit payments, in which case the Board will hold the payments in trust until a new representative payee is appointed.

Finally, one commenter suggested that the Board seek legislative authority to impose administrative penalties on representative payees who misuse funds. The Board agrees that this suggestion has merit and will take it under advisement.

The Board has determined that this is not a significant regulatory action for purposes of Executive Order 12866; therefore, no regulatory impact analysis is required. Information collection has been approved by the Office of Management and Budget under control numbers 3220–0151 and 3220–0052.

A distribution table is provided to show the distribution of the old part 266.

Old section	New section
266.1	Removed.
266.2	266.1(b).
266.3	266.3(a).
266.4	266.12.
266.5	266.2 and 266.5.
266.6	266.9(a).
266.7	266.10 (a) and (b).
266.8	266.11.
266.9	266.10(b).
266.10	266.10(c).
266.11	266.10(d).
266.12	266.7.
266.13	266.15.

A derivation table is provided to show the sources of the revised part 266.

Old section	New section
266.1	266.2.
266.2	266.5.
266.3	266.3.
266.4	none.
266.5	266.5.
266.6	none.
266.7	266.12.
266.8	none.
266.9	266.6.
266.10	266.7, 266.9, 266.10, 266.11.
266.10	266.8.
266.12	266.4.
266.13	none.
266.14	none.
266.15	266.13.

List of Subjects in 20 CFR Part 266

Railroad employees, Railroad retirement.

For the reasons set out in the preamble, title 20, chapter II, Part 266, of the Code of Federal Regulations is revised as follows:

PART 266—REPRESENTATIVE PAYMENT

Sec.

266.1 Introduction.
266.2 Recognition by the Board of a person to act in behalf of another.
266.3 Information considered in determining whether to make representative payments.
266.4 Information considered in selecting a representative payee.
266.5 Order of preference in selecting a representative payee.
266.6 Information to be submitted by a representative payee applicant; face-to-face interview.
266.7 Accountability of a representative payee.
266.8 Advance notice of the determination to make representative payment.
266.9 Responsibilities of a representative payee.
266.10 Use of benefit payments.
266.11 Conservation and investment of benefit payments.
266.12 Effect of matters or actions submitted or taken by legal guardian, etc.
266.13 When a new representative payee will be selected.
266.14 When representative payment will be stopped.
266.15 Transfer of accumulated benefit payments.

Authority: 45 U.S.C. 231k and 231f.

PART 266—REPRESENTATIVE PAYMENT

§ 266.1 Introduction.

(a) *Explanation of representative payment.* This part explains the principles and procedures that the Board follows in determining whether to make representative payment and in selecting a representative payee. It also explains the responsibilities that a representative payee has concerning the use of the funds which he or she receives on behalf of an annuitant. A representative payee may be either a person or an organization selected by the Board to receive benefits on behalf of an annuitant. A representative payee will be selected if the Board believes that the interest of an annuitant will be served by representative payment rather than direct payment of benefits. Generally, the Board will appoint a representative payee if it determines that the annuitant is not able to manage or direct the management of benefit payments in his or her interest.

(b) *Statutory authority.* Section 12 of the Railroad Retirement Act provides that every annuitant and claimant shall be conclusively presumed to have been competent until the date on which the Board receives a notice in writing that a legal guardian or other person legally vested with the care of the person or estate of an incompetent or a minor has been appointed: Provided, however, That despite receiving such notice, the Board may, if it finds the interests of such annuitant or claimant to be served thereby, recognize actions by, conduct transactions with, and make payments to such annuitant or claimant.

(c) *Policy used to determine whether to make representative payment.* (1) In accordance with section 12 of the Railroad Retirement Act, the Board's policy is that every annuitant has the right to manage his or her own benefits. However, some annuitants due to mental or physical condition or due to their youth may be unable to do so. If the Board determines that the interests of an annuitant would be better served if benefit payments were certified to another person as representative payee, the Board will appoint a representative payee in accordance with the procedures set forth in this part. The Board may appoint a representative payee even if the annuitant is a legally competent individual. If the annuitant is a legally incompetent individual, the Board may appoint the legal guardian or some other person as a representative payee.

(2) If payment is being made directly to an annuitant and a question arises concerning his or her ability to manage or direct the management of benefit payments, the Board may, if the annuitant is 18 years old or older and has not been adjudged legally incompetent, continue to pay the annuitant until the Board makes a determination about his or her ability to manage or direct the management of benefit payments and the selection of a representative payee.

§ 266.2 Recognition by the Board of a person to act in behalf of another.

(a) Regardless of the receipt of written notice of the appointment of a guardian or other person legally vested with the care of the person or estate of an incompetent or a minor who is receiving or claiming benefits or to whom any right or privilege is extended under the law, the Board may, in its discretion, validly recognize actions by and conduct transactions with others acting on behalf of the individual found by the Board to be a minor or to be unable to manage his or her affairs, if the Board finds such actions or transactions to be in the best interest of such individual.

(b) In the absence of a written notice of the appointment of a guardian or other person legally vested with the care of the person or estate of an incompetent or minor, the Board shall, except where special circumstances appear, recognize a person to act on behalf of an individual under the following circumstances:

(1) When the individual has been adjudged mentally incompetent by a court having jurisdiction to do so;

(2) When the individual has been committed to a mental institution by a court having jurisdiction to do so;

(3) When the individual is an inmate of a mental institution;

(4) When the individual is less than 16 years of age; or

(5) When the individual is between 16 and 18 years of age and is in the care of another person and does not have the capacity to act on his or her own behalf.

§ 266.3 Information considered in determining whether to make representative payments.

In determining whether to make representative payment, the Board may consider the following information:

(a) *Evidence of legal guardianship.* Evidence of the appointment of a legal guardian or other person legally vested with the care of the person or estate of an incompetent or a minor shall be a certified copy of the court's determination.

(b) *Medical evidence.* The Board may use medical evidence, when such is available, to help determine whether an annuitant is capable of managing or directing the management of benefit payments. For example, a statement by a physician or other medical professional based upon his or her recent examination of the annuitant and his or her knowledge of the annuitant's present condition will be used in the Board's determination, if it includes information concerning the nature of the annuitant's illness, the annuitant's chances for recovery and the opinion of the physician or other medical professional as to whether the annuitant is able to manage or direct the management of benefit payments.

(c) *Other evidence.* The Board may also consider statements of relatives, friends, and other people in a position to know and observe the annuitant, which contain information helpful to the Board in deciding whether the annuitant is able to manage or direct the management of benefit payments.

§ 266.4 Information considered in selecting a representative payee.

In selecting a representative payee, the Board tries to select the person, agency, organization or institution that will best serve the interest of the annuitant. In making this selection, the Board may consider such factors as the following:

(a) The relationship of the person to the annuitant, including the type of relationship, *e.g.*, family or legal guardianship; degree of relationship, if the person is a family member; and the length of association, if a non-family member;

(b) The amount of interest that the person shows in the annuitant, including the contributions the person makes to the welfare of the annuitant and the contacts and frequency of such contacts with the annuitant;

(c) Any legal authority the person, agency, organization or institution has to act on behalf of the annuitant;

(d) Whether the potential payee has custody of the annuitant;

(e) Whether the potential payee is in a position to know of and look after the needs of the annuitant;

(f) Verification of the social security account number, name, address, telephone number, place of employment, and main source of income if applicable, accepted as part of any person's application for designation as a representative payee, unless such person's identification has already been established to the satisfaction of the Board;

(g) Whether an applicant for designation as a representative payee has ever been convicted of a felony or misdemeanor under the statutes administered by the Board or the Social Security Act, or convicted of a felony under any other Federal or State law; and

(h) Whether the services of such person as representative payee have previously been terminated, suspended, or declined by the Board or the Social Security Administration for:

(1) Misuse of the benefits of the annuitant for whom they were intended;

(2) Failure to comply with any provision of or regulation under the Railroad Retirement Act or the Social Security Act; or

(3) Failure to meet the requirements of this part.

(i) Whether the potential payee is a creditor of the annuitant. A creditor who provides goods and services to the annuitant ordinarily may not serve as a representative payee unless such appointment poses no substantial conflict of interest and unless the creditor is:

(1) A relative who resides with the annuitant;

(2) A legal guardian or legal representative of the annuitant; or

(3) A licensed or certified care facility (or owner, administrator or employee thereof) where there annuitant resides.

§ 266.5 Order of preference in selecting a representative payee.

As a guide in selecting a representative payee, categories of preferred payees have been established. These preferences are flexible. The primary concern of the Board is to select the payee who will best serve the annuitant's interest. The preferences are:

(a) For annuitants 18 years old or older, the preference is:

(1) A legal guardian, spouse, or other relative who has custody of the annuitant or who demonstrates strong concern for the personal welfare of the annuitant;

(2) A friend who has custody of the annuitant or demonstrates strong concern for the personal welfare of the annuitant;

(3) A public or nonprofit agency or institution having custody of the annuitant;

(4) A private institution operated for profit and licensed under State law, which has custody of the annuitant; and

(5) Persons other than those listed above who are qualified to carry out the responsibilities of a representative payee and who are able and willing to serve as a payee for an annuitant; *e.g.*, members of community groups or organizations who volunteer to serve as representative payee for an annuitant.

(b) For annuitants under age 18, the preference is:

(1) A natural or adoptive parent who has custody of the annuitant, or a legal guardian;

(2) A natural or adoptive parent who does not have custody of the annuitant, but is contributing toward the annuitant's support and is demonstrating strong concern for the annuitant's well-being;

(3) A relative or stepparent who has custody of the annuitant;

(4) A natural or adoptive parent who does not have custody of the annuitant

and is not contributing toward his or her support but is demonstrating strong concern for the annuitant's well-being;

(5) A relative who does not have custody of the annuitant but is contributing toward the annuitant's support and is demonstrating concern for the annuitant's well-being;

(6) A relative or close friend who does not have custody of the annuitant but is demonstrating concern for the annuitant's well-being; and

(7) An authorized social agency or custodial institution.

§ 266.6 Information to be submitted by a representative payee-applicant; face-to-face interview.

Before the Board selects a representative payee, the Board may request the payee-applicant to provide information concerning the factors listed in § 266.4 of this part. An employee of the Board may also conduct a face-to-face interview with the payee-applicant.

(Approved by the Office of Management and Budget under control number 3220–0052.)

§ 266.7 Accountability of a representative payee.

(a) A representative payee is accountable for the use of benefits. The Board will require periodic written reports from representative payees. The Board may also, at the Board's option, verify how a representative payee used benefit payments. A representative payee must keep records of what was done with all benefit payments in order to make accounting reports. The Board may ask the following questions:

(1) The amount of benefit payments on hand at the beginning of the accounting period;

(2) How the benefit payments were used;

(3) How much of the benefit payments were saved and how the savings were invested;

(4) Where the annuitant lived during the accounting period;

(5) The amount of the annuitant's income from other sources during the accounting period. The Board may ask for information about other funds to enable the Board to evaluate the use of benefit payments; and

(6) Whether the representative payee has been convicted of a felony or misdemeanor offense under the statutes administered by the Board or by the Social Security Administration within the past 15 years or whether any such charges are pending.

(b) An individual to whom payments are certified as representative payee on behalf of an annuitant shall submit a written report in such form and at such times as the Board may require, accounting for the payments certified to him or her on behalf of the annuitant. If, however, such payee is a court-appointed fiduciary and, as such, is required to make an annual accounting to the court, a true copy of each such account filed with the court may be submitted in lieu of the accounting form prescribed by the Board. If any representative payee fails to submit the required accounting within a reasonable period of time after it is requested, no further payments shall be made to him or her on behalf of the annuitant unless for good cause shown, the default of the representative payee is excused by the Board, and the required accounting is thereafter submitted.

(c) At any time after the Board has selected a representative payee, the Board may ask such payee to submit information showing a continuing relationship to the annuitant and a continuing responsibility for the care of the annuitant. If the representative payee does not give the Board the requested information within a reasonable period of time, the Board may stop paying such payee unless the Board determines that the payee had a good reason for not complying with the Board's request, and the Board receives the information requested.

(Approved by the Office of Management and Budget under control numbers 3220–0052 and 3220–0151.)

(d) Where, pursuant to paragraphs (b) or (c) of this section, the Board suspends payments, such suspension shall not exceed a period of 30 days; thereafter, the payments will be made to the annuitant except where the annuitant is an unemancipated minor under age 18 or where in the Board's judgment the interests of the annuitant would not be served by releasing payment to the annuitant.

§ 266.8 Advance notice of the determination to make representative payment.

(a) As a general rule, whenever the Board intends to make representative payment and to name a representative payee, the Board will notify the annuitant or, in the case of an unemancipated minor under age 18, or an individual who is legally incompetent, the individual acting on his or her behalf of the Board's proposed actions. Such notice will tell the person that the Board plans to name a representative payee and who that payee will be. The notice will also ask the person to contact the Board within 15 days of the date of the notice if he or she objects to either proposed action. If he or she objects to either proposed action, the objecting party may—

(1) Review the evidence upon which the proposed actions will be based; and

(2) Submit any additional evidence regarding the proposed actions.

(b) If the objecting party objects to the proposed actions, the Board will review its proposed determinations and consider any additional information provided. The Board will then issue a decision on whether to appoint a representative payee and who that payee will be. If the objecting party is dissatisfied with either determination, he or she may request a reconsideration under part 260 of this chapter.

(c) If the objecting party does not file a timely objection to the proposed actions, the Board will issue a decision on whether to appoint a representative payee and who that payee will be. If the objecting party is dissatisfied with either determination, he or she may request a reconsideration under part 260 of this chapter.

(d) A request for reconsideration or an appeal from a determination under this section under part 260 of this chapter shall not prevent the Board from making payments to a representative payee during the pendency of such reconsideration or appeal.

(e) The Board's failure or refusal to select an individual as representative payee or the Board's termination of representative payee status with respect to an individual is not subject to a request for reconsideration or an appeal under part 260 of this chapter by such individual.

§ 266.9 Responsibilities of a representative payee.

(a) A representative payee shall, subject to review by the Board and to such requirements as it may from time-to-time prescribe, apply the payments made to him or her on behalf of the annuitant only for the use and benefit of such annuitant, and in a manner and for purposes which are in the annuitant's best interests.

(b) A representative payee shall notify the Board of any event that will affect the amount of benefits the annuitant receives or the right of the annuitant to receive benefits.

(c) A representative payee shall notify the Board of any change in his or her circumstances that would affect performance of the payee responsibilities.

§ 266.10 Use of benefit payments.

(a) *Current maintenance.* Payments made to an individual as representative payee on behalf of an annuitant shall be considered as having been applied for

the use and benefit of the annuitant when they are used for the annuitant's current maintenance. Current maintenance includes costs incurred in obtaining food, shelter, clothing, medical care, and personal comfort items.

Example: An aged annuitant is entitled to a monthly railroad retirement benefit of $800. His son, who is his representative payee, disburses his benefits in the following manner:

Rent and utilities	$500
Medical	50
Food	80
Clothing (coat)	90
Savings	60
Miscellaneous	20

The above expenditures would represent proper disbursements on behalf of the annuitant.

(b) *Institutional care.* If an annuitant is receiving care in a Federal, state, or private institution because of mental or physical incapacity, current maintenance includes the customary charges made by the institution in providing care and maintenance, as well as expenditures for those items which will aid in the annuitant's recovery or release from the institution or expenses for personal needs which will improve the annuitant's conditions while in the institution.

(c) *Support of legal dependents.* If the current maintenance needs of the annuitant are met, the representative payee may use part of the payments for the support of the annuitant's legally dependent spouse, child, and/or parent.

(d) *Claims of creditors.* Where a debt arose prior to the first month for which benefits are certified to a representative payee, the representative payee may satisfy such debt out of present benefit payments only if the current and reasonably foreseeable needs of the annuitant are met.

Example: A retroactive railroad retirement annuity check in the amount of $2,100, representing benefits due for November 1989 through January 1990, was issued on behalf of the annuitant to the annuitant's daughter, who is the representative payee. The check was certified in February 1990. The nursing home, where the annuitant resides, is owed money for maintenance expenses the annuitant incurred prior to February 1990.

If the accrual is not required for the annuitant's current maintenance and the annuitant had no foreseeable needs which would require large disbursements, the expenditure of the accrual or part thereof for the past due maintenance charges would be consistent with the Board's guidelines.

§ 266.11 Conservation and investment of benefit payments.

(a) *General.* If benefit payments made to a representative payee are not needed for the annuitant's current maintenance or reasonably foreseeable needs or the support of legal dependents or to pay creditors in accordance with § 266.10, they shall be conserved or invested on behalf of the annuitant. Such funds must be invested in accordance with the rules applicable to investment of trust estates by trustees. Any investment must show clearly that the representative payee holds the property in trust for the annuitant.

(b) *Preferred investments.* Preferred investments for excess funds are deposits in an interest or dividend paying account in a bank, trust company, credit union, or savings and loan association which is insured under either Federal or State law, direct obligations of the United States Government or obligations for which both principal and interest are guaranteed unconditionally by the United States Government. The account must be in a form which shows clearly that the representative payee has only a fiduciary, and not a personal, interest in the funds. If the payee is the legally appointed guardian or fiduciary of the annuitant, the account may be established to indicate this relationship. If the payee is not the legally appointed guardian or fiduciary, the accounts may be established as follows:

(1) For U.S. Savings Bonds—

_____
(Name of annuitant)

_____
(Social Security Number), for whom

_____
(Name of payee)
is representative payee for Railroad Retirement benefits;

(2) For interest or dividend paying accounts—

_____
(Name of annuitant) by

_____
(Name of payee), representative payee.

(c) *Interest and dividend payments.* The interest and dividends which result from an investment are the property of the annuitant and may not be considered to be the property of the representative payee.

(d) *Prohibition against commingling.* The representative payee shall not commingle his or her personal funds with the representative payments. A representative payee may consolidate and maintain an annuitant's funds in an account with other annuitants if he or she maintains a separate, accurate and complete accounting of each annuitant's funds under his or her control.

§ 266.12 Effect of matters or actions submitted or taken by legal guardian, etc.

All matters and actions in connection with an annuity submitted or taken by the guardian or other person legally vested with the care of the person or estate of an incompetent or a minor shall be considered by the Board in the same manner and with the same effect as though such matters or actions had been submitted or taken by the ward, if the ward had capacity to act in his or her own behalf; *Provided, however,* That the Board may, if it deems it necessary, require the guardian or other person legally vested with the care of the person or estate of an incompetent or a minor to submit a certified copy of an order from the court of appointment authorizing some particular action which the guardian or other person legally vested with the care of the person or estate desires to take in connection with the application.

§ 266.13 When a new representative payee will be selected.

When the Board learns that the interests of the annuitant are not served by continuing payment to the present representative payee or that the present representative payee is no longer able to carry out the payee responsibilities, the Board will undertake to find a new representative payee. The Board will select a new representative payee if the Board finds a preferred payee or if the present payee—

(a) Has not used the benefit payments on the annuitant's behalf in accordance with the guidelines in this part;

(b) Has not carried out the other responsibilities described in this part;

(c) Dies;

(d) No longer wishes to be representative payee;

(e) Is unable to manage the benefit payments; or

(f) Fails to cooperate, within a reasonable time, in providing evidence, accounting, or other information which the Board requests.

§ 266.14 When representative payment will be stopped.

If an annuitant receiving representative payment shows the Board that he or she is mentally and physically able to manage or direct the management of benefit payments, the Board will make direct payment to the annuitant. Information which the annuitant may give to the Board to support his or her request for direct payment include the following:

(a) A physician's statement regarding the annuitant's condition, or a statement

by a medical officer of the institution where the annuitant is or was confined, showing that the annuitant is able to manage or direct the management of his or her funds;

(b) A certified copy of a court order restoring the annuitant's rights in a case where an annuitant was adjudged legally incompetent; or

(c) Other evidence which establishes the annuitant's ability to manage or direct the management of benefits.

§ 266.15 Transfer of accumulated benefit payments.

A representative payee who has conserved or invested funds from railroad retirement payments made to him or her on behalf of an annuitant shall, upon direction of the Board, transfer any such funds (including interest or dividends earned from investment of such funds) to a successor representative payee appointed by the Board, or, at the option of the Board, shall transfer such funds, including interest, to the Board for payment to a successor payee or to the annuitant.

Dated: January 21, 1994.

By Authority of the Board.

Beatrice Ezerski,

Secretary to the Board.

[FR Doc. 94–1919 Filed 1–27–94; 8:45 am]

BILLING CODE 7905–01–P

---

20 CFR Part 336

RIN 3220–AA67

Duration of Normal and Extended Benefits

AGENCY: Railroad Retirement Board.

ACTION: Final rule.

SUMMARY: The Railroad Retirement Board (Board) hereby revises its regulations under the Railroad Unemployment Insurance Act (RUIA) to update the provisions concerning the duration of normal unemployment and sickness benefits under the RUIA and to add provisions concerning the establishment of extended benefit periods under the RUIA.

EFFECTIVE DATE: January 28, 1994.

ADDRESSES: Secretary to the Board, Railroad Retirement Board, 844 Rush Street, Chicago, Illinois 60611.

FOR FURTHER INFORMATION CONTACT: Thomas W. Sadler, Assistant General Counsel, Railroad Retirement Board, 844 Rush Street, Chicago, Illinois 60611, (312) 751–4513, TDD (312) 751–4701.

SUPPLEMENTARY INFORMATION: This revision to part 336 revises the part heading from "Exhaustion of Rights to Benefits" to "Duration of Normal and Extended Benefits", and consists of two subparts. Subpart A explains how long a qualified railroad employee may receive normal unemployment and sickness benefits. Subpart B explains under what circumstances an employee with 10 or more years of railroad service may receive extended unemployment or sickness benefits and the duration of an employee's extended benefit period. This rule also removes existing § 336.3, which relates to payment of extended unemployment benefits under the Temporary Extended Railroad Unemployment Insurance Benefits Act of 1961. Extended benefits are no longer payable under that Act. As revised, § 336.3 explains the duration of normal sickness benefits under the RUIA.

On August 17, 1993, the Board published this rule as a proposed rule (58 FR 43577), inviting comments on or before September 16, 1993. No comments were received.

The Board has determined that this is not a significant regulatory action for purposes of Executive Order No. 12866; therefore, no regulatory impact analysis is required. The information collection requirements contained in this rule have been approved by the Office of Management and Budget under control number 3220–0070.

List of Subjects in 20 CFR Part 336

Railroad employees, Railroad unemployment benefits.

For the reasons set out in the preamble, title 20, chapter II, part 336 of the Code of Federal Regulations is revised to read as follows:

PART 336—DURATION OF NORMAL AND EXTENDED BENEFITS

Subpart A—Normal Benefits

Sec.
336.1 Introduction.
336.2 Duration of normal unemployment benefits.
336.3 Duration of normal sickness benefits.
336.4 Base year compensation.
336.5 Notice to employee.

Subpart B—Extended Benefits

336.10 Eligibility.
336.11 Exhaustion of rights to normal unemployment benefits.
336.12 Exhaustion of rights to normal sickness benefits.
336.13 Years of service requirement.
336.14 Extended benefit period.
336.15 How to claim extended benefits.
336.16 Notice to employee.

Authority: 45 U.S.C. 362(l).

Subpart A—Normal Benefits

§ 336.1 Introduction.

(a) *General.* This subpart explains how long a qualified employee may receive normal unemployment or sickness benefits under the Railroad Unemployment Insurance Act during a benefit year. Under section 2(c) of that Act, normal unemployment benefits are payable for up to 130 days of unemployment within a benefit year, or in an amount equal to the amount of the employee's "base year compensation", whichever is less. A similar limitation applies to the payment of sickness benefits. An employee who exhausts his or her normal unemployment or sickness benefits may be eligible for payment of extended unemployment or extended sickness benefits under the conditions set forth in subpart B of this part.

(b) *Definitions.* The terms "benefit year", "base year", and "compensation" are defined in part 302 of this chapter. The term "registration period" is defined in parts 325 and 335 of this chapter. For the purposes of this subpart, and as explained in § 336.4 of this part, an employee's "base year compensation" may include compensation in excess of the monthly compensation base (as defined in part 302 of this chapter) even though such excess may not be counted for the purpose of determining whether such employee is a "qualified employee" within the meaning of part 302.

(c) *Recovery of benefits.* When unemployment or sickness benefits are recovered by the Board for one or more days, the Board will disregard those days in determining whether the employee has exhausted normal unemployment or sickness benefits with respect to the applicable benefit year.

§ 336.2 Duration of normal unemployment benefits.

(a) *130 compensable day limitation.* A qualified employee who has satisfied the waiting period for a benefit year may receive benefits for a maximum of 130 days of unemployment within such benefit year, subject to the limitation on payment explained in paragraph (b) of this section. In any registration period beginning after the end of the waiting period and before the beginning of the next ensuing benefit year, benefits are payable for days of unemployment in excess of four, but the aggregate number of compensable days may not exceed 130 for the benefit year. An employee who is unemployed on all days during a registration period could have a maximum of 10 compensable days of unemployment in such registration period. The amount of benefits for each compensable day of unemployment is the amount of the daily benefit rate computed for such employee pursuant to part 330 of this chapter.

(b) *Base year compensation limit.* Notwithstanding the provisions of paragraph (a) of this section, the Board will not pay unemployment benefits to a qualified employee, with respect to his or her days of unemployment within a benefit year, in an amount greater than the amount of his or her base year compensation, as computed under § 336.4 of this part.

(c) *Unemployment due to a strike.* The limitations set forth in paragraphs (a) and (b) of this section also apply to an employee whose unemployment is due to a stoppage of work because of a strike in the establishment, premises, or enterprise at which he was last employed. But no unemployment benefits are payable for the employee's first 14 days of unemployment due to such stoppage of work.

§ 336.3 Duration of normal sickness benefits.

The duration of normal sickness benefits is the same as the duration of normal unemployment benefits, as set forth in § 336.2 of this part. A qualified employee who has satisfied the benefit year waiting period and is otherwise eligible for sickness benefits may receive benefits for a maximum of 130 days of sickness within a benefit year, but the amount paid as sickness benefits may not exceed the amount of the employee's base year compensation, as computed under § 336.4 of this part.

§ 336.4 Base year compensation.

(a) *Formula.* For the purposes of this part, an employee's base year compensation includes any compensation in excess of the monthly compensation base (as defined in part 302 of this chapter) for any month in the applicable base year but shall not include any amount that exceeds the value of "X" in the following formula: X = $775(A/$600). In this formula, "A" is the dollar amount of the monthly compensation base with respect to months in such base year. For example, if an employee had railroad earnings of $1,500 per month in each of three months in base year 1990, the employee's base year compensation for purposes of part 302 of this chapter would be $2,235 (three times the monthly compensation base of $745 per month for months in 1990). But the employee's base year compensation for purposes of computing maximum normal unemployment (or sickness) benefits under this subpart would be $2,886 (three times $962), and his or her normal unemployment (or sickness) benefits would not be considered exhausted until he or she is paid unemployment (or sickness) benefits in an amount equal to $2,886. In this example, $962 is the amount computed as the value of "X" in the above formula when "A" is equal to $745.

(b) *Employer's duty to report.* The base year employer(s) of an employee shall provide information as to the amount of an employee's monthly compensation in excess of the monthly compensation base, as defined in part 302 of this chapter, unless the amount of the employee's compensation at the monthly compensation base limit, as already reported to the Board, is equal to or greater than an amount equal to 130 times the daily benefit rate applicable to the employee's days of unemployment or days of sickness.

(Approved by the Office of Management and Budget under control number 3220–0070.)

§ 336.5 Notice to employee.

The Board will notify an employee when it appears that his or her right to normal unemployment or normal sickness benefits will be exhausted. Such notice will include information about the availability of extended benefits under subpart B of this part if the employee has completed 10 years of railroad service and the availability of normal benefits for the next ensuing benefit year if the employee is not eligible for extended benefits.

Subpart B—Extended Benefits

§ 336.10 Eligibility.

(a) Except as provided in paragraph (b) of this section, an employee may receive extended unemployment or extended sickness benefits under this part if he or she:

(1) Has exhausted normal unemployment or normal sickness benefits (as the case may be) under subpart A of this part;

(2) Has completed 10 years of railroad service, as set forth in § 336.13 of this part; and

(3) Continues to have days of unemployment or days of sickness, as the case may be.

(b) An employee is not eligible for extended sickness benefits if he or she has voluntarily retired or has attained age 65. In the case of claims for unemployment benefits, an employee is not eligible for extended unemployment benefits if he or she has voluntarily left work without good cause or has voluntarily retired.

§ 336.11 Exhaustion of rights to normal unemployment benefits.

For the purposes of this part, the Board considers that an employee has exhausted his or her current rights to normal benefits for days of unemployment if:

(a) The employee received unemployment benefits for 130 days of unemployment in the benefit year; or

(b) The employee received unemployment benefits in the benefit year equal to the amount of his or her base year compensation; or

(c) At the end of a normal benefit year during which the employee was qualified for benefits, he or she received less than the maximum unemployment benefits for the benefit year and he or she is not qualified for benefits in the next succeeding benefit year.

§ 336.12 Exhaustion of rights to normal sickness benefits.

For the purposes of this part, the Board considers that an employee has exhausted his or her current rights to normal benefits for days of sickness if:

(a) The employee received sickness benefits for 130 days of sickness in the benefit year; or

(b) The employee received sickness benefits in the benefit year equal to the amount of his or her base year compensation; or

(c) At the end of the normal benefit year during which the employee was qualified for benefits, he or she received less than the maximum sickness benefits for the benefit year and he or she is not qualified for benefits in the next succeeding benefit year.

§ 336.13 Years of service requirement.

(a) *Statutory basis.* For the purposes of this part, an employee is not eligible for extended unemployment or sickness benefits if he or she does not have at least 10 years of railroad service. An employee who has 120 service months as defined in part 210 of this chapter, whether or not consecutive, is considered to have 10 years of railroad service, and an employee who has 180 service months, whether or not consecutive, is considered to have 15 years of railroad service.

(b) *Initial determination.* The Board will determine whether an employee has 10 years, or 15 years, of railroad service on the basis of reports filed by employers pursuant to part 209 of this chapter. The number of years of service shown in the Board's records will be accepted as correct for the purposes of this part, unless the employee claims credit for more service than that shown in the Board's records and such additional service is verified. In any such case, the Board will afford the employee an opportunity to establish credit for additional service if such service would be sufficient to bring the employee up to 10 years, or 15 years, of service. If the claim for credit for additional service is made by an

employee who has at least 10 years of railroad service but is claiming credit for at least 15 years, the Board will not delay the establishment of an extended benefit period based on 10 years of service but shall extend the ending date of such period if the employee is able to establish credit for 15 years of railroad service.

(c) *Effective date.* An employee acquires 10 years, or 15 years, of railroad service, as the case may be, as of the first day with respect to which creditable compensation is attributable in his 120th, or 180th, month of service.

§ 336.14 Extended benefit period.

(a) *Defined.* An extended benefit period consists of seven consecutive 14-day registration periods in the case of an employee having 10–14 years of railroad service and 13 consecutive 14-day registration periods in the case of an employee having 15 or more years of railroad service.

(b) *Beginning date.* In the case of unemployment benefits, an extended benefit period begins with the first day of unemployment after the day on which the employee exhausts his or her rights to normal unemployment benefits. In the case of sickness benefits, the beginning date is the first day of sickness after the employee exhausts normal sickness benefits. Such first day of unemployment or first day of sickness must be within the same benefit year with respect to which the employee exhausted normal unemployment or normal sickness benefits, as the case may be. However, no extended benefit period may begin on any day of unemployment or sickness prior to the date on which the employee acquired 10 years of railroad service.

(c) *Ending date.* If an employee has 10 but less than 15 years of railroad service, his or her extended benefit period ends on the 97th day after it began. If an employee has 15 or more years of railroad service, his or her extended benefit period ends on the 181st day after it began. If an employee attains age 65 during an extended sickness benefit period, such extended benefit period will terminate on the day next preceding the date on which the employee attains age 65, except that it may continue for the purpose of paying benefits for his or her days of unemployment, if any, during such extended benefit period. If an extended sickness benefit period terminates because the employee has attained age 65 and if at that point the employee has rights to normal sickness benefits, the employee will be paid normal sickness benefits if he or she is otherwise entitled to payment thereof.

(d) *Maximum number of compensable days.* During an extended benefit period consisting of seven consecutive 14-day registration periods, extended benefits may be paid for a maximum of 65 days of unemployment (or 65 days of sickness, as the case may be). During an extended benefit period consisting of 13 consecutive 14-day registration periods, extended benefits may be paid for a maximum of 130 days of unemployment (or 130 days of sickness, as the case may be).

§ 336.15 How to claim extended benefits.

An employee who has 10 or more years of railroad service who exhausts his or her rights to normal unemployment or normal sickness benefits and who wishes to claim extended unemployment or extended sickness benefits may do so by claiming benefits on the forms provided by the Board pursuant to parts 325 or 335 of this chapter. The claim forms provided for this purpose are the same as those provided for claiming normal benefits. No special application for extended benefits is required, and no waiting period applies to the payment of extended benefits.

§ 336.16 Notice to employee.

Upon determining that an employee is eligible for a period of extended unemployment or sickness benefits, the Board will notify the employee of the beginning and ending dates of such extended benefit period.

Dated: January 21, 1994.

By Authority of the Board.

Beatrice Ezerski,

Secretary to the Board.

[FR Doc. 94–1829 Filed 1–27–94; 8:45 am]

BILLING CODE 7905–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 74

[Docket No. 91C–0432]

Listing of Color Additives for Coloring Sutures; D&C Violet No. 2; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of December 16, 1993, for the final rule that amended the color additive regulations to provide for the safe use of D&C Violet No. 2 to color poliglecaprone 25 (ε-caprolactone/glycolide copolymer) absorbable sutures for general surgery.

DATES: Effective date confirmed: December 16, 1993.

FOR FURTHER INFORMATION CONTACT: Mitchell A. Cheeseman, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–254–9511.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 15, 1993 (58 FR 60106), FDA amended 21 CFR 74.3602 to provide for the safe use of D&C Violet No. 2 to color poliglecaprone 25 (ε-caprolactone/glycolide copolymer) absorbable sutures for general surgery.

FDA gave interested persons until December 16, 1993, to file objections or requests for a hearing. The agency received no objections or requests for a hearing on the final rule. Therefore, FDA finds that the final rule published in the **Federal Register** of November 15, 1993, should be confirmed.

List of Subjects in 21 CFR Part 74

Color additives, Cosmetics, Drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201, 401, 402, 403, 409, 501, 502, 505, 601, 602, 701, 721 (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), notice is given that no objections or requests for a hearing were filed in response to the November 15, 1993, final rule. Accordingly, the amendments promulgated thereby became effective December 16, 1993.

Dated: January 24, 1994.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 94–1885 Filed 1–27–94; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 330

[Docket No. 92N–0454]

RIN 0905–AA06

Labeling of Drug Products for Over-the-Counter Human Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its general labeling policy for over-the-

counter (OTC) drug products to allow for the interchangeable use of certain words in labeling required by an OTC drug monograph. Examples of these words include: "doctor" and "physician," "consult" and "ask," and "indications" and "uses." This final rule provides alternate terminology in the labeling of OTC drug products for words that have the same meaning.

EFFECTIVE DATE: February 28, 1994.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD–810), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 5, 1993 (58 FR 17553), the agency proposed to amend its general labeling policy for over-the-counter (OTC) drug products to allow for the interchangeable use of certain words in the labeling required by an OTC drug monograph. The agency had previously proposed in a number of tentative final monographs and included in a number of final monographs a provision that the words "doctor" and "physician" may be used interchangeably in the labeling of OTC drug products. (See, e.g., §§ 333.150(e), 333.350(e), and 336.50(e) (21 CFR 333.150(e), 333.350(e), and 336.50(e)).) Instead of including this provision in each OTC drug monograph, the agency proposed to include such a provision in § 330.1 (21 CFR 330.1) as part of the general conditions under which an OTC drug is generally recognized as safe, effective, and not misbranded. The agency also proposed that, at manufacturers' discretion, the word "ask" could be substituted for the word "consult," which appears in the directions for many OTC drug monograph ingredients. (See, e.g., §§ 333.150(c)(1), 333.350(c)(2), and 340.50(c)(2) (21 CFR 340.50(c)(2)).) Thus, the agency proposed that the phrases "consult a physician," "consult a doctor," "ask a physician," and "ask a doctor" could be used interchangeably. The agency invited comments and suggestions as to such other terms that could be used interchangeably, i.e., terms general in nature that appear in more than one OTC drug monograph.

One trade association, representing OTC drug manufacturers, and one drug manufacturer submitted comments in response to the agency's proposal. Copies of the comments are on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

I. Summary of the Comments Received

The comment from the trade association agreed with the agency's proposal to allow for the interchangeable use of the words "doctor" and "physician," and the words "consult" and "ask." The comment suggested the following additional sets of alternative terms and gave the following citations, showing inclusion in several OTC drug monographs, as support: (1) "Clean" or "cleanse" (§§ 333.150(d), 333.350(d)(1), and 346.50(d)(1) (21 CFR 346.50(d)(1))); (2) "persist" or "continue" (§§ 341.76(c)(5)(ii), 346.50(c)(7)(iii), 357.150(c)(1), and 357.850(c)(1)(i) (21 CFR 341.76(c)(5)(ii), 346.50(c)(7)(iii), 357.150(c)(1), and 357.850(c)(1)(i))); (3) "chronic" or "persistent" (§§ 336.50(c)(1), 338.50(c)(3), 341.74(c)(2), (c)(3), and (c)(4)(ii) through (c)(4)(iv), and 341.78(c)(1) (21 CFR 338.50(c)(3), 341.74(c)(2), (c)(3), and (c)(4)(ii) through (c)(4)(iv), and 341.78(c)(1))); (4) "assistance" or "help" (§§ 331.30(g), 332.30(c), 341.74(f), and 342.76(c)(5)(i) and (c)(6)(ii) (21 CFR 331.30(g), 332.30(c), 341.74(f), and 342.76(c)(5)(i) and (c)(6)(ii))); and (5) "pulmonary" or "lung" (§§ 336.50(c)(1) and 338.50(c)(3)). The comment stated that, in some instances, the paired terms already appear in the cited regulations and, in other cases, the alternative terms may be better understood by consumers. The comment mentioned the following examples: "Lung" disease may be better understood than the more technical "pulmonary" disease, and "persistent" may be better understood than "chronic." The comment stated its understanding that the rule is intended only to provide a glossary of comparable terms that may be used interchangeably, not to make substantive changes in the underlying required label statements. For example, the comment mentioned that the rule would not permit the term "health professional" as an alternative to the terms "doctor" or "physician," because a "health professional" may include pharmacists, nurses, midwives, and others who are not licensed to practice medicine. The comment requested that the agency clarify that this rule applies only to OTC drug monograph language otherwise required to be declared verbatim in OTC drug product labeling. The comment added that the rule would not apply to or otherwise affect the use of truthful and nonmisleading alternative terms that can be used for monograph indications.

The other comment also proposed that the terms "assistance" and "help" be allowed interchangeably in the general overdose warning, which states: "In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately."

II. The Agency's Final Conclusions

The agency has carefully evaluated the comments' proposals for the interchangeable use of certain terms and concludes that the interchangeable terms suggested by the comments ("clean" or "cleanse," "persist(s)" or "continue(s)," "assistance" or "help," and "pulmonary" or "lung") are acceptable and will help promote better label readability.

In addition, the agency has determined that the terms "indication(s)" or "use(s)" should be allowed to be used interchangeably. The agency considers the term "use(s)" to be simpler and better understood by consumers than the term "indication(s)." The agency is including this option in § 330.1(i).

The agency disagrees with the interchangeable use of the words "chronic" and "persistent." "Chronic," by definition, is of long duration, or may be subject to habit or disease for a lengthy period (Ref. 1). On the other hand, "persistent," by definition, is refusing to let go, insistently repetitive or continuous, or enduring (Ref. 2). While "chronic" is also "persistent," "persistent" is not necessarily "chronic." For instance, a chronic cough denotes one that has gone on for a lengthy period of time, while a persistent cough could be one of recent onset that does not respond to treatment. Thus, a chronic cough and a persistent cough may be the same, or they could be two separate entities. Therefore, interchangeable use of the terms "chronic" and "persistent" is not included in the final rule.

References

(1) "Webster's II New Riverside University Dictionary," Houghton Mifflin Co., Boston, 1984, s.v. "chronic."

(2) "Webster's II New Riverside University Dictionary," Houghton Mifflin Co., Boston, 1984, s.v. "persistent."

This final rule does not make substantive changes in the language required in OTC drug monographs. The rule allows for alternative terminology for certain terms that are sufficiently comparable to be used interchangeably. The rule does not affect the use of truthful and nonmisleading terminology as an alternative to monograph indications in accord with § 330.1(c)(2)(ii) and (c)(2)(iii).

The agency has examined the economic consequences of this final rule and determined that it does not require either a regulatory impact analysis, as specified in Executive Order 12866, or a regulatory flexibility analysis, as defined in the Regulatory Flexibility Act (Pub. L. 96–354). This final rule provides alternative labeling options that can be implemented at very little cost by manufacturers at the next printing of labels, for those products for which the manufacturer chooses to make a change. Thus, the rule will have no significant economic impact. The agency concludes that the final rule is not a major rule as defined in Executive Order 12866. Further, the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act.

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 330

Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 330 is amended as follows:

PART 330—OVER-THE-COUNTER (OTC) HUMAN DRUGS WHICH ARE GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE AND NOT MISBRANDED

1. The authority citation for 21 CFR part 330 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

2. Section 330.1 is amended by adding new paragraph (i) to read as follows:

§ 330.1 General conditions for general recognition as safe, effective and not misbranded.

* * * * *

(i) The following terms may be used interchangeably in any of the labeling established in parts 331 through 358 of this chapter:

(1) "Ask" or "consult".
(2) "Assistance" or "help".
(3) "Clean" or "cleanse".
(4) "Continue" or "persist".
(5) "Continues" or "persists".
(6) "Doctor" or "physician".
(7) "Indication" or "use".
(8) "Indications" or "uses".
(9) "Lung" or "pulmonary".

* * * * *

Dated: October 15, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 94–1791 Filed 1–27–94; 8:45 am]

BILLING CODE 4160–01–F

---

21 CFR Part 358

[Docket No. 82N–0214]

RIN 0905–AA06

Dandruff, Seborrheic Dermatitis, and Psoriasis Drug Products for Over-the-Counter Human Use; Amendment to the Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule amending the final monograph for over-the-counter (OTC) dandruff, seborrheic dermatitis, and psoriasis drug products to include 0.6 percent micronized selenium sulfide for the control of dandruff. This final rule is part of the ongoing review of OTC drug products conducted by FDA.

EFFECTIVE DATE: January 30, 1995.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD–810), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 4, 1991 (56 FR 63554), FDA issued a final monograph for OTC dandruff, seborrheic dermatitis, and psoriasis drug products in subpart H of part 358 (21 CFR part 358, subpart H). The monograph lists selenium sulfide 1 percent in § 358.710(a)(5) as an active ingredient that is used for the control of dandruff. The selenium sulfide included in the monograph is not micronized (reduced to a fine particle size).

In the **Federal Register** of April 5, 1993 (58 FR 17554), the agency published a notice of proposed rulemaking to amend the final monograph for OTC dandruff, seborrheic dermatitis, and psoriasis drug products to include 0.6 percent micronized selenium sulfide in § 358.710(a) as an active ingredient for the control of dandruff. The agency also proposed to add the following definition for micronized selenium sulfide in § 358.703(e): "Selenium sulfide that has been finely ground and that has a median particle size of approximately 5 micrometers (μm), with not more than 0.1 percent of the particles greater than 15 μm and not more than 0.1 percent of the particles less than 0.5 μm." Interested persons were invited to submit written comments and comments on the agency's economic impact determination by June 4, 1993.

No comments were received in response to the proposed amendment. As discussed in the proposal (58 FR 17554 at 17556), the agency advised that any final rule resulting from this proposed rule would be effective 12 months after its date of publication in the **Federal Register**. Therefore, on or after January 30, 1995, any OTC drug product that is not in compliance with this amendment to the final rule may not be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application or abbreviated application. Further, any OTC drug product subject to the rule that is repackaged or relabeled after the effective date of the rule must be in compliance with the rule regardless of the date that the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the rule at the earliest possible date.

No comments were received in response to the agency's request for specific comment on the economic impact of this rulemaking (58 FR 17554 at 17557). The agency has examined the economic consequences of this final rule in conjunction with other rules resulting from the OTC drug review. In a notice published in the **Federal Register** of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12866. The agency therefore concludes that no one of these rules, including this amendment of the final monograph for OTC dandruff, seborrheic dermatitis, and psoriasis drug products, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act (Pub. L. 96–354). That assessment included a discretionary regulatory flexibility analysis in the event that an

individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC dandruff, seborrheic dermatitis, and psoriasis drug products is not expected to pose such an impact on small businesses. This final rule will not remove any existing products from the market or require any reformulation or relabeling of existing products. The final rule will increase the scope of active ingredients available to industry for this class of OTC drug products. This final rule would allow OTC drug products containing 0.6 percent micronized selenium sulfide and labeled for the control of dandruff to be marketed without having to obtain an approved application, as is currently required. This will be beneficial to small manufacturers. Therefore, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 358

Labeling, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 358 is amended as follows:

PART 358—MISCELLANEOUS EXTERNAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR part 358 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

2. Section 358.703 is amended by adding paragraph (e) to read as follows:

§ 358.703 Definitions.

* * * * *

(e) Selenium sulfide, micronized. Selenium sulfide that has been finely ground and that has a median particle size of approximately 5 micrometers (μm), with not more than 0.1 percent of the particles greater than 15 μm and not more than 0.1 percent of the particles less than 0.5 μm.

3. Section 358.710 is amended by redesignating paragraph (a)(6) as paragraph (a)(7) and by adding new paragraph (a)(6) to read as follows:

§ 358.710 Active ingredients for the control of dandruff, seborrheic dermatitis, or psoriasis.

* * * * *

(a) * * *

(6) Selenium sulfide, micronized, 0.6 percent.

* * * * *

Dated: August 26, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 94–1789 Filed 1–27–94; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[IL 35–2–5847; FRL–4827–3]

Approval and Promulgation of Implementation Plans; Illinois

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: On March 24, 1993, the United States Environmental Protection Agency (USEPA) proposed to approve a January 4, 1989 revision to the Illinois sulfur dioxide (SO_2) State Implementation Plan (SIP), and solicited public comment on the proposed action. This document responds to the public comments received and announces approval of the requested revision, which amends the SIP to provide SO_2 emission limits for the Shell Oil Complex in Roxana, Wood River Township, Illinois. This action also clarifies USEPA's approval of related Illinois SO_2 rules which were included in Illinois' January 4, 1989 submittal but were subsequently revised and resubmitted. The USEPA's approval of these rules satisfies the September 28, 1984 notice of SIP deficiency for Wood River Township.

The USEPA's action is based upon a revision request which was submitted by the State to satisfy the requirements of the Clean Air Act.

EFFECTIVE DATE: This final rulemaking becomes effective on February 28, 1994.

ADDRESSES: A copy of this revision to the Illinois SIP is available here for inspection: Jerry Kurtzweg (ANR–443), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460.

Copies of the SIP revision, public comments on the rulemaking, and other materials relating to this rulemaking are available for inspection at the following address: Regulation Development Branch, Regulation Development Section (AR–18J), U.S. Environmental Protection Agency, Region 5, Chicago, Illinois 60604. (It is recommended that you telephone Mary Onischak at (312) 353–5954, before visiting the Region 5 Office.)

FOR FURTHER INFORMATION CONTACT: Mary Onischak at (312) 353–5954.

SUPPLEMENTARY INFORMATION:

I. Summary of State Submittal

On September 28, 1984, USEPA informed the Governor of Illinois that the Illinois SO_2 SIP was inadequate to protect the National Ambient Air Quality Standards (NAAQS) in Alton and Wood River Townships of Madison County, Illinois, and requested that the State submit revisions to the SIP to address the inadequacy. The determination that the SIP needed to be revised was based on modeling performed by the Illinois Environmental Protection Agency (IEPA) for a regional study which included Madison County. Modeled violations of the NAAQS in Wood River Township were attributed primarily to the Shell Oil refinery complex in Roxana, Illinois. IEPA was able to demonstrate NAAQS attainment in the Wood River area through significant emission reductions at the Shell Oil complex. The Shell Oil emission limits are set forth at 35 Illinois Administrative Code (35 IAC) 214.382, and were submitted to USEPA as a revision to the Illinois SO_2 SIP on January 4, 1989.

On March 24, 1993 (58 FR 15824), USEPA stated that the January 4, 1989 submittal could be approved if Illinois placed a set of recordkeeping and reporting requirements for enforcement purposes into a federally enforceable State operating permit for the Shell Oil Company. Operating permits issued under Illinois' federally enforceable operating permit program, which was approved and incorporated into the Illinois SIP by USEPA on December 17, 1992 (57 FR 59928) at 40 CFR 52.737, are federally enforceable parts of the SIP upon issuance by the State, unless USEPA deems them not federally enforceable. The USEPA transmitted a list of the necessary permit conditions for Shell Oil in a June 12, 1992 letter to the State. On November 10, 1992, the Shell Oil Company applied for an operating permit which would include the recordkeeping and reporting requirements identified by USEPA. On September 1, 1993, a public hearing was held in Wood River, Illinois, to receive comments on the Shell Oil permit. Shell Oil's operating permit (I.D. Number 199090AAA) was issued on November 2, 1993, in accordance with the

requirements of Illinois' federally approved SIP. On December 27, 1993, USEPA determined that permit number 199090AAA meets the requirements for Federal enforceability. Permit number 199090AAA adequately addresses the enforceability deficiencies in 35 IAC 214.382 by incorporating the recordkeeping and reporting requirements included in the June 12, 1992 letter. Because it is federally enforceable, this operating permit supplements Illinois' January 4, 1989 SIP submittal and renders the January 4, 1989 submittal fully approvable.

II. Public Comments/USEPA Response

Two public comments were received by USEPA regarding the March 24, 1993 proposed rule.

Public Comment: On April 22, 1993, USEPA received a comment from the Wood River Manufacturing Complex (Shell Oil), which stated that the Shell Oil Company supports the finalization of USEPA's proposed rulemaking action.

USEPA Response: No response is necessary.

Public Comment: On April 23, 1993, USEPA received comments on behalf of the Jefferson Smurfit Corporation (Smurfit), which operates a facility in Alton Township, Madison County. Smurfit does not appear to object to the substance of the Wood River Township SIP revision, but believes that USEPA should not approve the January 4, 1989 submittal for Wood River Township until the SO_2 attainment status of Alton Township has been finalized. Referring to USEPA's September 22, 1992 (57 FR 43846) action, in which USEPA proposed to redesignate Alton, Granite City, and Nameoki Townships, Madison County, to nonattainment for SO_2, Smurfit stated that any designation for Madison County regarding SO_2 should be consistent between Alton Township, Madison County, and Wood River Township, Madison County. Smurfit believes that Alton Township should not be redesignated to nonattainment if Wood River Township is excluded from the nonattainment area. Smurfit argues that emissions from Wood River Township contribute to ambient SO_2 concentrations in Alton Township, and that USEPA's approval of the January 4, 1989 SIP revision should be deferred until the State determines that the sources in Wood River Township will not interfere with Alton Township's ability to attain the SO_2 ambient standard. Smurfit remarked that it would not dispute USEPA's proposed approval of the January 4, 1989 submittal for Wood River if Alton Township were to remain designated attainment for SO_2.

USEPA Response: The January 4, 1989 Wood River SO_2 SIP was submitted in response to a September 28, 1984 notice of SIP deficiency. The USEPA's approval of the January 4, 1989 SIP revision for Wood River Township addresses this outstanding notice of SIP deficiency for the area. It in no way precludes USEPA from redesignating Wood River Township to nonattainment for SO_2 at a later date, if evidence exists which indicates the necessity for redesignation. Dispersion modeling studies associated with Illinois' SO_2 SIP development have shown that sources in Wood River Township are not currently causing NAAQS violations in Alton Township.

Alton Township was initially cited for SIP deficiencies along with Wood River Township on September 28, 1984. On January 28, 1991, USEPA advised the Governor of Illinois that the whole of Madison County should be designated nonattainment for SO_2. In a letter to USEPA dated March 14, 1991, the Governor of Illinois stated that if a nonattainment designation was necessary pursuant to the 1990 Amendments of the Clean Air Act, only Alton, Granite City, and Nameoki Townships in Madison County should be designated, rather than the entire county. The Director of the Illinois Environmental Protection Agency also stated in a separate letter to USEPA dated March 14, 1991 that Illinois' SO_2 SIP was deficient for these townships. Since 1991, IEPA has worked with Alton Township industries to address SO_2 attainment issues. IEPA requested that Wood River Township remain attainment for SO_2, since a SIP addressing deficiencies in the area had been submitted on January 4, 1989.

On December 21, 1993 (58 FR 67334), USEPA published its intent to defer the final designation to nonattainment of these townships, as the State is working to expeditiously correct the SIP deficiencies. The State submitted a SIP revision for Alton Township on November 18, 1993. USEPA will take action upon this submittal and make a final determination of Alton Township's attainment status in a subsequent action.

III. Final Rulemaking Actions

1. Based on the information contained in the State's January 4, 1989 submittal, and in the federally enforceable operating permit issued to the Shell Oil Company on November 2, 1993, and in consideration of the public comments received on USEPA's March 24, 1993 (58 FR 15824) proposed rule, USEPA is approving amendments to 35 IAC 214.102 and 214.382. The USEPA's approval of these rules satisfies the September 28, 1984 notice of SIP deficiency for Wood River Township, Madison County, Illinois.

In addition to the new rules covering the Shell Oil facility, the January 4, 1989 submittal includes amendments to Illinois' SO_2 Measurement Methods (35 IAC 214.101) and Incorporations by Reference (35 IAC 214.104). However, further amendments to 35 IAC 214.101 and 214.104 were submitted to USEPA on February 8, 1991. On December 20, 1991 (56 FR 66003), USEPA proposed to approve these rules, as submitted on February 8, 1991. On June 26, 1992 (57 FR 28617), USEPA approved 35 IAC 214.101 and incorporated it by reference into the Illinois SO_2 SIP. The USEPA is taking no action on the version of 35 IAC 214.101 which was submitted on January 4, 1989, since the version approved on June 26, 1992 supersedes this submittal.

2. On December 20, 1991 (56 FR 66003), the USEPA proposed to approve 35 IAC 214.104, Incorporations by Reference, which was adopted by the Illinois Pollution Control Board at 15 Ill. Reg. 1017 and became effective January 15, 1991. No public comments were received in response to USEPA's proposed rulemaking action. The USEPA is therefore approving the incorporation of this rule into the Illinois SO_2 SIP.

The following table summarizes USEPA's final rulemaking actions on the rules listed below.

State rule	Submittal date	Previous USEPA action	USEPA's action in this document
Rule 214.101 Measurement Methods.	►Submitted 1/4/89	►No final action taken	►No action.
	►Resubmitted 2/8/91	►Approved 6/26/92 (57 FR 28617).	►No action.
Rule 214.102 Abbreviations and Units.	►Submitted 1/4/89	►Proposal to approve published 3/24/93 (58 FR 15824).	►Approve and incorporate by reference into Illinois SIP.

State rule	Submittal date	Previous USEPA action	USEPA's action in this document
Rule 214.104 Incorporation by Reference.	►Submitted 1/4/89	►No final action taken	►No action.
	►Resubmitted 2/8/91	►Proposal to approve published 12/20/91 (56 FR 66003).	►Approve and incorporate by reference into Illinois SIP.
Rule 214.382 Petroleum and Petrochemical Processes.	►Submitted 1/4/89	►Proposal to approve published 3/24/93 (58 FR 15824).	►Approve and incorporate by reference into Illinois SIP.

Nothing in this action should be construed as permitting, allowing or establishing a precedent for any future request for revision to any SIP. The USEPA shall consider each request for revision to the SIP in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

This action has been classified as a Table 2 action by the Regional Administrator under the procedures published in the **Federal Register** on January 19, 1989 (54 FR 2214–2225). On January 6, 1989, the Office of Management and Budget (OMB) waived Table 2 and 3 SIP revisions (54 FR 2222) from the requirements of section 3 of Executive Order 12291 for a period of 2 years. The USEPA has submitted a request for a permanent waiver for Table 2 and 3 SIP revisions. OMB has agreed to continue the waiver until such time as it rules on USEPA's request. This request continues in effect under Executive Order 12866 which superseded Executive Order 12291 on September 30, 1993.

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by March 29, 1994. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Reporting and recordkeeping requirements, Sulfur oxides.

Dated: January 3, 1994.

Valdas V. Adamkus,

Regional Administrator.

40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

Subpart O—Illinois

2. Section 52.720 is amended by adding paragraph (c)(99) to read as follows:

§ 52.720 Identification of plan.

* * * * *

(c) * * *

(99) On January 4, 1989, the State submitted revisions to its sulfur dioxide rules.

(i) Incorporation by reference.

(A) Title 35: Environmental Protection, Subtitle B: Air Pollution, Chapter 1: Pollution Control Board, Subchapter c: Emission Standards and Limitations for Stationary Sources, Part 214 Sulfur Limitations, Subpart A: General Provisions, section 214.102 Abbreviations and Units. Amended at 12 Ill. Reg. 20778, effective December 5, 1988.

(B) Title 35: Environmental Protection, Subtitle B: Air Pollution, Chapter 1: Pollution Control Board, Subchapter c: Emission Standards and Limitations for Stationary Sources, Part 214 Sulfur Limitations, Subpart A: General Provisions, section 214.104 Incorporations by Reference. Amended at 15 Ill. Reg. 1017, effective January 15, 1991.

(C) Title 35: Environmental Protection, Subtitle B: Air Pollution, Chapter 1: Pollution Control Board, Subchapter c: Emission Standards and Limitations for Stationary Sources, Part 214 Sulfur Limitations, Subpart O: Petroleum Refining, Petrochemical and Chemical Manufacturing, section 214.382 Petroleum and Petrochemical Processes. Amended at 12 Ill. Reg. 20778, effective December 5, 1988.

[FR Doc. 94–1859 Filed 1–27–94; 8:45 am]

BILLING CODE 6560–50–P

---

40 CFR Part 52

[CO20–1–6253; FRL–4830–6]

Clean Air Act Approval and Promulgation of Title V, Section 507, Small Business Assistance Program Plan for the State of Colorado

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: On November 26, 1993, EPA published the notice of proposed rulemaking to approve the State Implementation Plan (SIP) revision submitted by the State of Colorado for the purpose of establishing a Small Business Assistance Program (PROGRAM) in the State. The implementation plan was submitted by the State to satisfy the Federal mandate, found in section 507 of the Clean Air Act (Act), to ensure that small businesses have access to the technical assistance and regulatory information necessary to comply with the Act. The rationale for the approval was set forth in the proposal. No comments were received pursuant to this proposed action. Therefore, EPA is proceeding with its approval of the revision to the Colorado SIP for establishing a PROGRAM in the State.

EFFECTIVE DATE: This rule will become effective on February 28, 1994.

FOR FURTHER INFORMATION CONTACT: Laura Farris, Mail Code–8ART-AP, USEPA Region VIII, 999 18th Street, Suite 500, Denver, Colorado 80202–2405, (303) 294–7539.

SUPPLEMENTARY INFORMATION:

I. Background

Implementation of the provisions of the Clean Air Act (Act), as amended in 1990, will require regulation of many small businesses so that areas may attain and maintain the National ambient air quality standards (NAAQS) and reduce the emission of air toxics. Small businesses frequently lack the technical expertise and financial resources necessary to evaluate such regulations and to determine the appropriate mechanisms for compliance. In anticipation of the impact of these requirements on small businesses, the Act requires that states adopt a PROGRAM, and submit this PROGRAM as a revision to the federally approved SIP. In addition, the Act directs the Environmental Protection Agency (EPA) to oversee these PROGRAMS and report to Congress on their implementation. The requirements for establishing a PROGRAM are set out in section 507 of title V of the Act. In February 1992, EPA issued *Guidelines*

for the Implementation of Section 507 of the 1990 Clean Air Act Amendments, in order to delineate the Federal and state roles in meeting the new statutory provisions and as a tool to provide further guidance to the states on submitting acceptable SIP revisions.

The State of Colorado has submitted a SIP revision to EPA in order to satisfy the requirements of section 507. In order to gain full approval, the State submittal must provide for each of the following PROGRAM elements:

(1) The establishment of a Small Business Assistance Program (SBAP) to provide technical and compliance assistance to small businesses;

(2) The establishment of a State Small Business Ombudsman to represent the interests of small businesses in the regulatory process; and

(3) The creation of a Compliance Advisory Panel (CAP) to determine and report on the overall effectiveness of the SBAP.

II. Summary of Submittal

The State of Colorado has met all of the requirements of section 507 by submitting a SIP revision that implements all required PROGRAM elements. At a public hearing held before the Colorado Air Quality Control Commission (Commission) on October 15, 1992, the plan for the PROGRAM was approved. A notice of approval dated October 30, 1992, was issued by the Technical Secretary of the Commission adopting the PROGRAM plan. Legal authority to implement the PROGRAM was obtained through Senate Bill 105 and is contained in the Colorado Act (ACT) Section 25–7–109.2. The collection of fees to cover the cost of implementing the PROGRAM is contained in the ACT Section 25–7–114.7. The Colorado PROGRAM was submitted to EPA by the Governor of Colorado on November 18, 1992, and was initially reviewed for administrative and technical completeness. In a letter dated December 23, 1992, EPA requested additional information from the State in order to make a positive determination on the submittal. After receiving the additional information on January 7, 1993, EPA notified the State in a letter dated January 26, 1993, that the submittal was administratively and technically complete. The submittal then underwent review by EPA headquarters, and received a concurrence from all reviewers.

The State has met the first PROGRAM element by committing in its PROGRAM plan pages 6 through 9 to meet the six requirements set forth in section 507(a)(3) for the Small Business Assistance Program. Additionally, a task force has been established to examine options for implementation of these six requirements, and prepare a report containing its recommendations. The State has met the second PROGRAM element by locating the position of the Small Business Ombudsman in the Office of Regulatory Reform, as specified in Section 25–7–109.2(5) of the ACT, and by outlining the powers and duties of the Ombudsman on pages 4 and 5 of its PROGRAM plan. The State has met the third PROGRAM element by establishing a Small Business Compliance Advisory Panel in the State of Colorado, as specified in Section 25–7–109.2(2) of the ACT, and by outlining in its PROGRAM plan on pages 5 and 6 the functions of the CAP and how the members will be determined, which is consistent with section 507(e). Additionally, the State of Colorado has established a mechanism for ascertaining the eligibility of a source to receive assistance under the PROGRAM, including an evaluation of a source's eligibility using the criteria in section 507(c)(1) of the Act. This mechanism is located on pages 2 and 3 of the State's PROGRAM plan.

III. Final Action

EPA is approving the SIP revision submitted by the State of Colorado. The revision was made to satisfy the requirements of section 507 of the Act.

This action has been classified as a Table 3 action by the Acting Regional Administrator under the procedures published in the **Federal Register** on January 19, 1989 (54 FR 2214–2225). On January 6, 1989, the Office of Management and Budget (OMB) waived Table 2 and 3 SIP revisions (54 FR 2222) from the requirement of section 3 of Executive Order 12291 for a period of two years. The EPA has submitted a request for a permanent waiver for Table 2 and Table 3 SIP revisions. The OMB has agreed to continue the waiver until such time as it rules on EPA's request. This request continues in effect under Executive Order 12866 which superseded Executive Order 12291 on September 30, 1993.

Under the Regulatory Flexibility Act, 5 U.S.C. 600 *et seq.*, EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603 and 604. Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

By this action, EPA is approving a State program created for the purpose of assisting small businesses in complying with existing statutory and regulatory requirements. This program does not impose any new regulatory burdens on small businesses; it is a program under which small businesses may elect to take advantage of assistance provided by the State. Therefore, because the EPA's approval of this program does not impose any new regulatory requirements on small businesses, I certify that it does not have a significant economic impact on any small entities affected.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control.

Dated: January 14, 1994.

Jack W. McGraw,

Acting Regional Administrator.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read asfollows:

Authority: 42 U.S.C. 7401–7671q.

Subpart G—Colorado

2. Section 52.347 is added to read as follows:

§ 52.347 Small business assistance program plan.

The Governor of Colorado submitted on November 18, 1992 a plan to develop and implement a Small Business Assistance Program to meet the requirements of section 507 of the Clean Air Act by November 15, 1994. The plan commits to provide technical and compliance assistance to small businesses, hire an Ombudsman to serve as an independent advocate for small businesses, and establish a Compliance Advisory Panel to advise the program and report to EPA on the program's effectiveness.

[FR Doc. 94–1958 Filed 1–27–94; 8:45 am]

BILLING CODE 6560–50–F

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 64

[Docket No. FEMA–7592]

List of Communities Eligible for the Sale of Flood Insurance

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Final rule.

SUMMARY: This rule identifies communities participating in the National Flood Insurance Program (NFIP). These communities have applied to the program and have agreed to enact certain floodplain management measures. The communities' participation in the program authorizes the sale of flood insurance to owners of property located in the communities listed.

EFFECTIVE DATE: The dates listed in the third column of the table.

ADDRESSES: Flood insurance policies for property located in the communities listed can be obtained from any licensed property insurance agent or broker serving the eligible community, or from the NFIP at: Post Office Box 457, Lanham, MD 20706, (800) 638–7418.

FOR FURTHER INFORMATION CONTACT: Robert F. Shea, Division Director, Program Implementation Division, Mitigation Directorate, 500 C Street, SW., room 417, Washington, DC 20472, (202) 646–3619.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase flood insurance which is generally not otherwise available. In return, communities agree to adopt and administer local floodplain management aimed at protecting lives and new construction from future flooding. Since the communities on the attached list have recently entered the NFIP, subsidized flood insurance is now available for property in the community.

In addition, the Director of the Federal Emergency Management Agency has identified the special flood hazard areas in some of these communities by publishing a Flood Hazard Boundary Map (FHBM) or Flood Insurance Rate Map (FIRM). The date of the flood map, if one has been published, is indicated in the fourth column of the table. In the communities listed where a flood map has been published, Section 102 of the Flood Disaster Protection Act of 1973, as amended, 42 U.S.C. 4012(a), requires the purchase of flood insurance as a condition of Federal or federally related financial assistance for acquisition or construction of buildings in the special flood hazard areas shown on the map.

The Director finds that the delayed effective dates would be contrary to the public interest. The Director also finds that notice and public procedure under 5 U.S.C. 553(b) are impracticable and unnecessary.

National Environmental Policy Act

This rule is categorically excluded from the requirements of 44 CFR Part 10, Environmental Considerations. No environmental impact assessment has been prepared.

Regulatory Flexibility Act

The Deputy Associate Director certifies that this rule will not have a significant economic impact on a substantial number of small entities in accordance with the Regulatory Flexibility Act, 5 U. S. C. 601 *et seq.*, because the rule creates no additional burden, but lists those communities eligible for the sale of flood insurance.

Regulatory Impact Analysis

This rule is not a major rule under Executive Order 11291, Federal Regulation, February 17, 1981, 3 CFR, 1981 Comp., p. 127. No regulatory impact analysis has been prepared.

Paperwork Reduction Act

This rule does not involve any collection of information for purposes of the Paperwork Reduction Act, 44 U.S.C. 3501 et seq.

Executive Order 12612, Federalism

This rule involves no policies that have federalism implications under Executive Order 12612, Federalism, October 26, 1987, 3 CFR, 1987 Comp., p. 252.

Executive Order 12778, Civil Justice Reform

This rule meets the applicable standards of section 2(b)(2) of Executive Order 12778, October 25, 1991, 56 FR 55195, 3 CFR, 1991 Comp., p. 309.

List of Subjects in 44 CFR Part 64

Flood insurance, Floodplains.

Accordingly, 44 CFR part 64 is amended as follows:

PART 64—[AMENDED]

1. The authority citation for part 64 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.*, Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 64.6 [Amended]

2. The tables published under the authority of § 64.6 are amended as follows:

State and location	Community No.	Effective date of authorization/cancellation of sale of flood insurance in community	Current effective map date
New Eligibles—Emergency Program:			
Indiana: Vermillion County, unincorporated areas.	180449	December 1, 1993	November 24, 1978.
Ohio: Leesburg, village of, Highland County.	390270	December 6, 1993	May 21, 1976.
Oklahoma: Washita County, unincorporated areas.	400223	.....do	Do.
Missouri: [1] Bull Creek, village of, Taney County.	290916	.....do	Do.
Michigan: Matteson, township of, Branch County.	260911	December 21, 1993	Do.
Iowa: Churdan, city of, Greene County	190395	December 27, 1993	August 29, 1975.
New Eligibles—Regular Program:			
Arkansas: Craighead County, unincorporated areas.	050427	December 20, 1993	September 27, 1991.
Texas: [2] Fair Oaks Ranch, city of, Bexar, Comal and Kendall Counties.	481644	.....do	Do.
Missouri: Sumner, town of, Chariton County.	290076	December 27, 1993	February 2, 1983.
Florida: Cottondale, city of, Jackson County.	120583	Effective date of December 30, 1993	Do. December 15, 1990.

State and location	Community No.	Effective date of authorization/cancellation of sale of flood insurance in community	Current effective map date
Reinstatements—Regular Program:			
Pennsylvania: Aldan, borough of, Delaware County.	420401	August 26, 1974, Emergency	September 30, 1993.
		September 17, 1980, Regular	Do.
		September 3, 1993, Suspension	Do.
		December 21, 1993, Reinstatement	Do.
Michigan: Torch Lake, township of, Antrim County.	260414	April 1, 1975, Emergency	June 16, 1992.
		June 16, 1992, Regular	Do.
		June 16, 1992, Suspension	Do.
		December 21, 1993, Reinstatement	Do.
Pennsylvania: Darby, township of, Delaware County.	421603	November 8, 1974, Emergency	September 30, 1993.
		April 3, 1984, Regular	Do.
		December 3, 1993, Suspension	Do.
		December 23, 1993, Reinstatement	Do.
Virginia: Roanoke, city of, (Independent City).	510130	September 11, 1973, Emergency	October 15, 1993.
		November 4, 1981, Regular	Do.
		October 15, 1993, Suspension	Do.
		December 23, 1993, Reinstatement	Do.
Pennsylvania: Allegheny, township of, Somerset County.	422509	August 4, 1983, Emergency	June 1, 1989.
		June 1, 1989, Regular	Do.
		June 1, 1989, Suspension	Do.
		December 24, 1993, Reinstatement	Do.
Missouri: Pierce City, city of, Lawrence County.	290203	May 6, 1975, Emergency	October 15, 1981.
		May 29, 1979, Withdrawm	Do.
		December 28, 1993,[3] Reinstatement	Do.
Region I:			
Rhode Island: North Smithfield, town of, Province County.	440021	December 3, 1993, Suspension Withdrawn.	December 3, 1993.
Region III:			
Pennsylvania:			
Bethel, township of, Delaware County ..	421606	.....do	September 30, 1993.
Brookhaven, borough of, Delaware County.	420403	.....do	September 30, 1993.
Clifton Heights, borough of, Delaware County.	420407	.....do	September 30, 1993.
Middletown, township of, Delaware County.	420422	.....do	September 30, 1993.
Ridley, township of, Delaware County ..	420429	.....do	September 30, 1993.
Rose Valley, borough of, Delaware County.	420431	.....do	September 30, 1993.
Thornbury, township of, Delaware County.	425390	.....do	September 30, 1993.
Upland, borough of, Delaware County .	420438	.....do	September 30, 1993.
Upper Darby, township of, Delaware County.	420440	.....do	September 30, 1993.
Upper Province, township of, Delaware County.	420441	.....do	September 30, 1993.
Region IV:			
North Carolina:			
Davie County, unincorporated areas	370308	December 17, 1993, Suspension Withdrawn.	December 17, 1993.
Winston-Salem, city of, Forsythe County.	375360	.....do	December 17, 1993.
Region VII:			
Missouri, Rolla, city of, Phelps County .	290285	.....do	December 17, 1993.

[1] This is a newly incorporated community. It has adopted Taney County's Flood Hazard Boundary Map (FHBM) dated January 18, 1984 for floodplain management and insurance purposes.

[2] The City of Fair Oaks Ranch has adopted the Counties of Bexar, Comal, and Kendall Flood Insurance Rate Maps (FIRMs) for floodplain management and flood insurance purposes. The FIRM dates are October 16, 1991, June 15, 1988, and December 28, 1990, respectively.

[3] December 28, 1993 is the initial Regular Program entry date for the City of Pierce City, Missouri.

Code for reading fourth column: Emerg.—Emergency; Reg.—Regular; Susp.—Suspension, Rein.—Reinstatement; With.—Withdrawn.

(Catalog of Federal Domestic Assistance No. 83.100, "Flood Insurance.")

Issued: January 24, 1994.

Robert H. Volland,

Acting Deputy Associate Director, Mitigation Directorate.

[FR Doc. 94–1883 Filed 1–27–94; 8:45 am]

BILLING CODE 6718–21–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 93–255; RM–8322]

Radio Broadcasting Services; Titusville, FL

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document substitutes Channel 251C1 for Channel 251C2 at Titusville, Florida, and modifies the license for Station WGNE(FM) to specify operation on Channel 251C1, at the request of Southern Starr Limited Partnership. See 58 FR 52734, October 12, 1993. Channel 251C1 can be allotted to Titusville in compliance with the Commission's minimum distance separation requirements with a site restriction of 23.6 kilometers (14.6 miles) southeast of the community. The coordinates for Channel 251C1 at Titusville are North Latitude 28–35–00 and West Longitude 80–34–10. With this action, this proceeding is terminated.

EFFECTIVE DATE: March 10, 1994.

FOR FURTHER INFORMATION CONTACT: Nancy J. Walls, Mass Media Bureau, (202) 634–6530.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MM Docket No. 93–255, adopted December 30, 1993, and released January 25, 1994. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center (room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Service, Inc., (202) 857–3800, 1919 M Street, NW., room 246, or 2100 M Street, NW., suite 140, Washington, DC 20037.

List of Subjects in 47 CFR Part 73

Radio broadcasting Part 73 of title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Florida, is amended by removing Channel 251C2 and by adding Channel 251C1 at Titusville.

Federal Communications Commission.

John A. Karousos,

Acting Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 94–1874 Filed 1–27–94; 8:45 am]

BILLING CODE 6712–01–M

47 CFR Part 73

[MM Docket No. 93–206; RM–8284]

Radio Broadcasting Services; Hermantown, MN

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document allots Channel 221A to Hermantown, Minnesota, as that community's first local service in response to a petition filed by Bruce F. Elving. See 58 FR 40400, July 28, 1993. There is a site restriction 2 kilometers (1.2 miles) northeast of the community. Canadian concurrence has been obtained for this allotment at coordinates 46–48–47 and 92–14–51. With this action, this proceeding is terminated.

DATES: Effective March 10, 1994. The window period for filing applications will open on March 11, 1994, and close on April 11, 1994.

FOR FURTHER INFORMATION CONTACT: Kathleen Scheuerle, Mass Media Bureau, (202) 634–6530.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order, MM Docket No. 93–206, adopted December 30, 1993, and released January 25, 1994. The full text of this Commission decision is available for inspection and copying during normal business hours in the Commission's Reference Center (room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Services, Inc., 2100 M Street, NW., suite 140, Washington, DC 20037, (202) 857–3800.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Part 73 of title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Minnesota, is amended by adding Hermantown, Channel 221A.

Federal Communications Commission.

John A. Karousos,

Acting Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 94–1875 Filed 1–27–94; 8:45 am]

BILLING CODE 6712–01–M

47 CFR Part 73

[MM Docket No. 93–256; RM–8326]

Radio Broadcasting Services; Taylorville, IL

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document allots Channel 232A to Taylorville, Illinois, as that community's second local FM transmission service, at the request of Miller Communications, Inc. See 58 FR 52734, October 12, 1993. Channel 232A can be allotted to Taylorville, Illinois, in compliance with the Commission's minimum distance separation requirements with a site restriction of 7.2 kilometers (4.5 miles) south in order to avoid short-spacings to the licensed sites of Station WRMS (FM), Channel 232A, Beardstown, Illinois, and Station WLRW (FM), Channel 233B, Champaign, Illinois. The coordinates for Channel 232A at Taylorville are North Latitude 39–29–22 and West Longitude 89–19–45. With this action, this proceeding is terminated.

DATES: Effective March 10, 1994. The window period for filing applications for Channel 232A at Taylorville, Illinois, will be open on March 11, 1994, and close on April 11, 1994.

FOR FURTHER INFORMATION CONTACT: Nancy J. Walls, Mass Media Bureau, (202) 634–6530.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MM Docket No. 93–256, adopted December 30, 1993, and released January 25, 1994. The full text of this Commission decision is available for inspection and copying during

normal business hours in the FCC Reference Center (room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Service, Inc., (202) 857–3800, 1919 M Street, NW., room 246, or 2100 M Street, NW., suite 140, Washington, DC 20037.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Part 73 of title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Illinois, is amended by adding Channel 232A at Taylorville.

Federal Communications Commission.

John A. Karousos,

Acting Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 94–1876 Filed 1–27–94; 8:45 am]

BILLING CODE 6712–01–M

---

47 CFR Part 73

[MM Docket No. 93–239; RM–8313]

Radio Broadcasting Services; Quincy, WA

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of Quincy Community Radio, allots Channel 240C3 at Quincy, Washington, as its second local FM transmission service. See 58 FR 46605, September 2, 1993. Channel 240C3 can be allotted to Quincy in compliance with the Commission's minimum distance separation requirements with a site restriction of 3.5 kilometers (2.2 miles) northeast to avoid a short-spacing to Station KLTX, Channel 239C, Seattle, Washington. The coordinates for Channel 240C3 at Quincy are North Latitude 47–15–13 and West Longitude 119–48–58. Since Quincy is located within 320 kilometers (200 miles) of the U.S.-Canadian border, concurrence by the Canadian government has been obtained. With this action, this proceeding is terminated.

DATES: Effective March 10, 1994. The window period for filing applications for Channel 240C3 at Quincy, will open on March 11, 1994, and close on April 11, 1994.

FOR FURTHER INFORMATION CONTACT: Sharon P. McDonald, Mass Media Bureau, (202) 634–6530.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MM Docket No. 93–239, adopted December 30, 1993, and released January 25, 1994.

The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center (room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Service, Inc., (202) 857–3800, 2100 M Street, NW., suite 140, Washington, DC 20037.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Part 73 of title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Washington, is amended by adding Channel 240C3 at Quincy.

Federal Communications Commission.

John A. Karousos,

Acting Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 94–1877 Filed 1–27–94; 8:45 am]

BILLING CODE 6712–01–M

---

47 CFR Part 73

[MM Docket No. 93–165; RM–8247]

Radio Broadcasting Services; Athens, OH

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of James Phillips, allots Channel 240A to Athens, Ohio, as the community's second local commercial FM channel. Channel 240A can be allotted to Athens in compliance with the Commission's minimum distance separation requirements with a site restriction of 11.6 kilometers (7.2 miles) east-northeast, at coordinates North Latitude 39–22–08 and West Longitude 81–58–42, to avoid short-spacings to Station WHOK, Channel 238B, Lancaster, Ohio, and Station WKWS, Channel 241B, Charleston, West Virginia. Canadian concurrence in the allotment has been received since Athens is located within 320 kilometers (200 miles) of the U.S.-Canadian border. With this action, this proceeding is terminated.

DATES: Effective March 10, 1994. The window period for filing applications will open on March 11, 1994, and close on April 11, 1994.

FOR FURTHER INFORMATION CONTACT: Leslie K. Shapiro, Mass Media Bureau, (202) 634–6530.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MM Docket No. 93–165, adopted December 30, 1993, and released January 25, 1993. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center (room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, Inc., (202) 857–3800, 2100 M Street, NW., suite 140, Washington, DC 20037.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Part 73 of Title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Ohio, is amended by adding Channel 240A at Athens.

Federal Communications Commission.

John A. Karousos,

Acting Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 94–1878 Filed 1–27–94; 8:45 am]

BILLING CODE 6712–01–M

---

47 CFR Part 73

[MM Docket No. 93–103; RM–8206]

Radio Broadcasting Services; Minetto, NY

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of Francis G. Toce, allots Channel 293A to Minetto, New York, as the community's first local aural broadcast service. See 58 FR 26089, April 30, 1993. Channel 293A can be allotted to Minetto in compliance with the Commission's minimum distance separation requirements, with respect to domestic allotments, with a site restriction of 10.9 kilometers (6.7 miles) northwest, at coordinates North Latitude 43–24–40 and West Longitude 76–36–40, to avoid a short-spacing to the pending application for Channel 294C3 at Copenhagen, New York (BMPH–930310IB). This allotment is short-spaced to Station CJBC5F, Channel 292B, Peterboro, Ontario, and to vacant Channel 293A at Brockville, Ontario, Canada. However, Canadian concurrence has been received for the allotment of Channel 293A as a specially negotiated allotment, since Minetto is located within 320 kilometers (200 miles) of the U.S.-Canadian border. With this action, this proceeding is terminated.

DATES: Effective March 10, 1994. The window period for filing applications will open on March 11, 1994, and close on April 11, 1994.

FOR FURTHER INFORMATION CONTACT: Leslie K. Shapiro, Mass Media Bureau, (202) 634–6530.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MM Docket No. 93–103, adopted December 30, 1993, and released January 25, 1994. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center (room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, Inc., (202) 857–3800, 2100 M Street, NW., suite 140, Washington, DC 20037.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Part 73 of Title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under New York, is amended by adding Minetto, Channel 293A.

Federal Communications Commission.

John A. Karousos,

Acting Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 94–1879 Filed 1–27–94; 8:45 am]

BILLING CODE 6712–01–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 675

[Docket No. 90899–0015; I.D. 012494A]

Groundfish of the Bering Sea and Aleutian Islands Area

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Change in observer coverage; suspension of effectiveness.

SUMMARY: On January 20, 1994, NMFS published a change in observer coverage for certain participants in the groundfish fishery of the Bering Sea and Aleutian Islands (BSAI). NMFS is suspending until February 13, 1994, the effectiveness of the requirement for operators of catcher or processor vessels equal to or greater than 60 feet (18.3 m) length overall (LOA) and less than 125 feet (38.1 m) LOA to have a NMFS-certified observer on board the vessel each day it is used to participate in a directed fishery for groundfish in statistical area 517 during the period that the 1994 directed fishery is open for Pacific cod in the BSAI management area. This action is necessary to provide adequate time for operators of catcher or processor vessels to comply with the new observer requirements.

EFFECTIVE DATE: Effective January 25, 1994, the effectiveness of the observer coverage requirements published January 20, 1994, at 59 FR 3000 is suspended until 12 noon, Alaska local time (A.l.t.), February 13, 1994, and expires 12 midnight, A.l.t., December 31, 1994.

FOR FURTHER INFORMATION CONTACT: Ellen R. Varosi, Fishery Biologist, Fisheries Management Division, Alaska Region, NMFS, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS published a notice in the **Federal Register** (58 FR 65574, December 15, 1993) for public review and comment that proposed a change in 1994 observer coverage requirements for vessels participating in a directed fishery for groundfish in statistical area 517 in the BSAI management area. A rule document implementing this action became effective January 13, 1994, the date of filing with the Office of the Federal Register (59 FR 3000, January 20, 1994). This action requires operators of catcher or processor vessels equal to or greater than 60 feet (18.3 m) LOA and less than 125 feet (38.1 m) LOA to have a NMFS-certified observer on board the vessel each day that it is used to participate in a directed fishery for groundfish in statistical area 517 during the period that the 1994 directed fishery is open for Pacific cod. Reasons for this action are set forth in the proposed and final **Federal Register** rule documents.

The 30-day delayed effectiveness period under section 553(d)(3) of the Administrative Procedure Act was waived for reasons contained in the final rule document implementing the change in observer coverage. NMFS has determined that not all vessel operators had sufficient notice of the change in observer coverage requirements to obtain a NMFS-certified observer prior to the January 13, 1994, effective date. Therefore, NMFS is suspending the effectiveness of the requirement until 12 noon A.l.t., February 13, 1994.

Classification

This action is taken under 50 CFR 675.25 and is in compliance with E.O. 12866. Because this action is required to provide relief to vessel owners who otherwise would be unable to comply with observer coverage requirements, it is unnecessary and not in the public interest to provide prior public comment under 5 U.S.C. 553(b)(3). Also, because this action temporarily relieves a restriction, it is being made effective immediately without a 30-day delay in effectiveness under 5 U.S.C. 553(d)(1).

List of Subjects in 50 CFR Part 675

Fisheries, Recordkeeping and reporting requirements.

Dated: January 25, 1994.

David S. Crestin,

Acting Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 94–1872 Filed 1–25–94; 2:15 pm]

BILLING CODE 3510–22–M

50 CFR Part 675

[Docket No. 931075–4012; I.D. 100893A]

RIN 0648–AF47

Groundfish of the Bering Sea and Aleutian Islands Area

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Final rule; final apportionments of the 1994 Pacific cod total allowable catch among gear types and seasons.

SUMMARY: NMFS announces the approval of Amendment 24 to the Fishery Management Plan (FMP) for the Groundfish Fishery of the Bering Sea and Aleutian Islands Area (BSAI) and issues final regulations to implement the amendment that allocates the Pacific cod total allowable catch (TAC) among vessels using trawl, hook-and-line or pot gear, and jig gear through 1996. These regulations also authorize seasonal apportionments of the portion of Pacific cod TAC allocated to vessels using hook-and-line or pot gear. Consistent with the regulations implementing Amendment 24, NMFS also specifies 1994 gear allocations and seasonal apportionments of the amount of the 1994 Pacific cod TAC allocated to vessels using hook-and-line or pot gear through 1996. This action is necessary to allocate Pacific cod among specified gear groups to respond to socioeconomic needs of the fishing industry that have been identified by the North Pacific Fishery Management Council (Council). It is intended to promote management and conservation of groundfish and other fish resources and to further the goals and objectives contained in the FMP.

EFFECTIVE DATE: February 28, 1994.

ADDRESSES: Copies of Amendment 24 and the environmental assessment/regulatory impact review/final regulatory impact analysis (EA/RIR/FRFA) may be obtained from the North Pacific Fishery Management Council, P.O. Box 103136, Anchorage, Alaska 99510 (telephone 907–271–2809).

FOR FURTHER INFORMATION CONTACT: Susan J. Salveson, Fisheries Management Division, Alaska Region, NMFS at 907–586–7228.

SUPPLEMENTARY INFORMATION: The domestic groundfish fisheries in the exclusive economic zone of the BSAI are managed by the Secretary of Commerce (Secretary) in accordance with the FMP. The FMP was prepared by the Council under the Magnuson Fishery Conservation and Management Act (Magnuson Act). Regulations authorized under the FMP that pertain to the U.S. groundfish fisheries appear at 50 CFR parts 620 and 675.

At its June 1993 meeting, the Council adopted Amendment 24 and recommended that NMFS prepare rulemaking to implement the amendment. A notice of availability of Amendment 24 was published in the **Federal Register** on October 15, 1993 (58 FR 53497), and invited comment on the amendment through December 7, 1993. No written comments were received. A proposed rule to implement Amendment 24 was published in the **Federal Register** October 27, 1993 (58 FR 57803). Comments on the proposed rule were invited through December 6, 1993. Five letters addressing eight comments were received and are summarized and responded to in the Response to Comments section, below.

Amendment 24 was approved by the Secretary of Commerce on January 5, 1994, under section 304(b) of the Magnuson Act. This amendment establishes FMP authority to allocate the Pacific cod TAC among vessels using different gear types and to seasonally apportion gear allocations of Pacific cod. Upon reviewing the reasons for Amendment 24, and the comments on the proposed rule to implement it, NMFS has determined that this action is necessary for fishery conservation and management and implements the following three measures through December 31, 1996, under authority of Amendment 24.

1. The BSAI Pacific cod total allowable catch (TAC) is allocated annually among gear types as follows: 2 percent to vessels using jig gear; 44 percent to vessels using hook-and-line or pot gear; and 54 percent to vessels using trawl gear. In monitoring the use of these gear allocations, all cod catch and cod bycatch by each of the three gear groups will be counted against its allocation;

2. The Secretary, after consultation with the Council, is authorized to seasonally apportion the amount of the Pacific cod TAC allocated to vessels using hook-and-line or pot gear. Seasonal apportionments will be divided among three seasons of 4 months duration each, and will be established through the annual September-December specifications process (§ 675.20(a)). Any seasonal apportionments of the amount of Pacific cod TAC allocated to vessels using hook-and-line or pot gear must be based on the following information: (A) Seasonal distribution of prohibited species; (B) seasonal distribution of Pacific cod relative to prohibited species distribution; (C) expected variations in Pacific halibut bycatch rates throughout the fishing year; and (D) economic effects of any seasonal apportionment of Pacific cod on the hook-and-line and pot gear fisheries.

3. The Director, Alaska Region, NMFS (Regional Director) is authorized to reallocate Pacific cod from vessels using trawl gear to vessels using hook-and-line or pot gear, and vice versa, anytime during the year the Regional Director determines that one gear group or the other will not be able to harvest its allocation of Pacific cod. That portion of the jig gear allocation that is expected to go unharvested may be transferred to vessels using trawl and hook-and-line or pot gear at the beginning of the third 4-month season.

The intent of the measures implemented under Amendment 24 is to provide stability in the trawl gear and fixed gear (jig, hook-and-line and pot) fisheries by establishing designated allocations of the Pacific cod TAC among vessels using these different gear types. Further explanation of, and reasons for, these measures are contained in the preamble to the proposed rule (58 FR 57803, October 27, 1993).

1994 Specifications of the Pacific cod TAC

The Council recommended proposed 1994 gear allocations and seasonal apportionments of the amount of Pacific cod allocated to vessels using hook-and-line or pot gear at its September 1993 meeting. The proposed specifications for the 1994 Pacific cod fishery were published in the **Federal Register** for public review and comment as part of the proposed rule implementing Amendment 24 (58 FR 57803, October 27, 1993). At its December 1993 meeting, the Council reaffirmed its September recommendations. NMFS concurs with the Council's recommendations and has included the final specifications for the 1994 Pacific cod fisheries in this action implementing Amendment 24 (Tables 1 and 2).

Consistent with regulations authorizing seasonal apportionments of the amount of Pacific cod allocated to vessels using hook-and-line or pot gear (§ 675.20(a)(2)(v)), a discussion of the seasonal apportionments relative to the seasonal distribution of Pacific cod and prohibited species, prohibited species bycatch rates, and economic effects on the hook-and-line and pot gear fisheries is presented in the preamble to the proposed rule implementing Amendment 24 (58 FR 57803, October 27, 1993). In 1994, 1995, and 1996, the proposed and final specifications for Pacific cod will be established through the annual TAC specification process undertaken by NMFS and the Council during the September and December Council meetings each year (§§ 675.20(a)(2) and 675.21(b)(3)).

TABLE 1.—1994 GEAR SHARES OF THE BSAI PACIFIC COD INITIAL TAC

Gear	Percent of initial TAC	Share of initial TAC (mt)
Jig	2.0	3,247
Hook-and-line or pot gear	44.0	71,434
Trawl gear	54.0	87,669
Total	100.0	162,350

TABLE 2.—FINAL1994 SEASONAL APPORTIONMENT OF THE AMOUNT OF PACIFIC COD ALLOCATED TO VESSELS USING HOOK-AND-LINE OR POT GEAR

Season	Percentage of Pacific cod	Amount of Pacific cod (mt)
Jan. 01–Apr. 30	90	64,291
May 01–Aug. 31	10	7,143
Sep. 01–Dec. 31	Remainder	Remainder

Response to Comments

Five letters of comments were received within the comment period that ended December 6, 1993. Four of the letters were supportive of Amendment 24 and one letter opposed it. A summary of comments and NMFS's response follow.

Comment 1. The rule implementing Amendment 24 should include a prohibition against using both trawl and fixed gear onboard a vessel to fish for groundfish during a year to prevent vessels that use one gear type from gaining access to another gear type's Pacific cod allocation.

Response. Limitations on the use of trawl or fixed gear to fish for Pacific cod or other groundfish species are beyond the scope of Amendment 24 as adopted by the Council and approved by the Secretary. Prohibitions against using more than one gear type to fish for Pacific cod during a year would require a separate amendment to the FMP and cannot be implemented at this time.

Comment 2. The proposed 1994 seasonal apportionment of the amount of Pacific cod allocated to vessels using hook-and-line or pot gear is supported.

Response. NMFS is implementing the seasonal apportionment of the amount of Pacific cod TAC that is allocated to vessels using hook-and-line or pot gear as proposed.

Comment 3. The regulations implementing Amendment 24 provide an equitable way to manage the Pacific cod fishery to reduce waste, periods of high bycatch, and gear conflicts. Allocation of Pacific cod among gear types is an important management measure during the period the Council is developing a comprehensive plan to manage the groundfish fisheries. The implementation of the amendment should proceed without delay.

Response. NMFS concurs. Amendment 24 has been approved and implementing regulations are issued under the schedule set forth under section 305(a) of the Magnuson Act.

Comment 4. Preferential allocation of Pacific cod or other groundfish species to the newly emergent longline freezer fleet in the BSAI is opposed. The Bering Sea cod fishery was developed by the trawl fleet and criteria historically applied by the Council in resource allocation issues would favor the BSAI trawl fleet in any cod allocation dispute with longline vessels. Although the trawl industry generally believes that a 60–40 split of the Pacific cod TAC between trawl and fixed gear would more closely reflect current utilization levels, the fixed gear allocation implemented under Amendment 24 will provide benefits from the stabilization of the trawl and fixed gear fisheries for Pacific cod. Such stabilization will allow for better and more efficient planning and will enable the trawl and fixed gear fleets to assure their respective markets of a dependable and predictable supply of product.

Response. NMFS recognizes that the development of Amendment 24 and alternatives for allocating Pacific cod TAC among different gear groups was a contentious issue that required significant input and effort by the industry to help resolve problems addressed by the Council. NMFS concurs that the fixed allocation of the Pacific cod TAC among gear groups will provide stability to the Pacific cod fisheries during the period the Council is developing a long-term comprehensive plan for the management of the Alaska groundfish resources.

Comment 5. The annual apportionment of the halibut bycatch limit established for BSAI fisheries and seasons should support the annual seasonal apportionment of Pacific cod.

Response. Regulations implementing Amendment 24 do not govern how Pacific halibut bycatch limits are apportioned among fisheries, although gear specific allocations of Pacific cod will be considered when apportioning prohibited species bycatch limits among fisheries and seasons during the annual specification process (§ 675.21(b)(3)). As required by regulations at § 675.21(b)(3), NMFS will review the seasonal apportionment of the amount of Pacific halibut bycatch mortality specified for the Pacific cod fisheries when the agency makes a final determination on the 1994 groundfish specifications.

Comment 6. The trawl industry generally supports Amendment 24 as a management measure that will support the stabilization of the Pacific cod fisheries provided that the annual process for apportioning the Pacific halibut trawl bycatch mortality limit among trawl fisheries is not used to undermine the intent of this amendment. Efforts by representatives for the fixed gear fisheries to restrict the amount of halibut annually apportioned to the Pacific cod trawl fishery would prevent the trawl gear allocation of Pacific cod from being harvested and result in a *de facto* preferential allocation of cod to the fixed gear fleet. The Council and NMFS must ensure that the annual process for the apportionment of PSC limits among trawl fisheries does not lead to the instability that Amendment 24 is intended to avoid.

Response. NMFS acknowledges that significant flexibility exists on how PSC limits are annually apportioned among fisheries and seasons. The resulting apportionments must be justified based on regulatory intent to optimize the harvest of available groundfish under a given PSC limit (§ 675.21 (b)(1) and (b)(3)). NMFS believes that the annual prohibited species bycatch allowances specified for the Pacific cod trawl fishery should be based on anticipated prohibited species bycatch needs. NMFS has advised the Council that it should consider PSC limit apportionments among fisheries and seasons that are consistent with regulations implementing Amendment 24. Nonetheless, the PSC limits established for the BSAI trawl fisheries likely will continue to constrain the ability of trawl fisheries to harvest available groundfish.

Comment 7. Amendment 24, as adopted by the Council, did not establish a fixed allocation of the BSAI trawl halibut bycatch limit to the Pacific cod trawl fishery and the proposed rule did not rectify this omission. This measure is necessary for reasons stated in Comment 6. The anticipated benefits under Amendment 24 in terms of fishery stability will not be realized as long as the possibility exists for fixed gear interests to continue to use the annual specification process to constrain the amount of halibut bycatch apportioned to the Pacific cod trawl fishery, thereby achieving a *de facto* preferential allocation to the fixed gear fleet.

Response. A separate amendment to the FMP would be needed to establish

a fixed allocation of the trawl halibut PSC limit to the BSAI Pacific cod trawl fishery. This measure could not be implemented as a regulatory amendment and included in the proposed rule to implement Amendment 24. The response to Comment 6 further describes NMFS's position on this issue. The Council may address this issue in the future.

Comment 8. Pacific cod catch during the duration of Amendment 24 should not be considered in calculating quota shares under any individual transferrable quota (ITQ) program the Council may adopt in the future because gear allocations of Pacific cod under Amendment 24 may alter catch patterns or otherwise skew the proportion of Pacific cod harvested by any gear type.

Response. ITQs are not the subject of this rulemaking. The Council and the Secretary have not determined whether access to the fishery will be controlled, or if a limited access system will be implemented. Once such determinations are made, eligibility criteria for participation in the fishery will be determined.

Classification

NMFS prepared a final regulatory flexibility analysis (FRFA), which concludes that this rule could have a significant economic impact on a substantial number of small entities. A copy of this analysis is available from the Council (see **ADDRESSES**).

List of Subjects in 50 CFR part 675

Fisheries, Reporting and recordkeeping.

Dated: January 24, 1994.

Nancy Foster,

Deputy Assistant Administrator for Fisheries, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 675 is amended as follows:

PART 675—GROUNDFISH FISHERY OF THE BERING SEA AND ALEUTIAN ISLANDS AREA

1. The authority citation for 50 CFR part 675 continues to read as follows:

Authority: 16 U.S.C. 1801, *et seq.*

2. In § 675.20, paragraphs (a)(2)(iv), (a)(2)(v), and (a)(3)(iv) are added to read as follows:

§ 675.20 General limitations.

(a) * * *

(2) * * *

(iv) *Applicable through December 31, 1996.* (A) The TAC of Pacific cod, after subtraction of reserves, will be allocated 2 percent to vessels using jig gear, 44 percent to vessels using hook-and-line or pot gear, and 54 percent to vessels using trawl gear. The Regional Director may establish separate directed fishing allowances and prohibitions authorized under paragraphs (a)(8) and (a)(9) of this section for vessels harvesting Pacific cod using jig gear, hook-and-line or pot gear, or trawl gear.

(B) If during a fishing year the Regional Director determines that vessels using trawl gear or hook-and-line or pot gear will not be able to harvest the entire amount of Pacific cod allocated to those vessels under paragraph (a)(2)(iv) of this section, then NMFS may reallocate the projected unused amount of Pacific cod to vessels harvesting Pacific cod using the other gear type(s) through publication in the **Federal Register**.

(C) On or about September 1 of each year, the Regional Director will reallocate 45 percent of any unused amount of Pacific cod allocated to vessels using jig gear to vessels using hook-and-line or pot gear and 55 percent of any unused amount of Pacific cod allocated to vessels using jig gear to vessels using trawl gear through publication in the **Federal Register**.

(v) *Applicable through December 31, 1996.* In the publications of proposed and final harvest limit specifications required under § 675.20(a) of this part, the Secretary, after consultation with the Council, may seasonally apportion the amount of Pacific cod TAC allocated to vessels using hook-and-line or pot gear under paragraph (a)(2)(iv) of this section among the following three periods: January 1 through April 30; May 1 through August 31; and September 1 through December 31. The Secretary will base any seasonal apportionment of the Pacific cod allocation for vessels using hook-and-line or pot gear on the following information:

(A) Seasonal distribution of Pacific cod relative to prohibited species distribution;

(B) Expected variations in prohibited species bycatch rates experienced in the Pacific cod fisheries throughout the fishing year; and

(C) Economic effects of any seasonal apportionment of Pacific cod on the hook-and-line and pot-gear fisheries.

(3) * * *

(iv) *Applicable through December 31, 1996.* Any amounts of the nonspecific reserve that are apportioned to Pacific cod as provided by paragraph (b) of this section must be apportioned between vessels using jig, hook-and-line or pot, and trawl gear in the same proportion specified in paragraph (a)(2)(iv)(A) of this section, unless the Regional Director determines under paragraph (a)(2)(iv)(B) of this section or paragraph (a)(2)(iv)(C) of this section that vessels using a certain gear type will not be able to harvest the additional amount of Pacific cod. In this case, the nonspecific reserve will be apportioned to vessels using the other gear type(s).

* * * * *

[FR Doc. 94–1871 Filed 1–25–94; 2:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 59, No. 19
Friday, January 28, 1994

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1210

RIN 0581–AB08

[FV–93–705PR]

Watermelon Research and Promotion Plan; Rules and Regulations; Realignment of Districts

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would change the boundaries of five of the seven districts established under the Watermelon Research and Promotion Plan (Plan) to apportion membership on the National Watermelon Promotion Board (Board). This action is necessary to reflect shifts in production since the original districts were established. The Plan requires the periodic realignment of the districts based on shifts in production to ensure equitable representation of producers and handlers on the Board.

DATES: Comments must be received by February 28, 1994.

ADDRESSES: Interested persons are invited to submit written comments concerning this proposed rule to: Docket Clerk, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, room 2535–S, Washington, DC 20090–6456. Three copies of all written materials should be submitted, and they will be made available for public inspection in the Office of the Docket Clerk during regular working hours. All comments should reference the docket number of this issue of the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Sonia N. Jimenez, Research and Promotion Branch, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, room 2535–S, Washington, DC 20090–6456; telephone (202) 720–9916.

SUPPLEMENTARY INFORMATION: This proposed rule is issued under the Watermelon Research and Promotion Plan (Plan) (7 CFR part 1210). The Plan is authorized under the Watermelon Research and Promotion Act (7 U.S.C. 4901–4916), hereinafter referred to as the Act.

The Department is issuing this proposed rule in conformance with Executive Order 12866.

This rule has been reviewed under Executive Order 12778, Civil Justice Reform. It is not intended to have retroactive effect. This rule would not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 1650 of the Act, a person subject to the Plan may file a petition with the Secretary stating that the Plan or any provision of the Plan, or any obligation imposed in connection with the Plan, is not in accordance with law and requesting a modification of the Plan or an exemption from the Plan. The petitioner is afforded the opportunity for a hearing on the petition. After such hearing, the Secretary will make a ruling on the petition. The Act provides that the district courts of the United States in any district in which a person who is a petitioner resides or carries on business are vested with jurisdiction to review the Secretary's ruling on the petition, if a complaint for that purpose is filed within 20 days after the date of the entry of the ruling.

Regulatory Flexibility Act

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), the Administrator of the Agricultural Marketing Service (AMS) has considered the economic impact of this rule on small entities.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened.

There are approximately 750 watermelon handlers and 5,000 watermelon producers in the contiguous 48 States of the United States who are subject to the Plan. Small agricultural service firms are defined by the Small Business Administration [13 CFR 121.601] as those having annual receipts of less than $3,500,000 and small agricultural producers are defined as those having annual receipts of less than $500,000. The majority of watermelon handlers and producers may be classified as small entities.

The Administrator of AMS has determined that this action would not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction

In accordance with the Paperwork Reduction Act of 1980 (40 U.S.C. chapter 35), the information collection requirements contained in the Plan have previously been approved by the Office of Management and Budget (OMB) and assigned OMB number 0581–0093, except for the Board nominee background statement form which is assigned OMB number 0505–0001. This action adds no additional reporting burden.

Background

Under the Plan, the National Watermelon Promotion Board (Board) administers a nationally coordinated program of research, development, advertising, and promotion designed to strengthen the watermelon's position in the market place and to establish, maintain, and expand markets for domestic watermelons. This program is financed by assessments on all producers, except those persons engaged in the growing of less than five acres of watermelons, and handlers of watermelons. The Plan specifies that handlers are responsible for collecting and submitting both the producer and handler assessments to the Board, reporting their handling of watermelons, and maintaining records necessary to verify their reportings.

Membership on the Board is determined on the basis of two producers and two handlers for each of seven districts established under the Plan. The districts are required to have approximately equal annual production volume. The initial (and current) districts were based on a three-year average production derived from U.S. Department of Agriculture (USDA) Crop Production Annual Summary Reports for 1979, 1980, and 1981.

These districts are:

District #1—South Florida, including all areas south of State Highway 50.

District #2—North Florida, including all areas north of State Highway 50.

District #3—The States of Alabama and Georgia.

District #4—The States of Connecticut, Delaware, Maine, Maryland, Massachusetts, Michigan, New Hampshire, New Jersey, New York, North Carolina, Ohio, Pennsylvania, Rhode Island, South Carolina, Vermont, Virginia, and West Virginia.

District #5—The States of Arkansas, Colorado, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Mississippi, Minnesota, Missouri, Nebraska, New Mexico, North Dakota, Oklahoma, South Dakota, Tennessee, and Wisconsin.

District #6—The State of Texas.

District #7—The States of Arizona, California, Idaho, Montana, Nevada, Oregon, Utah, Washington, and Wyoming.

The Plan provides that two years after its effective date (June 8, 1989) and at least every five years thereafter, the Board should review the districts to determine whether realignment of districts is necessary.

When making such reviews, the Plan specifies that the Board should consider such factors as the most recent three-year USDA production reports or Board assessment reports, if USDA production reports are unavailable, shifts and trends in quantities of watermelons produced, and any other relevant factors.

The Plan further specifies that, as a result of such reviews, the Board may realign the districts subject to the approval of the Secretary. Any such alignment should be recommended by the Board at least six months prior to the date of the call for nominations and should become effective at least 30 days prior to such date.

In accordance with the Plan, the Board appointed a subcommittee to review production and assessment collections in the current districts. During the review, the subcommittee used USDA and State production and marketing reports, as well as data derived from Board assessment reports and field notes. The subcommittee focused on information collected between 1990 and 1992.

After reviewing the available information, the subcommittee recommended that the boundaries of Districts 3 through 7 be changed and that Districts 1 and 2 remain unchanged. In order for each district to represent approximately 3 million hundredweights of annual watermelon production, the subcommittee's recommendation would: move Mississippi from District 5 to District 3; move Indiana, Kentucky, and Tennessee from District 5 to District 4; move Wyoming, Montana, Idaho, Utah, Nevada, Washington, Oregon, and California north of San Luis Obispo, Kern, and San Bernadino counties from District 7 to District 5; move Arkansas and Louisiana from District 5 to District 6; and move New Mexico from District 5 to District 7.

The subcommittee's recommendation was approved by the Board's executive committee, and the full Board voted by mail ballot. In the mail ballot, 19 members voted "yes," 4 members voted "no," and 5 members did not return a ballot.

Therefore, this proposal would realign the districts as follows:

District #1—South Florida, including all areas south of State Highway 50.

District #2—North Florida, including all areas north of State Highway 50.

District #3—The States of Alabama, Georgia, and Mississippi.

District #4—The States of Connecticut, Delaware, Indiana, Kentucky, Maine, Maryland, Massachusetts, Michigan, New Hampshire, New Jersey, New York, North Carolina, Ohio, Pennsylvania, Rhode Island, South Carolina, Tennessee, Vermont, Virginia, and West Virginia.

District #5—The States of California—north of San Luis Obispo, Kern, and San Bernardino counties, Colorado, Idaho, Illinois, Iowa, Kansas, Minnesota, Missouri, Montana, Nebraska, Nevada, North Dakota, Oklahoma, Oregon, South Dakota, Utah, Washington, Wisconsin, and Wyoming.

District #6—The States of Arkansas, Louisiana, and Texas.

District #7—The State of Arizona, the remainder of the State of California, including San Luis Obispo, Kern, and San Bernardino counties, and the State of New Mexico.

The Board has recommended that the new districts become effective for the three-year term of office which begins on January 1, 1995. If adopted, this proposal would affect the eligibility of three current Board members and could necessitate Board member nomination meetings for Districts 4, 5, 6, and 7 in spring 1994. In the normal cycle of nominating approximately one-third of the Board members each year, spring 1994 nomination meetings were already planned for Districts 2 and 3.

In addition, if this proposal is adopted, it will be necessary to make a conforming change to § 1210.401. Section 1210.401 currently states that the districts are defined in § 1210.320 of the Plan. Since, this rule would define new district boundaries in a new § 1210.501, this rule would also change § 1210.401(b) to reflect this new section number.

List of Subjects in 7 CFR Part 1210

Advertising, Agricultural practice and procedure, Agricultural research, Reporting and recordkeeping requirements, Watermelons.

For the reasons set forth in the preamble, part 1210, chapter XI of title 7 is proposed to be amended as follows:

PART 1210—WATERMELON RESEARCH AND PROMOTION PLAN

1. The authority citation for 7 CFR Part 1210 continues to read as follows:

Authority: 7 U.S.C. 4901–4916.

2. In § 1210.401(b), the words "1210.320" in the last sentence are revised to read "1210.501".

3. A new § 1210.501 is added to read as follows:

§ 1210.501 Realignment of districts.

Pursuant to § 1210.320(c) of the Plan, the districts shall be as follows:

District #1—South Florida, including all areas south of State Highway 50.

District #2—North Florida, including all areas north of State Highway 50.

District #3—The States of Alabama, Georgia, and Mississippi.

District #4—The States of Connecticut, Delaware, Indiana, Kentucky, Maine, Maryland, Massachusetts, Michigan, New Hampshire, New Jersey, New York, North Carolina, Ohio, Pennsylvania, Rhode Island, South Carolina, Tennessee, Vermont, Virginia, and West Virginia.

District #5—The States of California—north of San Luis Obispo, Kern, and San Bernardino counties, Colorado, Idaho, Illinois, Iowa, Kansas, Minnesota, Missouri, Montana, Nebraska, Nevada, North Dakota, Oklahoma, Oregon, South Dakota, Utah, Washington, Wisconsin, and Wyoming.

District #6—The States of Arkansas, Louisiana, and Texas.

District #7—The State of Arizona, the remainder of the State of California, including San Luis Obispo, Kern, and San Bernardino counties, and the State of New Mexico.

Dated: January 20, 1994.

Lon Hatamiya,

Administrator.

[FR Doc. 94–1905 Filed 1–27–94; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 358

[Docket No. 80N–0238]

RIN 0905–AA06

Wart Remover Drug Products for Over-the-Counter Human use; Proposed Amendment of the Final Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the final monograph for over-the-counter (OTC) wart remover drug products to revise the directions for products containing 15 percent salicylic acid in a karaya gum, glycol plaster vehicle. This proposal is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments by March 29, 1994. Written comments on the agency's economic impact determination by March 29, 1994. FDA is proposing that any final rule that may issue based on this proposal become effective 12 months after the date of publication in the **Federal Register**.

ADDRESSES: Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD–810), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 14, 1990 (55 FR 33246), FDA issued a final monograph for OTC wart remover drug products (21 CFR part 358). The final monograph included in § 358.110(c) (21 CFR 358.110(c)) products containing 15 percent salicylic acid in a karaya gum, glycol plaster vehicle. Such products were included in the monograph based on the agency's evaluation of data from three clinical studies (Ref. 1) (see comment 13, 55 FR 33246 at 33253). The directions for such products were included in § 358.150(d)(3) (21 CFR 358.150(d)(3)), as follows:

"Wash affected area." (Optional: "May soak wart in warm water for 5 minutes.") "Dry area thoroughly." (If appropriate: "Cut plaster to fit wart.") "Apply medicated plaster at bedtime, leave in place for at least 8 hours; in the morning, remove plaster and discard. Repeat procedure every 24 hours as needed (until wart is removed) for up to 12 weeks."

In discussing the labeling for these products (also in comment 13), the agency stated:

If there are any special directions that relate to using a particular product, then such information should appear as part of the manufacturer's additional directions for the product. The monograph provides the minimum directions necessary for use of the product. Manufacturers may supplement these directions with additional information necessary to use their specific product. For example, the agency notes that the manufacturer's directions for its specific product include statements to "keep plastic film on the top of pad facing up and to apply sticky bottom side to the wart." The agency finds no need to include such directions in this final monograph; however, manufacturers may add such information, as appropriate, to the labeling of their products.

Subsequently, the agency became aware that a manufacturer of this product had the following additional statements in its product's labeling (Ref. 2): (1) "Smooth wart surface with emery file supplied," and (2) "Apply a drop of warm water to the wart, keeping the surrounding skin dry." The agency has rereviewed the clinical studies (Ref. 1) for this product and determined that this additional labeling information is based on the manner in which the clinical studies were performed. The agency notes that use of an emery file and application of a drop of warm water to the wart site as part of the directions for this type of product were not included in the labeling suggestions made by the manufacturer when the final monograph was being prepared (see comment 13).

The agency is concerned that similar products in the marketplace may have different directions—some recommending use of an emery file and a drop of warm water to prepare the wart site and others not mentioning use of an emery file and a drop of warm water. The agency believes this situation could lead to consumer confusion. (Although the agency is aware of only one such marketed product, this does not rule out small volume operations and private label products.)

The clinical studies (Ref. 1) did not show that using an emery file and a drop of warm water were necessary to prepare the wart site before application of the medicated plaster. However, these studies also did not show that these procedures were not necessary, that any adverse effects occurred, or that any interference with the product's safety and effectiveness occurred when an emery file and a drop of warm water were used. Because the procedure used in the studies included the use of an emery file and a drop of warm water, the agency has determined that these items should be part of the directions for this product. The agency is also making a minor format revision in one sentence of the directions. Accordingly, the agency is proposing to amend the directions in § 358.150(d)(3) for 15 percent salicylic acid in a karaya gum, glycol plaster vehicle, to read as follows:

For products containing salicylic acid identified in § 358.110(c). "Wash affected area." (Optional: "May soak wart in warm water for 5 minutes.") "Dry area thoroughly. Gently smooth wart surface with emery file supplied." (If appropriate: "Cut plaster to fit wart.") "Apply a drop of warm water to the wart, keeping the surrounding skin dry. Apply medicated plaster at bedtime and leave in place for at least 8 hours. In the morning, remove plaster and discard. Repeat procedure every 24 hours as needed (until wart is removed) for up to 12 weeks."

References

(1) Comment No. RPT2, Docket No. 80N–0238, Dockets Management Branch.

(2) Labeling for Trans-Ver-Sal, included in OTC Volume 16CFMA, Docket No. 80N–0238, Dockets Management Branch.

The agency has examined the economic consequences of this proposed rulemaking in conjunction with other rules resulting from the OTC drug review. In a notice published in the **Federal Register** of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12866. The agency therefore concludes that no one of these rules, including this proposed rule amending the final monograph for OTC wart remover drug products, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act (Pub. L. 96–354). That assessment included a discretionary regulatory flexibility analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC wart remover drug products is not expected to pose such an impact on small business. The final rule may require some very minor relabeling; however, such relabeling should be a one time nominal cost. The agency is currently aware of only one such product in the marketplace, and it

already has this labeling. Other manufacturers who may market this product will have 1 year after publication of the final rule to implement this labeling. The cost to do so will be minimal. Therefore, the agency certifies that this proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities.

The agency invites public comment regarding any substantial or significant economic impact that this rulemaking would have on OTC wart remover drug products. Types of impact may include, but are not limited to, costs associated with relabeling or repackaging. Comments regarding the impact of this rulemaking on OTC wart remover drug products should be accompanied by appropriate documentation. The agency will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Interested persons may, on or before March 29, 1994, submit written comments on the proposed regulation to the Dockets Management Branch (address above). Written comments on the agency's economic impact determination may be submitted on or before March 29, 1994. Three copies of all comments are to be submitted, except that individuals may submit one copy. Comments and objections are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 358

Labeling, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 358 be amended as follows:

PART 358—MISCELLANEOUS EXTERNAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR part 358 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

2. Section 358.150 is amended by revising paragraph (d)(3) to read as follows:

§ 358.150 Labeling of wart remover drug products.

* * * * *

(d) * * *

(3) For products containing salicylic acid identified in § 358.110(c). "Wash affected area." (Optional: "May soak wart in warm water for 5 minutes.") "Dry area thoroughly. Gently smooth wart surface with emery file supplied." (If appropriate: "Cut plaster to fit wart.") "Apply a drop of warm water to the wart, keeping the surrounding skin dry. Apply medicated plaster at bedtime and leave in place for at least 8 hours. In the morning, remove plaster and discard. Repeat procedure every 24 hours as needed (until wart is removed) for up to 12 weeks."

* * * * *

Dated: September 13, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 94–1790 Filed 1–27–94; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[MN–14–1; FRL–4830–2]

Approval and Promulgation of Implementation Plans; Minnesota

AGENCY: United States Environmental Protection Agency (USEPA).

ACTION: Proposed rule.

SUMMARY: In this action, the USEPA is proposing to disapprove the revision to Minnesota's State Implementation Plan (SIP) for sulfur dioxide (SO_2) for the Dakota County/Pine Bend area of Air Quality Control Region 131. Assuming no other substantive, adverse public comments are received, the USEPA will proceed with a final approval of the submittal when the Minnesota Pollution Control Agency (MPCA) addresses the concerns detailed in this notice and submits the Administrative Orders to USEPA before the end of the 30-day comment period. The USEPA's action is based upon a revision request which was submitted by the State to satisfy the requirements of the Clean Air Act. The revisions are the result of a call for SIP revision issued by USEPA on December 5, 1984, based on monitored violations. The revisions in the Minnesota submittal are in the form of non-expiring Findings and Orders for Koch Refining Company and Koch Sulfuric Acid Unit, Continental Nitrogen and Resources Company, and Northern States Power Company–Inver Hills Generating Facility.

DATES: Comments on this requested revision and on the proposed USEPA action must be received by February 28, 1994.

ADDRESSES: Written comments should be addressed to: William L. MacDowell, Chief, Regulation Development Section, Air Enforcement Branch (AE–17J), United States Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604.

FOR FURTHER INFORMATION CONTACT: Randy Robinson, Air Enforcement Branch, Regulation Development Section (AE–17J), U.S. Environmental Protection Agency, Region 5, Chicago, Illinois 60604, (312) 353–6713.

SUPPLEMENTARY INFORMATION:

I. Background

USEPA published the designation of Air Quality Control Region (AQCR) 131 as a primary nonattainment area for SO_2 on March 3, 1978, and October 5, 1978. In response to Part D requirements of the Clean Air Act, Minnesota Pollution Control Agency (MPCA) submitted a final SO_2 plan on August 4, 1980. USEPA published its final rule approving and promulgating the Minnesota Part D SIP for SO_2 for AQCR 131 on April 8, 1981 (46 FR 20996). On December 5, 1984 (49 FR 47488), USEPA issued a call for SIP revisions for the Minnesota SO_2 SIP for Dakota County declaring the SIP inadequate based on 1982 monitored violations. The SIP call required that the MPCA submit a revision to the Twin Cities SO_2 SIP demonstrating attainment of the SO_2 National Ambient Air Quality Standard (NAAQS) in the Pine Bend Area by September 1985.

The promulgation of a Good Engineering Practice stack height rule, along with difficulties negotiating a control strategy with Koch Refining Company, and the selection of an appropriate computer model, delayed the submittal. On September 10, 1987, the MPCA submitted revisions to the operating permits for five sources and requested redesignation to attainment for all of AQCR 131 except the Pine Bend and St. Paul Park areas.

As a result of numerous USEPA comments, MPCA withdrew the Pine Bend SO_2 SIP while passage of the 1990 Clean Air Act Amendments delayed

action on the rest of the SO_2 revisions for AQCR 131.

On August 3, 1992, USEPA received from MPCA a revision to the SO_2 plan for the Dakota County/Pine Bend area of AQCR 131. The submittal consisted of administrative materials demonstrating that the State had adopted the revision as required and that a public hearing was held. The submittal also contained administrative orders and technical support for Koch Refining Company and Koch Sulfuric Acid Plant, Continental Nitrogen and Resources Corporation, and Northern States Power-Inver Hills Generating Facility. The rest of AQCR 131, including the St. Paul Park Area, are being addressed in separate rulemakings.

On February 16, 1993, USEPA received an amendment to the original administrative order for Koch Refining Company. The amendment revises the completion dates for construction and operation of a new stack and control equipment.

II. Analysis of State Submittal

This section will provide a review of:

(1) The attainment demonstration modeling methodology for the sources in the area;

(2) Specific aspects of the administrative orders (AOs); and

(3) Whether the submittal meets the requirements of section 172 of the Clean Air Act.

Modeling Methodology

The short-term dispersion modeling was performed using the Industrial Source Complex Short-term (ISCST version 90346) model. Dispersion modeling for annual impacts was performed using the Industrial Source Complex Long-Term (ISCLT version 90008) model. All modeling was conducted in accordance with applicable guidance in the "Guideline on Air Quality Models (Revised) (1986)," and "Supplement A (1987)." The dispersion modeling reflects USEPA Good Engineering Practice stack height regulations where applicable. The modeling also incorporated urban dispersion coefficients using 1973–1977 Minneapolis/St. Paul hourly surface meteorological data and St. Cloud mixing height data. These years were used to maintain consistency with the original SO_2 SIP. Although there is no reason to believe the 1973–1977 meteorological data is not representative of current meteorological conditions in the Dakota County area, it is suggested that future SIP revision modeling incorporate the five most recent years of available meteorological data, as is stated in the guidance. Combined SO_2 impacts resulting from modeling Koch Refinery, Koch Sulfuric Acid Unit, Continental Nitrogen Resource Corporation, and Northern States Power, were calculated at 549 receptors, with model resolution ranging from 1,000 meters near grid boundaries to 100 meters near hotspot locations.

Screening modeling was used initially to identify all events with the potential for an exceedance of the Ambient Air Quality Standards. These critical events were further processed using refined modeling techniques to determine if the NAAQS for SO_2 were protected. Several operating scenarios were modeled. The highest, second-highest predicted concentrations for the 3-hour and 24-hour averaging times, including background, were 965.1 and 361.6 $\mu g/m^3$, respectively. Annual average impacts were predicted by using a refined modeling approach. The maximum annual predicted concentration, including background, was 69.1 $\mu g/m^3$.

Additional short-term modeling investigated interstate impacts at distances between 10 and 50 km from an MPCA monitor site. The Wisconsin border is approximately 25 km to the east of the Koch Refinery facility. Modeling was performed using worst-case emission parameters. The modeling results demonstrated that Dakota County SO_2 emissions do not prevent attainment or maintenance of the NAAQS in any other State.

General Statutory Requirements

The purpose of this section is to discuss whether the submittal meets the statutory requirements set forth in the Clean Air Act. The Pine Bend area of Dakota County, Minnesota is designated nonattainment for the primary NAAQS for SO_2. As a result, SO_2 nonattainment area plans must meet the requirements of subpart 1 of part D of title I of the Clean Air Act, particularly section 172(c).

Section 172(c)(1) states that part D plans must require reasonably available control measures (RACM), (e.g., RACT). The definition of RACT for SO_2 is that control technology which is necessary to achieve the NAAQS. The Minnesota submittal includes modeling which, if comments are adequately addressed, demonstrates that the Pine Bend area of Dakota County will achieve attainment of the SO_2 NAAQS with the control measures fully implemented by April 1, 1993. This satisfies the RACM requirements of the Clean Air Act.

Section 172(c)(2) states that plans shall require reasonable further progress. The term "reasonable further progress" is defined in section 171(B)(1) as "such annual incremental reductions in emission of the relevant air pollutant as are required by this part or may reasonably be required by the Administrator for the purpose of ensuring attainment of the applicable NAAQS by the applicable data." The Minnesota submittal provides for attainment of the NAAQS by April 1, 1993.

Section 172(c)(3) requires a suitable emission inventory. A suitable inventory of SO_2 emissions in the Pine Bend nonattainment area was provided in Appendix D of the submittal.

Section 172(c)(4) mandates that any stationary source growth margin included in the submittal be expressly identified and quantified. The submittal provides for a zero growth margin.

Section 172(c)(5) mandates a suitable permit program for new and modified major stationary sources. A new source permitting program for nonattainment areas has been submitted to USEPA by MPCA and is currently undergoing review. It will be addressed in a separate rulemaking. The Prevention of Significant Deterioration (PSD) program is delegated to Minnesota and a general permitting rule has been SIP approved.

Section 172(c)(6) requires enforceable limitations sufficient to provide for attainment. Some enforceability concerns associated with the submittal are detailed in the next section. If these concerns are adequately addressed, the limitations will be sufficient to provide for attainment.

Section 172(c)(7) mandates satisfaction of section 110(a)(2). A primary requirement of section 110(a)(2) is that the State adopt its limitations following a suitable opportunity for public comment. The MPCA certifies that a public hearing was held on May 27, 1992.

Section 172(c)(8) states that the Administrator, in some circumstances, may allow the use of equivalent modeling emission inventory and planning procedures. In the Dakota County submittal, no "equivalent techniques" were used for modeling, emission inventory, and planning procedures.

Section 172(c)(9) requires the plan to provide for implementation of specific measures to be undertaken if the area fails to make reasonable further progress, or to attain the primary NAAQS by the attainment date applicable under this part (i.e. contingency measures). In the event of nonattainment of the SO_2 NAAQS, the MPCA has the authority to enforce all provisions of the AOs, as well as all applicable State and Federal rules and regulations.

Administrative Order Details

The purpose of this section is to provide details on the individual AOs and state any comments that apply. These comments, provided by Region 5, must be adequately addressed before final approval of the SIP revision for Dakota County can be published.

Continental Nitrogen and Resources Corporation (CNRC)

The Rosemount CNRC facility has three boilers which discharge SO_2 emissions into the atmosphere. The Company is required to limit emissions of SO_2 from each of the 3 emission points to 1.5 pounds of SO_2 per million British Thermal Units (lbs/mmBTU). In addition, the three boilers may not operate at a heat input greater than that listed in Exhibit 1 of the AO.

The Company is authorized to burn only natural gas and #6 fuel oil in the three boilers. The Company may not burn #6 fuel oil with greater than 1.5 percent sulfur by weight. Other restrictions include a limit of no more than 16,000 gallons of #6 fuel oil per 24-hour period (midnight to midnight), no more than 70,833 gallons of #6 fuel oil per month on a monthly, 12-month rolling average, and the Company cannot burn #6 fuel oil at more than two of the boilers at any one time.

Compliance with the limitations shall be demonstrated through sampling and analyzing the #6 fuel oil for sulfur content and heating value in accordance with approved ASTM methods. Also the Company shall measure the total gallons of #6 fuel oil burned at each emission unit. The Company is required to keep appropriate records to allow for determination of compliance with the order.

Region 5 Comments:

The emission limits in the administrative order are written as pounds of SO_2 per million British Thermal Units (lbs/mmBTU). None of the limits have an averaging time associated with them. This leads to the assumption that the limits exist on an instantaneous basis. If this is the case, the administrative order should state as such. Otherwise, other appropriate averaging times should be applied to the emission limits.

The administrative order, Part V.B.2.b.1 & 2, states, in part, that the Company must retain records containing information on sulfur content and heating value. The administrative order must include a formula to relate this information to the emission limit in order to determine compliance.

Northern States Power

There are six distillate and residual oil fired gas turbines at the Northern States Power (NSP) facility which discharge sulfur dioxide into the atmosphere. The Company is limited to 1.1 lbs of SO_2/mmBTU from each of the 6 emission units. Also, the Company may not operate the 6 gas turbines at greater than the rated heat input described in Exhibit 1 of the AO.

The Company is authorized to burn only distillate and residual fuel oil in each of the gas turbines, and the fuel oil sulfur content may not exceed 1.0 percent by weight. In addition, the Company may not burn more than 8.75 million gallons of fuel oil per month on a 12-month rolling average.

Compliance with the limitations shall be demonstrated through either sampling and analyzing the fuel for sulfur content and heating value in accordance with approved ASTM methods, or obtaining and retaining a fuel supplier certification. Also, the Company is to measure the total gallons of fuel oil burned at each emission unit both on a 3-hour basis, and a monthly, 12-month rolling average basis. The Company is required to keep appropriate records to allow for determination of compliance with the order.

Region 5 Comments:

The emission limits in the administrative order are written as lbs/mmBTU. None of the limits have an averaging time associated with them. This leads to the assumption that the limits exist on an instantaneous basis. If this is the case, the administrative order should state as such. Otherwise, other appropriate averaging times should be applied to the emission limits.

The Company is required to keep records on percent sulfur of the fuel, and heating value of the fuel. The administrative order, Part IV.B.2.a., does not specify a formula which would convert this data to a lbs/mmBTU basis. This is necessary since the emission limits are in lbs/mmBTU units. A formula is also required in the Annual Reports section of the administrative order (Part V.B.).

Part of the demonstration of compliance with emission and operating limits involves obtaining and maintaining a fuel supplier certification. The administrative order, Part I.D.1.a.4., states that the certification must include the method used to determine the sulfur content of the fuel oil. It must be made clear that the method used must be an approved ASTM method as listed in 40 CFR part 60, appendix A, method 19, § 5.2.2.

Koch Refining Company

The AO for Koch Refining includes a compliance schedule for required modifications at various locations around the facility. Each modification activity is accompanied by completion dates. All of the activities had been completed at the time the submittal was sent to USEPA.

The emission limits for the Refinery are listed in the AO and cover the Sulfur Reduction Unit (SRU) 1/2 facility, the Sulfur Reduction Unit 3 and 4 facility, the Sulfur Reduction Unit 5 facility, the FCC facility emission points 5, 6, and 8, the Oil Separation and Waste Treatment Plant (OSWTP), the Platformer facility, and the Powerformer facility. The table lists emission limitations for each applicable SO_2 standard averaging time, 3-hour, 24-hour, and annual. The 3-hour average is based on three consecutive one-hour periods, the 24-hour is based on 24 consecutive one-hour periods, and the annual is based on a 12-month rolling average.

The emission limits for the Koch Sulfuric Acid Unit (KSAU) facility are listed in Table 3 of the AO and cover Absorber emission points numbers 1 and 3. However, emission point 1 becomes inoperational when emission point 3 begins operation. Again, the applicable averaging times are based the same as for the Refinery limits mentioned above.

Koch Refinery may burn refinery fuel oil, from the refinery fuel oil distribution system, only at select locations. The fuel oil limits on quantity and sulfur content are specified in Table 2 and Table 2a of the AO. The Refinery may burn refinery fuel gas at specified locations. The Company may not put fuel gas into the refinery fuel gas distribution system which contains greater that 0.10 grains of hydrogen sulfide per dry standard cubic foot of gas. The diesel fuel used shall not have a sulfur content greater than 0.1 percent by weight.

Fuel restrictions at the KSAU facility limit the Boiler to burning only refinery fuel gas, propane, or commercial natural gas. The hydrogen sulfide content of refinery fuel gas burned at KSAU cannot exceed 0.10 grains of hydrogen sulfide per dry standard cubic foot of gas.

Compliance with the various limitations and restrictions applied to Koch Refinery are detailed in the AO. The compliance demonstration include calculations, monitoring, record keeping, diesel fuel certification, and stack tests. Compliance with the emission limits at KSAU also consist of calculations, monitoring, and data and record keeping.

Region 5 Comments:

Flares nos. 5, 6, and 7 may only use gases from Refinery operations when the gases are from pressure relief, from upsets of Refinery process equipment, or are required for equipment maintenance (Part II.B.6.C.). At all other times the flares must burn natural gas. Information must be provided to justify not limiting these sources and not including them in the modeling.

Compliance for emission points 348, 458, and 459, is to be based on initial stack tests as specified in Table 1, note #4. Some method needs to be specified for determining future compliance.

The administrative order states in Part V.C.2. that the company shall conduct performance stack tests to determine compliance with the emission limitations and fuel restrictions outlined in the order as required by the Commissioner. Stack tests must also be able to be required by appropriate USEPA personnel.

Exhibit 2–page 3 discusses the startup incinerators for SRU 3 and SRU 4. These startup incinerators operate when tail gas bypasses the Shell Claus Offgas Treatment (SCOT) Units and SCOT Unit incinerators. Information must be provided to justify not limiting or modeling these emission sources.

On page 9 of Exhibit 2, emission point 17 is listed as an active emission source. However, in Exhibit 2, Attachment 6 emission point 17 has a rated input of 0.0 mmBTU/hr. Also, emission point 17 was not included in the modeling demonstration. If #17 is shutdown, it must be removed from reference in the administrative order.

On page 8 of Exhibit 5, the Company is required to measure the amount of hydrogen sulfide in sour water tank purge gas by analysis once per calendar quarter. The limit on hydrogen sulfide in sour water tank purge gas is 162 parts per million as a 3-hour average. We would request than analysis be conducted with increased frequency (e.g., daily).

III. Proposed Rulemaking Action and Solicitation of Public Comment

The USEPA is proposing disapproval of the Minnesota SIP revision for SO_2 for the Dakota County/Pine Bend area of AQCR 131, contained in the Administrative Orders for Koch Refining Company and Koch Sulfuric Acid Unit, Continental Nitrogen and Resources Company, and Northern States Power Company–Inver Hills Generating Facility. However, if the above comments, detailed in this notice, are adequately addressed in revisions to this plan, and those revisions are submitted to USEPA by the end of the 30-day comment period, then, assuming no other substantive, adverse public comments are received, USEPA will proceed with a final rulemaking approving the SIP revision as a whole including the supplemental submittal. If at the end of the 30-day comment period, the issues are still unresolved, final rulemaking disapproving the SIP revision will be promulgated.

Public comments are solicited on the requested SIP revision and on USEPA's proposal to disapprove. Public comments received by February 28, 1994, will be considered in the development of USEPA's final rulemaking action.

Nothing in this action should be construed as permitting, allowing or establishing a precedent for any future request for revision to any SIP. USEPA shall consider each request for revision to the SIP in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

This action has been classified as a Table 2 action by the Regional Administrator under the procedures published in the **Federal Register** on January 19, 1989, (54 FR 2214–2225). On January 6, 1989, the Office of Management and Budget (OMB) waived Table 2 and 3 SIP revisions (54 FR 2222) from the requirements of section 3 of Executive Order 12291 for a period of 2 years. USEPA has submitted a request for a permanent waiver for Table 2 and 3 SIP revisions. OMB has agreed to continue the temporary waiver until such time as it rules on USEPA's request. This request continues in effect under Executive Order 12866 which superseded Executive Order 12291 on September 30, 1993.

Under the Regulatory Flexibility Act, 5 U.S.C. 600 *et seq.*, USEPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. (5 U.S.C. 603 and 604.) Alternatively, USEPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

The USEPA's disapproval of the State request under section 110 and subchapter I, part D of the Clean Air Act does not affect any existing requirements applicable to small entities. Any pre-existing Federal requirements remain in place after this disapproval. Federal disapproval of the State submittal does not affect its state-enforceability. Moreover, USEPA's disapproval of the submittal does not impose any new Federal requirements. Therefore, USEPA certifies that this disapproval action does not have a significant impact on a substantial number of small entities because it does not remove existing requirements nor does it impose any new Federal requirements.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Reporting and recordkeeping requirements, Sulfur oxides.

Authority: 42 U.S.C. 7401–7671q.

Dated: December 23, 1993.

Valdas V. Adamkus,

Regional Administrator.

[FR Doc. 94–1963 Filed 1–27–94; 8:45 am]

BILLING CODE 6560–50–F

---

40 CFR Part 438

[FRL–4830–8]

Public Meeting on Planned Effluent Guidelines for the Metal Products and Machinery Category

AGENCY: Environmental Protection Agency (EPA).

ACTION: Announcement of public meeting.

SUMMARY: The Environmental Protection Agency is announcing a public meeting prior to proposing effluent guidelines and standards for the Metal Products and Machinery category. EPA intends to propose a rule in November 1994, and this is the only public meeting that the Agency plans to sponsor prior to proposal. The meeting is intended to be a forum in which EPA can report on the status of regulatory development and in which interested parties can provide information and ideas to the Agency on key technical, scientific, and other issues.

DATES: The meeting will be held on February 23, 1994 from 9 a.m. to 5 p.m.

ADDRESSES: The meeting will be held at the U.S. Geological Survey (USGS) National Center Auditorium, 12201 Sunrise Valley Drive, Reston, Virginia. Seating will be available for approximately 300 attendees.

The USGS National Center is located approximately five miles from Dulles International Airport. To reach USGS, take the Dulles Toll Road to Reston Parkway, go south on Reston Parkway to Sunrise Valley Drive, right on Sunrise Valley Drive, 1/4 mile to the USGS entrance on the left side of the road.

FOR FURTHER INFORMATION CONTACT: Bill Cleary, Engineering and Analysis Division, Office of Science and

Technology/Office of Water, Mail Code 4303, US EPA, 401 M Street, SW., Washington, DC 20460. Telephone (202) 260–9817, fax (202) 260–7185.

SUPPLEMENTARY INFORMATION: EPA is developing effluent limitations guidelines and standards for the metal products and machinery category under authority of the Clean Water Act (33 U.S.C. 1251 *et seq.*). The metal products and machinery (MP&M) category includes facilities that manufacture, rebuild and maintain finished metal parts, products, or machines.

The public meeting will include discussions of the effluent guidelines regulatory development process, applicability of the forthcoming rule, regulatory approach (i.e. mass-based vs. concentration-based effluent limits), affected population estimates, and general MP&M issues. The meeting will not be recorded by a reporter or transcribed for inclusion in the record for the MP&M industry rulemaking.

Documents relating to the topics mentioned above and a more detailed agenda will be available at the meeting.

Dated: January 24, 1994.

Tudor T. Davies,

Director, Office of Science and Technology.

[FR Doc. 94–1965 Filed 1–27–94; 8:45 am]

BILLING CODE 6560–50–F

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 93–321, RM–8409]

Radio Broadcasting Services; Ocean Isle Beach, NC

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission comments on a petition filed by Ocean Isle Broadcasting Company seeking the allotment of Channel 228A to Ocean Isle Beach, North Carolina, as its first local aural transmission service. Channel 228A can be allotted to Ocean Isle Beach in compliance with the Commission's minimum distance separation requirements with a site restriction of 4.3 kilometers (2.7 miles) west, at coordinates North Latitude 33–53–40 and West Longitude 78–28–26, to avoid a short spacing to vacant but applied-for Channel 229A at Wrightsville Beach, North Carolina.

DATES: Comments must be filed on or before March 17, 1994, and reply comments on or before April 1, 1994.

ADDRESSES: Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, or its counsel or consultant, as follows: Gary S. Smithwick, Esq., Shaun A. Maher, Esq., Smithwick & Belendiuk, P.C., 1990 M Street NW., suite 510, Washington, DC 20036 (Counsel to petitioner).

FOR FURTHER INFORMATION CONTACT: Leslie K. Shapiro, Mass Media Bureau, (202) 634–6530.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rule Making, MM Docket No. 93–321, adopted December 21, 1993, and released January 25, 1994. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center (room 239), 1919 M Street NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Services, Inc., (202) 857–3800, 2100 M Street NW., suite 140, Washington, DC 20037.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

John A. Karousos,

Acting Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 94–1873 Filed 1–27–94; 8:45 am]

BILLING CODE 6712–01–M

Notices

Federal Register
Vol. 59, No. 19
Friday, January 28, 1994

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Packers and Stockyards Administration

Amendment to Certification of Central Filing System—Oklahoma

The Statewide central filing system of Oklahoma has been previously certified, pursuant to section 1324 of the Food Security Act of 1985, on the basis of information submitted by Hannah D. Atkins, Secretary of State, for farm products produced in that State (52 FR 49056, December 29, 1987).

The certification is hereby amended on the basis of information submitted by John Kennedy, Secretary of State, for additional farm products produced in that State as follows: Cattle semen, cattle embryos, milo.

This is issued pursuant to authority delegated by the Secretary of Agriculture.

Authority: Sec. 1324(c)(2), Pub. L. 99–198, 99 Stat. 1535, 7 U.S.C. 1631(c)(2); 7 CFR 2.18(e)(3), 2.56(a)(3), 55 FR 22795.

Dated: January 21, 1994

Calvin W. Watkins, Acting Administrator,
Packers and Stockyards Administration.

[FR Doc. 94–1847 Filed 1–27–94; 8:45 am]

BILLING CODE 3410–KD–P

Posting of Stockyards

Pursuant to the authority provided under section 302 of the Packers and Stockyards Act (7 U.S.C. 202), it was ascertained that the livestock markets named below are stockyards as defined by section 302(a). Notice was given to the stockyard owners and to the public as required by section 302(b), by posting notices at the stockyards on the dates specified below, that the stockyards are subject to the provisions of the Packers and Stockyards Act, 1921, as amended (7 U.S.C. 181 *et seq.*).

	Facility No., name, and location of stockyard	Date of posting
MN–191 .	Bagley Livestock Exchange, Inc., Bagley, Minnesota	November 5, 1993
NC–165 ..	Tri County Marketing, Beulaville, North Carolina	December 15, 1993
TN–191 ..	Somerville Livestock Sales, Inc., Somerville, Tennessee	December 10, 1993

Done at Washington, DC this 24th day of January 1994.

Harold W. Davis,
Director, Livestock Marketing Division, Packers and Stockyards Administration.

[FR Doc. 94–1904 Filed 1–27–94; 8:45 am]

BILLING CODE 3410–KD–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–351–819]

Antidumping Duty Order: Certain Stainless Steel Wire Rods From Brazil

AGENCY: Import Administration, International Trade Administration, Department of Commerce

EFFECTIVE DATE: January 28, 1994.

FOR FURTHER INFORMATION CONTACT: Jim Cunningham, Office of Antidumping Duty Investigations, Import Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone (202) 482–4207.

Scope of Order

For purposes of this investigation, certain stainless steel wire rods (SSWR) are products which are hot-rolled or hot-rolled annealed, and/or pickled rounds, squares, octagons, hexagons or other shapes, in coils. SSWR are made of alloy steels containing, by weight, 1.2 percent or less of carbon and 10.5 percent or more of chromium, with or without other elements. These products are only manufactured by hot-rolling, are normally sold in coiled form, and are of solid cross-section. The majority of SSWR sold in the United States is round in cross-sectional shape, annealed, and pickled. The most common size is 5.5 millimeters in diameter.

The SSWR subject to this investigation is currently classifiable under subheadings 7221.00.0005, 7221.00.0015, 7221.00.0020, 7221.00.0030, 7221.00.0040, 7221.00.0045, 7221.00.0060, 7221.00.0075, 7221.00.0080 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheadings are provided for convenience and customs purposes, our written description of the scope of this investigation is dispositive.

Antidumping Duty Order

In accordance with section 736 of the Act, the Department will direct Customs officers to assess, upon further advice by the administering authority pursuant to section 736(a)(1) of the Act, antidumping duties equal to the amount by which the foreign market value of the merchandise exceeds the United States price for all entries of certain stainless steel wire rods from Brazil. These antidumping duties will be assessed on all unliquidated entries of certain stainless steel wire rods from Brazil entered, or withdrawn from warehouse, for consumption on or before August 5, 1993, the date on which the Department published its preliminary determination notice in the **Federal Register** (58 FR 41726). On or after the date of publication of this notice in the **Federal Register**, U.S. Custom officers must require, at the same time as importers would normally deposit estimated duties, the following cash deposits for the subject merchandise:

Manufacturer/Producer/ Exporter	Weighted-average margin percentage
Eletrometal-Metal Especials S.A	24.63
Acos Finos Piratini S.A	26.50
Acos Villares S.A	26.50
All Others	25.88

In its final determination, the Department found that critical circumstances exist with respect to exports of SSWR from Brazil by Acos Finos Piratini S.A. and Acos Villares S.A. However, on January 21, 1994, the International Trade Commission (ITC) notified the Department that retroactive assessment of antidumping duties is not necessary to prevent recurrence of material injury from massive imports over a short period. As a result of the ITC's determination, pursuant to section 735(c)(3) of the Act, we shall order Customs to terminate the retroactive suspension of liquidation of entries of subject merchandise exported from Brazil by Piratini and Villares, and to release any bond or other security and refund any cash deposit required under section 733(e)(2) with respect to all entries of SSWR exported from Brazil by Piratini and Villares, and entered, or withdrawn from warehouse, for consumption prior to August 5, 1993.

This notice constitutes the antidumping duty order with respect to certain stainless steel wire rods from Brazil, pursuant to section 736(a) of the Act. Interested parties may contact the Central Records Unit, room B–099 of the Main Commerce Building, for copies of an updated list of antidumping duty orders currently in effect.

This order is published in accordance with section 736(a) of the Act and 19 CFR 353.21.

Dated: January 25, 1994.

Joseph A. Spetrini,

Acting Assistant Secretary for Import Administration.

[FR Doc. 94–2029 Filed 1–27–94; 8:45 am]

BILLING CODE 3510–DS–P

[A–427–811]

Amended Final Determination and Antidumping Duty Order: Certain Stainless Steel Wire Rods From France

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: January 28, 1994.

FOR FURTHER INFORMATION CONTACT: John Beck, Office of Antidumping Duty Investigations, Import Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone (202) 482–3464.

Scope of Order

For purposes of this investigation, certain stainless steel wire rods (SSWR) are products which are hot-rolled or hot-rolled annealed, and/or pickled rounds, squares, octagons, hexagons or other shapes, in coils. SSWR are made of alloy steels containing, by weight, 1.2 percent or less of carbon and 10.5 percent or more of chromium, with or without other elements. These products are only manufactured by hot-rolling, are normally sold in coiled form, and are of solid cross-section. The majority of SSWR sold in the United States is round in cross-sectional shape, annealed, and pickled. The most common size is 5.5 millimeters in diameter.

The SSWR subject to this investigation is currently classifiable under subheadings 7221.00.0005, 7221.00.0015, 7221.00.0020, 7221.00.0030, 7221.00.0040, 7221.00.0045, 7221.00.0060, 7221.00.0075, 7221.00.0080 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheadings are provided for convenience and customs purposes, our written description of the scope of this investigation is dispositive.

Amendment of Final Determination

In accordance with section 735 (a) and (d) of the Tariff Act of 1930, as amended (the Act), on December 29, 1993, the Department of Commerce (the Department) published its final determination that certain stainless steel wire rods from France were being sold at less than fair value (58 FR 68865).

On January 5, 1994, Imphy S.A. and Ugine-Savoie (respondent) alleged that the Department made clerical errors in its final calculations. Respondent argued that the Department erroneously applied best information available (BIA) to the Metalimphy Alloys Corporation (MAC) and Ugine Stainless and Alloys (US&A) (both divisions of MAC, which is a subsidiary of Imphy S.A.) further manufactured sales on the basis that the cost of further manufacturing data did not include costs associated with certain manufactured sales of MAC. Respondent contends that the further manufacturing costs were fully provided on the C–1 U.S. sales database under the field "FURMANU", which represented processing charges by outside subcontractors or by Techalloy as the subcontractor. Respondent further states that the Department accepted this submission, used it for the preliminary determination, made no request for further information, and appears to have agreed in the final determination that the appropriate information regarding these sales had been submitted.

The Department does not agree that this is a clerical error. The Department required detailed cost information for further manufacturing to be reported on the E–2 further manufacturing cost database. Respondent failed to provide this detailed cost information with respect to products further manufactured by MAC on the E–2 database, even though it indicated it had done so on page 2 of the narrative portion of its May 10, 1993, submission. Respondent reported detailed costs only for products further manufactured by Techalloy.

Specifically, in its clerical error allegation, respondent indicated that the cost information for products further manufactured by MAC was included in the "FURMANU" field of the C–1 U.S. sales tape and that the Department used this for the preliminary determination. First, we agree that the total further manufacturing costs for MAC were included on the C–1 U.S. sales tape. However, at the final determination, we made adjustments to certain elements of the further manufacturing costs. These elements were only included on the E–2 further manufacturing database. Since respondent failed to provide on the E–2 database those cost elements for the products further manufactured by MAC, the Department could not adjust the further manufacturing costs of the MAC products. Consequently, we also could not use the costs reported on the C–1 U.S. sales tape since this tape included only total costs and not the individual costs elements that we needed to adjust.

Respondent's argument that the Department used the further manufacturing cost totals on the C–1 U.S. sales tape at the preliminary determination is unavailing. At the preliminary determination, the Department used the further manufacturing totals from the C–1 sales tape only because respondent did not provide a means to link the C–1 and E–2 tapes in time for the preliminary determination. Since there was no way to link these tapes (until after the preliminary determination, when we received new tapes in response to the Department's request), and since the total product further manufacturing costs were the same on both the E–2 and C–1 databases, we simply used the total cost figures on the C–1 database. This was not the case at the final determination, where a way to link these tapes was available and where we

had to adjust certain cost elements on the E–2 database.

On January 10, 1994, petitioners alleged that the Department made three clerical errors in the final determination. First, petitioners alleged that the Department miscalculated the test which ensures that selling, general and administrative (SG&A) expenses are not less than ten percent of the cost of manufacture (COM). Specifically, petitioners stated that the Department's instructions require COM to be multiplied by one percent and not ten percent.

We agree that this error is a clerical error. In attempting to make sure that SG&A expenses were not less than ten percent of the COM, we mistakenly multiplied the COM by one percent instead of ten percent. Therefore, we corrected this error by multiplying the COM by ten percent.

Secondly, petitioners alleged that the Department failed to include United States commissions in the value-added tax (VAT) readjustment calculation, pursuant to which we made a deduction from foreign market value for purchase price comparisons.

After a review of petitioners' allegation and the Department's new VAT calculation methodology, we have determined that this was a clerical error. Therefore, we have included commissions in the VAT readjustment calculation.

Finally, petitioners alleged that the Department double counted home market indirect selling expenses when deducting this expense from foreign market value during comparisons of constructed value to exporter's sales price.

The Department agrees that the double deduction of indirect selling expenses from foreign market value during comparisons of constructed value to exporter's sales price was a clerical error. To correct this error, the Department eliminated the separate variable for indirect selling expenses from the foreign unit price string.

For further discussion of these clerical errors, see Memorandum from Richard W. Moreland to Barbara R. Stafford dated January 25, 1994.

Antidumping Duty Order

In accordance with section 736 of the Act, the Department will direct Customs officers to assess, upon further advice by the administering authority pursuant to section 736(a)(1) of the Act, antidumping duties equal to the amount by which the foreign market value of the merchandise exceeds the United States price for all entries of certain stainless steel wire rods from France. These antidumping duties will be assessed on all unliquidated entries of certain stainless steel wire rods from France entered, or withdrawn from warehouse, for consumption on or after August 5, 1993, the date on which the Department published its preliminary determination notice in the **Federal Register** (58 FR 41726). On or after the date of publication of this notice in the **Federal Register**, U.S. Custom officers must require, at the same time as importers would normally deposit estimated duties, the following cash deposits for the subject merchandise:

Manufacturer/Producer/ Exporter	Weighted-average margin percentage
Imphy	24.51
Ugine-Savoie	24.51
All Others	24.51

This notice constitutes the antidumping duty order and amended final determination with respect to certain stainless steel wire rods from France, pursuant to section 736(a) of the Act. Interested parties may contact the Central Records Unit, room B–099 of the Main Commerce Building, for copies of an updated list of antidumping duty orders currently in effect.

This order is published in accordance with section 736(a) of the Act and 19 CFR 353.21.

Dated: January 25, 1994.

Joseph A. Spetrini,

Acting Assistant Secretary for Import Administration.

[FR Doc. 94–2028 Filed 1–27–94; 8:45 am]

BILLING CODE 3510–DS–P

[A–557–807]

Final Determination of Sales at Less Than Fair Value: Welded Stainless Steel Pipe From Malaysia

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: January 28, 1994.

FOR FURTHER INFORMATION CONTACT: Pamela Ward or Shawn Thompson, Office of Antidumping Investigations, Import Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone (202) 482–1174 or (202) 482–3965, respectively.

FINAL DETERMINATION: We determine that welded stainless steel pipe from Malaysia is being, or is likely to be, sold in the United States at less than fair value, as provided in section 733 of the Tariff Act of 1930, as amended (the Act). The estimated margins are shown in the "Suspension of Liquidation" section of this notice.

Case History

Since the publication of our affirmative preliminary determination on September 7, 1993 (58 FR 47120), the following events have occurred.

On September 7, 1993, the sole respondent in this investigation, Kanzen Tetsu Sdn. Bhd. (KT), requested a postponement of the final determination. We granted this request, and on September 9, 1993, we postponed the final determination until not later than January 21, 1994 (58 FR 48849, September 20, 1993).

On September 13, 1993, KT submitted a response to the Department's cost of production (COP) questionnaire. On September 27, 1993, we issued a supplemental COP questionnaire to KT. We received the response to this questionnaire on October 25, 1993.

From November 8 through November 12, 1993, we conducted our verification in Malaysia of KT's responses to the Department's sales questionnaires.

On November 8, 1993, petitioners submitted a letter requesting that the Department reject KT's October 25, 1993, COP response because KT failed to report product-specific production costs, as requested in the cost questionnaire.

On November 10, 1993, KT responded to petitioners' November 8, 1993, submission. Also on November 10 we informed KT that we had determined that the cost of manufacture (COM) information contained in the October 25, 1993, submission was not adequately product-specific to meet the Department's requirements, and that, accordingly, we would not verify that portion of the October 25, 1993, submission.

From November 22 through November 25, 1993, we conducted our verification in Malaysia of KT's response to the Department's September 13, 1993, COP questionnaire.

Both petitioners and respondent filed case briefs on December 20, 1993, and rebuttal briefs on December 28, 1993.

On December 23, 1993, KT submitted revised sales, COP, constructed value (CV), and concordance databases, correcting minor errors discovered at verification. On January 5, 1994, petitioners submitted a letter requesting that the Department reject this submission because it contained revisions to KT's data which were unsupported by the record of this investigation. On January 7, 1994, KT replaced its COP, CV, and concordance databases in order to correct clerical

errors made in its December 23, 1993, submission. We reviewed this submission and confirmed that it contained no new information.

Scope of Investigation

The product covered by this investigation is welded austenitic stainless steel pipe of circular cross section (WSSP). WSSP is produced according to standards and specifications set forth by the American Society for Testing and Materials (ASTM). The designations for this product include, but are not limited to, ASTM A–312, ASTM A–358, ASTM A–409, and ASTM A–778. Welded pipes are generally used as conduits to transmit liquids or gases. The major applications for WSSP are: Digester lines; blow lines; pharmaceutical lines; petrochemical lines; brewery process and transport lines; general food processing lines; automotive lines; and paper processing machines.

This product is classified under the following Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 7306.40.1000, 7306.40.5005, 7306.40.5015, 7306.40.5045, 7306.40.5060, and 7306.40.5075. These subheadings are defined to encompass welded stainless steel tube as well as WSSP; however, the only product subject to this investigation is WSSP. Although the HTSUS subheadings are provided for convenience and customs purposes, our written description of the scope of this investigation is dispositive.

Period of Investigation

The period of investigation (POI) is September 1, 1992, through February 28, 1993.

Such or Similar Comparisons

We have determined that the product covered by this investigation comprises a single category of "such or similar" merchandise. We made similar merchandise comparisons on the basis of: (1) ASTM or equivalent specification, (2) grade of steel, (3) nominal size, (4) hot or cold finish, (5) wall thickness schedule, and (6) end finish, as described in Appendix V of the questionnaire. We made adjustments for differences in the physical characteristics of the merchandise, in accordance with section 773(a)(4)(C) of the Act.

Fair Value Comparisons

To determine whether sales of WSSP from Malaysia to the United States were made at less than fair value, we compared the United States price (USP) to the foreign market value (FMV), as specified in the "United States Price" and "Foreign Market Value" sections of this notice.

United States Price

We based USP on purchase price, in accordance with section 772(b) of the Act, because the subject merchandise was sold to unrelated purchasers in the United States prior to importation and because exporter's sales price methodology was not otherwise indicated.

After correcting the data used in our calculations for errors and omissions found at verification, we calculated purchase price based on packed F.O.B. prices to unrelated customers. In accordance with section 772(d)(2)(A) of the Act, we made deductions, where appropriate, for foreign inland freight, foreign brokerage and handling, ocean freight, marine insurance, and containerization expenses. Regarding marine insurance, KT paid an insurance premium plus a commission to one of its marine insurance suppliers. At verification, we found that KT had inconsistently reported its marine insurance expense for this supplier (*i.e.*, KT included the commission in one observation yet excluded it in another observation). KT explained that this commission was an intracompany service fee which its parent company charged KT for holding the group policy with the insurance company. However, KT could not substantiate at verification that it had properly excluded this commission. As a result, we resorted to the use of best information available (BIA), in accordance with section 776(c) of the Act. As BIA, we have made an adverse assumption and increased the amount reported for marine insurance to account for this commission for all transactions (except those we found at verification to be correct) by the amount of the commission.

Foreign Market Value

In order to determine whether there were sufficient sales of WSSP in the home market to serve as a viable basis for calculating FMV, we compared the volume of home market sales of WSSP to the volume of third country sales of the same product, in accordance with section 773(a)(1)(B) of the Act. KT had a viable home market with respect to sales of WSSP during the POI.

As stated in our preliminary determination, the Department initiated an investigation under section 773(b) of the Act to determine whether KT made home market sales at less than their COP.

If over 90 percent of respondent's sales of a given model were at prices above the COP, we did not disregard any below-cost sales because we determined that the below-cost sales were not made in substantial quantities. If between ten and 90 percent of the sales of a given model were made at prices below the COP, and such sales were made over an extended period of time, we discarded only the below-cost sales. Where we found that more than 90 percent of respondent's sales were at prices below the COP, and such sales were over an extended period of time, we disregarded all sales of that model and calculated FMV based on CV. No evidence was presented to indicate that below-COP prices would permit recovery of all costs within a reasonable period of time in the normal course of trade.

In order to determine that below-cost sales were made over an extended period of time, we performed the following analysis on a model-specific basis: (1) If respondent sold a model in only one month of the POI and there were sales in that month below the COP, or (2) if respondent sold a model during two months or more of the POI and there were sales below the COP during two or more of those months, then below-cost sales were considered to have been made over an extended period of time.

In order to determine whether home market prices were below the COP, we calculated the COP based on the sum of the respondent's cost of materials, fabrication, and general expenses. We corrected the reported COP and CV data for errors and omissions found at verification. We relied on the submitted COP and CV data, except in the following instances where the costs were not appropriately quantified or valued:

1. We increased KT's general and administrative expenses (G&A) to (1) account for G&A incurred by KT's parent company because KT was unable to demonstrate that it had included these expenses in its reported G&A, (2) account for the amortization of pre-operating expenses which were not included in the submission, and (3) adjust for a clerical error found at verification. (See, *Comment 5* in the "Interested Party Comments" section of this notice.)

2. We increased KT's cost of materials to offset the gain on foreign exchange reported by KT that was related to the acquisition of machinery used to produce non-subject merchandise. (See, *Comment 8.*)

In accordance with section 773(e)(1)(B)(i) of the Act, we included in CV the greater of respondent's reported general expenses, adjusted as detailed

above, or the statutory minimum of ten percent of the COM. For profit, we used the actual profit on home market sales because this amount was greater than the statutory minimum of eight percent of COM and general expenses. See, section 773(e)(1)(B)(ii) of the Act.

In cases where we made price-to CV comparisons, we made circumstances-of-sale adjustments, where appropriate, for bank charges and credit expenses. Regarding credit expenses, KT calculated both home market and U.S. credit expenses using its respective average short-term interest rates in Malaysian Ringitts during the POI. We recalculated home market credit expenses using the consolidated short-term interest rate of KT and its parent company, which was based upon KT and its parent company's borrowings denominated in Malaysian Ringitts. In addition, KT failed to deduct discounts from the gross unit price in its home market credit calculation. We made the appropriate deductions in our recalculation.

Regarding U.S. credit expenses, we recalculated KT's U.S. interest rate using the amounts of all U.S. dollar-denominated loans stated in U.S. dollars. (See, *Comment 13.*) We also recalculated the payment period for each transaction as the time between the date of shipment from KT's factory and the date of payment by the U.S. customer. (See, *Comment 14.*) We then recalculated U.S. credit expenses using the revised interest rate and payment period.

In cases where we made price-to price-comparisons, we compared U.S. sales to home market sales made at the same level of trade, where possible, in accordance with 19 CFR 353.58 (1993). In addition, we disregarded home market sales of odd-length merchandise because we determined that these sales were made outside the ordinary course of trade. We also disregarded certain sales to end user customers, because we found at verification that the dates of sale for these transactions were outside the POI.

We adjusted the reported home market data for errors and omissions found at verification. We then calculated FMV based on packed F.O.B. prices charged to unrelated customers in the home market. We made deductions, where appropriate, for discounts and rebates. We also made deductions, where appropriate, for inland freight. We deducted home market packing costs and added U.S. packing costs, in accordance with section 773(a)(1) of the Act.

Pursuant to 19 CFR 353.56(a)(1) and 19 CFR 353.56(a)(2), we made circumstance-of-sale adjustments, where appropriate, for differences in bank charges and credit expenses, adjusted as described above.

Currency Conversion

Because certified exchange rates from the Federal Reserve were not available, we made currency conversions based on the official monthly exchange rates in effect on the dates of the U.S. sales as certified by the International Monetary Fund.

Verification

As provided in section 776(b) of the Act, we verified information provided the respondent by using standard verification procedures, including the examination of relevant sales and financial records, and selection of original source documentation containing relevant sales information.

Critical Circumstances

Petitioners allege that "critical circumstances" exist with respect to imports of WSSP from Malaysia. Section 735(a)(3) of the Act provides that critical circumstances exist if we determine that there is a reasonable basis to believe or suspect that:

(A)(i) There is a history of dumping in the United States or elsewhere of the class or kind of merchandise which is the subject of the investigation, or

(ii) The person by whom, or for whose account, the merchandise was imported knew or should have known that the exporter was selling the merchandise which is the subject of the investigation at less than its fair value, and

(B) There have been massive imports of the class or kind of merchandise which is the subject of the investigation over a relatively short period.

Regarding a history of dumping, petitioners have argued that the existence of U.S. antidumping orders on WSSP from Taiwan and Korea is sufficient for the Department to find a history of dumping in this case. However, the Department's practice in this area is to consider only those orders on subject merchandise from the country under investigation as sufficient evidence of a history of dumping. Consequently, because there have been no antidumping orders on WSSP from Malaysia, we find no history of dumping.

In determining whether any importer had knowledge of dumping, we normally consider margins of 25 percent or more sufficient to impute knowledge of dumping under section 735(e)(1)(A) of the Act when USP is based on purchase price. Because the final dumping margin for KT is less than 25 percent, we do not impute importer knowledge of sales at less than fair value, under section 735(a)(3)(A)(ii) of the Act. Since the criteria necessary to find the existence of critical circumstances under section 735(a)(3)(A) are not present, we do not need to determine whether imports of subject merchandise have been massive over a relatively short period, in accordance with section 735(a)(3)(B) of the Act.

Accordingly, we determine that critical circumstances do not exist with respect to imports of WSSP from Malaysia.

Interested Party Comments

Comment 1: Petitioners argue that KT was unable to substantiate its cost data at verification. As a result, petitioners contend that these data are unusable and the Department is required to reject KT's cost data completely and base the final determination on BIA. Petitioners maintain that, under the statute and the Department's regulations, the Department must use BIA to set antidumping duty margins whenever a respondent "refuses or is unable to produce information requested in a timely manner and in the form required, or otherwise significantly impedes an investigation" (see, section 776(b) of the Act). Petitioners further assert that the Department must also use BIA if it is "unable to verify the accuracy of the information submitted" by a respondent (see, section 776(c) of the Act).

According to petitioners, the problems that the Department discovered during verification are significant and pervasive. (See, *Comment 2* through *Comment 8* for the specific issues raised by petitioners.) Petitioners contend that, because of the serious nature of the deficiencies in KT's cost data, the Department cannot, and should not, develop an alternative basis for constructing KT's production costs. Rather, petitioners argue that the Department should resort to total BIA. In selecting the BIA rate, petitioners assert that the Department should use the highest rate possible, which is the highest margin contained in the petition.

KT argues that the Department is authorized to use BIA if a party "refuses or is unable to produce information requested in a timely manner and in the form required," or if a party "significantly impedes an investigation." KT asserts that, in order for these conditions to be satisfied, the Department must have requested the information and the respondent must have either failed to supply the information or have been unable to

comply with the request. Furthermore, KT argues that, even where the Department has requested information, it is not authorized to use BIA unless it has provided respondent with a warning and an opportunity to correct any deficiencies. KT asserts that, since it (1) provided all of the information requested by the Department, (2) in no way impeded this investigation, and (3) did not have an opportunity to correct perceived deficiencies, there is no basis for the Department to resort to any form of BIA.

KT claims that if the Department determines that it is appropriate to use BIA for purposes of the final determination, it should use a non-punitive, partial BIA, to reallocate KT's fabrication costs. (See, *Comment 3*, below.) According to KT, since KT has fully cooperated with the Department throughout this investigation, there is no reason for the Department to completely disregard KT's entire cost submission.

DOC Position: We agree with KT. The Department has determined that KT reported the majority of its production cost with no material problems. (*See*, cost verification report, dated December 9, 1993.) Because we have determined the KT's cost submission is reliable, there is no reason to completely disregard KT's entire cost submission. (*See*, comments below for a discussion regarding specific issues of validity.)

Comment 2: KT contends that the Department should accept the material costs reported in its September 13, 1993, response. KT argues that the Department verified that KT accurately reported in this response its actual production quantities and actual material costs incurred during the POI. According to KT, since the submitted product-specific material costs are the result of actual material expenses divided by actual production quantities, there is no basis for suspecting that the reported per unit material costs are incorrect. KT also maintains that its calculation of steel coil costs on a grade-by-grade basis is appropriate because the cost of the coil did not vary based on gauge.

Additionally, KT maintains that, contrary to petitioners' assertions, product-specific material costs reported in its September 13 submission are different from product-specific material costs reported in its October 25 submission for a legitimate reason—because the methodologies used in each submission were different.

Finally, KT notes that although the weighted-average material expenses decreased slightly between the September and October responses, the percentage of the five most frequently sold home-market products that were sold at prices below the cost of production remained exactly the same, regardless of which response's material costs are used. Thus, KT maintains that the difference between the two submissions in material expenses does not materially affect the margin calculation.

According to petitioners, since KT did not submit actual costs on a product-specific basis, acceptance of its cost data would be improper and inconsistent with the Department's normal practice. Thus, petitioners contend that KT's cost submission should be rejected.

Moreover, petitioners claim that the calculation methodologies used to prepare KT's September and October responses were virtually identical. According to petitioners, for both the September and October responses, KT calculated its material costs by multiplying the average per-kilogram material cost by the nominal weight of the pipe. Petitioners assert that the nominal weights used for these calculations were identical because KT stated that the nominal weight of the pipe was determined according to ASTM A–312 specifications. Thus, petitioners contend that differences in the materials costs could only arise if KT used different average per kilogram materials costs for its September and October responses. Petitioners maintain that these per kilogram materials costs are different for no apparent reason and are therefore suspect.

Petitioners contend that KT is incorrect in its assertion that the difference in the material costs reported in the two cost responses is immaterial to whether home market sales were made at prices below KT's cost of production. According to petitioners, KT's analysis mistakenly assumes that the understatement of its costs can be corrected by merely using the costs in KT's unverified October response. Consequently, petitioners argue that the Department should reject both of KT's cost responses and use BIA to establish KT's final dumping margin.

DOC Position: We agree with KT. The Department verified that KT accurately reported its actual material expenses incurred during the POI. Although the Department noted at verification that KT did not break out material costs between specific dimensions of pipe within a particular grade for the verified submission, the record indicates that the company incurred the same per kilogram cost for differing gauges of coil within a particular grade of steel.

We find that a comparison of the methodologies used in September and October responses is irrelevant because we only verified the methodology used in the September response. Prior to verification, we determined that the costs contained in the October submission were not adequately product-specific to meet the Department's requirements; therefore, we informed KT that we would not verify the COM portion of that response. Rather, the Department verified the material costs used in the September submission.

Because the methodologies used to compile the data in the two submissions were different, the costs reported in the submissions also differed. Therefore, the fact that the September data differed from the October data does not provide sufficient grounds to reject these costs. Because we verified the reasonableness of the September costs, we have accepted them for purposes of the final determination.

Comment 3: Petitioners argue that the Department should reject the cost of production data contained in KT's original cost submission because the Department was unable to verify the reported fabrication costs. Specifically: (1) The fabrication costs reported by KT in its September 13, 1993, submission were allocated to cost centers based on budgeted usage rates which could not be reconciled to KT's actual POI experience; (2) KT's methodology of allocating fabrication costs between industrial and ornamental pipe yields a result which is inconsistent with its reported production process steps; and (3) total manufacturing costs for industrial pipe were allocated to each subject product based on the weight of production rather than machine time.

Petitioners note that, to the extent the Department resorted to weight-based allocations in a previous case involving WSSP (see, Final Determination of Sales at Less than Fair Value: Certain Welded Stainless Steel Pipe from Taiwan (58 FR 53705, November 12, 1992) (WSSP from Taiwan)), that case represents an aberration from the Department's usual practice and is clearly distinguishable from the facts in the present case. Petitioners maintain that in WSSP from Taiwan the Department accepted the Taiwanese respondent's allocation because it concluded that the allocation "did not materially affect the cost calculation because labor and overhead represented a small part of total cost of production." In this case, however, petitioners contend that KT's submitted data demonstrate that fabrication costs can hardly be considered immaterial in relation to the submitted total cost of production.

Thus, petitioners contend that KT's reliance on WSSP from Taiwan as a

basis for claiming that weight-based allocations are acceptable is misplaced. Alternatively, petitioners assert that the Department accepts allocation methodologies based on weight only when a respondent affirmatively shows that such allocations make sense in light of the specific fabrication process for the product under investigation and when allocations based on machine time cannot be performed. According to petitioners, neither criterion has been satisfied by KT, and thus the Department should reject KT's weight-based allocations in favor of BIA.

KT disagrees, claiming that the cost verification report clearly indicates that KT accurately reported all direct labor and factory overhead expenses incurred during the POI. Thus, KT contends that petitioners' claim that the Department was unable to verify KT's fabrication costs should be dismissed out of hand.

KT states that it allocated fabrication costs between industrial and ornamental pipe production based on the actual staffing for factory laborers, the actual usage of production equipment, the company's actual production experience and, for variable overhead expenses, budgeted usage rates. According to KT, the difference between fabrication expenses per kilogram for industrial and ornamental pipe reflects the fact that KT produces more industrial pipe than ornamental pipe.

Additionally, KT claims that the Department should accept its submission methodology of allocating fabrication costs on the basis of weight for three reasons. First, the methodology conforms with the way in which KT calculates the cost of goods sold in the normal course of business, and there is no evidence on the record that allocating fabrication expenses on the basis of weight is in fact distortive. Second, during the POI, KT did not track the information needed to allocate fabrication costs on the basis of machine time. Third, the Department has accepted weight-based allocations of these costs in past cases involving stainless steel pipe. Accordingly, KT argues that the Department should accept its allocation of fabrication expenses for purposes of the final determination.

DOC Position: At verification, we determined that KT accurately reported its aggregate fabrication costs during the POI. Therefore, we disagree with petitioners that KT's fabrication costs should be dismissed for purposes of the final determination.

In cases where machinery or processes were dedicated to the production of specific product types (e.g., WSSP), KT assigned costs directly to these products without allocation. For example, KT assigned depreciation expenses on machinery dedicated to the production of WSSP directly to WSSP. Only in cases where KT incurred fabrication costs common to the production of both subject and non-subject merchandise did KT allocate these costs.

We recognize that KT's basis for the allocation of these costs to the subject merchandise used budgeted estimates which KT was unable to reconcile to its actual production experience during the POI. However, we found at verification that KT did not maintain the level of detailed records in its normal accounting system that permitted such a reconciliation. Moreover, the Department determined that these estimates are reasonable based on visual inspection of the production process and analysis of KT's documentation. Contrary to petitioners' assertions, during the POI KT did not maintain its records at a sufficient level of detail to perform a more product-specific allocation (e.g., records of machine time, etc.). Accordingly, we find that KT's allocation methodology is reasonable, in light of the specific circumstances of this case. Thus, we have accepted the use of KT's methodology in this case for purposes of the final determination.

Comment 4: Petitioners argue that KT calculated its production costs on the basis of theoretical production weights that overstate the weight of finished production, thus artificially lowering its submitted per unit production costs. Therefore, petitioners contend that the cost data in KT's September 13, 1993, submission is unusable and should be rejected by the Department.

KT contends that the use of theoretical weights does not affect the accuracy of its submitted production costs. According to KT, since KT used the same conversion factor for its calculation to convert (1) pipe production stated in feet to production stated in kilograms, and (2) production cost per kilogram to a production cost per foot, the conversion factors are uniformly over- or under-stated by the same amount.

DOC Position: We agree with KT. KT's calculation of theoretical production weights overstates the actual weight of production during the POI. However, as information on the record indicates, this same theoretical production weight was used to convert the production costs from a per kilogram cost to a per foot cost. Thus, the effect of overstating the weight of production is offset by the use of the same formula in converting the per kilogram cost back to a per foot cost. Accordingly, no adjustment is deemed necessary.

Comment 5: KT contends that it properly reported all expenses associated with management and financial services provided to KT by its parent as part of its submitted G&A. KT states that fees for these services are charged directly to KT and are reflected in the management fee amount KT's parent company received from its subsidiaries in FY 1993. According to KT, because all management fees that are properly allocable to KT are already charged directly to the company, there is no basis for charging any additional amount to KT.

Petitioners contend that KT understated its submitted G&A by not including a portion of its parent company's expenses incurred during 1992. Petitioners argue that, since KT's parent is principally an investment holding company, all G&A incurred by the parent directly relate to its investment holdings. Petitioners maintain that KT's claim that all management fees and financial services provided by its parent company to KT are accounted for in its submission is unverified and unsupported. According to petitioners, the Department has no way of knowing if KT's management fees were correctly calculated and reported. Additionally, petitioners claim that the Department should increase KT's submitted G&A by the omitted amortization of pre-operating expenses as noted at verification.

DOC Position: We agree with petitioners. In cases where a parent company is an investment holding company, it is the Department's practice to allocate a portion of G&A expenses incurred by the parent company to the respondent under the theory that the parent's G&A expenses are incurred on behalf of the parent's investment holdings. (See, e.g., Final Determination of Sales at Less Than Fair Value: Ferrosilicon from Venezuela (58 FR 27524, May 10, 1993).) Since there is no verified information on the record to support KT's claim that all G&A expenses incurred by KT's parent for the benefit of KT were already charged to KT and included in the submitted G&A calculation, we adjusted KT's G&A to include a proportional amount of its parent's administrative costs based on KT's parent's stock ownership of KT. Additionally, we revised KT's G&A expense computation to include the omitted amortization of pre-operating expenses as recorded on the company's financial statements, as well as to correct for a clerical error found at verification.

Comment 6: Petitioners claim that the production yields reported by KT are inaccurate and unrealistic and cannot be relied upon by the Department for its final determination.

KT argues that production yields are irrelevant because the costs used for the final determination are KT's actual material expenses, not standard costs. Thus, KT maintains that whether or not the production yield used under the standard cost system is accurate is irrelevant to the Department's analysis.

DOC Position: The apparent unrealistic production yields appear to be generated from KT's usage of theoretical production weights. Since this same theoretical weight was used to convert production costs from a unit of weight basis to a unit of length basis, the effect of the apparent unrealistic yield rate is offset. (See, Comment 4, above.) Therefore, no adjustment was deemed necessary for the final determination.

Comment 7: Petitioners contend that the stainless steel coil costs KT used in its original response were not consistent with information on the coil invoices obtained by the Department at verification and, moreover, were inconsistent with the coil costs reported by KT in its second cost questionnaire response. Petitioners argue that the Department, therefore, should reject the stainless steel coil costs reported by KT.

KT argues that petitioners' claim that KT reported inconsistent stainless steel costs is incorrect. KT asserts that petitioners are basing this claim on a comparison of non-comparable figures. Specifically, KT states that the figures taken from Exhibit 16 of its original cost response are net of all adjustments for work in process, exchange gains, and scrap expense and revenue, whereas the figures in the second response include these expenses.

DOC Position: We disagree with petitioners. The Department verified the accuracy of the coil costs contained only in the first submission. (See, the "Case History" section of this notice for further discussion.) Thus, any differences between the first and second responses are irrelevant. Moreover, it is not relevant that the weighted-average material costs reported in the first submission differ from selected invoices included as exhibits to the cost verification report. Specifically, the weighted-average prices are based on the entire population of invoices which comprise KT's raw material requisition values, while the invoices included as verification exhibits are only a selected portion of them. To the extent that the individual values are not identical, they should differ from the average value.

Comment 8: Petitioners argue that the exhibits to the cost verification report demonstrate that an exchange rate gain claimed by KT as an offset to foreign exchange losses does not relate to the merchandise under investigation and, accordingly, should not be included in KT's submitted cost of manufacturing.

DOC Position: We agree. Accordingly, we have not allowed an offset for this gain for purposes of the final determination.

Comment 9: Petitioners contend that the Department cannot rely on KT's second cost submission because it contains unverified data. Thus, petitioners maintain that the Department's conclusion in the cost verification report that material costs in the first submission are lower than material costs reported in the second cost submission does not, and should not, lend any credibility to the data in the first submission. According to petitioners, both submissions are flawed and should be rejected in their entirety.

DOC Position: We agree with petitioners that the material cost data contained in KT's second submission was not verified and should not be relied upon by the Department. Therefore, no conclusions were drawn as a result of comparing material costs contained in both the first and second submissions.

Comment 10: KT argues that the Department should accept its reported value for work in process. KT asserts that, although its opening and closing work in process for the POI are valued at standard cost, without any adjustment for the variance during the period, it is mathematically impossible for this to result in an understatement of KT's costs because KT had a negative variance for FY 1993.

DOC Position: We agree. Since KT had a negative variance during the relevant periods, the effect of valuing work-in-process at standard cost would be to overstate its costs. Therefore, no adjustment is deemed necessary.

Comment 11: KT reported an average home market packing labor expense for the POI based on the packing labor expenses incurred during each month of the period. Petitioners contend that the Department should use the monthly packing labor expenses in calculating KT's home market packing expenses instead of the POI average. Petitioners assert that the Department's longstanding policy is to use data that are as sales-specific as possible. According to petitioners, in this case the most specific data available are the monthly costs.

KT argues that using monthly packing labor costs would distort KT's per unit packing expenses. KT maintains that it is appropriate to spread packing labor expenses over the sales quantities during the entire six-month POI because of fluctuations in monthly sales volumes. KT asserts that this methodology yields a more representative per unit expense for the POI because packing labor is a fixed cost.

DOC Position: We agree with KT. Normally, the Department prefers respondents to report transaction-specific expenses under the theory that individual prices are set to cover individual (*i.e.*, transaction-specific) costs. In this case, however, the costs are not transaction-specific. Moreover, because KT's packing labor expenses are fixed, they do not vary by sales volume. Therefore, fluctuations in the monthly sales volumes create differences in the monthly average expense amounts. Because these fluctuations in sales expenses are not translated into changes in the per unit prices, they distort the margin calculation. We agree with KT that using the POI-average minimizes the effect of these fluctuations.

Therefore, we find that the POI average is more representative of KT's per unit packing labor costs. Accordingly, we have accepted this average for purposes of the final determination.

Comment 12: KT argues that the Department should affirm its preliminary determination that critical circumstances do not exist with respect to KT's exports of subject merchandise to the United States. KT maintains that there is no history of dumping of subject merchandise imported from Malaysia. In addition, KT claims that its exports were not massive.

DOC Position: We agree. See, the Critical Circumstances section of this notice for further discussion.

Comment 13: Both KT and petitioners contend that the Department should calculate KT's short-term interest rate on U.S. dollar-denominated loans using the interest expenses incurred and the principal outstanding denominated in U.S. dollars rather than U.S. dollar-amounts converted to Malaysian Ringitts. KT notes that calculating the interest rate in this way eliminates from the calculation the effect of exchange rate fluctuations.

DOC Position: We agree. At verification, we noted that KT had calculated its U.S. interest rate by converting U.S. dollar-denominated loans and interest payments to Malaysian Ringitts. We recalculated its interest rate based on the original currency of the loans and the interest payments (*i.e.*, U.S. dollars) and used

this revised rate in our U.S. credit calculation.

Comment 14: Respondent argues that the Department should calculate KT's U.S. credit period using the date of invoice, rather than date of shipment from the factory. Respondent states that the invoice date is same as the bill of lading date and is the date on which the merchandise is shipped from Malaysia. Respondent adds that because the bill of lading date is the date on which the merchandise leaves KT's possession, the Department would be overstating KT's credit expenses for its U.S. sales if it used an earlier date. However, KT contends that, should the Department find it necessary to use shipment dates, the Department should use the shipment dates in its October 29, 1993, submission. KT notes that these data were verified by the Department.

Petitioners argue that KT's proposed methodology of using bill of lading date in its U.S. credit calculation should not be used by the Department in the final determination. Petitioners assert that this methodology is contrary to the Department's longstanding policy as stated in the Preliminary Determination of Sale at Less than Fair Value: Welded Stainless Steel Pipe from Malaysia, 58 FR 47,120 (September 7, 1993). Petitioners maintain that the Department should use the shipment dates submitted by KT on October 29, 1993.

DOC Position: We agree with petitioners. As stated in our preliminary determination, it is the Department's practice to calculate credit expenses using the period between shipment of the merchandise from the factory and payment. (See, e.g., Final Determination of Sales at Less Than Fair Value: Ferrosilicon From Venezuela, 58 FR 27522 (May 10, 1993) and Final Determination of Sales at Less Than Fair Value: Certain Hot-Rolled Lead and Bismuth Carbon Steel Products From the United Kingdom, 58 FR 6207 (January 27, 1993).) Moreover, we note that using the date of shipment from the factory does not overstate KT's U.S. credit expense because, contrary to KT's assertion, KT's factory shipment date generally follows the date of invoicing.

Comment 15: Petitioners argue that the Department should not make a difference in merchandise (difmer) adjustment in any instance where such an adjustment would lower KT's FMV. Petitioners base their argument on the fact that the difmer adjustments are based on KT's cost data which petitioners claim is unreliable.

Respondent maintains that the Department should make difmer adjustments in cases where sales of non-identical merchandise are compared.

DOC Position: We agree with respondent. Because the Department has relied on KT's COP data, we have used this data to make our difmer adjustments.

Continuation of Suspension of Liquidation

We are directing the Customs Service to continue to suspend liquidation of all entries of WSSP that are entered, or withdrawn from warehouse, for consumption on or after September 7, 1993, the date of publication of our affirmative preliminary determination in the **Federal Register**. The Customs Service shall require a cash deposit or the posting of a bond equal to the estimated amount by which the FMV of the merchandise subject to this investigation exceeds the USP as shown below. This suspension of liquidation will remain in effect until further notice. The weighted-average dumping margins are as follows:

Producer/manufacturer/exporter	Weighted-average margin percentage	Critical circumstances
Kanzen Tetsu Sdn. Bhd.	9.13	No.
All Others	9.13	No.

ITC Notification

In accordance with section 735(d) of the Act, we have notified the International Trade Commission (ITC) of our determination. As our final determination is affirmative, the ITC will determine whether these imports are materially injuring, or threaten material injury to, the U.S. industry within 45 days.

Notification to Interested Parties

This notice also serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 353.34(d). Failure to comply is a violation of the APO.

This determination is published pursuant to section 735(d) of the Act and 19 CFR 353.20(a)(4).

Dated: January 21, 1994.

Joseph A. Spetrini,

Acting Assistant Secretary for Import Administration.

[FR Doc. 94–1967 Filed 1–27–94; 8:45 am]

BILLING CODE 3510–DS–P

Export Trade Certificate of Review

ACTION: Notice of application.

SUMMARY: The Office of Export Trading Company Affairs, International Trade Administration, Department of Commerce, has received an application for an Export Trade Certificate of Review. This notice summarizes the conduct for which certification is sought and requests comments relevant to whether the Certificate should be issued.

FOR FURTHER INFORMATION CONTACT: Friedrich R. Crupe, Acting Director, Office of Export Trading Company Affairs, International Trade Administration, (202) 482–5131. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: Title III of the Export Trading Company Act of 1982 (15 U.S.C. 4001–21) authorizes the Secretary of Commerce to issue Export Trade Certificates of Review. A Certificate of Review protects the holder and the members identified in the Certificate from state and federal government antitrust actions and from private, treble damage antitrust actions for the export conduct specified in the Certificate and carried out in compliance with its terms and conditions. Section 302(b)(1) of the Act and 15 CFR 325.6(a) require the Secretary to publish a notice in the **Federal Register** identifying the applicant and summarizing its proposed export conduct.

Request for Public Comments

Interested parties may submit written comments relevant to the determination whether a Certificate should be issued. An original and five (5) copies should be submitted no later than 20 days after the date of this notice to: Office of Export Trading Company Affairs, International Trade Administration, Department of Commerce, room 1800H, Washington, DC 20230. Information submitted by any person is exempt from disclosure under the Freedom of Information Act (5 U.S.C. 552). Comments should refer to this application as "Export Trade Certificate of Review, application number 94–00001." A summary of the application follows.

Summary of the Application

Applicant: Northeast Florida Export Trading Company, Inc., Post Office Box 28136, Jacksonville, Florida 32226, Contact: Joseph Strain, Founder & President, Telephone: (904) 346–5435.

Application No.: 94–00001.

Date Deemed Submitted: January 14, 1994.

Members (in addition to applicant): None.

Northeast Florida Export Trading Company, Inc. seeks a Certificate to cover the following specific Export Trade, Export Markets, and Export Trade Activities and Methods of Operations.

Export Trade

1. Products

All products.

2. Services

All services.

3. Export Trade Facilitation Services (as They Relate to the Export of Products and Services)

All export trade facilitation services in connection with the export of Products and Services, including consulting, international market research, advertising, marketing, insurance, product research and design, legal assistance, transportation, trade documentation, freight forwarding, communication and processing of foreign orders, warehousing, foreign exchange and financing.

Export Markets

The Export Markets include all parts of the world except the United States (the fifty states of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, and the Trust Territory of the Pacific Islands) and the Republic of South Africa.

Export Trade Activities and Methods of Operation

Northeast Florida Export Trading Company, Inc. may:

1. Require that exporters using its Export Trade Facilitation Services sign exclusive dealing contracts allowing Northeast Florida Export Trading Company, Inc. to be their sole Export Intermediary for sales to specified markets.

2. Require exporters using its Export Trade Facilitation Services to export through the Jacksonville Port Authority Aviation and Marine Facilities.

3. Sign exclusive distributorship agreements with other Export Intermediaries that prohibit such other Export Intermediaries from handling competing Products and Services.

4. Sign exclusive arrangements with its clients that prohibit Northeast Florida Export Trading Company, Inc. from representing competing companies.

Definitions

"Export Intermediary" means a person who acts as a distributor, sales representative, sales or marketing agent, or broker, or who performs similar functions, including providing or arranging for the provision of Export Trade Facilitation Services.

Protection Provided by Certificate

This Certificate will protect the Northeast Florida Export Trading Company, Inc. and its directors, officers, and employees acting on its behalf from private treble damage actions and government criminal and civil suits under Federal and State antitrust laws for the export conduct specified in the Certificate and carried out during its effective period in compliance with its Terms and Conditions.

Dated: January 21, 1994.

Jude Kearney,

Deputy Assistant Secretary for Service Industries and Finance.

[FR Doc. 94–1773 Filed 1–27–94; 8:45 am]

BILLING CODE 3510–PR–P

Fordham University, et al.; Notice of Consolidated Decision on Applications for Duty-Free Entry of Electron Microscopes

This is a decision consolidated pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89–651, 80 Stat. 897; 15 CFR 301). Related records can be viewed between 8:30 A.M. and 5:00 P.M. in Room 4211, U.S. Department of Commerce, 14th and Constitution Avenue, N.W., Washington, D.C.

Docket Number: 93–119. *Applicant:* Fordham University, Bronx, NY 10458. *Instrument:* Electron Microscope, Model JEM-1010. *Manufacturer:* JEOL Ltd., Japan. *Intended Use:* See notice at 58 FR 51618, October 4, 1993. *Order Date:* June 24, 1993.

Docket Number: 93–131. *Applicant:* University of Idaho, Moscow, ID 83844. *Instrument:* Electron Microscope, Model JEM-2010. *Manufacturer:* JEOL Ltd., Japan. *Intended Use:* See notice at 58 FR 59012, November 5, 1993. *Order Date:* June 30, 1993.

Docket Number: 93–133. *Applicant:* San Francisco State University, San Francisco, CA 94132. *Instrument:* Electron Microscope, Model CM 120. *Manufacturer:* N.V. Philips, The Netherlands. *Intended Use:* See notice at 58 FR 63924, December 3, 1993. *Order Date:* June 15, 1993.

Docket Number: 93–135. *Applicant:* Texas Department of Health, Austin, TX 78756. *Instrument:* Electron Microscope, Model H-7100. *Manufacturer:* Nissei Sangyo, Japan. *Intended Use:* See notice at 58 FR 63924, December 3, 1993. *Order Date:* August 25, 1993.

Docket Number: 93–137. *Applicant:* University of Virginia, Charlottesville, VA 22908. *Instrument:* Electron Microscope, Model CM 200. *Manufacturer:* N.V. Philips, The Netherlands. *Intended Use:* See notice at 58 FR 63924, December 3, 1993. *Order Date:* March 30, 1993.

Comments: None received. *Decision:* Approved. No instrument of equivalent scientific value to the foreign instrument, for such purposes as these instruments are intended to be used, was being manufactured in the United States at the time the instruments were ordered. *Reasons:* Each foreign instrument is a conventional transmission electron microscope (CTEM) and is intended for research or scientific educational uses requiring a CTEM. We know of no CTEM, or any other instrument suited to these purposes, which was being manufactured in the United States either at the time of order of each instrument or at the time of receipt of application by the U.S. Customs Service.

Pamela Woods,

Acting Director, Statutory Import Programs Staff.

[FR Doc. 94–1968 Filed 1–27–94; 8:45 am]

BILLING CODE 3510–DS–F

Minority Business Development Agency

[Project I.D. No. 06–10–94004–01]

Business Development Center Applications: Little Rock MBDC

AGENCY: Minority Business Development Agency, Commerce

ACTION: Cancellation.

SUMMARY: The above solicitation was previously published at 57 FR 60604 on Wednesday, November 17, 1993. This solicitation has been cancelled.

11.800 Minority Business Development (Catalog of Federal Domestic Assistance)

Dated: January 24, 1994.

Bobby Jefferson,

Acting Regional Director, Dallas Regional Office.

[FR Doc. 94–1882 Filed 1–27–94; 8:45 am]

BILLING CODE 3510–21–M

[Project I.D. No. 06-10-94001-01]

Business Development Center Applications: Shreveport MBDC

AGENCY: Minority Business Development Agency, Commerce.

ACTION: Cancellation.

SUMMARY: The above solicitation was previously published at 57 FR 60605 on Wednesday, November 17, 1993. This solicitation has been cancelled.

11.800 Minority Business Development (Catalog of Federal Domestic Assistance)

Dated: January 24, 1994.

Bobby Jefferson,

Acting Regional Director, Dallas Regional Office.

[FR Doc. 94-1881 Filed 1-27-94; 8:45 am]

BILLING CODE 3510-21-M

National Institute of Standards and Technology

[Docket No. 920535-3305]

RIN 0693-AA99

Second Solicitation of Comments on Proposed Federal Information Processing Standard for Standard Security Label for the Government Open Systems Interconnection Profile

AGENCY: National Institute of Standards and Technology (NIST), Commerce.

ACTION: Notice; request for comments.

SUMMARY: The purpose of this notice is to announce the revised proposed Federal Information Processing Standard (FIPS) for Standard Security Label for the Government Open Systems Interconnection Profile. This proposed FIPS was originally announced in the **Federal Register** (57 FR 37948) on August 21, 1992.

NIST received comments from 28 government and industry organizations in response to the first notice on the proposed FIPS for Standard Security Label for the Government Open Systems Interconnection Profile. While many of the comments supported the proposed standard, other comments particularly those received from the Department of Defense, recommended changes to broaden the scope of the standard and make it compatible with other government efforts to develop secure communications processes.

NIST has been working with the Department of Defense and other organizations to revise the original proposal and to develop a common standard for security labels that will meet the needs of the interested parties.

NIST solicits views from the public, manufacturers, and Federal, State and local government users on this revised proposed standard prior to submission to the Secretary of Commerce for review and approval.

The revised proposed standard contains two sections: (1) An announcement section, which provides information concerning the applicability, implementation, and maintenance of the standard; and (2) a specifications section which deals with the technical aspects of the standard. Only the announcement section of the standard is provided in this notice. Interested parties may obtain copies of the specifications section from the Standards Processing Coordinator (ADP), National Institute of Standards and Technology, Technology Building, room B64, Gaithersburg, MD 20899, telephone (301) 975-2816.

DATES: Comments on this revised proposed standard must be received on or before March 29, 1994.

ADDRESSES: Written comments concerning the revised proposed standard should be sent to: Director, Computer Systems Laboratory, ATTN: Revised Proposed FIPS for Standard Security Label, Technology Building, room B154, National Institute of Standards and Technology, Gaithersburg, MD 20899.

Written comments received in response to this notice will be made part of the public record and will be made available for inspection and copying in the Central Reference and Records Inspection Facility, room 6020, Herbert C. Hoover Building, 14th Street between Pennsylvania and Constitution Avenues, NW., Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Mr. Noel Nazario, National Institute of Standards and Technology, Gaithersburg, MD 20899, telephone (301) 975-2837.

Dated: January 24, 1994.

Samuel Kramer,

Associate Director.

Federal Information Processing Standard Publication XXX

Draft 1993 September 30 Draft

Announcing a Standard Security Label for the Government Open Systems Interconnection Profile

Federal Information Processing Standards Publications (FIPS PUBS) are issued by the National Institute of Standards and Technology (NIST) after approval by the Secretary of Commerce pursuant to section 111(d) of the Federal Property and Administrative Services Act of 1949 as amended by the Computer Security Act of 1987, Public Law 100-235.

Name of Standard: Standard Security Label for the Government Open Systems Interconnection Profile.

Category of Standard: Computer Security, Security Labels

Explanation: This standard specifies the security label for the U.S. Government Open Systems Interconnection Profile (GOSIP). GOSIP security labels carry information used by protocol entities to determine how to handle data communicated between open systems. Information on a security label can be used to control access, specify protective measures, and determine additional handling restrictions required by a communications security policy.

This standard specifies the syntax for the labels and relies on a Computer Security Objects Register (CSOR) to provide the semantics. The separation of the label syntax from its semantics enables a common label format to support multiple security policies and facilitate cross-domain communications.

Given the inherent differences in layer functionality the security label defined in this document is expressed both as an abstract label syntax specification for the OSI Application Layer and an encoding optimized for use at the Network Layer. The Application and Network Layers are the initial targets of GOSIP security.

The label presented here defines security tags that may be combined into tag sets to carry security-related information. Five basic security tag types allow security information to be represented as bit maps, attribute enumerations, attribute range selections, hierarchical security levels, or as user-defined data.

Approving Authority: Secretary of Commerce.

Maintenance Agency: Computer Systems Laboratory, National Institute of Standards and Technology.

Cross Index:

Federal Information Resources Management Regulations, subpart 201-20.303, Standards, and subpart 201-39.1002, Federal Standards.

"Procedures for Registering Computer Security Objects", NISTIR XXXX, September 1993.

"U.S. Government Open Systems Interconnection Profile" (GOSIP), FIPS PUB 146-1, April 1991.

Scope: This standard specifies a security label for GOSIP-complaint implementations. It includes two label specifications, one suitable for the OSI Application Layer, and the other for the Network Layer. GOSIP will call for the use of this standard when optional

security protocols at these layers require the use of security labels.

Applicability: The specified Standard Security Label (SSL) applies to OSI communications systems handling U.S. Government unclassified but sensitive data. The SSL shall be used on OSI systems required to label data as indicated in the security chapter of GOSIP. Although this standard is intended for use on systems handling unclassified information, it could be adopted by the appropriate authorities for use on systems handling classified information.

The SSL may be used by OSI protocols to control access, specify protective measures, and indicate handling restrictions required by a network security policy as registered in a Computer Security Objects Register.

Complying implementations shall be capable of transmitting, receiving, and obtaining information from security labels based on the specifications in this document.

Specifications: Federal Information Processing Standard (FIPS xxx) Standard Security Label for the Government Open Systems Interconnection Profile (affixed).

Implementation Schedule: This standard becomes effective six months after publication of a notice in the **Federal Register** of its approval by the Secretary of Commerce.

Waiver Procedure: Under certain exceptional circumstances, the heads of Federal departments and agencies may approve waivers to Federal Information Processing Standards (FIPS). The head of such agency may redelegate such authority only to a senior official designated pursuant to section 3506(b) of title 44, United States Code. Waiver shall be granted only when:

a. Compliance with a standard would adversely affect the accomplishment of the mission of an operator of a Federal computer system; or

b. Compliance with a standard would cause a major adverse financial impact on the operator which is not offset by Government-wide savings.

Agency heads may act upon a written waiver request containing the information detailed above. Agency heads may also act without a written waiver request when they determine that conditions for meeting the standard cannot be met. Agency heads may approve waivers only by a written decision which explains the basis on which the agency head made the required finding(s). A copy of each decision, with procurement sensitive or classified portions clearly identified, shall be sent to: National Institute of Standards and Technology; ATTN: FIPS Waiver Decisions, Technology Building, room B–154, Gaithersubrg, MD 20899.

In addition, notice of each waiver granted and each delegation of authority to approve waivers shall be sent promptly to the Committee on Government Operations of the House of Representatives and the Committee on Government Affairs of the Senate and shall be published promptly in the **Federal Register.**

When the determination on a waiver applies to the procurement of equipment and/or services, a notice of the waiver determination must be published in the Commerce Business Daily as a part of the notice of solicitation for offers of an acquisition or, if the waiver determination is made after that notice is published, by amendment of such notice.

A copy of the waiver, any supporting documents, the document approving the waiver and any accompanying documents, with such deletions as the agency is authorized and decides to make under United States Code section 552(b), shall be part of the procurement documentation and retained by the agency.

Where to Obtain Copies: Copies of this publication are for sale by the National Technical Information Service, U.S. Department of Commerce, Springfield, VA 22161. When ordering, refer to Federal Information Processing Standards Publication XX (FIPS PUB XX), and identify the title. When microfiche is desired, this should be specified. Prices are published by NTIS in current catalogs and other issuances. Payment may be made by check, money order, deposit account or charged to a credit card accepted by NTIS.

[FR Doc. 94–1819 Filed 1–27–94; 8:45 am]
BILLING CODE 3510–CN–M

[Docket No. 931103–3303]

RIN 0693–AB12

Proposed Federal Information Processing Standard Open Document Architecture Raster Document Application Profile

AGENCY: National Institute of Standards and Technology (NIST), Commerce.

ACTION: Notice; request for comments.

SUMMARY: The purpose of this notice is to announce a proposed Federal Information Processing Standard (FIPS) for Open Document Architecture (ODA) Raster Document Application Profile (DAP). This proposed standard will enable Federal agencies to exercise more effective control over the production, management, and use of Government's raster graphics applications.

This proposed FIPS will adopt the proposed Draft International Standard Profile (pDISP) FOD112 Open Document Architecture (ODA) Document Application Profile (DAP), "ODA Raster DAP," which specifies the use of a subset of the Open Document Architecture (ODA) and Interchange Format Standard.

Prior to the submission of this proposed FIPS to the Secretary of Commerce for review and approval, it is essential to assure that consideration is given to the needs and views of manufacturers, the public, and state and local governments. The purpose of this notice is to solicit such views.

The proposed standard contains two sections: (1) An announcement section, which provides information concerning the applicability, implementation, and maintenance of the standard; and (2) a specifications section which deals with the technical requirements of the standard. Only the announcement section of the standard is provided in this notice. Interested parties may obtain copies of the technical specifications from the Standards Processing Coordinator (ADP), National Institute of Standards and Technology, Technology Building, room B–64, Gaithersburg, MD 20899, telephone (301) 975–2816.

DATES: Comments on this proposed FIPS must be received on or before April 28, 1994.

ADDRESSES: Written comments concerning this proposed FIPS should be sent to: Director, Computer Systems Laboratory, ATTN: Proposed FIPS for ODA Raster DAP, Technology Building, room B–154, National Institute of Standards and Technology, Gaithersburg, MD 20899.

Written comments concerning this proposed FIPS will be made part of the public record and will be made available for inspection and copying in the Central Reference and Records Inspection Facility, room 6020, Herbert C. Hoover Building, 14th Street between Pennsylvania and Constitution Avenues NW., Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Mr. Frank Spielman, National Institute of Standards and Technology, Gaithersburg, MD 20899, (301) 975–3257.

Dated: January 24, 1994.

Samuel Kramer,

Associate Director.

Federal Information Processing Standards Publication

(Draft Date: October 8, 1993)

Announcing the Standard for Open Document Architecture (ODA) Raster Document Application Profile (DAP)

Federal Information Processing Standards Publications (FIPS PUBS) are issued by the National Institute of Standards and Technology after approval by the Secretary of Commerce pursuant to section 111(d) of the Federal Property and Administrative Services Act of 1949 as amended by the Computer Security Act of 1987, Public Law 100–235.

1. Name of Standard. Open Document Architecture (ODA) Raster Document Application Profile (DAP).

2. Category of Standard. Software Standard, Graphics.

3. Explanation. This Federal Information Processing Standard adopts the International Standard Profile (ISP) FOD112 Open Document Architecture (ODA) Document Application Profile (DAP), "ODA Raster DAP," which specifies the use of a subset of the Open Document Architecture (ODA) and Interchange Format Standard.

The ODA standard supports the interchange of compound documents containing up to three types of contents: Character (text), raster graphics, and geometric graphics. Developed by international standards organizations, the ODA standard specifies rules for describing the logical and layout structures of documents as well as rules for specifying character, raster graphics, and geometric graphics content of documents, thus providing for the interchange of complex documents. The ODA standard was developed primarily by the International Organization for Standardization (ISO/IEC JTC1) and the International Telecommunication Union (ITU) Telecommunication Standardization Sector (TSS), formerly the Consultative Committee on International Telephone and Telegraph (CCITT).

A DAP is a functional subset of the ODA standard and facilitates the interchange of documents among different document systems by specifying the constraints on document structure and content according to the rules of the ODA Standard. The ODA Raster DAP specifies an interchange format suitable for the transfer of structured documents between systems designed for raster graphics applications. The documents supported by this standard are based on a paradigm of an electronic engineering drawing, illustration, or other electronic image. Only raster content in an ODA document is supported by this FIPS.

The ODA Raster DAP was initially developed by an ad-hoc Continuous Acquisition and Life-Cycle Support (CALS) Tiling Task Group. CALS, formerly known as the Computer-aided Acquisition and Logistic Support, is a Department of Defense (DoD) initiative. The ODA Raster DAP was further developed by vendors and users of computer networks/systems participating in the Open Systems Environment Implementors' Workshop (OIW), and finally harmonized with the International organizations participating in the Profile Alignment Group for ODA (PAGODA). It has been submitted to ISO/IEC JTC1/Special Group on Functional Standards (SGFS) for processing of an International Standard Profile (ISP).

4. Approving Authority. Secretary of Commerce.

5. Maintenance Agency. U.S. Department of Commerce, National Institute of Standards and Technology (Computer Systems Laboratory).

6. Cross Index.

a. International Organization for Standardization (ISO) 8613–1993, Information Processing—Text and Office Systems Open Document Architecture (ODA) and Interchange Format Standard.

b. NIST Special Publication 500–206, Stable Implementation Agreements for Open Systems Interconnection Protocols, Version 6, Edition 1, December 1992, with updates through September 1993.

c. Military Specification MIL–R–28002B, Requirements for Raster Graphics Representation in Binary Format, 14 December 1992, Appendix A, ODA Raster DAP.

7. Related Documents. Related ISO and ITU documents are listed in the normative reference section of the ODA Raster DAP. Other related documents are:

a. ANSI/AIIM MS53–1993, Standard Recommended Practice—File Format for Storage and Exchange of Images—Bi-Level Image File Format.

b. FIPS PUB 149, Telecommunications: Facsimile Coding Schemes and Coding Control Functions for Group 3 Facsimile Apparatus.

c. FIPS PUB 150, Telecommunications: Facsimile Coding Schemes and Coding Control Functions for Group 4 Facsimile Apparatus.

8. Objectives. The FIPS for ODA Raster DAP permits Federal departments and agencies to exercise more effective control over the production, management, and use of Government's raster graphics applications. The primary objectives of this standard are:

—To promote interchange of structured documents containing raster graphics images between image processing systems of different manufacturers,

—To facilitate the use of advanced technology by the Federal Government,

—To stimulate the development of commercial products compatible with the ODA Standard and with the GOSIP communications standards,

—To contribute to the economic and efficient use of image and document processing system resources, and

—To avoid the proliferation of vendor-unique solutions.

9. Applicability. The ODA Raster DAP is available for use by Federal Government agencies when acquiring and developing raster graphics applications. This FIPS applies to systems processing, generating, and receiving raster graphics images. It specifies the structure and parameters for describing and interchanging bi-level compressed images as well as tiled raster images. Each system acquired or developed by Federal agencies shall include appropriate system-to-DAP and DAP-to-system translators, such that incoming data streams are interpreted correctly and that outgoing data streams are generated correctly. Use of the standard is independent of the communications used to transfer documents produced by these applications, that is, this standard may be used within the existing framework of communication protocols.

10. Specifications. This FIPS adopts all provisions of the FOD112 ODA Raster DAP which is affixed. The document and raster layout specifications of ISO 8613 that are essential for raster graphics applications apply to the FIPS for ODA Raster DAP. The specifications for ODA data streams are also defined in ISO 8613 and apply to the FIPS for ODA raster DAP.

All implementations claiming conformance to this FIPS must adhere to the specific requirements defined in the "Conformance" clause of the ODA Raster DAP and to the general rules below.

Conformance Rules for Data Streams. A conforming data stream shall be syntactically, semantically, and structurally correct as defined in this standard.

Conformance rules for Generators. A generator which claims conformance to this standard shall create only

conforming data streams which correctly represent the raster graphics image which was input to the generator.

Conformance Rules for Receivers. A receiver which claims conformance to this standard shall be capable of reading and correctly processing any conforming data stream without halting or aborting such that it produces the correct results.

11. Implementation. The implementation of this standard involves three areas of consideration: acquisition of raster graphics implementations, interpretations of the standard, and validation of ODA Raster DAP implementations.

11.1 Acquisition of Raster Graphics Applications. This standard is effective six months after date of publication of final document in the **Federal Register**. For a period of twelve (12) months after the effective date, agencies are permitted to acquire alternative software that provides equivalent functionality to the ODA Raster DAP. Agencies are encouraged to use this standard for solicitation proposals for new raster processing systems to be acquired after the effective date. This standard is mandatory for use in all solicitation proposals for new raster application products acquired twelve (12) months after the effective date.

11.2. Interpretation of the Standard. NIST provides for the resolution of questions regarding FIPS for ODA Raster DAP specifications and requirements, and issues official interpretations as needed. Procedures for interpretations are specified in FIPS PUB 29–2. All questions about the interpretation of FIPS for ODA Raster DAP should be addressed to: Computer Systems Laboratory, ATTN: Raster Graphics Interpretation, National Institute of Standards and Technology, Gaithersburg, MD 20899.

11.3. Validation of ODA Raster DAP Implementations. Validation of ODA Raster DAP implementations is not mandatory at this time. Future versions of this FIPS may mandate the validation of ODA Raster DAP implementations for government use. Testing of an implementation's conformance to this FIPS will be optional by the agency. Until a formal conformance testing service is available, government agencies acquiring implementations in accordance with this standard may wish to require testing for conformance, interoperability, and performance. The tests to be administered and the testing organization are at the discretion of the government agency.

12. Waivers. Under certain exceptional circumstances, the heads of Federal departments and agencies may approve waivers to Federal Information Processing Standards (FIPS). The head of such agency may delegate such authority only to a senior official designated pursuant to section 3506(b) of title 44, U.S. Code. Waivers shall be granted only when:

a. Compliance with a standard would adversely affect the accomplishment of the mission of an operator of a Federal Computer system, or

b. Cause a major adverse financial impact on the operator that is not offset by Government wide savings.

Agency heads may act upon a written waiver request containing the information detailed above. Agency heads may also act without a written waiver request when they determine that conditions for meeting the standard cannot be met. Agency heads may approve waivers only by a written decision that explains the basis on which the agency head made the required finding(s). A copy of each such decision, with procurement sensitive or classified portions clearly identified, shall be sent to: National Institute of Standards and Technology; Attn: FIPS Waiver Decision, Technology Building, Room B–154; Gaithersburg, MD 20899.

In addition, notice of each waiver granted and each delegation of authority to approve waivers shall be sent promptly to the Committee on Government Operations of the House of Representatives and the Committee on Government Affairs of the Senate and shall be published promptly in the **Federal Register**.

When the determination on a waiver applies to the procurement of equipment and/or services, a notice of the waiver determination must be published in the Commerce Business Daily as a part of the notice of solicitation for offers of an acquisition or, if the waiver determination is made after that notice is published, by amendment to such notice.

A copy of the waiver, any supporting documents, the document approving the waiver and any supporting and accompanying documents, with such deletions as the agency is authorized and decides to make under 5 U.S.C. 552(b), shall be part of the procurement documentation and retained by the agency.

13. Where to Obtain Copies. Copies of this publication are for sale by the National Technical Information Service, U.S. Department of Commerce, Springfield, VA 22161. When ordering, refer to Federal Information Processing Standards Publication XXXXX (FIPS PUB XXXXX), and title. Specify microfiche, if desired. Payment may be made by check, money order, or NTIS deposit account.

[FR Doc. 94–1820 Filed 1–27–94; 8:45 am]
BILLING CODE 3510–CN–M

[Docket No. 931107–3307]

RIN 0693–AA70

Proposed Federal Information Processing Standard for Portable Operating System Interface (POSIX)—Part 2: Shell and Utilities

AGENCY: National Institute of Standards and Technology (NIST), Commerce.

ACTION: Notice; request for comments.

SUMMARY: The purpose of this notice is to announce the proposed Federal Information Processing Standard (FIPS), Portable Operating System Interface (POSIX)—Part 2: Shell and Utilities, which adopts Draft International Standard ISO/IEC 9945–2:1992, Information Technology—Portable Operating System Interface (POSIX)—Part 2: Shell and Utilities as a Federal Information Processing Standard (FIPS). ISO/IEC 9945–2:1992, which defines a command language interpreter (shell) and a set of utility programs, is expected to be approved as an International Standard (IS) in 1994. The FIPS will adopt the final IS after it is approved.

Prior to the submission of the proposed FIPS to the Secretary of Commerce for review and approval, it is essential to assure that consideration is given to the needs and views of manufacturers, the public, and State and local governments. The purpose of this notice is to solicit such views.

This proposed FIPS contains two sections: (1) An announcement section, which provides information concerning the applicability, implementation and maintenance of the standard; and (2) a specifications section which deals with the technical requirements of the standard. Only the announcement section of the standard is provided in this notice. Interested parties may obtain copies of the specifications (ISO/IEC 9945–2) from the IEEE Service Center, 445 Hoes Lane, P.O. Box 1331, Piscataway, NJ 08855–1331, telephone 1–800–678–4333.

DATES: Comments on this proposed FIPS must be received on or before April 28, 1994.

ADDRESSES: Written comments concerning the proposed FIPS should be sent to: Director, Computer Systems Laboratory, ATTN: Proposed FIPS for POSIX.2, Technology Building, room B154, National Institute of Standards and Technology, Gaithersburg, MD 20899.

Written comments concerning this proposed FIPS will be made part of the public record and will be made available for inspection and copying in the Central Reference and Records Inspection Facility, room 6020, Herbert C. Hoover Building, 14th Street between Pennsylvania and Constitution Avenues NW., Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Sheila Frankel, National Institute of Standards and Technology, Gaithersburg, MD 20899, telephone (301) 975–3297.

Dated: January 24, 1994.

Samuel Kramer,

Associate Director.

Proposed Federal Information Processing Standards Publication

(date)

Announcing the Standard for Portable Operating System Interface (POSIX)—Part 2: Shell and Utilities

Federal Information Processing Standards Publications (FIPS PUBS) are issued by the National Institute of Standards and Technology after approval by the Secretary of Commerce pursuant to section 111(d) of the Federal Property and Administrative Services Act of 1949 as amended by the Computer Security Act of 1987, Public Law 100–235.

Name of Standard. Portable Operating System Interface (POSIX)—Part 2: Shell and Utilities.

Category of Standard. Software Standard, Operating Systems.

Explanation. This publication announces the adoption of Draft International Standard ISO/IEC 9945–2:1992, Information Technology—Portable Operating System Interface (POSIX)—Part 2: Shell and Utilities as a Federal Information Processing Standard (FIPS). ISO/IEC 9945–2:1992, which defines a command language interpreter (shell) and a set of utility programs, is expected to be approved as an International Standard (IS) in 1994. The FIPS will adopt the final IS after it is approved.

This standard is for use by computing professionals involved in system and application software development and implementation and is part of a series of specifications needed for application portability. This standard addresses the Applications Portability Profile functional area that deals with methods by which a person interacts with the operating systems.

Approving Authority. Secretary of Commerce.

Maintenance Agency. U.S. Department of Commerce, National Institute of Standards and Technology, Computer Systems Laboratory.

Cross Index. Draft International Standard ISO/IEC 9945–2:1992, Information Technology—Portable Operating System Interface (POSIX)—Part 2: Shell and Utilities.

Related Documents

a. Federal Information Resources Management Regulations subpart 201–20.333, Standards, and subpart 201–39.1002, Federal Standards.

b. Federal Information Processing Standards Publication 151–2, Portable Operating System Interface (POSIX)—System Application Program Interface [C Language].

c. Federal Information Processing Standards Publication 160, C.

d. ISO/IEC 9899: Information Technology—Programming Languages—C.

e. Test Methods for Measuring Conformance to POSIX, IEEE Std 1003.3–1991.

f. Test Methods for Measuring Conformance to POSIX, IEEE Proposed Std 2003 (Draft 1.0).

g. Test Methods for Measuring Conformance to POSIX.1, IEEE Std 2003.1–1992.

h. Test Methods for Measuring Conformance to POSIX.2, IEEE Proposed Std 2003.2 (Draft 8).

i. Interpretation Procedures for Federal Information Processing Standards for Software, FIPS PUB 29–3, 1992 October 29.

j. NVLAP Program Handbook, Computer Applications Testing POSIX Conformance Testing, NISTIR 4522, March 1991 (latest revision).

k. NIST POSIX Testing Policy—General Information, April 15, 1993 (latest revision).

l. NIST POSIX Testing Policy, Certificate of Validation Requirements, FIPS 151–2, August 15, 1993 (latest revision).

Related On-Line Information. Information on the NIST POSIX Testing Program is available on an electronic mail (Email) file server system. Documents available are: registers of validated products, general information on NIST POSIX testing policy, and information on requirements for certificates of validation.

To access the system:

You must be able to send and receive Email via the Internet. For most Email systems, send a message to posix@nist.gov. When the Email system responds with "Subject", you may type anything. The next line should be a basic command for the Email server to send you one or more of the available documents. For example, to receive a listing of all available files, enter: send index.

After you issue your send command and a carriage return, the next line should signal the end of the Email message as required by your Email system.

Your Email system may respond with EOT for the end of transmission.

The mail server program reads the message and sends the requested document to the requester's Email address.

If you need help contact the Systems and Software Technology Division, B266 Technology Building, NIST, Gaithersburg, MD 20899, telephone: 301–975–3295.

Objectives. This FIPS permits Federal departments and agencies to exercise more effective control over the production, management, and use of the Government's information resources. The primary objectives of this FIPS are:

a. To promote portability of computer application programs at the source code level.

b. To simplify computer program documentation by the use of a standard portable system interface design.

c. To reduce staff hours in porting computer programs to different vendor systems and architectures.

d. To increase portability of acquired skills, resulting in reduced personnel training costs.

e. To maximize the return on investment in generating or purchasing computer programs by insuring operating system compatibility.

f. To allow people to operate a wide range of application platform implementations without additional training or study.

Government-wide attainment of the above objectives depends upon the widespread availability and use of comprehensive and precise standard specifications.

Applicability. This FIPS shall be used for POSIX command language interpreters and utilities that are either developed or acquired for Government use. This FIPS is applicable to the entire range of computer hardware, including:

a. Laptops,
b. Micro-computer systems,
c. Mini-computer systems,
d. Workstations,
e. Mainframes.

Specifications. The specifications for this FIPS are the specifications contained in the Draft International Standard ISO/IEC 9945–2:1992, Information Technology—Portable Operating System Interface (POSIX)—Part 2: Shell and Utilities, with the modifications specified below. ISO/IEC

9945–2:1992 defines a command language interpreter (shell) and a set of utility programs. ISO/IEC 9945–2:1992 (hereinafter referred to as POSIX.2) refers to and is a complement to ISO/IEC 9945–1, Information Technology—Portable Operating System Interface (POSIX)—Part 1: System Application Program Interface (API) [C Language].

POSIX.2 contains a number of features that are labelled obsolescent. These features violate the general syntactic guidelines of POSIX.2. They were included in POSIX.2 to provide upward compatibility of existing applications, and may be deleted from POSIX.2 at some future date. The POSIX.2 standard requires that strictly conforming applications do not use any of these features. It is strongly recommended that agencies that require the POSIX.2 FIPS prohibit users from using these features. Therefore, the following obsolescent features are not required for a system to be compliant with the POSIX.2 FIPS. (For each feature a reference to the associated POSIX.2 text is provided):

- Zero-length prefix in the PATH environment variable [See POSIX.2 Subclause 2.6 Lines 2699–2700]
- The *–option* in the *set* special built-in utility [See POSIX.2 Subclause 3.14.11 Lines 1599–1600 and 1726–1730]
- The *awk* string function *length* with no argument and no parentheses [See POSIX.2 Subclause 4.1.7.6.2.2 Lines 621–622]
- The octal number form of the *mode* operand in the *chmod* utility [See POSIX.2 Subclause 4.7.7 Lines 2090–2091]
- The *–option* in the *ed* utility [See POSIX.2 Subclause 4.20.1 Lines 3529–3530; Subclause 4.20.3 Line 3542]
- The *–option* in the *env* utility [See POSIX.2 Subclause 4.21.1 Lines 4034–4035; Subclause 4.21.3 Line 4048]
- The *–perm [–]onum* primary in the *find* utility [See POSIX.2 Subclause 4.24.4 Lines 4361–4368]
- The *egrep* and *fgrep* utilities [See POSIX.2 Subclause 4.28.1 Lines 4793–4799; Subclause 4.28.2 Lines 4815–4832; Subclause 4.28.3 Lines 4850–4851]
- The *–number* option in the *head* utility [See POSIX.2 Subclause 4.29.1 Lines 4953–4954; Subclause 4.29.3 Lines 4971–4974]
- The *–j field*, *–j1 field*, and *–j2 field* options and the *–o* list option (where *list* is composed of multiple arguments) in the *join* utility [See POSIX.2 Subclause 4.31.1 Lines 5133–5135; Subclause 4.31.3 Lines 5168–5170 and 5182–5184]
- The *–signal-name* and *–signal-number* options in the *kill* utility [See POSIX.2 Subclause 4.32.1 Lines 5259–5261; Subclause 4.32.3 Lines 5294–5311]
- The *+pos1* and *–pos2* options in the *sort* utility and the *–o* output option following a *file* operand [See POSIX.2 Subclause 4.58.1 Lines 9583–9585; Subclause 4.58.3 Lines 9599–9601, 9618–9620, and 9674–9675; Subclause 4.58.7 Lines 9746–9762]
- The *–[number] [c/l] [f]* and *+[number] [c/l] [f]* options in the *tail* utility [See POSIX.2 Subclause 4.60.1 Lines 10058–10060; Subclause 4.60.3 Lines 10098–10105]
- The *date—time* operand in the *touch* utility [See POSIX.2 Subclause 4.63.1 Lines 10337–10338; Subclause 4.63.4 Lines 10403–10416]
- The *–s* option in the *tty* utility [See POSIX.2 Subclause 4.66.1 Lines 10659–10660; Subclause 4.66.3; Lines 10669–10671]
- The octal number form of the *mask* operand in the *unmask* utility [See POSIX.2 Subclause 4.67.4 Lines 10755–10756 and 10759–10760]
- The *–n* and *+m* options in the *uniq* utility [See POSIX.2 Subclause 4.69.1 Lines 10890–10891; Subclause 4.69.3 Lines 10918–10919]

If the User Portability Utilities Option is required, the following obsolescent features are not required for a system to be compliant with the POSIX.2 FIPS:

- The *–* and *+command* options in the ex utility [See POSIX.2 Subclause 5.10.1 Lines 985–986; Subclause 5.10.3 Lines 1004 and 1028]
- The *–tabstop* and *–tab1, tab2, . . .* tabn options in the expand utility [See POSIX.2 Subclause 5.11.1 Lines 2056–2057; Subclause 5.11.3 Lines 2083–2085]
- The *+command* option in the *more* utility [See POSIX.2 Subclause 5.18.1 Lines 2726–2727; Subclause 5.18.3 Line 2769]
- The *–* option in the *newgrp* utility [See POSIX.2 Subclause 5.19.1 Lines 3123–3124; Subclause 5.19.3 Line 3185]
- The *–increment* option in the *nice* utility [See POSIX.2 Subclause 5.20.1 Lines 3242–3243; Subclause 5.20.3 Line 3260]
- The *nice_value* option in the renice utility; combinations of the *[–p] pid*, *–g gid*, and *–u user* options [See POSIX.2 Subclause 5.24.1 Lines 3795–3798; Subclause 5.24.3 Lines 3837–3838, 3847–3848, and 3850–3851; Subclause 5.24.4 Lines 3860–3864]
- The *–line_count* option in the *split* utility [See POSIX.2 Subclause 5.25.1 Lines 3906–3907; Subclause 5.25.3 Line 3942]
- The *–* and *–number* options in the *strings* utility [See POSIX.2 Subclause 5.26.1 Lines 3996–3997; Subclause 5.26.3 Lines 4010 and 4014]
- The *+command* option in the *vi* utility [See POSIX.2 Subclause 5.35.1 Lines 4722–4723; Subclause 5.35.3 Line 4744]

If the C-Language Development Utilities Option is required, the following obsolescent features are not required for a system to be compliant with the POSIX.2 FIPS:

- The *–c* option in the *lex* utility [See POSIX.2 Subclause A.2.1. Lines 218–219; subclause A.2.3 Line 231]

Recommendations

Users of this standard should be aware that it does not require the Portable Operating System Interfaces (POSIX)—Part 2: Shell and Utilities to be implemented on a FIPS 151–2 conforming implementation. Users should also be aware that certain utilities and functions are optional in ISO/IEC 9945–2:1992. To provide the greatest support for application portability, it is recommended that an implementation conforming to this FIPS also provide the following features:

1. User Portability Utilities Option (POSIX2_UPE, POSIX.2 Section 5) and Full Terminal Operations Option (POSIX2–_CHAR_TERM, POSIX.2 Section 2.14).
2. A FIPS 151–2 conforming operating system interface.
3. Software Development Utilities Option (POSIX2_SW_DEV, POSIX.2 Section 6), when software will be developed or source-level software will be installed on the systems being acquired.
4. C-Language Development Utilities Option (POSIX2_C_DEV, POSIX.2 Annex A), when software written in the C language will be developed or installed on the systems being acquired.
5. C-Language Bindings Option (POSIX2_C_BIND, POSIX.2 Annex B), when software written in the C language will be used on the systems being acquired.
6. FORTRAN Development Utilities Option (POSIX2_FORT_DEV, POSIX.2 Annex C.) when software written in FORTRAN will be developed or installed on the systems being acquired.
7. FORTRAN Runtime Utilities Option (POSIX2_FORT_RUN, POSIX.2 Annex C), when FORTRAN software will be used on the systems being acquired.

Furthermore, it is strongly recommended that Federal users require Feature 1 and, in addition, ensure that purchased systems are capable of supporting Features 2–5, listed above.

Even when these features are not needed at the time of initial purchase, changed requirements may demand some or all of these in the future, either for the development of new applications, for the importing of applications from other systems, or to maximize compatibility among multiple in-house systems.

Implementation. This standard becomes effective six (6) months after date of publication of the final document in the **Federal Register** announcing approval of the standard by the Secretary of Commerce. This standard is compulsory and binding for use in all solicitations and contracts for new operating systems and/or applications development where POSIX shell and utility interfaces are required.

a. Acquisition of Conforming Portable Shell and Utilities. Organizations developing applications which are to be acquired after the publication date of this standard and which have applications portability as a requirement should consider the use of this FIPS. Conformance to this FIPS should be considered whether the operating system environments are:

1. Developed internally,
2. Acquired as part of an ADP system procurement,
3. Acquired by separate procurement,
4. Used under an ADP leasing arrangement, or
5. Specified for use in contracts for programming services.

b. Interpretation of the FIPS for Shell and Utilities. NIST provides for the resolution of questions regarding the FIPS specifications and requirements, and issues official interpretations as needed. All questions about the interpretation of this FIPS should be addressed to: Director, National Computer Systems Laboratory, Attn: POSIX Shell and Utilities FIPS Interpretation, National Institute of Standards and Technology, Gaithersburg, MD 20899.

c. Validation of Conforming Operating Systems Environments. NIST is developing cooperatively with industry a validation suite for measuring conformance to this standard. This suite will be required for testing conformance of POSIX Shell and Utilities implementations. These testing requirements will be announced at a future date.

Where to Obtain Copies: Copies of this publication are for sale by the National Technical Information Service, U.S. Department of Commerce, Springfield, VA 22161. (Sale of the included specifications document is by arrangement with the Institute of Electrical and Electronics Engineers, Incorporated.) When ordering, refer to Federal Information Processing Standards Publication _____ (FIPSPUB _____), and title. Payment may be made by check, money order, or deposit account.

Appendix A—Application Portability Profile

The POSIX Shell and Utilities FIPS is the second component of a series of specifications needed for the operating system services area of an applications portability profile. FIPS 151–1 (and its replacement, FIPS 151–2) provided the crucial first step by providing a vendor independent interface specification between an application program and an operating system. When fully extended, POSIX will provide the functionality required to support source code portability for a wide range of applications across many different machines and operating systems.

NIST has published Special Publication 500–210, Application Portability Profile (APP), The U.S. Government's Open System Environment Profile, OSE/1, Version 2.0, June 1993. The APP has been developed to provide sufficient functionality to accommodate a broad range of application requirements. The functional components of the APP constitute a framework for organizing standard elements that can be used to develop and maintain portable applications. A key aspect of the APP is that it is based on an open system environment defined by non-proprietary specifications. Components may be added or deleted as technology changes and as Federal government requirements change.

[FR Doc. 94–1818 Filed 1–27–94; 8:45 am]
BILLING CODE 3510–CN–M

[Docket No. 931241–3341]

National Voluntary Laboratory Accreditation Program

AGENCY: National Institute of Standards and Technology, Commerce.

ACTION: Request for comments on need for establishing a laboratory accreditation program.

SUMMARY: The National Institute of Standards and Technology (NIST) has received a request to establish a laboratory accreditation program. In a letter dated September 16, 1993, the National Electrical Manufacturers Association, Washington, DC requested that NIST establish an accreditation program for testing electric motors for energy efficiency (but not for safety). A copy of the request letter is set out as an appendix to this notice. Announcement of this request by the National Electrical Manufacturers Association (NEMA), and of the NIST request for comments with respect thereto, are being made under the procedures of the National Voluntary Laboratory Accreditation Program (NVLAP) (15 CFR part 7, subpart B, § 7.11(d)) of the referenced Procedures.

DATES: Comments may be submitted on or before March 28, 1994.

ADDRESSES: Persons desiring to comment on the need for such an accreditation program are invited to submit their comments in writing within the 60 day period to Albert Tholen, Chief, National Voluntary Accreditation Program, National Institute of Standards and Technology, Building 411, room A162, Gaithersburg, MD 20899. Copies of comments received will be available for inspection and copying at the Department of Commerce Central Reference and Records Inspection Facility, room 6020, Hoover Building, Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT:

Lawrence Galowin, Deputy to Chief, Laboratory Accreditation Program, National Institute of Standards and Technology, Building 411, room A162, Gaithersburg, MD 20899, Telephone (301) 975–4022, FAX (301) 926–2884.

SUPPLEMENTARY INFORMATION:

Scope of Laboratory Accreditation

The request letter called for accreditation of test laboratories based on standard test methods for performance of energy efficient electric motors for the proposed program. The accreditation program will assist the efforts of industry to meet the requirements of the Energy Policy Act (EPACT) of 1992 regarding electric motors. The test methods for accreditation discussed at NEMA and DoE meetings with industry will be for IEEE Standard 112 Test Method B, and NEMA Standards Publication MG1–1987, as set forth in the EPACT legislation and other standards when and if the Secretary (DoE) amends the test procedures. NVLAP Procedures have recently been modified to be fully in accord with ISO Guide 25 that extends ISO 9002 recognition; such criteria will beneficially impact on the qualified applicants granted accreditation if approval is made to proceed with the program.

As a normal extension of support by NVLAP to other agencies the applicable requirements of DoE to be established under the Energy Policy Act (EPACT) would be made an integral part of the program for accreditation of laboratories.

Procedure Following Receipt of Comments

After the 60 days comment period, NIST will thoroughly evaluate all comments pertaining to the proposed accreditation program. Notification to all interested persons will be made by copy of a FR notice of the decision by the director of NIST regarding development of this program. Interested persons are the submitters of comments, or those requesting copy by placement on a NVLAP mailing distribution list. Approval of the program will call for technical assistance and input from interested and qualified parties and for comments to be made on the program handbook, test methods, and criteria applied in the program. NVLAP Procedures provide for public comment prior to final publication of the accreditation requirements.

Dated: January 11, 1994.

Arati Prabhakar,

Director.

Appendix

September 16, 1993

Director, National Institute of Standards and Technology, Gaithersburg, MD 20899

Dear Dr. Prabhakar: This letter is written on behalf of the Motor and Generator Section of NEMA to request that the National Institute of Standards and Technology establish a laboratory accreditation program (LAP) for electric motors through the National Voluntary Laboratory Accreditation Program.

The purpose of the program will be to accredit testing laboratories to certify that standard test methods for product performance (and not safety) are properly followed in testing electric motors. Standard test methods and related performance standards will be those developed through such accredited standards-making organizations as NEMA and the Institute of Electrical and Electronics Engineers, Inc.

The development of a NVLAP program on energy efficient motors will be beneficial to industry in meeting the requirements of the Energy Policy Act (EPACT) of 1992 regarding electric motors. The EPACT requires that certain types and sizes of electric motors meet minimum efficiency standards and that a program be established to verify the efficiencies. A NVLAP program will assure that data used to verify motor efficiencies are measured in competent testing laboratories. The NVLAP program on energy efficient lighting, developed in response to a previous request by NEMA, will serve as a model for a program on electric motors.

The NEMA Motor and Generator Section is willing to assist the National Institute of Standards and Technology in identifying and obtaining the necessary technical resources to establish the accreditation program.

Please give this request your immediate attention.

Sincerely,

Frank Kitzantides,

(Vice President, Engineering).

Dated: January 24, 1994.

Samuel Kramer,

Associate Director

[FR Doc. 94–1821 Filed 1–27–94; 8:45 am]

BILLING CODE 3510–13–M

National Oceanic and Atmospheric Administration

Endangered Species; Permits.

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Issuance of an extension to a scientific research permit (P45D).

On October 4, 1988 Permit 648 (P45D) was issued to the United States Fish and Wildlife Service (USFWS) to take listed shortnose sturgeon (*Acipenser brevirostrum*). Notice is hereby given that on January 19, 1994, NMFS issued an extension to Permit 648, authorizing research activities to be conducted through July 1, 1994, as authorized by the Endangered Species Act of 1973 (ESA) (16 U.S.C. 1531–1543) and the NMFS regulations governing listed fish and wildlife permits (50 CFR parts 217–222). This extension will provide the USFWS time to incorporate previous years' research into the development of a new application.

Issuance of this extension, as required by the ESA, was based on a finding that such permit: (1) Was applied for in good faith; (2) will not operate to the disadvantage of the listed species which is the subject of this permit; (3) is consistent with the purposes and policies set forth in Section 2 of the ESA. This permit was also issued in accordance with and is subject to parts 217–227 of title 50 CFR, the NMFS regulations governing listed species permits.

The application, permit, and supporting documentation are available for review by interested persons in the following offices by appointment:

Office of Protected Resources, National Marine Fisheries Service, 1335 East-West Highway, Silver Spring, MD 20910 (301–713–2322); and

National Marine Fisheries Service, Southeast Region, 9450 Koger Boulevard, St. Petersburg, FL 33702 (813–893–3141).

Dated: January 19, 1994.

Herbert W. Kaufman,

Deputy Director, Office of Protected Resources.

[FR Doc. 94–1915 Filed 1–27–94; 8:45 am]

BILLING CODE 3510–22–M

Endangered Species; Permits

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Issuance of Scientific Research Permit No. 885 for the New York Cooperative Fish and Wildlife Research Unit (P555).

On October 28, 1993, notice was published (58 FR 57990) that an application had been filed by the New York Fish and Wildlife Research Unit, to take shortnose sturgeon as authorized by the Endangered Species Act of 1973 (ESA) (16 U.S.C. 1531–1543) and the NMFS regulations governing listed fish and wildlife permits (50 CFR parts 217–222).

Notice is hereby given that on January 21, 1994; as authorized by the provisions of the ESA, NMFS issued Permit Number 885 for the above taking subject to certain conditions set forth therein.

Issuance of this permit, as required by the ESA, was based on a finding that such permit: (1) Was applied for in good faith; (2) will not operate to the disadvantage of the listed species which is/are the subject of this permit; (3) is consistent with the purposes and policies set forth in Section 2 of the ESA. This permit was also issued in accordance with and is subject to parts 217–222 of title 50 CFR, the NMFS regulations governing listed species permits.

The application, permit, and supporting documentation are available for review by interested persons in the following offices by appointment:

Office of Protected Resources, National Marine Fisheries Service, 1335 East-West Highway, room Silver Spring, MD 20910 (301–713–2322); and

National Marine Fisheries Service, Northeast Region, One Blackburn Drive, Gloucester, MA 01930 (508–281–9250).

Dated: January 21, 1994.

Herbert W. Kaufman,

Acting Director, Office of Protected Resources.

[FR Doc. 94–1916 Filed 1–27–94; 8:45 am]

BILLING CODE 3510–22–M

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Announcement of Import Restraint Limits for Certain Cotton, Man-Made Fiber, Silk Blend and Other Vegetable Fiber Textiles and Textile Products Produced or Manufactured in the People's Republic of Bangladesh

January 24, 1994.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs establishing limits for the new agreement year.

EFFECTIVE DATE: February 1, 1994.

FOR FURTHER INFORMATION CONTACT: Ross Arnold, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port or call (202) 927–5850. For information on embargoes and quota re-openings, call (202) 482–3715.

SUPPLEMENTARY INFORMATION:

Authority: Executive Order 11651 of March 3, 1972, as amended; section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854).

The Bilateral Textile Agreement, effected by exchange of notes dated February 19 and 24, 1986, as amended and extended, between the Governments of the United States and the People's Republic of Bangladesh, establishes limits for the period beginning on February 1, 1994 and extending through January 31, 1995.

In the letter published below, the Chairman of CITA directs the Commissioner of Customs to establish limits for the period February 1, 1993 through January 31, 1994. The limits for Categories 334, 340/640, 341, 351/651 and 634 have been reduced to account for carryforward used.

A copy of the bilateral textile agreement is available from the Textiles Division, Bureau of Economic and Business Affairs, U.S. Department of State, (202) 647–3889.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see **Federal Register** notice 58 FR 62645, published on November 29, 1993).

The letter to the Commissioner of Customs and the actions taken pursuant to it are not designed to implement all of the provisions of the agreement, but are designed to assist only in the implementation of certain of its provisions.

Ronald I. Levin,

Acting Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

January 24, 1994.

Commissioner of Customs,
Department of the Treasury, Washington, DC 20229.

Dear Commissioner: Under the terms of section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854), and the Arrangement Regarding International Trade in Textiles done at Geneva on December 20, 1973, as further extended on December 9, 1992; pursuant to the Bilateral Textile Agreement, effected by exchange of notes dated February 19 and 24, 1986, as amended and extended, between the Governments of the United States and the People's Republic of Bangladesh; and in accordance with the provisions of Executive Order 11651 of March 3, 1972, as amended, you are directed to prohibit, effective on February 1, 1994, entry into the United States for consumption and withdrawal from warehouse for consumption of cotton, man-made fiber, silk blend and other vegetable fiber textiles and textile products in the following categories, produced or manufactured in Bangladesh and exported during the twelve-month period beginning on February 1, 1994 and extending through January 31, 1995, in excess of the following levels of restraint:

Category	Twelve-month restraint limit
237	348,622 dozen.
331	883,220 dozen pairs.
334	100,393 dozen.
335	190,964 dozen.
336/636	325,462 dozen.
338/339	969,968 dozen.
340/640	2,112,395 dozen.
341	1,749,928 dozen.
342/642	320,751 dozen.
347/348	1,668,494 dozen.
351/651	480,852 dozen.
363	18,988,167 numbers.
369–S[1]	1,272,790 kilograms.
634	351,228 dozen.
635	241,072 dozen.
638/639	1,255,461 dozen.
641	776,273 dozen.
645/646	294,831 dozen.
647/648	1,049,368 dozen.
847	530,644 dozen.

[1] Category 369–S: only HTS number 6307.10.2005.

Imports charged to these category limits for the period February 1, 1994 through January 31, 1995 shall be charged against those levels of restraint to the extent of any unfilled balances. In the event the limits established for that period have been exhausted by previous entries, such goods shall be subject to the levels set forth in this directive.

The limits set forth above are subject to adjustment in the future pursuant to the provisions of the current bilateral agreement between the Governments of the United States and the People's Republic of Bangladesh.

In carrying out the above directions, the Commissioner of Customs should construe entry into the United States for consumption to include entry for consumption into the Commonwealth of Puerto Rico.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception of the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

Ronald I. Levin,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 94–1866 Filed 1–27–94; 8:45 am]

BILLING CODE 3510–DR–F

Adjustment of an Import Limit for Certain Cotton and Man-Made Fiber Textile Products Produced or Manufactured in Brazil

January 24, 1994.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs increasing a limit.

EFFECTIVE DATE: January 28, 1994.

FOR FURTHER INFORMATION CONTACT: Nicole Bivens Collinson, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–4212. For information on the quota status of this limit, refer to the Quota Status Reports posted on the bulletin boards of each Customs port or call (202) 927–5850. For information on embargoes and quota re-openings, call (202) 482–3715.

SUPPLEMENTARY INFORMATION:

Authority: Executive Order 11651 of March 3, 1972, as amended; section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854).

The current limit for Category 219 is being increased for carryover and swing.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see **Federal Register** notice 58 FR 62645, published on November 29, 1993). Also see 58 FR 14381, published on March 17, 1993.

The letter to the Commissioner of Customs and the actions taken pursuant to it are not designed to implement all of the provisions of the bilateral

agreement, but are designed to assist only in the implementation of certain of its provisions.

Ronald I. Levin,

Acting Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

January 24, 1994.

Commissioner of Customs,
Department of the Treasury, Washington, DC 20229.

Dear Commissioner: This directive amends, but does not cancel, the directive issued to you on March 12, 1993, by the Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of certain cotton, wool and man-made fiber textile products, produced or manufactured in Brazil and exported during the twelve-month period which began on April 1, 1993 and extends through March 31, 1994.

Effective on January 28, 1994, you are directed to amend the directive dated March 12, 1993 to increase the limit for Category 219 to 17,018,880 square meters [1], as provided under the terms of the current bilateral agreement between the Governments of the United States and the Federative Republic of Brazil.

The Committee for the Implementation of Textile Agreements has determined that this action falls within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

Ronald I. Levin,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 94–1867 Filed 1–27–94; 8:45 am]

BILLING CODE 3510–DR–F

Adjustment of Import Limits for Certain Cotton and Man-Made Fiber Textile Products Produced or Manufactured in Indonesia

January 24, 1994.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs adjusting limits.

EFFECTIVE DATE: January 25, 1994.

FOR FURTHER INFORMATION CONTACT: Jennifer Tallarico, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port or call (202) 927–6704. For information on embargoes and quota re-openings, call (202) 482–3715.

SUPPLEMENTARY INFORMATION:

Authority: Executive Order 11651 of March 3, 1972, as amended; section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854).

The current limit for Categories 334/335 is being increased by application of swing, reducing the limit for Category 219 to account for the increase.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see **Federal Register** notices 57 FR 54976, published on November 23, 1992; and 58 FR 62645, published on November 29, 1993). Also see 58 FR 31190, published on June 1, 1993.

The letter to the Commissioner of Customs and the actions taken pursuant to it are not designed to implement all of the provisions of the bilateral agreement, but are designed to assist only in the implementation of certain of its provisions.

Ronald I. Levin,

Acting Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

January 24, 1994.

Commissioner of Customs,
Department of the Treasury, Washington, DC 20229.

Dear Commissioner: This directive amends, but does not cancel, the directive issued to you on May 25, 1993, by the Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of certain cotton, wool, man-made fiber, silk blend and other vegetable fiber textiles and textile products, produced or manufactured in Indonesia and exported during the twelve-month period which began on July 1, 1993 and extends through June 30, 1994.

Effective on January 25, 1994, you are directed to amend further the directive dated May 25, 1993, to adjust the limits for the following categories, as provided under the terms of the current bilateral agreement between the Governments of the United States and Indonesia:

Category	Adjusted twelve-month limit [1]
Levels in Group I	
219	6,289,886 square meters.
334/335	158,973 dozen.

[1] The limits have not been adjusted to account for any imports exported after June 30, 1993.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

Ronald I. Levin,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 94–1865 Filed 1–27–94; 8:45 am]

BILLING CODE 3510–DR–F

Adjustment of Import Limits for Certain Cotton and Man-Made Fiber Textile Products and Silk Blend and Other Vegetable Fiber Apparel Produced or Manufactured in Sri Lanka

January 24, 1994.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs adjusting limits.

EFFECTIVE DATE: January 31, 1994.

FOR FURTHER INFORMATION CONTACT: Jennifer Aldrich, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port or call (202) 927–6708. For information on embargoes and quota re-openings, call (202) 482–3715.

SUPPLEMENTARY INFORMATION:

Authority: Executive Order 11651 of March 3, 1972, as amended; section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854).

The current limits for certain categories are being adjusted, variously, for swing, special shift and carryover.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see **Federal Register** notice 57 FR 54976, published on November 23, 1992; and 58 FR 62645, published on November 29, 1993). Also see 57 FR 29290, published on July 1, 1992; and 58 FR 34570, published on June 28, 1993.

The letter to the Commissioner of Customs and the actions taken pursuant to it are not designed to implement all of the provisions of the bilateral agreement, but are designed to assist

[1] The limit has not been adjusted to account for any imports exported after March 31, 1993.

only in the implementation of certain of its provisions.

Ronald I. Levin,

Acting Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

January 24, 1994.

Commissioner of Customs,
Department of the Treasury, Washington, DC 20229.

Dear Commissioner: This directive amends, but does not cancel, the directive issued to you on June 22, 1993, by the Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of certain cotton, wool and man-made fiber textile products and silk blend and other vegetable fiber apparel, produced or manufactured in Sri Lanka and exported during the twelve-month period beginning on July 1, 1993 and extending through June 30, 1994.

Effective on January 31, 1994, you are directed to amend further the directive dated June 22, 1993 to adjust the limits for the following categories, as provided under the terms of the current bilateral agreement between the Governments of the United States and the Democratic Socialist Republic of Sri Lanka:

Category	Adjusted twelve-month limit [1]
237	252,523 dozen.
331/631	2,347,778 dozen pairs.
333/633	7,538 dozen.
334/634	542,161 dozen.
335/835	223,766 dozen.
336/636/836	366,902 dozen.
338/339	1,174,293 dozen.
340/640	855,542 dozen of which not more than 330,578 dozen shall be in Categories 340–Y/640–Y [2].
341/641	1,685,250 dozen of which not more than 1,123,500 dozen shall be in Category 341 and not more than 1,050,000 dozen shall be in Category 641.
342/642/842*	579,318 dozen.
347/348/847	1,284,108 dozen of which not more than 675,736 dozen shall be in Categories 347–T/348–T/847–T [3].
350/650	110,536 dozen.
351/651	267,527 dozen.
352/652	1,188,345 dozen.
359–C/659–C [4]	713,746 kilograms.
363	6,247,337 numbers.
369–S [5]	673,779 kilograms.
635	270,455 dozen.
638/639/838	747,541 dozen.
645/646	135,868 dozen.
647/648	721,940 dozen.

[1] The limits have not been adjusted to account for any imports exported after June 30, 1993.

[2] Category 340–Y: only HTS numbers 6205.20.2015, 6205.20.2020, 6205.20.2046, 6205.20.2050 and 6205.20.2060; Category 640–Y: only HTS numbers 6205.30.2010, 6205.30.2020, 6205.30.2050 and 6205.30.2060.

[3] Category 347–T: only HTS numbers 6103.19.2015, 6103.19.4020, 6103.22.0030, 6103.42.1020, 6103.42.1040, 6103.49.3010, 6112.11.0050, 6113.00.0038, 6203.19.1020, 6203.19.4020, 6203.22.3020, 6203.42.4005, 6203.42.4010, 6203.42.4015, 6203.42.4025, 6203.42.4035, 6203.42.4045, 6203.49.3020, 6210.40.2033, 6211.20.1520, 6211.20.3010 and 6211.32.0040; Category 348–T: only HTS numbers 6104.12.0030, 6104.19.2030, 6104.22.0040, 6104.29.2034, 6104.62.2010, 6104.62.2025, 6104.69.3022, 6112.11.0060, 6113.00.0042, 6117.90.0042, 6204.12.0030, 6204.19.3030, 6204.22.3040, 6204.29.4034, 6204.62.3000, 6204.62.4005, 6204.62.4010, 6204.62.4020, 6204.62.4030, 6204.62.4040, 6204.62.4050, 6204.69.3010, 6204.69.9010, 6210.50.2033, 6211.20.1550, 6211.20.6010, 6211.42.0030 and 6217.90.0050; Category 847–T: only HTS numbers 6103.29.2044, 6103.49.3017, 6103.49.3024, 6104.29.2041, 6104.29.2045, 6104.69.3034, 6104.69.3038, 6112.19.2080, 6112.19.2090, 6117.90.0051, 6203.29.3046, 6203.49.3040, 6203.49.3045, 6204.29.4041, 6204.29.4047, 6204.69.3052, 6204.69.9044, 6211.20.3040, 6211.20.6040, 6211.39.0040, 6211.49.0040 and 6217.90.0070.

[4] Category 359–C: only HTS numbers 6103.42.2025, 6103.49.3034, 6104.62.1020, 6104.69.3010, 6114.20.0048, 6114.20.0052, 6203.42.2010, 6203.42.2090, 6204.62.2010, 6211.32.0010, 6211.32.0025 and 6211.42.0010; Category 659–C: only HTS numbers 6103.23.0055, 6103.43.2020, 6103.43.2025, 6103.49.2000, 6103.49.3038, 6104.63.1020, 6104.63.1030, 6104.69.1000, 6104.69.3014, 6114.30.3044, 6114.30.3054, 6203.43.2010, 6203.43.2090, 6203.49.1010, 6203.49.1090, 6204.63.1510, 6204.69.1010, 6210.10.4015, 6211.33.0010, 6211.33.0017 and 6211.43.0010.

[5] Category 369–S: only HTS number 6307.10.2005.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

Ronald I. Levin,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 94–1864 Filed 1–27–94; 8:45 am]

BILLING CODE 3510–DR–F

Amendment of an Import Limit and Restraint Period, Establishment of Import Limits and Guaranteed Access Levels and Amendment of Export Visa and Certification Requirements for Certain Cotton, Wool and Man-Made Fiber Textile Products Produced or Manufactured in Costa Rica

January 24, 1994.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs amending a limit and restraint period, establishing limits and guaranteed access levels and amending visa and certification requirements.

EFFECTIVE DATE: February 1, 1994.

FOR FURTHER INFORMATION CONTACT: Nicole Bivens Collinson, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port or call (202) 927–5850. For information on embargoes and quota re-openings, call (202) 482–3715.

SUPPLEMENTARY INFORMATION:

Authority: Executive Order 11651 of March 3, 1972, as amended; section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854).

In a Memorandum of Understanding (MOU) dated December 23, 1993 between the Governments of the United States and Costa Rica, agreement was reached to amend and extend their current bilateral textile agreement through December 31, 1995.

In the letter published below, the Chairman of CITA directs the Commissioner of Customs to amend the current restraint period for Category 447 to begin on March 1, 1993 and extend through December 31, 1993 at an increased level. As a result, the limit for Category 447, which is currently filled, will re-open. In addition, limits are being established for Categories 340/640, 342/642, 347/348, 443 and 447 for the period beginning on January 1, 1994 and extending through December 31, 1994. Guaranteed access levels (GALs) are being established for Categories 340/640, 342/642 347/348 and 443 the period January 1, 1994 through December 31, 1994; and Category 447 for the period February 1, 1994 through December 31, 1994.

Textile products in Category 447, produced or manufactured in Costa Rica and exported from Costa Rica on and

after February 1, 1994 shall require a visa.

Beginning on February 1, 1994, the U.S. Customs Service will start signing the first section of the form ITA–370P for shipments of U.S. formed and cut parts in Category 447 that are destined for Costa Rica and subject to the GAL established for Category 447 for the period beginning on February 1, 1994 and extending through December 31, 1994. These products are governed by Harmonized Tariff item number 9802.00.8015 and chapter 61 Statistical Note 5 and chapter 62 Statistical Note 3 of the Harmonized Tariff Schedule. Interested parties should be aware that shipments of cut parts in Category 447 must be accompanied by a form ITA–370P, signed by a U.S. Customs officer, prior to export from the United States for assembly in Costa Rica in order to qualify for entry under the Special Access Program.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see **Federal Register** notice 58 FR 62645, published on November 29, 1993). Also see 58 FR 34991, published on June 30, 1993.

Requirements for participation in the Special Access Program are available in **Federal Register** notices 51 FR 21208, published on June 11, 1986; 52 FR 26057, published on July 10, 1987; 54 FR 50425, published on December 6, 1989; and 55 FR 21047, published on May 22, 1990.

The letter to the Commissioner of Customs and the actions taken pursuant to it are not designed to implement all of the provisions of the MOU, but are designed to assist only in the implementation of certain of its provisions.

Ronald I. Levin,

Acting Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

January 24, 1994.

Commissioner of Customs,
Department of the Treasury, Washington, DC 20229.

Dear Commissioner: This directive amends, but does not cancel the directive issued to you on June 24, 1993 by the Chairman, Committee for the Implementation of Textile Agreements. This directive concerns imports of wool textile products in Category 447, produced or manufactured in Costa Rica and exported during the period beginning on February 25, 1993 and extending through February 24, 1994.

Effective on February 1, 1994, you are directed to amend the restraint period for Category 447 to begin on March 1, 1993 and extend through December 31, 1993 at a level of 10,000 dozen [1].

Under the terms of section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854), and the Arrangement Regarding International Trade in Textiles done at Geneva on December 20, 1973, as further extended on December 9, 1993; pursuant to the Memorandum of Understanding (MOU) dated December 23, 1993, between the Governments of the United States and Costa Rica; and in accordance with the provisions of Executive Order 11651 of March 3, 1972, as amended, you are directed to prohibit, effective on February 1, 1994, entry into the United States for consumption and withdrawal from warehouse for consumption of cotton, wool and man-made fiber textile products in the following categories, produced or manufactured in Costa Rica and exported during the twelve-month period beginning on January 1, 1994 and extending through December 31, 1994, in excess of the following restraint limits:

Category	Twelve-month limit*
340/640	769,479 dozen.
342/642	284,058 dozen.
347/348	1,296,741 dozen.
443	204,020 numbers.
447	11,000 dozen.

*The limits have not been adjusted to account for any imports exported after December 31, 1993.

Imports charged to these category limits for the periods January 1, 1993 through December 31, 1993 and March 1, 1993 through December 31, 1993 (Category 447) shall be charged against those levels of restraint to the extent of any unfilled balances. In the event the limits established for those periods have been exhausted by previous entries, such goods shall be subject to the levels set forth in this directive.

The limits set forth above are subject to adjustment in the future pursuant to the provisions of the MOU dated December 23, 1993 between the Governments of the United States and Costa Rica.

Also effective on February 1, 1994, you are directed to amend further the directive dated May 15, 1990 to require a visa for textile products in Category 447, produced or manufactured in Costa Rica and exported from Costa Rica on and after February 1, 1994.

Additionally, pursuant to the December 23, 1993 MOU; and under the terms of the Special Access Program, as set forth in 51 FR 21208 (June 11, 1986), 52 FR 26057 (July 10, 1987) and 54 FR 50425 (December 6, 1989), effective on February 1, 1994, guaranteed access levels have been established for properly certified cotton, wool and man-made fiber textile products in the following categories which are assembled in Costa Rica from fabric formed and cut in the United States and re-exported to the United States from Costa Rica during the periods beginning on January 1, 1994 and extending through December 31, 1994:

Category	Guaranteed access level
340/640	650,000 dozen.
342/642	250,000 dozen.
347/348	1,500,000 dozen.
443	200,000 numbers.

Effective on February 1, 1994, a guaranteed access level of 4,000 dozen is being established for Category 447 for the period beginning on February 1, 1994 and extending through December 31, 1994. Beginning on February 1, 1994, the U.S. Customs Service is directed to start signing the first section of form ITA–370P for shipments of U.S. formed and cut parts in Category 447 that are destined for Costa Rica and re-exported to the United States on and after February 1, 1994.

Any shipment for entry under the Special Access Program which is not accompanied by a valid and correct certification and Export Declaration in accordance with the provisions of the certification requirements established in the directive of May 15, 1990, shall be denied entry unless the Government of Costa Rica authorizes the entry and any charges to the appropriate specific limit. Any shipment which is declared for entry under the Special Access Program but found not to qualify shall be denied entry into the United States.

In carrying out the above directions, the Commissioner of Customs should construe entry into the United States for consumption to include entry for consumption into the Commonwealth of Puerto Rico.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception of the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

Ronald I. Levin,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 94–1863 Filed 1–27–94; 8:45 am]

BILLING CODE 3510–DR–F

[1] The limit has not been adjusted to account for any imports exported after February 28, 1993.

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to the Procurement List.

SUMMARY: This action adds to the Procurement List commodities and services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

EFFECTIVE DATE: February 28, 1994.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely

Disabled, Crystal Square 3, suite 403, 1735 Jefferson Davis Highway, Arlington, Virginia 22202–3461.

FOR FURTHER INFORMATION CONTACT: Beverly Milkman, (703) 603–7740.

SUPPLEMENTARY INFORMATION: On November 15, November 29, and December 10, 1993, the committee for Purchase From People Who Are Blind or Severely Disabled published notices (58 FR 60181, 62646 and 64932) of proposed additions to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the commodities and services, fair market price, and impact of the additions on the current or most recent contractors, the Committee has determined that the commodities and services listed below are suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the commodities and services to the Government.

2. The action does not appear to have a severe economic impact on current contractors for the commodities and services.

3. The action will result in authorizing small entities to furnish the commodities and services to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the commodities and services proposed for addition to the Procurement List. Accordingly, the following commodities and services are hereby added to the Procurement List:

Commodities

Sponge, Surgical
6510–00–559–3219
6510–00–119–9314
6510–00–116–1285
(Requirements for Defense Personnel Support Center only—1285)
6510–00–988–3838

Services

Administrative Services, U.S. Army Corps of Engineers, Nashville District, Estes Kefauver Building & Adjacent Buildings, Nashville, Tennessee

Janitorial/Grounds Maintenance, Soo Area Office, Soo Locks, Sault Ste. Marie, Michigan

This action does not affect current contracts awarded prior to the effective date of this addition or options exercised under those contracts.

Beverly L. Milkman,

Executive Director.

[FR Doc. 94–1949 Filed 1–27–94; 8:45 am]

BILLING CODE 6820–33–P

Procurement List; Proposed Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed additions to procurement list.

SUMMARY: The Committee has received proposals to add to the Procurement List commodities and services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

COMMENTS MUST BE RECEIVED ON OR BEFORE: February 28, 1994.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Crystal Square 3, suite 403, 1735 Jefferson Davis Highway, Arlington, Virginia 22202–3461.

FOR FURTHER INFORMATION CONTACT: Beverly Milkman, (703) 603–7740.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 47(a)(2) and 41 CFR 51–2–3. Its purpose is to provide interested persons an opportunity to submit comments on the possible impact of the proposed actions.

If the Committee approves the proposed additions, all entities of the Federal Government (except as otherwise indicated) will be required to procure the commodities and services listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the commodity and services to the Government.

2. The action does not appear to have a severe economic impact on the current contractors for the commodity and services.

3. The action will result in authorizing small entities to furnish the commodity and services to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the commodity and services proposed for addition to the Procurement List.

Comments on this certification are invited. Commenters should identify the statement(s) underlying the certification on which they are providing additional information.

The following commodity and services have been proposed for addition to Procurement List for production by the nonprofit agencies listed:

Commodity

Tool Box, Portable
5140–01–237–3233
NPA: Custom Manufacturing Services, Inc. Louisville, Kentucky.

Services

Janitorial/Custodial

Buildings 243, 255, 277, 322, 323, 325, 336, 382, 400, 401, 402, 405, 410, 412–419, 422, 423, 424, 430, 485, 497, 591, 592, 593, 887, 891, 902, 909, 911, 912, 914, R10, R20
Kirtland AFB, New Mexico.
NPA: Adelante Development Center, Inc. Albuquerque, New Mexico.

Switchboard Operation, Veterans Administration Medical Center, 1030 Jefferson Avenue, Memphis, Tennessee.
NPA: Memphis Goodwill Industries, Inc. Memphis, Tennessee.

Beverly L. Milkman,

Executive Director.

[FR Doc. 94–1950 Filed 1–27–94; 8:45 am]

BILLING CODE 6820–33–P

Procurement List Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to the Procurement List.

SUMMARY: This action adds to the Procurement List commodities to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

EFFECTIVE DATE: February 28, 1994.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Crystal Square 3, suite 403, 1735 Jefferson Davis Highway, Arlington, Virginia 22202–3461.

FOR FURTHER INFORMATION CONTACT: Beverly Milkman (703) 603–7740.

SUPPLEMENTARY INFORMATION: On October 22, 1993, the Committee for

Purchase From People Who Are Blind or Severely Disabled published notice (58 FR 54560) of proposed additions to the Procurement List.

Comments were received from the two current contractors for the folders. One of the commenters enclosed letters in support of its comments from three nonprofit agencies employing people with severe disabilities which have subcontracts to package folder tabs for the folders. That commenter indicated that addition of the folders to the Procurement List would have a severe impact on the firm and its employees, particularly when other recent Committee actions impacting the firm are taken into account. The commenter also indicated that these folders provide most of the work it subcontracts to three agencies employing people with severe disabilities which make tabs for use with the folders.

According to the figures available to the Committee, the impact of the loss of sales for the folders on this company, together with the impact of the earlier actions, does not rise to a level which the Committee normally considers severe adverse impact. As for the possible loss of employment for the commenter's workers, the Committee feels that it is outweighed by the creation of jobs for people with severe disabilities, whose unemployment rates greatly exceed those of people without disabilities. In addition, for at least the first two years after the JWOD agencies assume supply responsibility, the commenter will be afforded the opportunity to compete as a supplier of folder tabs to the nonprofit agencies which will produce the folders. Thus, any impact on this commenters and its employees would be mitigated by the opportunity they will have initially to compete to supply the folder tabs.

One of the three nonprofit agencies which are the commenter's subcontractors for the folder tabs participates in the JWOD Program. According to that agency, its subcontract with the commenter only recently produced work for its people with severe disabilities, and at very low wages. While the nonprofit agency has been led to expect a constant flow of this work, it has no guarantee that this will occur.

If the JWOD-participating agency's subcontract work volume is typical of that provided to the other two nonprofit agencies (which both the JWOD agency and the figure for subcontractor employees provided by the commenter suggest it is), the commenter's Government business for these folders is only a portion of its total folder business. Consequently, even if the commenter is not successful in competing to supply the folder tabs to the nonprofit agencies which will produce the folders, addition of these folders to the Procurement List should not markedly diminish the amount of subcontract work which would be available to the three nonprofit agencies employing people with disabilities. Moreover, if the commenter (or the JWOD-participating subcontractor agency) is successful in bidding to supply the folder tabs to the nonprofit agencies which will produce the folders, the work for the subcontractor agencies could actually increase for at least two years since the commenter currently provides less than half of the Government requirement for the folders.

Also, it should be noted that the commenter could discontinue providing this work to the nonprofit agencies employing persons with severe disabilities if it chose. The commenter indicated that it would take only a small investment to automate this work. On the other hand, placing the folders on the Procurement List guarantees that people with severe disabilities will be involved in producing them for the Government. The Committee believes the jobs its action would create outweigh the possible loss of employment for employees of the commenter's subcontractors.

The other commenter also indicated that it was being significantly impacted by this and other recent additions to the Procurement List. It also provided a small amount of information to substantiate its claim that small businesses like itself are being forced out of the commercial market by large office products companies. Because of this development, the impact of additions to the Procurement List is magnified as there are fewer opportunities to recoup losses to the Procurement List in the commercial market.

The impact of this and other recent Procurement List additions on this commenter, as a percentage of the commenter's sales, is less than half the impact on the first commenter. In the Committee's view, neither impact rises to the level of severe adverse impact. Given the small impact figure for this commenter, the Committee does not believe that the effect of a shrinking office products market for small businesses, if such is the case, is significant enough to make the impact on this commenter severe.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the commodities, fair market price, and impact of the addition on the current or most recent contractors, the Committee has determined that the commodities listed below are suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the commodities to the Government.

2. The action does not appear to have a severe economic impact on current contractors for the commodities.

3. The action will result in authorizing small entities to furnish the commodities to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41U.S.C. 46–48c) in connection with the commodities proposed for addition to the Procurement List.

Accordingly, the following commodities are hereby added to the Procurement List:

Folder, File, Hanging
7530–01–357–6854
7530–01–357–6855
7530–01–357–6856
7530–01–357–6857
7530–01–364–9487
7530–01–364–9495
7530–01–364–9496
7530–01–364–9497
7530–01–364–9498
7530–01–364–9499
7530–01–364–9500
7530–01–364–9501

This action does not affect current contracts awarded prior to the effective date of this addition or options exercised under those contracts.

Beverly L. Milkman,

Executive Director.

[FR Doc. 94–1951 Filed 1–27–94; 8:45 am]

BILLING CODE 6820–33–P

COMMODITY FUTURES TRADING COMMISSION

Common Banking and Settlement System of the Chicago Mercantile Exchange and the Board of Trade Clearing Corporation

The Chicago Mercantile Exchange ("CME") and the Board of Trade Clearing Corporation ("BOTCC") have submitted to the Commodity Futures Trading Commission ("Commission") a

proposal to establish a common banking and settlement system, pursuant to Section 5a(a)(12)(A) of the Commodity Exchange Act ("Act"), 7 U.S.C. 7a(a)(12)(A), and Commission Regulation 1.41(b), 17 CFR 1.41(b) (CME and BOTCC together being the "participating clearing organizations"). The proposal requires that participants be limited to entities that are themselves members of both the CME and BOTCC ("joint clearing members"), and provides for computing and transferring performance bond margin, settlement variation, and option premiums in respect of commodity futures and options contracts of such joint clearing members. The proposal also includes procedures governing the distribution of excess performance bond margin deposits between the CME and BOTCC in certain cases of suspension or expulsion of joint clearing members.

Whereas, the common banking and settlement procedures provide for performance bond margin deposited by joint clearing members to be held in the joint names of the participating clearing organizations at one or more depositories;

Whereas, the common banking and settlement procedures provide for the netting of daily settlement variation and option premium payments that joint clearing members pay to or receive from the participating clearing organizations;

Whereas, the common banking and settlement procedures can be used to reallocate cash performance bond margin deposits of joint clearing members between the participating clearing organizations;

Whereas, it is not intended that the common banking and settlement procedures result in a novation of the joint clearing members' obligations to either of the participating clearing organizations;

Whereas, in the event of the suspension or expulsion of a joint clearing member, the common banking and settlement procedures prohibit any excess performance bond margin, or proceeds thereof, attributable to customer origin positions from being transferred between the CME and the BOTCC to satisfy any deficit or unsatisfied settlement obligations attributable to proprietary origin positions;

Whereas, by letter dated September 29, 1993, the participating clearing organizations acknowledge that, in the event of the suspension or expulsion of a joint clearing member, the common banking and settlement procedures would permit the transfer of any excess performance bond margin, or proceeds thereof, between the CME and the BOTCC only if there was no shortfall in the funds required to meet the joint clearing member's customer segregated funds requirements for all of its customers, and, by letter dated December 13, 1993, the participating clearing organizations acknowledge that the proposed agreement among the joint clearing members and the participating clearing organizations is expressly subject to the terms of this Order;

Whereas, by letter dated December 9, 1993, the participating clearing organizations have represented that, before implementation of the proposal, the agreement between the participating clearing organizations will be amended to make clear that, in the event of a default by a joint clearing member, the clearing organization at which the default occurred will transfer funds to the other clearing organization in accordance with its respective gross payment obligations if there is a deficit in payment flows to the other clearing organization resulting from the netting of payment obligations pursuant to the common banking and settlement procedures, and will otherwise satisfy its gross payment obligations to non-defaulting joint clearing members in accordance with the routine settlement schedule;

Whereas, the proposal requires that participants be limited to entities that are themselves members of both the CME and BOTCC and does not permit participation by affiliated entities;

Whereas, the Commission has reviewed the common banking and settlement proposal, the proposed agreement between the participating clearing organizations, the proposed agreement among the joint clearing members and the participating clearing organizations, the representations of the participating clearing organizations as to the operation of the common banking and settlement system, and such other documents as constitute the complete record in this matter ("Record");

Now Therefore, based on the Record in this matter, and provided that the common banking and settlement proposal submitted by the CME and the BOTCC is implemented consistently with the representations and agreements cited herein;

It is Hereby Ordered, Pursuant to Sections 4d and 20 of the Act, 7 U.S.C. 6d and 24, and consistent with the Bankruptcy Code, that, in the event of the suspension or expulsion of a joint clearing member by both the CME and the BOTCC, the clearing organization to which performance bond margin has been allocated may transfer any excess performance bond margin, or proceeds thereof, to the other clearing organization only if there is no shortfall in the funds required to meet the joint clearing member's customer segregated funds requirements for all of its customers for whom segregation must be maintained.

It is Further Ordered, Pursuant to Section 5a(a)(12)(A) of the Act that the CME and the BOTCC's request for Commission approval of their proposal to establish a common banking and settlement system, including approval of proposed CME Rule 802, proposed amendments to CME Rule 832, proposed BOTCC Bylaws 118, 119, and 517, and proposed amendments to BOTCC Bylaws 503, 508, 604, and 804 is hereby granted.

Issued in Washington, DC, this 21st day of December, 1993.

By the Commission.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 94–1889 Filed 1–27–94; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary of Defense

Defense Intelligence Agency Scientific Advisory Board; Meetings

AGENCY: Defense Intelligence Agency Scientific Advisory Board.

ACTION: Notice of closed meeting.

SUMMARY: Pursuant to the provisions of subsection (d) of section 10 of Public Law 92–463, as amended by section 5 of Public Law 94–409, notice is hereby given that a closed meeting of the Defense Intelligence Agency Scientific Advisory Board has been scheduled as follows:

DATES: Thursday, 17 February 1994 (0900–1600).

ADDRESSES: The Defense Intelligence Agency, the Pentagon, Washington, DC 20301–7400.

FOR FURTHER INFORMATION CONTACT: Dr. W.S. Williamson, Executive Secretary, DIA Scientific Advisory Board, Washington, DC 20340–5100, (202) 373–4930.

SUPPLEMENTARY INFORMATION: The entire meeting is devoted to the discussion of classified information as defined in section 552b(c)(I), Title 5 of the U.S. Code and therefore will be closed to the public. The Panel will receive briefings on and discuss several current critical issues and advise the Director Military Intelligence, DIA, on related matters.

Dated: January 25, 1994.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 94–1900 Filed 1–27–94; 8:45 am]

BILLING CODE 5000–04–M

Defense Intelligence Agency Scientific Advisory Board; Meeting

AGENCY: Defense Intelligence Agency Scientific Advisory Board.

ACTION: Notice of closed meeting.

SUMMARY: Pursuant to the provisions of subsection (d) of section 10 of Public Law 92–463, as amended by section 5 of Public Law 94–409, notice is hereby given that a closed meeting of the Defense Intelligence Agency Scientific Advisory Board has been scheduled as follows:

DATES: Wednesday and Thursday 23–24, February 1994 (0830–1600).

ADDRESSES: The Defense Intelligence Agency, the Pentagon, Washington, DC 20301–7400.

FOR FURTHER INFORMATION CONTACT: Dr. W.S. Williamson, Executive Secretary, DIA Scientific Advisory Board, Washington, DC 20340–5100, (202) 373–4930.

SUPPLEMENTARY INFORMATION: The entire meeting is devoted to the discussion of classified information as defined in section 552b(c)(I), Title 5 of the U.S. Code and therefore will be closed to the public. The Panel will receive briefings on and discuss several current critical issues and advise the Director of Military Intelligence, DIA, on related matters.

Dated: January 25, 1994.

L.M. Bynum,

Altenate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 94–1901 Filed 1–27–94; 8:45 am]

BILLING CODE 5000–04–M

Office of the Secretary of the Army

Availability of the Draft Environmental Impact Statement for Closure and Disposal of Sacramento Army Depot, California

AGENCY: Department of the Army, DOD.

ACTION: Notice of Availability.

SUMMARY: In accordance with Public Law 101–510, the Defense Base Closure and Realignment Act of 1990, the Defense Base Closure and Realignment Commission recommended the closure of Sacramento Army Depot and transfer of depot missions to other installations/agencies. Maintenance missions would be competed to determine location of transfer. In accordance with the Act, the Secretary of Defense must implement all recommendations for closure or realignment. Subject document focuses on the environmental and socioeconomic impacts and mitigations associated with the disposal and reuse of Sacramento Army Depot.

No long-term adverse ecological or environmental health effects are expected due to this action. The increase in population anticipated by the reuse and disposal activities is expected to have a net positive impact on the local economy. The preferred alternative, prepared with the cooperation of the local community, is not expected to significantly impact environmental resources.

A scoping meeting was held in Sacramento, California, on 28 January 1993. Public notices requesting input and comments from the public were issued in the regional area surrounding Sacramento Army Depot.

DATES: Written public comments and suggestions received within 45 days of this Notice of Availability will be addressed in the Final Environmental Impact Statement.

ADDRESSES: Copies of the Draft Environmental Impact Statement can be obtained by writing to the United States Army Corps of Engineers, Sacramento District, ATTN: CESPK–ED–M (ISS), 1325 J Street, Sacramento, California 95814–2922.

FOR FURTHER INFORMATION CONTACT: Mr. Wandell Carlton (916) 557–7424.

Lewis D. Walker,

Deputy Assistant Secretary of the Army, (Environment, Safety and Occupational Health) OASA (IL&E).

[FR Doc. 94–1862 Filed 1–27–94; 8:45 am]

BILLING CODE 3710–08–M

Garnishment of Federal Civilian Employees Wages for Commercial Pay for Debt

AGENCY: Defense Finance and Accounting Service, Office of the Secretary, Department of Defense

ACTION: Notice.

SUMMARY: The Defense Finance and Accounting Service (DFAS) is giving notice that all requests for payments pursuant to court-ordered garnishments as authorized under Section 9 of Public Law No. 103–94, Hatch Act Reform Amendments of 1993, for all Department of Defense Civilian Employees, except those noted below, shall be submitted to the Defense Finance and Accounting Service—Cleveland Center, Office of General Counsel, Code L, 1240 East 9th Street, P.O. Box 998002, Cleveland OH 44199–8002.

For Requests that apply to employees of the Army and Air Force Exchange Service or civilian employees of the Defense Contract Audit Agency (DCAA) and the Defense Logistics Agency (DLA) who are employed outside the United States, see 5 CFR part 581, appendix A.

For requests that apply to civilian employees of the Army Corps of Engineers, the National Security Agency, the Defense Intelligence Agency, and non-appropriated fund civilian employees of the Air Force, contact the following offices:

Army Corps of Engineers

U.S. Army Corps of Engineers, Omaha District, Central Payroll Office, Attn: Garnishments, P.O. Box 1439 DTS, Omaha, NE 68101–1439.

National Security Agency

General Counsel, National Security Agency/Central Security Service, 9800 Savage Rd., Ft. G. Meade, MD 20755–6000.

Defense Intelligence Agency

Office of General Counsel, Defense Intelligence Agency, Pentagon, 2E238, Washington, DC 20340–1029.

Air Force Non-Appropriated Fund Employees

Office of General Counsel, Air Force Services Agency, 10100 Reunion Place, suite 503, San Antonio, TX 78216–4138.

For civilian employees of the Army, Navy, and Marine Corps who are employed outside the United States, contact the following offices:

Army Civilian Employees Europe

266th Theater Finance Command, ATTN: AEUCF–CPF, APO New York 09007–0137.

Army NAF Civilian Employees in Japan

Commander, US Army Finance & Accounting Office, Japan; Unit 45005, ATTN: APAJ–RM–FA–E–CP, APO AP 96343–0087.

Army Civilian Employees in Korea

175th Finance & Accounting Office, Korea, Unit 15300, ATTN: EAFC–FO (Civilian Pay), APO AP 96205–0073.

Army Civilian Employees in Panama

DCSRM Finance & Accounting Office, Unit 7153, ATTN: SORM–FAP–C, APO AA 34004–5000.

Navy and Marine Corps Civilian Employees Overseas

Director of the Office of Civilian Personnel Management; Office of the General Counsel, Navy Department, 800 N. Quincy St., Arlington, VA 22203–1998.

DATES: This action will be effective February 3, 1994.

ADDRESSES: Comments regarding this notice should be sent to Deputy Director Resource Management, Defense Finance and Accounting Service, 1931 Jefferson Davis Highway, Crystal Mall 3, room 416, Arlington, VA 22240–5291.

FOR FURTHER INFORMATION CONTACT: Mr. Rod Winn at (216) 522–5956 or DSN 580–5956.

SUPPLEMENTARY INFORMATION: Congress has authorized the garnishment of Federal civilian employees' wages for commercial debts pursuant to Section 9 of Public Law 103–94, Hatch Act Reform Amendments of 1993. The applications and orders and legal issues related thereto will be reviewed by the appropriate addressee Office of General Counsel.

Dated: January 4, 1994.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 94–1817 Filed 1–27–94; 8:45 am]

BILLING CODE 5000–04–M

Department of the Air Force

USAF Scientific Advisory Board; Meeting

The USAF Scientific Advisory Board (SAB) Ad Hoc Committee on Independent Review for the Air Force Office of Test and Evaluation (AF/TE) will meet from 8 a.m. to 5 p.m. on 1–3 March 1994 at Kirtland AFB, NM.

The purpose of this meeting is to conduct an Independent Review for an AF/TE program. The meeting will be closed to the public in accordance with section 552b of title 5, United States Code, specifically subparagraphs (1) and (4).

For further information, contact the SAB Secretariat at (703) 697–8404.

Patsy J. Conner,

Air Force Federal Register Liaison Officer.

[FR Doc. 94–1830 Filed 1–27–94; 8:45 am]

BILLING CODE 3910–01–W

USAF Scientific Advisory Board; Meeting

The USAF Scientific Advisory Board (SAB) Ad Hoc Committee on Independent Review for the Air Force Office of Test and Evaluation (AF/TE) will meet from 8 a.m. to 5 p.m. on 9–10 February 1994 at the Pentagon, Washington, DC.

The purpose of this meeting is to conduct an Independent Review for an AF/TE program. The meeting will be closed to the public in accordance with section 552b of title 5, United States Code, specifically subparagraphs (1) and (4).

For further information, contact the SAB Secretariat at (703) 697–8404.

Patsy J. Conner,

Air Force Federal Register Liaison Officer.

[FR Doc. 94–1831 Filed 1–27–94; 8:45 am]

BILLING CODE 3910–01–W

Department of the Army

Armed Forces Epidemiological Board Meeting

AGENCY: Armed Forces Epidemiological Board, DOD.

ACTION: Notice of open meeting.

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–462) announcement is made of the following committee meeting:

Name of Committee: Armed Forces Epidemiological Board.

Date of Meeting: 15–16 February 1994.

Time: 0730–1730

Place: Camp Pendleton, California.

Proposed Agenda: 15–15 February 1994—Service preventive medicine reports and current infectious disease concerns.

This meeting will be open to the public but limited space accommodations. Any interested person may attend, appear before or file statements with the committee at the time and in the manner permitted by the committee. Interested persons wishing to participate should advise the Executive Secretary, AFEB, Skyline Six, 5109 Leesburg Pike, room 667, Falls Church, VA 22041–3258, (703) 756–8012.

Kenneth L. Denton,

Army Federal Register Liaison Officer.

[FR Doc. 94–1826 Filed 1–27–94; 8:45 am]

BILLING CODE 3710–08–M

Corps of Engineers

Engineering Circular Issued by the Corps of Engineers

AGENCY: Army Corps of Engineers, DoD.

ACTION: Notice.

SUMMARY: The purpose of this notice is to provide a copy of the Engineering Circular (EC) 1130–2–204 to all known interested parties. The EC provides Corps of Engineers agency policy and guidance regarding implementation of new recreation user fee authority conferred in the Omnibus Budget Reconciliation Act of 1993 (Pub. L. 103–66). The legislation authorized the Corps to charge a fee of not more than $3.00 per vehicle per day for the use of certain developed day use recreation facilities.

FOR FURTHER INFORMATION CONTACT: Mr. Darrell Lewis, Natural Resources Management Branch, Office of the Chief of Engineers at (202) 272–0247.

SUPPLEMENTARY INFORMATION: The five appendices to the EC are not included. Copies are available on request from HQUSACE, CECW–ON, 20 Massachusetts Avenue NW., Washington, DC 20314–1000, or by calling the above telephone number.

Dated: January 21, 1994.

John P. Elmore,

Chief, Operations, Construction and Readiness Division, Directorate of Civil Works.

Expires December 31, 1996

Project Operation Recreation User Fees for Day Use Facilities

February 1, 1994.

1. *Purpose.* This circular provides information and guidance for the administration of a recreation user fee program for day use facilities at U.S. Army Corps of Engineers Civil Works water resource development projects. The guidance in this circular must be used in conjunction with the guidance in ER 1130–2–404.

2. *Applicability.* This circular applies to major subordinate commands, districts, laboratories and field operating activities having Civil Works responsibilities.

3. *References.*

a. Public Law 103–66, Omnibus Budget Reconciliation Act of 1993.

b. 5 CFR Part 1320, Code of Federal Regulations. Appendix B.

5. *Policy.* No fees will be charged for entrance to any Corps operated area. Fees will be charged for the use of developed day use recreation facilities provided by the Corps, as prescribed below and shown in Appendix C.

a. *General.* Day user fees will be charged for the use of Corps operated day use facilities which meet the requirements described below.

(1) Fees will be charged for the use of certain boat launching ramps and designated, developed swimming beaches in Corps operated day use recreation areas. Fees will not be

charged for drinking water, wayside exhibits, roads, scenic drives, overlook sites, picnic tables, toilet facilities, surface water areas, undeveloped or lightly developed shoreland, or general visitor information. Day user fees will not be charged for the use of visitor centers.

(2) Day user fees will be charged only where there is reasonable expectation that revenues will significantly exceed costs of collection, to include implementation costs. Estimates of annual revenue from a fee facility must exceed annual estimated cost to collect, including the cost of implementation amortized over the design life of the improvements, by 10% or $3,000, whichever is greater. The estimate should be reviewed periodically by Division Commanders to determine the justification for modifying the project fee collection program.

b. *Boat Launch User Fee.* A day user fee of $2.00 will be charged to launch a boat at a ramp in a Corps operated day use recreation area, provided that the net revenue test in paragraph 5.a.(2) is met.

(1) The fee will be charged at recreation areas having a boat ramp and one or more of the following facilities: restrooms, security lighting, picnicking facilities, swimming facilities, or other developed recreation facilities. The boat launch fee will not be charged at boat ramps located in recreation areas which are exclusively campgrounds and reserved exclusively for the use of campers, or in recreation areas which provide only a boat ramp and courtesy dock.

(2) Payment of this fee entitles the user to launch a boat at any Corps operated recreation area at any Corps project on that day, except at boat ramps located within a fee campground and reserved exclusively for the use of campers.

c. *Swimming Beach User Fee.* A day user fee of $1.00 per person, up to $3.00 per vehicle, will be charged for the use of a designated, developed swimming beach in a Corps operated day use recreation area, provided that the net revenue test in paragraph 5.a.(2) is met.

(1) The swimming beach fee will be charged at Corps operated, designated, developed swimming beaches, with the exception of swimming beaches located in recreation areas which are exclusively campgrounds and reserved exclusively for the use of campers. A designated, developed swimming beach is properly signed, buoyed and delineated in accordance with established design and safety requirements contained in EM 1110–1–400.

(2) Payment of this fee entitles the user to use any developed beach at any Corps operated recreation area at any Corps project on that day, with the exception of swimming beaches located within fee campgrounds and reserved exclusively for the use of campers.

d. *Daily User Fee Exclusivity.* The daily boat launch ramp and swimming beach user fees are mutually exclusive. Payment of a daily boat launch ramp user fee does not permit swimming at a designated beach, and vice versa.

e. *Annual Day User Fee Pass.* An annual pass may be purchased for $25.00, which permits the holder and all accompanying passengers in the vehicle to use any or all boat launch ramps and/or designated, developed swimming beaches at any Corps operated recreation area at any Corps project for that calendar year, except at facilities located within a fee campground and reserved exclusively for the use of campers. A sample annual pass is shown in Appendix D.

f. *Paid Camping Permits.* A paid camping permit will entitle the holder to use any or all day use facilities without paying additional day user fees at the same project, on any day for which the permit is valid. In certain instances, some form of vehicle pass may be required for campers who have more than one vehicle or where the camping unit is also the mode of transportation. A separate pass, locally printed for this situation, is acceptable. Resource managers should consider local situations when determining applicability.

g. *Lessees.* Lessees may not charge a fee for Corps operated facilities. They may charge, however, for Corps constructed facilities located on their leasehold in accordance with real estate policy, prescribed in CERE–MC memorandum, dated 15 Oct 1993, Subject: Fees Charged at Leased Recreation Sites.

h. *Native American Indian Tribes.* The District Engineer may waive user fees under this circular for Native American Indian Tribal members, consistent with rights reserved to the Tribes under the law.

i. *Children.* No day user fee charge will be made for children under 12 years of age.

6. *Procedures.*

a. The district commander will provide the established schedule of day user fees to the major subordinate command NLT 30 December each year, beginning in 1994. The major subordinate command commander will periodically review/audit the district's establishment of fee schedules.

b. Information on approved user fee areas and charges will be submitted through the National Resource Management System (NRMS), as outlined in ER 1130–2–414.

7. *Cost of Collection.* Since day user fees will be collected only at facilities where revenue significantly exceeds cost of collection, strict attention must be given to tracking costs associated with the collection of day user fees at designated facilities. An annual analysis of revenues versus cost of collection, including amortized implementation costs, must be available for review by Major Subordinate Commands and by HQUSACE by 30 December of each year.

8. *Effective Dates for Fee Collection.* District commanders will assess seasonal visitation patterns of individual fee areas to determine the period during which a fee program will be in effect.

9. *Signs.* All areas designated as recreation user fee areas will be marked with appropriate signs that provide necessary instructions to users of the area with regard to collection of fees. The official U.S. fee area symbol will be displayed at the entrance to designated user fee areas. The U.S. fee area symbol will be installed prior to collection of fees in the area. All signs and symbols will conform to the guidance provided in EP 610–1–6a and b and ER 1130–2–431.

10. *Fee Collection.*

a. *Methods of Collection.* Fees may be collected by one or more of the following methods:

(1) *Control stations.* Fees may be collected by either contract or Corps personnel. Contractors will be properly identified to prevent unauthorized personnel from collecting fees.

(a) A cash register may be used in the fee collection process to issue receipts to users. Visitors will be instructed to display the cash register receipt on the left side of the vehicle dashboard. Specifications for cash registers are included in Appendix E.

(b) The Automated User Permit System (AUPS) may be used to collect day user fees.

(2) *Self-deposit vault system.* Where and when appropriate, the self-deposit vault system may be used to reduce the cost of collection.

(a) A registration point will be provided which has:

—A deposit vault similar to the one shown in ER 1130–2–404, Appendix C.

—A sign instructing the user on the self-deposit system, stating the fee for the area and indicating a 50 percent reduction of fees for bearers of Golden

Age or Golden Access Passports. It should also provide instructions for displaying the permit stub.

—ENG Form 4839A, Self-Deposit Day User Permit. This is a sealable envelope with detachable stub that will be used to pay fees. The user will be instructed to retain the stub as a receipt for display on the left side of the vehicle dashboard. These forms are available at the USACE Publication Depot.

(b) Revenues will be collected from the deposit vault on a regular basis by authorized Corps or contractor personnel. Personnel will check to insure area users have appropriate permits.

(3) *Other methods.* Fees may be collected by authorized Corps and contractor employees at project offices, visitor centers or on visits through a fee area. These collections may be made using a cash register, AUPS or ENG Form 4457.

b. *Types of payment.* In order of preference, types of acceptable payment are in (1) U.S. currency, (2) traveler's checks or (3) personal checks for the amount of purchase only.

c. *Contractor collection.* Whenever contractor employees are utilized for fee collection, the requirements in ER 1130–2–404 and ER 37–2–10 will apply.

11. *Remittance.* All user fee funds will be remitted in accordance with ER 37–2–10.

12. *Enforcement.* Persons failing to pay established fees will be subject to enforcement action in accordance with 36 CFR 327.23, Recreation Use Fees.

13. *Accounting.* All income derived from fee collection will be deposited into Special Receipt Account 965007 and reported in accordance with ER 37–2–10 and ER 1130–2–414.

14. *Credit Vouchers and Refunds.* No credit vouchers or refunds will be given for day user fees.

15. *Golden Age and Golden Access Passports.* Golden Age and Golden Access Passport discounts will apply to day user fees. The Passport will entitle the holder and all accompanying passengers in a single, private, non-commercial vehicle to a 50 percent discount of the daily or annual day user fee. Passport discounts will not apply to commercial vehicles, transporting visitors for hire. Golden Eagle Passports do not apply to user fees. The schedule of day user fees and Golden Age and Access Passport discounts is contained in Appendix C.

16. *Specialized Facility Reservations and Special Events.* The charging of a day user fee at a recreation area does not preclude the charging of a fee for the reservation of a specialized facility or for a special event within the area. Neither does the charging of a fee for the reservation of a specialized facility or special event preclude the collecting of the established day user fee for the recreation area. Resource managers should consider local situations when determining fee applicability.

17. *Public Information.* In the interest of informing the public of the fee collection program, public information activities will be conducted to disseminate information regarding this program at least two months before the collection of fees begins at newly designated user fee areas. District commanders will notify congressional delegations, as appropriate, of the fee collection program in their congressional districts. Public information meetings, convened to discuss the new program for a project or group of projects, as well as the philosophy and rational for the new fee program, are strongly encouraged. Various additional coordination activities should also occur with any other interested parties.

18. *Controlling Paperwork Burden on the Public.* The guidance in 5 CFR Part 1320 establishes the framework for the paperwork control process. Generally, this CFR provides that an agency shall not engage in a collection of information (from the public) without obtaining Office of Management and Budget approval. There are no procedures contained in this regulation that should be interpreted to require the public provide information other than general data.

For the Commander.

John R. Brown,

Colonel, Corps of Engineers, Executive Director of Civil Works.

5 Appendices

App A—Pertinent Legislative Language

App B—Summary of the Corps User Fee Program

App C—Day User Fee Schedule

App D—Annual Day Use Pass

App E—Cash Register Specifications

[FR Doc. 94–1839 Filed 1–27–94; 8:45 am]

BILLING CODE 3710–92–M

Department of the Navy

Notice of Intent To Reopen Scoping for a Joint Environmental Impact Statement for Proposed Disposal and Reuse of Long Beach Naval Hospital, Long Beach, CA

Pursuant to the National Environmental Policy Act (NEPA) as implemented by the Council on Environmental Quality (CEQ) regulations (40 CFR parts 1500–1508), the Department of the Navy announces its intent to reopen scoping for an Environmental Impact Statement (EIS) to evaluate the environmental effects of the disposal and reuse of Naval Hospital (NAVHOSP) Long Beach, Long Beach, California.

In accordance with requirements of the 1991 Base Closure and Realignment Commission, the Navy plans to disestablish NAVHOSP Long Beach on 31 March 1994. Operations conducted at NAVHOSP Long Beach are currently relocating to other naval hospitals located in the continental United States. The proposed action involves the disposal of land, buildings, and infrastructure of NAVHOP Long Beach for subsequent reuse. The property currently occupied by the hospital totals 65.2 acres located at 7500 E. Carson Street and generally bounded by Carson Street, Dovey Drive, El Dorado Regional Park, and the 605 Freeway. However, a parcel of approximately 35 acres will revert to ownership by the City of Long Beach in accordance with the deed conveying that parcel to the Navy. The disposal and reuse of the remaining approximately 30 acres will comprise the focus of the NEPA documentation.

The Navy intends to analyze the environmental effects of the disposal of NAVHOSP Long Beach based on the reasonably foreseeable reuse of the property, taking into account uses identified by the City of Long Beach and as determined during the scoping process. Potential reuses of NAVHOSP Long Beach that have been identified include (1) demolition of the existing hospital complex and accessory structures and construction of approximately one million square feet of retail, restaurant, and entertainment commerical space, (2) continued use of the existing hospital complex for medical use, and (3) use of the existing facilities for educational, office, and administrative spaces.

The City of Long Beach owns the adjacent property to the west of the hospital site and plans to develop it, along with the property that will revert to City control as soon as possible.

Major environmental issues that will be addressed in the EIS include, but are not limited to, air quality, water quality, wetlands, endangered species, cultural resources, transportation, and socioeconomic impacts.

In May 1993, the Navy initiated a scoping process for the purpose of determining the scope of significant issues to be addressed related to this action. A scoping meeting was held in the City of Long Beach on 27 May 1993

and the process of preparing the EIS was begun. More recently, however, the Navy has become aware that additional potential reuses of the hospital site may have been identified that need to be evaluated through the NEPA process. Therefore, the scoping process is being reopened for a period of 90 days from the date of this notice to allow communities, organizations, and the public to submit to the Navy additional reuse alternatives or substantive environmental issues of concern. The Navy will then fully evaluate potential reuse recommendations that have a reasonable basis for implementation and which would generate jobs and/or revenues for the local economy.

Public scoping meetings will be conducted in late March 1994 to allow oral public scoping comments. A notice of time and place for these meetings will be advertised in local newspapers and mailed to local city officials. It is important that federal, state, and local agencies and interested individuals take this opportunity to identify environmental concerns that should be addressed during the preparation of the EIS. Agencies and the public are invited and encouraged to provide written comment in addition to, or in lieu of, oral comments at the public meetings. To be most helpful, scoping comments should clearly describe specific issues or topics which the commentor believes the EIS should address. Written comments regarding this proposed action should be mailed no later than April 28, 1994, to Commanding Officer, Southwest Division, Naval Facilities Engineering Command, 1220 Pacific Highway, San Diego, California 92132–5190 (Attn: Mr. Dan Muslin, Code 232), telephone (619) 532–3403.

Dated: January 25, 1994.

Michael P. Rummel,

LCDR, JAGC, USN, Federal Register Liaison Officer.

[FR Doc. 94–1887 Filed 1–27–94; 8:45 am]

BILLING CODE 3810–AE–M

Intent To Prepare a Supplemental Environmental Impact Statement for the Proposed Dredging of the Pier D Area at Naval Shipyard, Puget Sound, Bremerton, WA

Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969, as implemented by the Council on Environmental Quality regulations (40 CFR parts 1500–1508), the Department of the Navy announces its intent to prepare a Supplemental Environmental Impact Statement (SEIS) to further assess impacts associated with dredging, dredge material disposal, and other in-water work to support the homeporting of two Fast Combat Support Ships (AOE–6 Class) at Puget Sound Naval Shipyard (PSNS), Bremerton, Washington.

A Programmatic Environmental Impact Statement (PEIS) for the AOE–6 Class West Coast Homeporting Program, issued in the fall of 1991, included the tiered analysis of the proposed homeporting at PSNS. The AOE–6 PEIS proposed the upgrading of Pier D to a deep-draft pier by dredging 170,400 cubic yards of material adjacent to both sides of the pier to deepen the berthing area. The impact analysis assessed anticipated impacts resulting from dredging operations, open water dredged materials disposal, and upland dredged materials disposal. A Record of Decision for this action was issued by the Department of the Navy in March 1992.

The Suquamish Indian Tribe appealed a permit for this project that was issued by the City of Bremerton under the Washington State Shorelines Management Act and the City of Bremerton Shorelines Master Program. The permit is required by the State of Washington before certifying a proposal under Section 401 of the Clean Water Act. The appeal was resolved when the Navy, State of Washington, City of Bremerton, and the Suquamish Tribe agreed that the Navy would prepare an SEIS addressing the Pier D upgrade dredging project and additional work related to the dredging project and operations at the pier.

The Pier D upgrade project involves dredging sediment and making upgrades to Pier D at PSNS in Sinclair Inlet at Puget Sound. The proposed action will provide two upgraded berths at Pier D capable of handling a minimum of two AOE–6 Class ships and will also provide the flexibility to berth other deep-draft ships assigned to PSNS. Dredging is proposed to enlarge the berths at Pier D, currently used for inactive ships. Depths at the AOE–6 berth (1,073 feet × 117 feet) would be increased by this project from the current depths to −44.4 feet mean lower low water (MLLW). The deep draft berth (1,073 feet × 145 feet) would be increased to −46.4 feet MLLW, and include a 400 feet × 116 feet area for sea chest intake clearance that would be increased to −49.4 feet MLLW. A new steel fender pile system will be added to Pier D to increase the capacity of the existing timber fender piles; remaining timber fender piles will be replaced. As currently designed, approximately 105,000 cubic yards of marine sediments would be dredged and disposed of at one or more disposal sites approved for this purpose by various federal, state, and local environmental laws.

As agreed during the appeal process, the scope of the SEIS will be limited to the potential impacts associated with the proposed dredging in the vicinity of Pier D, including rehandling dredged material, transportation of dredged material, and disposal of dredged material. The SEIS will address, but not be limited to, the following issues: (1) Potential alternatives to the proposal and appropriate mitigation measures; (2) project monitoring to ensure that environmental quality is maintained; and (3) potential environmental impacts at the Pier D dredge site, including impacts to land, air, water, plants and animals, environmental health, land and shoreline uses, transportation, public services, utilities, and related socioeconomic conditions. Specific dredging related impacts to be analyzed include: (1) Potential impacts to aquatic species; (2) potential impacts associated with the resuspension and exposure of contaminated sediments in the vicinity of Pier D during dredging operations; (3) potential impacts associated with post-dredging exposure of contamination, future contamination associated with Pier D dredging activities, and coordination with cleanup efforts to be undertaken pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act; and (4) potential impacts associated with the handling, transportation, and disposal of dredged material.

Agencies and the public are invited and encouraged to provide written comments regarding issues of concern. To be most helpful, these comments should clearly describe specific issues or topics which the commentor believes the SEIS should address. Written statements and/or questions regarding the SEIS should be mailed no later than 30 days from the date of this publication to Mr. Peter Havens, Code 232, Engineering Field Activity Northwest, Naval Facilities Engineering Command, 3505 NW Anderson Hill Road, Silverdale, WA 98383–9130, telephone (206) 396–5976.

Dated: January 25, 1994.

Michael P. Rummel,

LCDR, JAGC, USN, Federal Register Liaison Officer.

[FR Doc. 94–1888 Filed 1–27–94; 8:45 am]

BILLING CODE 3810–AE–M

Finding of No Significant Impact; Short-Term Storage of Naval Spent Fuel; Availability for Public Review

SUMMARY: The Naval Nuclear Propulsion Program has prepared an Environmental Assessment of short-term storage of Naval spent nuclear fuel. The preferred alternative is the "No Action" alternative. Naval spent fuel removed from nuclear powered ships would be retained in shipping containers at five shipyards: Portsmouth Naval Shipyard in Kittery, Maine; Norfolk Naval Shipyard in Portsmouth, Virginia; Newport News Shipbuilding in Newport News, Virginia; Puget Sound Naval Shipyard in Bremerton, Washington; and Pearl Harbor Naval Shipyard in Pearl Harbor, Hawaii. Naval spent fuel also would remain in the Surface Ship Support Barge at Newport News Shipbuilding. The Department of Energy (DOE), with the Navy as a cooperating agency, is preparing an Environmental Impact Statement on longer-term storage of all DOE spent fuel, including Naval spent fuel. The time period evaluated in the short-term storage Environmental Assessment is the period through implementation of the Record of Decision for the DOE Environmental Impact Statement.

The Environmental Assessment discusses alternatives to the preferred alternative and evaluates the environmental impacts of both the preferred and other alternatives. The Environmental Assessment concludes that the environmental impact of any of the alternatives would be very small. Therefore, there is no basis for determining that any of these alternatives would be environmentally preferable to the others. The No Action alternative, which is the preferred alternative, would allow all shipyard work, including refueling and defueling of nuclear powered ships, to continue unimpeded by the short-term accumulation of Naval spent fuel.

The Naval Nuclear Propulsion Program provided a draft of this Environmental Assessment to officials of Virginia, Maine, New Hampshire, Washington, and Hawaii for review and comment. Letters were received from Congressman Norm Dicks of Washington and Mr. T.R. Strong of the State of Washington Department of Health, both of whom agreed that the No Action alternative is appropriate, and Mr. Brian Choy of the State of Hawaii Office of Environmental Quality Control, who had no comment.

Mr. Strong suggested that the Navy and the State of Washington collaborate in monitoring of radiation levels in the vicinity of Puget Sound Naval Shipyard and share results of past radiation monitoring. The Program agreed with these suggestions. Mr. Strong also suggested that the Navy pro-actively inform the public of its plans, emphasizing that this is a short-term measure, and not in consideration as a long-term solution. In the letters seeking State comments on the Environmental Assessment, the Navy stated that if the Environmental Assessment justified a Finding of No Significant Impact, the Navy would make the Finding available for public review prior to a final determination. Accordingly, the Program is making this Finding and the Environmental Assessment available to State and local officials, the news media, and the public for a 30 day comment period. The Environmental Assessment on short-term storage of Naval spent fuel evaluates short-term storage only, and the Finding of No Significant Impact would only cover short-term storage. However, it should be noted that long-term storage at shipyards is one of the alternatives being considered for Naval spent fuel in a separate Environmental Impact Statement which DOE is preparing with Navy assistance on spent fuel management.

Based on the analysis in the Environmental Assessment, the Naval Nuclear Propulsion Program considers that the preferred alternative is not a major Federal action significantly affecting the quality of the human environment, within the meaning of the National Environmental Policy Act of 1969, (42 U.S.C. 4321 et seq.). In accordance with the Council on Environmental Quality regulations which allow agencies to determine circumstances under which public review of Findings of No Significant Impact are appropriate, the Program is making this Finding available for public comment for a period of 30 days following the date of **Federal Register** publication of this notice. Comments postmarked within the 30 day public comment period will be considered by the Program prior to a final determination. To facilitate review of this matter, copies of the Environmental Assessment have been placed in public libraries in the vicinity of the five shipyards. Additionally, persons desiring a copy of the Environmental Assessment may request one from the address indicated below.

DATES: Comments on the Finding of No Significant Impact may be sent to Mr. Richard A. Guida, Associate Director for Regulatory Affairs, Naval Nuclear Propulsion Program at the address indicated below. Comments must be postmarked within the 30 day public comment period to ensure consideration.

ADDRESSES AND FURTHER INFORMATION: Persons requesting additional information on the Finding of No Significant Impact for short-term storage of Naval spent fuel, the National Environmental Policy Act process associated with this preferred alternative, or wishing a copy of the Environmental Assessment should contact Ms. Lisa Megargle, Naval Nuclear Propulsion Program, Code NAVSEA 08U, Naval Sea Systems Command, 2521 Jefferson Davis Highway, Arlington, VA 22242–5160, (703–603–6126). Persons desiring to review the Environmental Assessment at a public library should contact the Public Information Office at Portsmouth (207–438–1260), Norfolk (804–396–9550), Puget Sound (206–476–7111), or Pearl Harbor (808–474–0272) Naval Shipyards.

SUPPLEMENTARY INFORMATION:

Background

The Naval Nuclear Propulsion Program is a joint Navy/Department of Energy (DOE) organization responsible for all matters pertaining to Naval nuclear propulsion. The Program is responsible for the nuclear propulsion plants aboard more than 120 warships powered by over 140 Naval reactors; two moored training ships used for Naval nuclear propulsion plant operator training; nuclear work performed at eight shipyards; two DOE government-owned laboratories devoted solely to Naval nuclear propulsion research, development, and design; and eight land-based prototype Naval reactors used for research and development work and training of Naval nuclear propulsion plant operators.

Beginning in 1957, spent fuel removed from nuclear powered ships and prototypes has been sent to the Expended Core Facility for examination to evaluate its performance and confirm design and operational predictions. The Expended Core Facility is part of the Naval Reactors Facility which is located within the DOE Idaho National Engineering Laboratory.

The Federal Government has been involved in litigation with the State of Idaho regarding spent nuclear fuel issues at the Idaho National Engineering Laboratory in Idaho. The Navy became involved in this lawsuit when Idaho requested an injunction in 1992 against shipments of all spent fuel, including Naval fuel, until DOE completed an Environmental Impact Statement under the National Environmental Policy Act

evaluating activities involving all spent nuclear fuel at the Idaho National Engineering Laboratory.

On June 28, 1993, the Federal District Court in Idaho granted the State of Idaho's request for an injunction and directed DOE to evaluate "The direct and indirect environmental effects of all major federal actions involving the transportation, receipt, processing, and storage of spent nuclear fuel at the Idaho National Engineering Laboratory." Furthermore, the Court Order directed DOE to consider the alternative of "transporting, receiving, processing, and storing spent nuclear fuel at sites other than the [Idaho] National Engineering Laboratory."

The DOE is separately preparing an Environmental Impact Statement on spent nuclear fuel management throughout the DOE, which includes Naval spent fuel. The Navy is a cooperating agency in this effort. The DOE Environmental Impact Statement will evaluate alternatives for managing Naval spent fuel from 1995 through 2035, and will consider Naval Shipyards and other sites for this purpose. A previous **Federal Register** announcement provides further information (Vol. 58, No. 170, page 46951). The DOE Environmental Impact Statement is scheduled to be published in April 1995 with a Record of Decision by June 1, 1995.

Preferred Alternative

If no action were taken, loaded Naval spent fuel shipping containers would accumulate at five shipyards: Portsmouth Naval Shipyard in Kittery, Maine; Norfolk Naval Shipyard in Portsmouth, Virginia; Newport News Shipbuilding in Newport News, Virginia; Puget Sound Naval Shipyard in Bremerton, Washington; and Pearl Harbor Naval Shipyard in Pearl Harbor, Hawaii. Naval spent fuel also would remain in the Surface Ship Support Barge at Newport News Shipbuilding. The No Action alternative, which is the preferred alternative, would allow all shipyard work, including refueling and defueling of nuclear powered ships, to continue unimpeded by the short-term accumulation of Naval spent fuel.

Consolidation Alternative

Under the Consolidation alternative, Naval spent nuclear fuel in shipping containers would be consolidated at Norfolk Naval Shipyard on the east coast and at Puget Sound Naval Shipyard for the Pacific Ocean shipyards. The Surface Ship Support Barge would remain in use at Newport News Shipbuilding. All other shipyard work, including refueling and defueling of nuclear powered ships, would continue unimpeded under the Consolidation alternative. However, this alternative offers no operational advantages to the Navy compared to the No Action alternative, and it would entail otherwise unnecessary shipping of naval spent fuel.

Moored Ship Alternative

Under the Moored Ship alternative, nuclear powered ship inactivations would be deferred. The nuclear propulsion plants would be taken to a cold shutdown condition and physically modified to prevent reactor operation, such as by eliminating the capability to withdraw control rods. Only the ship systems necessary to support eventual defueling would be maintained. The ship would be tied up at a pier within the controlled industrial area of the shipyard where it was scheduled to be defueled. Reduced crews would provide surveillance and necessary maintenance of the ships.

The Moored Ship alternative has operational disadvantages compared to the No Action and Consolidation alternatives. It would disrupt shipyard work schedules, idle skilled shipyard defueling and inactivation workers, and utilize highly trained Navy nuclear ship operators in the unproductive task of watching over shut down ships.

Other Alternatives

There are no other alternatives for short-term storage of Naval spent fuel which could be implemented within the time frame under consideration. Alternatives which were considered but found to be impractical for short-term storage included (1) shipment to Idaho as in the past, which is precluded by the Federal District Court injunction; (2) storage in commercial dry storage casks, which could not be procured and adapted quickly for use with Naval fuel; and (3) storage in Navy or DOE water pools, which is precluded in the short-term by space limitations and lack of the necessary storage racks.

Environmental Considerations

The impacts of the three alternatives have been evaluated both in terms of their specific impacts and the cumulative impacts of shipyard operation. Since the radioactivity in the spent fuel is totally isolated from the environment in either the shipping containers, the Surface Ship Support Barge, or in shutdown ships, short-term storage under any of these alternatives would not result in any additional release of radioactivity under normal conditions.

The Environmental Assessment considers several hypothetical accidents involving Naval spent fuel including release of radioactivity from the fuel during the accident. To summarize, all of the overall accident risks are very small, less than one chance in 10,000 of a single fatal cancer in the entire population. While the numerical results of the calculations differ for the various storage modes and locations, the overall risks are so small that accident risks provide no realistic basis for selecting among the alternatives.

Proposed Determination

Based on the information and analysis in the Environmental Assessment, the Naval Nuclear Propulsion Program considers the No Action alternative not to constitute a major Federal action significantly affecting the quality of the human environment, within the meaning of the National Environmental Policy Act. Therefore, the Naval Nuclear Propulsion Program issues this Finding of No Significant Impact and will make a final determination following a 30 day public review period.

Dated: January 14, 1994.

B. DeMars,

Admiral, U.S. Navy, Director, Naval Nuclear Propulsion Program.

Dated: January 20, 1994.

Michael P. Rummel,

LCDR, JAGC, USN, Federal Register Liaison Officer.

[FR Doc. 94–1914 Filed 1–27–94; 8:45 am]
BILLING CODE 3810–AE–M

DEPARTMENT OF ENERGY

Intent To Prepare Hanford Tank Waste Remediation System Environmental Impact Statements, Richland, WA

AGENCY: Department of Energy.

ACTION: Notice of Intent (NOI) to prepare two Environmental Impact Statements (EISs) for proposed actions at the Hanford Site, Richland, Washington. One EIS will address the proposed Tank Waste Remediation System (TWRS) activities, and the second will address the proposed construction of six new tanks for the storage of high-level radioactive waste as an interim action to the TWRS EIS.

SUMMARY: The U.S. Department of Energy (DOE) announces its intent to prepare two EISs pursuant to the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 *et seq.*), in accordance with the Council on Environmental Quality (CEQ) regulations for implementing the procedural provisions of NEPA (40 CFR

parts 1500–1508) and the DOE implementing procedures (10 CFR part 1021), and to conduct a series of public scoping meetings. It is intended that the TWRS EIS cover all TWRS activities that are ripe for decision. In addition, DOE proposes to prepare an EIS for the construction and operation of six new storage tanks as an interim action while the TWRS EIS is being prepared, consistent with the provisions of 40 CFR 1506.1. The public scoping period being announced in this NOI provides an opportunity for the public to comment on the scope of issues to be addressed in both the TWRS EIS and the new tanks EIS.

The TWRS program is conducted in concert with the Hanford Federal Facility Agreement and Consent Order (also called the Tri-Party Agreement or TPA) among DOE, the U.S. Environmental Protection Agency (EPA) and the Washington State Department of Ecology (Ecology). The scope of the TWRS Program includes: Resolution of high-level radioactive waste tank safety issues; management of high-level waste tank farm operations; upgrading the tank farm infrastructure; waste characterization; storage of wastes generated from Hanford cleanup activities; tank farm waste retrieval, conditioning (e.g., evaporation/dilution), pretreatment (e.g., radionuclide separation), and immobilization (e.g., vitrification); construction of new high-level waste tanks; storage of immobilized high-activity waste; storage/disposal of immobilized low-activity waste; management of encapsulated strontium and cesium; and technology development.

DOE has identified the immediate need for additional interim high-level waste storage capacity to support the resolution of safety issues associated with "Watchlist" tanks as identified pursuant to "Safety Measures for Waste Tanks at Hanford Nuclear Reservation," section 3137 of the National Defense Authorization Act for Fiscal Year 1991, P.L. 101–510. As an interim action to the TWRS EIS, the new tanks EIS will address the proposed construction and operation of six new underground storage tanks to support the resolution of safety issues concerning the high-level waste in existing tanks.

In March 1993, DOE completed a rebaselining of the TWRS program to ensure that the program to remediate Hanford tank wastes is comprehensive, integrated and technically sound. Subsequently, the TPA was renegotiated and revised. Public meetings on the revised TPA were held in several locations statewide during November 1993. The revised TPA is expected to be signed by all parties on January 25, 1994.

The proposed TWRS program actions constitute a major Federal action significantly affecting the environment and, accordingly, DOE has developed a strategy for providing the appropriate NEPA reviews for the actions. The strategy consists of a TWRS EIS for the overall proposed action to treat, store, and dispose of Hanford's stored high-level tank waste, and an EIS for the new tanks as an interim action. In addition, separate NEPA reviews for other interim actions may need to be initiated during preparation of the TWRS EIS and the new tanks EIS. Such interim actions would include activities needed to maintain the current waste management system; collect data and resolve urgent pretreatment issues; and protect both the workers, the public and the environment. The TWRS EIS will address the cumulative impacts of the TWRS program including the new tanks and other interim actions.

In December 1987 the DOE completed the "Final Environmental Impact Statement on the Disposal of Hanford Defense High-Level, Transuranic and Tank Wastes" (HDW EIS), which addressed the environmental consequences of alternatives for disposal of wastes generated during national defense activities and stored at the Hanford site. A Record of Decision (ROD) issued in April 1988 has formed the basis for DOE's programs to manage these wastes at the Hanford site.

In the HDW EIS ROD, DOE deferred final disposal decisions for the tank wastes contained in single-shell tanks (SSTs), pending further evaluations in a supplemental EIS. However, to meet regulatory requirements, DOE's current planning basis is to retrieve SST waste, and to integrate double-shell tank (DST) and SST waste management activities leading to final disposal. Because DOE now proposes to integrate SST and DST waste management programs, the TWRS EIS described in this NOI will replace the previously planned supplement to the HDW EIS.

The TWRS EIS will address the DOE's proposal for the management, treatment, storage, and disposal of the waste currently stored in the existing 149 SSTs and 28 DSTs and other wastes to be generated during future decontamination and decommissioning activities at Hanford. DOE recognizes that removal of waste from the tanks may trigger Resource Conservation and Recovery Act (RCRA) treatment and disposal requirements to complete closure of the tanks. However, the impacts of tank closure cannot be meaningfully evaluated at this time. DOE will conduct an appropriate NEPA review, such as an EIS to support tank closure, in the future.

The planned interim action EIS will address the construction of six new tanks and associated new transfer lines, and the tank operations. For the purposes of this interim action EIS, operations considered would be limited to the retrieval, pH adjustment or alkalinity control, and storage of wastes from the Watchlist safety tanks. The primary focus of the EIS would be the resolution of safety issues related to the three tanks that are on the Watchlist because of hydrogen generation (241–SY–101, 241–SY–103 and 241–AN–104), but the tanks may also be used to alleviate safety concerns in other Watchlist tanks (50 tanks are currently on the Watchlist). Further decisions regarding the retrieval, treatment and disposal of wastes from the Watchlist tanks will be the subject of the TWRS EIS.

DATES: DOE invites all interested parties to submit written comments or suggestions concerning the scope of the issues to be addressed, alternatives to be analyzed, and the environmental impacts to be assessed in the TWRS EIS and the new tanks EIS, during a 45-day comment period ending March 14, 1994. The public is also invited to attend scoping meetings in which oral comments will be received on the proposed TWRS EIS and the new tanks EIS. Oral and written comments will be considered equally in preparation of the EISs. Written comments must be postmarked by March 14, 1994. Comments postmarked after that date will be considered to the extent practicable. Oral and written comments will be received at public scoping meetings to be held on the dates and at the locations given below:

Richland, Washington	February 14, 1994	Hanford House—Red Lion 802 George Washington Way. Richland, WA 99352
Hood River, Oregon	February 16, 1994	The Hood River Inn/Best Western 1108 East Marina Way Hood River, OR 97031.

Portland, Oregon	February 17, 1994	Bonneville Power Administration Auditorium, 911 N.E. 11th Avenue Portland, OR 97204.
Seattle, Washington	February 22, 1994	The Mountaineer's 300 Third Ave. West Seattle, WA 98105.
Spokane, Washington	February 24, 1994	Spokane Convention Center 334 West Spokane Falls Blvd. Spokane, WA 99201.

Each scoping session will begin with a welcome and introduction of DOE officials, followed by short presentations by DOE officials on the EIS process, the Hanford TWRS program and the proposed interim actions. Individuals and organization spokespersons will then have an opportunity to present oral comments to DOE representatives. The agenda will be repeated twice a day at each location, in afternoon and evening sessions. The hours for the sessions are: 1 pm to 4:30 pm and 6:30 pm to 10 pm.

Requests to speak at these meetings may be made by calling the toll-free telephone number, 1–800–500–1660, by 3 p.m. the day before the meeting or by writing to Donald Alexander (see **ADDRESSES**, below).

The meetings will be chaired by a presiding officer but will not be conducted as evidentiary hearings; speakers will not be cross-examined although the presiding officer and DOE representatives present may ask clarifying questions. Individuals requesting to speak on behalf of an organization must identify the organization. A 5-minute limit will be imposed on each individual speaker except that a speaker representing an organization (one per organization) will be given a 10-minute limit. These limits are to ensure that all who wish to speak have an opportunity to do so. Comments will be recorded by a court reporter and will become part of the scoping meeting record.

Persons who have not submitted a request to speak in advance of the scoping meetings may register at the meetings and will be called on to speak on a first-come first-served basis as time permits. Written comments will also be accepted at the meetings, and speakers are encouraged to provide written versions of their oral comments for the record.

DOE will review scoping comments to determine their applicability to the two proposed EISs. Records of, and responses to, the scoping comments will be provided as appropriate in either the Implementation Plan (IP) for the TWRS EIS or the IP for the new tanks EIS. The IPs will provide guidance for preparation of the TWRS and new tanks EISs and establish their scopes and content (10 CFR 1021.312). The IPs will be issued prior to the release of the draft EISs and copies will be available for inspection in public reading room locations to be announced.

ADDRESSES: Written comments on the scope of the TWRS EIS and the new tanks EIS, questions concerning the tank waste program, requests for speaking times, and requests for copies of the IPs and/or the Draft EISs (DEISs) should be directed to the designated contact below. If any additional DEISs are prepared for other interim actions, their availability will be announced in the **Federal Register** and opportunity will be provided for public review and comment as required by CEQ and DOE regulations. Any interim action DEISs may also be obtained from the designated contact below.

FOR FURTHER INFORMATION CONTACT: Donald H. Alexander, Attn: Scoping Comments, U.S. Department of Energy, Post Office Box 550, Richland, WA 99352, Telephone: 509–372–2453 or 1–800–500–1660.

For information on the DOE NEPA process, contact: Carol M. Borgstrom, Director, Office of NEPA Oversight (EH–25), U.S. Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585, Telephone: 202–586–4600 or leave a message at 1–800–472–2756.

SUPPLEMENTARY INFORMATION:

Background

The Federal government created the Hanford Site, near Richland, Washington, in 1943, as part of the Manhattan Project, to produce plutonium for national defense. Metallic uranium fuel was irradiated in nuclear reactors and then the fuel was chemically processed to recover plutonium. Plutonium production at the Hanford Site stopped in 1988.

Processing of reactor fuel and other waste management activities created a wide variety of radioactive wastes, including high-level wastes that have been stored in underground tanks. The high-level wastes came from many different processes and sources, and they have been processed and transferred among tanks so that chemical and physical characteristics of the wastes vary greatly among tanks and even within individual tanks. Typically, the tank wastes are highly radioactive and chemically hazardous.

SSTs have one steel wall, surrounded by reinforced concrete; they were constructed between 1944 and 1964 and received waste until 1980. The capacity of most SSTs is 0.5 million gallons (Mgal) to 1.0 Mgal. The tanks are situated below grade and are covered with 6 to 10 feet of earth.

Waste in SSTs consists of liquids, sludges, and saltcake, i.e., crusty solids made of crystallized salts. Some of the liquids in the SSTs are contained in the pores of the sludges and saltcake, and some liquids are free standing in the tanks.

There are 149 SSTs storing about 36 Mgal of waste. This waste is comprised of approximately 0.6 Mgal of free-standing liquid, 23.2 Mgal of saltcake, and 12.5 Mgal of sludge. About half of the SSTs have leaked or are assumed to have leaked. Approximately 0.6 to 0.9 Mgal of waste has leaked or spilled into the nearby soil. Over the years, much of the liquid stored in SSTs has evaporated or been pumped to DSTs.

There are 28 one Mgal DSTs at Hanford. The DSTs were constructed between 1970 and 1986. Most of these tanks are designed for up to 50 years of storage. DSTs have a second steel containment wall. The space between the two walls is monitored for leaks. DOE has used the DSTs since 1970 and none has been known to leak. The DSTs are used to treat and store a variety of liquid radioactive wastes from the SSTs and from various Hanford Site processes. The wastes are stored in tanks based upon composition, level of radioactivity, or origin. The DSTs now contain about 25 Mgal of waste.

In the 1960s and 1970s, radioactive strontium and cesium were extracted from wastes in some SSTs. The strontium and cesium were converted to salt forms and placed in double-walled capsules. Most of the 610 strontium capsules and 1323 cesium capsules are stored at Hanford. Some capsules were shipped offsite for beneficial use as heat or radiation sources. Because the capsules were only leased from DOE, it is anticipated that they will be returned to Hanford.

In the April 1988 HDW EIS ROD, DOE decided to proceed with preparing the DST waste for final disposal because it

was readily retrievable. Wastes were to be processed in a pretreatment facility (planned to be the Hanford B-Plant and AR Vault) to separate DST waste into two portions. The larger portion would be low activity waste, and a much smaller portion would be highly radioactive. The low activity waste was to be mixed with a cement-like material to form grout. The grout was to be poured into large, lined, concrete, near-surface, underground vaults where it would solidify.

The high activity waste fraction was to be made into a borosilicate glass and poured into stainless-steel canisters (approximately 0.6 m diameter by 3 m long) at the proposed Hanford Waste Vitrification Plant (HWVP). The canisters were to be stored there until a geologic repository was ready to receive this waste.

Existing and future DST wastes were to be characterized for hazardous chemical constituents as well as other constituents that might affect glass or grout formulations before processing. This characterization would also help ensure that proper treatment, in accordance with hazardous waste regulations, occurred before disposal of the waste.

The HDW EIS ROD also called for storage of cesium and strontium capsules to continue until a geologic repository is ready to receive this waste for disposal. Before shipment to the repository, the capsules would be packaged to meet repository acceptance criteria.

In the HDW EIS ROD, DOE decided to conduct additional development and evaluation before making decisions on final disposal of SST wastes. This development and evaluation effort was to focus both on methods to retrieve and process SST wastes for disposal and to stabilize and isolate the wastes near-surface. SST waste would continue to be stored and monitored. Before a decision on the final disposal of the wastes could be made, the alternatives were to be analyzed in a supplement to the HDW EIS.

Several significant changes have occurred subsequent to the HDW EIS. These include the identification of significant waste tank safety issues; the DOE, EPA and Ecology signing the TPA; the elimination of B-Plant from consideration as a waste pretreatment facility; the delay of the HWVP; and the proposal to treat SST waste with DST waste. These changes resulted in DOE's proposal to integrate all Hanford tank waste remediation efforts. As a result, resolving waste tank safety issues, planning for SST waste retrieval, and developing pretreatment facilities have become major elements of the proposed Hanford tank waste remediation program.

Purpose and Need for Agency ACTION:

DOE needs to take action to treat, store, and dispose of Hanford's stored high-level tank waste and encapsulated strontium and cesium and to reduce the overall potential risks posed by the tank wastes. This entails addressing four major programmatic elements: Retrieval, pretreatment, immobilization, and storage/disposal. More specifically, these programmatic elements include:

- Retrieval of SST and DST wastes.
- Conditioning (e.g., evaporation/dilution) of wastes.
- Waste pretreatment.
- New infrastructure such as facilities, tanks, and transfer lines.
- Production of a stabilized high-activity waste form.
- Interim storage for the stabilized high-activity waste form.
- Production and disposal of a stabilized low-activity waste form.
- Management of encapsulated strontium and cesium inventory.

DOE also needs to address closure of tanks (including disposal of tanks, piping, ancillary facilities, and contaminated soil). Although tank closure is included in the TPA, closure is not included in the proposed action for the TWRS EIS because the impacts of tank closure cannot be meaningfully evaluated at this time. DOE will conduct an appropriate NEPA review, such as preparing a tank closure EIS, in the future.

TWRS EIS Alternatives

A number of alternatives can be constructed from the range of options available for the four major subcomponents of the TWRS, which are retrieval, pretreatment, immobilization and storage/disposal. Combinations of these options comprise the range of reasonable alternatives currently envisioned for TWRS. The TPA establishes one specific case within the range of alternatives to be considered in the TWRS EIS. The TWRS EIS will also evaluate a number of other alternatives constructed from the range of options described for the four major subcomponents of the TWRS and a no-action alternative in order to adequately evaluate the full range of potential environmental impacts.

TPA Preferred Alternative

On March 31, 1993, DOE, EPA, and Ecology agreed to enter into formal negotiations on matters relating to Hanford tank waste remediation, environmental restoration activities, cost control, and implementation and administration of the Hanford Federal Facility Agreement and Consent Order. The negotiations were concluded in September 1993, with tentative agreement on all matters under negotiation. The revised TPA received public review during November 1993, and the TPA was scheduled to be signed by the three parties on January 25, 1994. The full TPA covers subjects outside the purview of the TWRS program. The elements of the TPA which are within the scope of the TWRS program constitute elements of the preferred alternative for purposes of the TWRS EIS. Accordingly, the TPA preferred alternative consists of the following activities:

- Upgrading the infrastructure of the high-level waste tank farms to provide improved facility management and operation.
- Characterization of the wastes in all 177 SSTs and DSTs to facilitate treatment, immobilization and disposal.
- Construction and operation of additional DSTs (beyond the six tanks proposed in the interim action EIS noticed here) as necessary to support waste management and disposal.
- Stabilization of SST waste by removing and storing the pumpable liquids in DSTs, thus reducing the potential for leaks to the surrounding soil.
- Retrieval of the waste from SSTs and DSTs with priority on the SSTs. The retrieval criterion is removal of 99% of the waste from all SSTs on a tank-by-tank basis.
- Construction and operation of a waste pretreatment facility to treat the tank waste and to prepare the low-activity fraction for final processing. The high-activity fraction of the waste would be stored pending final processing. Separate complexes would be constructed to house enhanced sludge washing and cesium and strontium ion exchange processes. An evaporator would be included in the low-activity waste pretreatment complex. These complexes could be stand-alone facilities, a set of distributed facilities, or part of a central processing complex.
- Construction and operation of a low-activity waste vitrification plant of appropriate capacity. Bounding analysis may be used if definitive designs are not available. DOE would maintain in a standby condition the capability to restart the grout facility if its operation is necessary before new DSTs are available to provide tank space to resolve safety issues.

- Storage/disposal of the vitrified low-activity waste on-site at Hanford.
- Construction and operation of a high-activity waste vitrification plant of appropriate capacity. Bounding analysis may be used if definitive designs are not available.
- Construction and operation of storage for vitrified high-activity waste until a repository for permanent disposal is available.
- Existing cesium and strontium capsules would be either over-packed and stored, or dissolved and blended with the high-activity vitrification waste stream.

Additional Alternatives

Additional alternatives will be constructed from the range of options described below in order to adequately evaluate the full range of potential environmental impacts.

Options for Retrieval

Waste can be retrieved by hydraulic sluicing, pneumatic or mechanical systems. Hydraulic sluicing injects liquid into the tank to dislodge and mobilize or dissolve the waste. Pumps transfer the liquid and slurry out of the tank. Mechanical or pneumatic systems are placed in contact with the waste. This equipment conditions the waste and transfers it out of the tank. The retrieved waste is transferred to the pretreatment process.

Options for Pretreatment

Pretreatment is performed to separate the waste into its high-activity and low-activity components. One option is to perform no pretreatment. Another option is to limit the volume of waste going to a geologic repository by pretreating waste to accomplish some level of high- and low-activity waste separation. Two bounding alternatives for pretreating tank wastes have been identified, corresponding to the reasonable limits of waste pretreatment (such as evaporation, acid digestion, nuclide separation, ion exchange) to concentrate the radionuclides in a smaller volume. For purposes of this discussion, these bounds are referred to as "minimal" and "extensive" pretreatment. The pretreatment bounds may also influence the relative volumes of high- and low-activity wastes to be stabilized and stored/disposed of. The pretreated waste would be transferred to the waste immobilization process.

Minimal pretreatment would use sludge washing to separate the waste into a smaller volume fraction of high-activity waste (containing the majority of radionuclide activity), and a larger volume fraction of low-activity waste. The low-activity waste might be subjected to an evaporation step to reduce the volume resulting from the sludge washing process.

Extensive pretreatment would use advanced solvent extraction methods to provide the maximum level of radionuclide partitioning. Hazardous nitrates, metals, and other selected chemicals would be removed from the low-activity waste stream, and the volume of the high-activity waste fraction would be minimized.

Options for Immobilization

The immobilization would stabilize the waste coming from the pretreatment process. Both the low-activity waste stream and the high-activity waste stream would be stabilized. The stabilized waste would be transferred to storage or disposal.

High-activity waste stabilization options include vitrification, ceramic forms and calcination. After stabilizing, the high-activity waste fraction would comply with any likely waste form criteria for geologic repository acceptance and transportation.

Low-activity waste stabilization options include vitrification, glass cullet in a sulfur cement and cement polymer-based grout. The current plan provides that the encapsulated cesium and strontium would meet the waste form criteria for geologic repository acceptance and transportation. The first option is overpacking the capsules. If the repository waste form criteria cannot be achieved by overpacking, the capsules would be stabilized the same as the high-activity waste fraction above (e.g., vitrification, ceramic or calcination).

Options for Disposal/Storage

The disposal options include disposal onsite, disposal offsite and interim storage pending disposal.

High-activity waste disposal options include emplacement of the stabilized waste in an offsite geologic repository or in interim storage onsite pending availability of an offsite geologic repository.

Low-activity waste disposal options depend on the stabilized waste form and include: Burial in onsite landfills in containers; burial in onsite vaults; burial onsite in steel culverts with liners and leachate collection; and soil melt slurry injection to a landfill. Some of these options would accommodate retrievability if desired.

No Action Alternative

The no action alternative for TWRS would be continued storage of tank wastes and encapsulated cesium and strontium without preparation for disposal. However, the no action alternative includes continued maintenance, monitoring, and safety upgrades. No action also includes maintaining the low-activity waste grouting facility in a standby condition in case its operation is necessary before new DSTs are available to provide tank space to resolve safety issues. The no-disposal action alternative was analyzed in the HDW EIS and the DOE intends to update the HDW EIS analyses in the TWRS EIS. The no action alternative is included to comply with the CEQ regulations (40 CFR 1502.14(d)) for consideration of a no action alternative.

Interim Actions

DOE plans to complete the TWRS EIS by approximately October 1996. DOE may need to undertake interim actions while the TWRS EIS is being prepared. Any interim actions undertaken would have to be independently justified because, for example, they are activities needed to maintain the current waste management system; collect data and resolve urgent pretreatment issues; or protect workers, the public and the environment. Any interim actions would be actions on which decisions were needed prior to the scheduled completion of the TWRS EIS. None of the interim actions would prejudice the ultimate decision to be made on the basis of the TWRS EIS because they would be needed regardless of which alternatives are selected in that EIS. As described previously in this notice, DOE has already identified the construction of new tank capacity needed to resolve tank safety issues (identified in the TPA as the Multi-function Waste Tank Facility) as an interim action, and is planning to prepare a separate EIS for that project. DOE plans to complete the new tanks EIS by September 1994 to support a near-term TPA milestone.

Other interim actions may include system and infrastructure upgrades, replacement of the cross-site transfer system, waste characterization, technology development and demonstration activities including a compact processing unit, and initial retrieval or pretreatment and immobilization activities. These activities, if undertaken, would also require preparation of independent NEPA reviews while the TWRS EIS is in preparation.

Proposed Actions, New Tanks EIS

The proposed new tanks would provide waste storage space needed for resolution of tank safety issues and would not be used for storage of newly generated high-level waste. The new

tanks would be improved versions of the existing DSTs. Each tank would be constructed of double shell stainless steel surrounded by a concrete liner, and would have a 1 million gallon capacity. All tanks would have leak detection monitoring systems and filtered ventilation systems. The EIS will address the construction of new tanks and associated new transfer lines, and the tank operations. For the purposes of this interim action EIS, operations considered would be limited to the retrieval, pH adjustment or alkalinity control, and storage of wastes from the Watchlist safety tanks. The primary focus of the EIS would be the resolution of safety issues related to the three tanks that are on the Watchlist because of hydrogen generation (241–SY–101, 241–SY–103 and 241–AN–104), but the tanks may also be used to alleviate safety concerns in other Watchlist tanks (50 tanks are currently on the Watchlist). Further decisions regarding the disposition of these wastes will be addressed by the TWRS EIS.

Alternatives, New Tanks EIS

The new tanks EIS will evaluate all reasonable alternatives. Alternatives which have been tentatively identified for possible evaluation in this EIS include but are not limited to the following:

TPA Preferred Alternative

The TPA preferred alternative is to construct two DSTs in the 200 West Area by 1997 and four DSTs in the 200 East Area by 1998. These new tanks would be utilized to store wastes retrieved from Watchlist tanks in order to resolve tank safety issues. Resolution of safety issues for these Watchlist tanks may include up to a three-to-one dilution of the wastes with water and/or caustic solutions. In order to achieve this dilution a combination of new and existing tank space would be used.

Construct Fewer Tanks

Under this alternative, the need for additional tanks would be reduced using alternatives to retrieval for tank safety issue mitigation. An example would be the use of mixer pumps for mitigating the flammable gas safety issue.

No Action

The EIS will also address the no action alternative, under which no additional underground high-level waste storage tanks would be built in the near term. No action would leave the safety issues for the Watchlist safety tanks unresolved.

Preliminary Identification of Environmental Issues

The issues listed below have been tentatively identified for analysis in both EISs. This list is presented to facilitate public comment on the scope of the EISs. It is not intended to be all-inclusive or to predetermine the potential impacts of any of the alternatives.

(1) Potential effects on the public and on-site workers from releases of radiological and nonradiological materials during normal operations and from reasonably postulated accidents;

(2) Pollution prevention and waste minimization;

(3) Potential effects on air and water quality and other environmental consequences of normal operations and potential accidents;

(4) Potential cumulative effects of operations at the Hanford Site, including relevant impacts from other past, present, and reasonably foreseeable activities at the site;

(5) Potential effects on endangered species, floodplain/wetlands, archaeological/historical sites;

(6) Potential effects on future decommissioning decisions;

(7) Effects from normal transportation and postulated transportation accidents;

(8) Potential socioeconomic impacts on surrounding communities;

(9) Unavoidable adverse environmental effects;

(10) Short-term uses of the environment versus long-term productivity;

(11) Potential irretrievable and irreversible commitment of resources.

Regulatory Framework

The TPA sets milestones to achieve coordinated cleanup of the Hanford Site and provides a legal and procedural framework for regulatory compliance during cleanup. During the development of both EISs, DOE intends to fully comply with the TPA, as modified by the change control process.

Federal and State laws that are of major importance to waste management activities at Hanford include the Atomic Energy Act of 1954; RCRA; the Washington State Hazardous Waste Management Act, Chapter 70.105 RCW; and the Federal Facility Compliance Act of 1992. The Atomic Energy Act requires the management, processing, and use of radioactive materials in a manner that protects workers, public health, and the environment. RCRA and the Washington State Hazardous Waste Management Act establish requirements for management of hazardous waste, including generation, treatment, storage, transportation, and disposal. RCRA also requires cleanup of hazardous waste releases from past and present operations when the releases pose a threat to human health or the environment.

Related NEPA Documentation

NEPA documents that have been or are being prepared for activities at Hanford include, but are not limited to, the following:

(1) Final Environmental Impact Statement for Disposal of Hanford Defense High-Level Transuranic and Tank Wastes, Hanford Site, Richland Washington, DOE/EIS–0113, Vol. 1, 2, 3, 4, and 5, December 1987. U.S. Department of Energy, Washington, D.C. As discussed in the Background section of this notice, the HDW EIS analyzed the impacts of Hanford tank waste treatment and disposal.

(2) Final Environmental Statement for Waste Management Operations, Hanford Reservation, Richland Washington, ERDA–1538, Vol.1 and 2, 1975. U.S. Energy Research and Development Administration, Washington, D.C. This EIS analyzed the environmental impacts of Hanford Site waste management operations.

(3) Hanford Remedial Action-Environmental Impact Statement. The HRA-EIS will assess the potential environmental consequences of alternatives for conducting a remedial action program at the Hanford Site for inactive hazardous, high- and low-level radioactive, transuranic and mixed-waste sites. DOE published a NOI to prepare the HRA-EIS on August 21, 1992 (47 FR 37959–37964) and intends to issue the draft HRA-EIS in 1994.

(4) Programmatic Environmental Impact Statement for Environmental Restoration and Waste Management. The EM-PEIS will analyze the complex-wide environmental restoration and waste management issues and alternatives. DOE published the NOI to prepare the EM-PEIS on October 22, 1990 (55 FR 42633) and issued the Implementation Plan on December 23, 1993. The TWRS EIS will discuss its relationship to the EM-PEIS and how issues addressed in the EM-PEIS could affect the alternatives analyzed in the TWRS EIS.

(5) Programmatic Environmental Impact Statement for Reconfiguration of the Nuclear Weapons Complex (DP-PEIS). The DP-PEIS will analyze longterm reconfiguration strategies and evaluate those strategies against the consequences of maintaining existing defense production facilities. DOE published an Implementation Plan in February 1992. In July 1993, DOE

published a revised NOI and intends to issue a revised Implementation Plan based on that NOI.

(6) Tank Safety Environmental Assessments. DOE has completed eight environmental assessments and issued corresponding findings of no significant impact for activities to sample and characterize tank wastes or to modify tank equipment to improve safety conditions.

(7) Stabilization Operations at the Plutonium Finishing Plant. In September 1993, DOE announced plans to prepare an EA for this proposed action and invited public comments on the scope. On the basis of comments, including those received at four public meetings, DOE is considering whether to prepare an EIS instead. Alternatives under consideration may generate liquid high-level wastes requiring storage in the Hanford tank farm.

Issued in Washington, DC, this 25th day of January, 1994.

Peter N. Brush,

Acting Assistant Secretary, Environment, Safety and Health.

[FR Doc. 94–1932 Filed 1–27–94; 8:45 am]

BILLING CODE 6450–01–P

Floodplain Statement of Findings for Proposed Installation of Bedrock and Unconsolidated Monitoring Wells at the K–25 Site, Oak Ridge, TN

AGENCY: Department of Energy (DOE).

ACTION: Floodplain statement of findings.

SUMMARY: This is a Floodplain Statement of Findings for proposed installation of bedrock and unconsolidated monitoring wells on the Oak Ridge K–25 Site. DOE proposes to drill four monitoring wells in the Poplar Creek Floodplain, located in Roane County, Tennessee. DOE prepared a Floodplain Assessment describing the effects, alternatives, and measures designed to avoid or minimize potential harm to or within the affected floodplain. DOE will endeavor to allow 15 days of public review after publication of the Statement of Findings before implementing the proposed action.

FOR FURTHER INFORMATION CONTACT: Information on the proposed action (including maps of potentially disturbed floodplain areas) is available from: Mr. Robert C. Sleeman, Director, Environmental Restoration Division, Oak Ridge Operations Office, U.S. Department of Energy, Post Office Box 2001, Oak Ridge, Tennessee 37831–8541, (615) 576–0715, (615) 576–6074 (Fax).

FURTHER INFORMATION ON GENERAL DOE FLOODPLAIN/WETLANDS ENVIRONMENTAL REVIEW REQUIREMENTS IS AVAILABLE FROM: Ms. Carol M. Borgstrom, Director, Office of NEPA Oversight (EH–25), U.S. Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585, (202) 586–4600 or (800) 472–2756.

SUPPLEMENTARY INFORMATION: This is a Floodplain Statement of Findings for the Proposed Installation of Bedrock and Unconsolidated Monitoring Wells on the Oak Ridge K–25 Site, prepared in accordance with 10 CFR part 1022. A Notice of Floodplain Involvement was published in the **Federal Register** on October 4, 1993, and a floodplain assessment was prepared.

To facilitate future remedial actions at the K–25 Site under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), DOE is proposing to drill four borings. Two borings would be into bedrock to depths ranging from approximately 30 to 150 feet, and the two other borings would be in the unconsolidated sediments overlying the bedrock to depths from approximately 15 to 50 feet. Two locations would be involved, with one bedrock and one unconsolidated monitoring well at each location. Each borehole would be converted to a monitoring well for the purpose of collecting hydrologic and water quality data. The wells are proposed to be located in the floodplain because the sites were selected to intersect and monitor subsurface flow paths near Poplar Creek.

Alternatives to the proposed action included (1) No action, and (2) alternate sites. The no action alternative would result in DOE being unable to accurately measure possible contaminant releases to the local environment. Alternate sites away from Poplar Creek (outside of the floodplain) could not adequately monitor subsurface flow paths. The proposed action is necessary to enable DOE to pursue future remedial actions and meet the requirements of CERCLA. The assessment reveals that the installation of monitoring wells at the K–25 site would have no adverse impact on the 100-year floodplain of Poplar Creek, nor alter the existing normal channel cross section or storage capacity of Poplar Creek. No measures are needed to minimize potential harm to or within the affected floodplain. The proposed action would conform to applicable State or local floodplain protection standards. DOE will endeavor to allow 15 days of public review after publication of the Statement of Findings prior to implementing the proposed action.

Issued in Washington, DC, on January 10, 1994.

James J. Fiore,

Director, Office of Eastern Area Programs, Office of Environmental Restoration.

[FR Doc. 94–1955 Filed 1–27–94; 8:45 am]

BILLING CODE 6450–01–P

Office of Fossil Energy

Clean Coal International Technology Transfer Program; Amendment to Notice Meeting

AGENCY: Office of Fossil Energy, DOE.

ACTION: Amendment to notice of meeting; Clean Coal International Technology Transfer Program.

SUMMARY: On December 17, 1993, the United States Department of Energy (DOE), Office of Fossil Energy, published in the **Federal Register** (58 FR 65980) a Notice of Meeting; Clean Coal International Technology Transfer Program.

The objective of the Notice was to notify interested companies, the international community, and the public of the Department's intent to hold a public meeting that will assist DOE in meeting its statutory requirements of section 1332 of Public Law 102–486, the Energy Policy Act of 1992 (EPACT).

SUPPLEMENTARY INFORMATION: The Opening Plenary Session of the meeting on February 10, 1994, will begin at 9 a.m. instead of 10 a.m. as stated in the original notice.

The meeting on February 11, 1994, to address financing will begin at 9 a.m. and is scheduled to end at 4:50 p.m.; this is instead of a three-hour panel called for in the original **Federal Register** notice.

FOR FURTHER INFORMATION CONTACT: Background information, a detailed agenda, and a pre-registration form may be obtained by contacting Jean Lerch by phone 202–586–7320, fax 202–586–8488 or by writing to: Ms. Jean Lerch, U.S. Department of Energy, FE–20, room 4G–052, Washington, DC 20585.

Issued in Washington, DC, January 25, 1994.

Jack S. Siegel,

Acting Assistant Secretary, Fossil Energy.

[FR Doc. 94–1943 Filed 1–27–94; 8:45 am]

BILLING CODE 6450–01–M

Coal Policy Committee National Coal Council; Open Meeting

Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770), notice is hereby given of the following meeting:

Name: Coal Policy Committee of the National Coal Council (NCC).

Date and Time: Thursday, February 17, 1994, 8:30–10 am.

Place: Stouffer Concourse Hotel, St. Louis, 9801 Natural Bridge Road, Berkely, MO 63134.

Contact: Margie D. Biggerstaff, U.S. Department of Energy, Office of Fossil Energy (FE–5), Washington, DC 20585, Telephone: 202/586–3867.

Purpose of the Parent Council: To provide advice, information, and recommendations to the Secretary of Energy on matters relating to coal and coal industry issues.

Purpose of the Meeting: The draft study on "Clean Coal Technology for Sustainable Development" will be presented for discussion and recommendations.

Tentative Agenda;

—Call to order and opening remarks by Joseph Craft, Chairman of the Coal Policy Committee.
—Discussion and recommendations on the study "Clean Coal Technology for sustainable Development."
—Discussion of any other business to be properly brought before the Committee.
—Public comment—10-minute rule.
—Adjournment.

Public Participation: The meeting is open to the public. The Chairman of the Committee is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Any member of the public who wishes to file a written statement with the Committee will be permitted to do so, either before or after the meeting. Members of the public who wish to make oral statements pertaining to agenda items should contact Ms. Margie D. Biggerstaff at the address or telephone number listed above. Requests must be received at least five days prior to the meeting and reasonable provisions will be made to include the presentation on the agenda.

Transcript: Available for public review and copying at the Public Reading Room, room 1E–190, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC, between 9 am and 4 pm, Monday through Friday, except Federal holidays.

Issued at Washington, DC, on January 25, 1994.

Marcia Morris,

Deputy Advisory Committee, Management Officer.

[FR Doc. 94–1957 Filed 1–27–94; 8:45 am]

BILLING CODE 6450–01–M

National Coal Council; Meeting

Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92–463, 92–463, 86 Stat. 770), notice is hereby given of the following meeting:

Name: National Coal Council.

Date and time: Thursday, February 17, 1994, 10:30–11:30 a.m.

Place: Stouffer Concourse Hotel, St. Louis, 9801 Natural Bridge Road, Berkely, MO 63134.

Contact: Margie D. Biggerstaff, U.S. Department of Energy, Office of Fossil Energy (FE–5), Washington, DC 20585, telephone: 202/586–3867.

Purpose of the council: To provide advice, information, and recommendations to the Secretary of Energy on matters relating to coal and coal industry issues.

Tentative agenda:

—Call to order by William R. Wahl, Chairman of the National Coal Council.
—Remarks by Chairman Wahl.
—Report of the Coal Policy Committee.
—Discussion and approval of the Council report "Clean Coal Technology for Sustainable Development."
—Discussion of any other business properly brought before the Council.
—Public comment—10-minute rule.
—Adjournment.

Public participation: The meeting is open to the public. The Chairman of the Council is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Any member of the public who wishes to file a written statement with the Council will be permitted to do so, either before or after the meeting. Members of the public who wish to make oral statements pertaining to agenda items should contact Margie D. Biggerstaff at the address or telephone number listed above. Requests must be received at least five days prior to the meeting and reasonable provisions will be made to include the presentation on the agenda.

Transcript: Available for public review and copying at the Public Reading Room, room 1E–190, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

Issued at Washington, DC, on January 25, 1994.

Marcia Morris,

Deputy Advisory Committee Management Officer.

[FR Doc. 94–1956 Filed 1–27–94; 8:45 am]

BILLING CODE 6450–01–M

[FE Docket No. 93–137–NG]

Amoco Energy Trading Corp.; Blanket Authorization To Import Natural Gas From Mexico

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of order.

SUMMARY: The Office of Fossil Energy of the Department of Energy gives notice that it has issued an order granting Amoco Energy Trading Corporation (Amoco) authorization to import up to 220 Bcf of natural gas from Mexico over a two-year term, beginning on the date of first delivery.

Amoco's order is available for inspection and copying in the Office of Fuels Programs Docket Room, 3F–056, Forrestal Building, 1000 Independence Avenue, S.W., Washington, D.C. 20585, (202) 586–9478. The docket room is open between the hours of 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC, January 19, 1994.

Clifford P. Tomaszewski,

Director, Office of Natural Gas, Office of Fuels Programs, Office of Fossil Energy.

[FR Doc. 94–1946 Filed 1–27–94; 8:45 am]

BILLING CODE 6450–01–P

[FE Docket No. 94–01–NG]

Kimball Energy Corp.; Order Granting Blanket Authorization To Import Natural Gas From Canada

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of an Order.

SUMMARY: The Office of Fossil Energy of the Department of Energy gives notice that it has issued an order granting Kimball Energy Corporation blanket authorization to import up to 75 Bcf of natural gas from Canada over a two-year term, beginning on the date of first delivery after March 31, 1994.

A copy of this order is available for inspection and copying in the Office of Fuels Programs Docket Room, 3F–056, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–9478. The docket room is open between the hours of 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC, January 13, 1994.

Clifford P. Tomaszewski,

Director, Office of Natural Gas, Office of Fuels Programs, Office of Fossil Energy.

[FR Doc. 94–1944 Filed 1–27–94; 8:45 am]

BILLING CODE 6450–01–P

[FE Docket No. 93–132–NG]

Tenaska Gas Co. and Tenaska Washington Partners II, L.P.; Long-Term Authorization To Import Natural Gas From Canada

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of order.

SUMMARY: The Office of Fossil Energy of the Department of Energy gives notice that it has issued an order granting Tenaska Gas Co. and Tenaska

Washington Partners II, L.P. joint authorization to import up to 14,311 MMBtu of Canadian natural gas per day for a period of 20 years, expected to begin in 1996. The gas would be supplied by Husky Oil Operations Ltd. and consumed at a 248-megawatt electric power generation facility to be built in Pierce County, near Tacoma, Washington.

This order is available for inspection and copying in the Office of Fuels Programs Docket Room, 3F–056, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–9478. The docket room is open between the hours of 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC, January 10, 1994.

Clifford P. Tomaszewski,

Director, Office of Natural Gas, Office of Fuels Programs, Office of Fossil Energy.

[FR Doc. 94–1947 Filed 1–27–94; 8:45 am]

BILLING CODE 6450–01–P

[FE Docket No. 93–145–NG]

Wisconsin Gas Co.; Long-Term Authorization To Import Natural Gas From Canada

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of order.

SUMMARY: The Office of Fossil Energy of the Department of Energy gives notice that it has granted Wisconsin Gas Company (Wisconsin Gas) authorization to import up to 89,411 Mcf per day of Canadian natural gas beginning December 30, 1993, and continuing through November 1, 2003. This gas would be imported from Western Gas Marketing Limited pursuant to a contract dated October 20, 1993.

Wisconsin Gas order is available for inspection and copying in the Office of Fuels Programs Docket Room, 3F–056, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–9478. The docket room is open between the hours of 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC, January 10, 1993.

Clifford P. Tomaszewski,

Director, Office of Natural Gas, Office of Fuels Programs, Office of Fossil Energy.

[FR Doc. 94–1945 Filed 1–27–94; 8:45 am]

BILLING CODE 6450–01–P

Federal Energy Regulatory Commission

[Docket No. TM94–3–48–002]

ANR Pipeline Co.; Proposed Changes in FERC Gas Tariff

January 24, 1994.

Take notice that on January 14, 1994, ANR Pipeline Company (ANR) tendered for filing as part of its FERC Gas Tariff, Substitute First Revised Sheet No. 164, to be effective January 1, 1994.

ANR states that the above referenced tariff sheet is being filed to replace First Revised Sheet No. 164, filed on December 1, 1993. Such sheet was changed to comply with the conditions of ordering Paragraph (A) of the Commission's Order dated December 30, 1993 that "pipelines should determine new customers' load factor and access the surcharge for each month based on the actual throughput for each prior month of service until a 12-month history is established."

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with 385.211 of the Commission's Rules and Regulations. All such protests should be filed on or before January 31, 1994. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this application are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 94–1808 Filed 1–27–94; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. TM94–3–22–001]

CNG Transmission Corp.; Proposed Changes in FERC Gas Tariff

January 24, 1994.

Take notice that on January 14, 1994, CNG Transmission Corporation (CNG), tendered for filing proposed changes in its FERC Gas Tariff, Second Revised Volume No. 1:

First Revised Sheet No. 345

CNG requests the Commission to allow this tariff sheet to become effective on January 1, 1994.

CNG states that it is filing this sheet as required by the Commission's order dated December 30, 1993, in this proceeding. CNG further states that the effect of this filing is to update CNG's tariff provision describing its calculation of load factors for assessment of the research, development, and demonstration (RD&D) program costs of the Gas Research Institute (GRI), in accordance with the methodology of the "Stipulation and Agreement Concerning Post–1993 GRI Funding Mechanism" (GRI Settlement), as approved by the Commission.

CNG states that copies of the filing were served upon CNG's jurisdictional customers and interested state commissions.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with 385.211 of the Commission's Rules and Regulations. All such protests should be filed on or before January 31, 1994. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection in the public reference room.

Lois D. Cashell,

Secretary.

[FR Doc. 94–1805 Filed 1–27–94; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. TM94–2–51–001]

Great Lakes Gas Transmission Limited Partnership; Proposed Changes in FERC Gas Tariff

January 24, 1994.

Take notice that on January 13, 1994, Great Lakes Gas Transmission Limited Partnership (Great Lakes) tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No. 1, the following revised tariff sheet, proposed to become effective as of January 1, 1994:

Substitute First Revised Sheet No. 7

Great Lakes states that the proposed tariff sheet was filed to reflect Great Lakes' compliance with the Commission's decision in Docket No. TM94–2–51–000 issued on December 30, 1993 (Order).

Great Lakes states that the Commission's Order clarified that historical throughput is to be used for determining the GRI surcharge for both historical and new shippers and that the revised tariff sheet was filed to comply with that clarification. In addition, Great Lakes states that in compliance with the Commission's Order, the revised tariff

sheet included a note indicating that the minimum GRI charge shall be $0.000 per Mcf.

Great Lakes requested that the above tariff sheet become effective as of January 1, 1994, to coincide with the effective date of the GRI funding unit rates approved in the above-described commission Order.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure. All such protests should be filed on or before January 31, 1994. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection in the Commission's public reference room.

Lois D. Cashell,

Secretary.

[FR Doc. 94–1803 Filed 1–27–94; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. TM94–2–46–001]

Kentucky West Virginia Gas Co.; Proposed Changes in FERC Gas Tariff

January 24, 1994.

Take notice that on January 14, 1994, Kentucky West Virginia Gas Company (Kentucky West), tendered for filing with the Federal Energy Regulatory Commission the following tariff sheets to its FERC Gas Tariff, Third Revised Volume No. 1, to become effective January 1, 1994:

Substitute First Revised Sheet No. 162,
Original Sheet No. 162A,
Second Revised Sheet No. 163.

Kentucky West states that the purpose of this filing is to correct the Gas Research Institute tariff sheets to comply with the conditions set forth in the order issued December 30, 1993 by the Commission. Kentucky West has added language to its GRI tariff sheets covering the calculation of load factors for new and existing customers and establishing the minimum GRI surcharge of zero. Sheet No. 163 is being filed to remove Section 28.4 from the page. No other changes to Sheet No. 163 is being made. The changes to Sheet Nos. 162 and 162A affect Sections 28.2, 28.4 and 28.5.

Kentucky West states that, by its filing, or any request or statement made therein, it does not waive any rights to collect amounts, nor the right to collect carrying charges applicable thereto, to which it is entitled pursuant to the mandate of the United States Court of Appeals for the Fifth Circuit issued on March 6, 1986, in Kentucky West Virginia Gas Co. v. FERC, 780 F.2d 1231 (5th Cir. 1986), or to which it becomes entitled pursuant to any other judicial and/or administrative decisions.

Kentucky West states that a copy of its filing has been served upon each of its jurisdictional customer and interested state commissions.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Section 385.211 of the Commission's Rules and Practice and Procedure. All such protests should be filed on or before January 31, 1994. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 94–1801 Filed 1–27–94; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. CP94–177–000]

KN Interstate Gas Transmission Co.; Notice of Request Under Blanket Authorization

January 24, 1994.

Take notice that on January 11, 1994, KN Interstate Gas Transmission Company (KNI), P.O. Box 281304, Lakewood, Colorado 80228, filed in Docket no. CP94–177–000 a request pursuant to §§ 157.205, and 157.212 of the Commission's Regulations under the Natural Gas Act for authorization to install six new delivery taps in Custer, Hall, Adams, Howard and Webster Counties, Nebraska, under its blanket certificate issued in Docket Nos. CP83–140–000 and CP83–140–001, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

Any person or the Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to § 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefor, the proposed activity shall be deemed to be authorized effective the date after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7(c) of the Natural Gas Act.

Lois D. Cashell,

Secretary.

[FR Doc. 94–1797 Filed 1–27–94; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. TM94–2–11–001 and RP94–54–001]

Koch Gateway Pipeline Co.; Proposed Changes in FERC Gas Tariff

January 24, 1994.

Take notice that on January 13, 1994, Koch Gateway Pipeline Company (KGPC) tendered for filing as part of its FERC Gas Tariff, Fifth Revised Volume No. 1, the following tariff sheets to be effective January 1, 1994:

Substitute Original Sheet No. 3201, Original Sheet No. 3202.

KGPC states that the above referenced tariff sheets reflect language additions in compliance with the December 30, 1993 Commission Order Accepting Tariff Changes (65 FERC 61,430). Language detailing the calculation of a new customer's load factor and the minimum GRI surcharge was added.

KGPC also states that the tariff sheets are being mailed to all parties on the official service list created by the Secretary in this proceeding.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426, in accordance with Section 385.211 of the Commission's regulations. All such protests should be filed on or before January 31, 1994. Protests will be considered by the Commission in determining appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 94–1802 Filed 1–27–94; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. TM94–1–92–001]

Mojave Pipeline Co.; Tariff Filing

January 24, 1994.

Take notice that on January 14, 1994, Mojave Pipeline Company (Mojave) tendered for filing as part of its FERC Gas Tariff, First Revised Volume No. 1, its Substitute First Revised Sheet Nos. 11 and 126.

This sheet is being revised in order to implement revisions to Mojave's implementation of its new GRI rates as required by the Commission in an order dated December 30, 1993. As ordered by the Commission, the revised tariff sheets will have an effective date of January 1, 1994.

Mojave states that copies of this filing were served upon all of Mojave's jurisdictional transportation customers.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with 385.211 of the Commission's Rules and Regulations. All such protests should be filed on or before January 31, 1994. Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection in the public reference room.

Lois D. Cashell,

Secretary.

[FR Doc. 94–1800 Filed 1–27–94; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. TM94–2–37–001]

Northwest Pipeline Corporation; Proposed Change in FERC Gas Tariff

January 24, 1994.

Take notice that on January 13, 1994, Northwest Pipeline Corporation (Northwest) tendered for filing as part of its FERC Gas Tariff, the following tariff sheets, with a proposed effective date of January 1, 1994:

Third Revised Volume No. 1

Substitute First Revised Sheet No. 5
Substitute First Revised Sheet No. 5–A
Substitute Original Sheet No. 5–B
Substitute First Revised Sheet No. 18
Sheet No. 223
Original Sheet No. 224
Substitute First Revised Sheet No. 225

Original Volume No. 2

Sixteenth Revised Sheet No. 2.2
Substitute Thirty-Fourth Revised Sheet No. 2.3

Northwest states that the purpose of this filing is to (1) comply with the provisions of the December 29, 1993, Letter Order in Docket No. TM94–2–37–000, (2) make certain other minor revisions to the tariff sheets relating to the Gas Research Institute provisions, and (3) make conforming changes to the provisions of Sheet No. 2.2.

Northwest states that a copy of this filing has been served upon each person designated on the official service list compiled by the secretary in Docket No. TM94–2–37–000 and upon all of Northwest's jurisdictional customers and state regulatory commissions in Northwest's market area.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Section 385.211 of the Commission's Rules of Practice and Procedure. All such protests should be filed on or before January 31, 1994. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection in the public reference room.

Lois D. Cashell,

Secretary.

[FR Doc. 94–1890 Filed 1–27–94; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. TM94–3–28–001]

Panhandle Easter Pipe Line Co.; Proposed Changes in FERC Gas Tariff

January 24, 1994.

Take notice that on January 14, 1994, Panhandle Easter Pipe Line Company (Panhandle) tendered for filing as part of its FERC Gas Tariff, First Revised Volume No. 1, the following revised tariff sheets:

Substitute Third Revised Sheet No. 4
Substitute Third Revised Sheet No. 5
Substitute Third Revised Sheet No. 6
Substitute Third Revised Sheet No. 7
Substitute Third Revised Sheet No. 8
Substitute First Revised Sheet No. 290

Panhandle proposes that these tariff sheets become effective January 1, 1994.

Panhandle states that such revised filing reflects compliance with Ordering Paragraph (A) of the "Order Accepting Tariff Sheets Subject to Conditions" (order), issued in the above-referenced proceeding on December 30, 1993. The order required Panhandle to make certain modifications to the tariff sheets previously submitted. Thus, Section 18.1 of the General Terms and Conditions has been modified to define the method of calculating load factors for new customers. In addition, as required by the Order, Panhandle has clarified the rate tariff sheets to reflect that the minimum GRI surcharge is zero.

Panhandle states that copies of this filing have been served on all affected customers subject to the applicable tariff sheets and applicable state regulatory commissions.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Section 385.211 of the commission's Rules and Regulations. All such protests should be filed on or before January 31, 1994. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection in the public reference room.

Lois D. Cashell,

Secretary.

[FR Doc. 94–1807 Filed 1–27–94; 8:45 am]

BILLING CODE 6717–01–M

[Docket Nos. RP94–66–002, RP93–125–000, RP93–181–000 and 002]

Texas Eastern Transmission Corp.; Proposed Changes in FERC Gas Tariff

January 24, 1994.

Take notice that as required by the Commission's Order December 30, 1993 Order in Docket Nos. RP94–66–000, *et al.* (December 30 Order), Texas Eastern Transmission Corporation (Texas Eastern) on January 14, 1994, submitted for filing as part of its FERC Gas Tariff, Sixth Revised Volume No. 1, the tariff sheets listed on Appendix A of the filing.

Texas Eastern states that the December 30 Order accepted tariff sheets filed on December 1, 1993 (December 1 Filing) by Texas Eastern to recover gas supply realignment costs (GSR Costs). The December 1 Filing was Texas Eastern's third quarterly filing to recover such costs and was filed pursuant to section 15.2(C) of the General Terms and Conditions of Texas Eastern's FERC Gas Tariff, Sixth Revised Volume No. 1. Ordering Paragraph (A) of the December 30 Order required certain tariff sheets be "refiled within fifteen days of this order to conform to the conditions set forth in the body of this order, and the ordering paragraphs below." Texas Eastern states that the

tariff sheets listed in Appendix A are submitted to satisfy the requirements of the December 30 Order.

Texas Eastern states that section 15.2(C) of the General Terms and Conditions has been revised in compliance with the December 30 Order as follows:

(1) Section 15.2(C)(2)(a) has been revised to extend the amortization and recovery period to two (2) years for buyout costs which are incurred after January 1, 1994 and which, in the aggregate, exceed fifteen (15) million dollars for a quarterly filing;

(2) Section 15.2(C)(2)(a)(i) has been revised to reflect that applicable customers under Rate Schedules CDS, FT–1, LLFT and VKFT will be billed each month for a GSR Demand Surcharge Amount calculated by multiplying their current MDQ for a month times the GSR Demand Surcharge rate;

(3) Section 15.2(C)(2)(a)(ii) has been revised to reflect that with the exception of the GSR Demand Surcharge component already designed to be paid over twenty-four (24) months, each customer shall have the option of paying its GSR Demand Surcharge obligation for any quarter in twenty-four (24) monthly installments.

(4) Section 15.2(C)(2)(a)(iv) has been revised to clarify that the payment obligation for the GSR Demand Surcharge Amounts, together with applicable carrying charges, accrues in full as of the close of the month in which service was provided.

(5) Section 15.2(C)(5) has been added to reflect an annual true-up, as of any twelve (12) month period ending June 30, of the recovery of GSR costs allocated to be recovered from customers under Rate Schedules CDS, FT–1, LLFT and VKFT.

Texas Eastern states that pursuant to section 15.2(C) of the General Terms and Conditions, ninety percent (90%) of GSR Costs are allocated to customers under Texas Eastern's Rate Schedules CDS, FT–1, LLFT, and VKFT in the form of a CSR Demand Surcharge calculated using customer MDQs. Texas Eastern's December 1 Filing allocated $12,701,656 of GSR Costs, inclusive of prior period adjustments and carrying charges, to its customers under Rate Schedules CDS, FT–1, LLFT and VKFT. However, Texas Eastern states that total customer MDQs under Rate Schedules CDS, FT–1, LLFT and VKFT have changed slightly since the December 1 Filing. Attachment A details the calculation of the new GSR Demand Surcharge unit rate based upon MDQs effective January 1, 1994. As a result, Texas Eastern submits Sub Sixth Revised Sheet No. 25, Sub Sixth Revised Sheet No. 30, Sub Third Revised Sheet No. 34A, Sub Third Revised Sheet No. 34B, Sub Third Revised Sheet No. 42A, and Sub Second Revised Sheet No. 42B to reflect this slight change in total firm customer MDQs. Texas Eastern states that the rates for Rate Schedules IT–1, PTI, LLIT and VKIT are not impacted by the slight change in total firm customer MDQs.

The proposed effective date of the tariff sheets is January 1, 1994, consistent with the December 30 Order or the effective date of the tariff sheets they replace.

Texas Eastern states that copies of the filing were served on firm customers of Texas Eastern and interested state commission. Copies were also served on all parties to Docket No. RP94–66–000.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capital Street, NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure. All such protests should be filed on or before January 31, 1994. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 94–1799 Filed 1–27–94; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. TM94–3–17–001]

Texas Eastern Transmission Corp.; Proposed Changes in FERC Gas Tariff

January 24, 1994.

Take notice that on January 14, 1994 Texas Eastern Transmission Corporation (Texas Eastern) submitted for filing as part of its FERC Gas Tariff, Sixth Revised Volume No. 1 and Original Volume No. 2, the tariff sheets listed on Appendix A of the filing.

Texas Eastern states that ordering Paragraph (A) of the Order Accepting Tariff Sheets Subject to Conditions (Order), issued in the above referenced proceeding on December 30, 1993, required it to make certain modifications to the tariff sheets previously submitted by Texas Eastern on November 29, 1993 to establish the revised Gas Research Institute (GRI) surcharges effective January 1, 1994.

Texas Eastern states that in compliance with the Order, Section 15.4 of the General Terms and Conditions has been modified to define the method of calculating load factors for firm customers without a historical load factor for purposes of the GRI Surcharge. In addition, as required by the Order, Texas Eastern states that it has added a column to the affected rate sheets to reflect that the minimum GRI Surcharge is zero.

The proposed effective date of the tariff sheets is January 1, 1994, consistent with the Order in this proceeding and the effective date of the tariff sheets they replace.

Texas Eastern states that copies of the filing were served on firm customers of Texas Eastern and interested state commissions. Copies were also served on all parties to Docket No. TM94–3–17–000.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure. All such protests should be filed on or before January 31, 1994. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 94–1804 Filed 1–27–94; 8:45 am]

BILLING CODE 6717–01–M

[Docket Nos. RP94–59–000, RP94–46–001 and RP94–27–000]

Transcontinental Gas Pipe Line Corp. Technical Conference

January 24, 1994.

In the Commission's order issued on December 17, 1993, in the above-captioned proceeding, the Commission held that the filing raises issues for which a technical conference is to be convened. The conference to address the issues has been scheduled for Thursday, February 3, 1994 at 10 a.m. in a room to be designated at the offices of the Federal Energy Regulatory Commission, 810 First Street NE., Washington, DC 20426.

All interested persons and Staff are permitted to attend.

Lois D. Cashell,

Secretary

[FR Doc. 94–1798 Filed 1–27–94; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. TM94-6-29-001]

Transcontinental Gas Pipe Line Corp.; Tariff Filing

January 24, 1994.

Take notice that on January 14, 1994, Transcontinental Gas Pipe Line Corporation (TGPL) tendered for filing revised tariff sheets to its FERC Gas Tariff, Third Revised Volume No. 1, which tariff sheets are contained in Appendix A attached to the filing. The proposed effective date of such tariff sheets is January 1, 1994.

TGPL states that the purpose of the instant filing is to comply with the Commission's order issued December 30, 1993 in the referenced docket (December 30 Order). The December 30 Order accepted, subject to conditions, TGPL's tariff filing of December 1, 1993 (December 1 Filing) wherein TGPL proposed to establish the revised Gas Research Institute (GRI) surcharges effective January 1, 1994.

TGPL states that copies of the instant filing are being mailed to customers, State Commissions and other interested parties.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with 385.211 of the Commission's Rules and Regulations. All such protests should be filed on or before January 31, 1994. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection in the public reference room.

Lois D. Cashell,

Secretary.

[FR Doc. 94-1809 Filed 1-27-94; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. TM94-3-30-001]

Trunkline Gas Co.; Proposed Changes in FERC Gas Tariff

January 24, 1994.

Take notice that on January 14, 1994, Trunkline Gas Company (Trunkline) tendered for filing as part of its FERC Gas Tariff, First Revised Volume No. 1, the following revised tariff sheets:

Sub First Revised Sheet No. 216
Sub First Revised Sheet No. 217

Trunkline proposes that these revised tariff sheets become effective January 1, 1994.

Trunkline states that Ordering Paragraph (A) of the Commission's "Order Accepting Tariff Sheets Subject to Conditions" (Order), issued in the above-referenced proceeding on December 30, 1993, required Trunkline to make certain modifications to the tariff sheets previously submitted. As required by the Order, Section 20 (Gas Research Institute (GRI) Surcharge Provision) of the General Terms and Conditions has been modified to define the method of calculating load factors for new customers.

Trunkline states that it has served a copy of the filing on its jurisdictional customers, interested state commissions and parties to the proceeding in the above-referenced docket number.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure 18 CFR 385.211. All such protests should be filed on or before January 31, 1994. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 94-1806 Filed 1-27-94; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. CP91-2778-001]

Valero Transmission, L.P.; Petition to Amend

January 24, 1994.

Take notice that on January 11, 1994, Valero Transmission, L.P. (Valero), P.O. Box 500, San Antonio, Texas 78215, filed an application in Docket No. CP91-2778-001, pursuant to Section 3 of the Natural Gas Act (NGA), 15 U.S.C. 717b, part 153 of the Commission's Regulations, Executive Order Nos. 10485 and 12038, and the Secretary of Energy's Delegation Order No. 0204-112. Valero seeks to amend its Presidential Permit and prior authorizations granted in Docket No. CP91-2778-000[1] to permit the use of its existing facilities at the United States-Mexico Border for the importation, as well as exportation of natural gas. Valero's request is more fully set forth in the application on file with the Commission and open to public inspection.

Valero states that the facilities are currently being used to export natural gas to Mexico. Valero states that the opening-up of these facilities to a two-way gas trade will provide needed flexibility to respond to changing market conditions. Valero indicates that its border facilities will be available on an "open-access" basis to any shipper/supplier with authorization from the Department of Energy (DOE) to import or export natural gas from or to Mexico. Finally, Valero states that the switch to two-way gas trade will not require the construction of any additional facilities. Therefore, there will be no adverse environmental impact associated with the approval of its application.

Any person desiring to be heard or to make any protest with reference to said petition to amend should on or before February 7, 1994, file with the Federal Energy Regulatory Commission, Washington, DC 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 384.214 or 385.211) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Lois D. Cashell,

Secretary.

[FR Doc. 94-1796 Filed 1-27-94; 8:45 am]

BILLING CODE 6717-01-M

ENVIRONMENTAL PROTECTION AGENCY

[FRL-4829-9]

Region 10; Notice of Issuance of PSD/OCS Permit to ARCO Alaska, Incorporated

Notice is hereby given that on December 14, 1993, the Environmental Protection Agency (EPA) issued a Prevention of Significant Deterioration (PSD) and Outer Continental Shelf (OCS) permit to ARCO Alaska, Incorporated to conduct exploratory oil well drilling in the Beaufort Sea, Alaska.

This PSD/OCS permit has been issued under EPA's Prevention of Significant Deterioration (40 CFR 52.21) and Outer Continental Shelf (40 CFR part 55) regulations, subject to certain conditions specified in the permit.

This final permit decision shall become effective on February 28, 1994 unless review is requested under 40 CFR 124.19.

Petition for review of this final PSD/OCS permit decision must be filed by February 28, 1994 in accordance with 40 CFR 124.19.

Copies of the PSD/OCS permit and administrative record are available for public inspection upon request at the following location: Environmental Protection Agency, Region 10, 1200 Sixth Avenue, M/S AT–082, Seattle, Washington 98101.

FOR FURTHER INFORMATION CONTACT: Ray Nye at (206) 553–4226.

Dated: January 19, 1994.

Gerald A. Emison,

Acting Regional Administrator.

[FR Doc. 94–1966 Filed 1–27–94; 8:45 am]

BILLING CODE 6560–50–P

[FRL–4831–2]

Public Water Supply Supervision Program Revision for the State of Florida

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Notice is hereby given that the State of Florida is revising its approved State Public Water Supply Supervision Primacy Program. Florida has adopted drinking water regulations for Lead and Copper, and Phase II (IOCs/SOCs). EPA has determined that these sets of State program revisions are no less stringent than the corresponding Federal regulations. Therefore, EPA has tentatively decided to approve these State program revisions in accordance with the conditions set forth in the December 22, 1993 letter from the Florida Department of Environmental Protection to the USEPA, Region IV.

All interested parties may request a public hearing. A request for a public hearing must be submitted by March 17, 1994 to the Regional Administrator at the address shown below. Frivolous or insubstantial requests for a hearing may be denied by the Regional Administrator. However, if a substantial request for a public hearing is made by March 17, 1994, a public hearing will be held. If no timely and appropriate request for a hearing is received and the Regional Administrator does not elect to hold a hearing on his own motion, this determination shall become final and effective on March 17, 1994.

Any request for a public hearing shall include the following information:

(1) The name, address, and telephone number of the individual organization, or other entity requesting a hearing;

(2) A brief statement of the requesting person's interest in the Regional Administrator's determination and a brief statement of the information that the requesting person intends to submit at such hearing; and

(3) The signature of the individual making the request, or, if the request is made on behalf of an organization or other entity, the signature of a responsible official of the organization or other entity.

ADDRESSES: All documents relating to this determination are available for inspection between the hours of 8 a.m. and 4:30 p.m., Monday through Friday, at the following offices:

Florida Department of Environmental Protection, Twin Towers Office Building, 2600 Blair Stone Road, Tallahassee, Florida 32399–2400.

Environmental Protection Agency, Region IV, 345 Courtland Street, NE., Atlanta, Georgia 30365.

FOR FURTHER INFORMATION CONTACT: Philip H. Vorsatz, EPA Region IV Drinking Water Section at the Atlanta address given above or telephone (404) 347–2913.

Authority: (Section 1413 of the Safe Drinking Water Act, as amended (1986), and 40 CFR 142.10 of the National Primary Drinking Water Regulations).

Dated: January 14, 1994.

Patrick M. Tobin,

Acting Regional Administrator, EPA, Region IV.

[FR Doc. 94–1964 Filed 1–27–94; 8:45 am]

BILLING CODE 6560–50–F

[ER-FRL–4707–8]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 260–5076 OR (202) 260–5075. Weekly receipt of Environmental Impact Statements Filed January 17, 1994 Through January 21, 1994 Pursuant to 40 CFR 1506.9.

EIS No. 940013, Final EIS, FAA, TX, New Austin Airport at Bergstrom Air Force Base (AFB) 1993 Master Plan, Approval, Funding, Property Acquisition and Construction, City of Austin, Travis County, TX, Due: February 28, 1994, Contact: Bill Perkins (817) 222–5652.

EIS No. 940014, Draft EIS, COE, NC, Texasgulf Open Pit Mine Continuation, Construction and Operation, Permits Approval, Pamlico River, Aurora, Beaufort County, NC, Due: March 14, 1994, Contact: Hugh Heine (919) 251–4070.

Amended Notices

EIS No. 930397, Revised Draft EIS, FAA, MN, Minneapolis-St. Paul International Airport, Runway 4–22 Extension, Revised Information and Funding, Wold-Chamberlain Field, Hennepin County, MN, Due: February 18, 1994, Contact: Glen Orcutt (612) 725–4221. Published FR—11–19–93—Review period extended.

EIS No. 930460, Final EIS, FHW, CA, CA–87/Guadalupe Parkway Upgrading, between Julian Street and US 101 in the City of San Jose, Funding and Section 404 Permit, Santa Clara County, CA, Due: February 07, 1994, Contact: John R. Schultz (916) 551–1314. Published FR—1–7–94—Due Date Correction

Dated: January 24, 1994.

William D. Dickerson,

Deputy Director, Office of Federal Activities.

[FR Doc. 94–1961 Filed 1–27–94; 8:45 am]

BILLING CODE 6560–50–P

[ER-FRL–4707–9]

Environmental Impact Statements and Regulations; Availability of EPA Comments

Availability of EPA comments prepared January 10, 1994 Through January 14, 1994 pursuant to the Environmental Review Process (ERP), under section 309 of the Clean Air Act and section 102(2)(c) of the National Environmental Policy Act as amended. Requests for copies of EPA comments can be directed to the Office of Federal Activities at (202) 260–5076.

An explanation of the ratings assigned to draft environmental impact statements (EISs) was published in FR dated April 10, 1993 (58 FR 18392).

Draft EISs

ERP No. D-AFS-K65153–00 Rating EC2, Klamath National Forest Land and Resource Management Plan, Implementation, Siskyou Co., CA and Jackson Co., OR.

Summary: EPA expressed environmental concerns for air quality impacts, cumulative impacts (including impacts on non-federal lands), and treatment of old-growth forest stands on nonrestricted lands. EPA urged the Forest Service to provide sufficient opportunity for review of the Plan in relation to the Spotted Owl FSEIS so as to determine the specific management prescriptions for and impacts to the forest.

ERP No. D-AFS-K65154–CA Rating EC2, Mendocine National Forest Land

and Resource Management Plan, Implementaton, Colusa, Glenn, Lake, Mendocino, Tehama and Trinity Counties, CA.

Summary: EPA expressed environmental concerns for air quality impacts, cumulative impacts (including impacts on non-federal lands), and treatment of old-growth forest stands on nonrestricted lands. EPA urged the Forest Service to provide sufficient opportunity for review of the Plan in relation to the Spotted Owl FSEIS so as to determine the specific management prescriptions for and impacts to the forest.

ERP No. D-AFS-K65155–CA Rating EC2, Six Rivers National Forest Land and Resource Management Plan, Implementation, Humboldt, Trinity, Del Norte and Siskiyou Counties, CA.

Summary: EPA expressed environmental concerns for air quality impacts, and water quality. EPA urged the Forest Service to provide sufficient opportunity for review of the Plan in relation to the Spotted Owl FSEIS so as to determine the specific management prescriptions for and impacts to the forest.

ERP No. D-AFS-K65156–CA Rating EC2, Shasta-Trinity National Forests Land and Resource Management Plan, Implementation, Humboldt, Modoc, Shasta, and Siskiyou, Tehama and Trinity Counties, CA.

Summary: EPA expressed environmental concerns for air quality impacts, and minerals management. EPA urged the Forest Service to provide sufficient opportunity for review of the Plan in relation to the Spotted Owl FSEIS so as to determine the specific management prescriptions for and impacts to the forest.

ERP No. DS-NPS-K61085–00 Rating EC2, Lake Mead National Recreation Area, General Management Plan, Updated Information on Willow Beach Development Concept Plan Amendment, Implementation, AZ and CA.

Summary: EPA expressed environmental concerns regarding project impacts to water quality. EPA request that additional information be included in the final document on minimization and mitigation of impacts to waters of the US and nonpoint source water pollution control measures.

Final EISs

ERP No. F-AFS-L60097–ID, Spruce Creek Timber Sale, Implementation, Boise National Forest, Valley County, ID.

Summary: Review of the Final EIS has been completed and the project found to be satisfactory. No formal letter was sent to the preparing agency.

ERP No. F-AFS-L65194–ID, Mid-Skull/Upper Bear Timber Sales, Timber Harvest, Road Construction and Reconstruction, Clearwater National Forest, North Fork Ranger District, Skull Creek, Clearwater County, ID.

Summary: Review of the Final EIS has been completed and the project found to be satisfactory. No formal letter was sent to the preparing agency.

ERP No. F-BLM-G02001–NM, Dark Canyon Special Management Area, Oil and Gas Leasing, Permit for Approval to Drill near Carlsbad Caverns National Park, Eddy County, NM.

Summary: EPA had determined that the Final EIS adequately assesses potential impacts to cave resources as well as the reasonable foreseeable development of oil and gas resources. EPA had no objection to the selection of the preferred alternative.

ERP No. F-BLM-K67017–NV, Newmont Gold Quarry Open-Pit Mine and Ore Processing Facility Expansion and Operation, Plan of Operation Approval, NPDES and COE Section 404 Permits, Eureka and Elko Counties, NV.

Summary: EPA expressed continued environmental concern regarding project impacts to groundwater, streams, springs, wetlands and riparian areas and how these impacts will be sufficiently mitigated and monitored.

ERP No. F-DOE-L61195–AK, Healy 50 Megawatt-Electric Coal Fired Power Plant Construction and Operation, Clean Coal Technologies Demonstration, Funding, NPDES and Section 404 Permits, Borough of Denali, AK.

Summary: Review of the Final EIS has been completed and the project found to be satisfactory. No formal letter was sent to the preparing agency.

Dated: January 25, 1994.

William D. Dickerson,

Deputy Director, Office of Federal Activities.

[FR Doc. 94–1962 Filed 1–27–94; 8:45 am]

BILLING CODE 6560–50–U

[FRL–4831–1]

Environmental Leadership Program: Update

EPA announces the next steps in the development of the Environmental Leadership Program (ELP). After reviewing many possible options, the Agency has decided to proceed with pilot projects to test the feasibility of a voluntary program to recognize industrial facilities. The pilots will explore ways to encourage facilities to develop innovative audit and compliance programs and to reduce the risk of non-compliance through pollution prevention practices.

The wide variety of public comments on the original ELP proposal (published in the Federal Register on January 15, 1993) clearly indicated an interest in a program to recognize and encourage "environmental excellence." While no true consensus emerged on the best structure or goals for the program, several themes were common to the majority of the comments:

- EPA should encourage companies and facilities of all sizes and from all industries to participate in the program.
- EPA should focus its program on individual facilities rather than on entire corporations.
- Any EPA-developed statement of environmental principles would duplicate existing private-sector efforts and would be difficult to enforce.

In response to these comments, EPA has decided to continue developing a voluntary, facility-based program. The Agency will develop pilot projects with specific industries and states to evaluate the many unresolved issues raised during the comment period. These include a possible multiple-tier structure to encourage broad participation, determining the role of compliance, self-reporting of violations, public accountability, the role of incentives in encouraging companies to exceed minimum requirements, and how pollution prevention practices can help facilities reduce or avoid the risk of non-compliance.

EPA Deputy Administrator Bob Sussman and Steve Herman, the Assistant Administrator for the Office of Enforcement and Compliance Assurance (OECA) have been asked to coordinate this effort. The Agency will provide more information on the process for selecting pilot participants and on the development of test projects in the early spring of 1994. The Office of Compliance within OECA will be responsible for this process. Please call Mike Schiavo at (202) 260–2824 for more information.

Also in response to the comments, the Agency has concluded that it will not issue its own guidelines for corporate environmental principles, but rather work cooperatively with the many other organizations that have developed corporate and industry-wide codes of environmental conduct. The Office of Pollution Prevention and Toxics will take responsibility for representing the Agency in this area, and for ensuring the involvement of other EPA offices where appropriate. Please call David Kling at (202) 260–3557 for more information. EPA thanks all of those who have expressed an interest in the ELP concept

and looks forward to making this program an exciting and effective approach to pollution prevention and compliance.

Dated: January 14, 1994.

Carol M. Browner,

Administrator.

[FR Doc. 94–1953 Filed 1–27–94; 8:45 am]

BILLING CODE 6560–50–P

[FRL–4828–5]

Environmental Technology; U.S. EPA Technology Innovation Strategy and U.S. EPA Environmental Technology Initiative FY 1994 Program Plan

AGENCY: Environmental Protection Agency.

ACTION: Notice of availability, request for comment and invitation to become a project partner.

SUMMARY: Notice is hereby given that the U.S. Environmental Protection Agency's (EPA) draft Technology Innovation Strategy (S/N 055–000–00466–8), is available for review and comment. EPA is seeking public comments on the draft Strategy by March 14, 1994. To identify parties interested in the President's Environmental Technology Initiative, EPA is also releasing the Environmental Technology Initiative: Fiscal Year 1994 (FY 1994) Program Plan (S/N 055–000–00465–8) which identifies 73 projects that EPA and other agencies and organizations are initiating to implement the Initiative. Copies of both documents are available through the U.S. Government Printing Office.

ADDRESSES: Copies of the Technology Innovation Strategy (S/N 055–000–00466–8) or Environmental Technology Initiative: FY 1994 Program Plan (S/N 055–000–00465–8) are available from the nearest government bookstore, the Government Printing Office phone order information desk (202/783–3238) or by requesting an order form by FAX (202/512–2250). Mail orders may be addressed to the: Superintendent of Documents, U.S. Government Printing Office, P.O. Box 371954, Pittsburgh, Pennsylvania 15250–7954. When ordering, please identify the document's title and indicate the Government Printing Office publication number.

Comments on the Technology Innovation Strategy should be mailed to: Strategy Committee, Innovative Technology Council, Mail Code 2111, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460. Comments on the Strategy will be accepted until March 14, 1994. EPA is planning to convene three public hearings on the Strategy, in Washington, DC, Chicago, Illinois and San Francisco, California. Specific dates and locations for these hearings will be announced in a future **Federal Register** notice.

FOR FURTHER INFORMATION CONTACT: Mr. Brendan Doyle, Office of Policy, Planning and Evaluation (2127), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460, (202) 260–3354, or one of the EPA regional office contacts listed below:

Barbara Brown, U.S. EPA Region 1, One Congress Street—RAA, Boston, MA 02203–2211, Tel #: 617–565–3397.

Pat Lafornara, U.S. EPA Region 2, 2890 Woodbridge Avenue, Raritan Depot Building 10—MS 100, Edison, NJ 08837–3679, Tel #: 908–906–6988.

Norm Kulujian, U.S. EPA Region 3, 841 Chestnut Street, Philadelphia, PA 19107, Tel #: 215–597–1113.

Bob Jourdan, U.S. EPA Region 4, 345 Courtland Street, NE—4WNSRB, Atlanta, GA 30365, Tel #: 404–347–7791.

Mike Lin, U.S. EPA Region 5, 77 West Jackson Boulevard—WQ–16J, Chicago, IL 60604–3590, Tel #: 312–886–6104.

Norman Dyer, U.S. EPA Region 6, 1445 Ross Avenue, 12th Floor, Suite 1200, Dallas, TX 75202–2733, Tel #: 214–655–8349.

Jody Hudson, U.S. EPA Region 7, 25 Funston Road, Kansas City, KS 66115,Tel #: 913–551–5064.

Dave Smith, U.S. EPA Region 8, 999 18th Street, Suite 500, Denver, CO 80202–2466, Tel #: 303–293–1475.

Winona Victery, U.S. EPA Region 9, 75 Hawthorne Street, San Francisco, CA 94105, Tel #: 415–744–1021.

John Barich, U.S. EPA Region 10, 1200 6th Avenue—ES–098, Seattle, WA 98101, Tel #: 206–553–8562.

EPA's Technology Innovation Strategy

The Environmental Protection Agency's (EPA) Innovative Technology Council, comprised of EPA management and staff from across the Agency, has drafted a strategy to focus and target its efforts to accelerate environmental technology development, commercialization and use. The Council recognizes a need to accelerate the development, commercialization, and use of innovative environmental technologies to maintain and improve environmental quality at home and abroad into the 21st century. Environmental quality would deteriorate, given foreseeable population growth and industrialization, unless technology is developed and more broadly applied, that is more effective in preventing and reducing pollution levels, less costly than existing technology and supportive of sustainable development. EPA, state and local agencies are in a unique position to influence the rate and focus of environmental technology innovation and use because of their legislative and programmatic mandates and regulatory responsibilities (which often influence the demand for environmental technologies, goods and services).

In funding the President's Environmental Technology Initiative, the House Committee on Appropriations directed EPA, "* * * to develop a comprehensive environmental technology strategy characterized by innovation and a nonbureaucratic approach." [1]

EPA's draft Strategy provides a plan to directly and indirectly support private sector innovation and diffusion activities sponsored by the public and private sector and close coordination among Federal agencies. It focuses on creating incentives for the development and use of innovative technologies in federal and state environmental regulations, reducing barriers to technology innovation and use, and improving the competitiveness of the environmental technology industry in domestic and international markets. EPA and other Federal, state and local agencies, universities, trade associations and consortia, and numerous private companies are already working in many of the areas identified in the Strategy. EPA is seeking public comment on the Strategy to focus and target efforts to accelerate environmental technology development, commercialization and use. The Agency's Innovative Technology Council plans to revise and update the Strategy based on the comments received.

The definition of "environmental technologies" being addressed in the Strategy varies widely for a number of reasons. The "environmental technology industry" has only recently become a focal point for market analysts and policy-makers, and it is highly diversified in terms of the current demand for and supply of technologies, goods and services. Demand often varies based on local environmental conditions. "Environmental technologies" include technologies, goods, and services whose development is triggered primarily by environmental improvement objectives. Sometimes referred to as "dark green" technologies, these include: products and services to monitor and assess pollutant releases

[1] House of Representatives, 103rd Congress, Committee on Appropriations report, June 22, 1993, Report 103–150, p. 47.

and exposure levels; innovative technologies which prevent pollution, control air and water pollution levels, and remediate contaminated soil and groundwater; and, manage environmental data. EPA's Strategy also addresses "light green" technologies that are developed primarily for non-environmental reasons; those technologies can have indirect, but important consequences for improving environmental quality. An example, would be local area computer networks designed to enhance office communication, but which also reduce paper use.

EPA is interested in promoting all phases of technological change such as: the research and development of new concepts; preliminary design testing and pilot applications of evolving technologies; performance demonstrations and testing; evaluations of early commercial applications; and diffusion into domestic and international markets.

The draft "Technology Innovation Strategy" outlines the general principles that guide EPA in its efforts to foster innovation in its existing programs and new projects being initiated under the President's Environmental Technology Initiative (see below). It outlines four objectives:

1. Adapt EPA's policy, regulatory, and compliance framework to promote innovation;
2. Strengthen the capacity of technology developers and users to succeed in environmental technology innovation;
3. Strategically invest EPA funds in the development and commercialization of promising new technologies; and,
4. Accelerate diffusion of innovative technologies at home and abroad.

EPA invites comments on the draft Strategy and the following questions:

(1) What roles are appropriate for EPA to play in stimulating the development and use of innovative technological solutions to environmental problems?

(2) Do you agree with the Strategy's objectives and with EPA's approaches to achieving them? Which objectives should receive the highest priority for action?

(3) Are there additional areas of emphasis that EPA should address in planning and funding its technology development, commercialization, and diffusion activities?

(4) Are there particular environmental technology needs or impediments to development on which you feel the Agency should focus more of its attention?

(5) How do you propose that EPA measure the success of its efforts?

Technology Program Focus Areas for FY 1995

The *Technology Innovation Strategy* will be used to guide the Agency's planning and budgeting for specific projects in both base programs and under the President's Environmental Technology Initiative during this fiscal year and in future years. The *Environmental Technology Initiative (ETI) FY 1994 Program Plan*, described later in this notice, provides detailed descriptions of the ETI budget themes and projects being funded this fiscal year. Planning for FY 1995 is now underway and EPA is interested in receiving comments from the public on specific focus areas that should be emphasized in funding projects next year. These focus areas may be within the broad context of an entire technology innovation area or may be specific to one facet of EPA's *Strategy*. An example of a broad focus area recommendation would be the need for EPA assistance in all aspects of encouraging the development and use of more cost-effective technologies for small businesses. An example of a focus area recommendation specific to one part of the *Strategy* (e.g., Objective #2) would be the need for EPA to help assure the quality and credibility of performance data for new technologies by creating more locations for safe technology testing.

The President's Environmental Technology Initiative

In his State of the Union speech on February 17, 1993, President Clinton outlined a new initiative to improve environmental quality and strengthen the American economy. The goal of the President's Environmental Technology Initiative (ETI) is to spur the development and use of more advanced environmental systems and treatment techniques that can yield domestic environmental benefits and increase exports of American technologies to other countries. "Dark green" environmental technologies are being emphasized in the Initiative that is, technologies, goods, and services whose development is triggered primarily by environmental improvement objectives. "Dark green" technologies include: products and services to monitor and assess pollutant releases and exposure levels; innovative technologies which prevent pollution, control air and water pollution levels, and remediate contaminated soil and groundwater; and, manage environmental data. The Initiative is funded at $36 million in FY 1994 and, in the President's plan, is to be funded at $80 million in FY 1995, with overall funding projected to be $1.8 billion over nine years. In approving funding for Fiscal Year 1994, the Senate Appropriations Committee instructed the Agency to develop a detailed program plan[2]. Today, EPA is announcing the availability of the *Environmental Technology Initiative: FY 1994 Program Plan (S/N 055–000–00465–8)* which describes 73 specific projects that will be initiated by the end of September, 1994. These projects span four general areas outlined below:

1. Accelerating the development and use of innovative environmental and restoration technologies;
2. Fostering clean technologies through pollution prevention for small businesses;
3. Fostering the use of U.S. technologies to solve international environmental problems;
4. Defining technology gaps, and identifying barriers to, and incentives for developing and commercializing environmental technologies.

The Program Plan released today is not a solicitation or request for proposals for grants or contracts from EPA. It describes the nature and scope of work in each project area and invites interested parties to contact individual project managers, especially if they are working on a similar project or they are interested in becoming a project partner. Project managers will, in turn, be developing partnerships among interested parties who can share in the projects' activities and results. EPA anticipates that federal agencies, state and local governments, tribes, educational institutions, non-profit and not-for profit entities, and private sector parties may be interested in discussing partnership opportunities. By this approach, EPA is seeking to engage and leverage the creativity, expertise, and resources of other government agencies and the private sector in areas of mutual interest.

Both the Administration and the Congress have stressed the need for partnerships that provide both direct support to private sector innovation and close coordination with other Federal agencies. These partnerships may take many forms. For example, in the "Clean Car Technology Demonstration Program" (Project No. 11), EPA's National Vehicle and Fuel Emissions laboratory and Office of Air and Radiation, the Department of Energy, and the National Institute for Science and Technology, other Federal laboratories, and domestic

[2] U.S. Senate, 103rd Congress, Appropriations Committee report 103–137, September 9, 1993, p. 105, Washington, DC.

manufacturers are demonstrating ways to improve passenger car and light truck fuel economy and technologies which lower carbon dioxide emissions. To promote technologies that prevent pollution in small businesses, EPA, the International Fabricare Institute, Neighborhood Cleaners Association, Greenpeace, and the Occupational Health Foundation are working on dry and wet cleaning technologies that do not use perchloroethylene (Project No. 33). To improve the U.S. environmental technology industry's competitiveness abroad, EPA, the Agency for International Development, the U.S. Trade and Development Agency, the Export-Import Bank and the Overseas Private Investment Corporation are proposing ways to demonstrate the performance of pollution control, monitoring and pollution prevention technologies globally and at sites to be selected in Asia, Central or Eastern Europe or Mexico (Project No. 53).

For some projects, EPA may transfer funding to another Federal agency that will match those funds with funds of their own or with those of a private sector partner. Not all collaborative efforts, however, may entail transfers of funding among Federal partners or private partners. Rather, EPA is more interested in finding partners who can offer collaboration, resources and expertise to make each project a success. Many partnership opportunities are available. For example:

—Developing technologies to depolymerize/repolymerize plastics for recycling (Project No. 4);
—Changing to cleaner processes in plating and metal finishing that reduce the use of toxic chemicals, generate less waste, and reduce energy and natural resource consumption (Project No. 5);
—Piloting applications of advanced adsorption technologies that can filter wastewater, drinking water and contaminated groundwater and clean-up polluted aquatic ecosystems (Project No. 7);
—Developing alternative surface cleaning technologies to replace products and systems using hazardous chemicals or volatile organic solvents that pose health or environmental risks (Project No. 8);
—Evaluating techniques that are used to reduce metallic ores to base metals for applications in managing solid and hazardous wastes (Project No. 18);
—Demonstrating supercritical carbon dioxide extraction technologies that reduce reliance on toxic solvents and the generation of hazardous wastestreams (Project No. 19);
—Documenting the performance of soil washing as an alternative remedial technology for cleaning up contaminated sites (Project No. 20);
—Demonstrating pilot-scale chemical dechlorination by the recently-licensed, base-catalyzed decomposition process to clean-up soils contaminated with PCBs, pentachlorophenol, and chlorinated insecticides and herbicides (Project No. 23); and,
—Developing and demonstrating new metalforming technologies to find substitutes for toxic chlorinated solvents, cyanides and cadmium that prevent pollution and reduce the generation of hazardous wastestreams (Project No. 38).

Parties interested in these or any other projects, or becoming a project partner, may contact the project manager identified in the *FY 1994 Program Plan*. Project managers are interested in hearing from those who are working on similar projects; those who are interested in offering expertise, experience, test sites or other resources; and, those who are qualified to comment on the technical aspects of each project's value, significance and appropriateness.

Dated: January 21, 1994.

David M. Gardiner,

Assistant Administrator for Policy, Planning and Evaluation.

[FR Doc. 94–1739 Filed 1–27–94; 8:45 am]

BILLING CODE 6560–50–P

[OPPTS–44605; FRL–4754–4]

TSCA Chemical Testing; Receipt of Test Data

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the receipt of test data on acrylic acid (CAS No. 79–10–7), submitted pursuant to a testing consent order under the Toxic Substances Control Act (TSCA). Publication of this notice is in compliance with section 4(d) of TSCA.

FOR FURTHER INFORMATION CONTACT: Susan B. Hazen, Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. E–543B, 401 M St., SW., Washington, DC 20460, (202) 554–1404, TDD (202) 554–0551.

SUPPLEMENTARY INFORMATION: Under 40 CFR 790.60, all TSCA section 4 consent orders must contain a statement that results of testing conducted pursuant to these testing consent orders will be announced to the public in accordance with section 4(d).

I. Test Data Submissions

Test data for acrylic acid were submitted by the Basic Acrylic Monomer Manufacturers on behalf of the test sponsors and pursuant to a testing consent order at 40 CFR 799.5000. They were received by EPA on December 2, 1993. The submission contains a comparative bioavailability study in male mice and rats, an amendment to the study, and an analysis of tissues. This chemical is used in surface coatings; polyacrylic acid and salts, including superabsorbant polymers, detergents, water treatment and dispersants; textiles and nonwovens; exports; adhesives and sealants; leather and polishes; paper coating; miscellaneous acid and ester uses, including specialty acrylates.

EPA has initiated its review and evaluation process for these data submissions. At this time, the Agency is unable to provide any determination as to the completeness of the submissions.

II. Public Record

EPA has established a public record for this TSCA section 4(d) receipt of data notice (docket number OPPTS–44605). This record includes copies of all studies reported in this notice. The record is available for inspection from 12 noon to 4 p.m., Monday through Friday, except legal holidays, in the TSCA Public Docket Office, Rm. ET–G102, 401 M St., SW., Washington, DC 20460.

Authority: 15 U.S.C. 2603.

List of Subjects

Environmental protection, Test data.

Dated: January 14, 1994.

Charles M. Auer,

Director, Chemical Control Division, Office of Pollution Prevention and Toxics.

[FR Doc. 94–1959 Filed 1–27–94; 8:45 am]

BILLING CODE 6560–50–F

FEDERAL COMMUNICATIONS COMMISSION

Public Information Collection Requirement Approved by the Office of Management and Budget

January 24, 1994.

The following information collection requirement has been approved by the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, (44 U.S.C. 3507). For further information, contact Judy Boley,

Federal Communications Commission, (202) 632–0276.

OMB No.: 3060–0586.

Title: Immplentation of Sections 3(n) and 332 of the Communications Act, GN Docket No. 93–252, First Report and Order.

OMB Expiration Date: 02/28/94.

The Omnibus Budget Reconciliation Act of 1993, Public Law 103–66, Title VI, Section 6002(b), 107 Stat 312, 395 (1993), amended Sections 3(n) and 332 of the Communications Act of 1934, as amended, 47 U.S.C. 153(n) and 332, to create a comprehensive regulatory framework for all mobile radio services. Under the amended statute, certain private land mobile radio licensees will be reclassified as "commercial mobile radio service" licensees will be treated as common carriers subject to the foreign ownership and control restrictions of Section 310(b) of the Communications Act. A "grandfathering" provision, however, permits the Commission to grant waivers of Section 310(b) to private land mobile licensees that petition the Commission by February 10, 1994. This present action clarifies the filing procedures for such petitions and reminds all potentially affected private radio licensees of the February 10, 1994 filing deadline.

Federal Communications Commission

William F. Caton,

Acting Secretary.

[FR Doc. 94–1827 Filed 1–27–94; 8:45 am]

BILLING CODE 6712–01–M

Public Information Collection Requirement Submitted to Office of Management and Budget for Review

January 24, 1994.

The Federal Communications Commission has submitted the following information collection requirement to OMB for review and clearance under the Paperwork Reduction Act of 1980 (44 U.S.C. 3507).

Copies of this submission may be purchased from the Commission's copy contractor, International Transcription Service, Inc., 2100 M Street, NW., suite 140, Washington, DC 20037, (202) 857–3800. For further information on this submission contact Judy Boley, Federal Communications Commission, (202) 632–0276. Persons wishing to comment on this information collection should contact Timothy Fain, Office of Management and Budget, room 3235 NEOB, Washington, DC 20503, (202) 395–3561.

OMB Number: 3060–0410.

Title: Forecast for Investment Usage Report and Actual Usage of Investment Report.

Form Number: FCC Forms 495A and 495B.

Action: Extension of a currently approved collection.

Respondents: Businesses or other for-profit.

Frequency of Response: Annual reporting requirement.

Estimated Annual Burden: 300 responses; 40 hours average burden per response; 12,000 hours total annual burden.

Needs and Uses: The FCC Forms 495A and 495B implement the FCC's Joint Cost Order, CC Docket No. 86–111, which requires that certain telephone plant investments used for both regulated and nonregulated purposes be allocated on the basis of forecasted regulated and nonregulated use. The detection and correction of forecasting errors requires reporting of both forecasted and actual investment usage data. The Forecast of Investment Usage Report is used by carriers to submit the forecasts of investments used. The Actual Usage of Investment Report is used to submit the actual investments used. These reports are part of the Automated Reporting and Management Information System (ARMIS). The information contained in these two reports provides the necessary detail to enable the Commission to fulfill its regulatory responsibility to ensure that the regulated operations of the carriers do not subsidize the nonregulated operations of those same carriers.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 94–1828 Filed 1–27–94; 8:45 am]

BILLING CODE 6712–01–M

FEDERAL MARITIME COMMISSION

ATFI Working Group et al.; Agreement(s) Filed

The Federal Maritime Commission hereby gives notice of the filing of the following agreement(s) pursuant to section 5 of the Shipping Act of 1984.

Interested parties may inspect and obtain a copy of each agreement at the Washington, DC Office of the Federal Maritime Commission, 800 North Capitol Street NW., 9th Floor. Interested parties may submit comments on each agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days after the date of the **Federal Register** in which this notice appears. The requirements for comments are found in § 572.603 of Title 46 of the Code of Federal Regulations. Interested persons should consult this section before communicating with the Commission regarding a pending agreement.

Agreement No.: 203–011405–006.

Title: ATFI Working Group Agreement.

Parties:

American West African Freight Conference
A.P. Moller-Maersk Line
Caribbean and Central America Discussion Agreement
Crowley American Transport, Inc.
The "8900" Lines Agreement
Evergreen Marine Corporation (Taiwan) Ltd.
Inter-American Discussion Agreement
Inter-American Freight Conference
Israel Trade Conference
King Ocean Service de Venezuela, S.A.
P&O Containers Limited
Sea-Land Service, Inc.
South Europe/U.S.A. Freight Conference
Trans-Atlantic Agreement
Transpacific Westbound Rate Agreement
Tropical Shipping & Construction Company, Limited
United States Atlantic & Gulf/Australia-New Zealand Conference
United States Atlantic & Gulf/Western Mediterranean Rate Agreement
Wilhelmsen Lines AS
Zim Israel Navigation Co.

Synopsis: The proposed amendment modifies the membership and voting procedures of the Agreement.

Agreement No.: 224–200836.

Title: The Port Authority of New York & New Jersey/Containership Agency, Inc. (Agents for Empremar Line) Container Incentive Agreement.

Parties:

The Port Authority of New York & New Jersey ("Port")
Containership Agency, Inc. (Agents for Empremar Line Shipping Co., Inc.) ("Empremar")

Synopsis: The Agreement provides for the Port to pay Empremar a container incentive of $20.00 for each import container and $30.00 for each export container loaded or unloaded from a vessel at the Port's marine terminals during calendar year 1994, provided each container is shipped by rail to or from points more than 260 miles from the Port.

Agreement No.: 224–200837.

Title: The Port Authority of New York & New Jersey/Containership Agency, Inc. (Agents for Mediterranean Shipping Co., Inc.) Container Incentive Agreement.

Parties:

The Port Authority of New York & New Jersey ("Port")
Containership Agency, Inc. (Agents for Mediterranean Shipping Co., Inc.) ("CAI")

Synopsis: The Agreement provides for the Port to pay CAI a container incentive of $20.00 for each import container and $30.00 for each export container loaded or unloaded from a vessel at the Port's marine terminals during calendar year 1994, provided each container is shipped by rail to or from points more than 260 miles from the Port.

Agreement No.: 224–200838.
Title: The Port Authority of New York & New Jersey/Zim American Israeli Shipping, Co. Inc. Container Incentive Agreement.
Parties:
The Port Authority of New York & New Jersey ("Port")
Zim-American Israeli Shipping, Co. Inc. ("Zim")

Synopsis: the Agreement provides for the Port to pay Zim a container incentive of $20.00 for each import container and $30.00 for each export container loaded or unloaded from a vessel at the Port's marine terminals during calendar year 1994, provided each container is shipped by rail to or from points more than 260 miles from the Port.

Agreement No.: 224–200839.
Title: The Port Authority of New York & New Jersey/Allegro Maritime Services, Inc. Container Incentive Agreement.
Parties:
The Port Authority of New York & New Jersey ("Port")
Allegro Maritime Services, Inc. ("Allegro")

Synopsis: The Agreement provides for the Port to pay Allegro a container incentive of $20.00 for each import container and $30.00 for each export container loaded or unloaded from a vessel at the Port's marine terminals during calendar year 1994, provided each container is shipped by rail to or from points more than 260 miles from the Port.

Agreement No.: 224–200840.
Title: Port of San Francisco/Blue Star Line (North America) Ltd. Terminal Agreement.
Parties:
Port of San Francisco ("Port")
Blue Star Line (North America) Ltd. ("Blue Star")

Synopsis: The proposed Agreement provides for Blue Star to pay reduced dockage and wharfage rates to the Port for the three year term of the Agreement.

Agreement No.: 224–200841.
Title: Port of San Francisco/NYK Line (Margarita Express Service) Terminal Agreement.
Parties:
Port of San Francisco ("Port")
NYK Line (Margarita Express Service) ("NYK")

Synopsis: The proposed Agreement provides for NYK to pay reduced dockage and wharfage rates to the Port for the five year term of the Agreement.

Dated: January 21, 1994.

By Order of the Federal Maritime Commission.

Joseph C. Polking,
Secretary.

[FR Doc. 94–1860 Filed 1–27–94; 8:45 am]
BILLING CODE 6730–01–M

Security for the Protection of the Public Indemnification of Passengers for Nonperformance of Transportation; Issuance of Certificate (Performance)

Notice is hereby given that the following have been issued a Certificate of Financial Responsibility for Indemnification of Passengers for Nonperformance of Transportation pursuant to the provisions of Section 3, Public Law 89–777 (46 U.S.C. 817(e)) and the Federal Maritime Commission's implementing regulations at 46 CFR part 540, as amended:

Commodore Cruise Line, Inc., 800 Douglas Road, Coral Gables, Florida 33134.
Vessel: ENCHANTED SEAS

Dated: January 24, 1994.

Joseph C. Polking,
Secretary.

[FR Doc. 94–1909 Filed 1–27–94; 8:45 am]
BILLING CODE 6730–01–M

Security for the Protection of the Public Financial Responsibility To Meet Liability Incurred for Death or Injury to Passengers or Other Persons on Voyages; Issuance of Certificate (Casualty)

Notice is hereby given that the following have been issued a Certificate of Financial Responsibility to Meet Liability Incurred for Death or Injury to Passengers or Other Persons on Voyages pursuant to the provisions of section 2, Public Law 89–777 (46 U.S.C. 817(d)) and the Federal Maritime Commission's implementing regulations at 46 CFR part 540, as amended:

Commodore Cruise Line, Inc., Commodore Shipholding Corp. I, Inc. and Effjohn International Cruise Holding Inc., 800 Douglas Road, Coral Gables, Florida 33134
Vessel: ENCHANTED SEAS

Dated: January 24, 1994.

Joseph C. Polking,
Secretary.

[FR Doc. 94–1907 Filed 1–27–94; 8:45 am]
BILLING CODE 6730–01–M

Security for the Protection of the Public Indemnification of Passengers for Nonperformance of Transportation; Issuance of Certificate (Performance)

Notice is hereby given that the following have been issued a Certificate of Financial Responsibility for Indemnification of Passengers for Nonperformance of Transportation pursuant to the provisions of section 3, Public Law 89–777 (46 U.S.C. 817(e)) and the Federal Maritime Commission's implementing regulations at 46 CFR part 540, as amended:

Nur Touristic GmbH, (d/b/a Neckermann Und Reisen), Zimmersmuhlenweg 55, Postfach 2050, 6370 Oberursel 1, Germany
Vessel: FEDOR DOSTOYEVSKIY

Dated: January 24, 1994.

Joseph C. Polking,
Secretary.

[FR Doc. 94–1708 Filed 1–27–94; 8:45 am]
BILLING CODE 6730–01–M

Security for the Protection of the Public Financial Responsibility To Meet Liability Incurred for Death or Injury to Passengers or Other Persons on Voyages; Issuance of Certificate (Casualty)

Notice is hereby given that the following have been issued a Certificate of Financial Responsibility to Meet Liability Incurred for Death or Injury to Passengers or Other Persons on Voyages pursuant to the provisions of section 2, Public Law 89–777 (46 U.S.C. 817(d)) and the Federal Maritime Commission's implementing regulations at 46 CFR part 540, as amended:

Regency Cruises Inc., Regency Maritime Corp. and Ridan Investment Trust Inc., 260 Madison Avenue, New York, N.Y. 10016.
Vessel: REGENT SEA

Dated: January 24, 1994.

Joseph C. Polking,
Secretary.

[FR Doc. 94–1906 Filed 1–27–94; 8:45 am]
BILLING CODE 6730–01–M

FEDERAL RESERVE SYSTEM

Arvest Bank Group, Inc., et al.; Notice of Applications to Engage de novo in Permissible Nonbanking Activities

The companies listed in this notice have filed an application under §

225.23(a)(1) of the Board's Regulation Y (12 CFR 225.23(a)(1)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to commence or to engage *de novo*, either directly or through a subsidiary, in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than February 17, 1994.

A. Federal Reserve Bank of St. Louis (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166:

1. Arvest Bank Group, Inc., Bentonville, Arkansas; to engage *de novo* through its subsidiary, Arvest Savings Bank, Tulsa, Oklahoma, in operating a savings association pursuant to § 225.25(b)(9) of the Board's Regulation Y. These activities will be conducted in the State of Oklahoma.

B. Federal Reserve Bank of Kansas City (John E. Yorke, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. Sky Valley Bank Corporation, Alamosa, Colorado; to engage *de novo* through its subsidiary, Sky Valley Insurance Corporation, Alamosa, Colorado, in credit-related insurance activities pursuant to § 225.25(b)(8)(i) of the Board's Regulation Y. These activities will be conducted in the following counties in Colorado: Alamosa, Rio Grande, Mineral, Saguache, Conejos, and Costilla.

Board of Governors of the Federal Reserve System, January 24, 1994.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 94-1936 Filed 1-27-94; 8:45 am]

BILLING CODE 6210-01-F

First Bancorporation of Ohio, et al.; Acquisitions of Companies Engaged in Permissible Nonbanking Activities

The organizations listed in this notice have applied under § 225.23(a)(2) or (f) of the Board's Regulation Y (12 CFR 225.23(a)(2) or (f)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to acquire or control voting securities or assets of a company engaged in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated for the application or the offices of the Board of Governors not later than February 22, 1994.

A. Federal Reserve Bank of Cleveland (John J. Wixted, Jr., Vice President) 1455 East Sixth Street, Cleveland, Ohio 44101:

1. First Bancorporation of Ohio, Akron, Ohio; to acquire Great Northern Financial Corporation, Barberton, Ohio, and thereby indirectly acquire Great Northern Savings Co., Barberton, Ohio, and thereby engage in operating a savings association pursuant to § 225.25(b)(9) of the Board's Regulation Y.

B. Federal Reserve Bank of Dallas (Genie D. Short, Vice President) 2200 North Pearl Street, Dallas, Texas 75201-2272:

1. Security Shares, Inc., Abilene, Texas; to acquire First Independent Computers, Inc., Abilene, Texas, and thereby engage in transmission services, facilities, and data bases or access to them pursuant to § 225.25(b)(7) of the Board's Regulation Y. These activities will be conducted in the State of Texas.

Board of Governors of the Federal Reserve System, January 24, 1994.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 94-1937 Filed 1-27-94; 8:45 am]

BILLING CODE 6210-01-F

First Rainsville Bancshares, Inc., et al.; Notice of Applications to Engage de novo in Permissible Nonbanking Activities

The companies listed in this notice have filed an application under § 225.23(a)(1) of the Board's Regulation Y (12 CFR 225.23(a)(1)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to commence or to engage *de novo*, either directly or through a subsidiary, in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a

hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than February 17, 1994.

A. Federal Reserve Bank of Atlanta (Zane R. Kelley, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303:

1. First Rainsville Bancshares, Inc., Rainsville, Alabama; to engage *de novo* in making, acquiring, or servicing loans or other extensions of credit, through its finance company, First Finance Corporation, Rainsville, Alabama, pursuant to § 225.25(b)(1) of the Board's Regulation Y.

B. Federal Reserve Bank of Minneapolis (James M. Lyon, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480:

1. First Bank System, Inc., Minneapolis, Minnesota; to engage *de novo* in data processing and data transmission services pursuant to § 225.25(b)(7) of the Board's Regulation Y. These activities will be conducted in the States of Arizona, Texas, Florida, Kansas, Missouri, and Utah. **Comments on this application must be received by February 11, 1994.**

Board of Governors of the Federal Reserve System, January 24, 1994.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 94-1938 Filed 1-27-94; 8:45 am]

BILLING CODE 6210-01-F

First Union Corporation, et al.; Formations of; Acquisitions by; and Mergers of Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Unless otherwise noted, comments regarding each of these applications must be received not later than February 22, 1994.

A. Federal Reserve Bank of Richmond (Lloyd W. Bostian, Jr., Senior Vice President) 701 East Byrd Street, Richmond, Virginia 23261:

1. First Union Corporation, Charlotte, North Carolina; to acquire 100 percent of the voting shares of First Union Home Equity Bank, National Association, Charlotte, North Carolina, a *de novo* bank.

B. Federal Reserve Bank of Chicago (James A. Bluemle, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. Central Illinois Bancorp, Inc., Sidney, Illinois; to acquire 100 percent of the voting shares of Hillside Investors, Ltd., Hillside, Illinois, and thereby indirectly acquire Bank of Hillside, Hillside, Ilinois.

2. Cleveland Development Bancorporation, Chicago, Illinois; to become a bank holding company by acquiring 100 percent of the voting shares of Potters Bank & Trust Company, East Liverpool, Ohio.

3. The Shorebank Corporation, Chicago, Illinois; to acquire 100 percent of the voting shares of Potters Bank & Trust Company, East Liverpool, Ohio.

C. Federal Reserve Bank of St. Louis (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166:

1. CNB Bancshares, Inc., Evansville, Indiana; to acquire, through its subsidiary, First Federal Savings Bank of Kentucky, Madisonville, Kentucky, the assets and liabilities of CNB Bank of Kentucky, Shively, Kentucky.

D. Federal Reserve Bank of Minneapolis (James M. Lyon, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480:

1. Vergas Bancorporation, Inc., Vergas, Minnesota, to become a bank holding company by acquiring 80 percent of the voting shares of Vergas State Bank, Vergas, Minnesota.

E. Federal Reserve Bank of Kansas City (John E. Yorke, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. Citizens State Bancshares, Inc., Wichita, Kansas; to become a bank holding company by acquiring 100 percent of the voting shares of Citizens State Bank of Cheney, Cheney, Kansas.

Board of Governors of the Federal Reserve System, January 24, 1994.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 94-1939 Filed 1-27-94; 8:45 am]

BILLING CODE 6210-01-F

Mahaska Investment Company, et al.; Formations of; Acquisitions by; and Mergers of Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Unless otherwise noted, comments regarding each of these applications must be received not later than February 22, 1994.

A. Federal Reserve Bank of Chicago (James A. Bluemle, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. Mahaska Investment Company, Oskaloosa, Iowa; to acquire 100 percent of the voting shares of Taintor Savings Bank, New Sharon, Iowa.

B. Federal Reserve Bank of Dallas (Genie D. Short, Vice President) 2200 North Pearl Street, Dallas, Texas 75201-2272:

1. First National Bank of Clovis Employee Stock Ownership Trust, Clovis, New Mexico; to become a bank holding company by acquiring 26 percent of the voting shares of National Bancshares, Inc., Clovis, New Mexico, and thereby indirectly acquire First

National Bank of Clovis, Clovis, New Mexico.

Board of Governors of the Federal Reserve System, January 24, 1994.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 94-1940 Filed 1-27-94; 8:45 am]

BILLING CODE 6210-01-F

Pointe Financial Corporation, et al.; Formations of, Acquisitions by, and Mergers of Bank Holding Companies; and Acquisitions of Nonbanking Companies

The companies listed in this notice have applied under § 225.14 of the Board's Regulation Y (12 CFR 225.14) for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) to become a bank holding company or to acquire voting securities of a bank or bank holding company. The listed companies have also applied under § 225.23(a)(2) of Regulation Y (12 CFR 225.23(a)(2)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to acquire or control voting securities or assets of a company engaged in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies, or to engage in such an activity. Unless otherwise noted, these activities will be conducted throughout the United States.

The applications are available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than February 22, 1994.

A. Federal Reserve Bank of Atlanta (Zane R. Kelley, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303:

1. Pointe Financial Corporation, Boca Raton, Florida; to become a bank holding company by acquiring 100 percent of the voting shares of Flamingo Bank, Pembroke Pines, Florida.

In connection with this application, Applicant also proposes to acquire Pointe Federal Savings Bank, Boca Raton, Florida, and thereby engage in operating a savings association pursuant to § 225.25(b)(9) of the Board's Regulation Y.

B. Federal Reserve Bank of St. Louis (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166:

1. Trans Financial Bancorp, Inc., Bowling Green, Kentucky; to merge with or acquire at least 58.35 percent of the voting shares of Peoples Financial Services, Inc., Cookeville, Tennessee, and thereby indirectly acquire Peoples Bank and Trust of the Cumberlands, Cookeville, Tennessee, and Citizens Federal Savings Bank, Rockwood, Tennessee.

In connection with this application, Applicant also proposes to acquire Citizens Federal Savings Bank, Rockwood, Tennessee, and thereby engage in operating a savings association pursuant to § 225.25(b)(9) of the Board's Regulation Y. These activities will be conducted in the State of Tennessee.

Board of Governors of the Federal Reserve System, January 24, 1994.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 94-1942 Filed 1-27-94; 8:45 am]

BILLING CODE 6210-01-F

Wiley William Smith, et al.; Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. Once the notices have been accepted for processing, they will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than February 17, 1994.

A. Federal Reserve Bank of Kansas City (John E. Yorke, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. Wiley William Smith, Sapulpa, Oklahoma; to acquire an additional 3.8 percent for a total of 16.03 percent; and Edward A. Carson, Sapulpa, Oklahoma, to acquire an additional 0.13 percent for a total of 16.03 percent of the voting shares of Security National Bancshares of Sapulpa, Inc., Sapulpa, Oklahoma, and thereby indirectly acquire Security National Bank of Sapulpa, Sapulpa, Oklahoma.

Board of Governors of the Federal Reserve System, January 24, 1994.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 94-1941 Filed 1-27-94; 8:45 am]

BILLING CODE 6210-01-F

GENERAL ACCOUNTING OFFICE

Government Auditing Standards Advisory Council; Meeting

AGENCY: General Accounting Office.

ACTION: Notice.

SUMMARY: The United States General Accounting Office has scheduled a meeting of the Government Auditing Standards Advisory Council on February 9, 1994, from 8:30 a.m. until 5 p.m., and February 10 from 8:30 a.m. until 1 p.m. in room 7313 of the General Accounting Office, 441 G St., NW., Washington, DC.

The agenda for the meeting will consist of a review of the minutes of the February 1993 meeting, and discussion of the comments received on the exposure draft of Government Auditing Standards.

Any interested person may attend the meeting as an observer.

FOR FURTHER INFORMATION CONTACT: Marcia B. Buchanan, Project Manager, U.S. General Accounting Office, 441 G St., NW., room 6025, Washington, DC 20548 or call (202) 512-9321.

DATES: February 9-10, 1994.

ADDRESSES: 441 G St., NW., room 7313, Washington, DC 20548.

Dated: January 11, 1994.

William C. Oelkers,

Director of Operations.

[FR Doc. 94–1764 Filed 1–27–94; 8:45 am]

BILLING CODE 1610-01-M

GENERAL SERVICES ADMINISTRATION

Border Station, Highgate Springs, VT; Environmental Impact Statement

AGENCY: General Services Administration.

ACTION: Notice of intent to prepare an Environmental Impact Statement.

SUMMARY: The General Services Administration (GSA) is issuing this notice to advise the public that an Environmental Impact Statement (EIS) will be prepared and considered for the construction of a new Border Station in Highgate Springs, Vermont.

FOR FURTHER INFORMATION CONTACT: Ralph A. Scalise, Senior Planner, General Services Administration, Public Buildings Service, 10 Causeway Street, Boston, MA 02222, (617) 565–5821.

SUPPLEMENTARY INFORMATION: The GSA will prepare an Environmental Impact Statement for the construction of a Border Station in Highgate Springs, Vermont. The proposed Border Station will contain approximately 37,800 occupiable square feet of space and house 75 employees. The operations of the U.S. Immigration and Naturalization Service and U.S. Customs Service at the existing Border Station in Highgate Springs are severely hindered due to the functional obsolescence of the existing facilities. The proposed project is being undertaken to accommodate the expansion requirements of the U.S. Customs Service, Immigration and Naturalization Service (INS), and the U.S. Department of Agriculture (USDA).

The EIS will evaluate alternatives, including the no-action alternative. The EIS will evaluate impacts on the affected environment for the following resource areas: subsurface and geological conditions, landforms, vegetation and wildlife, natural hazards, air quality/meteorological conditions, population/fiscal conditions, land use and zoning, traffic and transportation, utilities, cultural resources, and hazardous wastes.

Public Scoping Meeting

To ensure that the full range of issues relating to the proposed project are addressed and all potential significant issues are identified, comments and suggestions are being solicited. To facilitate the receipt of comments, a public scoping meeting will be held on March 8, 1994, from 3 p.m. to 5 p.m. and from 7 p.m. to 9 p.m. at the Town Hall in Highgate Center, Vermont. The Highgate Center Town Hall is located on Route 78 (exit 21 on Route 89).

Written comments may be mailed to the informational contact person no later than March 23, 1994.

Issued in New York, NY on January 13, 1994.

Karen R. Adler,

Regional Administrator, General Services Administration, Region 2.

[FR Doc. 94–1844 Filed 1–27–94; 8:45 am]

BILLING CODE 6820-23-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Notice of Interest Rate on Overdue Debts

Section 30.13 of the Department of Health and Human Services' claims collection regulations (45 CFR part 30) provides that the Secretary shall charge an annual rate of interest as fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date that HHS becomes entitled to recovery. The rate generally cannot be lower than the Department of Treasury's current value of funds rate or the applicable rate determined from the "Schedule of Certified Interest Rates with Range of Maturities." This rate may be revised quarterly by the Secretary of the Treasury and shall be published quarterly by the Department of Health and Human Services in the **Federal Register.**

The Secretary of the Treasury has certified a rate of 13.25% for the quarter ended December 31, 1993. This interest rate will remain in effect until such time as the Secretary of the Treasury notifies HHS of any change.

Dated: January 24, 1994.

George, H. Strader,

Deputy Assistant Secretary, Finance.

[FR Doc. 94–1884 Filed 1–27–94; 8:45 am]

BILLING CODE 4150-04-M

Administration for Children and Families

Agency Information Collection Under OMB Review

Under the provisions of the Federal Paperwork Reduction Act (44 U.S.C. chapter 35), we have submitted to the Office of Management and Budget (OMB) a request for approval for the continued use of an information collection titled: "Worksheet for Integrated AFDC, Food Stamps and Medicaid Eligibility Quality Control Reviews." This information collection is jointly designed and used by the Office of Family Assistance (OFA) of the Administration for Families and Children (ACY) and Health Care Financing Administration (HCFA) both of the Department of Health and Human Services and the Food and Nutrition Service (FNS) of the Department of Agriculture.

ADDRESSES: Copies of this information collection request may be obtained from Stephen R. Smith of the Office of Information Systems Management, ACY, by calling (202) 401–6964.

Written comments and questions regarding the requested approval for information collection should be sent directly to: Laura Oliven, OMB Desk Officer for ACF, OMB Reports Management Branch, New Executive Office Building, room 3002, 725 17th Street NW., Washington, DC 20503, (202) 395–7316.

Information on Document

Title: Worksheet for Integrated AFDC, Adult, Food Stamps and Medicaid Eligibility Quality Control Reviews Form ACF–4340.

OMB No.: 0970–0072.

Description: This information collection is authorized by Sections 2, 408, 1402, and 1602 of the Social Security Act and required under regulatory authority found at 45 CFR 205.40. The Worksheet for Integrated Quality Control Reviews is a joint form developed and utilized by the Administration for Children and Families and Health Care Financing Administration both of the Department of Health and Human Services and the Food and Nutrition Service of the Department of Agriculture for quality reviews of the Aid to Families with Dependent Children (AFDC), Food Stamps and Medicaid programs. The Quality Control (QC) Reviews of the three programs are conducted by the State agencies which administer the programs for the sponsoring federal agencies. Form 4340 is used by the States to document the findings of state quality reviewers who review the correctness of a sample of eligibility decisions made by the states for the AFDC, Food Stamps and Medicaid programs. The purpose of this QC reviews are to assure that individuals are not being denied categories of Federal assistance for which they are eligible and to take necessary corrective measures to reduce the incidence of

improperly authorized or denied assistance.

This information is utilized in determining the principal causes of incorrect actions and in developing appropriate corrective action.

Annual Number of Respondents: 59,500
Annual Frequency: 1
Average Burden Hours Per Response: 11.0236
Total Burden Hours: 655,904

Dated: January 21, 1994.

Larry Guerrero,

Deputy Director, Office of Information Systems Management.

[FR Doc. 94–1920 Filed 1–27–94; 8:45 am]

BILLING CODE 4184–01–M

Agency Information Collection Under OMB Review

Under the provisions of the Federal Paperwork Reduction Act (44 U.S.C. chapter 35), we have submitted to the Office of Management and Budget (OMB) a request for approval for the continued use of an information collection titled: "Quality Control Negative Case Action Worksheet/ Review Schedule Form ACF–6401." This request for clearance is made by the Office of Family Assistance (OFA) of the Administration for Children and Families (ACF).

ADDRESSES: Copies of the Information Collection request may be obtained from Stephen R. Smith, of the Office of Information Systems Management, ACF, by calling (202) 401–6964.

Written comments and questions regarding the requested approval for information collection should be sent directly to: Laura Oliven, OMB Desk Officer for ACF, OMB Reports Management Branch, New Executive Office Building, room 3002, 725 17th Street NW., Washington, DC 20503, (202) 395–7316.

Information on Document

Title: Quality Control Negative Case Action Worksheet/Review Schedule Form ACF–6401

OMB No.: 0970–0006

Description: This information collection is authorized by section 2(a)(6), section 408(b)(1) and section 1402(a) of the Social Security Act and required under regulatory authority found at 45 CFR 205.40. The purpose of this collection of information is to assure that individuals are not being denied categories of Federal assistance for which they are eligible and to take necessary corrective measures to reduce the incidence of improperly authorized or denied assistance. Specifically, categories of assistance covered by this collection of information are Aid to Families With Dependent Children (AFDC) and Medicaid in all States and jurisdictions, and Adult Assistance Programs under titles I, X, XIV, and XVI of the Social Security Act in Guam, Puerto Rico, and the Virgin Islands.

This collection of information was jointly designed and used by the Health Care Financing Administration and the Administration for Children and Families both of the Department of Health and Human Services.

The Quality Control Negative Case Action system is a joint State/Federal effort to obtain data on the correctness of State actions to deny or terminate AFDC/Adult financial assistance or Medicaid eligibility. This information is utilized in determining the principal causes of incorrect actions and in developing appropriate corrective action. The Quality Control Negative Case Action system promotes proper State administration of their AFDC and adult programs by helping to assess performance in the denial or termination of benefits. Negative case action quality control therefor provides: (a) Continuous review of a statistically reliable statewide samples of negative actions; and (b) periodic compilation and analysis of findings to determine the incidence of incorrect actions. The Negative Case Action review supplements the Quality Control review of active cases and, thus, provides a balanced quality control system capable of measuring overall program performance.

Annual Number of Respondents: 20,057
Annual Frequency: 1
Average Burden Hours Per Response: 1.00284
Total Burden Hours: 20,114

Dated: January 21, 1994

Larry Guerrero,

Deputy Director, Office of Information Systems Management.

[FR Doc. 94–1921 Filed 1–27–94; 8:45 am]

BILLING CODE 4184–01–M

Cancellation of Notice of Availability of Funding for Grants To Assist Interested Refugees To Effect Planned Secondary Resettlement to Favorable Communities Under the Planned Secondary Resettlement (PSR) Program

AGENCY: Office of Refugee Resettlement, ACF, HHS.

ACTION: Cancellation of notice of available funding for grants to assist interested refugees to effect planned secondary resettlements to favorable communities under the Planned Secondary Resettlement Program. The notice, published in the **Federal Register** on April 8, 1992 (57 FR 12130) is hereby cancelled.

(Catalog of Federal Domestic Assistance number 93.038)

Dated: January 21, 1994.

Lavinia Limon,

Director, Office of Refugee Resettlement.

[FR Doc. 94–1842 Filed 1–27–94; 8:45 am]

BILLING CODE 4184–01–M

Runaway and Homeless Youth Program Proposed Priorities for Fiscal Year 1994

AGENCY: Administration on Children, Youth and Families (ACYF), Administration for Children and Families (ACF), HHS.

ACTION: Notice of proposed fiscal year 1994 runaway and homeless youth program priorities for the administration for children and families.

SUMMARY: The Runaway and Homeless Youth Act requires the Secretary to publish annually, for public comment, a proposed plan specifying priorities the Department will follow in awarding grants and contracts under the Act. The final priorities selected will take into consideration the comments an recommendations received from the public in response to this notice.

The public, particularly those knowledgeable about and experienced in providing services to runaway and homeless youth, are urged to respond. The actual solicitations for grant applications will be published at later dates in the **Federal Register**. No proposals, concept papers or other forms of application should be submitted at this time.

DATES: To be considered, comments must be received no later than March 14, 1994.

ADDRESSES: Please address comments to: Olivia A. Golden, Commissioner, Administration on Children, Youth and Families. Attention: Family and Youth Services Bureau, P.O. Box 1182, Washington, DC 20013.

SUPPLEMENTARY INFORMATION:

I. Organization, Mission and Goals of the Family and Youth Services Bureau

The Family and Youth Services Bureau (FYSB) is a component of the Administration on Children, Youth and Families (ACYF) in the Administration for Children and Families (ACF). The Bureau administers five Federal programs dealing with children, youth and families:

(1) The Runaway and Homeless Youth (Basic Center) Program (RHYP),
(2) The Transitional Living Program for Homeless Youth (TLP),
(3) The Drug Abuse Prevention Program for Runaway and Homeless Youth (DAPP),
(4) The Youth Gang Drug Prevention Program (YGDPP), and
(5) The Family Resource and Support Program (FRSP).

The mission of FYSB is to provide national leadership on youth issues and to empower individuals and organizations to provide effective, comprehensive services for at-risk youth and their families, ensuring the safety and maximizing the stability and long-term self-sufficiency of the youth.

Two of the FYSB programs listed above, the Runaway and Homeless Youth (Basic Center) Program and the Transitional Living Program for Homeless Youth, are authorized under the Runaway and Homeless Youth Act (Title III of the Juvenile Justice and Delinquency Prevention Act of 1974, as amended, hereinafter cited as "the Act") and are the subject of the priorities proposed in this notice.

The Act specifically authorizes the Secretary to make grants to entities that establish and operate local runaway and homeless youth centers (Basic Centers) to address the immediate needs of at-risk youth. Currently, 348 such projects are being funded. The Act also authorizes activities that support the local centers, and that increase knowledge about the conditions of runaway and homeless youth and their families.

The Act further authorizes the Secretary to make grants to entities that establish and operate Transitional Living projects for homeless youth to enable the youth to become self-sufficient and to avoid long-term dependency on social services. Currently, 73 such projects are being funded.

The Act also authorizes financial support for:

- A National Communications System (NCS, a toll-free 25-hour runaway hotline) which serves as a neutral channel of communication between at-risk youth and their families and as a source of referral to needed services;
- Grants to statewide and regional non-profit organizations for the provision of Training and Technical Assistance (T&TA) to agencies and organizations eligible to establish and operate runaway and homeless youth centers; and
- Grants to conduct research, demonstration, and evaluation projects.

Annual Program Priorities. Sections 384(a) and 384(b) of the Act instruct the Secretary to develop for each fiscal year, and to publish annually in the **Federal Register** for public comment, a proposed plan specifying the priorities the Department will follow in making grants under the Basic Center and the Transitional Living Programs. The Secretary is further instructed to take into consideration the comments received in developing and publishing the subsequent plan specifying the final fiscal year priorities. This notice constitutes the Department's proposed priorities in these two program areas for fiscal year (FY) 1994.

No acknowledgement will be made of the comments received in response to this notice, but all comments received by the deadline will be considered in preparing the runaway and homeless youth final priorities. Final priorities will be published in the **Federal Register** at the time of solicitation of grant applications.

One program announcement soliciting applications for both Basic Center Program grants and Transitional Living Program grants will appear in the **Federal Register** as in previous years. Because all current grants to carry out training and technical assistance (T&TA) activities will expire this fiscal year, the announcement will also request proposals to provide T&TA to staff of FYSB-funded projects. Finally, the announcement will solicit grant proposals to analyze and interpret the considerable data that are being produced by the Runaway and Homeless Youth Management Information System, the Runaway and Homeless Youth Monitoring System, a number of Runaway and Homeless Youth Evaluation Studies, and recent Research and Demonstration projects. Copies of the announcement will be sent to all persons who comment on these proposed priorities.

The current grant to manage the National Communication System also expires this fiscal year. A separate **Federal Register** announcement will be published soliciting applications to manage the National Communications System.

II. Priorities for Ongoing Direct Service Programs

A. Priorities for Basic Centers

Approximately 350 Basic Center grants, of which about two-thirds will be non-competitive continuations and about one-third competitive new starts, will be funded in FY 1994 to support organizations which provide services to fulfill the four major goals of the Runaway and Homeless Youth Program (RHYP): alleviating the problems of runaway and homeless youth; reuniting youth with their families; strengthening family relationships; and helping youth decide upon a future course of action.

The goals of the RHYP are achieved through the Basic Centers, which provide services in support of the immediate needs (temporary shelter, food, clothing, counseling, and related services) of runaway or homeless youth and their families in a manner which is outside the law enforcement system, the child welfare system, the mental health system, and the juvenile justice system. Further, the Basic Centers provide services, directly and through referrals, to promote the long-term stability and safety of such youth.

Funds for Basic Center grants are allotted annually among the States and other qualifying jurisdictions on the basis of their relative populations of individuals who are less than 18 years of age. For the past several years, Basic Center grants have been awarded for three-year project periods. Approximately one-third of the Basic Center grants expire each year, requiring these agencies to compete for new awards. The remaining two-thirds of the Basic Center grants receive non-competitive continuation awards. Within any given State, in consequence, individual grantees may fall within any one of three different funding cycles: new starts, second-year continuations, and third-year continuations. In FY 1994, this cyclical funding pattern will be continued, assuming satisfactory performance on the part of current grantees and the availability of funds. Thus, approximately two-thirds of the current grantees will be awarded noncompetitive continuation funds, and the remaining grantees (those whose grant periods expire in FY 1994) will have the opportunity to submit new competitive applications. All other eligible youth-serving agencies not holding current awards may also apply for these new competitive funds.

Section 385(a)(2) of the Act requires that not less than 90 percent of the funds appropriated under Part A (The Runaway and Homeless Youth Grant Act) be used to establish and strengthen runaway and homeless youth Basic Centers. Total funding under Part A of the Act for FY 1994 is expected to be approximately $36.1 million. Approximately $32.5 million will be allocated to the Basic Centers.

An announcement of the availability of funds for the Basic Centers, along with the instructions and forms needed to prepare and submit applications, will be published in a **Federal Register** announcement as early as possible in

calendar year 1994 after the comment period ends.

B. Priorities for Transitional Living Grants

Part B, Section 321 of the Runaway and Homeless Youth Act, as amended, authorizes grants to establish and operate Transitional Living projects for homeless youth. This program is structured to help older homeless youth achieve self-sufficiency and avoid long-term dependency on social services. Transitional Living projects provide shelter, skills training, and support services to homeless youth ages 16 through 21 for a continuous period not exceeding 18 months.

The first 45 Transitional Living Program (TLP) grants were added in September 1990 for three-year project periods. An additional 32 grants were awarded in FY 1991 and 10 grants in FY 1992, also for three-year project periods. All funds available under this program in FY 1993 were awarded in the form of non-competitive continuation awards to then-ongoing grantees.

In order to award new TLP grants as early as possible in FY 1994, however, an open competition was held in the summer of calendar year 1993 for new awards to be supported with FY 1994 funds. Project periods of the new grants were to begin on October 1, 1994, or as soon thereafter as funds were available. This was to allow grantees with project periods ending in September 1994 to compete for new grants and to continue their existing projects with minimal disruption of services if they were successful in the competition.

Thirty-two new TLP grants were awarded following the competition, with starting dates on or after October 1, 1993 (the first day of FY 1994). First-year funding for these projects totaled approximately $6.0 million. It is anticipated that remaining FY 1994 TLP funds will be awarded to continuation grantees initially funded in earlier years.

Inasmuch as funds for additional new-start TLP grants will probably be available in FY 1995, an open competition will be held in the summer of calendar year 1994 for new awards to be supported with FY 1995 funds. Project periods of these new awards will begin no sooner than October 1, 1994. It is anticipated that approximately $6.0 million will be available for these new grants in FY 1995.

C. Priorities for the National Communications System

Part C, Section 331 of the Runaway and Homeless Youth Act, as amended, mandates support for a National Communications System to assist runaway and homeless youth in communicating with their families and with service providers. In FY 1991, a three-year grant was awarded to the National Runaway Switchboard, Inc., in Chicago, Illinois, to operate the system. This grant will expire in February 1994. An announcement soliciting competing grant applications to operate the system for five years will be published in the **Federal Register** late in 1993 or early in 1994. Priority will be given to applicants having experience in providing telephone services to runaway and homeless youth. It is anticipated that $826,900 in first-year funds will be awarded to the grantee in FY 1994.

III. Support Services for Runaway and Homeless Youth Programs

A. Training and Technical Assistance

Part D, Section 342 of the Act authorizes the Department to make grants to statewide and regional nonprofit organizations to provide training and technical assistance (T&TA) to organizations that are eligible to receive service grants under the Act. Organizations eligible to receive this T&TA include the Basic Centers authorized under Part A of the Act and the Transitional Living grantees authorized under Part B. In addition, Section 3511 of the Anti-Drug Abuse Act of 1988, which authorized the Drug Abuse Prevention Program for Runaway and Homeless Youth (DAPP), authorizes support for T&TA to runaway and homeless youth service providers. The purpose of this T&TA is to strengthen the programs and to enhance the knowledge and skills of youth service workers.

In FY 1991, the Family and Youth Services Bureau awarded ten Cooperative Agreements, one in each of the ten Federal Regions, to provide T&TA to agencies funded under the three Federal programs for runaway and homeless youth (the Basic Center Program, the Transitional Living Program, and the Drug Abuse Prevention Program). Each Cooperative Agreement was unique, being based on the characteristics and different T&TA needs in the respective Regions. Each of the Cooperative Agreements had a three-year project period that will expire in FY 1994.

An announcement of the availability of funds for cooperative agreements to provide T&TA to eligible grantees, along with instructions and forms needed to prepare and submit applications, will be published in the **Federal Register** early in 1994. Earlier cooperative agreements allowed support for networking and membership efforts. We are proposing that these activities not be continued under the new agreements. Instead, we are proposing that the agreements provide for T&TA focused on findings resulting from the monitoring of runaway and homeless youth grantees. Grantee project periods will be for five years, and approximately $1.5 million in first-year funds will be available in FY 1994.

B. National Clearinghouse on Runaway and Homeless Youth

In June 1992, a five-year contract was awarded by the Department to establish and operate the National Clearinghouse on Runaway and Homeless Youth. The purpose of the Clearinghouse is to serve as a central information point for professionals and agencies involved in the development and implementation of services to runaway and homeless youth. To this end, the Clearinghouse:

(1) Collects, evaluates and maintains reports, materials and other products regarding the provision of services to runaway and homeless youth:

(2) Develops and disseminates reports and bibliographies useful to the field;

(3) Identifies areas in which new or additional reports, materials and products are needed; and

(4) Carries out other activities designed to provide the field with the information needed to improve services to runaway and homeless youth.

It is anticipated that non-competitive continuation funding will be awarded to sustain the Clearinghouse in FY 1994.

C. Management Information System (MIS) Implementation

In FY 1992, a five-year contract was awarded to implement the Runaway and Homeless Youth Management Information System (MIS) across three FYSB programs: the Runaway and Homeless Youth Basic Center Program, the Transitional Living Program, and the Drug Abuse Prevention Program. The MIS data elements include identification of the program in which the youth is enrolled, a profile on each youth served (demographics, presenting problems, services received), and an agency profile (agency description, program information, staff profile, and related information). Participation in the MIS is mandatory.

In FY 1993, using an existing computer-based, information gathering protocol, the contractor began providing training and technical assistance to grantees in the use of the MIS. The system will become fully operational by the end of FY 1994. The data generated by the system will be used to produce reports and information regarding the

programs, including information for the required reports to Congress on each of the three programs. The MIS is also designed to serve as a management tool for FYSB and for the individual programs.

It is anticipated that continuation funding for the MIS will be provided in FY 1994.

D. Monitoring Support for FYSB Programs

In FY 1992, FYSB awarded a contract for initial development of a comprehensive monitoring instrument and set of site visit protocols, including a peer-review component, for the Runaway and Homeless Youth Basic Center Program, the Transitional Living Program, and the Drug Abuse Prevention Program. Pilot testing of the instrument and related protocols began in FY 1993. Also in FY 1993 an expanded contract was awarded to provide nationwide logistical support for the peer review monitoring process. The projected nationwide use of the new instrument and peer review process will improve Federal oversight of the programs and will identify program strengths and weaknesses. The findings will also be used to direct T&TA activities and FYSB policy development.

It is anticipated that continuation funding for the logistical contractor will be provided in FY 1994.

IV. Research and Demonstration Initiatives

Section 343 of the Act authorizes the Department to make grants to States, localities, and private entities to carry out research, demonstration, and service projects designed to increase knowledge concerning and to improve services for runaway and homeless youth. These activities are important in order to identify emerging issues and to develop and test models which address such issues.

A. Services for Youth in Rural Areas

Because of geographic distances, low population density and, in some cases, cultural differences, it is difficult to provide effective services to runaway and homeless youth in rural areas. In many such areas, scarcity of funds and other resources precludes the funding of separate, autonomous Basic Center programs.

There is a need for innovative and effective models for the provision of runaway and homeless youth services in rural areas, including Indian reservations. These models would make services accessible to youth without setting up inordinately expensive service agencies in low populated areas.

In FY 1993, first-year funding was awarded to eight grantees to develop such models. These grants are expected to produce written descriptions of the proposed service models, identify issues related to model implementation, and generate information on youth and program outcomes. The models will also incorporate formal collaboration with other major youth-serving agencies in the areas served.

It is anticipated that continuation funding of these eight grants will be provided in FY 1994.

B. Analysis, Synthesis, and Interpretation of Information Concerning Runaway and Homeless Youth Programs

Over the past few years, systems for the accumulation of new knowledge have been developed regarding the delivery of services to runaway and homeless youth and their families through programs administered by FYSB. These systems currently provide, or during FY 1994 will provide, new data of considerable interest. The four main sources of this new information are:

1. The Management Information System (MIS)

The information now being collected by the MIS includes descriptions of FYSB's grantee agencies and detailed data on the youth and families served, including demographic profiles, presenting problems, services provided, and service outcomes.

2. The Monitoring System

Data now being collected through the monitoring system will identify program strengths and weaknesses in such areas as outreach and intake; provision of appropriate shelter, food, clothing, and counseling; making of referrals, as needed, for health care, employment, and educational services; family reunification and aftercare; and program administration.

3. Evaluation Studies of FYSB Programs

Current studies nearing completion include:

- "Evaluation of Runaway and Homeless Youth Programs—A Follow-Up Study" (FY 1991–present);
- "Incidence and Prevalence of Drug Abuse Among Runaway and Homeless Youth" (FY 1990–present);
- "Evaluation of the Transitional Living Program for Homeless Youth" (FY 1991–present);
- "Study of the Underlying Causes of Youth Homelessness" (1989–present); and
- "National Evaluation of Home-Based Services Programs" (FY 1992–present).

4. Research and Demonstration (R&D) Studies Supported by FYSB

Priority areas in which FYSB has recently sponsored Research and Demonstration Studies include:

- "Home-Based Services: an Alternative to Out-of-Home Shelter";
- "Transitional Living/Independent Living Collaboration";
- "Cooperation Between Law Enforcement Agencies and Runaway and Homeless Youth Centers";
- "Prevention and Treatment of Alcohol Abuse Among Native American Youth in Runaway and Homeless Youth Centers";
- "Improving Minority Participation in Runaway and Homeless Youth Centers"; and
- "Developing an Urban Strategy for the Prevention of Youth Suicide."

There is need for analysis, synthesis, and interpretation of this new information, leading to the identification of issues and trends in regard to both the client population served and the services being provided.

This information will be used to initiate a dialogue with the field around current program requirements, practices, and concerns, and to identify needed changes in the manner in which FYSB programs are funded and implemented. For example, directors of FYSB grantee agencies and Federal officials have raised a number of program and management issues that an analysis, synthesis and interpretation of the emerging data will help clarify and prioritize. These issues include youth eligibility for FYSB's Runaway and Homeless Youth programs, fees for services, consolidation of Runaway and Homeless Youth programs, availability of physical and mental health care for runaway and homeless youth, and State and local laws affecting runaway and homeless youth programs.

Readers are invited to suggest other areas in which program guidance is needed.

An announcement of the availability of grant funds for these purposes, along with needed forms and instructions, will be published in the **Federal Register** as early in 1994 as possible after the comment period ends.

IV. Evaluation Studies

Continuation funding will be awarded to two ongoing evaluation studies:

- "Evaluation of the transitional Living Program for Homeless Youth" (FY 1991—present). In addition to describing the number and characteristics of youth served by the grantees and the types of services provided, this study is examining the effectiveness of the program in alleviating the

immediate problems of the youth, in preparing the youth for self-sufficiency through education and work, and in strengthening family relationships.

• "Development of Manuals for ACYF to Use in Evaluating Demonstration Projects" (FY 1993—present). This project is developing general and specific manuals to assist ACYF grantees in the design and implementation of their internal program evaluations. One of the specific manuals will be designed for FYSB grantees.

(Catalogue of Federal Domestic Assistance, Program Number 93.623, Runaway and Homeless Youth Program, and Program Number 93.550, Transitional Living Program for Homeless Youth.)

Dated: January 3, 1994.

Olivia A. Golden,

Commissioner, Administration on Children, Youth and Families.

[FR Doc. 94–1857 Filed 1–27–94; 8:45 am]

BILLING CODE 4184–01–M

Social Security Administration

Social Security Ruling SSR 94–3c; Timely Filing for Attorney Fees Under the Equal Access to Justice Act

AGENCY: Social Security Administration, HHS.

ACTION: Notice of Social Security Ruling.

SUMMARY: In accordance with 20 CFR 422.406(b)(1), the Commissioner of Social Security gives notice of Social Security Ruling 94–3c. This Ruling, based on the Supreme Court's decision in *Shalala* v. *Schaefer*, _____ U.S. _____, 113 S.Ct. 2625 (1993), concerns the time period for filing for attorney fees under the Equal Access to Justice Act (EAJA). Specifically, the issue before the Court was whether the 30-day period for filing a petition for EAJA fees begins immediately upon expiration of the time for appeal of a remand order issued by a court under sentence four of section 205(g) of the Social Security Act, or after the administrative proceedings on remand are complete.

EFFECTIVE DATE: January 28, 1994.

FOR FURTHER INFORMATION CONTACT: Joanne K. Castello, Office of Regulations, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235, (410) 965–1711.

SUPPLEMENTARY INFORMATION: Although we are not required to do so pursuant to 5 U.S.C. 552 (a)(1) and (a)(2), we are publishing this Social Security Ruling in accordance with 20 CFR 422.406(b)(1).

Social Security Rulings make available to the public precedential decisions relating to the Federal old-age, survivors, disability, supplemental security income, and black lung benefits programs. Social Security Rulings may be based on case decisions made at all administrative levels of adjudication, Federal court decisions, Commissioner's decisions, opinions of the Office of the General Counsel, and other policy interpretations of the law and regulations.

Although Social Security Rulings do not have the force and effect of the law or regulations, they are binding on all components of the Social Security Administration, in accordance with 20 CFR 422.406(b)(1), and are to be relied upon as precedents in adjudicating other cases.

If this Social Security Ruling is later superseded, modified, or rescinded, we will publish a notice in the **Federal Register** to that effect.

(Catalog of Federal Domestic Assistance Programs Nos. 93.802 Social Security—Disability Insurance; 93.803 Social Security—Retirement Insurance; 93.805 Social Security—Survivors Insurance; 93.806 Special Benefits for Disabled Coal Miners; 93.807 Supplemental Security Income.)

Dated: January 11, 1994.

Shirley S. Chater,

Commissioner of Social Security.

Sections 205(g) and 223 of the Social Security Act (42 U.S.C. 405(g) and 423) Timely Filing for Attorney's Fees Under the Equal Access to Justice Act

Shalala v. *Schaefer*, _____ U.S. _____, 113 S.Ct. 2625 (1993)

This Ruling concerns whether the 30-day period for filing an application for attorney's fees under the Equal Access to Justice Act (EAJA) begins immediately upon expiration of the time for appeal of a remand order issued by a court under sentence four of section 205(g) of the Social Security Act (the Act), or after the administrative proceedings on remand are complete. Sentence four states, "[t]he court shall have power to enter, upon the pleadings and transcript of the record, a judgment affirming, modifying, or reversing the decision of the Secretary, with or without remanding the cause for a rehearing."

The claimant filed for and was denied title II disability benefits. The claimant sought review in district court under section 205(g) of the Act. Reversing the Secretary, the district court held that the Secretary had erred in her decision on this case and remanded the case under sentence four of section 205(g) of the Act to the Secretary for further consideration. The Secretary subsequently awarded benefits.

More than a year later, the claimant filed a petition for attorney's fees under the EAJA. The Secretary, in response, noted that the claimant was required to file the petition for EAJA fees "within 30 days of final judgment in the action" pursuant to 28 U.S.C. 2412(d)(1)(B), and argued that the "final judgment" in this case was the administrative decision on remand.

The district court relied on *Welter* v. *Sullivan* in which the eighth circuit held that the district court did not intend to enter final judgment when it remanded the plaintiffs' cases under sentence four. When the Secretary appealed *Schaefer* to the circuit court, the court declined the Secretary's suggestion for *en banc* reconsideration of *Welter*.

The circuit court affirmed the district court's award of EAJA fees to the claimant. On review by the Supreme Court, the Secretary argued that, in light of the Supreme Court's decisions in *Sullivan* v. *Finkelstein* and *Melkonyan* v. *Sullivan*, a district court cannot retain jurisdiction of a case after a remand under sentence four of section 205(g) of the Act. Although the Supreme Court affirmed the circuit court's decision to award EAJA fees, it rejected its analysis. The Court held that, under the clear language of section 205(g) of the Act, a district court may not retain jurisdiction after a sentence four remand. The Court found that a sentence four remand is an appealable final judgment of the district court that terminates the action and makes a plaintiff a "prevailing party" for the purposes of the EAJA. The Court clarified dicta in *Sullivan* v. *Hudson*, emphasizing that a sentence four remand (as opposed to a remand under sentence six of section 205(g), in which the court retains jurisdiction of the case) confers prevailing party status on the plaintiff.

The Court also clarified that, in a sentence four remand, the time period in which an EAJA petition must be filed begins at the conclusion of the appeal period following the district court's entry of a judgment. However, in this case, the Court found that, because the district court failed to enter a judgment pursuant to Rule 58 of the Federal Rules of Civil Procedure, neither the appeal period nor the EAJA 30-day filing period had lapsed.

For the foregoing reasons, the Court affirmed the judgment of the court of appeals.

SCALIA, Supreme Court Justice

This case concerns the proper timing of an application for attorney's fees under the Equal Access to Justice Act (EAJA) in a Social Security case. Under 42 U.S.C. 405(g), a claimant has the right to seek judicial review of a final decision of the Secretary of Health and Human Services denying Social Security benefits. One possible outcome of such a suit is that the district court, pursuant to sentence four of section 405(g), will enter "a judgment * * * reversing the decision of the Secretary * * * (and) remanding the cause for a rehearing." The issue here is whether the 30-day period for filing an application for EAJA fees begins immediately upon expiration of the time for appeal of such a "sentence-four remand order," or sometime after the administrative proceedings on remand are complete.

In 1986, respondent Richard Schaefer filed an application for disability benefits under Title II of the Social Security Act, 49 Stat. 622, as amended,

42 U.S.C. 401 *et seq.* (1988 ed. and Supp. III). He was denied benefits at the administrative level, and sought judicial review by filing suit against the Secretary as authorized by section 405(g). Schaefer and the Secretary filed cross-motions for summary judgment. On April 4, 1989, the District Court held that the Secretary had committed three errors in ruling on Schaefer's case and entered an order stating that "the Secretary's decision denying disability insurance benefits to [Schaefer] is reversed, that the parties' cross-motions for summary judgment are denied, and that the case is remanded to the Secretary for further consideration in light of this Order." App. to Pet. for Cert. 27a.

In accordance with this order, Schaefer's application for benefits was reconsidered at the administrative level, and was granted. On July 18, 1990, Schaefer returned to the District Court and filed an application for attorney's fees pursuant to EAJA. In response, the Secretary noted that Schaefer was required to file any application for EAJA fees "within thirty days of final judgment in the action," 28 U.S.C. 2412(d)(1)(B), and argued that the relevant "final judgment" in the case was the administrative decision on remand, which had become final on April 2, 1990. The District Court stayed action on Schaefer's EAJA application pending this Court's imminent ruling in *Melkonyan* v. *Sullivan*, 501 U.S. _____, 111 S.Ct. 2157, 115 L.Ed.2d 78 (1991).

Melkonyan was announced shortly thereafter, holding that a final administrative decision could not constitute a "final judgment" for purposes of section 2412(d)(1)(B). *Id.*, at _____, 111 S.Ct., at 2162. In light of *Melkonyan*, the Secretary changed positions to argue that EAJA's 30-day clock began running when the District Court's April 4, 1989 order (not the administrative ruling on remand) became final, which would have occurred at the end of the 60 days for appeal provided under Federal Rule of Appellate Procedure 4(a). Thus, the Secretary concluded, Schaefer's time to file his EAJA application expired on July 3, 1989, over a year before the application was filed. The District Court, however, found Schaefer's EAJA application timely under the controlling circuit precedent of *Welter* v. *Sullivan*, 941 F.2d 674 (CA8 1991), which held that a sentence-four remand order is not a final judgment where "the district court retain[s] jurisdiction * * * and plan[s] to enter dispositive sentence four judgmen[t]" after the administrative proceedings on remand are complete. *Id.*, at 675. The District Court went on to rule that Schaefer was entitled to $1,372.50 in attorney's fees.

The Secretary fared no better on appeal. The Eighth Circuit declined the Secretary's suggestion for en banc reconsideration of *Welter*, and affirmed the District Court in an unpublished *per curiam* opinion. The Secretary filed a petition for certiorari, urging us to reverse the Court of Appeals summarily. We granted certiorari, 506 U.S. _____, 113 S.Ct. 594, 121 L.Ed.2d 532 (1992), and set the case for oral argument.

II

The first sentence of 28 U.S.C. 2412(d)(1)(B) provides:

"A party seeking an award of fees and other expenses shall, *within thirty days of final judgment in the action*, submit to the court an application for fees and other expenses which shows that the party is a prevailing party and is eligible to receive an award under this subsection, and the amount sought, including an itemized statement from any attorney or expert witness representing or appearing in behalf of the party stating the actual time expended and the rate at which fees and other expenses were computed." (Emphasis added.)

In *Melkonyan* v. *Sullivan*, we held that the term "final judgment" in the highlighted phrase above "refers to judgments entered by a court of law, and does not encompass decisions rendered by an administrative agency." See 501 U.S., at _____, 111 S.Ct., at 2162. Thus, the only order in this case that could have resulted in the starting of EAJA's 30-day clock was the District Court's April 4, 1989 order, which reversed the Secretary's decision denying disability benefits and remanded the case to the Secretary for further proceedings.

In cases reviewing final agency decisions on Social Security benefits, the exclusive methods by which district courts may remand to the Secretary are set forth in sentence four and sentence six of section 405(g), which are set forth in the margin.[1] See *Melkonyan*, *supra*, at _____–_____, 111 S.Ct., at 2163–2164. Schaefer correctly concedes that the District Court's remand order in this case was entered pursuant to sentence four.[2] He argues, however, that a district court proceeding under that provision need not enter a judgment at the time of remand, but may postpone it and retain jurisdiction pending completion of the administrative proceedings. That argument, however, is inconsistent with the plain language of sentence four, which authorizes a district court to enter a judgment "with or without" a remand order, not a remand order "with or without" a judgment.

See *Sullivan* v. *Finkelstein*, 496 U.S. 617, 629, 110 S. Ct. 2658, 2666, 110 L.Ed.2d 563 (1990). Immediate entry of judgment (as opposed to entry of judgment after postremand agency proceedings have been completed and their results filed with the court) is in fact the principal feature that distinguishes a sentence-four remand from a sentence-six remand. See *Melkonyan*, 501 U.S. at _____–_____, 111 S.Ct., at 2164–2165.

Nor is it possible to argue that the judgment authorized by sentence four, if it includes a remand, does not become a "final judgment"—as required by section 2412(d)—upon expiration of the time for appeal. If that were true, there would never be any final judgment in cases reversed and remanded for further agency proceedings (including those which suffer that fate after the Secretary has filed the results of a sentence-six remand). Sentence eight of section 405(g) states that "(t)he judgment of the court"—which must be a reference to a sentence-four judgment, since that is the only judgment authorized by section 405(g)—"shall be final except that it shall be subject to review in the same manner as a judgment in other civil actions." Thus, when the time for seeking appellate review has run, the sentence-four judgment fits squarely within the term "final judgment" as used in section 2412(d), which is defined to mean "a judgment that is final and not appealable." 28 U.S.C. 2412(d)(2)(G). We described the law

[1] Sentences four and six of section 405(g) provide:

"[4] The [district] court shall have power to enter, upon the pleadings and transcript of the record, a judgment affirming, modifying, or reversing the decision of the Secretary, with or without remanding the cause for a rehearing * * *. [6] The court may, on motion of the Secretary made for good cause shown before he files his answer, remand the case to the Secretary for further action by the Secretary, and it may at any time order additional evidence to be taken before the Secretary, but only upon a showing that there is now evidence which is material and that there is good cause for the failure to incorporate such evidence into the record in a prior proceeding; and the Secretary shall, after the case is remanded, and after hearing such additional evidence if so ordered, modify or affirm his findings of fact or his decision, or both, and shall file with the court any such additional and modified findings of fact and decision, and a transcript of the additional record and testimony upon which his action in modifying or affirming was based."

[2] Sentence-six remands may be ordered in only two situations: where the Secretary requests a remand before answering the complaint, or where new, material evidence is adduced that was for good cause not presented before the agency. See section 405(g) (sentence six); *Melkonyan* v. Sullivan, 501 U.S. _____, _____, and n. 2, 111 S.Ct. 2157, 2163–2164, and n. 2, (1991); cf. *Sullivan* v. *Finkelstein*, 496 U.S. 617, 626, 110 S.Ct. 2658, 2664, 110 L.Ed.2d 563 (1990). The District Court's April 4, 1989 remand order clearly does not fit within either situation.

with complete accuracy in *Melkonyan*, when we said:

> In sentence four cases, the filing period begins after the final judgment ("affirming, modifying, or reversing") is entered by the court and the appeal period has run, so that the judgment is no longer appealable * * *. In sentence six cases, the filing period does not begin until after the postremand proceedings are completed, the Secretary returns to court, the court enters a final judgment, and the appeal period runs. 501 U.S. at _____, 111 S.Ct., at 2165.

Schaefer raises two arguments that merit further discussion. The first is based on our decision in *Sullivan* v. *Hudson*, 490 U.S. 877, 892, 109 S.Ct. 2248, 2257, 104 L.Ed.2d 941, (1989), which held that fees incurred during administrative proceedings held pursuant to a district court's remand order could be recovered under EAJA. In order "to effectuate *Hudson*," Schaefer contends, a district court entering a sentence-four remand order may properly hold its judgment in abeyance (and thereby delay the start of EAJA's 30-day clock) until postremand administrative proceedings are complete; otherwise, as far as fees incurred during the yet-to-be-held administrative proceedings are concerned, the claimant would be unable to comply with the requirement of section 2412(d)(1)(B) that the fee application include "the amount sought" and "an itemized statement * * * [of] the actual time expended" by attorneys and experts. In response, the Secretary argues that *Hudson* applies only to cases remanded pursuant to sentence six of section 405(g), where there is no final judgment and the clock does not begin to run. The difficulty with that, Schaefer contends, is that *Hudson itself* clearly involved a sentence-four remand.

On the last point, Schaefer is right. Given the facts recited by the Court in *Hudson*, the remand order there could have been authorized only under sentence four. See 490 U.S., at 880–881, 109 S.Ct.,at 2252; cf. n. 2, *supra*. However, the facts in *Hudson* also show that the District Court had not terminated the case, but had retained jurisdiction during the remand. And that was a central element in our decision, as the penultimate sentence of the opinion shows:

> We conclude that where a court orders a remand to the Secretary in a benefits litigation *and retains continuing jurisdiction over the case pending a decision from the Secretary which will determine the claimant's entitlement to benefits*, the proceedings on remand are an integral part of the "civil action" for judicial review, and thus attorney's fees for representation on remand are available subject to the other limitations in the EAJA. 490 U.S., at 892, 109 S.Ct., at 2258 (emphasis added).

We have since made clear, in *Finkelstein*, that that retention of jurisdiction, that failure to terminate the case, was error: Under section 405(g), "each final decision of the Secretary [is] reviewable by a *separate* piece of litigation," and a sentence-four remand order "terminate[s] the civil action" seeking judicial review of the Secretary's final decision. 496 U.S., at 624–625, 110 S.Ct., at 2663 (emphases added). What we adjudicated in *Hudson*, in other words, was a hybrid: a sentence-four remand that the District Court had improperly (but without objection) treated like a sentence-six remand.[3] We specifically noted in Melkonyan that *Hudson* was limited to a "narrow class of qualifying administrative proceedings" where "the district court retains jurisdiction of the civil action" pending the completion of the administrative proceedings. 501 U.S. at _____, 111 S.Ct., at 2162. We therefore do not consider the holding of *Hudson* binding as to sentence-four remands that are ordered (as they should be) without retention of jurisdiction, or that are ordered with retention of jurisdiction that is challenged.[4]

Schaefer's second argument is that a sentence-four remand order cannot be considered a "final judgment" for purposes of section 2412(d)(1)(B) because that provision requires the party seeking fees to submit an application "show[ing] that [he] is a prevailing party." That showing, Schaefer contends, cannot be made until the proceedings on remand are complete, since a Social Security claimant does not "prevail" until he is awarded Social Security benefits. The premise of this argument is wrong. No holding of this Court has ever denied prevailing-party status (under section 2412(d)(1)(B)) to a plaintiff who won a remand order pursuant to sentence four of section 405(g). Dicta in *Hudson* stated that "a Social Security claimant would not, as a general matter, be a prevailing party within the meaning of the EAJA merely because a court had remanded the action to the agency for further proceedings." 490 U.S., at 887, 109 S.Ct., at 2255. But that statement (like the holding of the case) simply failed to recognize the distinction between a sentence-four remand, which terminates the litigation with victory for the plaintiff, and a sentence-six remand, which does not. The sharp distinction between the two types of remand had not been made in the lower-court opinions in *Hudson*, see *Hudson* v. *Secretary of Health and Human Services*, 839 F.2d 1453 (CA11 1988); App. to Pet. for Cert. in *Sullivan* v. *Hudson*, O.T.1988, No. 616, pp. 17a–20a (setting forth unpublished District Court opinion), was not included in the question presented for decision,[5] and was mentioned for the first time in the closing pages of the Secretary's reply brief, see Reply Brief for Petitioner in *Sullivan* v. *Hudson*, O.T.1988, No. 616, pp. 14–17. It is only decisions after *Hudson*—specifically *Finkelstein* and *Melkonyan*—which establish that the sentence-four, sentence-six distinction is crucial to the structure of judicial review established under section 405(g). See *Finkelstein*, 496 U.S., at 626, 110 S.Ct., at 2664; *Melkonyan*, 501 U.S., at _____–_____, 111 S.Ct., at 2162–2163.

Hudson's dicta that remand does not generally confer prevailing-party status relied on three cases, none of which supports that proposition as applied to sentence-four remands. *Hanrahan* v. *Hampton*, 446 U.S. 754, 758–759, 100

---

[3] The Secretary not only failed to object to the District Court's retention of jurisdiction, but affirmatively endorsed the practice as a means of accommodating the lower court cases holding that a section 405(g) plaintiff does not become a prevailing party until Social Security benefits are actually awarded. Reply Brief for Petitioner in *Sullivan* v. *Hudson*, O.T. 1988, No. 616, pp. 12–13. Those precedents were highly favorable to the Government, of course, because they relieved the Secretary of liability for EAJA fees in all cases where Social Security benefits were ultimately denied. But they were also at war with the view—expressed later in the Secretary's *Hudson* reply brief—that a sentence-four remand order is a "final judgment" in the civil action. *Id.*, at 16. Essentially, the Secretary in *Hudson* wanted it both ways: He wanted us to regard retention of jurisdiction as proper for purposes of determining prevailing-party status, but as improper for purposes of awarding fees on remand.

[4] Justice STEVENS says that our holding "overrul[es]" *Sullivan* v. *Hudson*, 490 U.S. 877, 109 S.Ct. 2248, 104 L.Ed.2d 941, (1989). *Post*, at 2633, 2636. We do not think that is an accurate characterization. *Hudson* remains good law as applied to remands ordered pursuant to sentence six. And since the distinction between sentence-four and sentence-six remands was neither properly presented nor considered in *Hudson*, *see supra*, at 2630 and n. 3, and *infra*, at 2631, limiting *Hudson* to sentence-six cases does not "overrule" the decision even in part. See *Brecht* v. *Abrahamson*, 507 U.S. _____, _____, 113 S.Ct., 1710, 1718, 123 L.Ed.2d 353 (1993). We agree with Justice STEVENS that until today there has been some contradiction in our case law on this subject. In resolving it, however, we have not simply chosen *Melkonyan's* dicta over *Hudson*, but have grounded our decision in the text and structure of the relevant statutes, particularly section 405.

[5] As formulated in the Secretary's petition, the question on which the Court granted certiorari in *Hudson* was: "Whether Social Security administrative proceedings conducted after a remand from the courts are 'adversary adjudications' for which attorney fees are available under the [EAJA]." Pet. for Cert. in *Sullivan* v. *Hudson*, O.T.1988, No. 616, p. I.

S.Ct. 1987, 1990, 64 L.Ed.2d 670 (1980), rejected an assertion of prevailing-party status, not by virtue of having secured a remand, but by virtue of having obtained a favorable procedural ruling (the reversal on appeal of a directed verdict) during the course of the judicial proceedings. *Hewitt* v. *Helms*, 482 U.S. 755, 107 S.Ct. 2672, 96 L.Ed.2d 654 (1987), held that a plaintiff does not become a prevailing party merely by obtaining "a favorable judicial statement of law in the course of litigation that results in *judgment against the plaintiff*," *id.*, at 763, 107 S.Ct., at 2677 (emphasis added). (A sentence-four remand, of course, is a judgment *for* the plaintiff.) And the third case cited in *Hudson, Texas Teachers Assn.* v. *Garland Independent School Dist.*, 489 U.S. 782, 109 S.Ct. 1486, 103 L.Ed.2d 866 (1989), affirmatively supports the proposition that a party who wins a sentence-four remand order is a prevailing party. *Garland* held that status to have been obtained "[i]f the plaintiff has succeeded on any significant issue in litigation which achieve[d] some of the benefit * * * sought in bringing suit." *Id.*, at 791–792, 109 S.Ct., at 1493 (citation and internal quotation marks omitted). Obtaining a sentence-four judgment reversing the Secretary's denial of benefits certainly meets this description. See also *Farrar* v. *Hobby*, 506 U.S. _____, 113 S.Ct., 566, 121 L.Ed.2d 494 (1992).

III

Finally, Schaefer argues that, even if the District Court should have entered judgment in connection with its April 4, 1989 order remanding the case to the Secretary, the fact remains that it did not. And since no judgment was entered, he contends, the 30-day time period for filing an application for EAJA fees cannot have run. We agree.

An EAJA application may be filed until 30 days after a judgment becomes "not appealable"—*i.e.*, 30 days after the time for appeal has ended. See section 2412(d)(1)(B), (d)(2)(G); see also *Melkonyan*, 501 U.S., at _____, 111 S.Ct., at 2165. Rule 4(a) of the Federal Rules of Appellate Procedure establishes that, in a civil case to which a federal officer is a party, the time for appeal does not end until 60 days after "entry of judgment," and that a judgment is considered entered for purposes of the rule only if it has been "entered in compliance with Rul[e] 58 * * * of the Federal Rules of Civil Procedure." Fed. R. App. Proc. 4(a)(1), (7). Rule 58, in turn, requires a district court to set forth every judgment "on a separate document" and provides that "[a] judgment is effective only when so set forth." See *United States* v. *Indrelunas*, 411 U.S. 216, 220, 93 S.Ct. 1562, 1564, 36 L.Ed.2d 202 (1973) *(per curiam)*.

Since the District Court's April 4 remand order was a final judgment, see *ante*, at 2630, a "separate document" of judgment should have been entered. It is clear from the record that this was not done. The Secretary does not dispute that, but argues that a formal "separate document" of judgment is not needed for an order of a district court to *become* appealable. That is quite true, see 28 U.S.C. 1291; *Bankers Trust Co.* v. *Mallis*, 435 U.S. 381, 98 S.Ct. 1117, 55 L.Ed.2d 357 (1978) *(per curiam)*; *Finkelstein, supra*, 496 U.S. at 628, n. 7, 110 S.Ct., at 2665, n. 7, but also quite irrelevant. EAJA's 30-day time limit runs from the *end* of the period for appeal, not the *beginning*. Absent a formal judgment, the District Court's April 4 order remained "appealable" at the time that Schaefer filed his application for EAJA fees, and thus the application was timely under section 2412(d)(1).[6]

For the foregoing reasons, the judgment of the Court of Appeals is Affirmed.

Justice Scalia delivered the opinion of the Court, in which Chief Justice Rehnquist, and Justices White, O'Connor, Kennedy, Souter, and Thomas joined. Justice Stevens filed an opinion concurring in the judgment, in which Justice Blackmun joined.

[FR Doc. 94–1922 Filed 1–27–94; 8:45 am]

BILLING CODE 4190–29–P

[6] We disagree with Justice STEVENS' assertion that "the respondent has prevailed precisely *because* the District Court in this case did enter a remand order without entering a judgment." *Post*, at 2633, n. 2 (emphasis in original). By entering a sentence-four remand order, the District Court did enter a *judgment*; it just failed to comply with the formalities of Rule 58 in doing so. That was error but, as detailed in the text, the relevant rules and statutes impose the burden of that error on the party seeking to assert an untimeliness defense, here the Secretary. Thus, contrary to Justice STEVENS' suggestion, *see post*, at 2633, n. 2, our ruling in favor of respondent is not at all inconsistent with the proposition that sentence four and sentence six provide the exclusive methods by which district courts may remand a section 405 case to the Secretary.

Centers for Disease Control and Prevention

[CDC–305A]

Fiscal Year 1994 Preventive Health Services; Addendum to Program Announcement 305; Cooperative Agreements for National/Regional Minority Organization HIV/STD Prevention, Immunization, and TB Projects

Summary

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1994 supplemental funds for current awardees of the National/Regional Minority Organizations (NRMO) program to provide technical assistance and training to community planning groups and the State and local health departments working with them to facilitate representation, inclusiveness, and parity in the implementation of HIV-prevention community planning. This competitive announcement is an addendum to **Federal Register** (FR) Notice 305, published in the **Federal Register** on June 4, 1993 [58 FR 31721], in which current recipients are collaborating with community organizations and health agencies to coordinate technical assistance and training programs that serve racial and ethnic minority populations. Approximately $750,000 is expected to be available for a one-time award in FY 1994 to supplement up to 5 cooperative agreements. The awards are not expected to exceed $150,000 each and will not be funded beyond the current budget period. It is expected that these supplemental awards will be made on or about February 28, 1994.

The purpose of this addendum to Program Announcement 305 is to provide State and local health departments and other community organizations with the necessary technical assistance and training to: (1) Assure that inclusion, representation, and parity occur in the community planning process; and (2) Enhance selection processes for equitable representation in HIV prevention planning activities, thereby enhancing the capacity of affected communities and non-governmental organizations to participate effectively and equally in the planning process.

The CDC shall be responsible for coordinating all requests for technical assistance and training between the NRMO and the community organizations (via State and local health departments) that are requiring the technical assistance; providing

consultation and technical assistance in planning, operating, and evaluating program activities under this announcement; assisting in developing plans for evaluation of all program activities and services and interpreting evaluation findings; assisting successful applicants in collaborating with State and local health departments and other PHS grantees; facilitating the transfer of successful prevention interventions and program models to other areas; monitoring the successful applicant's program activities, protection of client confidentiality, and compliance with other requirements; and facilitating the exchange of program information and technical assistance among community organizations, health departments, and NRMOs.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority areas of Educational and Community-Based Programs, HIV Infection, Sexually Transmitted Diseases (STDs), and Immunization and Infectious Diseases. (To order a copy of "Healthy People 2000," see the section entitled "Where to Obtain Additional Information.")

Authority

This program is authorized under sections 301(a) and 317 of the Public Health Service Act, [42 U.S.C. 241(a) and 247b], as amended.

Eligibility

Eligible applicants for this competitive supplement are the current cooperative agreement recipients under announcement 305, "National/Regional Minority Organizations HIV/STD Prevention, Immunization, and TB Projects." Eligibility is limited to these organizations since this is a competitive supplement to a pre-existing program announcement. The program announcement and application kit have been sent to all eligible applicants.

Other Requirements

OMB Clearance

Projects that involve the collection of information from 10 or more individuals and funded by cooperative agreement will be subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

HIV Program Review Panel Requirements

Recipients must comply with the terms and conditions included in the document titled, "Content of HIV/AIDS-Related Written Materials, Pictorials, Audiovisuals, Questionnaires, Survey Instruments, and Educational Sessions in Centers for Disease Control and Prevention (CDC) Assistance Programs (June 1992)," a copy of which is included in the application kit. In complying with the program review panel requirements contained in this document, recipients are encouraged to use a current program review panel such as the one created by the State health department's HIV/AIDS Prevention Program. If the recipient forms its own program review panel, at least one member must also be a designated representative of a State or local health department.

Executive Order 12372 Review

Applications are subject to Intergovernmental Review of Federal Programs as governed by Executive Order (E.O.) 12372. E.O. 12372 sets up a system for State and local government review of proposed Federal assistance applications. Potential applicants should have already contacted their State Single Point of Contact (SPOC) to alert them to the prospective applications and to receive instructions on the State process. For proposed projects that serve more than one State, the applicant should contact the SPOC for each State served. If SPOCs have any State process recommendations on applications submitted to CDC, they should forward them, no later than February 25, 1994, to Clara M. Jenkins, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., room 320, Mail Stop E–15, Atlanta, GA 30305. The CDC does not guarantee to accommodate or explain State process recommendations it receives after February 25, 1994.

Public Health System Reporting Requirements

This program is not subject to the Public Health System Reporting Requirements.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance Number is 93.939, HIV Prevention Activities—Non-Governmental Organization Based.

Where To Obtain Additional Information

If you are interested in obtaining additional information regarding these projects, please refer to Announcement 305A and contact Sharron Orum or Van Malone, Grants Management Specialists, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., room 320, Mail Stop E–15, Atlanta, GA 30305, telephone (404) 842–6575.

A copy of "Healthy People 2000" (Full Report, Stock No. 017–001–00474–0) or "Healthy People 2000" (Summary Report, Stock No. 017–001–00473–1) referenced in the SUMMARY may be obtained through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 783–3238.

Dated: January 24, 1994.

Robert L. Foster,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 94–1880 Filed 1–27–94; 8:45 am]

BILLING CODE 4160–18–P

Food and Drug Administration

[Docket No. 94N–0013]

Drug Export; UBI® HIV 1/2 PHA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that United Biomedical, Inc., has filed an application requesting approval for the export of the human biological product UBI® HIV 1/2 PHA (passive hemagglutination assay) to Belgium, The Netherlands, Sweden, and the United Kingdom.

ADDRESSES: Relevant information on this application may be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of human biological products under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT: Frederick W. Blumenschein, Center for Biologics Evaluation and Research (HFM–660), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–1070.

SUPPLEMENTARY INFORMATION: The drug export provisions in section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382) provide that FDA may approve applications for the export of human biological products

that are not currently approved in the United States. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an application for approval. Section 802(b)(3)(C) of the act requires that the agency review the application within 30 days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the **Federal Register** within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that United Biomedical, Inc., 25 Davids Dr., Hauppauge, NY 11788, has filed an application requesting approval for the export of the human biological product UBI® HIV 1/2 PHA to Belgium, The Netherlands, Sweden, and the United Kingdom. The UBI® HIV 1/2 PHA is an in vitro qualitative, passive hemagglutination assay test for the detection of human immunodeficiency virus (HIV–1 and HIV–2) antibodies in serum or plasma. The application was received and filed in the Center for Biologics Evaluation and Research on October 26, 1993, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by February 7, 1994, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Biologics Evaluation and Research (21 CFR 5.44).

Dated: January 18, 1994.

P. Michael Dubinsky,

Acting Director, Office of Compliance, Center for Biologics Evaluation and Research.

[FR Doc. 94–1794 Filed 1–27–94; 8:45 am]

BILLING CODE 4160–01–F

Advisory Committees; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces the renewal of the Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants by the Secretary of Health and Human Services. This notice is issued under the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92–463 (5 U.S.C. app. 2)).

DATES: Authority for this committee will expire on December 2, 1995, unless the Secretary of Health and Human Services formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Donna M. Combs, Committee Management Office (HFA–306), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–2765.

Dated: January 14, 1994.

Jane E. Henney,

Deputy Commissioner for Operations.

[FR Doc. 94–1793 Filed 1–27–94; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 87N–0056]

Food Code: 1993 Recommendations of the United States Public Health Service/Food and Drug Administration; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the "Food Code: 1993 Recommendations of the United States Public Health Service/Food and Drug Administration" (the 1993 Food Code). The 1993 Food Code consists of model requirements for regulating the retail segment of the food industry to safeguard public health and to ensure that the food is not adulterated and is honestly presented when offered to the consumer. The 1993 Food Code updates, combines, and replaces three separate preceding models: The 1976 Food Service Sanitation Code; the 1978 Food and Beverage Vending Code; and the 1982 Retail Food Store Sanitation Code. It covers management and personnel; food; equipment, utensils, and linens; water, plumbing, and waste; physical facilities; poisonous or toxic materials; and compliance and enforcement. This project was initiated at the recommendation of the Conference for Food Protection (the Conference).

ADDRESSES: The 1993 Food Code may be ordered from the National Technical Information Service (NTIS), U.S. Department of Commerce, by calling 703–487–4650 for regular service or 800–553–NTIS for rush service and by using a major charge card or NTIS deposit account. For information on ordering by mail or at the NTIS Bookstore in Springfield, Virginia, please call NTIS on 703–487–4650. For electronic access (via FedWorld™) to ordering and downloading options, dial 703–321–8020 with a modem (Internet: fedworld.gov). The 1993 Food Code is available in paper copy and on diskette. To order a spiral-bound printed copy of field-manual quality, ask for PB94–113941/AS at $23.00 per copy. To order a microcomputer diskette copy (WordPerfect), ask for PB94–501285/AS at $17.50 per copy. Between the time of notice of availability and the printing of the spiral-bound copies, a limited number of photo-reproduced copies is available. This reproduced copy is suitable for immediate use but does not have the appearance, durability, or tabulation of the printed, spiral-bound copy. To order a reproduced copy, ask for PB94–113933/AS at $44.50 per copy. Payment may be made by check, money order, charge card (American Express, Visa, or Mastercard), or billing arrangements made with NTIS. Charge card orders must include the charge card account number and expiration date. The 1993 Food Code is available for public examination in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Arthur L. Banks, Center for Food Safety and Applied Nutrition (HFS–627), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–8140.

SUPPLEMENTARY INFORMATION: FDA is responsible under section 311 of the Public Health Service Act (42 U.S.C. 243) and 21 CFR 5.10(a)(2) and (a)(4), and the statutory provisions cited therein, for providing assistance to State and local governmental jurisdictions with respect to the prevention of communicable disease and the enforcement of their public health regulations. For many years, FDA has used model food codes as one means of assisting the several thousand Federal, State, and local agencies that have primary responsibility for regulating

retail-level food establishments such as restaurants, institutions, grocery stores, and food vending locations. The model codes that FDA has prepared are not Federal laws or regulations and are not preemptive but are widely referenced, adopted, and applied at all levels of government. FDA periodically updates and reissues the model codes.

FDA has determined that a new model food code revision is necessary for the retail segment of the food industry because new technologies are being applied by the industry; new information about the nature, contributing factors, and means of preventing foodborne illness have become available; and new approaches to inspection have been developed since FDA last revised its three existing model codes on retail food. FDA has also concluded that there was a need to combine the provisions of these codes into a single document because the traditional lines of demarcation between the types of food operations covered by each of the separate codes, as well as between food service firms versus food stores, have largely disappeared. Pursuant to this determination, FDA issued a notice in the **Federal Register** of April 13, 1987 (52 FR 11885), that announced the agency's plan to revise the retail food codes. In that notice, FDA cited the problems that States were having with the model codes and the opportunities offered by a new unified code.

In the **Federal Register** of May 9, 1988 (53 FR 16472), FDA announced the availability for comment of a draft model Food Protection Unicode that would update and combine the food protection and sanitation provisions contained in the separate model codes covering food service, food vending, and retail food stores. Interested persons were given until August 8, 1988, to comment. FDA subsequently extended the comment period until October 7, 1988 (53 FR 29953, August 9, 1988), in response to requests from three trade associations, one State agency, and the Conference.

FDA received over 150 letters, each containing 1 or more comments, in response to the draft model Food Protection Unicode. FDA considered each of the comments and modified the document as appropriate based on the information that it received. Among the comments that FDA considered were those of the Conference, which were submitted after the Conference's 1992 meeting in Baltimore, MD.

The 1993 Food Code provides definitions of terms; standards for management and personnel, food operations, equipment, and facilities; and guidance on food establishment plan review, permit issuance, inspection, restriction of infected food employees, holding and examination of food, and permit suspension. This new combined model code also includes: (1) New provisions covering management responsibilities and knowledge and employee health and practices; (2) a new framework for the application of hazard analysis critical control point principles at the retail level; (3) a variance procedure for approving food processing at the retail level; (4) enhanced and more flexible criteria for safe time/temperature management of potentially hazardous foods; (5) new provisions pertaining to consumer information and public disclosure; and (6) more comprehensive code enforcement provisions.

Dated: January 11, 1994.

Michael R. Taylor,

Deputy Commisioner for Policy.

[FR Doc. 94–1642 Filed 1–21–94; 4:31 pm]

BILLING CODE 4160–01–F

Health Resources and Services Administration

Ryan White Title IV—HIV Demonstration Program for Children, Adolescents, and Families

AGENCY: Health Resources and Services Administration (HRSA), PHS.

ACTION: Notice of availability of funds.

SUMMARY: The Maternal and Child Health Bureau (MCHB), HRSA, announces that fiscal year (FY) 1994 funds are available for grants for demonstration projects to provide services for children, adolescents, women and families infected with or affected by the Human Immunodeficiency Virus (HIV). Projects will be funded to demonstrate strategies and innovative models of family-centered, community-based coordinated care and research for children, youth, women of childbearing age, and families infected and affected by HIV infection, AIDS or other related conditions, or those at risk for developing infection. Funds were appropriated for this purpose under Section 2671, Title IV, of the Ryan White Comprehensive AIDS Resource Emergency (CARE) Act of 1990, Public Law 101–381, which amended Title XXVI of the Public Health Service Act (42 U.S. Code 300ff–11 *et seq.*).

The PHS is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS national activity for setting priority areas. Title IV directly addresses the Healthy People 2000 objectives related to the priority area of HIV infection. Potential applicants may obtain a copy of Healthy People 2000 (Full Report; Stock Number 017–001–0474–0) or Healthy People 2000 (Summary Report: Stock No. 017–001–00473–1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325 (telephone 202 783–3238).

ADDRESSES: Grant applications for HIV Demonstration Program for Children, Adolescents, and Families (PHS form #5161–1, approved under OMB #0937–0189) must be obtained from and submitted to: Chief, Grants Management Branch, Office of Program Support, Maternal and Child Health Bureau, Health Resources and Services Administration, room 18–12, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443–1440.

DATES: The application deadline date is April 8, 1994. Competing applications will be considered to be on time if they are either: (1) Received on or before the deadline date, or (2) postmarked on or before the deadline date and received in time for orderly processing. (Applicants should request a legibly dated receipt from a commercial carrier or U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.

Late applications not accepted for processing or those sent to an address other than specified in the **ADDRESSES** section will be returned to the applicant.

Applicants will be notified of grant awards in July 1994. The starting dates for projects will be specified in the program guidance.

FOR FURTHER INFORMATION CONTACT: Additional information regarding technical and program issues may be obtained from: Beth Roy, Division of Services for Children with Special Health Needs, Maternal and Child Health Bureau, Health Resources and Services Administration, room 18A–19, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–9051. Requests for information concerning business management issues should be directed to: John Gallicchio, Grants Management Officer (GMO), Maternal and Child Health Bureau, at the address specified in the **ADDRESSES** section.

SUPPLEMENTARY INFORMATION:

Program Background and Objectives

The Pediatric AIDS Demonstration Program was initiated in 1988. The

program grew from 13 projects funded at $4.4 million to a total of 44 projects funded at $20.8 in 1993. Since 1988, the program has evolved from a primary focus on the coordination of services for the management and care of infected children and their families to also address the broader prevention and care needs of youth and women affected by the HIV infection, AIDS or related conditions. In FY 1994, Congress funded the Pediatric AIDS Demonstration Program under Title IV of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act (Title IV). The program will be permanently authorized in section 2671 of the Public Health Service Act. Title IV authorizes demonstration grants to organizations to provide comprehensive services and enhance access to clinical research trials for children, youth, women, and families with or affected by HIV infection. As a result of this transfer to Title IV, the focus of the program is further expanded to develop innovative models that link systems of comprehensive primary/community-based medical and social services for the affected population with NIH and other clinical research trials.

Purpose

The purpose of the funding is to improve and expand the system of comprehensive care services for children, youth, women, and families who are infected with or affected by HIV and AIDS and to link comprehensive care systems with clinical research. Funds authorized and appropriated under Title IV will be used to demonstrate and test potentially replicable models of service delivery and clinical research to respond to the unique and challenging problems of access to a comprehensive care system faced by HIV and AIDS affected children, youth, women, and families.

While children, youth, and women represent the most rapidly growing population groups affected by HIV and AIDS, they also represent the groups facing the greatest barriers in accessing care and research. These groups disproportionately are minorities and living in poverty. Children, youth, and women have a complex array of economic and social problems that increase their need for comprehensive services and increase the cost and intensity of care. Furthermore, since they comprise the most recent and fastest growing population groups impacted by HIV and AIDS, the care infrastructure and provider capacity are often not developed and require targeted resources and efforts to develop an appropriate system of care.

Given these unmet needs, activities under the demonstration grants should address the following goals:

—Foster the development of comprehensive care infrastructures, including primary care, that increase access to culturally-competent, family-centered, community-based, coordinated care.
—Emphasize prevention within the comprehensive care system in order to reduce the spread of the HIV infection to vulnerable populations.
—Link comprehensive systems of care with HIV/AIDS clinical research trials resulting in increased access for currently under represented populations of children, youth, women, and their families.

Funding Categories

Two categories of projects will be funded in FY 1994. Applications which do not fall within these program categories will not be considered.

The first category of grants, the HIV Demonstration Projects for Children, Adolescents, and Families, continues development of comprehensive care demonstrations, including efforts to develop innovative models that foster collaboration between clinical research institutions and family-centered primary/community-based medical and social service programs for children, youth, women and their families. Projects will focus on local capacity-building, making maximum use of all available public and private resources for reaching and providing health care and supportive services to the target population. Projects should strengthen the infrastructure for the comprehensive system of care by broadening the coalition of agencies, providers, community organizations and families participating in services planning, coordination, and financing. These include other appropriate Federal, State, and local programs serving children with special health care needs under Title V Maternal and Child Health programs, hemophilia treatment centers, Ryan White Title I, II and III programs, providers funded by the Substance Abuse and Mental Health Services Administration (SAMSHA) and Centers for Disease Control and Prevention (CDC), and other programs serving the target population (e.g., Medicaid, developmental disabilities, special education) and providers, payers, organizations, and support groups in the private sector with a similar focus.

Preference for funding in this category will be given to the competing renewal of currently funded Pediatric/Family AIDS Demonstration projects serving children, youth, women, and families infected with or affected by the HIV infection which demonstrate an established model of a comprehensive and coordinated system of care that is culturally-competent, family-centered, and community-based. This means that these projects will be funded ahead of new groups of applications in this category.

The second category of funding will be used to initiate the development of comprehensive care systems for HIV affected children, adolescents and families in cities or states where there is no currently funded pediatric health care demonstration project nor well organized care system for the target population and where there are barriers to access to care and clinical research trials. Applicants for funding in this category will be supported for initial planning activities to develop their infrastructure for comprehensive care with the ultimate goal of a mature demonstration of family-centered, community-based coordinated care described in Category (1).

Availability of Funds

Approximately $22.0 million is available for the HIV Demonstration Program for Children, Adolescents, and Families, of which approximately $10.3 million will be available for competing renewals and new competitive grants. The following is an approximation of funds available and the number of grants anticipated to be awarded in each category:

—Category (1)—$10.0 million, up to 20 grants.
—Category (2)—$.3 million, up to 4 grants. Individual grants are not expected to exceed $75,000 per year.

For Category (1), project periods are three years. For Category (2), project periods are from one to two years, depending upon the proposed scope of work.

Special Concerns

HIV Demonstration Program for Children, Adolescents, and Families grantees supported by HRSA should coordinate their projects with other Federal, State, and local programs concerned with AIDS and/or serving the target population of children, youth, women and families affected by or at risk for HIV/AIDS, particularly Title V Maternal and Child Health programs and other Ryan White programs.

The MCHB places special emphasis on improving service delivery to women and children from culturally identifiable populations who have been disproportionately affected by barriers to accessible care. This means that

projects are expected to serve and appropriately involve in project activities members of ethnoculturally distinct groups, unless there are compelling programmatic or other justifications for not doing so. The Bureau's intent is to ensure that project interventions and outcomes are of benefit to culturally distinct populations and to insure that the broadest possible representation of culturally distinct and historically under-represented groups is supported through programs and projects sponsored by the MCHB.

The Department will review applications for funds under the above mentioned categories as competing applications and, with particular attention to inclusion of women and persons from culturally distinct populations, will fund those which, in the Department's view, best meet the statutory purposes of the HIV Demonstration Program for Children, Adolescents, and Families and address achievement of the Healthy People 2000 objectives related to HIV infection.

Review Criteria

Applications for grant categories will be reviewed and rated by objective review panels using the review criteria specified below, as appropriate. Please note that there are different criteria for Category (1) and Category (2) applicants.

• For Category (1) HIV Demonstration Projects:

—Adequacy of documentation of the impact of HIV/AIDS on children, youth, women, and families in the service area including: identification of HIV risk factors, description of trends in the HIV epidemic, and determination and documentation of unmet service needs.
—Ability to demonstrate an organized comprehensive system of family-centered, community-based, coordinated care, including the following features: (1) Collaboration/coordination with appropriate community agencies and providers, particularly State Title V agencies, other Ryan White programs, and Healthy Start agencies (2) linkages to primary care, and (3) appropriate referral mechanisms.
—Adequacy of efforts to develop linkages with clinical trials and activities undertaken to facilitate access of the target population to trials, or identification of proposed activities to overcome barriers.
—Clarity of delineation of goals and objectives for the grant period and appropriateness of the timeline for proposed activities. Consistency of the plan with the goals of Title IV and the extent to which the plan addresses the needs identified in the needs assessment.
—Adequacy of the strategy and proposed steps to utilize and report data and evaluation for program planning and management, as well as for measuring the efficacy and effectiveness of the program.
—Organizational structure, staffing, and oversight necessary to implement the proposed goals and objectives.
—Adequacy of the proposed budget; budget justification based on project methodology and required resources.
—Evidence of ability to obtain funding from other public and private funding sources or indication of problems in accessing such funds.
—For competing renewal applicants only, demonstration of an organized, comprehensive system of care and progress in meeting the goals of the current project period will be assessed.

• For Category (2) Comprehensive Care Initial Development Grants:

—Adequacy of the description of the impact of HIV/AIDS on children, youth, women, and families in the service area including: identification of HIV risk factors, and description of trends in the HIV epidemic.
—Adequacy of the planned approach to conducting a needs assessment to identify existing resources to serve the target population and to determine and document unmet service needs.
—Evidence of knowledge and understanding of HIV service delivery and experience in providing services to the population to be served.
—Evidence of understanding of methods for developing comprehensive care linkages with clinical trials in order to increase access to trials for the target population.
—Evidence of the potential to collaborate with appropriate State/community agencies and providers in planning and developing an organized, comprehensive system of family-centered, community-based, coordinated care.
—Clear delineation of goals and objectives with a timeline for accomplishment of proposed activities.
—Clarity and appropriateness of budget based on project methodology and required resources.
—Adequacy of the proposed data and evaluation plan.

Eligible Applicants

Grants may be awarded to public or nonprofit private entities that provide or arrange for primary health care. Eligible entities may include, but are not limited to, State or local health departments, university medical centers, public or nonprofit private hospitals, community health centers (as defined in section 330(a) of the Act), hemophilia treatment centers, drug abuse treatment agencies, tribal health programs, school based clinics and institutions of higher education. All currently funded pediatric AIDS demonstration grantees are eligible for grant funds.

Allowable Costs

The MCHB may support reasonable and necessary costs of HIV Demonstration Project grants within the scope of approved projects. Allowable costs may include salaries, equipment and supplies, travel, contractual, consultants, and others, as well as indirect costs. The MCHB adheres to administrative standards reflected in the Code of Federal Regulation 45 CFR part 92 and 45 CFR part 74. All other sources of funding to support this project must be accurately reflected in the applicant's budget.

Reporting Requirements

A successful applicant under this notice will submit reports in accordance with the provisions of the general regulations which apply under 45 CFR part 74, subpart J, Monitoring and Reporting of Program Performance, with the exception of State and local governments to which 45 CFR part 92, subpart C reporting requirements will apply. Financial reporting will be required in accordance with 45 CFR part 74, subpart H, with the exception of State and local governments, to which 45 CFR 92.20 will apply.

Public Health System Reporting Requirements

This program is subject to the Public Health System Reporting Requirements (approved under OMB No. 0937–0195). Under these requirements, the community-based nongovernmental applicant must prepare and submit a Public Health System Impact Statement (PHSIS). The PHSIS is intended to provide information to State and local health officials to keep them apprised of proposed health services grant applications submitted by community-based nongovernmental organizations within their jurisdictions.

Community-based nongovernmental applicants are required to submit the following information to the head of the appropriate State and local health agencies in the area(s) to be impacted no later than the Federal application receipt due date:

(a) A copy of the face page of the application (SF 5161).

(b) A summary of the project (PHSIS), not to exceed one page, which provides:

(1) A description of the population to be served.

(2) A summary of the services to be provided.

(3) A description of the coordination planned with the appropriate State and local health agencies.

Executive Order 12372

The HIV Demonstration Program for Children, Adolescents, and Families has been determined to be a program which is subject to the provisions of Executive Order 12372 concerning intergovernmental review of Federal programs by appropriate health planning agencies, as implemented by 45 CFR part 100. Executive Order 12372 allows States the option of setting up a system for reviewing applications from within their States for assistance under certain Federal programs. The application packages to be made available under this notice (Form PHS 5161–1 with revised face sheet HHS Form 424 and with Program Narrative and Checklist approved under OMB 0937–0189) will contain a listing of States which have chosen to set up such a review system and will provide a single point of contact (SPOC) in the States for review. Applicants (other than federally-recognized Indian tribal governments) should contact their State SPOCs as early as possible to alert them to the prospective applications and receive any necessary instructions on the State process. For proposed projects serving more than one State, the applicant is advised to contact the SPOC of each affected State. The due date for State process recommendations is 60 days after the application deadline for new and competing awards. The granting agency does not guarantee to "accommodate or explain" State process recommendations it receives after that date. (See part 148, Intergovernmental Review of PHS Programs under Executive Order 12372 and 45 CFR part 100 for a description of the review process and requirements.)

(The OMB Catalog of Federal Domestic Assistance number for the HIV Demonstration Program for Children, Adolescents, and Families is 93.153.)

Dated: December 16, 1993

John H. Kelso,

Acting Administrator.

[FR Doc. 94–1886 Filed 1–27–94; 8:45 am]

BILLING CODE 4160–15–P

Public Health Service

Participation in the Great American Workout

AGENCY: President's Council on Physical Fitness and Sports (PCPFS), PHS, DHHS.

ACTION: Notice of opportunity for participation.

SUMMARY: The President's Council on Physical Fitness and Sports announces the opportunity for an events planning organization to participate with the PCPFS in the Great American Workout scheduled for May 2, 1994.

DATES: To receive consideration, requests to participate must be received by the close of business Feb. 18, 1994 by Matthew Guidry, Deputy Executive Director of the PCPFS at the address below. Requests will meet the deadline if they are either (1) received on or before the deadline date; or (2) postmarked on or before the deadline date. Private metered postmarks will not be acceptable as proof of timely mailing. Hand delivered requests must be received by 5 p.m. Feb. 18, 1994. Requests that are received after the deadline will be returned to the sender.

FOR FURTHER INFORMATION CONTACT: Matthew Guidry, Deputy Executive Director, President's Council on Physical Fitness and Sports, Suite 250, 701 Pennsylvania Avenue NW., Washington, DC 20004, (202) 272–3424.

SUPPLEMENTARY INFORMATION:

Background

The President's Council on Physical Fitness and Sports promotes and encourages the development of physical fitness and sports programs for all Americans. In 1990, as part of its agenda, the PCPFS initiated the first Great American Workout as a major event to focus on exercise. A second and third workout were held in 1991 and 1992 respectively. The south lawn of the White House served as the backdrop for this fitness event for the Nation. The Great American Workout for this year is scheduled to take place on May 2, 1994, pending approval from the White House.

Requirements of Participation

The PCPFS is seeking to hold this year's Great American Workout with an events planning organization which has demonstrated the ability and experience to coordinate this type of national event. Under the guidance of the PCPFS, the organization selected as events planner will be responsible for the following:

(1) Develop a publicity campaign for the event, including the printing of official brochures, invitations and tickets, submitted for PCPFS' concurrence.

(2) Manage hotel and transportation arrangements for special invitees.

(3) Assist in the planning and logistical efforts needed for the workout stations for the activity demonstrations.

(4) Plan and organize the overall activities as directed by the PCPFS.

(5) Plan and organize any reception and breakfast arrangements agreed upon by the PCPFS.

(6) Provide insurance and first aid stations.

(7) Assist with obtaining corporate sponsors of the event.

(8) Under the direction of the White House, the Department of Health and Human Services and the PCPFS, work with various vendors to ensure provision of high quality services for the event, within the agreed-upon time frames.

Availability of Funds

There are no Federal Funds available for the Great American Workout. It will be the function of the events planning organization to assist with the raising of necessary funds for the event.

Eligibility for Participation

To be eligible, an entity should be: (1) A private, events planning organization; and (2) and organization that by virtue of its nature and purpose has a legitimate interest in physical fitness and sports.

Content of Request for Participation

Each request for participation as the events planning organization should contain: (1) a description of the organization and its capabilities; (2) a summary of the manner in which it would carry out its duties; and (3) its plan for assisting with the arranging for the funding of the event.

Evaluation Criteria

The events planning organization will be selected by the PCPFS, following a review of the proposals, based on the following review criteria:

(1) Organization's qualifications and capabilities to perform duties that are required for events of this nature; and

(2) Adequacy of current staff to perform all required duties.

(3) The ability of the organization to arrange for the funding of the event.

Other Information

Prior to the selection of the events planning organization, the PCPFS staff will meet separately with those organizations whose written submissions best meet the evaluation

criteria. Since it is anticipated that the Great American Workout will involve events held on the grounds of the White House, certain restrictions apply to the commercial use of an events planning organization's source or sources of funding. The successful organization will be required to enter into a memorandum of understanding with the Department of Health and Human Services setting forth the details of the event. In addition, agreements with other interested parties may be required. Participation by any organization or source of funding may in no way be construed as an endorsement of any commercial product by the PCPFS.

Dated: January 24, 1994.

Sandra P. Perlmutter,

Executive Director, President's Council on Physical Fitness and Sports.

[FR Doc. 94–1786 Filed 1–27–94; 8:45 am]

BILLING CODE 4160–17–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Community Planning and Development

[Docket No. N–94–1917; FR–3350–N–68]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

EFFECTIVE DATE: January 28, 1994.

ADDRESSES: For further information, contact Mark Johnston, Department of Housing and Urban Development, room 7262, 451 Seventh Street, SW., Washington, DC 20410; telephone (202) 708–4300; TDD number for the hearing- and speech-impaired (202) 708–2565, (these telephone numbers are not toll-free), or call the toll-free Title V information line at 1–800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with the December 12, 1988 court order in *National Coalition for the Homeless* v. *Veterans Administration*, No. 88–2503–OG (D.D.C.), HUD publishes a Notice, on a weekly basis, identifying unutilized, underutilized, excess and surplus Federal buildings and real property that HUD has reviewed for suitability for use to assist the homeless. Today's Notice is for the purpose of announcing that no additional properties have been determined suitable or unsuitable this week.

Dated: January 21, 1994.

Jacquie M. Lawing,

Deputy Assistant Secretary for Economic Development.

[FR Doc. 94–1672 Filed 1–27–94; 8:45 am]

BILLING CODE 4210–29–M

Office of the Assistant Secretary for Housing—Federal Housing Commissioner

[Docket No. N–94–3708; FR–3641–N–01]

Mortgagee Review Board Administrative Actions

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: In compliance with section 202(c) of the National Housing Act, notice is hereby given of the cause and description of administrative actions taken by HUD's Mortgagee Review Board against HUD-approved mortgagees.

FOR FURTHER INFORMATION CONTACT: William Heyman, Director, Office of Lender Activities and Land Sales Registration, 451 Seventh Street, SW., Washington, DC 20410, telephone (202) 708–1824. The Telecommunications Device for the Deaf (TDD) number is (202) 708–4594. (These are not toll-free numbers).

SUPPLEMENTARY INFORMATION: Section 202(c)(5) of the National Housing Act (added by Section 142 of the Department of Housing and Urban Development Reform Act of 1989 (Pub.L. 101–235, approved December 15, 1989) requires that HUD "publish in the **Federal Register** a description of and the cause for administrative action against a HUD-approved mortgagee" by the Department's Mortgagee Review Board. In compliance with the requirements of section 202(c)(5), notice is hereby given of administrative actions that have been taken by the Mortgagee Review Board from October 1, 1993 through December 31, 1993.

1. Certified Mortgage Bankers, Inc., Coral Gables, Florida

Action: Proposed Settlement Agreement that includes indemnification to the Department for claim losses in connection with three improperly originated loans, and payment of a civil money penalty in the amount of $500 for reporting violations under the Home Mortgage Disclosure Act (HMDA).

Cause: A HUD monitoring review that cited the company for violations of HUD–FHA program requirements that included: failure to comply with HUD–FHA reporting requirements under the Home Mortgage Disclosure Act (HMDA); failure to verify mortgagors' source of funds used for downpayment and/or closing costs; failure to properly verify a mortgagor's employment, income and property occupancy; and failure to maintain an adequate Quality Control Plan.

2. Pioneer Mortgage, Inc., Haddon Heights, New Jersey

Action: Proposed Settlement Agreement that includes indemnification to the Department for claim losses in connection with three improperly originated loans, and corrective action to assure compliance with HUD–FHA requirements.

Cause: A HUD monitoring review that disclosed violations of HUD–FHA program requirements including: failure to implement a Quality Control Plan in compliance with HUD–FHA requirements; failure to verify a mortgagor's source of funds used for downpayment and closing costs; and failure to adequately verify mortgagors' income.

3. American Mortgage Corp., Seattle, Washington

Action: Proposed Settlement Agreement that includes indemnification to the Department for claim losses in connection with five improperly originated loans, and corrective action to assure compliance with HUD–FHA requirements.

Cause: A HUD monitoring review that disclosed violations of HUD–FHA program requirements that included: failure to implement a Quality Control Plan; sharing office space and commingling employees with another firm; failure to verify the source of mortgagor funds used for downpayment and closing costs; permitting a mortgagor and real estate agent to handcarry a verification of employment and verification of deposit; failure to properly verify monthly effective income; and failure to ensure that face-to-face interviews are conducted with mortgagors prior to submission of HUD–FHA loan applications to AMC's underwriter.

4. Gulf States Mortgage Co., Atlanta, Georgia

Action: Proposed Settlement Agreement that provides for indemnification to the Department for

claim losses in connection with ten improperly originated loans, and corrective action to assure compliance with HUD–FHA requirements.

Cause: A HUD monitoring review that cited the company for violations of HUD–FHA program requirements that included: overinsured mortgages; failure to verify mortgagors' source and/or adequacy of funds for downpayment and/or closing costs; failure to conduct adequate face-to-face interviews with mortgagors; permitting mortgagors to handcarry verifications of employment; and failure to properly complete the Form HUD 92900.

5. Mortgage Resource Center, Inc., Greensboro, North Carolina

Action: Proposed Settlement Agreement that includes payment of a civil money penalty in the amount of $1,000, and corrective action to assure compliance with HUD–FHA requirements.

Cause: A HUD monitoring review that cited the company for violations of HUD–FHA requirements that included: failure to comply with the reporting requirements under the Home Mortgage Disclosure Act (HMDA); failure to implement a Quality Control Plan; charging unallowable fees to mortgagors; and failure to maintain complete loan files.

6. Alcola Mortgage Corporation, Northridge, California

Action: Probation and proposed civil money penalty in the amount of $1,500.

Cause: A HUD monitoring review that disclosed violations of HUD–FHA requirements that included: failure to comply with the Department's requirements for office facilities; failure to implement an adequate Quality Control Plan; failure to comply with reporting requirements under the Home Mortgage Disclosure Act (HMDA); and submitting a false certification to HUD–FHA concerning the location of the company's office facilities.

7. L.J. Wright Financial Resource Company, Phoenix, Arizona

Action: Letter of Reprimand.

Cause: A HUD monitoring review that cited the company for failure to comply with HUD–FHA reporting requirements under the Home Mortgage Disclosure Act (HMDA).

8. Mortgagees Cited for Failure To Comply with HUD–FHA Reporting Requirements Under the Home Mortgage Disclosure Act (HMDA) and/or Maintain an Adequate Quality Control Plan.

Action: Letters of Reprimand and proposed civil money penalty in the amount of $500.

Cause: HUD monitoring reviews that disclosed noncompliance by the following mortgagees with the Department's reporting requirements under HMDA and/or failure to comply with HUD–FHA requirements for maintaining a Quality Control Plan.

Mortgagees issued a Letter of Reprimand with a proposed civil money penalty for failure to meet HMDA reporting requirements and to maintain an adequate Quality Control Plan.

All Service Mortgage Corporation, Largo, FL; Cannon Mortgage Company, Tustin, CA; Karma Mortgage, Orange, CA; Colorado Mortgage Professionals, Englewood, CO; Cypress Mortgage, Inc., Austin, TX; Franklin-Harris Associates, Longmont, CO; and Lincoln Home Mortgage, Inc., Roselle, IL.

Mortgagees issued a Letter of Reprimand with a proposed civil money penalty for failure to report HMDA data only.

Affordable Mortgage Corporation, Wappinger Falls, NY; and Mission Hills Mortgage Corporation, Santa Ana, CA.

Dated: January 19, 1994.

Nicolas P. Retsinas,

Assistant Secretary for Housing—Federal Housing Commissioner.

[FR Doc. 94–1785 Filed 1–27–94; 8:45 am]

BILLING CODE 4210–27–P

[Docket No. N–94–3707; FR–3634–N–01]

Mortgage and Loan Insurance Programs Under the National Housing Act—Debenture Interest Rates

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, (HUD).

ACTION: Notice of Change in Debenture Interest Rates.

SUMMARY: This notice announces changes in the interest rates to be paid on debentures issued with respect to a loan or mortgage insured by the Federal Housing Commissioner under the provisions of the National Housing Act (the "Act"). The interest rate for debentures issued under section 221(g)(4) of the Act during the six-month period beginning January 1, 1994, is 5¾ percent. The interest rate for debentures issued under any other provision of the Act is the rate in effect on the date that the commitment to insure the loan or mortgage was issued, or the date that the loan or mortgage was endorsed (or initially endorsed if there are two or more endorsements) for insurance, whichever rate is higher. The interest rate for debentures issued under these other provisions with respect to a loan or mortgage committed or endorsed during the six-month period beginning January 1, 1994, is 6⅝ percent.

FOR FURTHER INFORMATION CONTACT: Fred E. McLaughlin, Financial Services Division, Department of Housing and Urban Development, 470 L'Enfant Plaza East, room 3119, Washington, DC 20024. Telephone (202) 755–7450, or TDD (202) 708–4594 for hearing- or speech-impaired callers. These are not toll-free numbers.

SUPPLEMENTARY INFORMATION: Section 224 of the National Housing Act (24 U.S.C. 1715o) provides that debentures issued under the Act with respect to an insured loan or mortgage (except for debentures issued pursuant to section 221(g)(4) of the Act) will bear interest at the rate in effect on the date the commitment to insure the loan or mortgage was issued, or the date the loan or mortgage was endorsed (or initially endorsed if there are two or more endorsements) for insurance, whichever rate is higher. This provision is implemented in HUD's regulations at 24 CFR 203.405, 203.479, 207.259(e)(6), and 220.830. Each of these regulatory provisions states that the applicable rates of interest will be published twice each year as a notice in the **Federal Register.**

Section 224 further provides that the interest rate on these debentures will be set from time to time by the Secretary of HUD, with the approval of the Secretary of the Treasury, in an amount not in excess of the interest rate determined by the Secretary of the Treasury pursuant to a formula set out in the statute.

The Secretary of the Treasury (1) has determined, in accordance with the provisions of Section 224, that the statutory maximum interest rate for the period beginning January 1, 1994, is 6⅝ percent and (2) has approved the establishment of the debenture interest rate by the Secretary of HUD at 6⅝ percent for the six-month period beginning January 1, 1994. This interest rate will be the rate borne by debentures issued with respect to any insured loan or mortgage (except for debentures issued pursuant to Section 221(g)(4)) with an insurance commitment or endorsement date (as applicable) within the first six months of 1994.

For convenience of reference, HUD is publishing the following chart of debenture interest rates applicable to mortgages committed or endorsed since January 1, 1980:

Effective interest rate	On or after	Prior to
9½	Jan. 1, 1980	July 1, 1980.
9⅞	July 1, 1980	Jan. 1, 1981.
11¾	Jan. 1, 1981	July 1, 1981.
12⅞	July 1, 1981	Jan. 1, 1982.
12¾	Jan. 1, 1982	Jan. 1, 1983.
10¼	Jan. 1, 1983	July 1, 1983.
10⅜	July 1, 1983	Jan. 1, 1984.
11½	Jan. 1, 1984	July 1, 1984.
13⅜	July 1, 1984	Jan. 1, 1985.
11⅝	Jan. 1, 1985	July 1, 1985.
11⅛	July 1, 1985	Jan. 1, 1986.
10¼	Jan. 1, 1986	July 1, 1986.
8¼	July 1, 1986	Jan. 1, 1987.
8	Jan. 1, 1987	July 1, 1987.
9	July 1, 1987	Jan. 1, 1988.
9⅛	Jan. 1, 1988	July 1, 1988.
9⅜	July 1, 1988	Jan. 1, 1989.
9¼	Jan. 1, 1989	July 1, 1989.
9	July 1, 1989	Jan. 1, 1990.
8⅛	Jan. 1, 1990	July 1, 1990.
9	July 1, 1990	Jan. 1, 1991.
8¾	Jan. 1, 1991	July 1, 1991.
8½	July 1, 1991	Jan. 1, 1992.
8	Jan. 1, 1992	July 1, 1992.
8	July 1, 1992	Jan. 1, 1993.
7¾	Jan. 1, 1993	July 1, 1993.
7	July 1, 1993	Jan. 1, 1994.
6⅝	Jan. 1, 1994	

Section 221(g)(4) of the Act provides that debentures issued pursuant to that paragraph (with respect to the assignment of an insured mortgage to the Secretary) will bear interest at the "going Federal rate" in effect at the time the debentures are issued. The term "going Federal rate", as used in that paragraph, is defined to mean the interest rate that the Secretary of the Treasury determines, pursuant to a formula set out in the statute, for the six-month periods of January through June and July through December of each year. Section 221(g)(4) is implemented in the HUD regulations at 24 CFR 221.790.

The Secretary of the Treasury has determined that the interest rate to be borne by debentures issued pursuant to Section 221(g)(4) during the six-month period beginning January 1, 1994, is 5¾ percent.

HUD expects to publish its next notice of change in debenture interest rates in July 1994.

The subject matter of this notice falls within the categorical exclusion from HUD's environmental clearance procedures set forth in 24 CFR 50.20(1). For that reason, no environmental finding has been prepared for this notice.

(Secs. 211, 221, 224, National Housing Act, 12 U.S.C. 1715b, 1715l, 1715o; sec. 7(d), Department of HUD Act, 42 U.S.C. 3535(d)).

Dated: January 14, 1994.

Nicolas P. Retsinas,

Assistant Secretary for Housing—Federal Housing Commissioner.

[FR Doc. 94-1782 Filed 1-27-94; 8:45 am]

BILLING CODE 4210-27-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[MT-930-4320-01]

Notice To Cancel Intent To Amend the Dillon Management Framework Plan; Butte District Office; Montana

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice to cancel intent to amend the Dillon MFP.

SUMMARY: The Butte District issued a **Federal Register** notice on November 29, 1993, announcing a Notice of Intent to Amend the Dillon Management Framework Plan (MFP). The Butte District is canceling the intent to amend the Dillon MFP. The decision to use only aerial shooting of predators in this area will continue to be in effect until it is reviewed on an ecosystem management basis during the preparation of the Dillon Resource Management Plan (RMP) scheduled to begin October 1996.

FOR FURTHER INFORMATION CONTACT: Sandy Brooks, Project Lead, Montana State Office, P.O. Box 36800, Billings, Montana 59107; or contact by phone at (406) 255-2929.

SUPPLEMENTARY INFORMATION: In the Dillon MFP, it was decided that selective aerial predator control be the only means by which predatory animals, other than wolves be removed from the BLM land between the town of Lima and Bloody Dick Creek. The rationale was that the most positive indication of gray wolf occupancy recorded at that time had been documented in the Lemhi Pass area. Since then, however, the United States Fish and Wildlife Service has better defined occupied wolf habitat in Montana. The area between Lima and Blood Dick Creek is not considered occupied wolf habitat at this time. The proposed Dillon MFP Amendment would have allowed for Integrated Pest Management in the described area, where predator control was limited to aerial shooting of predators. However, due to the preparation of an RMP in the Dillon Resource Area beginning in 1997, the Butte District has decided to cancel their intent to amend the Dillon MFP and review the decision on an ecosystem-wide basis as part of the Dillon RMP.

Dated: January 20, 1994.

Robert H. Lawton,

State Director.

[FR Doc. 94-1845 Filed 1-27-94; 8:45 am]

BILLING CODE 4310-DN-M

[WY-920-41-5700; WYW113059]

Proposed Reinstatement of Terminated Oil and Gas Lease

January 14, 1994.

Pursuant to the provisions of 30 U.S.C. 188(d) and (e), and 43 CFR 3108.2-3(a) and (b)(1), a petition for reinstatement of oil and gas lease WYW113059 for lands in Sweetwater County, Wyoming, was timely filed and was accompanied by all the required rentals accruing from the date of termination. The lessee has agreed to the amended lease terms for rentals and royalties at rates of $10.00 per acre, or fraction thereof, per year and 16⅔ percent, respectively.

The lessee has paid the required $500 administrative fee and $125 to reimburse the Department for the cost of this **Federal Register** notice. The lessee has met all the requirements for reinstatement of the lease as set out in section 31 (d) and (e) of the Mineral Lands Leasing Act of 1920 (30 U.S.C. 188), and the Bureau of Land Management is proposing to reinstate lease WYW113059 effective October 1, 1993, subject to the original terms and conditions of the lease and the increased rental and royalty rates cited above.

Mary Jo Rugwell,

Acting Supervisory Land Law Examiner.

[FR Doc. 94-1835 Filed 1-27-94; 8:45 am]

BILLING CODE 4310-22-M

[WY-920-41-5700; WY92164]

Proposed Reinstatement of Terminated Oil and Gas Lease

January 14, 1994.

Pursuant to the provisions of 30 U.S.C. 188 (d) and (e), and 43 CFR 3108.2-3(a) and (b)(1), a petition for reinstatement of oil and gas lease WYW92164 for lands in Campbell County, Wyoming, was timely filed and was accompanied by all the required rentals accruing from the date of termination. The lessee has agreed to the amended lease terms for rentals and royalties at rates of $5.00 per acre, or

fraction thereof, per year and 16⅔ percent, respectively.

The lessee has paid the required $500 administrative fee and $125 to reimburse the Department for the cost of this **Federal Register** notice. the lessee has met all the requirements for reinstatement of the lease as set out in section 31 (d) and (e) of the Mineral Lands Leasing Act of 1920 (30 U.S.C. 188), and the Bureau of Land Management is proposing to reinstate lease WYW92164 effective June 1, 1993, subject to the original terms and conditions of the lease and the increased rental and royalty rates cited above.

Mary Jo Rugwell,

Acting Supervisory Land Law Examiner.

[FR Doc. 94–1836 Filed 1–27–94; 8:45 am]

BILLING CODE 4310–22–M

[WY–920–41–5700; WYW96173]

Proposed Reinstatement of Terminated Oil and Gas Lease

January 14, 1994.

Pursuant to the provisions of 30 U.S.C. 188(d) and (e), and 43 CFR 3108.2–3(a) and (b)(1), a petition for reinstatement of oil and gas lease WYW96173 for lands in Campbell County, Wyoming, was timely filed and was accompanied by all the required rentals accruing from the date of termination. The lessee has agreed to the amended lease terms for rentals and royalties at rates of $5.00 per acre, or fraction thereof, per year and 16⅔ percent, respectively.

The lessee has paid the required $500 administrative fee and $125 to reimburse the Department for the cost of this **Federal Register** notice. The lessee has met all the requirements for reinstatement of the lease as set out in section 31 (d) and (e) of the Mineral Lands Leasing Act of 1920 (30 U.S.C. 188), and the Bureau of Land Management is proposing to reinstate lease WYW96173 effective June 1, 1993, subject to the original terms and conditions of the lease and the increased rental and royalty rates cited above.

Mary Jo Rugwell,

Acting Supervisory Land Law Examiner.

[FR Doc. 94–1837 Filed 1–27–94; 8:45 am]

BILLING CODE 4310–22–M

[ID–010–03–4210–04; IDI–28798]

Notice of Availability; Amendment of the Cascade Resource Management Plan (RMP)/Notice of Realty Action (NORA); Sale of Two Parcels and Exchange of Public Lands in Canyon, Gem and Ada Counties, Idaho

AGENCY: Bureau of Land Management—Interior.

SUMMARY: Pursuant to the BLM Planning Regulations (43 CFR 1610.5–2), notice is hereby given that the BLM is proposing to amend the Cascade RMP to allow for transfer of certain public lands to Gem and Canyon Counties via sale and transfer of certain public lands in Ada County to a private party via exchange.

The following described lands have been examined and through the public supported land use planning process have been determined to be suitable for disposal by direct sale pursuant to Section 203 of the Federal Land Policy and Management Act (FLPMA) of 1976 (43 U.S.C. 1713) at no less than the appraised fair market value. The lands will not be offered for sale until at least 60 days after the date of publication of this notice in the **Federal Register.**

1. IDI–28798—Sale to Gem County:

Boise Meridian, Idaho

T. 6 N., R. 1 W.,
Section 27; W½SW¼,
Section 28; E½SE¼.
Containing 160 acres more or less.

2. IDI–29240, Sale to Canyon County:

Boise Meridian, Idaho

T. 2 N., R. 3 W.,

Section 21; W½SW¼NE¼, W½W½SE¼, S½SE¼SW¼.

Containing 80 acres more or less.

The following described lands have been examined and through the public supported land use planning process have been determined to be suitable for transfer by land exchange pursuant to section 206 of the Federal Land Policy and Management Act (FLPMA) of 1976 (43 U.S.C. 1713).

3. IDI–29143, Private Exchange to W. P. Stillwell Sr. Estate:

Non-Federal lands to be acquired are described as:

Boise Meridian, Idaho

T. 5 N., R. 1 E., B.M., Idaho
Section 14; S½NW¼, NW¼SW¼,
Section 23; S½S½.
Containing 280 acres more or less.

Public lands to be transferred are described as:

Boise Meridian, Idaho

T. 5 N., R. 1 E., B.M., Idaho
Section 20; Lot 1, E½SE¼,
Section 21; NW¼NW¼, S½NW¼, NW¼SW¼, S½SE¼.
Containing 357.81 acres more or less.

Administrative access across Stillwell's private lands would also be acquired.

The purpose of the land sales is to provide Gem County with a new sanitary landfill site and Canyon County with lands necessary to meet new standards for their existing landfill.

The purpose of the exchange is to acquire the non-Federal lands which contain important populations of *Allium aaseae* (Aase's onion), a C1 Candidate species to prevent possible listing of the species under the Endangered Species Act. The subject lands were previously identified for acquisition in the plan amendment designating ACECs for protection of Aase's onion and determining the management prescriptions under which the lands are to be managed. The subject lands will be added to the designated ACEC and will be managed with the same restrictions as the other public lands within the ACEC to protect the critical habitat.

The value of the lands to be exchanged will be approximately equal; some of the above-described public lands may not be included and some of the private lands may not be acquired in order to equalize values and protect resource values.

ADDRESSES: Comments should be sent to the District Manager, Bureau of Land Management, Boise District, 3948 Development Avenue, Boise, Idaho 83705.

FOR FURTHER INFORMATION CONTACT: John Fend, Cascade Resource Area Manager, Bureau of Land Management, 3948 Development Avenue, Boise, Idaho 83705, (208) 384–3352 or 384–3300.

PLANNING PROTESTS: Any party that participated in the plan amendment and is adversely affected by the amendment may protest this action only as it affects issues submitted for the record during the planning process. The protest shall be in writing and filed with the Director (760), Bureau of Land Management, 1800 "C" Street, NW., Washington, DC 20240, within 30 days of publication of this notice.

SALE AND LAND EXCHANGE COMMENTS: For a period of 45 days from the publication of this notice, interested parties may submit comments regarding the sales or land exchange to the District Manager, Bureau of Land Management, 3948 Development Ave., Boise, ID 83705. Objections will be reviewed by the State Director who may sustain, vacate, or modify this realty action. In the absence of any planning protests or objections

regarding the land exchange, this realty action will become the final determination of the Department of Interior and the planning amendment will be in effect.

SUPPLEMENTARY INFORMATION: Upon publication of this notice in the **Federal Register**, any lands described above which are not already segregated will be segregated from appropriation under the public land laws, including the mining laws, except the sale and exchange provisions of FLPMA. The segregative effect will end upon issuance of patent or 270 days for sales and 2 years for exchanges from the date of publication, whichever occurs first.

Lands to be transferred from the United States will be subject to the following reservations, terms, and conditions:

EXCEPTING AND RESERVING TO THE UNITED STATES: 1. A right-of-way thereon for ditches and canals constructed by the authority of the United States, Act of August 30, 1890 (43 U.S.C. 945). Sales IDI–29240 and IDI–28798:

2. All oil, gas, and geothermal resources thereon together with the right to prospect for, mine, and remove the minerals.

SUBJECT TO: Sale IDI–29240 to Canyon County shall also include:

3. Those rights for a communication site, access road and powerline granted to Radio Paging Service, its successors or assigns by Right-of-Way IDI–23106, under the Act of October 21, 1976 (90 Stat. 2776; 43 U.S.C. 1761). Private Exchange IDI–29145:

4. The following rights-of-way of record: IDI–20004 granted to Merle and Jean Long for a road and IDI–20976 granted to U.S. West Communications for a buried telephone line, both under the Act of October 21, 1976 (90 Stat. 2776; 43 U.S.C. 1761); and IDI–20038 asserted by the Ada County Highway District under Revised Statute 2477 (43 U.S.C. 932).

Continued use of the land by valid right-of-way holders or their successors or assigns is proper subject to the terms and condition of the grant. Administrative responsibility previously held by the United States will be assumed by the patentee.

Dated: January 20, 1994.

Barry C. Cushing,

District Manager.

[FR Doc. 94–1686 Filed 1–27–94; 8:45 am]

BILLING CODE 4310–GG–M

[ID–030–04–4056–05; IDI–29906]

Realty Action; Exchange of Public Lands in Jefferson County, ID

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of realty action; exchange of public lands in Jefferson County, Idaho.

SUMMARY: The following described public lands have been determined to be suitable for disposal by exchange under section 206 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1716:

Boise Meridian, Idaho

T. 5 N., R. 39 E.,
Sec. 19, lots 23 and 24;
Sec. 20, lots 13 and 19.

The area described contains 36.90 acres in Jefferson County.

In exchange for these lands, the United States will acquire the following described lands from Gary H. Rhodes:

Boise Meridian, Idaho

T. 5N., R. 39 E.,
Sec. 18, lot 5.

The area described contains 32.33 acres in Madison County.

DATES: The publication of this notice in the **Federal Register** will segregate the public lands described above to the extent that they will not be subject to appropriation under the public lands laws. As provided by the regulation of 43 CFR 2201.1(b), any subsequently tendered application, allowance of which is discretionary, shall not be accepted, shall not be considered as filed and shall be returned to the applicant. The segregative effect of this notice will terminate upon issuance of patent or in two years, whichever occurs first.

ADDRESSES: Detailed information concerning the exchange is available for review at the Idaho Falls District Office, 940 Lincoln Road, Idaho Falls, Idaho 83401.

SUPPLEMENTARY INFORMATION: The purpose of the land exchange is to allow BLM to acquire riparian land which is in good condition and identified as prime bald eagle habitat. The public land selected by the proponent would enhance his livestock operation and is currently difficult for BLM to manage because of the land pattern. The exchange is consistent with the Bureau of Land Management land use plans, and the public interest will be well served by making this exchange. The exchange will include surface and mineral estates.

The federal and non-federal lands were appraised at equal fair market value.

The exchange will be subject to:

1. All valid existing rights, including any right-of-way easement, permit or lease of record.

2. A reservation to the United States of a right-of-way for ditches and canals constructed by the authority of the United States under the Act of August 30, 1890 (43 U.S.C. 945).

For a period of 45 days from the date of publication of this notice in the **Federal Register**, interested parties may submit comments to the District Manager at the above address. Objections will be reviewed by the State Director who may sustain, vacate, or modify this realty action. In the absence of any objections, this realty action will become final determination of the Department of the Interior.

Dated: January 12, 1994.

Richard G. Murua,

Acting District Manager.

[FR Doc. 94–1840 Filed 1–27–94; 8:45 am]

BILLING CODE 4310–GG–M

DEPARTMENT OF AGRICULTURE

Forest Service

[OR–035–00–4333–02; GP04–053]

Wallowa/Grade Ronde River Management Plan; Vale District, Baker Resource Area, Umatilla and Wallowa-Whitman National Forest, and Union and Wallowa Counties, OR, and Asotin County, WA

AGENCY: Bureau of Land Management, USDI, and Forest Service, USDA.

ACTION: Notice of availability.

SUMMARY: On December 13, 15, and 15, Umatilla Deputy Forest Supervisor, John P. Kline, Wallowa-Whitman Forest Supervisor, R.M. Richmond, and Baker Resource Acting Area Manager, Dorothy Mason, respectively, made a joint decision to amend the Land and Resource Management Plans (Forest Plans) for the Umatilla and Wallowa-Whitman National Forests and append the Bureau of Land Management, Baker Resource Area Management Plan, to include the Wallowa/Grande Ronde River Management Plan (including the Grande Ronde Wild and Scenic River).

This plan identifies use levels, facility development levels, resource protection measures, and set the general management direction for managing the Wallowa/Grande Ronde River, including the designated Grande Ronde Wild and Scenic segment. This

amendment is necessary to implement the Omnibus Oregon Wild and Scenic Rivers Act which required the Forest Service and Bureau of Land Management to develop a management plan for the Grande Ronde River. Interim direction was identified in the Forest Plans and Resource Management Plan.

The environmental assessment documents the analysis of alternatives for managing the Grande Ronde Wild Scenic River in accordance with the Omnibus Oregon Wild and Scenic Rivers Act.

For the Umatilla and Wallwoa-Whitman National Forest, this decision is subject to appeal pursuant to Forest Service regulations 36 CFR part 217. The 45 day appeal period begins February 1, 1994 and ends March 17, 1994. Notices of Appeals must meet the requirements of 36 CFR 217.9.

For the Bureau of Land Management, this decision is subject to protest pursuant to bureau of Land Management regulations 43 CFR part 4. The 45 day protest period begins February 1, 1994 and ends Match 17, 1994. Notices of Protest must meet the requirement of 43 CFR 4.21.

The final corridor boundary of the designated segment of the Grande Ronde River lies entirely with the general legal description below:

Beginning at Rondowa, Oregon

Willamette Meridian

T.3N., R.40E.,
Portions of Sections: 23, 14, 11, 12, 1.
T.4N., R.40E.,
Portions of Section: 36.
T.4N., R.41E.,
Portions of Section: 31.
T.4N., R.40E.,
Portions of Section: 5.
T.4N., R.41E.,
Portions of Section: 30
T.4N., R.40E.,
Portions of Section: 24.
T.4N., R.41E.,
Portions of Section: 19.
T.4N., R.40E.,
Portions of Section: 13
T.4N., R.41E.,
Portions of Section: 18.
T.4N., R.40E.,
Portions of Section: 12.
T.4N., R.41E.,
Portions of Sections: 7, 6, 5.
T.5N., R.41E.,
Portions of Sections: 32, 33, 28, 27, 34, 35, 26, 36, 25.
T.4N., R.41E.,
Portions of Section: 1.
T.4N., R.42E.,
Portions of Section: 6.
T.5N., R.42E.,
Portions of Sections: 31, 32, 29, 28, 33, 27, 22, 23, 26, 24.
T.5N., R.43E.,
Portions of Sections: 19, 18, 20, 17, 16, 8, 9, 4, 3.
T.6N., R.43E.,
Portions of Sections: 34, 27, 35, 26, 25, 23, 24, 13.
Ending at the Oregon/Washington stateline.

A More detailed legal description is available upon request.

The environmental assessment for the Wallowa/Grande Ronde River Management Plan, including the Grande Ronde Wild and Scenic River segment, is available for the public review at the Wallowa-Whitman National Forest Supervisor's Office in Baker City, Oregon, or the Bureau of Land Management, Baker Resource Area Office in Baker City, Oregon.

EFFECTIVE DATE: Implementation of this decision will occur no earlier than the end of the appeal/protest period identified above (February 1 through March 17, 1994).

FOR FURTHER INFORMATION CONTACT: For further information, contact Marty Gardner, Wallowa-Whitman National Forest, P.O. Box 907, Baker City, Oregon 97814 or phone (503) 523–6391, or Gerry Meyer, Bureau of Land Management, Baker Resource Area, P.O. Box 987, Baker City, Oregon 97814 or phone (503) 523–6391.

Dated: January 13, 1994.

John P. Kline,

Deputy Forest Supervisor, Umatilla National Forest.

Dated: January 18, 1994.

R.M. Richmond,

Forest Supervisor, Wallowa-Whitman National Forest.

Dated: January 18, 1994.

Dorothy Mason,

Acting Area Manager, Bureau of Land Management, Baker Resource Area.

[FR Doc. 94–1843 Filed 1–27–94; 8:45 am]

BILLING CODE 4310–33–M

[AZ–942–03–4730–02]

Arizona; Filing of Plats of Survey

January 18, 1994.

1. The plats of survey of the following described lands were officially filed in the Arizona State Office, Phoenix, Arizona, on the dates indicated:

A supplemental plat showing new lot 6, section 8, Township 23 South, Range 24 East, Gila and Salt River Meridian, Arizona, was accepted October 1, 1993, and was officially filed October 8, 1993.

A supplemental plat, in 2 sheets, showing amended lottings in section 35, Township 3 South, Range 29 East, Gila and Salt River Meridian, Arizona, was accepted November 10, 1993, and was officially filed November 18, 1993.

These plats were prepared at the request of the Bureau of Land Management, Safford District Office.

A plat representing the dependent resurvey of a portion of the Fifth Standard Parallel North (south boundary), the west boundary, a portion of the north boundary, and a portion of the subdivisional lines, in Township 21 North, Range 30 East, Gila and Salt River Meridian, Arizona, was accepted October 5, 1993, and was officially filed October 14, 1993.

A plat representing the dependent resurvey of a portion of the Fifth Standard Parallel North (south boundary) through Township 21 North, Range 31 East, Gila and Salt River Meridian, Arizona, was accepted October 5, 1993, and was officially filed October 14, 1993.

These plats were prepared at the request of the Navajo and Hopi Indian Relocation Commission.

A plat representing the dependent resurvey of a portion of the north boundary, a portion of the subdivisional lines, and a portion of Mineral Survey Nos. 3847 and 3985; and the subdivision and a metes-and-bounds survey in section 4, Township 21 North, Range 21 West, Gila and Salt River Meridian, Arizona, was accepted November 8, 1993, and was officially filed November 8, 1993.

This plat was prepared at the request of the Regional Director, National Park Service, Western Region.

A plat representing the dependent resurvey of a portion of the subdivisional lines in Towship 29 North, Range 6 East, Gila and Salt River Meridian, Arizona, was accepted December 20, 1993, and was officially filed December 29, 1993.

A plat representing the dependent resurvey of a portion of the subdivisional lines in Township 30 North, Range 6 East, Gila and Salt River Meridian, Arizona, was accepted December 20, 1993, and was officially filed December 29, 1993.

These plats were prepared at the request of the United States Forest Service, Kaibab National Forest.

2. These plats will immediately become the basic records for describing the land for all authorized purposes. These plats have been placed in the open files and are available to the public for information only.

3. All inquiries relating to these lands should be sent to the Arizona State Office, Bureau of Land Management,

P.O. Box 16563, Phoenix, Arizona 85011.

James. P. Kelley,

Chief Cadastral Surveyor of Arizona.

[FR Doc. 94–1841 Filed 1–27–94; 8:45 am]

BILLING CODE 4310–32–M

[NM–060–04–4760–01–(605); NMNM 92089]

Proposed Withdrawal and Opportunity for Public Meeting; New Mexico

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice—withdrawal application.

SUMMARY: The United States Department of Agriculture, Forest Service, has filed an application to withdraw 24,780.65 acres of National Forest System land for protection of the Guadalupe Escarpment Wilderness Study Area. This notice closes the land for up to two (2) years from location and entry under the United States mining laws. The land will remain open to all other uses which may by law be made of National Forest System land.

DATES: Comments and requests for meetings should be received on or before April 28, 1994.

ADDRESSES: Comments and meeting requests should be sent to the New Mexico State Director (92313), BLM, P.O. Box 27115, Santa Fe, New Mexico 87502–7115.

SUPPLEMENTARY INFORMATION: On November 17, 1993, the United States Department of Agriculture filed an application to withdraw the following described National Forest System land from location and entry under the United States mining laws, from location and entry under the United States mining laws, subject to valid existing rights:

New Mexico Principal Meridian

Lincoln National Forest

T. 25 S., R. 22 E.,
Sec. 13, ALL;
Sec. 14 SE¼;
Sec. 22, SE¼;
Sec. 23, ALL;
Sec. 26, ALL;
Sec. 27, ALL;
Sec. 28, E½, E½W½;
Sec. 29, W½SE¼;
Sec. 31, E½E½, W½SW¼;
Sec. 32, ALL;
Sec. 33, ALL;
Sec. 34, ALL;
T. 26 S., R 21 E.,
Sec. 1, ALL;
Sec. 2, E½, SW¼;
Sec. 10, E½E½;
Sec. 11, ALL;
Sec. 12, ALL;
Sec. 13, ALL;
Sec. 14, ALL;
Sec. 15, ALL;
Sec. 16, S½;
Sec. 20, SE¼;
Sec. 21, ALL;
Sec. 22, ALL;
Sec. 23, ALL;
Sec. 24, ALL;
Sec. 25, ALL;
Sec. 26, ALL;
Sec. 27, ALL;
Sec. 28, ALL;
Sec. 29, E½;
Sec. 32, N½NE¼, Lots 1, 2;
Sec. 33, N½N½, Lots 1, 2, 3, 4;
Sec. 34, N½N½, Lots 1, 2, 3, 4;
Sec. 35, N½N½, Lots 1, 2, 3, 4;
Sec. 36, N½N½, Lots 1, 2, 3, 4;
T. 26 S., R. 22 E.,
Sec. 3, ALL;
Sec. 4, ALL;
Sec. 5, ALL;
Sec. 6, E½, E½W½, Lots 1, 2, 3, 4;
Sec. 7, E½, E½W½, Lots 1, 2, 3, 4;
Sec. 8, ALL;
Sec. 9, ALL;
Sec. 10, ALL;
Sec. 15, ALL;
Sec. 16, ALL;
Sec. 17, ALL;
Sec. 18, E½, E½W½, Lots 1, 2, 3, 4.

The area described contains approximately 24,780.65 acres in Eddy county.

For a period of 90 days from the date of publication of this notice, all persons who wish to submit comments, suggestions, or objections in connection with the proposed withdrawal may present their views in writing to the New Mexico State Director of the Bureau of Land Management.

Notice is hereby given that an opportunity for a public meeting is afforded in connection with the proposed withdrawal. All interested persons who desire a public meeting for the purpose of being heard on the proposed withdrawal must submit a written request to the New Mexico State Director within 90 days from the date of publication of this notice. Upon determination by the authorized officer that a public meeting will be held, a notice of time and place will be published in the **Federal Register** at least 30 days before the scheduled date of the meeting.

The application will be processed in accordance with the regulations set forth in 43 CFR part 2300.

For a period of 2 (two) years from the date of publication of this notice in the **Federal Register**, the land will be segregated as specified above unless the application is denied or canceled or the withdrawal is approved prior to that date. The temporary uses which will be permitted during this segregative period are any land uses, except location under the mining laws, permitted by the Forest Service under existing laws and regulations.

Dated: January 19, 1994.

Leslie M. Cone,

District Manager.

[FR Doc. 94–1846 Filed 1–27–94; 8:45 am]

BILLING CODE 4310–FB–M

Fish and Wildlife Service

Conference of the Parties to the Convention on International Trade in Endangered Species of Wild Fauna and Flora; Ninth Regular Meeting; Thirty-First Meeting of the Standing Committee; Public Meeting

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice.

SUMMARY: The U.S. Fish and Wildlife Service (Service) publishes the time and place for the ninth regular meeting of the Conference of the Parties to the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), and announces a public meeting to discuss the upcoming thirty-first meeting of the CITES Standing Committee and agenda items for the upcoming meeting of the Conference of the Parties.

DATES: The public meeting will be held on February 22, 1994 from 2–4 p.m. The Service will consider information and comments from the public concerning items of concern to the ninth meeting of the Conference of the Parties received by March 1, 1994 (except for items relating to listing of species in the Appendices).

ADDRESSES: The public meeting will be held in Conference Room 200 of the Fish and Wildlife Service building, 4401 N. Fairfax Drive, Arlington, VA. Comments on the provisional agenda should be sent to the Director, U.S. Fish and Wildlife Service, c/o Office of Management Authority, 4401 N. Fairfax Drive, room 432, Arlington, VA 22203.

SUPPLEMENTARY INFORMATION:

Background

The Convention on International Trade in Endangered Species of Wild Fauna and Flora, TIAS 8249, hereinafter referred to as CITES, is an international treaty designed to control and regulate international trade in certain animal and plant species which are or may become threatened with extinction, and are listed in Appendices to the Convention (and are available from the Office of Management Authority at the address, above). Currently, 120 countries, including the United States, are CITES Parties. CITES calls for biennial meetings of the Conference of the Parties (COP) which review its

implementation, make provisions enabling the CITES Secretariat in Switzerland to carry out its functions, consider amendments to the list of species in Appendices I and II, consider reports presented by the Secretariat, and make recommendations for the improved effectiveness of the Convention.

This is the second in a series of notices which, together with public meetings, provide the public with an opportunity to participate in the development of the United States negotiating positions for the ninth regular meeting of the Conference of the Parties to CITES (COP9). The first **Federal Register** notice was published on November 18, 1993 (58 FR 60873) which detailed possible changes in the criteria for listing species on the CITES appendices and requested comments from the public on aspects of these changes which should be considered by the U.S. The Service's regulations governing this public process are found in Title 50 of the Code of Federal Regulations §§ 23.31–23.39.

Notice of the Ninth Regular Meeting of the Conference of the Parties

The Service hereby notifies the public of the convening of the ninth meeting of the Conference of the Parties (COP9) to be held in Fort Lauderdale, Florida, U.S.A. from November 7–18, 1994.

Provisional Agenda for COP9

The Service will participate in the 31st meeting of the CITES Standing Committee, and by this notice calls for a public meeting to discuss the agenda for this meeting and items of concern for COP9. A copy of the agenda for the Standing Committee meeting, scheduled for March 21–25, 1994, is available from the Office of Management Authority (see **ADDRESSES**, above). While it has not yet received formal notice of the provisional agenda for COP9, the Service expects the issues noted below to be on the agenda, which will likely follow the sample format outlined below. A brief discussion follows of those agenda items that may not be self-evident to the public:

I. Opening ceremony by the Authorities of the United States
II. Welcoming addresses
III. Adoption of the Rules of Procedure
IV. Election of Chair and Vice-Chair of the meeting and of Chair of Committees I and II
V. Adoption of the Agenda and Working Programme
VI. Establishment of the Credentials Committee and Committees I and II
VII. Report of the Credentials Committee
VIII. Admission of observers
IX. Matters related to the Standing Committee
  1. Report by the Chair
  2. Election of new members and alternate regional members: The Standing Committee is the governing body of CITES between meetings of the COP. It is composed of representatives of North America (currently Canada), South and Central America and the Caribbean (Trinidad and Tobago), Asia (Thailand), Oceania (New Zealand), Africa (Senegal) and Europe (Sweden), along with the Depositary Government (Switzerland), the host of the last COP (Japan), and the host of the next COP (the United States). The United States will attend the next Standing Committee in its capacity as host government for the next CITES COP.
X. Report of the Secretariat
XI. Financing and budgeting of the Secretariat and of meetings of the Conference of the Parties
  1. Financial report for 1992–1993–1994
  2. Anticipated expenditures for 1995
  3. Budget for 1995–1997 and Medium Term Plan for 1995–2000
  4. External funding
XII. Committee reports and recommendations
  1. Animals Committee
  2. Plants Committee
  3. Identification Manual Committee
  4. Nomenclature Committee
XIII. Interpretation and implementation of the Convention

It is expected that resolutions will be submitted by one or more Parties dealing with many of these agenda items. Resolutions can only be submitted by Parties, and must be submitted to the Secretariat by June 10, 1994. With this notice, the United States begins the process of receiving input from the public on possible resolutions the United States may submit.

1. Report on national reports under Article VIII, paragraph 7, of the Convention:

Each Party is required by the Convention to submit an annual report containing a summary of the permits it has granted, and the types and numbers of specimens of species in the CITES Appendices that it has imported and exported. The U.S. CITES Annual reports are available from the Office of Management Authority (see **ADDRESSES**, above).

2. Review of alleged infractions:

The Secretariat prepares an Infractions Report for each meeting of the Conference of the Parties, which details instances that species listed in the Appendices are being adversely affected by trade or the Convention is not being effectively implemented, or actions by Party countries that undermine the effectiveness of the Convention. The COP8 Infractions Report highlighted those cases of the most serious infractions, in order to focus the attention of the Parties; the COP9 Infractions Report is expected to do the same. A future **Federal Register** notice will notify the public of the availability of the Infractions Report.

3. Exports of leopard hunting trophies and skins: This refers to the importation of leopard skins, including hunting trophies, under a quota system approved by the Conference of the Parties.

4. Trade in specimens of species transferred to Appendix II subject to annual export quotas: This refers to species of crocodilians listed in Appendix I, which have populations that have been transferred to Appendix II pursuant to annual export quotas, which are voted upon by the Conference of the Parties.

5. Trade in rhinoceros products:

This refers to the illegal trade in rhino horn, principally for the Asian medicinal market. The problem has been discussed at the last two Standing Committee meetings, will be discussed at the March 21–25 Standing Committee meeting (SC31) and is expected to be an issue of particular concern to the Parties and a subject of discussion at COP9.

6. Trade in tiger products:

This refers to the illegal trade in tiger parts and products, principally for the Asian medicinal market. The problem has been discussed at the last two Standing Committee meetings, will be discussed at the March 21–25 Standing Committee meeting (SC31) and is expected to be an issue of particular concern to the Parties and a subject of discussion at COP9.

7. Proposed new criteria for listing species on the Appendices: At COP8 in Kyoto, the Standing Committee was instructed to examine the current criteria used in listing species on the Appendices. A Joint Committee Meeting of the Animals, Plants, and Standing Committees met in Brussels, in September 1993, and drafted a resolution for possible revision of the current CITES listing criteria (Resolutions 1.1 and 1.2, the so-called "Berne Criteria"), based on a document prepared for the Parties by IUCN, the World Conservation Union. At SC31, The Standing Committee will review comments received from the Parties and possibly complete a revised draft resolution for the consideration of the

Parties at COP9. Extensive discussion of this revised draft resolution, and the entire issue of criteria for listing species in the Appendices, will take place at COP9.

8. Trade in birds:

The trade in live wild-caught birds is an issue of great concern to both the United States and the CITES Parties, in that the trade in many species of birds listed in Appendix II may be detrimental to their survival. The U.S. now prohibits the import into the U.S. of birds listed on CITES Appendix II unless the Secretary of the Interior finds that such trade will not endanger the survival of the species, based on the Wild Bird Conservation Act of 1992. The Service is not certain whether this item will be placed on the agenda by any Party.

9. Trade in crocodilian products:

This refers to work by the Animals Committee to institute a system of universal marking for all crocodilian skins in trade, as a response to serious problems of illegal trade in crocodilian skins, parts, and products.

10. Trade in plant specimens:

Nursery registration for artificially propagated Appendix I species, among other issues relating to plant species, will most likely be discussed.

11. Significant trade in Appendix II species:

This refers to the trade in those Appendix II species identified as subject to significant trade, for which insufficient biological information exists to warrant trade at current levels. Resolution Conf. 8.9 dealt with this topic, and established a procedure for review of the status of significantly traded species, and the implementation of Article IV of the Convention by the exporting countries involved. It is anticipated that this topic will be placed on the agenda for COP9 as well.

12. Standardization of CITES permits and certificates:

This refers to the development of harmonized CITES permits.

13. Transport of live specimens:

This refers to a report by the Working Group on Transport of Live Specimens, which is chaired by the U.S. Office of Management Authority. The Transport Working Group met in 1993 in Senegal to assess the implementation of requirements in the CITES treaty that live animals be prepared without injury, damage to health, or cruel treatment. One or more Parties that have been active in the Working Group may propose a resolution for the Conference of the Parties dealing with species subject to high mortality rates in transport.

XIV. Consideration of proposals for amendment of Appendices I and II: These topics will be the subject of future notices in the Federal Register.
1. Proposals submitted pursuant to Resolution on Ranching
2. Ten Year Review proposals
3. Proposals concerning export quotas
4. Other proposals

XV. Conclusion of the meeting
1. Determination of the time and venue of the next regular meeting of the Conference of the Parties
2. Closing remarks

Announcement of Public Meeting

To discuss with the public the upcoming thirty-first meeting of the Standing Committee and discuss issues to be considered at COP9, the Service announces that it will hold a public meeting on February 22, 1994, from 2-4 p.m. in room 7000 of the Department of the Interior building, 18th & C Streets NW., Washington, DC . Persons wishing directions to the public meeting or additional information should contact the Office of Management Authority in writing (see ADDRESSES, above) or at (703) 358–2093.

Request for Information and Comments

The Service invites information and comments on the COP9 possible agenda items discussed above and possible resolutions the U.S. may wish to submit, excluding item XIV, "Consideration of proposals for amendment of Appendices I and II". A separate Federal Register notice has been published on these items on July 15, 1993 (58 FR 38112), which requested information from the public on animal or plant species that should be considered by the U.S. as possible amendments to the Appendices. Item XIV will be the subject of two more separate notices. Information and comments should be submitted to the Service no later than March 1, 1994 to be ensured of consideration.

Observers

Article XI, paragraph 7 of the Convention provides:

Any body or agency technically qualified in protection, conservation or management of wild fauna and flora, in the following categories, which has informed the Secretariat of its desire to be represented at meetings of the Conference by observers, shall be admitted unless at least one-third of the Parties object:

(a) International agencies or bodies, either governmental or non-governmental, and national governmental agencies and bodies; and

(b) National non-governmental agencies or bodies which have been approved for this purpose by the State in which they are located.

Once admitted, these observers shall have the right to participate but not to vote.

Persons wishing to be observers representing United States national non-governmental organizations must receive prior approval of the Fish and Wildlife Service. After granting of that approval, a national non-governmental organization is eligible to register with the CITES Secretariat to participate in the COP as an observer. Requests for such approval should include evidence of technical qualification in protection, conservation or management of wild fauna and flora, on the part of both the organization and the individual representative. Organizations previously approved by the Service shall submit a request but do not need to provide as detailed information concerning their qualifications as those seeking approval for the first time. Organizations seeking approval for the first time should detail their experience in the protection, conservation, or management of wild fauna and/or flora, as well as their purposes for wishing to participate in the COP as an observer. Such requests should be sent to the Office of Management Authority (OMA; see ADDRESSES, above). Upon approval by OMA, an organization will receive instructions for registration with the CITES Secretariat in Switzerland. Any organization requesting approval for observer status at COP9 will be added to the Service's CITES Mailing List, and will receive copies of all future Federal Register notices and other information pertaining to COP9. A list of organizations approved for COP9 observer status will be available from OMA just prior to COP9.

Other Meetings and Notices

The CITES Secretariat has notified the Parties that they must submit by June 10, 1994 any draft resolutions, other documents for consideration, proposals to register the first commercial captive-breeding operation for an Appendix I animal species, and proposed amendments to the Appendices. The Service plans to publish additional Federal Register notices containing the following information: Species it intends to propose for amendments to the CITES Appendices; resolutions the U.S. intends to propose for consideration at COP9; a list of resolutions and proposed amendments to the Appendices received by the CITES Secretariat, for consideration at COP9, from other Party governments;

proposed U.S. negotiating positions on these resolutions and proposals; and the final U.S. negotiating positions for COP9. The Service plans to hold a public meeting in September, 1994 to receive public input on its proposed negotiating positions.

Author

This notice was prepared by Dr. Susan S. Lieberman, Office of Management Authority, U.S. Fish and Wildlife Service (703/358–2093; FAX 703/358–2280).

Dated: January 24, 1994.

Bruce Blanchard,

Deputy Director.

[FR Doc. 94–1923 Filed 1–27–94; 8:45 am]

BILLING CODE 4310–55–P

National Park Service

Environmental Impact Statement; Natchez Trace Parkway, MS

AGENCY: National Park Service, Interior.

ACTION: Notice of intent to prepare an Environmental Impact Statement for the Southern Terminus of the Natchez Trace Parkway and notice of public meetings.

SUMMARY:

1. Background and Description of the Proposed Action

In accordance with section 102(2)(C) of the National Environmental Policy Act of 1969, Public Law 91–190, the National Park Service (NPS) is preparing an Environmental Impact Statement (EIS) to determine the final alignment and the impacts of constructing this final portion of the Natchez Trace Parkway in Adams County, Mississippi. This portion will include the southern terminus of the parkway and extend from U.S. 84/98 through the city of Natchez to the vicinity of the Mississippi River, a distance of approximately 7 miles. The EIS will evaluate potential impacts from a range of alternatives which address cultural and natural resources protection, transportation and socioeconomic concerns, visitor use, visual characteristics, and interpretation.

The Natchez Trace Parkway, established in 1938, is a 445-mile long scenic road that follows the historic route of the Natchez Trace. The parkway links the cities of Natchez, Mississippi and Nashville, Tennessee. About 400 miles of the parkway have been completed. The purpose of the parkway is to provide and maintain a scenic and recreational roadway commemorating the historic Old Natchez Trace and to provide access to significant natural and cultural resources along the route.

2. Scoping Process/Public Involvement

Scoping meetings will be held for the general public as well as particular interest and community groups during the winter of 1994. The purpose of scoping is to determine the scope of issues to be addressed and to identify the significant issues related to the project. Meetings will be conducted in the cities of Natchez and Jackson. Meeting dates, locations, and times will be announced through local media.

FOR FURTHER INFORMATION CONTACT: To obtain information or provide comments other than at the meetings, please contact Dan Brown, Superintendent, Natchez Trace Parkway, Rural Route 1, NT–143, Tupelo, Mississippi 38801, telephone (601 680–4003. The responsible official for this EIS is James W. Coleman, Jr., Regional Director, Southeast Region, 75 Spring Street, SW., Atlanta, Georgia 30303.

SUPPLEMENTARY INFORMATION: Representatives from the EIS team will be present to receive comments and answer questions at the public meetings. The public is encouraged to attend and submit verbal and/or written comments regarding the proposed action and EIS.

The draft and final EIS will be distributed to all known interested parties and appropriate agencies. Full public participation by Federal, State, and local agencies as well as other concerned organizations and private citizens is invited during this scoping process and throughout preparation of the document.

Dated: January 19, 1994.

James W. Coleman, Jr.,

Regional Director, Southeast Region.

[FR Doc. 94–1935 Filed 1–27–94; 8:45 am]

BILLING CODE 4310–70–M

Jimmy Carter National Historic Site Advisory Commission; Meeting

AGENCY: National Park Service, Interior.

ACTION: Notice of advisory commission meeting.

SUMMARY: Notice is hereby given in accordance with the Federal Advisory Commission Act that a meeting of the Jimmy Carter National Historic Site Advisory Commission will be held at 8:30 a.m. to 4 p.m., at the following location and date.

DATES: April 12, 1994.

ADDRESSES: The Carter Presidential Center, One Copenhill, Atlanta, Georgia 30307, (404) 331–3900.

FOR FURTHER INFORMATION CONTACT: Mr. Fred Boyles, Superintendent, Jimmy Carter National Historic Site, Route 1 Box 800, Andersonville, Georgia 31711, (912) 924–0343.

SUPPLEMENTARY INFORMATION: The purpose of the Jimmy Carter National Historic Site Advisory Commission is to advise the Secretary of the Interior or his designee on achieving balanced and accurate interpretation of the Jimmy Carter National Historic Site.

The members of the Advisory Commission are as follows:

Dr. Steven Hochman
Dr. James Sterling Young
Dr. Donald B. Schewe
Dr. Henry King Stanford
Dr. Barbara Fields
Director, National Park Service, Ex-Officio member

The matters to be discussed at this meeting include the status of park development and planning activities. This meeting will be open to the public. However, facilities and space for accommodating members of the public are limited. Any member of the public may file with the commission a written statement concerning the matters to be discussed. Written statements may also be submitted to the Superintendent at the address above. Minutes of the meeting will be available at Park Headquarters for public inspection approximately 4 weeks after the meeting.

Dated: January 7, 1994.

C.W. Ogle,

Acting Regional Director, Southeast Region.

[FR Doc. 94–1934 Filed 1–27–94; 8:45 am]

BILLING CODE 4310–70–M

Salt River Bay National Historical Park and Ecological Preserve at St. Croix, VI Commission; Meeting

AGENCY: National Park Service, Interior.

ACTION: Notice of advisory commission meeting.

SUMMARY: Notice is hereby given in accordance with the Federal Advisory Commission Act that a meeting of the Salt River Bay National Historical Park and Ecological Preserve at St. Croix, Virgin Islands Commission will be held at 9:30 a.m. to 12:00 noon, at the following location and date.

DATES: February 18, 1994.

ADDRESSES: District Court, 3rd Floor, Jury Selection Room, 30313 Estate Golden Rock, Lot #13, St. Croix, Virgin Islands 00820–4355.

FOR FURTHER INFORMATION CONTACT: Francis Peltier, Superintendent, Virgin

Islands National Park, 6310 Estate Nazareth, St. Thomas, U.S. Virgin Islands 00802.

SUPPLEMENTARY INFORMATION: The purpose of the Salt River Bay National Historical Park and Ecological Preserve at St. Croix, Virgin Islands Commission is to make recommendations on how all lands and waters within the boundaries of the park can be jointly managed by the Governments of the United States Virgin Islands and the United States in accordance with Public Law 102–247; to consult with the Secretary of the Interior or the development of the general management plan required by section 105 of Public Law 102–247; and to provide advice and recommendations to the Government of the United States Virgin Islands, upon request of the Government of the United States Virgin Islands.

Matters to be discussed at this meeting include administrative items; further interpretation of the enabling legislation; solicitor's response to questions raised at the previous meeting regarding training; recommendations to the Virgin Islands and United States Governments on the co-management of the area.

This meeting will be open to the public. However, facilities and space for accommodating members of the public are limited. Any member of the public may also file with the commission a written statement concerning the matters to be discussed. Written statements may also be submitted to the Superintendent at the address above. Minutes of the meeting will be available at the Virgin Islands National Park headquarters at the above address for public inspection approximately 4 weeks after the meeting.

Dated: January 7, 1994.

C.W. Ogle,

Acting Regional Director, Southeast Region.

[FR Doc. 94–1933 Filed 1–27–94; 8:45 am]

BILLING CODE 4310–70–M

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–363]

Certain Multibrand Infrared Remote Control Transmitters; Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Institution of investigation pursuant to 19 U.S.C. 1337.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on December 21, 1993, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, on behalf of Zenith Electronics Corporation, 1000 Milwaukee Avenue, Glenview, Illinois 60025–4593. An amended complaint was filed on January 10, 1994. The complaint, as amended, alleges violations of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain multibrand infrared remote control transmitters, by reason of alleged induced and contributory infringement of the two claims of U.S. Letters Patent 4,425,647, and that there exists an industry in the United States as required by subsection (a)(2) of section 337.

The complainant requests that the Commission institute an investigation and, after a hearing, issue a permanent exclusion order and permanent cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, is available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., room 112, Washington, DC 20436, telephone 202–205–1802. Hearing-impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810.

FOR FURTHER INFORMATION CONTACT: Smith R. Brittingham IV, Esq., Office of Unfair Import Investigations, U.S. International Trade Commission, telephone 202–205–2576.

AUTHORITY: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, and in section 210.12 of the Commission's Interim Rules of Practice and Procedure, 19 CFR 210.12.

SCOPE OF INVESTIGATION: Having considered the complaint, the U.S. International Trade Commission, on January 21, 1994, *Ordered That*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of section 337(a)(1)(B)(i) in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain multibrand infrared remote control transmitters, by reason of alleged infringement of claim 1 or 2 of U.S. Letters Patent 4,425,647, and whether there exists an industry in the United States as required by subsection (a)(2) of section 337.

(2) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is—Zenith Electronics Corporation, 1000 Milwaukee Avenue, Glenview, Illinois 60025–4593.

(b) The respondents are the following companies alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

Universal Security Instruments, Inc., 10324 South Dolfield Road, Owings Mills, Maryland 21117.
Recoton Corporation, 2950 Lake Emma Road, Lake Mary, Florida 32746.
Universal Electronics, Inc., 1864 Enterprise Parkway, Hudson, Ohio 44236.
Memtek Products, 3131 W. Bolt Street, Fort Worth, Texas 76110.
Bondwell Industrial Company, 47785 Seabridge Bridge, Freemont, California 94538.
Jasco Products Co., Inc., 311 Northwest 122nd Street, Oklahoma City, Oklahoma 73114.
Fox Electronics & Technology, Inc., 2200–F Zenker Road, San Jose, California 95131.
Team Concepts International, Inc., 5/F Yan Hing Centre, 9–13 Wong Chuk Yeung Street, Fo Tan, Shatin, New Territories, Hong Kong.
U.S. Electronics, 600D North Bicycle Path, Port Jefferson Station, New York, New York 11776.
GC Electronics, 1801 Morgan Street, Rockford, Illinois 61102.
Tandy Corporation, 1800 One Tandy Center, Fort Worth, Texas 76102.
Nippon America Company, 1195 NW 97th Avenue, Miami, Florida 33172.
Casio, Inc., 570 Mount Pleasant Avenue, P.O. Box 7000, Dover, New Jersey 07801.
GO-Video, Inc., 570 North Hayden Road, Suite 219, Scottsdale, Arizona 85260.
Remotec Ltd., 1301 Swire & Maclaine House, 19–23 Austin Avenue, TST, Kowloon, Hong Kong.
Gemini Industries, Inc., 215 Entin Road, Clifton, New Jersey 07014.

(c) Smith R. Brittingham IV, Esq., Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street, SW., room 401–M, Washington, DC 20436, who shall be the Commission investigative attorney, party to this investigation; and

(3) For the investigation so instituted, Janet D. Saxon, Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.21 of the Commission's Interim Rules of Practice and Procedure, 19 CFR 210.21. Pursuant to sections 201.16(d) and 210.21(a) of the Commission's Rules, 19 CFR 201.16(d) and 210.21(a), such responses will be considered by the Commission if received not later than 20 days after the date of service of the complaint. Extensions of time for submitting responses to the complaint will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondents, to find the facts to be as alleged in the complaint and this notice and to enter both an initial determination and a final determination containing such findings, and may result in the issuance of a limited exclusion order or a cease and desist order or both directed against such respondent.

Issued: January 24, 1994.

By order of the Commission.

Donna R. Koehnke,

Secretary.

[FR Doc. 94–1910 Filed 1–27–94; 8:45 am]

BILLING CODE 7020–02–P

INTERSTATE COMMERCE COMMISSION

Notice of Intent to Engage in Compensated Intercorporate Hauling Operations

This is to provide notice as required by 49 U.S.C. 10524(b)(1) that the named corporations intend to provide or use compensated intercorporate hauling operations as authorized in 49 U.S.C. 10524(b).

1. Parent corporation and address of principal office: Orion Enterprises, Inc., 2930 West Maple Street, P.O. Box 780, Sioux Falls, SD 57101. State of Incorporation: South Dakota.

2. Wholly-owned subsidiaries which will participate in the operations and states of incorporation:

(i) HSFS Holdings, Inc.

State of Incorporation: South Dakota.

(ii) Hot Stuff Food Systems, Inc.

State of Incorporation: South Dakota.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 94–1911 Filed 1–27–94; 8:45 am]

BILLING CODE 7035–01–M

[Finance Docket No. 32443]

West Central Ohio Port Authority—Acquisition Exemption—Consolidated Rail Corporation

West Central Ohio Port Authority (WESTCO PA), a noncarrier, has filed a notice of exemption to acquire from Consolidated Rail Corporation (Conrail) approximately 64.4 miles of rail line known as the Bellefontaine Cluster in Clark, Champaign, and Logan Counties, OH. The lines are described as follows: (1) The Bellefontaine Secondary Track, from milepost 98.8 near Bellefontaine to milepost 129.4, at a point of connection with the Catawba Secondary Track in Springfield; (2) The Catawba Secondary Track, from milepost 129.4 in Springfield to milepost 130.6, at a point of connection with Conrail's Cincinnati line in Springfield; (3) The Catawba Secondary Track, from milepost 0.0 in Springfield to milepost 17.2 at the end of the track in Mechanicsburg; (4) The Urbana Industrial Track, from milepost 45.2 to milepost 50.03 in Urbana; (5) The Urbana Secondary Track, from milepost 48.1 in Urbana to milepost 54.2 in Bowlusville; (6) The Maitland Secondary Track, from milepost 124.5 to milepost 122.2 near Maitland; (7) a portion of the former main line of the Erie Railroad, from milepost 351.5 near Glen Echo to milepost 353.1 in Urbana; (8) a portion of the Old St. Mary's Branch, from milepost 53.3 to milepost 52.73 in Bellefontaine.[1] The parties expected to consummate the transaction on or after January 14, 1994.

The transaction is directly related to a concurrently filed notice of exemption in Finance Docket No. 32444, *The Indiana & Central Ohio R. Co., Inc.—Trackage Rights Exempt.—West Central Ohio Port Auth.*, in which WESTCO PA seeks an exemption to grant trackage rights over the subject lines to The Indiana & Central Ohio Railroad Company, Inc.

Any comments must be filed with the Commission and served on: Robert L. Calhoun, 1025 Connecticut Avenue, NW., suite 1000, Washington, DC 20036.

[1] WESTCO PA is also acquiring from Conrail approximately 8.1 miles of the underlying right-of-way of the Maitland Secondary Track, from milepost 124.5 near Glen Echo to milepost 132.6, at Cold Springs. Conrail will retain ownership of the track and other rail assets as well as an easement interest in the right-of-way in order to provide continued rail service over the line.

The notice is filed under 49 CFR 1150.31. If the notice contains false or misleading information, the exemption is void *ab initio*. Petitions to revoke the exemption under 49 U.S.C. 10505(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction.

Decided: January 21, 1994.

By the Commission, David M. Konschnik, Director, Office of Proceedings.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 94–1769 Filed 1–27–94; 8:45 am]

BILLING CODE 7035–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Academy of Justice San Diego; Denial of Application

On October 5, 1993, the Deputy Assistant Administrator (then-Director), Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Academy of Justice [San Diego] (Applicant), of San Diego, California proposing to deny its applications, executed on February 19, 1991, for registration as a teaching institution and as a researcher. The statutory basis for the Order to Show Cause was that the Applicant did not have authorization to conduct research with, or otherwise handle, controlled substances under the laws of the State in which it intended to operate, and that its registration would be inconsistent with the public interest under 21 U.S.C. 823(f).

The Order to Show Cause was served on the Applicant on October 14, 1993. More than thirty days have passed since the Order to Show Cause was received by the Applicant and the Drug Enforcement Administration has received no response from the Applicant or anyone purporting to represent it.

Pursuant to 21 CFR 1301.54(d), the Acting Administrator finds that the Applicant has waived its opportunity for a hearing. The Acting Administrator has carefully considered the investigative file in this matter, and enters his final order under the provisions of 21 CFR 1301.54(e) and 1301.57, based on findings of fact and conclusions of law as hereinafter set forth.

The Acting Administrator finds that the Applicant applied for registration as a researcher and as a teaching institution to handle controlled substances in Schedules I through V apparently to engage in providing

training to law enforcement personnel in several areas, including those the Applicant identified as drug identification, drug abuse, and psychopharmacology. Neither the Applicant nor its principal holds any California State controlled substance registration as a practitioner, or in any other capacity. The Applicant has not offered any evidence contrary to that stated in the Order To Show Cause, nor has it provided any information that it is otherwise qualified as a teaching institution or researcher under 21 U.S.C. 802(21).

The Acting Administrator also finds that although the Applicant proposes to handle such highly abusable controlled substances such as heroin, marijuana, LSD, methamphetamine and methaqualone, it did not outline their proposed use in its instructional activities, nor did it indicate that appropriate security safeguards are in place to ensure against diversion. The Applicant also proposed to have an instructor staff of approximately fifty people who would transport the controlled substances, on their person, to various training sites throughout the state. Furthermore, the Applicant's proposed "teaching institution" has had no permanent site from which DEA can judge the adequacy of its security provisions.

The Administrator may deny an application for registration if he determines that such registration would be inconsistent with the public interest. Pursuant to 21 U.S.C. 823(f), "[i]n determining the public interest, the following factors will be considered:

(1) The recommendation of the appropriate State licensing board or disciplinary authority.

(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety."

It is well established that these factors are to be considered in the disjunctive, i.e., the Administrator may properly rely on any one or a combination of factors, and give each factor the weight he deems appropriate. Henry J. Schwarz, Jr., M.D., Docket No. 88–42, 54 FR 16422 (1989).

The Acting Administrator finds that the Applicant has failed to provide any information to indicate that the institution would be engaged in bona fide research; any recommendations from its State licensing boards; any supporting evidence that it has had experience in dispensing controlled substances or conducting research; any evidence that it or its facility is able to comply with all laws relating to controlled substances; and any research protocol or statement describing its proposed research activities.

Furthermore, the Acting Administrator has no statutory authority to register practitioners if they are not licensed in the State in which they practice. 21 U.S.C. 823(f); George P. Gotsis, M.D., 49 FR 33750 (1984); James W. Mitchell, M.D., 44 FR 71466 (1979). Thus, the Administrator must deny an application for a DEA Certificate of Registration if he determines that the applicant is not authorized to dispense, or conduct research with respect to, controlled substances under the laws of the State in which he operates. Based on all of the foregoing, the Acting Administrator concludes that the applications of Academy of Justice San Diego are inconsistent with the public interest and must be denied.

Accordingly, the Acing Administrator of the Drug Enforcement Administration, pursuant to the authority vested in him by 21 U.S.C. 823 and 824 and 28 CFR 0.100(b), hereby orders that the applications for registration, executed on February 19, 1991, by Cindy Rawlins, Director, on behalf of Academy of Justice San Diego, be, and they hereby are, denied. This order is effective January 28, 1994.

Dated: January 21, 1994.

Stephen H. Greene,

Acting Administrator of Drug Enforcement.

[FR Doc. 94–1815 Filed 1–27–94; 8:45 am]

BILLING CODE 4410–09–M

Miguel A. Santos, M.D.; Denial of Application

On April 5, 1993, the Deputy Assistant Administrator (then-Director), Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Ordered to Show Cause to Miquel A. Santos, M.D. (Respondent), HC–01 Box 6507, Bo. Magas Abajo, Guayamillas, Puerto Rico 00656–9715. The Order to Show Cause sought to deny Respondent's application for a DEA Certificate of Registration, dated May 29, 1990, pursuant to 21 U.S.C. 823(f). The Order to Show Cause alleged that Respondent's registration would be inconsistent with the public interest.

By letter dated May 19, 1993, Respondent waived his right to a hearing and presented a written statement regarding his position on the matters of fact and law set forth in the Order to Show Cause. Pursuant to 21 CFR 1301.57, the Administrator hereby issues his final order based on the investigative file and Respondent's written statement.

The Acting Administrator finds that in February 1984 in Rabun County, Georgia, Respondent was indicted on twenty-one felony counts of violating the Georgia Controlled Substances Act. The indictment was based on Respondent's issuing prescriptions for various Schedule III controlled substances for other than legitimate medical purposes. By Order dated February 16, 1984, the Composite State Board of Medical Examiners of the State of Georgia (Georgia Board) concluded that Respondent's ability to practice medicine posed a threat to the public health, safety and welfare, and determined that emergency action was required. The Georgia Board therefore ordered Respondent to surrender his DEA Certificate of Registration, and any triplicate prescription forms and order forms. In addition, the Georgia Board suspended Respondent's license to practice medicine in the State of Georgia.

On February 17, 1984, Respondent surrendered his DEA Certificate of Registration, AS1270660. Respondent pled guilty to all twenty-one felony counts and, on March 7, 1984, was sentenced to ten years probation, ordered to pay $12,000.00 and prohibited from returning to the Mountain Judicial Circuit for the period of probation.

The investigative file reveals that on October 11, 1990, Respondent appeared before the Georgia Board to request reinstatement of his medical license. On December 26, 1990, the Georgia Board notified Respondent of its decision to deny his request. The investigative file also indicates that Respondent is authorized by the Commonwealth of Puerto Rico to handle controlled substances.

In his letter of May 19, 1993, Respondent explained that he was currently practicing medicine in Ponce, Puerto Rico. Respondent also alleged that in 1984, he issued numerous prescriptions for controlled substances at the bequest of the Georgia Bureau of Investigation (GBI). Respondent claimed that he was working in cooperation with the GBI in the GBI's effort to "break a ring of drug and arms" trafficking.

The Acting Administrator finds, however, that the investigative file, which contains voluminous reports from the GBI, does not support Respondent's assertion that he wrote the prescriptions at issue at the direction of

the GBI. On the contrary, the investigative file indicates that the GBI had received information that Respondent was issuing prescriptions without valid medical reason and commenced an investigation. Special Agents from the GBI conducted several undercover operations and were able to obtain prescriptions from Respondent in the absence of a legitimate medical purpose.

Section 823(f) of the Controlled Substances Act lists five factors which are to be considered when making a determination as to whether a registration would be in the public interest. These factors include: (1) The recommendation of the appropriate State licensing board or professional disciplinary authority; (2) the applicant's experience in dispensing, or conducting research with respect to controlled substances; (3) the applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances; (4) compliance with applicable State, Federal or local laws relating to controlled substances; and, (5) such other conduct which may threaten the public health and safety. The Administrator may rely on any one or any combination of these factors when determining whether an application should be denied or a registration revoked. See Neveille H. Williams, D.D.S., 51 FR 17556 (1986); Anne L. Hendricks, M.D., 51 FR 41030 (1986).

Pursuant to 21 U.S.C. 823(f), the Acting Administrator concludes that Respondent's registration would be inconsistent with the public interest. The Acting Administrator bases this conclusion on the actions of the Georgia Board, which has chosen not to reinstate Respondent's medical license, Respondent's past history of prescribing controlled substances in the absence of a legitimate medical reason, and Respondent's felony conviction relating to controlled substances.

Accordingly, the Acting Administrator of the Drug Enforcement Administration, pursuant to the authority vested in him by 21 U.S.C. 823 and 824 and 28 CFR 0.100(b), hereby orders that Respondent's application for a DEA Certificate of Registration be, and it hereby is, denied. This order is effective January 28, 1994.

Dated: January 21, 1994.

Stephen H. Greene,

Acting Administrator of Drug Enforcement.

[FR Doc. 94–1816 Filed 1–27–94; 8:45 am]

BILLING CODE 4410–09–M

Jayen C. Shah, M.D.; Revocation of Registration

On September 23, 1993, the Deputy Assistant Administrator (then-Director), Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Jayen C. Shah, M.D. of 624 Benner Road, Allentown, Pennsylvania, proposing to revoke his DEA Certificates of Registration, AS2199328 (Missouri), AS2094756 (Illinois), BS3036185 (Iowa), and BS3067142 (New Jersey); and deny his pending application for registration as a practitioner in Pennsylvania, for reason that his continued registration would be inconsistent with the public interest.

The Order to Show Cause was sent by registered mail to Dr. Shah at his registered locations in St. Louis, Missouri; East St. Louis, Illinois; Waterloo, Iowa; Woodbury, New Jersey; and his most recent address in Allentown, Pennsylvania. The copy sent to the East St. Louis address was returned to the DEA by St. Mary Hospital with the notation that Dr. Shah was not at that address. Also, the hospital apparently forwarded a copy to Dr. Shah at a Fairview Heights, Illinois address, which copy was also returned to the DEA, with a notation that Dr. Shah was not there. The Waterloo, Iowa copy of the Order to Show Cause was returned to the DEA by Emergency Practice Associates with a notation that Dr. Shah is not an employee there. The Allentown, Pennsylvania copy was returned with the notation that delivery was refused and it indicated a forwarding postal box address in Ahmedabad, India for Dr. Shah. Delivery of the Order to Show Cause was accepted at the Woodbury, New Jersey and St. Louis, Missouri addresses on September 27, and 29, 1993, respectively.

Dr. Shah is no longer in practice or present at two of his registered locations. More than thirty days have passed since receipt of the Order to Show Cause and no response has been received from Dr. Shah or from any person purporting to represent him.

Pursuant to 21 CFR 1301.54(d), the Acting Administrator finds that Dr. Shah has waived his opportunity for a hearing. The Acting Administrator has carefully considered the investigative file in this matter, and enters his final order under the provisions of 21 CFR 1301.54(e) and 1301.57.

The Acting Administrator finds that in January 1989, the Illinois Department of Professional Regulation initiated an investigation of Dr. Shah based on a complaint that he was over-prescribing the controlled substances Didrex and Dilaudid. At the same time, Missouri Bureau of Narcotics and Dangerous Drugs provided Illinois information that Dr. Shah had been regularly prescribing controlled substances such as Didrex, Dilaudid, Percodan, Halcion, Tylox, and Xanax to persons identified as "professional patients".

The Acting Administrator finds that during the period October 1988 through August 1989, Dr. Shah prescribed controlled substances to eight patients not for a legitimate medical purpose and not in the usual course of professional practice. Also, on three occasions during the period October 20, 1989 through November 10, 1989, Dr. Shah prescribed the controlled substances Tylox and Percodan for use by a person other than the name indicated on the prescription.

The Acting Administrator finds that in October 1989, and at other times during 1988 and 1989, Dr. Shah sold a fraudulent prescription for the controlled substance Dilaudid in exchange for $400.00 cash, and on November 29, 1989, he sold a prescription for the controlled substance Percodan in exchange for $40.00 cash. Also, on November 14, 1989, Dr. Shah proposed to a patient and her relatives that he would provide them two controlled substance prescriptions per month in exchange for signed Medicare forms and secretarial services.

The Acting Administrator further finds that the United States Air Force, Scott Air Force Base, Illinois, suspended Dr. Shah's clinical privileges based upon an allegation that he filed a false report in May 1990. Based on the above Air Force action, on March 17, 1993, the State of Illinois Department of Professional Regulation suspended Dr. Shah's license to practice medicine indefinitely. On March 26, 1993, Dr. Shah voluntarily surrendered his medical license to the Missouri Board of Registration for the Healing Arts and is foreclosed from reinstatement for a period of seven years.

Accordingly, the Acting Administrator concludes that Dr. Shah is not authorized to administer, dispense, prescribe, or otherwise handle controlled substances under the laws of Illinois and Missouri, both States in which he is registered to practice with DEA.

The Administrator may revoke or suspend a DEA Certificate of Registration under 21 U.S.C. 824(a), upon a finding that the registrant:

(1) Has materially falsified any application filed pursuant to or required by this subchapter or subchapter II of this chapter;

(2) Has been convicted of a felony under this subchapter or subchapter II of this chapter or any other law of the United States, or of any State relating to any substance defined in this subchapter as a controlled substance;

(3) Has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances or has had the suspension, revocation, or denial of registration recommended by competent State authority;

(4) Has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section;

(5) Has been excluded (or directed to be excluded) from participation in a program pursuant to Section 1320A–7(a) of Title 42.

Pursuant to 21 U.S.C. 823(f), "[i]n determining the public interest, the following factors will be considered:

(1) The recommendation of the appropriate State licensing board or disciplinary authority.

(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety."

It is well established that these factors are to be considered in the disjunctive, i.e., the Administrator may properly rely on any one or a combination of factors, and give each factor the weight he deems appropriate. *Henry J. Schwarz, Jr., M.D.*, Docket No. 88–42, 54 FR 16422 (1989).

The Acting Administrator finds that the first, second, fourth, and fifth factors are relevant in this case. Here, the State licensing bodies of Illinois and Missouri have taken adverse action against Dr. Shah; Dr. Shah has improperly dispensed controlled substances without a legitimate medical purpose and outside the scope of usual professional practice; Dr. Shah has violated the Federal Controlled Substances Act and regulations pertaining to controlled substances; and Dr. Shah's propensity to sell controlled substances for cash or favors, and his improper conduct with the U.S. Air Force threaten the public health and safety. Furthermore, the Acting Administrator has no statutory authority to register practitioners if they are not licensed in the State in which they practice. DEA has consistently held that termination of a registrant's State authority to handle controlled substances requires that DEA revoke the registrant's DEA Certificate of Registration. *Sam S. Misasi, D.O.*, 50 FR 11469 (1985); *George P. Gotsis, M.D.*, 49 FR 33750 (1984); *Henry Weitz, M.D.*, 46 FR 34858 (1981).

Based on all of the foregoing, the Acting Administrator concludes that Dr. Shah's continued registration is inconsistent with the public interest and must be revoked. 21 U.S.C. 823(f) and 824(a). Accordingly, the Acting Administrator of the Drug Enforcement Administration, pursuant to the authority vested in him by 21 U.S.C. 823 and 824 and 28 CFR 0.100(b), hereby orders that DEA Certificates of Registration, AS2199328, AS2094756, BS3036185, and BS3067142, previously issued to Jayen C. Shah, M.D., be, and they hereby are, revoked, and that his pending application for registration, be, and it hereby is, denied. This order is effective on February 28, 1994.

Dated: January 21, 1994.

Stephen H. Greene,

Acting Administrator of Drug Enforcement.

[FR Doc. 94–1814 Filed 1–27–94; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF LABOR

Employment and Training Administration

Job Corps: Finding of No Significant Impact for the Relocation of the Detroit Job Corps Center in Detroit, MI

Pursuant to the Council on Environmental Quality Regulations (40 CFR part 1500 to 1508) implementing procedural provisions of the National Environmental Policy Act (NEPA), the Department of Labor, Employment and Training Administration, Office of Job Corps, in accordance with 29 CFR 11.11(d), gives notice that an Environmental Assessment (EA) has been prepared and the proposed plans for the relocation of the Detroit Job Corps Center in Detroit, Michigan, will have no significant environmental impact.

The proposed site, located in the area of 1800 Tuxedo Street, Detroit, Michigan, is comprised of 13.9 acres, and is made up of three parcels, which are designated A, B, and C for reference purposes. Parcel A is comprised of 6 vacant lots (totaling 0.87 acre), located on Webb Street between 12th Street and Woodrow Wilson Boulevard; Parcel B is a 3.2 acre vacant lot located between the John C. Lodge Freeway and Woodrow Wilson Boulevard, just south of Elmhurst. Parcel C, comprised of 9.83 acres (currently utilized as a community-oriented outpatient health-care facility) has several structures: a main building constructed in 1935; three additions built between 1960 and 1972, and two auxiliary buildings built in 1966. The campus includes paved asphalt parking lots, concrete sidewalks, and a well maintained lawn with trees and vegetation. A 6-foot chain link fence, topped with barbed wire, surrounds the perimeter of Parcel C. Within the buildings there are operating and treatment rooms, a dining hall served by vending machines, a library, conference rooms, an optical laboratory, an emergency room suite, a gift shop, a pharmacy, auxiliary spaces, and administrative space converted from patient rooms.

The purpose of the proposed action is to convert the Metropolitan Hospital into the Detroit Job Corps Center for 320 resident and 50 non-resident students. The original patient hospital is adaptable to dormitory accommodations and offers the necessary facilities for the Job Corps program to provide basic education, vocational skills training, work experience, counseling, health care, and related support services.

This new center will provide dormitories, recreational, medical/dental, administrative services, educational and vocational training, and storage space that is consistent with Job Corps guidelines and center needs. Establishing a Job Corps Center at this location will require some constructive change to existing buildings. To meet recreational needs, based on the Job Corps prototype for recreational activities, some construction is needed; e.g., a recreational building, a new ball field to be constructed on Parcel B, outdoor basketball courts on existing parking areas, and modification of the existing fencing to extend completely around all three parcels. The proposed project will be constructed in accordance with local fire, building, and zoning code requirements and will not adversely impact the City of Detroit police, fire or emergency services.

The site is located in an urban setting and is currently zoned R6 (high-density multiple-family residential); however, over the years residential occupancy has declined substantially. Prior to proceeding with the acquisition of the Metropolitan Hospital, the Department of Labor secured a letter from the City Planning Office and Community & Economic Development Department that

states that the proposed Job Corps Center is an allowable use under the existing zoning, thus, no zoning conflict will result from the proposed change in occupancy and rehabilitation of the former Metropolitan Hospital. The site is bordered on the east by an expressway. The northern boundary is occupied by some multi-dwelling structures, commercial business, and a store-front type church facility. The western boundary is comprised of a soup kitchen, a bible missionary center, vacant lots, vacant store fronts, and a large medical supply company. The southern border includes minimal residential dwellings, a nursing home, a foster-care center for children, and an apartment building for teenage mothers.

The portion of the site identified as Parcel B (which is presently owned by the State of Michigan but will be transferred to the City of Detroit in the first quarter of 1994) is vacant land and is presently used for illegal dumping of waste, vehicle tires, roofing and building materials, concrete, and miscellaneous rubbish. It is unknown whether an abandoned underground storage tank, identified as present on this parcel, has been properly closed. In addition, an underground tunnel is known to exist at the site but its closure status is not known. Based on the Environmental Assessment, it has been determined that neither of these site conditions will adversely impact the proposed activities. Conversion of this part of the site to the Detroit Job Corps Center through environmental restoration would be a positive asset to the area and would alleviate the State or City of Detroit of a substantial burden and liability.

The alternatives considered in the preparation of the EA were (1) the "No Purchase" alternative and (2) to continue as proposed. Choosing the "No Purchase" alternative would require the continued operation of the Detroit Job Corps Center under the present inadequate poor conditions. The potential for an enhanced facility and improved operational efficiency afforded by the proposed action indicates that the proposed purchase and improvement of the center is the preferred alternative.

The proposed use has no significant impact on any natural systems or resources. The existing site and buildings at the proposed Job Corps Center location are not designated as "historically significant" and no areas of archaeological significance are present. The activities of the proposed Job Corps Center are not of a contaminant generating nature. The geologic, water, and climatic characteristics of the general vicinity of the site, coupled with the historically known land use, minimizes the site's potential to be contaminated from possible off-site sources and further minimizes the impact of contamination. The migration of any contamination that may have occurred through past activities at the site is likewise minimized, due to impervious soils and deeply located ground water.

No significant levels of radon exist on the site. Water samples, taken from drinking fountains within the buildings on the site have been analyzed for lead content and were found to be well below EPA recommended limits. An asbestos assessment was performed on the existing facility with subsequent containment and removal of asbestos-containing materials. Some on-going repairs of past containment efforts are required. Analysis of composite paint chip samples made during the investigation for the EA indicated the presence of lead at levels that would require removal of the lead-based paint, if construction activities would disturb this material. This is common for structures constructed prior to 1980. Procedures for the containment and removal of lead, if deemed necessary, will be prepared by a qualified lead-abatement contractor and will be properly managed during any future construction activities. The abandoned on-site underground storage tank and underground tunnel on Parcel B may require additional investigation. These items are addressed in the EA.

Existing environmental concerns (e.g., air quality issues resulting from the improperly controlled and monitored medical waste incinerator, lens-process waste effluent discharge into sanitary sewer by the optical laboratory, management of hazardous materials, etc.) created by the operations of the current facilities on parcel C, although not a significant impact on the proposed activities, would become moot through a change of operations and activities at the proposed Job Corps Center.

Noise levels generated from air conditioning and other equipment at the existing facilities are consistent with City of Detroit regulations. Short-term impact from additional noise will occur during the construction activities; however, construction activities will be limited to the hours of 7 a.m. to 3:30 p.m. The use of sound control devices and muffled exhausts on all noise-generating construction equipment will be required. The use of appropriate techniques to minimize construction dust emissions will mitigate construction-related air pollution concerns. Any noise generated by the completed facility is expected to remain within allowable noise limits and will not adversely impact neighboring properties.

The existing site and security lighting consists of facility-owned and maintained building-mounted, photocell-controlled, high-intensity discharge (HID) luminaries and utility company-owned and maintained pole-mounted, photocell-controlled HID luminaries located along the streets and in the parking areas. This proposed project will bring the exterior lighting conditions into compliance with City lighting ordinances.

Water is available to the site through municipal lines. Storm water run-off and sanitary wastes are accommodated by discharge to municipal sewers. Based on the nature of the proposed construction activities at the site, storm water quality will not be degraded.

Detroit has an abundance of water, electrical power, and natural gas to easily serve facilities of this size and substantially larger. Although the proposed project will cause an increase in traffic in the community, the increase in traffic value is not expected to adversely affect traffic flow on neighborhood streets. A neighborhood city hall and post office are located in close proximity to the site. Several emergency response companies service the area. Police and fire stations are closely located near the subject property. Several major and world known hospitals are within a five-mile radius of the subject site. Several bus routes offer readily available transportation to and through the subject area at a reasonable cost. Four of Detroit's six Interstate Highways are within a five-mile radius of the subject site and allow fast and easy access throughout the Detroit area. The surrounding community, with its markedly diverse ethnicity, offers adequate recreational, educational and cultural opportunities for the students. The implementation of the Job Corps on the proposed site will provide jobs for vicinity residents and could add stability to the area.

Based on the information gathered during the preparation of the EA for the Department of Labor, Employment and Training Administration, the Office of Job Corps finds that the relocation of the Detroit Job Corps Center to the 1800 Tuxedo area location in Detroit, will not cause any significant impact on the environment and, therefore, recommends that the project continue as proposed. This proposed action is not considered to be highly controversial. Copies of the EA and additional information are available to interested

parties by contacting Mr. Gordon Carlson, Director, Region V, Office of Job Corps, at (312) 353–1311 (this is not a toll free number).

Dated at Washington, DC, this 24th day of January, 1994.

Peter E. Rell,

Director of Job Corps.

[FR Doc. 94–1913 Filed 1–27–94; 8:45 am]

BILLING CODE 4510–30–M

Availability of Funds; Employment and Training Needs of Migrant and Seasonal Farmworkers

ACTION: Notice.

SUMMARY: The U.S. Department of Labor, Employment and Training Administration (DOL/ETA), announces the availability of funds for a demonstration project to encourage and promote innovative responses to the employment and training needs of migrant and seasonal farmworkers. This notice describes the application process, possible demonstration models, how grantees will be selected and the responsibility of the grantee. One (1) grant, not to exceed $550,000 will be awarded on a competitive basis. This grant will be for a 12 month period with the possibility of 2 option years. The Department reserves the option to fund additional demonstration projects, based on a review and evaluation of applications received as a result of this solicitation. Applications with proposed costs in excess of $550,000 will not be considered.

DATES: Applications for grant awards will be accepted commencing January 28, 1994. The closing date for receipt of applications shall be March 14, 1994, at 2 p.m. (Eastern Standard Time) at the address below.

ADDRESSES: Mail on hand deliver applications to: U.S. Department of Labor, Employment and Training Administration, Office of Grants and Contract Management, Division of Acquisition and Assistance, room S4203, 200 Constitution Avenue, NW., Washington, DC 20210. Attention: Irene Taylor-Pindle or Shirley Horton. Reference SGA/DAA–94–001.

FOR FURTHER INFORMATION CONTACT: Ms. Irene Taylor-Pindle or Ms. Shirley Horton, Division of Acquisition and Assistance. Telephone: (202) 219–8702. (This is not a toll free number.).

SUPPLEMENTARY INFORMATION: This solicitation consists of four parts. Part I provides the background and purpose of the demonstration project(s). Part II identifies possible demonstration models. Part III describes the application process and provides detailed guidelines for use in applying for the demonstration grant and the selection criteria used in reviewing the applications. Part IV describes the reporting requirements.

Part I. Background

Studies have indicated that although large numbers of farmworkers actively leave agricultural employment annually, equally large numbers depend on continued long-term employment in agriculture for their livelihood. For those seeking to leave agriculture, programs annually funded under section 402 of the JTPA offer classroom and skill training leading to employment opportunities.

Farmworkers opting to remain in agriculture are dependent on an agricultural employment system that is at times affected by weather conditions and changing local labor market needs and economic factors, but is always constant in its unforgiving working conditions and long term negative effect on the farmworker's health and economic well being.

The Department is interested in aiding farmworkers seeking employment opportunities and a future outside of agriculture, while at the same time stabilizing the farm labor force by providing labor market information and enhancing the skills and well being of farmworkers (and their dependents) wishing to remain in agriculture.

The Department of Labor is focusing this solicitation on demonstration efforts that will address issues that directly impact the daily lives of farmworkers—both seasonal and migrant.

The Department will consider and fund one or more demonstration project(s) that encompass (one or more) aspects of the following topic areas: (a) A labor market information system that would provide farmworkers with accurate and timely data concerning crop planting and harvest conditions, employment opportunities, housing conditions and the availability of supportive services, etc.; (b) a program model that employs work-based learning concepts to demonstrate a new approach in retraining farmworkers (either in upgraded farmwork employment or in employment opportunities outside of agriculture); (c) a program model that serves to transition farmworkers into newly emerging fields of technology—taking into account the barriers faced by farmworkers, while at the same time satisfying the skill and cognitive needs of the targeted industry; (d) a program model that serves to reinvent the manner in which the hardest of farmworkers to serve are provided retraining and/or training in areas that will directly impact and enhance their lives and the lives of their families; (e) a program model that creates an information network linking farmworker service delivery agents for the purpose of creating a data base that could be used for sharing client information. This in turn could have the effect of more efficiently and effectively rendering services to the farmworker.

In calling for grant applications, the Department is not limiting or suggesting geographic areas or regions, nor is the Department limiting the design of projects to those suggested above. Applicants are free to identify the geographic area in which their proposed demonstration project will be tested. Applicants should also understand that the Department will exercise its option of funding one or more demonstration projects based on a review and appraisal of those received under this SGA notice.

Demonstration projects under this initiative may try out new approaches to serving farmworkers and in the process assess and test new ideas that may integrate the provision of services, classroom training and structured worksite learning. The demonstration project(s) may establish a fundamental change in the way farmworker organizations and agents of technical and skill training provide assistance to migrant and seasonal farmworkers.

Part II. Statement of Work

This Statement of Work sets forth the objectives, general specifications and conditions for submission of applications to conduct a demonstration project for a 12-month base period. Each demonstration project must offer services and activities, necessary to assist migrant and seasonal farmworkers, preferably, in a combination and format not currently found in Section 402 programs. The applicant may select one of the models presented below or develop a different model that addresses the specific problems faced by this target group. The desired services sought under a demonstration grant through this SGA will include but may not be limited to the following activities and areas of expertise:

*Model #1. The development and dissemination of a labor market system benefiting migrant and seasonal farmworkers.

A proposal under this model should identify the geographic area to be targeted for this demonstration project along with the rationale for its selection; the manner in which information and data concerning crop planting,

harvesting and related employment opportunities, availability of temporary housing and supportive services will be gathered and shared; the manner in which those organizations currently serving farmworkers in the targeted area will be utilized for distribution of information purposes; the form/media in which information will be shared with farmworkers and the projected number to be reached.

The grantee shall establish a methodology for collecting, analyzing and distributing information concerning crop planting and harvesting and attendant employment opportunities; shall establish linkages with farmworker organizations and farm labor entities and the agricultural recruitment system within the geographic area to be covered; shall collect and communicate pertinent information on a timely basis; shall develop internal monitoring and evaluation instruments to gauge the effectiveness of the distribution system and the information collected.

* Model #2. The development of a training model that would establish a new approach to retraining farmworkers.

A proposal submitted under this model, should involve the structuring of worksite learning (that would include innovative approaches in combining classroom and skill training) which would be effectuated to meet the specific learning needs of farmworkers.

This would include the geographic location in which the model would be conducted and the rationale for its selection; the technology and methodology to be employed; a listing of participating employers where worksite learning would occur; an identification of the specific learning needs to be focused upon which may be unique to farmworkers; and a description of how coordination will take place with farmworker organizations within the proposed service area and a listing of those organizations. The grantee shall, after establishing a timeframe for initiating the proposed project, commence operations within the first four months; shall select or develop alternative and innovative approaches to instruction and the uses of teaching techniques and instructional materials, work relevant curricula and motivational resources designed for participants who read at the eighth grade level; shall conduct and provide the Department with an assessment of both current and future local service area labor market needs with concomitant entry-level requirements; shall structure worksite learning (in concert with the participating employers) for participating section 402 eligible farmworkers; shall establish cooperative agreements between selected employers (for worksite learning activities) and service area farmworker program operators and the grantee; shall evaluate, assess and provide the Department with a report concerning the outcomes of the methodology employed through this effort and its effect on the participants.

* Model #3. The development of a training model that would incorporate new methodologies in transitioning farmworkers with limited English-speaking ability and skills into the newly emerging and technically demanding workplace.

The applicant should include the geographic area in which this demonstration project will be tested along with the rationale for its selection; the methodology to be employed; a description of the industry(ies) selected with a focus on those aspects which now require higher skilled entry-level workers and the manner in which farmworkers from rural areas with limited English will be trained for these new jobs; a description regarding how the project will coordinate with local organizations serving farmworkers—and how this would benefit the participants.

The grantee shall develop a methodology for transitioning participating farmworkers from agricultural employment in rural areas into employment training opportunities where new technology has produced more demanding entry-level jobs and where long-term job opportunities now exist; shall develop linkages with farmworker organizations within and serving the designated project area for the purpose of recruitment, selection and the provision of supportive services to the participants; shall provide rationale for selection of participating industries; shall provide analysis and rationale for selection of training methods to be used and a timeframe projection for success of project; shall provide an approach to easing the transition process for the farmworker participants whose native language is not English.

* Model #4. The development of a training model that would include a methodology which may innovatively address the needs of the hardest to serve farmworkers while at the same time imparting employability skills.

The applicant should include an identification of the geographic area selected and the rationale for the site selection. It should also include a description of the following: How participants would be identified and recruited, the instructional methodology to be employed and how this would be tied into skill instruction (either in skill areas outside of agricultural employment or leading to upgraded positions within agriculture). Included would be a description of the manner in which farmworker organizations within the designated demonstration service area would be utilized.

The grantee shall select or develop a methodology or technique that is reflective of addressing the unique needs of the farmworker clientele of the section 402 programs who have been identified as the hardest to serve—those being individuals with the disadvantage of having limited skills, limited English and limited reading and cognitive abilities; shall demonstrate how this methodology may prove to be more effective—in terms of outcomes—than previously used practices; shall identify, recruit and enroll farmworkers who satisfy the afore-stated barriers for participation in the demonstration model; shall provide the Department with progress assessments of the participants at agreed upon periods during the grant; and shall establish measurable benchmarks to determine the success and effectiveness of the model.

* Model #5. The development of a training model that sets out a technical approach to link farmworker service delivery agents in order to share clientele information, and the establishment of a related data base.

The proposal should identify the geographic region selected and the rationale for it. It should include a description of the methodology to be used and those organizations selected to participate. It should describe the data to be collected, how it will be used and how it will benefit the farmworkers—either directly or indirectly.

In the development and submission of a grant application to this SGA, applicants must demonstrate an understanding of the farmworker population—including socio-economic conditions and prevailing regional and ethnic cultures of the people whom the Department is mandated to serve; a knowledge and understanding of the migratory streams which farmworkers travel in search of employment in agriculture and the living and working conditions which prevail in migrant farmworker streams; a knowledge and understanding of the methods of providing employment and training activities and services in behalf of migrant and seasonal farmworkers; a knowledge and understanding of the current agricultural recruitment and employment system; a knowledge and understanding of demonstrated

expertise in the proffered activities under the proposed effort; and finally, demonstrated support of the community and knowledge of the labor market for which the project is proposed.

Perhaps one of the more important goals of this initiative is focusing attention on the unique employment and training needs of migrant and seasonal farmworkers and bringing to bear upon this challenge a creative and innovative approach. With this in mind, these demonstration grants are intended to lay the foundation for a new approach in serving farmworkers and/or providing an augmentation to existing employment and training efforts.

The grantee shall establish cooperative arrangements with all organizations serving farmworkers within the designated geographic region of this demonstration model; shall develop a data base for the collection of relevant information; shall demonstrate how this data will be beneficial to the participating farmworker organizations, the U.S. Department of Labor, and to the farmworkers; shall provide the Department with periodic status reports on the progress toward the goals of this model demonstration; shall establish a methodology for linking all farmworker programs in the designated area so that they may access, contribute to, and benefit from the data base.

Part III. Application Process

A. Eligible Applicants

Eligible applicants for these demonstration projects to be funded under this announcement are public agencies and private nonprofit organizations.

B. Application Procedures

1. Submission of Proposal

All instructions and forms required for submittal of applications are included in this announcement. An original and three (3) copies of the application shall be submitted. The application package shall consist of two (2) separate and distinct parts. Part I, The Financial Proposal and Part II, the Technical proposal. The Financial Proposal, Part I, shall contain the SF–424, "Application for Federal assistance" (Attachment No. 1) and SF424–A, "Budget" (Attachment No. 2). The budget shall include on a separate page(s) a cost analysis of the budget, identifying in detail the amount of each budget line item attributable to each cost category. The Technical Proposal, Part II shall address the Statement of Work as called for in this application along with documenting the applicants previous experience and capability to carry out the proposed demonstration project.

Applicants should describe the proposed technical approach including the phasing of tasks and the scheduling of time and personnel. No cost data or reference to price shall be included in the Technical Proposal, Part II, so that an independent evaluation can be made solely on the basis of technical merit.

2. Late Proposals

Any proposal not reaching the U.S. Department of Labor, Employment and Training Administration, Office of Grants and Contract Management, Division of Acquisition and Assistance, room S4203, 200 Constitution Avenue, NW., Washington, DC 20210 by the specified time and date as set forth under the section noted as **DATES** will not be considered, unless postmarked five (5) days prior to the stated closing date. The term "postmark" means a printed, stamped or otherwise placed impression (exclusive of postage meter-machine impression) that is readily identifiable without further action having been supplied or affixed on the date of mailing by employees of the U.S. Postal Service.

3. Hand-Delivered Proposals

Although it is preferred that all proposals be submitted through the U.S. Postal Service, hand delivered proposals will be accepted if received and time stamped by the U.S. Department of Labor, Employment and Training Administration, Office of Grants and Contract Management, Division of Acquisition and Assistance, room S4203, 200 Constitution Avenue, NW., Washington, DC 20210 by 2 p.m., Eastern Standard Time by March 14, 1994. Telegraphed and/or faxed proposals will not be accepted. Failure to adhere to the above instructions will be a basis for a determination of nonresponsiveness.

4. Period of Performance

The period of performance will be twelve (12) months from the date of execution by the government.

5. Option To Extend

Depending upon the availability of funds, and the assessment of the grantee's performance by the U.S. Department of Labor, the government reserves the right to extend the grant for up to two (2) one year extensions beyond the initial 12-month period of performance.

C. Proposal Format

Each application should contain the information necessary for the Department to evaluate it in terms of the selection criteria, identified in part III.D. The general format that should be followed is outlined below:

1. A statement of the problem to be addressed and a brief summary of the proposed demonstration project.

2. A historic overview of your organization and a statement of relevant experience supporting the proposed demonstration project.

3. A full and comprehensive description of the proposed demonstration project, methodology and design, and a summary of personnel to be employed in carrying out the project.

4. As applicable, include information on the targeted group(s), location of sites, numbers to be served, timelines, and expected outcomes and goals to be achieved.

5. A description of key staff and the names and telephone numbers of persons to be contacted for further information.

D. Rating Criteria for Award

Prospective offeror(s) are advised that the selection of grantee(s) for award is to be made after careful evaluation of proposals by a panel of specialists. Each panelists will evaluate the proposals for acceptability with emphasis on the various factors enumerated below.

Evaluations will be made not only on the basis of what the proposed offeror intends to do during the 12-month grant, but also on the usefulness of the demonstration after the end of the grant period, including possible extensions of the grant. The panel results are advisory in nature and not binding on the Grant Officer.

(1) Knowledge and Understanding of Program Population

Clear evidence of the offeror's knowledge and understanding of migrant and seasonal farmworkers—inclusive of the socio-economic conditions and geographic area of the demonstration project; familiarity with the Department's Section 402 program of the JTPA; and employment and training programs in the proposed geographic area.

This factor rates the offeror's analysis of the needs of migrant and seasonal farmworkers, including socio-economic conditions and the prevailing ethnic culture and mores. Applicant must demonstrate a knowledge of the service area by providing a clear and concise description of the proposed geographic area and the characteristics of the clientele population. (20 points)

2. Capability of Applicant

Documentation of the offeror's capacity to develop a technical approach to accomplish the objectives as enumerated in this SGA in support of the demonstration model selected; furthermore, the proposal should include staffing charts which lists names, qualifications and experiences of key staff and the concomitant amount of time for each to be spent on the project (if those identified are to be less than fulltime). (20 points)

3. Project Design

Documentation of program design; which, if the applicant selects one of the models suggested under Part II, Statement of Work, or proposes a model other than those suggested, should (a) clearly identify the goals to be achieved through the proposed model, along with benchmarks by which the success of the model could be measured; (b) demonstrate a thorough knowledge of the proposed methodology and delineate the manner in which this methodology will be applied; (c) provide rationale and justification for the model as it relates to the geographic location where it will be implemented; and finally (d) provide a rationale that would support the replication of the proposed model in parts of the country (other than where the model is to be implemented), to serve the targeted population. (40 points)

4. Applicant's Experience

A description of the offeror's qualifications in terms of relevant previous experience, facilities and other resources. The offeror should provide descriptions of one or more prior activities and expertise which are relevant to the proposed demonstration model. The offeror must provide the name and telephone number of any relevant reference. (20 points)

Applicants are advised that discussions may be necessary in order to clarify any inconsistencies in their applications. Applications may be rejected where the information required is not provided in sufficient detail to permit adequate assessment of the proposal. The final decision on the award will be based on what is most advantageous to the Federal Government as determined by the ETA Grant Officer. Evaluations by reviewers are advisory only to the Grant Officer.

Part IV. Reporting Requirements

The Grant Recipient shall submit the following reports, at the time and in the number of copies specified to the project officer designated by the grant.

1. Quarterly reports (3 copies). The first such report will be due 90 days after the grant beginning date and subsequent reports will be due quarterly thereafter.

2. Quarterly financial reports as required by the grant award documents. (Standard Form 269., Financial Status Report form).

3. Final report (3 copies). The Grant Recipient shall provide the project officer with a final report summarizing the activities performed under this grant within 30 days of the close of the grant. Should the Government exercise its option for a second one year period, the Grant Recipient is still required to submit the final report (for the first year's effort) thirty (30) days following the renewal of the grant.

Signed at Washington, DC, this 19th day of January, 1994.

James C. DeLuca,

Grant Officer.

BILLING CODE 4510-10-M

INSTRUCTIONS FOR THE SF 424

This is a standard form used by applicants as a required facesheet for preapplications and applications submitted for Federal assistance. It will be used by Federal agencies to obtain applicant certification that States which have established a review and comment procedure in response to Executive Order 12372 and have selected the program to be included in their process, have been given an opportunity to review the applicant's submission.

Item: Entry:

1. Self-explanatory.
2. Date application submitted to Federal agency (or State if applicable) & applicant's control number (if applicable).
3. State use only (if applicable).
4. If this application is to continue or revise an existing award, enter present Federal identifier number. If for a new project, leave blank.
5. Legal name of applicant, name of primary organizational unit which will undertake the assistance activity, complete address of the applicant, and name and telephone number of the person to contact on matters related to this application.
6. Enter Employer Identification Number (EIN) as assigned by the Internal Revenue Service.
7. Enter the appropriate letter in the space provided.
8. Check appropriate box and enter appropriate letter(s) in the space(s) provided:
   - "New" means a new assistance award.
   - "Continuation" means an extension for an additional funding/budget period for a project with a projected completion date.
   - "Revision" means any change in the Federal Government's financial obligation or contingent liability from an existing obligation.
9. Name of Federal agency from which assistance is being requested with this application.
10. Use the Catalog of Federal Domestic Assistance number and title of the program under which assistance is requested.
11. Enter a brief descriptive title of the project. if more than one program is involved, you should append an explanation on a separate sheet. If appropriate (e.g., construction or real property projects), attach a map showing project location. For preapplications, use a separate sheet to provide a summary description of this project.

Item: Entry:

12. List only the largest political entities affected (e.g., State, counties, cities).
13. Self-explanatory.
14. List the applicant's Congressional District and any District(s) affected by the program or project.
15. Amount requested or to be contributed during the first funding/budget period by each contributor. Value of in-kind contributions should be included on appropriate lines as applicable. If the action will result in a dollar change to an existing award, indicate *only* the amount of the change. For decreases, enclose the amounts in parentheses. If both basic and supplemental amounts are included, show breakdown on an attached sheet. For multiple program funding, use totals and show breakdown using same categories as item 15.
16. Applicants should contact the State Single Point of Contact (SPOC) for Federal Executive Order 12372 to determine whether the application is subject to the State intergovernmental review process.
17. This question applies to the applicant organization, not the person who signs as the authorized representative. Categories of debt include delinquent audit disallowances, loans and taxes.
18. To be signed by the authorized representative of the applicant. A copy of the governing body's authorization for you to sign this application as official representative must be on file in the applicant's office. (Certain Federal agencies may require that this authorization be submitted as part of the application.)

OMB Approval No. 0348-0043

APPLICATION FOR FEDERAL ASSISTANCE

2. DATE SUBMITTED	Applicant Identifier
3. DATE RECEIVED BY STATE	State Application Identifier
4. DATE RECEIVED BY FEDERAL AGENCY	Federal Identifier

1. TYPE OF SUBMISSION:

Application	Preapplication
☐ Construction	☐ Construction
☐ Non-Construction	☐ Non-Construction

5. APPLICANT INFORMATION

Legal Name:	Organizational Unit:
Address (give city, county, state, and zip code):	Name and telephone number of the person to be contacted on matters involving this application (give area code)

6. EMPLOYER IDENTIFICATION NUMBER (EIN): ☐☐ – ☐☐☐☐☐☐☐

8. TYPE OF APPLICATION:

☐ New ☐ Continuation ☐ Revision

If Revision, enter appropriate letter(s) in box(es): ☐ ☐

A. Increase Award B. Decrease Award C. Increase Duration

D. Decrease Duration E. Other (specify): _____

7. TYPE OF APPLICANT: (enter appropriate letter in box) ☐

A. State H. Independent School Dist.
B. County I. State Controlled Institution of Higher Learning
C. Municipal J. Private University
D. Township K. Indian Tribe
E. Interstate L. Individual
F. Intermunicipal M. Profit Organization
G. Special District N. Other (Specify): _____

9. NAME OF FEDERAL AGENCY:

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER: ☐☐ – ☐☐☐

TITLE:

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:

12. AREAS AFFECTED BY PROJECT (cities, counties, states, etc.):

13. PROPOSED PROJECT:		14. CONGRESSIONAL DISTRICTS OF:	
Start Date	Ending Date	a. Applicant	b. Project

15. ESTIMATED FUNDING:		
a. Federal	$	.00
b. Applicant	$	.00
c. State	$	.00
d. Local	$	.00
e. Other	$	.00
f. Program Income	$	.00
g. TOTAL	$	.00

16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?

a. YES. THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:

DATE _____

b. NO. ☐ PROGRAM IS NOT COVERED BY E.O. 12372

☐ OR PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

17. IS THE APPLICANT DELINQUENT ON ANY FEDERAL DEBT?

☐ Yes If "Yes," attach an explanation. ☐ No

18. TO THE BEST OF MY KNOWLEDGE AND BELIEF, ALL DATA IN THIS APPLICATION/PREAPPLICATION ARE TRUE AND CORRECT, THE DOCUMENT HAS BEEN DULY AUTHORIZED BY THE GOVERNING BODY OF THE APPLICANT AND THE APPLICANT WILL COMPLY WITH THE ATTACHED ASSURANCES IF THE ASSISTANCE IS AWARDED

a. Typed Name of Authorized Representative	b. Title	c. Telephone number
d. Signature of Authorized Representative		e. Date Signed

Previous Editions Not Usable

Standard Form 424 (REV 4-8)
Prescribed by OMB Circular A-10

BUDGET INFORMATION – Non Construction Programs

Catalog of Federal Domestic Assistance	Estimated Unobligated Funds		New or Revised Budget	
CFDA NUMBER	FEDERAL	NON-FEDERAL	FEDERAL	NON-FEDERAL
1. _____	$_____	$_____	$_____	$_____
2. _____	$_____	$_____	$_____	$_____

COST CATEGORY	FEDERAL FUNDING			NON-FEDERAL CONTRIBUTION		
DIRECT COST	CURRENT FEDERAL BUDGET	REVISIONS AND/OR EXTENSIONS	REVISED FEDERAL BUDGET	CURRENT AWARDEE BUDGET	REVISIONS AND/OR EXTENSIONS	REVISED AWARDEE BUDGET
(A) PERSONNEL						
(B) FRINGE BENEFITS						
(C) TRAVEL & PER DIEM						
(D) EQUIPMENT **						
(E) SUPPLIES						
(F) CONTRACTUAL (Consultants)						
(G) OTHER Staff/Product Devel. Eval/Dissemination						
TOTAL DIRECT COST						
INDIRECT COST						
TOTAL ESTIMATED COST						

** SEE PART IV - SPECIAL CONDITION #9 AUTHORIZED FOR LOCAL REPRODUCTION SF424-A

[FR Doc. 94-1600 Filed 1-27-94; 8:45 am]
BILLING CODE 4510-10-C

Employment Standards Administration

Wage and Hour Division

Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination Decisions

General wage determination decisions of the Secretary of Labor are issued in accordance with applicable law and are based on the information obtained by the Department of Labor from its study of local wage conditions and data made available from other sources. They specify the basic hourly wage rates and fringe benefits which are determined to be prevailing for the described classes of laborers and mechanics employed on construction projects of a similar character and in the localities specified therein.

The determinations in these decisions of prevailing rates and fringe benefits have been made in accordance with 29 CFR part 1, by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR part 1, appendix, as well as such additional statutes as may from time to time be enacted containing provisions for the payment of wages determined to be prevailing by the Secretary of Labor in accordance with the Davis-Bacon Act. The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public comment procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in the effective date as prescribed in that section, because the necessity to issue current construction industry wage determinations frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General wage determination decisions, and modifications and supersedes decisions thereto, contain no expiration dates and are effective from their date of notice in the **Federal Register**, or on the date written notice is received by the agency, whichever is earlier. These decisions are to be used in accordance with the provisions of 29 CFR parts 1 and 5. Accordingly, the applicable decision, together with any modifications issued, must be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR part 5. The wage rates and fringe benefits, notice of which is published herein, and which are contained in the Government Printing Office (GPO) document entitled "General Wage Determinations Issued Under The Davis-Bacon And Related Acts," shall be the minimum paid by contractors and subcontractors to laborers and mechanics.

Any person, organization, or governmental agency having an interest in the rates determined as prevailing is encouraged to submit wage rate and fringe benefit information for consideration by the Department. Further information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Wage and Hours Division, Division of Wage Determinations, 200 Constitution Avenue NW., Room S–3014, Washington, DC 20210.

Modification to General Wage Determination Decisions

The number of decisions listed in the Government Printing Office document entitled "General Wage Determinations Issued Under the Davis-Bacon and Related Acts" being modified are listed by Volume and State. Dates of publication in the **Federal Register** are in parentheses following the decisions being modified.

Volume I:

None.

Volume II:

None.

Volume III:

None.

General Wage Determination Publication

General wage determinations issued under the Davis-Bacon and related Acts, including those noted above, may be found in the Government Printing Office (GPO) document entitled "General Wage Determinations Issued Under The Davis-Bacon and Related Acts". This publication is available at each of the 50 Regional Government Depository Libraries and many of the 1,400 Government Depository Libraries across the country. Subscriptions may be purchased from: Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (202) 783–3238.

When ordering subscription(s), be sure to specify the State(s) of interest, since subscriptions may be ordered for any or all of the three separate volumes, arranged by State. Subscriptions include an annual edition (issued on or about January 1) which includes all current general wage determinations for the States covered by each volume. Throughout the remainder of the year, regular weekly updates will be distributed to subscribers.

Signed at Washington, DC this 28th day of December 1994.

Alan L. Moss,

Director, Division of Wage Determinations.

[FR Doc. 94–1601 Filed 1–27–94; 8:45 am]

BILLING CODE 4510–27–M

Mine Safety and Health Administration

Petitions for Modification

The following parties have filed petitions to modify the application of mandatory safety standards under section 101(c) of the Federal Mine Safety and Health Act of 1977.

1. Martinka Coal Company

[Docket No. M–94–01–C]

Martinka Coal Company, 750 Levels Road, Fairmont, West Virginia 26554, has filed a petition to modify the application of 30 CFR 75.364(b)(2) (weekly examination) to its Tygart River Mine (I.D. No. 46–03805) located in Marion County, West Virginia. Due to hazardous roof conditions, certain areas of the mine cannot be traveled safely. The petitioner proposes to establish evaluation points to monitor for methane and quantity of air in the affected areas. Petitioner asserts that the proposed alternate method would provide at least the same measure of protection as would the mandatory standard.

2. T & T Energy, Inc.

[Docket No. M–94–02–C]

T & T Energy, Inc., P.O. Box 206, Bruceton Mills, West Virginia 26525, has filed a petition to modify the application of 30 CFR 75.380(d)(3) and (4) (escapeways; bituminous and lignite mines) to its Mine No. 1 (I.D. No. 46–01822) located in Preston County, West Virginia. The petitioner proposes to leave the affected area undisturbed, stating that the area has been used for ten years without a problem and that compliance with the standard would result in a diminution of safety. Petitioner asserts that the miners are guaranteed no less than the same

measure of protection as would be provided by the mandatory standard.

3. Peabody Coal Company

[Docket No. M–94–03–C]

Peabody Coal Company, 1951 Barrett Court, P.O. Box 1990, Henderson, Kentucky 42420–1990, has filed a petition to modify the application of 30 CFR 75.364(b)(4) (weekly examination) to its Camp No. 1 Mine (I.D. No. 15–02709) located in Union County, Kentucky. Due to hazardous roof conditions, certain areas of the mine cannot be traveled safely. The petitioner proposes to monitor for methane and quantity of air in the affected areas and asserts that this proposed alternative would provide at least the same measure of protection as would the mandatory standard.

4. Consolidation Coal Company

[Docket No. M–94–04–C]

Consolidation Coal Company, Consol Plaza, 1800 Washington Road, Pittsburgh, Pennsylvania 15241–1421, has filed a petition to modify the application of 30 CFR 75.364(c)(2) (weekly examination) to its Osage No. 3 Mine (I.D. No. 46–01455) located in Monogalia County, West Virginia. Due to deteriorated conditions, certain areas of the mine cannot be traveled safely. The petitioner proposes to establish evaluation points to monitor for methane and quantity of air in the affected areas. The petitioner asserts that the proposed alternate method would provide at least the same measure of protection as would the mandatory standard.

5. Trent Coal, Inc.

[Docket No. M–94–05–C]

Trent Coal, Inc., 600 Grant Street, Pittsburgh, Pennsylvania 15219, has filed a petition to modify the application of 30 CFR 75.380(f) (escapeways; bituminous and lignite mines) to its Rice No. 2 Mine (I.D. No. 36–03636) located in Cambria County, Pennsylvania. Due to the size of the electric golf carts used in the primary escapeway and the relative size of fire suppression systems, these golf carts would not be able to operate satisfactorily with such a system. The petitioner proposes to construct the golf carts of fire-resistant material, protect the battery/motor circuit by a fuse, perform all battery charging on the surface, and provide all golf carts with a multipurpose dry chemical fire extinguisher. Petitioner asserts that the proposed alternate method would provide at least the same measure of protection as would the mandatory standard.

6. Eldorado Chemical Co.

[Docket No. M–94–01–M]

Eldorado Chemical Company, P.O. Box 419082, St. Louis, Missouri 63141–1782, has filed a petition to modify the application of 30 CFR 56.6309 (fuel oil requirements for ANFO) to its Martiki Mine (I.D. No. 15–07295) located in Marion County, Kentucky. The petitioner proposes to implement a "recycled used oil/ANFO mixture operation" at the mine site and states that the product would parallel that of a conventional Ammonium Nitrate/No. 2 diesel fuel conventional ANFO blasting agent product.

7. San Juan Asphalt

[Docket No. M–94–02–M]

San Juan Asphalt, P.O. Box 490, Goshen, California 93227, has filed a petition to modify the application of 30 CFR 56.14107(a) (moving machine parts) to its Asphalt Mine (I.D. No. 04–04896) located in San Benito County, California. The petitioner states that it is impossible to provide the guard required by the standard due to pinch points and a heavily congested area in a confined space. Petitioner proposes to prohibit entry of miners while plant is energized by installing a heavy door with a lock.

8. Moline Consumers Company

[Docket No. M–94–03–M]

Moline Consumers Company, 1701 Fifth Avenue, Moline, Illinois 61265 has filed a petition to modify the application of 30 CFR 56.14107 (moving machine parts) to its Midway Stone No. 45 mine (I.D. No. 11–00134) located in Rock Island County, Illinois. The petitioner proposes to prohibit entry of employees while equipment is operating by enclosing equipment within a 6-foot fence with a padlocked gate, the gate to be equipped with an electrical interlock wired directly to the motor control circuit which de-energizes the motor if the gate is opened. Petitioner states that this method of guarding will afford the miners at least the same level of safety as would the guarding required by the standard.

9. Magma Copper Company

[Docket No. M–94–04–M]

Magma Copper Company, 7400 North Oracle Road, Suite 200, Tucson, Arizona 85704, has filed a petition to modify the application of 30 CFR 57.9360(a) (shelter holes) to its San Manuel Mine (I.D. No. 02–00151) located in Pinal County, Arizona. The petitioner proposes two alternative sets of stipulations. The first set of stipulations would use pony set shelter holes located 10 feet above the panel floor as designated "shelter holes" in all haulage panels at intervals of approximately 35 feet regardless of clearance; to provide training to all crews working on haulage on the use of the pony sets when trains are in the panel; to include new procedures and policies for haulage levels in its new policy manual; to post signs throughout the haulage panels directing crews to use the pony sets as shelter holes when trains are moving in the panel; and to keep train speeds in the haulageways at less than 5 mph to allow ample time to access the pony set shelter holes. Also, petitioner proposes a second alternative set of stipulations to use certain existing manway shelter holes as designated shelter holes in all haulage panels; to train all crews working on haulage; and to include new procedures and policies in its policy manual. The petitioner states that application of the mandatory standard would result in a diminution of safety to the miners. In addition, the petitioner asserts that either of the proposed alternative methods would provide at least the same measure of protection as would the mandatory standard.

Request for Comments

Persons interested in these petitions may furnish written comments. These comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, room 627, 4015 Wilson Boulevard, Arlington, Virginia 22203. All comments must be postmarked or received in that office on or before February 28, 1994. Copies of these petitions are available for inspection at that address.

Dated: January 21, 1994.

Patricia W. Silvey,

Director, Office of Standards, Regulations and Variances.

[FR Doc. 94–1912 Filed 1–27–94; 8:45 am]

BILLING CODE 4510–43–P

Pension and Welfare Benefits Administration

Prohibited Transaction Exemption 94–8; Exemption Application No. D–9093, et al.]

Grant of Individual Exemptions

AGENCY: Pension and Welfare Benefits Administration, Labor.

ACTION: Grant of individual exemptions.

SUMMARY: This document contains exemptions issued by the Department of Labor (the Department) from certain of

the prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974 (the Act) and/or the Internal Revenue Code of 1986 (the Code).

Notices were published in the **Federal Register** of the pendency before the Department of proposals to grant such exemptions. The notices set forth a summary of facts and representations contained in each application for exemption and referred interested persons to the respective applications for a complete statement of the facts and representations. The applications have been available for public inspection at the Department in Washington, DC. The notices also invited interested persons to submit comments on the requested exemptions to the Department. In addition the notices stated that any interested person might submit a written request that a public hearing be held (where appropriate). The applicants have represented that they have complied with the requirements of the notification to interested persons. No public comments and no requests for a hearing, unless otherwise stated, were received by the Department.

The notices of proposed exemption were issued and the exemptions are being granted solely by the Department because, effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred the authority of the Secretary of the Treasury to issue exemptions of the type proposed to the Secretary of Labor.

Statutory Findings

In accordance with section 408(a) of the Act and/or section 4975(c)(2) of the Code and the procedures set forth in 29 CFR part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990) and based upon the entire record, the Department makes the following findings:

(a) The exemptions are administratively feasible;

(b) They are in the interests of the plans and their participants and beneficiaries; and

(c) They are protective of the rights of the participants and beneficiaries of the plans.

Frederick J. Grant, M.D., A.P.C. Profit Sharing Plan (the Plan) Located in San Luis Obispo, California

[Prohibited Transaction Exemption 94–8; Exemption Application No. D–9093]

Exemption

The restrictions of sections 406(a) and 406(b)(1) and (2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code, shall not apply to the sale of an interest in certain improved real property (the Property) from the individually directed account in the Plan of Frederick J. Grant, M.D. (Grant), a party in interest with respect to the Plan, to Grant, provided that the following conditions are met:

1. The terms of the sale are at least as favorable as those the Plan could obtain in an arm's-length transaction with an unrelated party;

2. The sale will involve only Grant's individual account in the Plan;

3. The fair market value of the Property (and as a result the Plan's equity in the Property) will be established by an independent real estate appraiser;

4. The Plan will receive no less than the greater of its share of the fair market value of the Property (minus the pro rata portion of the encumbrance) or the total amount the Plan has expended in relation to the Property as of the date of sale; and

5. The Plan will receive all cash in regard to the transaction.

For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption, refer to the notice of proposed exemption published on December 17, 1993, at 58 FR 66033.

FOR FURTHER INFORMATION CONTACT: Paul Kelty of the Department, telephone (202) 219–8883. (This is not a toll-free number.)

Retirement Plan for Employees of Holsum Bakery, Inc. (the Plan) Located in Phoenix, Arizona

[Prohibited Transaction Exemption 94–9; Exemption Application No. D–9457]

Exemption

The restrictions of sections 406(a), 406(b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code, shall not apply to the sale (the Sale) by the Plan of certain improved real property (the Property) to Holsum Bakery, Inc. (the Employer), a party in interest with respect to the Plan.

This exemption is conditioned upon the following requirements: (1) The Sale is a one-time cash transaction; (2) the Plan is not required to pay any commissions, costs or other expenses in connection with this transaction; (3) the Property is appraised by qualified, independent appraisers; (4) the sales price for the Property is the greater of either: (a) $250,000, representing the original amount paid by the Plan at the time of acquisition; or (b) its fair market value on the date of the Sale; (5) an independent, qualified fiduciary, who has made an initial determination that the proposed sale is appropriate for the Plan, monitors its terms for the Plan; and (6) within ninety days of the publication in the **Federal Register** of the grant of this exemption, the Employer files Forms 5330 with the Internal Revenue Service (the Service) and pays all applicable additional excise taxes that are due by reason of the prohibited lease transactions.

For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption, refer to the notice of proposed exemption published on December 10, 1993 at 58 FR 64982.

FOR FURTHER INFORMATION CONTACT: Kathryn Parr of the Department, telephone (202) 219–8971. (This is not a toll-free number.)

Couch Distributing Company Amended and Restated Money Purchase Pension Plan (the Plan) Located in Watsonville, CA

[Prohibited Transaction Exemption 94–10; Exemption Application No. D–9482]

Exemption

The restrictions of sections 406(a), 406(b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code, shall not apply to the proposed sale by the Plan of a judgment (the Judgment), to Mr. George W. Couch, III, a party in interest with respect to the Plan, provided: (1) The sale is a one-time transaction for cash; (2) the Plan is not required to pay any fees or commissions in connection therewith; (3) Mr. Couch purchases the Judgment for its outstanding principal amount and pays any past due interest as well as additional interest accruing at the statutory rate on the Judgment to the date of the purchase; (4) the Plan receives a complete return of its investment; (5) any additional consideration that Mr. Couch receives pursuant to the Judgment which is in excess of the purchase price is applied to litigation expenses and the balance paid to the Plan; (6) an independent fiduciary determines that the transaction is appropriate for the Plan and in the best interest of its participants and beneficiaries.

For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption, refer to the notice of proposed exemption published on December 3, 1993 at 58 FR 64012.

FOR FURTHER INFORMATION CONTACT: Ms. Jan D. Broady of the Department,

telephone (202) 219–8881. (This is not a toll-free number.)

W.J. Casey Trucking & Rigging Co., Inc. Employees Profit Sharing Plan and Trust (the Plan) Located in Union, New Jersey

[Prohibited Transaction Exemption 94–11 ; Exemption Application No. D–9506]

Exemption

The restrictions of sections 406(a), 406(b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code, shall not apply to: (1) The seven-year loan of $300,000 (the Loan) by the Plan to W. J. Casey Trucking & Rigging Co., Inc. (the Employer), a party in interest with respect to the Plan; and (2) the personal guarantees of the Employer's obligations under the Loan by James P. and Nicholas J. Biondi (the Biondis), parties in interest with respect to the Plan.

This exemption is conditioned upon the following requirements: (a) All terms and conditions of the Loan are at least as favorable to the Plan as those obtainable in an arm's-length transaction with an unrelated party; (b) the Loan will not exceed twenty-five percent of the Plan's assets at any time during the transaction; (c) the Loan is secured by a first lien interest on certain equipment (the Equipment), which has been appraised by a qualified, independent appraiser to ensure that the fair market value of the Equipment is at least 200 percent of the amount of the Loan; (d) the Employer's obligations under the Loan are personally guaranteed by the Biondis; (e) the fair market value of the Equipment remains not less than 200 percent of the outstanding balance of the Loan throughout the duration of the Loan; (f) an independent, qualified fiduciary determines on behalf of the Plan that the Loan is administratively feasible, in the best interests of the Plan, and protective of the Plan and its participants and beneficiaries; and (g) the independent, qualified fiduciary monitors compliance with the terms and conditions of the exemption and the Loan throughout the duration of the transaction, taking any action necessary to safeguard the Plan's interest, including foreclosure on the Equipment in the event of default.

For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption, refer to the notice of proposed exemption published on December 10, 1993 at 58 FR 64983.

FOR FURTHER INFORMATION CONTACT: Kathryn Parr of the Department, telephone (202) 219–8971. (This is not a toll-free number.)

Schwebke-Shiskin & Associates, Inc. Profit Sharing Plan and Trust (the Plan) Located in Miramar, Florida

[Prohibited Transaction Exemption 94–12; Exemption Application No. D–9520]

Exemption

The restrictions of sections 406(a), 406(b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code, shall not apply to the proposed sale by the Plan to Schwebke-Shiskin & Associates, Inc. (SSA), the Plan's sponsor and a party in interest with respect to the Plan, of certain real property (the Property), for cash, provided the following conditions are satisfied: (a) The Plan pays no fees or commissions in connection with the transaction; (b) the sales price of the Property will be the greater of $1,068,000 or the fair market value of the Property on the date of the sale as determined by a qualified, independent appraiser; (c) SSA will pay to the Internal Revenue Service in timely fashion all excise taxes due in connection with the past leasing of the Property by the Plan to SSA; and (d) to the extent that the Plan received less than fair market rental value from SSA in connection with the past leasing of the Property, SSA will make the Plan whole, with appropriate interest, for any such shortfall, within 60 days of the granting of this exemption.

For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption, refer to the notice of proposed exemption published on December 3, 1993 at 58 FR 64015.

FOR FURTHER INFORMATION CONTACT: Gary H. Lefkowitz of the Department, telephone (202) 219–8881. (This is not a toll-free number.)

NCR Corporation Savings Plan (the Plan) Located in Dayton, Ohio

[Prohibited Transaction Exemption 94–13; Exemption Application No. D–9536]

Exemption

The restrictions of sections 406(a), 406(b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) of through (E) of the Code, shall not apply to (1) An interest-free loan to the Plan (the Loan) by NCR Corporation, the sponsor of the Plan, with respect to guaranteed investment contract number GA–GIC–01226 (the GIC) issued by Executive Life Insurance Company of California (Executive Life); and (2) the Plan's potential repayment of the Loan (the Repayment); provided that the following conditions are satisfied:

(A) No interest and/or expenses are paid by the Plan;

(B) The Loan is made to reimburse the Plan for amounts invested with Executive Life under the terms of the GIC;

(C) The Repayment is restricted to cash proceeds paid to the Plan (the GIC Proceeds) by Executive Life and/or any other responsible third party with respect to the GIC, and no other Plan assets are used to make the Repayments; and

(D) The Repayments will be waived to the extent the Loan exceeds the GIC Proceeds.

For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption, refer to the notice of proposed exemption published on November 24, 1993 at 58 FR 62144.

FOR FURTHER INFORMATION CONTACT: Ronald Willett of the Department, telephone (202) 219–8881. (This is not a toll-free number.)

Randall W. Smith, M.D., A.P.C., Defined Benefit Pension Plan (the Plan), Located in San Diego, California

[Prohibited Transaction Exemption 94–14; Exemption Application No. D–9547]

Exemption

The sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code, shall not apply to the cash sale (the Sale) of certain real property (the Property) by the Plan to Randall W. Smith, M.D. and Florence E Smith, husband and wife and disqualified persons with respect to the Plan, provided that the consideration paid for the Property is no less than the fair market value of the Property on the date of the Sale as determined by a qualified, independent appraiser.

For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption refer to the notice of proposed exemption published on December 17, 1993, at 58 FR 66036.

FOR FURTHER INFORMATION CONTACT: Mr. C. E. Beaver of the Department, telephone (202) 219–8881. (This is not a toll-free number.)

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under section 408(a) of the Act and/or section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person from certain other

provisions to which the exemptions does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(B) of the Act; nor does it affect the requirement of section 401(a) of the Code that the plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries;

(2) These exemptions are supplemental to and not in derogation of, any other provisions of the Act and/or the Code, including statutory or administrative exemptions and transactional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction; and

(3) The availability of these exemptions is subject to the express condition that the material facts and representations contained in each application are true and complete and accurately describe all material terms of the transaction which is the subject of the exemption. In the case of continuing exemption transactions, if any of the material facts or representations described in the application change after the exemption is granted, the exemption will cease to apply as of the date of such change. In the event of any such change, application for a new exemption may be made to the Department.

Signed at Washington, DC, this 25th day of January, 1994.

Ivan Strasfeld,

Director of Exemption Determinations, Pension and Welfare Benefits Administration, U.S. Department of Labor.

[FR Doc. 94–1952 Filed 1–27–94; 8:45 am]

BILLING CODE 4510–29–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Arts in Education Advisory Panel; Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), as amended, notice hereby given that a meeting of the Arts in Education Advisory Panel (Special Projects Grants Section) to the National Council on the Arts will be held on February 15, 1994, from 1 p.m. to 4 p.m. This meeting will be held in room M–07, at the Navy Hanks Center, 1100 Pennsylvania Avenue NW., Washington, DC 20506.

Portions of this meeting will be open to the public, from 1 p.m. to 1:30 p.m. for welcome and introductions and from 3:30 p.m. to 4 p.m. for a policy discussion.

The remaining portion of this meeting, from 1:30 p.m. to 3:30 p.m. is for the purpose of panel review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman of November 24, 1992, this session will be closed to the public pursuant to subsection (a)(4), (6)(B) of section 552b of title 5, United States Code.

Any person may observe meetings, or portions thereof, of advisory panels which are open to the public, and may be permitted to participate in the panel's discussions at the discretion of the panel chairman and with the approval of the full-time Federal employee in attendance.

If you need special accommodations due to disability, please contact the Office of Special Constituencies, National Endowment for the Arts, 1100 Pennsylvania Avenue NW., Washington, DC 20506, 202/682–5532, TYY 202/682–5496, at least seven (7) days prior to the meeting.

Further information with reference to this meeting can be obtained from Ms. Yvonne Sabine, Committee Management Officer, National Endowment for the Arts, Washington, DC 20506, or call 202/682–5439.

Dated: January 24, 1994.

Yvonne M. Sabine,

Offfice of Panel Operation, National Endowment for the Arts.

[FR Doc. 94–1849 Filed 1–27–94; 8:45 am]

BILLING CODE 7537–01–M

Arts in Education Advisory Panel; Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (pub. L. 92–463), as amended, notice is hereby given that a meeting of the Arts in Education Advisory Panel (Partnership Grants Section) to the National Council on the Arts will be held on February 16–18, 1994. The panel will meet from 9 a.m. to 6 p.m. on Friday 16–17, 1994 and from 9 a.m. to 4 p.m. on February 18, 1994. This meeting will be held in Room M–07, at the Nancy Hanks Center, 1100 Pennsylvania Avenue NW., Washington, DC 20506.

Portions of the meeting will be open to the public on February 16, 1994, from 9 a.m. to 2 a.m. for welcome, introductions, and a panelist orientation, and on February 18, 1994 from 2:20 p.m. to 4 p.m. for a guideline and policy discussion.

The remaining portions of this meeting on February 16, 1994 from 2 p.m. to 6 p.m.; from 9 a.m. to 6 p.m. on February 17, 1994; and, from 9 a.m. to 2:30 p.m. on February 18, 1994 are for the purpose of panel review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and Humanities Act of 1965, as amended, including information given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman of November 24, 1992, these sessions will be closed to the public pursuant to subsection (c)(4), (6)(B) of section 552b of Title 5, United States Code.

Any person may observe meetings, or portions thereof, of advisory panels which are open to the public, and may be permitted to participate in the panel's discussions at the discretion of the panel chairman and with the approval of the full-time Federal employee in attendance.

If you need special accommodations due to a disability, please contact the Office of Special Constituencies, National Endowment for the Arts, 1100 Pennsylvania Avenue NW., Washington, DC 20506, 202/682–5532, TYY 202/682–5496, at least seven (7) days prior to the meeting.

Further information with reference to this meeting can be obtained from Ms. Yvonne Sabine, Committee Management Officer, National Endowment for the Arts, Washington, DC 20506, or call 202/682–5439.

Dated: January 24, 1994.

Yvonne M. Sabine,

Director, Office of Panel Operation, National Endowment for the Arts.

[FR Doc. 94–1854 Filed 1–27–94; 8:45 am]

BILLING CODE 7537–01–M

Challenge and Advancement Advisory Panel; Meeting

Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), as amended, notice is hereby given that a meeting of the Challenge and Advancement Advisory Panel (Advancement Phase I Dance Section) to the National Council on the Arts will be held on February 14, 1994 from 9:30 a.m. to 5:30 p.m. This meeting

will be held in room M–07, at the Nancy Hanks Center, 1100 Pennsylvania Avenue NW., Washington, DC 20506.

A portion of this meeting will be open to the public from 9:30 a.m. to 10:15 a.m. for introductions and a brief Advancement Overview, and from 4:30 p.m. to 5:30 p.m. for a Policy Discussion.

The remaining portion of this meeting from 10:15 a.m. to 4:30 p.m. is for the purpose of Panel review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman of November 24, 1992, this session will be closed to the public pursuant to subsection (c)(4), (6) and (9)(B) of section 552b of title 5, United States Code.

Any person may observe meetings, or portions thereof, of advisory panels which are open to the public, and may be permitted to participate in the panel's discussions at the discretion of the panel chairman and with the approval of the full-time Federal employee in attendance.

If you need special accommodations due to a disability, please contact the Office of Special Constituencies, National Endowment for the Arts, 1100 Pennsylvania Avenue NW., Washington, DC 20506, 202/682–5532, TYY 202/682–5496, at least seven (7) days prior to the meeting.

Further information with reference to this meeting can be obtained from Ms. Yvonne Sabine, Committee Management Officer, National Endowment for the Arts, Washington, DC 20506, or call 202/682–5439.

Dated: January 24, 1994.

Yvonne M. Sabine,

Director, Office of Panel Operation, National Endowment for the Arts.

[FR Doc. 94–1850 Filed 1–27–94; 8:45 am]

BILLING CODE 7537–01–M

Challenge and Advancement Advisory Panel; Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), as amended, notice is hereby given that a meeting of the Challenge and Advancement Advisory Panel (Advancement Phase I Visual Arts Section) to the National Council on the Arts will be held on February 10–11, 1994. The panel will meet from 9:30 a.m. to 5:30 p.m. on February 10, 1994 and from 9:30 a.m. to 4 p.m. on February 11, 1994. This meeting will be held in room 730, at the Nancy Hanks Center, 1100 Pennsylvania Avenue NW., Washington, DC 20506.

Portions of this meeting will be open to the public from 9:30 a.m. to 10:30 a.m. on February 10, 1994 for welcome and orientation, and from 2 p.m. to 4 p.m. on February 11, 1994 for a policy discussion.

The remaining portions of this meeting from 10:30 a.m. to 5:30 p.m. on February 10, 1994 and from 9:30 a.m. to 2 p.m. are for the purpose of Panel review, discussion, evaluation, and recommendation on applicants for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman of November 24, 1992, these sessions will be closed to the public pursuant to subsection (c)(4), (6) and (9)(B) of section 552b of title 5, United States Code.

Any person may observe meetings, or portions thereof, of advisory panels which are open to the public, and may be permitted to participate in the panel's discussions at the discretion of the panel chairman and with the approval of the full-time Federal employee in attendance.

If you need special accommodations due to a disability, please contact the Office of Special Constituencies, National Endowment for the Arts, 1100 Pennsylvania Avenue NW., Washington, DC 20506, 202/682–5532, TYY 202/682–5496, at least seven (7) days prior to the meeting.

Further information with reference to this meeting can be obtained from Ms. Yvonne Sabine, Committee Management Officer, National Endowment for the Arts, Washington, DC 20506, or call 202/682–5439.

Dated: January 24, 1994.

Yvonne M. Sabine,

Director, Office of Panel Operation, National Endowment for the Arts.

[FR Doc. 94–1851 Filed 1–27–94; 8:45 am]

BILLING CODE 7537–01–M

Expansion Arts Advisory Panel; Meeting

Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), as amended, notice is hereby given that a meeting of the Expansion Arts Advisory Panel (Theater Section) to the National Council on the Arts will be held on February 15–18, 1994. The panel will meet from 9 a.m. to 6 p.m. on February 15–17, 1994 and from 9 a.m. to 4:30 p.m. on February 18, 1994. This meeting will be held in room 730, at the Nancy Hanks Center, 1100 Pennsylvania Avenue NW., Washington, DC 20506.

Portions of this meeting will be open to the public from 9:15 a.m. to 10:30 a.m., on February 15, 1994 for Opening Remarks and a General Overview and from 3 p.m. to 4:30 p.m. on February 18, 1994 for a Policy Discussion.

The remaining portions of this meeting from 10:30 a.m. to 6 p.m. on February 15, 1994; 9 a.m. to 6 p.m. on February 16–17, 1994; and from 9 a.m. to 3 p.m. on February 18, 1994 are for the purpose of Panel review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman of November 24, 1992, these sessions will be closed to the public pursuant to subsection (c)(4), (6) and (9)(B) of section 552b of Title 5, United States Code.

Any person may observe meetings, or portions thereof, of advisory panels which are open to the public, and may be permitted to participate in the panel's discussions at the discretion of the panel chairman and with the approval of the full-time Federal employee in attendance.

If you need special accommodations due to a disability, please contact the Office of Special Constituencies, National Endowment for the Arts, 1100 Pennsylvania Avenue NW., Washington, DC 20506, 202/682–5532, TYY 202/682–5496, at least seven (7) days prior to the meeting.

Further information with reference to this meeting can be obtained from Ms. Yvonne Sabine, Committee Management Officer, National Endowment for the Arts, Washington, DC 20506, or call 202/682–5439.

Dated: January 24, 1994.

Yvonne M. Sabine,

Director, Office of Panel Operations, National Endowment for the Arts.

[FR Doc. 94–1855 Filed 1–27–94; 8:45 am]

BILLING CODE 7537–01–M

Literature Advisory Panel; Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), as amended, notice is hereby given that meeting of the Literature Advisory Panel (Audience Development Section) to the National

Council on the Arts will be held on February 16–17, 1994. The panel will meet from 9 a.m. to 5:30 p.m. on February 16–17, 1994 and from 9 a.m. to 5 p.m. on February 18, 1994. This meeting will be held in room 714, at the Nancy Hanks Center, 1100 Pennsylvania Avenue, N.W., Washington, DC 20506.

A portion of this meeting will be open to the public from 1:45 p.m. to 5 p.m. on February 18, 1994 for a guideline review and policy discussion.

The remaining portions of this meeting from 9 a.m. to 5:30 p.m. on February 16–17, 1994 and 9 a.m. to 1:45 p.m. on February 18, 1994 are for the purpose of Panel review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman of November 24, 1992, these sessions will be closed to the public pursuant to subsection (c)(4),(6) and (9)(B) of section 552b of title 5, United States Code.

Any person may observe meetings, or portions thereof, of advisory panels which are open to the public, and may be permitted to participate in the panel's discussions at the discretion of the panel chairman and with the approval of the full-time Federal employee in attendance.

If you need special accommodations due to a disability, please contact the Office of Special Constituencies, National Endowment of the Arts, 1100 Pennsylvania Avenue, NW., Washington, DC 20506, 202/682–5532, TYY 202/682–5496, at least seven (7) days prior to the meeting.

Further information with reference to this meeting can be obtained from Ms. Yvonne Sabine, Committee Management Officer, National Endowment for the Arts, Washington, DC 20506, or call 202/682–5439.

Dated: January 24, 1994.

Yvonne M. Sabine,

Director, Office of Panel Operation, National Endowment for the Arts.

[FR Doc. 94–1848 Filed 1–27–94; 8:45 am]

BILLING CODE 7537–01–M

Media Arts Advisory Panel; Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), as amended, notice hereby given that a meeting of the Media Arts Advisory Panel (Film Video Production Narrative Prescreening Section) to the National Council on the Arts will be held on February 9–10, 1994. The panel will meet from 9 a.m. to 6:30 p.m. on February 9, 1994 and from 9 a.m. to 5:30 p.m. on February 10, 1994. This meeting will be held in room 716, at the Nancy Hanks Center, 1100 Pennsylvania Avenue NW., Washington, DC 20506.

This meeting is for the purpose of application evaluation, under the National Foundation on the Arts and the Humanities Act of 1965, as amended including discussion of information given in confidence to the Agency by grant applicants. In accordance with the determination of the Chairman of November 24, 1992, these sessions will be closed to the public pursuant to subsections(c)(4), (6)(B) of section 552b of Title 5, United States Code.

Further information with reference to this meeting can be obtained from Ms. Yvonne Sabine, Advisory Committee Management Office, National Endowment for the Arts, Washington, DC 20506, or call (202) 682–5439.

Dated: January 10, 1994.

Yvonne M. Sabine,

Director, Panel Operations, National Endowment for the Arts.

[FR Doc. 94–1856 Filed 1–27–94; 8:45 am]

BILLING CODE 7537–01–M

National Council on the Arts

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), as amended, notice is hereby given that a meeting of the Literature Program's Field Study Working Group to the National Council on the Arts will be held on February 11, 1994 from 10 a.m. to 4 p.m. This meeting will be held in room 714, at the Nancy Hanks Center, 1100 Pennsylvania Avenue NW., Washington, DC 20506.

This meeting will be open to the public on a space available basis. The group will discuss the details and a preliminary draft of the literature field overview study.

Any interested person may observe meetings or portions thereof, which are open to the public, and may be permitted to participate in the discussions at the discretion of the meeting chairman and with the approval of the full-time Federal employee in attendance.

If you need special accommodations due to a disability, please contact the Office of Special Constituencies, National Endowment for the Arts, 1100 Pennsylvania Avenue NW., Washington, DC 20506, 202/682–5532, TYY 202/682–5496, at least seven (7) days prior to the meeting.

Further information with reference to this meeting can be obtained from Ms. Yvonne M. Sabine, Committee Management Officer, National Endowment for the Arts, Washington, DC 20506, or call 202/682–5439.

Dated: January 24, 1994.

Yvonne M. Sabine,

Director, Office of Panel Operations, National Endowment for the Arts.

[FR Doc. 94–1852 Filed 1–27–94; 8:45 am]

BILLING CODE 7537–01–M

National Council on the Arts; Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), as amended, notice is hereby given that a meeting of the National Council on the Arts will be held on February 4–5, 1994. The Council will meet from 9 a.m. to 6:15 p.m. on February 4, 1994 and from 8:30 a.m. to 1:15 p.m. on February 5, 1994, in room M–09 at the Nancy Hanks Center, 1100 Pennsylvania Avenue NW., Washington, DC 20506.

This meeting will be open to the public. Topics for discussion will include opening remarks, Legislative Update, reports from the Council members on their activities, Report on the President's Committee on the Arts and Humanities, Update on the National Arts Education Information Network future agenda items, Budget and Program Reviews and/or Guidelines for the Music, Folk Arts, Opera-Musical Theater, Local Arts Agencies, State and Regional, Arts Administration Fellows, and Visual Arts Programs, as well as application review.

If, in the course of application discussion review, it becomes necessary for the Council to discuss non-public commercial or financial information of intrinsic value, the Council will go into closed session pursuant to subsection 9(c)(4) of the Government in the Sunshine Act, 5 U.S.C. 552b. Additionally, discussion concerning purely personal information about individuals, submitted with grant applications, such as personal biographical and salary data or medical information, may be conducted by the Council in closed session in accordance with subsection (c)(6) of 5 U.S.C. 552b.

Any interested persons may attend, as observers, Council discussions and reviews which are open to the public.

If you need special accommodations due to a disability, please contact the Office of Special Constituencies, National Endowment for the Arts, 1100 Pennsylvania Avenue NW., Washington, DC 20506, 202/682/5532, TYY 202/682–5496, at least seven (7) days prior to the meeting.

Further information with reference to this meeting can be obtained from Ms.

Karen Murphy, Office of Public Affairs, National Endowment for the Arts, Washington, DC 20506, at 202/682/5570.

Dated: January 24, 1994.

Yvonne M. Sabine,

Director, Office of Panel Operations, National Endowment for the Arts.

[FR Doc. 94–1853 Filed 1–27–94; 8:45 am]

BILLING CODE 7537–01–M

NATIONAL SCIENCE FOUNDATION

DOE/USGS/NSF Council for Continental Scientific Drilling; Meeting

In accordance with the Federal Advisory Committee Act (Public Law 92–463, as amended), the National Science Foundation announces the following meeting.

Name: Council for Continental Scientific Drilling.

Date and time: February 9 & 10, 1994; 8 a.m. to 6 p.m. each day.

Place: Room 360; National Science Foundation; 4201 Wilson Boulevard; Arlington, VA 22230.

Type of meeting: Open to the public. Persons may participate in the meeting as time and space permit.

Contact: Dr. James F. Hays, Division Director, Division of Earth Sciences, room 785, National Science Foundation, Arlington, VA 22230 (703) 306–1550; and Donald W. Klick, ICG/CSD Executive Secretary, 922 National Center, U.S. Geological Survey, Reston, VA 22092, (703) 648–6346.

Minutes: May be obtained from the Contact Person(s) listed above.

Agenda: Briefings on accomplishments, current activities, and future plans of the DOE, NSF, and USGS CSD programs; discussions of recommendations for organizational structure, procedures, schedule, and related matters for the U.S. CSDP overview by the Council for CSD.

Dated: January 24, 1994.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 94–1834 Filed 1–27–94; 8:45 am]

BILLING CODE 7555–01–M

Committee of Visitors of the Advisory Committee for Geosciences; Meeting

In accordance with the Federal Advisory Committee (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting.

Name: Advisory Committee for Geosciences.

Date and time: February 16–18, 1994; 9 a.m. to 5 p.m.

Place: February 16, 1994, room 390, NSF, 4201 Wilson Blvd, Arlington, VA February 17–18, 1994, room 330, NSF, 4201 Wilson Blvd, Arlington, VA.

Type of meeting: Closed.

Purpose of meeting: To carry out Committee of Visitors (COV) review, including examination of decisions on proposals, reviewer comments, and other privileged materials.

Agenda: To provide oversight review of the three facilities programs in the Oceanographic Centers and Facilities Section. The programs are Ship Operations, Shipboard Science Support Equipment, and Instrumentation and Technical Services.

Reason for closing: The meeting is closed to the public because the Committee is reviewing proposal actions that will include privileged intellectual property and personal information that could harm individuals if they were disclosed. If discussions were open to the public, these matters that are exempt under 5 U.S.C. 552b(c) (4) and (6) of the Government in the Sunshine Act would be improperly disclosed.

Dated: January 24, 1994.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 94–1833 Filed 1–27–94; 8:45 am]

BILLING CODE 7555–01–M

Agency Relocation

ACTION: Notice.

This announcement is to communicate the new location of the National Science Foundation (NSF). NSF has completed an agency-wide relocation to offices in Arlington, VA. All activities previously located in the District of Columbia are in the new facility. The new address is as follows: National Science Foundation, 4201 Wilson Blvd., Arlington, VA, 22230.

EFFECTIVE DATE: January 24, 1994.

FOR FURTHER INFORMATION CONTACT: NSF Information Center at 703–306–1234.

Dated: January 24, 1994.

Joseph F. Burt,

Relocation Project Manager.

[FR Doc. 94–1832 Filed 1–27–94; 8:45 am]

BILLING CODE 7555–01–M

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards; Subcommittee Meeting on Planning and Procedures

The ACRS Subcommittee on Planning and Procedures will hold a meeting on Wednesday, February 9, 1994, room P–422, 7920 Norfolk Avenue, Bethesda, MD.

The entire meeting will be open to public attendance, with the exception of a portion that may be closed pursuant to 5 U.S.C. 552b(c) (2) and (6) to discuss organizational and personnel matters that relate solely to internal personnel rules and practices of ACRS, and matters the release of which would represent a clearly unwarranted invasion of personal privacy.

The agenda for the subject meeting shall be as follows:

Wednesday, February 9, 1994—2 p.m. Until 4:30 p.m.

The Subcommittee will discuss proposed ACRS activities, practices and procedures for conducting the Committee business, and organizational and personnel matters relating to ACRS and its staff. The Committee will also discuss qualifications of candidates nominated for appointment to the ACRS. The purpose of this meeting is to gather information, analyze relevant issues and facts, and to formulate proposed positions and actions, as appropriate, for deliberation by the full Committee.

Oral statements may be presented by members of the public with the concurrence of the Subcommittee Chairman; written statements will be accepted and made available to the Committee. Electronic recordings will be permitted only during those portions of the meeting that are open to the public, and questions may be asked only by members of the Subcommittee, its consultants, and staff. Persons desiring to make oral statements should notify the ACRS staff member named below as far in advance as practicable so that appropriate arrangements can be made.

Further information regarding topics to be discussed, the scheduling of sessions open to the public, whether the meeting has been cancelled or rescheduled, the Chairman's ruling on requests for the opportunity to present oral statements, and the time allotted therefor can be obtained by contacting the cognizant ACRS staff person, Dr. John T. Larkins (telephone (301/492–4516), between 7:30 a.m. and 4:15 p.m. (EST). Persons planning to attend this meeting are urged to contact the above named individual five days before the scheduled meeting to be advised of any changes in schedule, etc., that may have occurred.

Dated: January 19, 1994.

Sam Duraiswamy,

Chief, Nuclear Reactors Branch.

[FR Doc. 94–1868 Filed 1–27–94; 8:45 am]

BILLING CODE 7590–01–M

[Docket No. 50–142]

UCLA Research Reactor; Closing of Local Public Document Room

Notice is hereby given that the Nuclear Regulatory Commission (NRC) is closing the local public document room (LPDR) for records pertaining to the University of California at Los Angeles (UCLA) Research Reactor located at the West Los Angeles Regional Library, Los Angeles, California. The LPDR is no longer needed and will close effective February 11, 1994.

The West Los Angeles Regional Library has been the LPDR for the UCLA Research Reactor since December 1980 when it was established for the proposed license renewal. Since that time the LPDR has remained operational maintaining documents on the termination of the UCLA License No. R–71 through the decommissioning of the facility. On December 28, 1993, the NRC issued an Order releasing the UCLA Research Reactor Facility for unrestricted use. Therefore, effective February 11, 1994, the LPDR will be closed.

Dated at Bethesda, Maryland, this 25th day of January, 1994.

For the Nuclear Regulatory Commission.

Donnie H. Grimsley,

Director, Division of Freedom of Information and Publications Services, Office of Administration.

[FR Doc. 94–1869 Filed 1–27–94; 8:45 am]

BILLING CODE 7590–01–M

[Docket Nos. 50–275 and 50–323]

Pacific Gas and Electric Co.; Consideration of Issuance of Amendments to Facility Operating Licenses, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of amendments to Facility Operating License Nos. DPR–80 and DPR–82 issued to Pacific Gas and Electric Company (the licensee) for operation of the Diablo Canyon Nuclear Power Plant located in San Luis Obispo County, California.

The proposed amendments would revise the combined Technical Specifications (TS) 3/4.32, "Engineered Safety Features Actuation System Instrumentation," and TS 3/4.6.2.3. "Containment Cooling System." TS 3/4.3.2, Table 3.3–3, "Engineered Safety Features Actuation System Instrumentation Surveillance Requirements," would be revised to clarify acceptable containment fan cooling unit (CFCU) configurations that satisfy the safety analysis requirements and to clarify the minimum required component cooling water flow supplied to the CFCU cooling coils. The specific TS changes proposed are as follows:

(1) TS 3.3.2, Table 3.3–3 and Table 4.3–2, Functional Units 2.c. and 3.b.3), would be revised to expand the mode applicability to Mode 4.

(2) TS 3.6.2.3 would be revised to require that at least four containment fan cooling units (CFCUs), or three CFCUs, each supplied by a separate vital bus, be operable.

(3) TS 3.6.2.3, action statement a., would be revised to clarify the equipment required to be operable when in the action statement.

(4) TS 3.6.2.3, action statement b., would be deleted.

(5) TS 3.6.2.3, action statement c., would be renumbered to action statement b. and revised to clarify the equipment required to be operable when in the action statement.

(6) TS 4.6.2.3.a.2) would be revised to clarify the minimum component cooling water (CCW) flow to the CFCUs as 1650 gpm during normal operation which will assure that the required accident flow is satisfied.

(7) A footnote would be added to the surveillance requirement of TS 4.6.2.3.a.2) allowing all CFCUs to have flow CCW flow for ASME Section XI testing and Mode 4 operation with the residual heat removal (RHR) heat exchangers in service for decay heat removal.

(8) TS 4.6.2.3.a.3) would be revised to remove cycle specific information that is no longer applicable.

Before issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act) and the Commission's regulations.

The Commission has made a proposed determination that the amendment request involves no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

(1) Does the change involve a significant increase in the probability or consequences of an accident previously evaluated?

Neither the [component cooling water] CCW system nor the containment pressure high-high signal initiate any accident, and therefore, do not affect the probability of an accident occurring.

Addition of Mode 4 to the applicability of the containment high-high pressure signal provides assurance that the containment spray system will automatically actuate and the CCW nonvital header will automatically isolate is response to the high containment pressure.

Deletion of action statement b. of TS 3.6.2.3 is conservative since it assures that adequate containment heat removal is available and assures that the assumptions of the bounding Mode 1 containment [design basis accident] DBA are satisfied.

Revising the CCW flow rates to the CFCUs clarifies the expected CCW flow rates during normal operation. Operation within the flow requirements assures that adequate flow will be available to the CFCUs to satisfy the assumptions in the containment DBA in [final safety analysis report] FSAR Section 6.2B.3.

PG&E analysis has determined that with three CFCUs available for containment heat removal , adequate CCW flow will be available with both [residual heat removal] RHR heat exchangers in service to provide assurance that the maximum design pressure of containment is not exceeded, assuming a single failure does not occur.

The revisions to clarify CFCU configurations that satisfy the [limiting condition for operation] LCO and action statements and the removal of cycle specific information from the containment cooling TS are administrative changes that do not affect the operating methodology of Diablo Canyon.

Therefore, the proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

(2) Does the change create the possibility of a new or different kind of accident from any accident previously evaluated?

The revision to the minimum CCW flow requirement to the CFCU cooling

coils updates a requirement currently in the TS. The new flow requirement assures that the maximum containment design pressure will not be exceeded during a DBA and assures that the CCW system is not overheated. The changes do not result in any physical modification to any plant system.

The revisions to clarify CFCU configurations that satisfy the LCO and action statements and the removal of cycle specific information from the containment cooling TS are administrative changes that do not affect the operating methodology of Diablo Canyon.

Therefore, the proposed changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

(3) Does the change involve a significant reduction in a margin of safety?

Revising the CCW flow rates to the CFCUs clarifies the expected CCW flow rates during normal operation that satisfy the assumptions in the containment design basis accident described in FSAR Update Section 6.2B.3. The revision is an administrative change that clarifies the intent of the TS.

PG&E analysis has determined that with three CFCUs available for containment heat removal, adequate CCW flow will be available with both RHR heat exchangers in service to provide assurance that the maximum design pressure of containment is not exceeded, assuming a single failure does not occur.

The revisions to clarify CFCU configurations that satisfy the LCO and action statements and the removal of cycle specific information from the containment cooling TS are administrative changes that do not affect the operating methodology of Diablo Canyon.

Therefore the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of the 30-day notice period. However, should circumstances change during the notice period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 30-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received. Should the Commission take this action, it will publish in the **Federal Register** a notice of issuance and provide for opportunity for a hearing after issuance. The Commission expects that the need to take this action will occur very infrequently.

Written comments may be submitted by mail to the Rules Review and Directives Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and should cite the publication date and page number of this **Federal Register** notice. Written comments may also be delivered to room P–223, Phillips Building, 7920 Norfolk Avenue, Bethesda, Maryland, from 7:30 a.m. to 4:15 p.m. Federal workdays. Copies of written comments received may be examined at the NRC Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555.

The filing of requests for hearing and petitions for leave to intervene is discussed below.

By February 28, 1994, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.714 which is available at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555 and at the local public document room located at California Polytechnic State University, Robert F. Kennedy Library, Government Documents and Maps Department, San Luis Obispo, California 93407. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to 15 days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than 15 days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner shall provide a brief explanation of the bases of the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. Petitioner must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to file such

a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Services Branch, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555, by the above date. Where petitions are filed during the last 10 days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at 1–(800) 248–5100 (in Missouri 1–(800) 342–6700). The Western Union operator should be given Datagram Identification Number N1023 and the following message addressed to Theodore R. Quay, Director, Project Directorate V: petitioner's name and telephone number, date petition was mailed, plant name, and publication date and page number of this **Federal Register** notice. A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to Christopher J. Warner, Esq., Pacific Gas and Electric Company, P.O. Box 7442, San Francisco, California 94120, attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the presiding Atomic Safety and Licensing Board that the petition and/or request should be granted based upon a balancing of the factors specified in 10 CFR 2.714(a)(1)(i)–(v) and 2.714(d).

For further details with respect to this action, see the application for amendment dated January 10, 1994, which is available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555 and at the local public document room located at California Polytechnic State University, Robert E. Kennedy Library, Government Documents and Maps Department, San Luis Obispo, California 93407.

Dated at Rockville, Maryland, this 25th day of January 1994.

For the Nuclear Regulatory Commission.

Sheri R. Peterson,

Project Manager, Project Directorate V, Division of Reactor Projects III/IV/V, Office of Nuclear Reactor Regulation.

[FR Doc. 94–1954 Filed 1–27–94; 8:45 am]

BILLING CODE 7590–01–M

[Docket No. 030–09792, License No. 13–02752–08 EA 93–111]

Indiana University School of Medicine; Indianapolis, IN; Order Imposing Civil Monetary Penalty

I

Indiana University School of Medicine (licensee) is the holder of Byproduct Material License No. 13–02752–08 issued by the Nuclear Regulatory Commission (NRC or Commission) on September 26, 1973. The license was amended in its entirety on October 6, 1989, and is due to expire on November 30, 1994. The license was most recently amended on April 9, 1992. The license authorizes the licensee to possess Cobalt-60 sealed teletherapy sources for medical use described in 10 CFR 35.600 and for irradiation of blood and blood products in accordance with the conditions specified therein.

II

An inspection of the licensee's activities was conducted on December 14, 1992, through January 13, 1993. The results of this inspection indicated that the licensee had not conducted its activities in full compliance with NRC requirements. A written Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was served upon the licensee by letter dated October 7, 1993. The Notice states the nature of the violation, the provisions of the NRC's requirements that the licensee had violated, and the amount of the civil penalty proposed for the violation. The licensee responded to the Notice by a letter dated October 29, 1993. In its response, the licensee disputes the validity of the cited violation. Further, the licensee takes exception to the NRC Staff's application of the civil penalty adjustment factors in the areas of identification and licensee performance.

III

After consideration of the licensee's response and the statements of fact, explanation, and argument for mitigation contained therein, the NRC staff has determined, as set forth in the Appendix to this Order, that the violation occurred as stated and that the penalty proposed for the violation designated in the Notice should be imposed.

IV

In view of the foregoing and pursuant to section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205, *It is hereby ordered that:*

The licensee pay a civil penalty in the amount of $5,000 within 30 days of the date of this Order, by check, draft, money order, or electronic transfer, payable to the Treasurer of the United States and mailed to the Director, Office of the Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555.

V

The Licensee may request a hearing within 30 days of the date of this Order. A request for a hearing should be clearly marked as a "Request for an Enforcement Hearing" and shall be addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555. Copies also shall be sent to the Assistant General Counsel for Hearings and Enforcement at the same address and to the Regional Administrator, NRC Region III, 801 Warrenville Road, Lisle, Illinois 60532–4351

If a hearing is requested, the Commission will issue an Order designating the time and place of the hearing. If the licensee fails to request a hearing within 30 days of the date of this Order, the provisions of this Order shall be effective without further proceedings. If payment has not been made by that time, the matter may be referred to the Attorney General for collection.

In the event the licensee requests a hearing as provided above, the issues to be considered at such hearing shall be:

(a) Whether the licensee was in violation of the Commission's requirements as set forth in the Notice referenced in Section II above, and

(b) Whether, on the basis of such violation, this order should be sustained.

Dated at Rockville, Maryland this 18th day of January 1994.

For the Nuclear Regulatory Commission.

James Lieberman,

Director Office of Enforcement.

Appendix

Evaluation and Conclusion

On October 7, 1993, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued for a violation identified during an NRC inspection on December 14, 1992, through January 13, 1993. Indiana University School of Medicine responded to the Notice in a letter dated October 29, 1993. In its response, the licensee disputes the validity of the cited violation. Further, the licensee takes exception to the NRC Staff's application of identification and licensee performance civil penalty adjustment factors. The NRC's evaluation and conclusions regarding the licensee's requests are as follows:

Restatement of Violation

10 CFR 35.32(a) states, in part, that each licensee shall establish and maintain a written quality management program to provide high confidence that radiation from byproduct material will be administered as directed by the authorized user. Pursuant to 10 CFR 35.32(a) (1) and (3), the quality management program must include written policies and procedures to meet specific objectives that: (1) Prior to administration, a written directive is prepared for any teletherapy radiation dose; and (2) final plans of treatment and related calculations for teletherapy are in accordance with the written directive.

10 CFR 35.2 defines a written directive as an order in writing for a specific patient, dated and signed by an authorized user prior to administration of radiation and containing, for teletherapy, the following information: The total dose, dose per fraction, treatment site, and overall treatment period.

Contrary to the above, as of January 13, 1993, the licensee's quality management program for teletherapy dated January 16, 1992, did not have a procedure for: (1) Ensuring the written directive contained the total dose, dose per fraction, treatment site, and overall treatment period and (2) verifying the dose calculations for administrations of three fractions or less to confirm that the final plans of treatment are in accordance with the written directive. Consequently, on November 13, 1992, the licensee's authorized user signed and dated a written directive for teletherapy treatment that failed to include the overall treatment period and the licensee failed to verify the dose calculations, since the treatment called for less than 3 fractions, to ensure the final plans of treatment were in accordance with the written directive.

Summary of Licensee's Response to the Violation

The licensee disputes the validity of the cited violation, the assigned Severity Level, and the NRC root cause analysis, as follows:

1. The licensee asserts that the proposed violation did not cause the misadministration even though the written directive did include the overall treatment period. In the written directive for the patient treated November 13, 1992, the number of fractions is written as "2 fx" which means the treatment period is to include two fractions or treatments. This is the licensee's interpretation of the overall treatment period. The licensee asserts that the term "overall treatment period" is not defined in the regulations or in Regulatory Guide 8.33. According to the licensee, the presence or absence of the documentation of the overall treatment period would have no bearing on the initial interpretational error made by the dosimetrist or the subsequent oversights by individuals who were verifying the correctness of the treatment.

2. The licensee notes that the treatment was performed on an emergency basis and that this fact causes the standard verification procedure to change depending upon the availability of staff. According to the licensee, while neither the Quality Control/Quality Assurance Program (QA/QCP) nor the Quality Management Program (QMP) include specific procedures for verification when less than four treatments are prescribed, no change in the subsequent chart checking procedures would have resulted because the treatment in question as an emergency.

The licensee also asserts that it verified the dose calculations in that the prescribing physician/authorized user and two radiation therapists attempted to verify that the treatment to be delivered was in accordance with the written directive. According to the licensee, while none of these individuals identified the calculational error made by the dosimetrist, their failure to identify the error was related to the wording of the written directive rather than the failure to follow proper procedure.

3. The licensee challenges the categorization of the proposed violation as a Severity Level III violation. The licensee asserts that the misadministration occurred due to inconsistencies in the format of the written directive, and that the QMP was followed and the appropriate checks were made. According to the licensee, the violation would be more appropriately categorized at Severity Level IV since it does not represent a programmatic weakness in the implementation of the QMP, the failure was isolated to the single event, and the consequences were limited and did not adversely affect the patient.

4. The licensee disagrees with the NRC's statement that, "The violation contributed to the occurrence of a misadministration on November 13, 1992."

NRC Evaluation of Licensee's Response to the Violation

This enforcement action focuses on the licensee's failure to develop and implement an adequate QMP. As a result of the misadministration, the NRC performed a detailed review of the licensee's QMP during the followup inspection and enforcement deliberations. The result of this detailed review was that the NRC identified substantial deficiencies. The inspection determined that the licensee's written QMP did not have procedures for: (1) Ensuring that the written directive contained the total dose, dose per fraction, treatment site, and the overall treatment period; and (2) verifying the dose calculations for administrations of three fractions or less to confirm that the final plans of treatment are in accordance with the written directive. The licensee has not provided any information to demonstrate that its written QMP addressed these procedures. These deficiencies represent a programmatic (as opposed to isolated) failure in the implementation of the QMP; therefore, the violation was categorized at Severity Level III in accordance with the NRC Enforcement Policy, Supplement VI.C.6 (57 FR 5792).

NRC has defined the term "overall treatment period" in the Statement of Considerations for the QMP rule (56 FR 34104). According to the Statement of Considerations, "the phrase 'overall treatment period' was added to emphasize that the treatments will end after the specified number of weeks, unless the treatment period is revised by the authorized user prior to continuing." Therefore, the treatment period is a unit of time and not the number of fractions as used in the licensee's definition.

The licensee argues that three different individuals (the authorized user and two radiation therapists) attempted to verify that the treatment to be delivered was in accordance with the written directive, and that the failure to identify the error was related to the working of the written directive rather than a failure to follow proper procedure. However, the same authorized user had created the written directive that same afternoon. Therefore, it is extremely unlikely that his failure to identify the error was related to the wording of his own written directive. The licensee's QMP procedure required that the authorized user review and initial the treatment chart to verify that he had reviewed the written prescription and the calculated dose per fraction. As noted in the inspection report, the information written on the patient chart clearly indicated that the dose per fraction was incorrect. It appears that the authorized user initialed the chart and that his review was cursory or inadequate.

Moreover, the violation focuses on the fact that, while the licensee's QMP requires that a physics staff member review the accuracy of all dosimetric calculations for treatments that are delivered in four or more fractions, it has no equivalent provision for treatments that are delivered in less than four fractions. Had such an independent review been required by the Licensee's QMP and performed in this case, the error could have been avoided.

The Licensee's QMP waived review of dose calculations by the physics staff member for extenuating circumstances such as staff shortages and emergency treatments. Neither

the QMP regulations nor the accompanying regulatory guide suggest that this independent review may be waived for staff shortages or emergent treatments, such as those that must be performed after working hours. A footnote to 10 CFR 35.32(a)(1) states, "if, because of the emergent nature of the patient's medical condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive." Neither 10 CFR 35.32(a) nor the footnote permit the waiving of the independent review of the dosimetric calculations due to the emergent nature of a treatment. The independent verification is especially important during times when the licensee is more subject to error such as with staff shortages and emergent treatments.

Based on the above, the NRC concludes that the violation did occur as stated, and that there was not an adequate basis for a reduction of the severity level.

Summary of Licensee's Request for Mitigation

1. Identification

The licensee asserts that the NRC improperly takes credit for identifying the proposed violation of the QMP because the QMP was submitted to the NRC approximately 1.5 years ago in accordance with 10 CFR 35.32(f)(2); and, since that submission, the licensee has received no indication that the QMP was deficient. According to the licensee, the "less than four treatment" deficiency was detected concurrently by the NRC and the licensee as a result of this misadministration; and therefore, escalation of enforcement based on the NRC's claim of identifying the deficiency is inappropriate.

2. Licensee Performance

The licensee asserts that the NRC improperly escalated the base civil penalty by 100 percent for "poor past performance" and notes that this was apparently due to a misadministration which occurred in May of 1990, some 2.5 years before the most recent one. According to the licensee, while the NRC claims that these two misadministrations were "similar", the only similarities were that they were both brain treatments and the dose per fraction was doubled. The licensee notes that the dissimilarities include an emergency treatment versus treatment during normal working hours, a short-term versus a more conventional long-term treatment, and a single port treatment versus a multiple port treatment. According to the licensee, there appears to be no relationship between the causes of the two misadministrations. The licensee indicates that this escalation implies that the NRC's sole evaluation of past performance relates to the number of misadministrations which have occurred and been reported over an undefined period of time. The licensee points out that the May 1990 misadministration was discovered through its QA/QCP and, until January of 1992, most licensees were not required to have any type of QMP; therefore, comparing the licensee's performance to that of other licensees in not appropriate (i.e., other licensees may have had misadministrations which went undetected due to the fact that they had no QMP).

The licensee asserts that while a QMP helps reduce the possibility of misadministrations, normal statistical probabilities would predict that the potential for misadministrations will increase with the number of patient treatments due to human error. In the licensee's particular instance, its Radiation Oncology Department treated approximately 1418 patients including some 52,000 separate treatments with external beam therapy during the time interval between the two misadministrations. Five hundred and eighteen (518) of those patients (approximately 15,000 separate treatments) were specifically treated with cobalt-60 teletherapy. According to the licensee, one patient with two ports in error is a very small percentage of the overall number of treatments and should not be sufficient to escalate a civil penalty based upon "poor past performance."

NRC Evaluation of Licensee's Request for Mitigation

1. Identification

Licensees may not expect, or rely on, NRC to identify safety problems or violations for them. The Enforcement Policy provides that the purpose of the identification factor is to encourage licensees to monitor, supervise, and audit activities in order to assure safety and compliance. By the licensee's own admission, it did not detect the problems noted in the violation during the 1.5 years that its QMP has been in existence, nor is there any evidence that the licensee identified the specific problems noted in the violation before NRC did. For example, these problems are not noted in the licensee's December 17, 1992 misadministration report, which includes a section entitled, "Improvements and Actions Taken to Prevent Recurrence."

Based on the above, the NRC concludes that 50 percent escalation of the base civil penalty is warranted for NRC identification.

2. Licensee Performance

The NRC Enforcement Policy states that prior performance refers to the licensee's performance normally (1) within the last two years of the inspection at issue, or (2) the period within the last two inspections, whichever is longer. On this case the period covered by the last two inspections is applicable, i.e., two inspections prior to the inspection at issue. The two previous inspections to be considered are the inspection conducted on September 11, 1991, and the inspection conducted on May 21–23, 1990.

The NRC did not compare the licensee's performance with other licensees. The Enforcement Policy provides that the effectiveness of previous corrective action for similar problems is a consideration in assessing the licensee performance factor. The May 1990 inspection was conducted to review the circumstances surrounding a teletherapy misadministration. The physicist performing the treatment dose calculation misinterpreted the physician's written prescription. The error continued undetected despite at least four separate opportunities for the dosimetry and physician staffs and several opportunities for the technologists to identify the problem. In its misadministration report of May 24, 1990, the licensee noted that loss of objectivity was a causative factor in that the various QA checks had not been performed as an independent review. The licensee's corrective action was to turn an existing requirement that the authorized user initial the chart before the treatment begins into a full QA check involving a review by the physician of, among other things, the calculated dose per fraction. A memorandum entitled "Chart checking of treatment doses and calculations" was circulated to emphasize to physicians and other key personnel the importance of vigilant and critically minded checking of doses and dose calculations. Thus, the NRC concludes that the root causes of the misadministrations are sufficiently similar to warrant escalation for past performance.

The licensee also argues good past performance in that a very small percentage of its treatments were misadministrations. On the contrary, the NRC is concerned that the licensee was performing a high volume of treatments with a deficient QMP.

Based on the above, 100 percent escalation of the base civil penalty is warranted for poor licensee performance.

NRC Conclusion

Based on its evaluation of the licensee's response, the NRC staff concludes that the violation did occur as stated, and that neither an adequate basis for a reduction of the severity level nor for mitigation of the civil penalty has been provided by the licensee. Accordingly, NRC concludes that a civil monetary penalty of $5,000 should be imposed by order.

[FR Doc. 94–1870 Filed 1–27–94; 8:45 am]
BILLING CODE 7590–01–M

OFFICE OF PERSONNEL MANAGEMENT

Federal Prevailing Rate Advisory Committee Open Committee Meeting

According to the provisions of section 10 of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given that meetings of the Federal Prevailing Rate Advisory Committee will be held on—

Thursday, Feb. 17, 1994
Thursday, Feb. 24, 1994
Thursday, Mar. 10, 1994
Thursday, Mar. 24, 1994

The meetings will start at 10:45 a.m. and will be held in Room 5A06A, Office of Personnel Management Building, 1900 E Street, NW., Washington, DC.

The Federal Prevailing Rate Advisory Committee is composed of a Chairman,

representatives from five labor unions holding exclusive bargaining rights for Federal blue-collar employees, and representatives from five Federal agencies. Entitlement to membership on the Committee is provided for in 5 U.S.C. 5347.

The Committee's primary responsibility is to review the Prevailing Rate System and other matters pertinent to establishing prevailing rates under subchapter IV, chapter 53, 5 U.S.C., as amended, and from time to time advise the Office of Personnel Management.

These scheduled meetings will start in open session with both labor and management representatives attending. During the meeting either the labor members or the management members may caucus separately with the Chairman to devise strategy and formulate positions. Premature disclosure of the matters discussed in these caucuses would unacceptably impair the ability of the Committee to reach a consensus on the matters being considered and would disrupt substantially the disposition of its business. Therefore, these caucuses will be closed to the public because of a determination made by the Director of the Office of Personnel Management under the provisions of section 10(d) of the Federal Advisory Committee Act (Pub. L. 92–463) and 5 U.S.C. 552b(c)(9)(B). These caucuses may, depending on the issues involved, constitute a substantial portion of the meeting.

Annually, the Committee publishes for the Office of Personnel Management, the President, and Congress a comprehensive report of pay issues discussed, concluded recommendations, and related activities. These reports are available to the public, upon written request to the Committee's Secretary.

The public is invited to submit material in writing to the Chairman on Federal Wage System pay matters felt to be deserving of the Committee's attention. Additional information on these meetings may be obtained by contacting the Committee's Secretary, Office of Personnel Management, Federal Prevailing Rate Advisory Committee, Room 1340, 1900 E Street, NW., Washington, DC 20415 (202) 606–1500.

Dated: January 14, 1994.

Anthony F. Ingrassia,

Chairman, Federal Prevailing Rate Advisory Committee.

[FR Doc. 94–1728 Filed 1–27–94; 8:45 am]

BILLING CODE 6325–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–33501; File No. SR–Amex–93–42]

Self-Regulatory Organizations; Filing of Proposed Rule Change by American Stock Exchange, Inc. Relating to Disciplinary Rules

January 21, 1994.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on December 23, 1993, the American Stock Exchange, Inc. ("Amex" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The American Stock Exchange is proposing to amend its disciplinary rules relating to the retention of disciplinary jurisdiction and the settlement of disciplinary actions.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Retention of disciplinary jurisdiction. Under the Act, the Exchange is required to investigate possible wrongdoing by persons and entities subject to its jurisdiction and, if warranted, initiate appropriate disciplinary action. The Exchange's disciplinary jurisdiction extends to its members, member organizations, and their registered employees. Article V, Section 6 of the Exchange Constitution and Rule 341 permit the Exchange to retain disciplinary jurisdiction even after the termination of a person's or an entity's status as a member, member organization, or registered employee, provided that it gives them written notice that it is retaining jurisdiction within one year immediately following its receipt of written notice of their termination.

Member firms are required to file a termination notice with the Exchange whenever a registered employee leaves their employ. In most cases, these reflect voluntary resignations. However, member firms are also required to file amended termination notices, subsequent to the registered employee's departure, if they become aware of customer complaints or other possible wrongdoing by the employee. The Exchange has always taken the position that the one year period to retain jurisdiction under its rules begins to run only after it is notified by the member firm of possible violative conduct by the registered employee. We believe that this is a logical position since the Exchange would have no reason to retain jurisdiction and initiate an investigation unless it had reason to believe a violation may have been committed.

Recently, in an appeal to the SEC, a respondent in an Exchange disciplinary proceeding asserted that the Exchange lacked jurisdiction over him because it failed to notify him within one year from the time his former firm filed a termination notice reporting his voluntary resignation.[1] In that case, the Exchange retained jurisdiction within one year of receiving an amended termination notice reporting a customer complaint against the registered representative. The SEC agreed with the respondent, adopting the more narrow, literal reading of our jurisdictional provision, requiring the Exchange to retain jurisdiction within one year of its receipt of a termination notice, regardless of whether such notice contains any indication of actionable conduct. However, the Commission in its decision indicated that it was sensitive to the Exchange's position and would be receptive to the Exchange amending its rules to expressly provide that the one year time period begins upon receipt of the original termination notice or any subsequent amendment of such notice, whichever is later.

By so amending the applicable Constitutional and rule provisions, the Exchange will close an existing gap in

[1] *In re* Leavitt, Securities Exchange Act Release No. 32441, 1993 Sec Lexis 1427 (June 10, 1993) (Admin. Proc. File No. 3–7836).

its disciplinary process which permits possible wrongdoers to escape investigation by the Exchange into potentially serious misconduct. It should be noted that the CBOE and the NASD have rule provisions relating to retention of discipolinary jurisdiction comparable to the changes we are proposing.

Settlement of disciplinary actions. The Exchange's Enforcement Department is charged with the responsibility of issuing disciplinary charges if, following an investigation, it is determined that persons or entities within the Exchange's jurisdiction committed serious infractions of the exchange's rules or the Federal securities laws. The issuance of formal charges begins a rather lengthy process involving the filing of an answer to the charges, the exchange of documents, and the scheduling of a disciplinary hearing. Very often, however, persons who are the subject of Exchange investigations wish to settle the matter before formal charges are issued by stipulating to certain facts and consenting to a penalty. At present, Article V, section 1(b)(4) of the Constitution and Rule 345(c) require the issuance of formal charges before a disciplinary matter can be settled. In contrast, the comparable rules at the NYSE, NASD, and CBOE permit potential respondents to settle disciplinary proceedings without the service of formal charges.

It is proposed that the Exchange conform its procedures for settling disciplinary actions to those now in effect at all the other major self-regulatory organizations. There would be several advantages to amending the procedures in the manner proposed. First, it would save the substantial time and expense that is now devoted to the formal charging process in settled cases. Second, it would give the Exchange more flexibility in negotiating the resolution of enforcement actions. Third, conforming the Exchange's settlement procedures to those in place at the other principal self-regulatory organizations would serve the interests of regulatory uniformity and simplicity. Finally, potential respondents would still retain the option of following the current disciplinary procedures if they are so inclined.

2. Statutory Basis

The proposed rule change is consistent with section 6(b) of the Act in general and furthers the objectives of section 6(b)(6) in particular in that it is intended to assure that members, member firms, and member firm employees are disciplined for rule violations.

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change will impose no burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the publication of this notice in the **Federal Register** or within such other period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve the proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Station, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing will also be available for inspection and copying at the principal office of the Amex. All submissions should refer to File No. SR–Amex–93–42 and should be submitted by February 18, 1994.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 94–1812 Filed 1–27–94; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 34–33499; File No. SR–CHX–93–33]

Self-Regulatory Organizations; Filing of Proposed Rule Change by the Chicago Stock Exchange, Inc. ("CHX") Relating to the Filing of Form U–5

January 21, 1994.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on December 23, 1993, the Chicago Stock Exchange, Inc. ("CHX" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization. On January 21, 1994, the Exchange submitted to the Commission Amendment No. 1 to the proposed rule change.[1] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to add interpretation and policy .03 to Rule 3, Article VI of the Exchange's rules and relates to the filing of a Uniform Termination Notice for Securities Industry Registration ("Form U–5").[2]

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text

[1] See letter from David T. Rusoff, Attorney, Foley & Lardner, to Louis A. Randazzo, Attorney, Branch of Exchange Regulation, Commission, dated January 21, 1994. Amendment No. 1 made certain clarifying amendments to the proposal.

[2] The Form U–5 is employed in connection with the National Association of Securities Dealers, Inc. ("NASD") Central Registration Depository ("CRD") system and is used by the various securities self-regulatory organizations ("SROs") as part of their registration and oversight of member organization personnel. Form U–5 contains information relating to the circumstances surrounding the termination of an applicant's prior employment.

of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to require certain members of the Exchange to file Form U–5 termination notices with the Exchange.[3] The Form U–5 is used by a broker-dealer to give official notice that it has terminated a registered employee. Requiring the filing of the Form U–5 with the Exchange is consistent with the rules of other SROs and will allow the Exchange to more precisely monitor the authority of registered persons to act on behalf of member firms and monitor the reasons for termination.[4]

2. Statutory Basis

The proposed rule change is consistent with Section 6(b)(5) of the Act in that it is designed to promote just and equitable principles of trade, to remove impediments and to perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule will impose any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No comments were solicited or received.

[3] Proposed Interpretation and Policy .03 to Rule 3 of Article VI would apply to member organizations for which the Exchange is the Designated Examining Authority ("DEA") and to registered persons of any other member organization (for whom the CHX is not the DEA) that are active on the CHX trading floor.

[4] Proposed Interpretation and Policy .03 to Rule 3 of Article VI states that following the termination of a person associated with a member in a registered capacity, such member shall promptly, but in no event later than thirty (30) calendar days after such termination, give written notice of such termination to the Exchange on Form U–5, and concurrently provide a copy of such notice to the person whose association has been terminated. This requirement shall only apply to member organizations for which the Exchange is the DEA and to registered persons of other member organizations active on the CHX trading floor.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and published its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) by order approve the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Room, 450 Fifth Street, NW., Washington, DC 20549. Copies of the filing will also be available for inspection and copying at the principal office of the CHX. All submissions should refer to File No. SR–CHX–93–33 and should be submitted by February 18, 1994.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 94–1811 Filed 1–27–94; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 34–33500; File No. SR–MSE–93–05]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the Midwest Stock Exchange, Inc. Relating to Agency Crosses Between the Disseminated Exchange Market

January 21, 1994.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on March 2, 1993, the Midwest Stock Exchange, Inc. ("MSE," "Exchange" or "Chicago Stock Exchange")[1] filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization. On December 10, 1993, the MSE submitted to the Commission Amendment No. 1 to the proposed rule change in order to summarize and respond to a comment letter it received in opposition to this proposal.[2] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The MSE proposes to add an "Interpretation and Policy" to Article XX, Rule 23 of its Rules which would allow MSE floor brokers to "cross" stock on the Exchange floor without the possibility of break-up by a specialist under certain circumstances. The policy would apply where a broker has an order to buy and an order to sell the same stock at a price between the disseminated Exchange market.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of an basis for the proposed rule change and discussed any comments it received on

[1] As of July 8, 1993, the Midwest Stock Exchange, Inc. ("MSE") changed its name to the Chicago Stock Exchange, Inc. ("CHX"). See Securities Exchange Act Release Nos. 32488 (June 18, 1993), 58 FR 34284 (June 24, 1993) (File No. SR–SME–93–13) (immediate effectiveness of proposed rule change to amend the MSE's Certificate of Incorporation and Constitution to effect a name change) and 32489 (June 18, 1993), 58 FR 34285 (June 24, 1993) (File No. SR–MSE–93–16) (immediate effectiveness of proposed rule change to make conforming changes to the MSE Rules).

[2] See letter from David T. Rusoff, Foley & Lardner, to Beth A. Stekler, Attorney, Division of Market Regulation, SEC, dated December 9, 1993 ("Amendment No. 1").

the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to increase the possibility of immediate execution of agency crosses [3] on the Exchange when the cross price is between the disseminated MSE market.

At present, Exchange rules require members, or member organizations, with both an order to buy and an order to sell the same security to offer publicly such security at a price which is higher than the bid by the minimum variation permitted in such security (generally an ⅛th) before making a transaction with himself, or itself. The ability of specialists, in particular, to participate in agency crosses, even when they are not disseminating a bid or offer at the cross price, greatly decreases the likelihood of immediate execution of the cross orders for order sending firms. The proposed rule change therefore is designed to give order sending firms greater assurances that their cross orders will be executed quickly and without interference.

Because this proposal addresses only the circumstances under which an MSE specialist must refrain from participating in a cross transaction, the proposal would not excuse members from the requirement to bid and offer stock as set out in Rule 23. As such, the proposal would still permit a member in the crowd to participate at the cross price, or better, during the bidding and offering at the post. However, a specialist would not be permitted to interfere with the cross during the bidding and offering at a price which he is not currently disseminating in his quote.[4] However, a specialist could participate in the cross at the cross price if he was previously sought out for assistance in executing any part of the cross trade.

Under the proposed rule, a customer order in the book could not be "disadvantaged" by a cross transaction because the proposal would apply only to crosses at prices between the disseminated Exchange market. Moreover, the Exchange's existing rules of priority and precedence would not be affected in any way under this proposal. Therefore, even though a specialist would be precluded from participating with a cross at a price between his disseminated market, he would still be required to satisfy orders in this book at the cross price, even if those orders are not being disseminated through an oversight on the part of the specialist.

Finally, the proposed rule would apply to only floor-brokered orders where neither order is for the account of a member or member organization.[5] The proposed rule would apply to all agency crosses regardless of size.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b)(5) of the Act, in that it is designed to promote just and equitable principles of trade, to remove impediments to and to perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that no burdens will be placed on competition as a result of the proposed rule change.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange received one comment letter in opposition to the proposed rule change from an Exchange specialist. However, the Exchange's Committee on Floor Procedure has approved the proposed rule change.

According to the Exchange,[6] on October 20, 1992, the Exchange received a comment letter from an Exchange specialist in opposition to the proposed rule change. The commentator opposes the rule change for several reasons. Specifically, the commentator states that the proposed rule does not provide for the protection of customer orders; that the proposed rule is not necessary because there is not a problem now except for a few specialists; that the proposed rule will be subject to abuse because of the inability to determine whether or not the crosses are really agency crosses on an immediate basis; that the Exchange should be encouraging more orders and less crosses; and that, as a result of the new rule, specialists will not be able to participate, among other things.

The Exchange believes that the commentator's concerns are misplaced. First, the proposed rule change will not interfere with public orders in the book. Customer orders will continue to be protected under the proposed rule, even if, through oversight, they are not displaced. The specialist must fill a customer order at the limited price even if an agency cross takes place at the limit price. This should also encourage specialists to be more efficient in displaying customer orders.

Second, the proposal will encourage more institutional trades to be sent to the floor; whether this will result in more revenue to the Exchange is a secondary consideration. The proposal will provide a more attractive marketplace for institutional orders without sacrificing traditional agency/auction principles.

Third, the potential that some firms may abuse the rule by not having an agency order on both sides of the trade is not an argument for not having the rule. There are literally dozens of rules in place today which inherently cannot be surveilled on an immediate basis to monitor compliance. If the Exchange finds that firms are abusing the rule, it will take appropriate action.

Lastly, the proposed rule does not reduce the possibility of order interaction on the floor. The specialist is the only one who cannot participate in a cross if he is not displaying his market at the cross price; this should encourage specialists to quote their true markets. The requirement for a firm with agency orders to cross to bid or offer at the post still remains and any other interest in the crowd can participate. It is only the specialist who cannot, unless he is quoting at the cross price or unless he has been previously solicited for his help. This is not a major departure from agency auction principles and should encourage more orders to the Exchange floor to participate in the auction process.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the publication of this notice in the **Federal Register** or

[3] For purposes of this proposal, the Exchange has defined an agency cross to be a cross where neither the order to buy nor the order to sell is for the account of *any* member or member organization (*i.e.*, including, but not limited to, the member or member organization executing the cross). Telephone conversation between David T. Rusoff, Foley & Lardner, and Beth A. Stekler, Attorney, Division of Market Regulation, SEC, on January 5, 1994.

[4] Conversely, this proposal would allow a specialist who has a disseminated bid or offer at the cross price to participate at that cross price, even in a size greater then the specialist's disseminated market. Telephone conversation between David T. Rusoff, Foley & Lardner, and Beth A Stekler, Attorney, Division of Market Regulation, SEC, on December 20, 1993.

[5] See *supra*, note 3.

[6] See Amendment No. 1, *supra*, note 2.

within such other period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve the proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing will also be available for inspection and copying at the principal office of the Chicago Stock Exchange. All submissions should refer to File No. SR–MSE–93–05 and should be submitted by February 18, 1994.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 94–1813 Filed 1–27–94; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 35–25975]

Filings Under the Public Utility Holding Company Act of 1935 ("Act")

January 21, 1994.

Notice is hereby given that the following filing(s) has/have been made with the Commission pursuant to provisions of the Act and rules promulgated thereunder. All interested persons are referred to the application(s) and/or declaration(s) for complete statements of the proposed transaction(s) summarized below. The application(s) and/or declaration(s) and any amendments thereto is/are available for public inspection through the Commission's Office of Public Reference.

Interested persons wishing to comment or request a hearing on the application(s) and/or declaration(s) should submit their views in writing by February 14, 1994 to the Secretary, Securities and Exchange Commission, Washington, DC 20549, and serve a copy on the relevant applicant(s) and/or declarant(s) at the address(es) specified below. Proof of service (by affidavit or, in case of an attorney at law, by certificate) should be filed with the request. Any request for hearing shall identify specifically the issues of fact or law that are disputed. A person who so requests will be notified of any hearing, if ordered, and will receive a copy of any notice or order issued in the matter. After said date, the application(s) and/or declaration(s), as filed or as amended, may be granted and/or permitted to become effective.

The Columbia Gas System, Inc. et al. (70–8317)

The Columbia Gas System, Inc. ("Columbia"), a registered holding company,[1] and its nonutility subsidiary company Columbia LNG Corporation ("Columbia LNG"), both of 20 Montchanin Road, Wilmington, Delaware 19807, have filed an application-declaration under sections 6(a), 7, 9(a), 10, 12(b) and 12(c) of the Act and rules 42, 43, 45 and 46 thereunder.

Columbia LNG owns and is currently maintaining in a standby mode a one Bcf per day liquefied natural gas ("LNG") importation terminal at Cove Point, Maryland ("Terminal"). Columbia LNG also owns and operates an 87-miles, 36-inch natural gas pipeline from Cove Point to Loudoun County, Virginia ("Pipeline," collectively, the "Facility"). Columbia owns 90.8% of the issued and outstanding common stock of Columbia LNG, and Shell LNG Company ("Shell LNG") owns the balance (9.2%).

Columbia LNG and PEPCO Enterprises, Inc. ("PEI"), a wholly owned subsidiary of Potomac Electric Power Company ("PEPCO"), a public-utility company unaffiliated with Columbia, have agreed to develop a peak shaving service ("Peaking") at the Terminal.[2] The business plan contemplates the use of the Terminal's existing storage tanks, vaporization equipment, and other plant infrastructure to provide the Peaking service. A liquefaction facility ("Liquefaction Unit") would be constructed at the Terminal to liquefy natural gas received from Peaking customers for storage in the existing tanks.

Applicants-declarants propose that, a limited partnership between Columbia LNG and a subsidiary of PEI, Cove Point Energy Company ("Partnership") will: (i) Own and operate the Facility; (ii) provide Peaking and pipeline transportation services; and (iii) pursue the implementation of an ongoing baseload LNG import trade.

The Partnership agreement will provide for the contribution of the Facility (including specified associated rights and liabilities) by Columbia LNG to the Partnership, and for PEI's contribution to the Partnership of up to $25 million which will consist of $10 million in cash to the Partnership in the form of equity plus a $15 million loan secured by the assets of the Partnership. The transfer of assets and PEI's contribution of capital would take place at a closing to occur on a date after all necessary regulatory approvals are obtained and certain conditions precedent are satisfied ("Construction Capital Closing"). Columbia LNG and PEI, either directly or through subsidiaries, will each obtain a 50% interest and equal voting rights in the Partnership. Applicants-declarants expect that Columbia LNG will hold a limited partner interest and a general partner interest either directly or indirectly through one or more new, wholly owned subsidiaries of Columbia LNG ("CLG Subsidiaries") that will be the operator of, and/or hold partnership interests in, the Partnership.

PEI's equity contributions and loan proceeds will be used for recommissioning the Facility (including building the Liquefaction Unit and related equipment), operating and maintenance expenses, and working capital. Amounts in excess of $25 million necessary prior to the completion of the recommissioning of the Facility, including any necessary

---

[1] On July 31, 1991, Columbia and Columbia Gas Transmission Corporation, a wholly owned subsidiary which is not an applicant-declarant hereunder, filed petitions for reorganization under Chapter 11 of Title 11 of the United States Code with the United States Bankruptcy Court for the District of Delaware (Case Nos. 91–803 and 91–804) and were thereupon continued in the management of their respective businesses and possession of their respective properties as debtors-in-possession.

[2] A peak shaving facility has the ability to deliver large amounts of gas on very short notice over brief periods of time for use on occasions, such as very cold winter days or very hot summer days, when such increased supplies are needed to meet the requirements of heating or electric generating customers. Peaking service is distinguishable from storage service because storage is typically designed to provide meaningful deliveries of natural gas on a more frequent basis over a longer period of time, e.g., 120 days.

construction backstop and working capital, will be provided by Columbia LNG and/or the CLG Subsidiaries, as an equity contribution, up to $7.0 million.

By Commission order dated September 29, 1993 (HCAR No. 25896) ("September Order"), Columbia and Columbia LNG were authorized to defer principal and interest payments on Columbia LNG's long- and short-term debt for the period September 30, 1993 through February 28, 1994. The aggregate amount of such deferred principal and interest payments is estimated to be $3.8 million.

Columbia and Columbia LNG now propose to continue to defer principal and interest payments on Columbia LNG's long- and short-term debt for the period March 1, 1994 through December 31, 1994, or Construction Capital Closing, whichever is earlier. The aggregate amount of such principal and interest payments proposed to be deferred is $7.9 million.

Columbia and Columbia LNG propose to proceed immediately upon Commission approval and prior to the issuance of the additional common stock by Columbia LNG to reduce the par value of Columbia LNG's common stock from $25 to $1 and increase the number of Columbia LNG's authorized shares to up to 15,000,000.

Accomplishing this reduction in par value would involve the following steps: (i) Columbia LNG's certificate of incorporation would be amended to reduce the common stock's par value from $25.00 per share to $1.00 per share and to increase the number of Columbia LNG's authorized shares to up to 15,000,000; and (ii) the value of Columbia LNG's stated capital would be reduced by up to $24.00 per share of common stock outstanding, and such amount would be transferred to additional paid in capital.

Columbia and Columbia LNG also propose to proceed immediately after Construction Capital Closing with a recapitalization of Columbia LNG to establish a 100% equity capital structure for Columbia LNG. To effect this recapitalization, Columbia and Columbia LNG propose that Columbia make a capital contribution to Columbia LNG of up to $48.1 million of installment promissory notes and short-term debt. An additional amount up to $3.9 million would also be contributed which would consist of accrued interest to the effective date of the recapitalization deferred pursuant to this application-declaration and the interest which was deferred pursuant to the September Order.

Columbia LNG also proposes to contribute the Facility to the Partnership at Construction Capital Closing in exchange for a 50% interest in the Partnership to be held directly by Columbia LNG and/or indirectly through one or more of the CLG Subsidiaries.

Further, Columbia LNG and Columbia propose that through December 31, 1995, Columbia LNG offer to issue and sell to Columbia and Shell LNG, in proportion to their respective common stock holdings in Columbia LNG, up to 7,000,000 shares of common stock, $1 par value, in an aggregate amount up to $7.0 million. The up to $7.0 million, together with funds on hand and anticipated tax benefits, will (i) provide for the continued operation and maintenance of the Facility pending Columbia LNG's contribution of the Facility to the Partnership; (ii) provide for continued expenditure of developmental costs prior to Construction Capital Closing; (iii) provide for any direct and indirect Columbia LNG cash capital contributions to the Partnership, including the recommissioning costs, if any, and (iv) provide for all other operating requirements of Columbia LNG through December 31, 1995. If Shell LNG chooses not to purchase any common stock, the entire amount up to $7.0 million will be purchased by Columbia, with a corresponding increase in Columbia's ownership of Columbia LNG. Some or all of the additional developmental costs incurred prior to Construction Capital Closing may be reimbursed to Columbia LNG by Cove Point Energy Company.

Columbia LNG also proposes to create and fund the CLG Subsidiaries which will be operator of, and/or hold interests as partners in, the Partnership. At the time of the Construction Capital Closing, Columbia LNG anticipates transferring all current Columbia LNG employees to one or more of the CLG Subsidiaries which will hire additional employees as necessary to undertake day-to-day responsibility for operation of the various Partnership assets. The Partnership will reimburse the operator for all costs incurred by it in such operations and pay the operator certain management fees. After this transfer, Columbia LNG's principal assets will consist of its Partnership interest and its common stock holdings in the CLG Subsidiaries. To fund the CLG Subsidiaries' operating requirements through December 31, 1995, Columbia LNG proposes to acquire from the CLG Subsidiaries in the aggregate up to $1.0 million of common stock, $1 par value, to be issued and sold by the CLG Subsidiaries.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 94–1810 Filed 1–27–94; 8:45 am]

BILLING CODE 8010–01–M

DEPARTMENT OF STATE

[Public Notice 1939]

Privacy Act of 1974; Altered System of Records

Notice is hereby given that the Department of State proposes to alter an existing system of records, STATE–51, pursuant to the provisions of the Privacy Act of 1974, as amended (5 U.S.C. 552a(r)) and the Office of Management and Budget Circular No. A–130, Appendix I. The Department's report was filed with the Office of Management and Budget on January 14, 1994.

It is proposed that the current system "Classification/Declassification Center Part-Time Employee Records" be renamed "Office of Freedom of Information, Privacy and Classification Review WAE Re-employed Annuitants and Contractor Records, STATE–51." Also proposed are revisions and/or additions to the classification, the categories of individuals and records covered by the system, authority for maintenance, routine uses, retrievability, safeguards, retention and disposal, system manager, notification procedure, record access and amendment procedures, and record source categories. These changes to the existing system description are proposed in order to reflect more accurately the Office of Freedom of Information, Privacy and Classification Review's enhanced record-keeping system and a reorganization of its activities and operations. Any persons interested in commenting on the altered system of records may do so by submitting comments in writing to Margaret P. Grafeld, Chief, Privacy, Plans and Appeals Division, Office of Freedom of Information, Privacy and Classification Review, Room 1239, Department of State, 2201 C Street, NW., Washington, DC 20520–1239. This system of records will be effective forty days from the date of publication (March 9, 1994), unless we receive comments which will result in a contrary determination. The "Office of Freedom of Information, Privacy and Classification Review WAE Re-employed Annuitants and Contractor Records, STATE–51," will read as set forth below.

Dated: January 14, 1994.

Patrick F. Kennedy,

Assistant Secretary for the Bureau of Administration.

STATE–51

SYSTEM NAME:

Office of Freedom of Information, Privacy and Classification Review WAE Re-employed Annuitants and Contractor Records.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Department of State, 2201 C Street, NW, Washington, DC 20520–1239.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Retired Foreign Service and Civil Service officers and contract employees who serve as re-employed annuitants or contractors, and those eligible for such re-employment, but whose assignments/contracts are pending with the Office of Freedom of Information, Privacy and Classification Review.

CATEGORIES OF RECORDS IN THE SYSTEM:

Manual files, maintained by name of re-employed annuitant, prospective employee or contractor, contain administrative information, such as, full name, home address, home telephone number, bureau endorsements, results of pre-employment panel meetings, annual work schedule preferences, annual work schedules, Social Security Number, date of birth, date and period of appointment, position title and number, and salary at time of retirement.

Computer records, maintained primarily by name of the annuitant, include information of area (bureau) specialties, agency from which annuitant retired, approximate number of days that annuitant can work each year, assignment by division, hours worked by pay period, hourly pay rate, grade, and hours worked on special projects or in areas outside of the assigned division.

Computer records are also maintained by Freedom of Information Act, Privacy Act and Executive Order request case number which includes information on specific cases assigned to annuitants showing case number, type and size of case, and dates the case was assigned and completed.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

22 U.S.C. 2658 (Rules and Regulations; Promulgation by Secretary; Delegation of Authority); 22 U.S.C. 3921 (Secretary of State).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Information in this system is used for scheduling the work of re-employed annuitants and contractors, monitoring and controlling expenditures, tracking and controlling cases, and for accountability and payment of contractors. The information is used primarily by the staff of the Office of Freedom of Information, Privacy and Classification Review; however, some information concerning hours worked and salary costs of annuitants is provided on a need-to-know basis to support other offices when requested.

Also see "Routine Uses" paragraphs of Prefatory Statement published in the Federal Register (42 FR 49699, September 27, 1977).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Hard copy, electronic media.

RETRIEVABILITY:

By individual name and Freedom of Information Act or Privacy Act case number.

SAFEGUARDS:

All employees and contractors of the Department of State have undergone a thorough background security investigation. Access to the Department and its annexes is controlled by security guards, and admission is limited to those individuals possessing a valid identification card or individuals under proper escort. All records containing personal information are maintained in secured file cabinets or in restricted areas, access to which is limited to authorized personnel. The Office of Freedom of Information, Privacy and Classification Review is located within a secure area of the Department. Access to computerized files is password-protected and under the direct supervision of the system manager. The system manager has the capability of printing audit trails of access from the computer media, thereby permitting regular *ad hoc* montioring of computer usage.

RETENTION AND DISPOSAL:

Retention of records of re-employed annuitants, prospective employees and contractors is indefinite because of a need to maintain a record of work availability over an extended period of time. The record is destroyed five years after the re-employed annuitant or contractor who is the subject of the record is no longer employed or under contract by the Office of Freedom of Information, Privacy and Classification Review. More specific information may be obtained by writing the Director, Office of Freedom of Information, Privacy, and Classification Review, Room 1239, Department of State, 2201 C Street NW, Washington, DC 20520–1239.

SYSTEM MANAGER AND ADDRESS:

Director, Office of Freedom of Information, Privacy, and Classification Review, Room 1239, Department of State, 2201 C Street NW, Washington, DC 20520–1239.

NOTIFICATION PROCEDURE:

Individuals who have reason to believe that the Office of Freedom of Information, Privacy, and Classification Review might have records pertaining to themselves should write to the Director, Office of Freedom of Information, Privacy and Classification Review, Room 1239, Department of State, 2201 C Street NW, Washington, DC 20520–1239. The individual must specify that he/she wishes the Office of Freedom of Information, Privacy and Classification Review WAE Re-employed Annuitants and Contractor Records to be checked. At a minimum, the individual must include: Name, date and place of birth, current mailing address and zip code, and signature.

RECORD ACCESS AND AMENDMENT PROCEDURES:

Individuals who wish to gain access to or amend records pertaining to themselves should write to the Director, Office of Freedom of Information, Privacy and Classification Review (address above).

RECORD SOURCE CATEGORIES:

The individual, Department of State Personnel Records and Department officials who endorse the nomination of an annuitant.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 94–1917 Filed 1–27–94; 8:45 am]

BILLING CODE 4710–24

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Noise Exposure Map Notice; Receipt of Noise Compatibility Program and Request for Review, Kissimmee Municipal Airport, Kissimmee, FL

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice.

SUMMARY: The Federal Aviation Administration (FAA) announces its determination that the noise exposure maps submitted by the City of Kissimmee for Kissimmee Municipal Airport under the provisions of title I of the Aviation Safety and Noise Abatement Act of 1979 (Public Law 96–193) and 14 CFR part 150 are in compliance with applicable requirements. The FAA also announces that it is reviewing a proposed noise compatibility program that was submitted for Kissimmee Municipal Airport under part 150 in conjunction with the noise exposure map, and that this program will be approved or disapproved on or before July 10,1994.

EFFECTIVE DATE: The effective date of the FAA's determination on the noise exposure maps and of the start of its review of the associated noise compatibility program is January 11, 1994. The public comment period ends March 12, 1994.

FOR FURTHER INFORMATION CONTACT: Mr. Tommy J. Pickering, P.E., Federal Aviation Administration, Orlando Airports District Office, 9677 Tradeport Drive, suite 130, Orlando, Florida 32827–5397, (407) 648–6583. Comments on the proposed noise compatibility program should also be submitted to the above office.

SUPPLEMENTARY INFORMATION: This notice announces that the FAA finds that the noise exposure maps submitted for Kissimmee Municipal Airport are in compliance with applicable requirements of part 150, effective January 11, 1994. Further, FAA is reviewing a proposed noise compatibility program for that airport which will be approved or disapproved on or before July 10, 1994. This notice also announces the availability of this program for public review and comment.

Under section 103 of title I of the Aviation Safety and Noise Abatement Act of 1979 (hereinafter referred to as "the Act"), an airport operator may submit to the FAA noise exposure maps which meet applicable regulations and which depict noncompatible land uses as of the date of submission of such maps, a description of projected aircraft operations, and the ways in which such operations will affect such maps. The Act requires such maps to be developed in consultation with interested and affected parties in the local community, government agencies, and persons using the airport.

An airport operator who has submitted noise exposure maps that are found by FAA to be in compliance with the requirements of Federal Aviation Regulations (FAR) part 150, promulgated pursuant to title I of the Act, may submit a noise compatibility program for FAA approval which sets forth the measures the operator has taken or proposes for the reduction of existing noncompatible uses and for the prevention of the introduction of additional noncompatible uses.

The City of Kissimmee submitted to the FAA on December 2, 1993, noise exposure maps, descriptions and other documentation which were produced during development of the Kissimmee Municipal Airport FAR Part 150 Noise Study between July 1, 1991, and November 29, 1993. It was requested that the FAA review this material as the noise exposure maps, as described in section 103(a)(1) of the Act, and that the noise mitigation measures, to be implemented jointly by the airport and surrounding communities, be approved as a noise compatibility program under section 104(b) of the Act.

The FAA has completed its review of the noise exposure maps and related descriptions submitted by the City of Kissimmee. The specific maps under consideration are "Existing (1992) Noise Contours on Existing Land Use" and "Alternate 5 Recommended Future (1997) Noise Contours on Existing Land Use" in the submission. The FAA has determined that these maps for Kissimmee Municipal Airport are in compliance with applicable requirements. This determination is effective on January 11, 1994. FAA's determination on an airport operator's noise exposure maps is limited to a funding that the maps were developed in accordance with the procedures contained in appendix A of FAR part 150. Such determination does not constitute approval of the applicant's data, information or plans, or a commitment to approve a noise compatibility program or to fund the implementation of that program.

If questions arise concerning the precise relationship of specific properties to noise exposure contours depicted on a noise exposure map submitted under section 103 of the Act, it should be noted that the FAA is not involved in any way in determining the relative locations of specific properties with regard to the depicted noise contours, or in interpreting the noise exposure maps to resolve questions concerning, for example, which properties should be covered by the provisions of section 107 of the Act. These functions are inseparable from the ultimate land use control and planning responsibilities of local government. These local responsibilities are not changed in any way under part 150 or through FAA's review of noise exposure maps. Therefore, the responsibility for the detailed overlaying of noise exposure contours onto the map depicting properties on the surface rests exclusively with the airport operator which submitted those maps, or with those public agencies and planning agencies with which consultation is required under section 103 of the Act. The FAA has relied on the certification by the airport operator, under § 150.21 of FAR part 150, that the statutorily required consultation has been accomplished.

The FAA has formally received the noise compatibility program for Kissimmee Municipal Airport, also effective on January 11, 1994. Preliminary review of the submitted material indicates that it conforms to the requirements for the submittal of noise compatibility programs, but that further review will be necessary prior to approval or disapproval of the program. The formal review period, limited by law to a maximum of 180 days, will be completed on or before July 10, 1994.

The FAA's detailed evaluation will be conducted under the provisions of 14 CFR part 150, § 150.33. The primary considerations in the evaluation process are whether the proposed measures may reduce the level of aviation safety, create an undue burden on interstate or foreign commerce, or be reasonably consistent with obtaining the goal of reducing existing noncompatible land uses and preventing the introduction of additional noncompatible land uses.

Interested persons are invited to comment on the proposed program with specific reference to these factors. All comments, other than those properly addressed to local land use authorities, will be considered by the FAA to the extent practicable. Copies of the noise exposure maps, the FAA's evaluation of the maps, and the proposed noise compatibility program are available for examination at the following locations:

Federal Aviation Administration, Orlando Airports District Office, 9677 Tradeport Drive, suite 130, Orlando, Florida 32827–5397.

Office of the Director of Aviation, Kissimmee Municipal Airport, 301 N. Dyer Boulevard, suite 101, Kissimmee, Florida 34741–4613.

Questions may be directed to the individual named above under the heading, **FOR FURTHER INFORMATION CONTACT:**

Issued in Orlando, Florida on January 11, 1994.

Charles E. Blair, Manager,

Orlando Airports District Office.

[FR Doc. 94–1930 Filed 1–27–94; 8:45 am]

BILLING CODE 4910–13–M

[Summary Notice No. PE–94–4]

Petition for Exemption; Summary of Petitions Received; Dispositions of Petitions Issued

AGENCY: Federal Aviation Administration; Transportation.

ACTION: Notice of petitions for exemption received and of dispositions of prior petitions; Correction.

SUMMARY: This action makes a correction to the summary described for Docket No. 27539 in a notice of petitions for exemption published on January 7, 1994, (59 FR 1055). This action corrects that error.

DATES: Comments on petitions received must identify the petition docket number involved, and must be received on or before November 26, 1992.

ADDRESSES: Send comments on any petition in triplicate to: Federal Aviation Administration, Office of Chief Counsel, attn: Rules Docket (AGC–200), Petition Docket No. _____, 800 Independence Avenue, SW., Washington, DC 20591.

FOR FURTHER INFORMATION CONTACT: Mr. Frederick M. Haynes, Office of Rulemaking (ARM–1), Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267–3939.

SUPPLEMENTARY INFORMATION: The Association of Air Medical Services and Helicopter Association International petition for exemption summary, published on page 1055 of the January 7, 1994, **Federal Register**, incorrectly stated the Docket No. as 27539. The correct Docket No. is 27491.

Issued in Washington, DC on January 21, 1994.

Donald P. Byrne,

Assistant Chief Counsel for Regulations.

[FR Doc. 94–1925 Filed 1–27–94; 8:45 am]

BILLING CODE 4910–13–M

Aviation Rulemaking Advisory Committee Meeting on Transport Airplane and Engine Issues

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of meeting.

SUMMARY: The FAA is issuing this notice to advise the public of a meeting of the Federal Aviation Administration's Aviation Rulemaking Advisory Committee to discuss transport airplane and engine issues.

DATES: The meeting will be held on February 16, 1994 at 8 a.m. Arrange for oral presentations by February 7, 1994.

ADDRESSES: The meeting will be held at Air Transport Association of America, 1301 Pennsylvania Ave., NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Lewis Lebakken, Office of Rulemaking, FAA, 800 Independence Avenue, SW., Washington, DC 20591, telephone (202) 267–9682.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463; 5 U.S.C. App. II), notice is given of a meeting of the Aviation Rulemaking Advisory Committee to be held on February 16, 1994 at Air Transport Association of America, 1301 Pennsylvania Ave., NW., Washington, DC. The agenda for the meeting will include:

- Opening Remarks.
- Review of Action Items.
- Reports of working groups.

Attendance is open to the interested public, but will be limited to the space available. The public must make arrangements by February 7, 1994, to present oral statements at the meeting. The public may present written statements to the committee at any time by providing 25 copies to the Assistant Executive Director for Transport Airplane and Engine Issues or by bringing the copies to him at the meeting. In addition, sign and oral interpretation can be made available at the meeting, as well as an assistive listening device, if requested 10 calendar days before the meeting. Arrangements may be made by contacting the person listed under the heading **FOR FURTHER INFORMATION CONTACT.**

Issued in Washington, DC, on January 19, 1994.

Chris A. Christie,

Executive Director, Aviation Rulemaking Advisory Committee.

[FR Doc. 94–1928 Filed 1–27–94; 8:45 am]

BILLING CODE 4910–13–M

Proposed Modification of the Houston, TX, Class B Airspace Area; Public Meeting

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of meeting.

SUMMARY: This notice is announcing a fact-finding informal airspace meeting to solicit information from airspace users and others concerning a proposal to modify the Class B airspace area at Houston, TX. The proposed Class B airspace area modification is in response to user suggestions for changes that would make the Class B airspace area design more efficient and user friendly. This airspace meeting is being held to provide interested parties an opportunity to present input on the proposed modification. All comments received during the meeting will be considered prior to any modification.

TIME AND DATE: The informal airspace meeting will be held on Tuesday, April 19, 1994, starting at 7 p.m. Comments must be received on or before June 17, 1994.

PLACE: San Jacinto Community College, Student Union Ballroom, 8060 Spencer Highway, Pasadena, TX 77505.

COMMENTS: Send or deliver comments on the proposal in triplicate to: Manager, Air Traffic Division, ASW–500, Federal Aviation Administration, 4400 Blue Mound Road, Fort Worth, TX 76193–0500

FOR FURTHER INFORMATION CONTACT: Craig Wooldridge, Assistant Manager, Airspace and Procedures, Houston Approach Control, telephone (713) 230–8400.

SUPPLEMENTARY INFORMATION:

Meeting Procedures

(a) The meeting will be informal in nature and will be conducted by a representative of the FAA Southwest Region. Representatives from the FAA will present a formal briefing on the proposed Class B airspace area modification. Each participant will be given an opportunity to deliver comments or make a presentation.

(b) The meeting will be open to all persons on a space-available basis. There will be no admission fee or other charge to attend and participate.

(c) Any person wishing to make a presentation to the FAA panel will be asked to sign in and estimate the amount of time needed for such presentation. This will permit the panel to allocate an appropriate amount of time for each presenter. The panel may allocate the time available for each presentation in order to accommodate all speakers. The meeting will not be adjourned until everyone on the list has had an opportunity to address the panel. The meeting may be adjourned at any time if all persons present have had the opportunity to speak.

(d) Position papers or other handout material relating to the substance of the meeting will be accepted. Participants wishing to submit handout material

should present three copies to the presiding officer.There should be additional copies of each handout available for other attendees.

(e) The meeting will not be formally recorded. However, a summary of the comments made at the meeting will be filed in the docket.

Agenda for the Meeting

Opening Remarks and Discussion of Meeting Procedures

Briefing on Background for Proposal

Public Presentations

Closing comments

Issued in Washington, DC, on January 13, 1994.

Willis C. Nelson,

Acting Manager, Airspace-Rules and Aeronautical Information Division.

[FR Doc. 94–1920 Filed 1–27–94; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF THE TREASURY

Fiscal Service

Renegotiation Board Interest Rate Prompt Payment Interest Rate Contracts Disputes Act

Although the Renegotiation Board is no longer in existence, other Federal Agencies are required to use interest rates computed under the criteria established by the Renegotiation Act of 1971 (P.L. 92–41). For example, the Contracts Disputes Act of 1978 (P.L. 95–563) and the Prompt Payment Act (P.L. 97–177) are required to calculate interest due on claims at a rate established by the Secretary of the Treasury pursuant to Public Law 92–41 (85 Stat. 97) for the Renegotiation Board (31 U.S.C. 3902).

Therefore, notice is hereby given that, pursuant to the above mentioned sections, the Secretary of the Treasury has determined that the rate of interest applicable for the purpose of said sections, for the period beginning January 1, 1994 and ending on June 30, 1994, is 5½ per centum per annum.

Dated: January 14, 1994.

Gerald Murphy,

Fiscal Assistant Secretary.

[FR Doc. 94–1787 Filed 1–27–94; 8:45 am]

BILLING CODE 4810–35–M

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

[Docket No. 301–91]

Request for Public Comment: Determination in Section 301 Investigation Concerning Acts, Policies and Practices of Brazil With Respect to Protection and Enforcement of Intellectual Property Rights

AGENCY: Office of the United States Trade Representative.

ACTION: Notice of request for written comment from interested persons.

SUMMARY: The United States Trade Representative ("USTR") is seeking further public comment on acts, policies and practices of the Government of Brazil concerning the protection and enforcement of intellectual property rights in that country. In particular, USTR seeks public comment on whether such acts, policies or practices are unreasonable and burden or restrict U.S. commerce, and if so, what responsive action, if any, should be taken pursuant to section 301 of the Trade Act of 1974, as amended (the "Trade Act").

DATES: Written comments of interested persons are due on or before Monday, February 28, 1994.

FOR FURTHER INFORMATION CONTACT: Jon Huenemann, Deputy Assistant USTR for Latin America and Caribbean Affairs (202) 395–5190, Joseph Papovich, Deputy Assistant USTR for Intellectual Property (202) 395–6864, or Thomas Robertson, Assistant General Counsel (202) 395–6800, Office of the United States Trade Representative.

SUPPLEMENTARY INFORMATION: On May 28, 1993, the USTR initiated an investigation of deficiencies in the acts, policies and practices of the Government of Brazil (Brazil) related to the denial of adequate and effective protection of intellectual property rights in Brazil. See 58 FR 31788 (June 4, 1993). Since that time, four rounds of bilateral discussions have been held to resolve these issues.

In the context of these discussions, the Government of Brazil indicated that it has undertaken and will undertake as part of its domestic reform efforts a number of actions to improve the protection of intellectual property in Brazil, and to provide greater market access for products relying on the protection of intellectual property. These include progress in the areas of protection for trademarks, semiconductor mask works (layout designs), and computer programs; market access for computer programs; and improvements in the enforcement of intellectual property rights, including efforts regarding the importation of pirated and counterfeit goods and the penalties of infringement of intellectual property rights.

However, additional issues remain to be resolved. These include, among other things, full implementation of the Uruguay Round Trade Related Aspects of Intellectual Property (TRIPs) text, most importantly with respect to patents, trade secrets, copyrights and semiconductor layout designs. The two governments are also discussing issues related to fair and equitable access to the Brazilian market for U.S. industries that rely on intellectual property protection.

The original deadline for determinations under section 304(a)(1) of the Trade Act with respect to the investigation was November 28, 1993. Because the issues that remained outstanding at that time were complex and required additional time for resolution, the deadline by which the determinations must be made was extended until February 28, 1994. See 58 FR 64351 (December 6, 1993). In accordance with section 304(b)(1)(A) of the Trade Act, USTR invites the presentation of views of interested persons concerning the foregoing determinations. In particular, USTR would like written comments on whether the Government of Brazil's acts, policies or practices with respect to the outstanding issues noted above are unreasonable and constitute a burden or restriction on U.S. commerce, and, if so, on what actions, if any, would be appropriate. The United States in the past has determined that removal of Generalized System of Preferences benefits and/or increased tariff rates are appropriate after a determination has been made that a trading partner fails to provide adequate protection and enforcement of intellectual property rights.

Requirements for Submissions

Comments must be filed in accordance with the requirements set forth in 15 CFR 2006.8(b) (55 FR 20593) and are due no later than Monday, February 28, 1994. Comments must be in English and provided in twenty copies to: Chairman, Section 301 Committee, room 223, USTR, 600 17th Street, NW., Washington, DC 20506.

Comments will be placed in a file (Docket 301–91) open to public inspection pursuant to 15 CFR 2006.13. Confidential business information submitted in accordance with 15 CFR 2006.15 must be clearly marked

"BUSINESS CONFIDENTIAL" in a contrasting color ink at the top of each page on each of the 20 copies, and must be accompanied by a nonconfidential summary of the confidential information. (Only the nonconfidential summary will be placed in the Docket.) The Docket will be available for public inspection in the USTR Reading Room (room 101), Office of the U.S. Trade Representative, 600 17th Street, NW., Washington, DC. An appointment to review the Docket may be made by calling Brenda Webb at (202) 395–6186. The USTR Reading Room is open to the public from 10 a.m. to 12 noon, and from 1 p.m. to 4 p.m., Monday through Friday (except holidays).

Irving Williamson,

Chairman, Section 301 Committee.

[FR Doc. 94–2080 Filed 1–27–94; 8:45 am]

BILLING CODE 3190–01–M

DEPARTMENT OF VETERANS AFFAIRS

Information Collection Under OMB Review: Notice of Default, VA Form 26–6850

AGENCY: Department of Veterans Affairs.

ACTION: Notice.

The Department of Veterans Affairs has submitted to OMB the following proposal for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35). This document lists the following information: (1) The title of the information collection, and the Department form number(s), if applicable; (2) a description of the need and its use; (3) who will be required or asked to respond; (4) an estimate of the total annual reporting hours, and recordkeeping burden, if applicable; (5) the estimated average burden hours per respondent; (6) the frequency of response; and (7) an estimated number of respondents.

ADDRESSES: Copies of the proposed information collection and supporting documents may be obtained from Janet G. Byers, Veterans Benefits Administration (20A5), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 233–3021.

Comments and questions about the items on the list should be directed to VA's OMB Desk Officer, Joseph Lackey, NEOB, room 3002, Washington, DC 20503, (202) 395–7316. Do not send requests for benefits to this address.

DATES: Comments on the information collection should be directed to the OMB Desk Officer within 30 days of this notice.

Dated: January 11, 1994.

By direction of the Secretary:

B. Michael Berger,

Director, Records Management Service.

Revision

1. Notice of Default, VA Form 26–6850
2. The form is used by holders of guaranteed or insured loans to notify VA of loans which are in default. The information is used by VA to determine the need for an extent of supplemental servicing to avoid foreclosure and claim under guaranty.
3. Businesses or other for-profit
4. 20,833 hours
5. 10 minutes
6. On occasion
7. 125,000 responses

[FR Doc. 94–1823 Filed 1–27–94; 8:45 am]

BILLING CODE 8320–01–M

Information Collection Under OMB Review: Application for Amounts on Deposit for Deceased Veterans, VA Form 21–6898

AGENCY: Department of Veterans Affairs.

ACTION: Notice.

The Department of Veterans Affairs has submitted to OMB the following proposal for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35). This document lists the following information: (1) The title of the information collection, and the Department form number(s), if applicable; (2) a description of the need and its use; (3) who will be required or asked to respond; (4) an estimate of the total annual reporting hours, and recordkeeping burden, if applicable; (5) the estimated average burden hours per respondent; (6) the frequency of response; and (7) an estimated number of respondents.

ADDRESSES: Copies of the proposed information collection and supporting documents may be obtained from Janet G. Byers, Veterans Benefits Administration (20A5), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 (202) 233–3021.

Comments and questions about the items on the list should be directed to VA's OMB Desk Officer, Joseph Lackey, NEOB, room 3002, Washington, DC 20503, (202) 395–7316. Do not send requests for benefits to this address.

DATES: Comments on the information collection should be directed to the OMB Desk Officer within 30 days of this notice.

Dated: January 11, 1994.

By direction of the Secretary.

B. Michael Berger,

Director, Records Management Service.

Revision

1. Application for Amounts on Deposit for Deceased Veterans, VA Form 21–6898
2. The form is used to gather the necessary information to determine who is the proper payee of gratuitous benefits deposited by VA into the Personal Funds of Patients for a veteran during hospitalization and due the veteran at the date of his or her death.
3. Individuals or households
4. 175 hours
5. 15 minutes
6. On occasion
7. 700 respondents

[FR Doc. 94–1824 Filed 1–27–94; 8:45 am]

BILLING CODE 8320–01–M

Information Collection Under OMB Review: Application and Enrollment Certification for Individualized Tutorial Assistance, VA Form 22–1990t

AGENCY: Department of Veterans Affairs.

ACTION: Notice.

The Department of Veterans Affairs has submitted to OMB the following proposal for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). This document lists the following information: (1) The title of the information collection, and the Department form number(s), if applicable; (2) a description of the need and its use; (3) who will be required or asked to respond; (4) an estimate of the total annual reporting hours, and recordkeeping burden, if applicable; (5) the estimated average burden hours per respondent; (6) the frequency of response; and (7) an estimated number of respondents.

ADDRESSES: Copies of the proposed information collection and supporting documents may be obtained from Janet G. Byers, Veterans Benefits Administration (20A5), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 (202) 233–3021.

Comments and questions about the items on the list should be directed to VA's OMB Desk Officer, Joseph Lackey, NEOB, room 3002, Washington, DC 20503, (202) 395–7316. Do not send requests for benefits to this address.

DATES: Comments on the information collection should be directed to the

OMB Desk Officer on or before February 28, 1994.

Dated: January 11, 1994.

By direction of the Secretary:

B. Michael Berger,

Director, Records Management Service.

Extension

1. Application and Enrollment Certification for Individual Tutorial Assistance, VA Form 22–1990t
2. The form is used by students who are receiving VA educational assistance and who require tutoring to overcome a deficiency in one or more courses. The information is used by VA to determine if the veteran or eligible person is entitled to the benefit.
3. Individuals or households—State or local governments—Businesses or other for-profit—Non-profit institutions
4. 2,333 hours
5. 35 minutes
6. On occasion
7. 2,000 respondents

[FR Doc. 94–1825 Filed 1–27–94; 8:45 am]

BILLING CODE 8320–01–M

Veterans' Advisory Committee on Environmental Hazards; Charter Renewal

This gives notice under the Federal Advisory Committee Act (Pub. L. 92–463) of October 6, 1972, that the Department of Veterans Affairs Veterans' Advisory Committee on Environmental Hazards has been renewed for a 2-year period beginning January 12, 1994, through January 12, 1996.

Dated: January 14, 1993.

By direction of the Secretary:

Heyward Bannister,

Committee Management Officer.

[FR Doc. 94–1822 Filed 1–27–94; 8:45 am]

BILLING CODE 8320–01–M

Sunshine Act Meetings

Federal Register
Vol. 59, No. 19
Friday, January 28, 1994

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

DATE AND TIME: February 8, 1994, 2:00 p.m. (Eastern Time).

PLACE: Conference room on the Ninth Floor of the EEOC Office Building, 1801 "L" Street, N.W., Washington, D.C. 20507.

STATUS: Part of the Meeting will be open to the public and part of the Meeting will be closed.

MATTERS TO BE CONSIDERED:

Open Session

1. Announcement of Notation Votes.
2. Reports to the Commission—Office of Federal Operations and Office of Program Operations.

Closed Session

Litigation Authorization: General Counsel Recommendations.

Note: Any matter not discussed or concluded may be carried over to a later meeting. (In addition to publishing notices on EEOC Commission meetings in the **Federal Register**, the Commission also provides a recorded announcement a full week in advance on future Commission sessions.) Please telephone (202) 663–7100 (voice) and (202) 663–4077 (TTD) at any time for information on these meetings.

CONTACT PERSON FOR MORE INFORMATION: Frances M. Hart, Executive Officer on (202) 663–4070.

Dated: January 25, 1994.

Frances M. Hart,

Executive Officer, Executive Secretariat.

[FR Doc. 94–2072 Filed 1–26–94; 1:24 pm]

BILLING CODE 6750–06–M

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

TIME AND DATE: 10:00 a.m., Thursday, January 27, 1994.

PLACE: 11th Floor, 1730 K Street, N.W., Washington, DC.

STATUS: Open.

MATTERS TO BE CONSIDERED: The Commission will consider and act upon the following:

1. *W. J. Bokus Industries, Inc.*, Docket No. YORK 92–106–M, etc. (issues include whether the judge erred in finding that certain items of equipment were not subject to the jurisdiction of the Federal Mine Safety and Health Act of 1977, 30 U.S.C. § 801 et seq.)

A meeting on this matter previously scheduled for January 20, 1994, was cancelled due to a snow emergency. It was determined by the Commission that no earlier announcement of this rescheduled meeting was possible.

Any person attending this meeting who requires special accessibility features and/or auxiliary aids, such as sign language interpreters, must inform the Commission in advance of those needs. Subject to 29 CFR 2706.150(a)(3) and 2706.160(e).

CONTACT PERSON FOR MORE INFORMATION: Jean Ellen (202) 653–5629/(202) 708–9300 for TDD Relay/1–800–877–8339 for toll free.

Dated: January 24, 1994.

Jean H. Ellen,

Chief Docket Clerk.

[FR Doc. 94–2071 Filed 1–26–94; 1:24 pm]

BILLING CODE 6735–01–M

BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

TIME AND DATE: 12:00 noon, Wednesday, February 2, 1994.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, N.W., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452–3204. You may call (202) 452–3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: January 25, 1994.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 94–2024 Filed 1–26–94; 9:03 am]

BILLING CODE 6210–01–P

BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: 59 FR 3649, January 25, 1994.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: 11:00 a.m., Monday, January 31, 1994.

CHANGES IN THE MEETING: Addition of the following closed item(s) to the meeting:

Proposed acquisition of disk equipment within the Federal Reserve System.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452–3204.

Dated: January 25, 1994.

Jennifer J. Johnson,

Associate Secretary of the Board.

FR Doc. 94–2025 Filed 1–26–94; 9:03 am]

BILLING CODE 6210–01–P

UNITED STATES POSTAL SERVICE BOARD OF GOVERNORS

The Board of Governors of the United States Postal Service, pursuant to its Bylaws (39 C.F.R. Section 7.5) and the Government in the Sunshine Act (5 U.S.C. Section 552b), hereby gives notice that it intends to hold a meeting at 10:00 a.m. on Monday, February 7, 1994, and at 9:00 a.m. on Tuesday, February 8, 1994, in Sacramento, California. The February 7 meeting, at which the Board will discuss preparations for the rate case filing (See 59 FR 1590, January 11, 1994) is closed to the public.

The February 8 meeting is open to the public and will be held at the Red Lion Hotel, 2001 Point West Way, in the Oak section of the Redwood Ballroom. The Board expects to discuss the matters stated in the agenda which is set forth below. Requests for information about the meeting should be addressed to the Secretary for the Board, David F. Harris, at (202) 268–4800.

Agenda

Monday Session

February 7–10:00 a.m. (Closed)

1. Consideration of Rate Case Filing. (Messrs. Riley, Porras, Heselton, Foucheaux and Mses. Elcano and Sonnenberg)

Tuesday Session

February 8–9:00 a.m. (Open)

1. Minutes of the Previous Meeting, January 3–4, 1994.
2. Remarks of the Postmaster General/Chief Executive Officer. (Marvin Runyon)
3. Appointment of Board Committee Members. (Sam Winters, Chairman of the Board)
4. Quarterly Report on Service Performance. (Ann McK. Robinson, Vice President, Consumer Advocate)
5. Quarterly Report on Financial Performance. (Michael J. Riley, Chief Financial Officer and Senior Vice President, Finance)
6. Report on the Sacramento, California, District. (Arthur I. Montoya, District Manager, Customer Service and Sales, and Kathie Hawley, Plant Manager, Sacramento, P&DC)
7. Capital Investment. (Peter A. Jacobson, Senior Vice President, Processing and Distribution)
   a. Truck Tractors and Spotters
8. Tentative Agenda for the March 7–8, 1994, meeting in Washington, D.C.

David F. Harris,

Secretary.

[FR Doc. 94–2101 Filed 1–26–94; 3:19 pm]

BILLING CODE 7710–12–M

Corrections

Federal Register
Vol. 59, No. 19
Friday, January 28, 1994

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 33

[Docket No. 93-ANE 68; Notice No. 33-ANE-07]

Special Conditions; Pratt & Whitney Model(s) PW4073, PW4084, and PW4088 Turbofan Engines

Correction

In proposed rule document 93-31754 beginning on page 68784 in the issue of Wednesday, December 29, 1993, the Docket number should appear as set forth above.

BILLING CODE 1505-01-D

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 8500]

RIN 1545-AG98

Allocations Reflecting Built-in Gain or Loss on Property Contributed to a Partnership

Correction

In rule document 93-31004 beginning on page 67676 in the issue of Wednesday, December 22, 1993, make the following corrections:

§ 1.704-3 [Corrected]

1. On page 67682, in § 1.704-3(c)(4), *Example 1*(i), in the table, in the second column, in the last line, remove "$".

2. On page 67683, in the first column, in § 1.704-3(c)(4), *Example 3*(i), in the second line, "1J and K form" should read "J and K form".

BILLING CODE 1505-01-D

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 40, 48 and 602

[T.D. 8496]
RIN 2545-AS13

Diesel Fuel Excise Tax; Registration Requirements Relating to Gasoline and Diesel Fuel Excise Tax

Correction

In rule document 93-28647 beginning on page 63069 in the issue of Tuesday, November 30, 1993, make the following corrections:

1. On page 63071, in the second column, in the third full paragraph, in the fifth line, "Credits and payments." should read "*Credits and payments.*" and should appear as a separate paragraph.

§ 48.4082-3T [Corrected]

2. On page 63074, in the first column, in the heading of § 48.4082-3T, in the first line, insert "fuel" after "Diesel".

BILLING CODE 1505-01-D

federal register

Friday
January 28, 1994

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 123 and 1240

Proposal To Establish Procedures for the Safe Processing and Importing of Fish and Fishery Products; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 123 and 1240

[Docket Nos. 90N–0199 and 93N–0195]

Proposal To Establish Procedures for the Safe Processing and Importing of Fish and Fishery Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to adopt regulations to ensure the safe processing and importing of fish and fishery products (hereinafter referred to as seafood). These procedures include the monitoring of selected processes in accordance with Hazard Analysis Critical Control Point (HACCP) principles. HACCP is a preventive system of hazard control that can be used by food processors and importers. FDA is proposing these regulations because a system of preventive controls is the most effective and efficient way to ensure that these products are safe.

DATES: Written comments by March 29, 1994. The agency is proposing that any final rule that may be issued based upon this proposal become effective 1 year following its publication.

ADDRESSES: Written comments, data, or information to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Philip Spiller, Center for Food Safety and Applied Nutrition (HFS–401), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–254–3885.

For further information concerning the guidance entitled "Fish and Fishery Products Hazards and Controls Guide," contact: Donald W. Kraemer (address above).

For further information concerning the economic impact analysis contained in this proposal, contact: Richard A. Williams, Jr., Center for Food Safety and Applied Nutrition (HFS–726), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5271.

SUPPLEMENTARY INFORMATION:

I. Overview

The purpose of these proposed regulations is to establish mandatory preventive controls to ensure the safety of seafood products sold commercially in the United States and exported abroad. These preventive controls will be based on a system known as HACCP. HACCP is a system by which food processors and importers can evaluate the kinds of hazards that could affect their products, institute controls necessary to keep these hazards from occurring, monitor the performance of these controls, and maintain records of this monitoring as a matter of routine practice.

FDA is proposing to require that domestic and foreign processors and importers adopt HACCP controls to prevent the occurrence of hazards that could affect the safety of these seafood products for consumers. If these regulations are adopted, FDA will review the adequacy of HACCP controls as part of its program of mandatory inspections and import examinations. Such a review will occur in addition to traditional inspection activities. FDA is also encouraging, but not proposing to require, that processors and importers adopt the same types of controls for nonsafety hazards relating to economic adulteration and quality.

FDA is proposing to make HACCP mandatory for the seafood industry for the following reasons:

1. Adoption of HACCP controls by the seafood industry, coupled with inspections by FDA based on the HACCP system, will produce a more effective and more efficient system for ensuring the safety of seafood products than currently exists. The current inspection system places too great a burden on Government inspectors to uncover problems and to take regulatory action to address those problems. HACCP places primary responsibility upon the industry to demonstrate that hazards are understood and are being prevented.

2. A nationally mandated HACCP system will provide a basis for enhanced consumer confidence in the safety of seafood products. Consumers should not be afraid to eat foods, such as seafood, that are recommended as useful lower fat and lower saturated fat substitutes for higher fat meats (Ref. 1, p. 13; Ref. 2, p. 21).

3. The know-how for applying HACCP to seafood is in an advanced state of development. A considerable amount of work on applying HACCP to seafood has already been done by some States, academia, and the Federal Government as well as through cooperative activities between the Federal Government and industry and through independent industry efforts.

4. Seafood industry representatives have urged the Federal Government to institute a mandatory, HACCP-type inspection system for their products.

5. A nationally mandated HACCP-type system of controls appears to be a prerequisite for continued access to world markets.

II. Safety

A. Background

Ensuring the safety of seafood presents special challenges to both the industry that produces it and to Government agencies charged with protecting the public health. Seafood is unique in many respects. While often thought of as homogeneous in nature, seafood is actually a variety of products encompassing literally hundreds of species that have little in common other than an aquatic origin. Collectively, seafoods have perhaps the most diverse and complex microbiology of any food commodity (Ref. 3, p. xi).

The range of habitats for edible species is also extraordinary and diverse ranging from cold to warm water, bottom dwelling to surface feeding, deep sea to near shore, and fresh water to saltwater. Fish are exposed to the bacteria and viruses that naturally occur in their environment as well as to those that enter the water through pollution. Chemicals, some of which are toxic to humans, can accumulate in fish as well. Fish can also accumulate natural toxins and parasites that are specific to marine animals. As a consequence, fish are subject to a wide range of hazards before harvest.

B. The Safety Data

The question of how safe is the seafood in the marketplace has been the subject of public debate in recent years. This debate has occurred partly because precise data on the numbers and causes of foodborne illnesses in the United States do not exist. Foodborne illnesses tend to be significantly underreported to public health authorities. Data on foodborne illnesses that are meaningful from an epidemiological standpoint are difficult and expensive to develop.

The Centers for Disease Control and Prevention (CDCP) of the U.S. Public Health Service (PHS) compiles data in its Foodborne Disease Surveillance System that are reported from State and local health authorities. All foodborne illnesses are underreported to this system (Ref. 4).

Nonetheless, CDCP data are the best available and can at least be used to identify trends and emerging concerns about various diseases (Ref. 5, p. 219). The data suggest that most seafood-related illnesses result from certain natural toxins in finfish and from viruses in molluscan shellfish consumed raw or partially cooked (Ref.

4). The wide range of other hazards that can affect seafood undoubtedly result in illnesses, but the available data indicate that such illnesses are not as common. Thus, according to the CDCP data, the actual occurrence of problems tends to be limited relative to the range of hazards that could cause problems and tends to be associated with a minority of commercially available species.

In the CDCP system, seafood accounted for 4.8 percent of reported cases of foodborne illness for the period 1973 to 1987 (Ref. 4). However, as CDCP has pointed out, variations in rates of underreporting among different foods and varying etiologies make it impossible to compare safety among different foods based solely on CDCP data (Ref. 4). This is certainly true for seafood. Some seafood-related illnesses tend to be overreported to CDCP's system relative to other foodborne diseases, due largely to their distinctive characteristics, while others are probably underreported relative to other causes because they are less distinctive and more difficult to diagnose (Ref. 4).

FDA has attempted to determine the relative safety of seafood through risk assessment. The results of this effort indicate that the risk of illness associated with molluscan shellfish consumed raw or partially cooked is greater than for any cooked flesh food. However, seafood overall is as safe or safer than other flesh foods in terms of frequency of illness (Refs. 5, p. 25; and 6).

The conclusions of the National Academy of Sciences' (NAS) Institute of Medicine, in its 1991 report entitled "Seafood Safety," are consistent with the CDCP data and the FDA risk assessment. According to NAS, "Most seafoods available to the U.S. public are wholesome and unlikely to cause illness in the consumer" (Ref. 7, p. 1). Moreover, in reviewing the CDCP data, the report noted that the 23 percent increase in seafood consumption in the United States in the 10-year period ending 1989 was not accompanied by a concomitant increase in reported seafood-borne illnesses (Ref. 7, p. 27). Nevertheless, as NAS pointed out, "there are areas of risk" (Ref. 7, p. 1). The report addressed at some length virtually every possible risk that could affect seafood and made numerous recommendations relating to existing and proposed control measures. NAS recommended that improvements be made in the present system of regulatory control (Ref. 7, p. 1) and repeatedly recommended HACCP controls wherever appropriate. "Inspection and testing should focus on actual problems (as in HACCP systems)," NAS concluded (Ref. 7, p. 16).

C. The Principal Hazards

The most notable seafood-related hazards involve the following:

1. Bacteria

Because bacteria either naturally live in, or can survive in, aquatic habitats, there are a large number of pathogenic bacteria that can be found in seafood, particularly molluscan shellfish. Many of these bacteria are far more harmful to specific human subpopulations, such as the elderly, immunocompromised, or persons with specific underlying diseases, than to the population as a whole. The size of these subpopulations is increasing, however. Therefore, concerns about bacterial contamination of seafood, particularly molluscan shellfish, are increasing.

In the United States, 4.4 percent of botulism outbreaks have been attributed to seafood. The predominant type of botulism organism in aquatic environments is the kind most readily destroyed by heat. Thus, many types of processing, if done properly, can negate the risk of botulism from seafood. Nonetheless, with the trend toward greater use of modified atmosphere and vacuum packaging (i.e., packaging that excludes oxygen) to enhance the shelf life and the desirability of refrigerated foods, traditional controls need to be enhanced because *Clostridium botulinum* can grow in the absence of oxygen.

Other bacteria of concern include *Listeria monocytogenes*, a hazardous foodborne microorganism that is ubiquitous in nature and is commonly found in food processing environments; *Salmonella*, which is not a marine organism but can contaminate seafood through improper handling and sanitation practices; and *Staphylococcus aureus*, another pathogen associated with sanitation and handling (Ref. 8, pp. 14 and 15).

2. Viruses

Several viruses that are infectious to humans enter aquatic habitats through sewage. These viruses can concentrate in shellfish and be present and infective even when bacterial indicators of fecal pollution are absent. Viruses probably cause the bulk of seafood-associated disease, particularly the Norwalk and Norwalk-like agents, which are linked to the consumption of contaminated raw or undercooked molluscan shellfish (Ref. 7, p. 30).

3. Natural Toxins

Problems associated with naturally occurring toxins in fish have been recognized for centuries. Ciguatera poisoning is perhaps the most significant problem associated with a natural toxin. The toxin is produced by microscopic organisms and can be transmitted to humans through the consumption of finfish that have eaten these organisms through the food chain (Ref. 7, p. 89). The larger, more predacious fish (groupers, snappers, barracuda, amberjack) and reef fish belonging to the crevally or ulua (Carangidae) family are generally more likely to contain ciguatoxin than other types of fish (Ref. 7, p. 89). Because the toxin is heat stable, cooking does not make the fish safe to eat (Ref. 9, p. 1).

On average, 70 cases of ciguatera poisoning are reported annually in the United States and its possessions and territories (Ref. 7, p. 89). Deaths are rare, and the acute symptoms of the disease are usually of short duration; however, neurological symptoms can persist for extended periods. Ciguatera is geographically localized, with the majority of illnesses reported from tropical or subtropical areas.

Other toxins of public health concern include domoic acid, which was detected in seafood from the U.S. Pacific coast for the first time in the fall and winter of 1991–1992 (Ref. 10, p. 1,113); and saxitoxin, or paralytic shellfish poison, which has periodically made molluscan bivalves toxic and has recently affected Pacific Northwest crab harvests (Ref. 11).

4. Parasites

Parasites, such as anasakid nematodes (round worms), naturally infect certain fish and ocean mammals (Ref. 12, p. 724). Human parasitic infections almost always occur from the consumption of raw (sushi, sashimi) or undercooked fish. Historically, probably no more than five cases are reported on average in the United States each year and the likelihood of occurrence is estimated to be very low (Ref. 5, p. 25). Problems with parasites are avoidable through commercial freezing of the raw fish before consumption.

5. Chemical Contaminants

The presence of toxic chemicals in the aquatic environment creates the potential for contamination of seafood products. These chemicals include pesticides; other industrial chemicals, such as polychlorinated biphenyls; heavy metals, such as lead, cadmium, and mercury; and petroleum hydrocarbons.

Marine species, especially deep sea varieties, comprise the majority of seafood consumed in this country. This seafood has little potential to contain most chemical contaminants at levels of toxicological concern (Ref. 13, p. 6). However, there are some contaminants that can be present at significant levels, methylmercury in certain species being perhaps the most notable. Fresh water species, especially nonmigratory bottom feeders, are generally the most exposed to a variety of chemical contaminants (Ref. 13, p. 6).

6. Decomposition

Finfish are generally regarded as being much more perishable than terrestrial flesh foods (Ref. 14, p. 3). Decomposition is a problem with seafood products frequently encountered by FDA and is the subject of the majority of regulatory actions taken by the agency against violative seafood products (Ref. 15). It is largely an economic and aesthetic problem; however, in some species it can lead to illness because of the formation of scombrotoxin (histamine) during decomposition. Scombroid poisoning is completely preventable by proper handling, i.e., by proper time and temperature controls.

D. Additional Factors Affecting Safety

Unlike beef and poultry, seafood is still predominately a wild-caught flesh food that frequently must be harvested under difficult conditions and at varying distances from processing, transport, and retail facilities. There are nearly 100,000 vessels in the U.S. fishing fleet alone (Ref. 7, p. 22). These conditions, distances, and duration of fishing trips, can tax any system of controls designed to ensure safety and prevent spoilage.

In addition, several hundred vessels are seagoing processing factories, many of which operate in remote waters. For regulators, these ships that process at sea can be difficult and expensive to reach while they are operating, and individual inspectors face hazards such as ship-to-ship transfers on the high seas.

There may be as many as 350 commercially marketed species (Refs. 16; and 19, p. 35). Consumer preferences for one species over another and significant price differences between species can lead to economic fraud through the substitution of cheaper species for more expensive ones.

Unlike beef and poultry, seafood is subject to significant recreational harvest. Beyond the 15 pounds of seafood consumed per capita from commercial channels, an additional 4 pounds may be consumed from recreational sources. Some recreational catch finds its way into commercial channels as well.

Thus, recreational fishing can have a bearing on the safety of commercial seafood. Commercial fishermen avoid or are prohibited from harvesting from polluted areas, but recreational fishermen, especially recreational harvesters of molluscan shellfish, might not be as aware of, or might ignore, local advisories or water closures. Processors need to be aware of and control the source of their raw materials, and importers must ensure that their shipments are obtained from acceptable sources.

An additional complicating factor in ensuring the safety of seafood is the fact that no other flesh food is imported in the quantity, or from as many countries, as seafood. Imports include finished products as well as products to be further processed domestically. Over 55 percent of seafood consumed in this country is imported. It comes from approximately 135 countries. Several of these countries have advance regulatory structures for seafood safety, but many others are developing nations that lack structures for seafood regulation comparable to those in more developed nations (Ref. 35, pp. 113 and 114).

Therefore, it is of utmost importance, that those who handle and process seafood commercially, including importers, understand the hazards associated with this type of food, know which hazards are associated with the types of products with which they are involved, and keep these hazards from occurring through a routine system of preventive controls. The seafood industry, indeed, the food industry as a whole, must be primarily responsible for the safety and quality of the food that it produces. The regulator's primary role should be to verify that the industry is meeting this responsibility and to take remedial action when it is not. The alternative of relying solely on Government inspectors to identify problems and provide solutions would involve enormous costs to the public and would be extremely inefficient, assuming it could be done at all.

For the most part, seafood processors and importers are not required, through licensure or examination, to understand seafood hazards as a prerequisite to being able to do business. (There are exceptions. A few States, such as Alaska, do require processors to conform to HACCP as a condition of doing business (Ref. 17).) While many processors and importers have such an understanding, this knowledge is not universal. It is not unusual for FDA to receive inquiries about safety requirements and related matters from those who wish to process or import seafood, or who already do, that indicate a lack of awareness of hazards specific to their products. Most of the industry does not have HACCP-trained personnel, and many firms lack dedicated quality assurance personnel (Ref. 18, p. 35).

Seafood processing in the United States is done by several thousand businesses, many of which are small, old, and family operated (Ref. 19, p. 35). This situation is in contrast to the beef and poultry industries, in which market share is concentrated among a small number of large processors. Seafood firms tend to be small, fragmented operations sized in reference to anticipated benefits, because of the significant, uncontrollable risks involved in this business (Ref. 5, p. 225). Also, because many harvests are seasonal, many of their operations are intermittent (Ref. 20). The seasonal nature of the industry can affect worker skills and practices relating to safety, while older facilities and equipment can be more difficult to maintain in terms of adequate sanitation and proper processing and storage temperatures (Ref. 20).

III. The Need for Regulations

A. The Current Inspection System Is Not Well-Suited to Seafood

Seafood processors are subject to periodic, unannounced, mandatory inspection by FDA. Seafood processors and importers are also able to purchase inspection services from the National Marine Fisheries Service (NMFS) of the U.S. Department of Commerce. These inspection services have been primarily trade-related, such as grading.

Until recently, FDA's overall regulatory program for seafood received slightly over $20 million per year. Because much of the program involves activities such as research, laboratory analyses, and technical assistance and training to States, a substantial portion of it has tended to be invisible to the general public. Public interest and debate tends to focus on the more visible aspects of regulation, primarily inspection. The congressional debate of the past several years over the adequacy of the Federal regulatory program for seafood has been framed, more often than not, in terms of the need for mandatory inspection. Traditionally, FDA inspected the equivalent of a quarter of its total domestic inventory of seafood establishments per year.

Since 1990, however, FDA has received significant funding increases for seafood. The current budget of slightly over $40 million has permitted the agency to increase the frequency of its inspections. It now inspects so-called high risk processors at least once per year and all others at least biennially. (Because States also inspect processors, the collective frequency is actually higher.)

Even so, because of seafood's unique characteristics (e.g., the fact that it is predominantly wild caught and presents a wide range of possible hazards), it is questionable whether the current regulatory system, which was developed for the general food supply, is best suited for the seafood industry. The current system provides the agency with a "snapshot" of conditions at a facility at the moment of the inspection. However, assumptions must be made about conditions before and after that inspection on the basis of the "snapshot," as well as about important factors beyond the facility that have a bearing on the safety of the finished product. The reliability of these assumptions over the intervals between inspections creates questions about the adequacy of the system, particularly, as the congressional hearings on the subject over the past several years have shown, for seafood.

FDA's inspections are based upon the regulations on current good manufacturing practice in manufacturing, packing, or holding human food at part 110 (21 CFR part 110). For the most part, these guidelines consist of broad statements of general applicability to all food processing on sanitation, facilities, equipment and utensils, processes, and controls. HACCP-type controls are listed as one of several options available to prevent food contamination (§ 110.80(b)(13)(i)) but they are otherwise not integral to the guidelines.

Current Federal inspection and surveillance strategies verify the industry's knowledge of hazards and preventive control measures largely by inference, i.e., whether a company's products are in fact adulterated, or whether conditions in a plant are consistent with current good manufacturing practice (CGMP). Consequently, the current system places the burden on the Government to prove that a problem exists rather than on the firm to establish for itself, for the regulator, and for consumers, that adequate controls exist to ensure safety. The current approach is inefficient and, unless Government inspections are conducted with some frequency, can lead to conditions that can elevate risk and erode public confidence. It also has the potential to cause some inequities. While the same standards of adulteration apply to all products in interstate commerce, processors and importers who use a system of preventive controls coupled with adequate monitoring must compete against those who do not.

A survey conducted by FDA in 1992–1993 of manufacturers of ready-to-eat seafood products revealed conditions that strongly suggest the need for a system that emphasizes preventive controls to ensure that products are safe by design. Ready-to-eat products require special care in processing because they do not require, and are unlikely to receive, any further cooking by consumers that would destroy pathogenic microorganisms. The survey focused on whether preventive controls exist rather than on the results of expensive end-product sampling. The agency found that, in significant measure, firms have not been employing the types of preventive processing steps necessary to ensure a safe and wholesome product. Some of the preliminary results are as follows (Ref. 21).

1. Fifty-four percent of the firms that pasteurized products had not established the adequacy of their pasteurization process to destroy pathogenic microorganisms such as the spores of *C. botulinum*, type E, which can cause significant illness and death in humans. The pasteurization process is not simple and must be done with precision in order to consistently deliver a thermal process that will inactivate the spores of *C. botulinum*, type E and prevent recontamination of the product after it has been heat treated. The CGMP at part 110 state that pasteurization must be adequate. Realistically, the only way for FDA to determine, or at least infer, the adequacy of the process now is to analyze samples of finished product for the presence of pathogens.

2. Twenty-seven percent of the firms that pasteurized products did not have temperature-indicating devices on their pasteurizers, and 35 percent did not have temperature-recording devices. Temperature monitoring is essential to ensure that a thermal process is properly controlled. Part 110 addresses temperature indicating and recording devices only for refrigeration, while pasteurization involves cooking. A temperature-recording device is important for purposes of preventive control because it provides a continuous history of the cooking step.

3. Forty-two percent of firms that pasteurized products did not perform can seam evaluations or performed them less frequently than every 12 hours. Such evaluations are necessary to ensure that there will not be microbiological contamination of the finished pasteurized product. FDA's regulations for the processing of low acid canned food (parts 108 and 113 (21 CFR parts 108 and 113)) require such evaluations every 4 hours as an HACCP-type control, but products that need refrigeration (e.g., pasteurized products) are outside the scope of those regulations. Again, part 110 states only that the pasteurization process should be adequate. FDA must conduct end-product sampling and analysis to determine, or at least infer, whether a pasteurization process is adequate.

4. Forty-three percent of firms that pasteurized products did not perform cooling water sanitizer strength checks to ensure that the pasteurized product would not be contaminated during this process. The presence of a sanitizer in the cooling water is important to prevent contamination of the product after pasteurization because during cooling, some water can be drawn into hot cans. Part 110 does not specifically mention a cooling water sanitizer. The "adequate" provision cited above is the closest relevant provision, and FDA must conduct end-product sampling and analysis to determine, or at least infer, whether a pasteurization process is adequate.

5. Eighty-four percent of the firms did not monitor the internal temperature of products during the various stages of processing. Such monitoring is important because time/temperature abuse can result in the growth of pathogenic microorganisms, decomposition, and, in some cases, the formation of histamine. Part 110 states that all reasonable precautions should be taken to prevent contamination and recommends temperature control as one type of precaution. Again, end-product sampling is the only practical way for FDA to measure compliance.

6. Fourteen percent of the firms did not have temperature-indicating devices on their finished product coolers, and 89 percent did not have temperature-recording devices. Part 110 states that processors should have one or the other but does not specifically require that processors monitor either one. While 14 percent were out of compliance, most who were in compliance opted for the control that did not provide a continuous record.

7. Thirty-one percent of the temperature-indicating devices on finished product coolers were more than 5 °F out of adjustment. Fifty-five percent of these were giving readings that were

too low. For these, the deviation would permit the growth of pathogenic microorganisms, decomposition, and histamine formation. Part 110 specifically states that thermometers should be accurate. Five degree deviations are clearly out of compliance. A significant percentage of firms surveyed were not paying attention to a significant preventive control.

8. Twenty-three percent of temperature-indicating devices on pasteurizers and 80 percent of such devices on finished product coolers were never calibrated. Again, part 110 calls for accuracy. The failure to calibrate means that these firms have no assurance that their devices are accurate. A preventive control is not being applied, and thus a significant percentage of processors are apparently relying on Government investigators to determine accuracy during inspections. Also, this deficiency may account in part for the deviations described in section III.A.7. of this document.

9. Twenty-nine percent of temperature-recording devices on finished product coolers were never checked for accuracy, while 34 percent of such devices on pasteurizers and 74 percent on finished product coolers were checked less frequently than once a month. Temperature-recording devices are easily jarred out of calibration and must be routinely adjusted to agree with an accurate temperature-indicating device. Thus, they need to be checked for accuracy at least at the start and the end of each processing day in order to determine whether they remained accurate throughout the day's production.

10. Forty-eight percent of the firms cleaned and sanitized the processing equipment less frequently than every 4 hours, while 13 percent cleaned and sanitized less than every 12 hours. Part 110 states that sanitation practices should occur as frequently as necessary. In order to control salmonella and other undesirable bacteria within a facility, the frequency should be at least every 4 hours, and more frequently if feasible. This frequency helps reduce the likelihood that these microorganisms will enter a rapid phase of growth during which their numbers increase logarithmically (Ref. 22, p. 114; Ref. 23, p. 2).

11. Twenty-two percent of the firms did not perform plant or equipment sanitation audits (i.e., inspections), and 35 percent did not check the strength of hand or equipment sanitizing solutions. These results reveal that a significant number of plants are not checking up on themselves to ensure that they were doing an adequate job of sanitation. In such plants, the only check on sanitation is provided by the Government investigators who visit the plant.

Other survey and inspection findings by FDA and others strongly indicate that the seafood industry does not always operate on the basis of preventive controls. For example, recent FDA and State surveys showed that many processors of smoked and smoke-flavored fish are operating outside of the parameters that have been demonstrated through scientific research to be necessary to ensure that the hazard from botulism is adequately controlled. These parameters are process times and temperatures and salinity levels. A number of firms surveyed did not even know their own operating parameters, let alone the scientifically established ones (Refs. 24, 25, and 26). For seafood products such as these that require no cooking by the consumer, preventive measures by the processor to eliminate *C. botulinum*, type E to the maximum extent possible are critically important.

B. Alternatives Other Than HACCP

Continuous visual inspection of seafood is not a viable alternative. Few hazards associated with seafood are detectable through visual inspection. Moreover, the costs of such a system would likely exceed the nearly half-billion-dollar public outlay now required to operate this kind of system for meat and poultry.

Another alternative would be to direct significant additional resources toward greatly increasing the frequency of FDA's inspection of seafood, as well as increasing the agency's sampling, laboratory analysis, and related regulatory activities with respect to seafood. While thousands of samples of domestic and imported seafood products are collected each year for analysis in FDA laboratories, and these samples are scientifically designed to represent a broad range of products, they are generally perceived by the public to represent only a small fraction of the total poundage of seafood consumed in this country. Substantial new expenditures would be needed to increase laboratory analyses to nationally statistically significant levels.

Even if the funds for increased inspection and increased sampling and analysis were available (which they are not), this approach alone would likely not be the best way for the agency to spend its money to protect the public health. Reliance on end-product testing involves a certain amount of inefficiency that can require very large sample sizes to overcome. NAS recently observed that "the statistical uncertainties associated with lot sampling make this an unreliable method for ensuring safety of food products * * *" (Ref. 7, p. 283). FDA has traditionally sought to minimize this type of inefficiency by targeting its efforts based on its experiences, but some inefficiency is unavoidable. NAS recommended the HACCP system as an alternative (Ref. 7, p. 283).

C. Current Import System Is Not Well-Suited to Seafood

Similar considerations apply to imports. FDA does not generally inspect processing facilities in other countries to determine whether seafood products are being prepared, packed, or held there under appropriate conditions. Such inspections are extremely costly and require an invitation from the foreign country. Traditionally, therefore, FDA's primary strategy for seafood imports has involved: (1) Reviewing all customs entries documents to determine which imported products to examine or sample; (2) conducting wharf examinations of selected products based on that review; and (3) sampling and laboratory analyses as appropriate.

One concern about this process that has been voiced with some regularity in the media, Congress, and elsewhere is that FDA physically looks at less than 5 percent of all imports. This figure is somewhat misleading because it refers to seafood lots that can vary substantially in size. Also, it does not take into account such factors as the representative nature of the examinations, FDA's automatic detention program for imports that requires importers of products with a history of problems to obtain a laboratory analysis and certification prior to entry, or the fact that imports receiving further processing in the United States become subject to domestic inspection. Nonetheless, it is certainly true that most imported seafood is not physically sampled or examined by a Federal health official.

The total number of customs entries for seafood each year is approaching 200,000 (Ref. 27) from about 135 countries (compared to about 33 countries for beef and poultry (Ref. 28)), and huge sums of money would be needed to enable FDA to increase its physical examination and sampling program to nationally, statistically significant levels. Still, many developing countries export seafood products to this country, and their regulatory protections tend to be comparatively weak, if they exist at all. Processing conditions in such countries do not always meet U.S. standards for sanitation.

While many importers are conscientious about the safety and quality of the products that they import, others have little understanding of potential hazards. The denial of entry of a violative lot may be regarded as simply a cost of doing business, which is offset in many cases by insurance purchased against just such an eventuality. Such policies are identified as "'FDA rejection' insurance" and usually the premium is 2 to 3 percent of the value of the shipment (Ref. 29). It is reasonable to assume that this cost is being passed on to the consumer. The insurance also permits importers to buy seafood from foreign processors without first ensuring that it meets FDA requirements, i.e., that it is safe, wholesome, and properly labeled.

This system leaves much to be desired. It, too, is a "snapshot"-type approach that places a significant burden on the Government to uncover problems without fostering or promoting industry responsibility. It lacks the preventive controls that the agency has tentatively concluded are the minimum necessary to ensure safety. Moreover, it has not provided full public confidence in the safety of imported seafood.

D. Public Confidence

Continuing public concerns about the safety of seafood provide additional evidence that the current regulatory system is not well-suited for seafood. Consumers have become increasingly concerned about the effects of pollution on seafood. Medical wastes washing up on beaches, ocean dumping of toxic wastes, chemical run-off, and multiple oil spills continually dramatize the fact that bodies of water, no matter how large, can be adversely affected by human activity.

Media and other public attention on seafood safety and quality, and on the adequacy of the current regulatory program for seafood, has been substantial in recent years, and there is no reason to expect that this attention will decrease. Problems with some seafood products draw attention to, and has tended to raise concerns about, all seafood, a situation that is bad for consumers because seafood is a low fat product, and bad for an industry that can ill afford it.

Several hearings on the sufficiency and direction of the Federal seafood safety program have been held in both houses of Congress since in 1989. In addition, numerous bills have been introduced in Congress for the stated purpose of establishing a Federal program of mandatory inspection of seafood. Different bills passed the House and the Senate in 1990 but were not reconciled before the end of the 101st Congress.

This legislative activity has tended to reinforce the view that the public is placed at some risk because no Federal mandatory program for seafood exists. While this view is inaccurate in a number of respects, it is fueled in part by the notable differences in the frequency with which regulatory agencies inspect the processors of different types of flesh foods. As stated above, beef and poultry slaughterhouses are subject to continuous visual inspection under programs operated by the U.S. Department of Agriculture (USDA).

Public concerns about seafood regulation persist despite the recent increases in Federal resources and inspections for seafood. A major U.S. newspaper recently published an article entitled "A Sea of Uncertainties," which expressed anxiety about the coverage of seafood inspection. "The odds are," it observed, "that the bit of fish you cook tonight got to your table without ever being poked or prodded or even glanced at by a government inspector" (Ref. 30).

No realistic system, however, could possibly look at every piece of fish. Moreover, in the current budget climate, improvements in the system for ensuring the safety of seafood will likely have to be qualitative rather than quantitative. Estimated combined Federal, State, and local outlays for regulatory activities relating to seafood are about $100 million annually (Ref. 31), but pressures to cut back funding exist at all of these levels.

IV. The HACCP Option

Thus, the Government must find new approaches to food safety that enable it to become more efficient and minimize costs wherever possible. A new paradigm is needed for seafood inspection, one that provides an ongoing, scientifically established system of intensive, preventive monitoring but that does not require undue resources.

When faced with similar pressures, Canadian health authorities responsible for seafood safety came to the following conclusion:

> One of the key challenges will be to endure the scrutiny of the informed consumer and demanding marketplace * * *. The Canadian Government, as well as other western governments will be under constant pressure to limit spending as the aging population places more and more demands on services and as the Federal deficit is addressed. This means inspection programs cannot expect to have ever increasing resources to meet the challenges of the 1990's. Smarter and more cost effective ways must be developed to carry out their mandate.

(Ref. 32, p. 502.)

The "smarter and more cost effective way" chosen by the Canadians is HACCP.

A. What is HACCP?

HACCP is a preventive system of hazard control. Its application to food production was pioneered by the Pillsbury Company (Pillsbury) during that company's efforts in the early 1960's to create food for the U.S. space program. Pillsbury concluded that then existing quality control techniques could not provide adequate assurance that the food being produced was not contaminated. The end-product testing necessary to provide such assurance would be so extensive that little food would be left for space flights. According to Howard E. Bauman:

> We concluded after extensive evaluation that the only way we could succeed would be to develop a preventive system. This would require us to have control over the raw materials, process, environment, personnel, storage, and distribution as early in the system as we possibly could. We felt certain that if we could establish this type of control, along with appropriate record keeping, we should be able to produce * * * a product we could say was safe. For all practical purposes, if this system was implemented correctly, there would be no testing of the finished packaged product other than for monitoring purposes.

(Ref. 33, p. 2.)

In the succeeding years, the system devised by Pillsbury has been recognized worldwide as an effective system of controls. The system has undergone considerable analysis, refinement, and testing. FDA believes that HACCP concepts have matured to the point where they can be formally implemented for seafood on an industry wide basis.

HACCP consists first of an identification of the likely hazards that could be presented by a specific product, followed by the identification of the critical control points in a specific production process where a failure would likely result in a hazard being created or allowed to persist. These critical control points are then systematically monitored, and records are kept of that monitoring. Corrective actions are also documented.

The National Advisory Committee on Microbiological Criteria for Foods (NACMCF), which was established by USDA in conjunction with FDA at the recommendation of NAS, has developed seven widely accepted HACCP principles that explain this process in

greater detail (Ref. 34). These HACCP principles follow.

1. Hazard Analysis

The first step in the establishment of an HACCP system for a food process is the identification of the hazards associated with the product. NACMCF defined a hazard as a biological, chemical, or physical property that may cause a food to be unsafe for consumption (Ref. 34, p. 186). The hazard analysis step should include an assessment of both the likelihood that these hazards will occur and their severity if they do occur. It should also involve the establishment of preventive measures to control them. To be addressed by the HACCP system, the hazards must be such, according to NACMCF, that their prevention, elimination, or reduction to acceptable levels is essential to the production of a safe food. Even factors beyond the immediate control of the processor, such as how the food will be distributed and how it will be consumed, must be considered because these factors could influence how it should be processed. Hazards that involve low risk and that are not likely to occur need not be considered for purposes of HACCP.

NACMCF has developed numerous issues to be considered during hazard analysis. These issues relate to matters such as ingredients, processing, distribution, and the ultimate intended use of the product. FDA urges seafood processors and importers to become familiar with these issues. They include, for example, whether a food contains any sensitive ingredients that may present microbiological hazards, chemical hazards, or physical hazards; whether sanitation practices can affect the safety of the food that is being processed; and whether the finished food will be heated by the consumer. For seafood, this analysis is particularly important because it is consumed raw or partially cooked to an extent unrivaled for other flesh foods. Examples of seafoods that are consumed in this way include raw molluscan shellfish, sushi, steamed clams, and cold smoked salmon.

2. Identify the Critical Control Points in the Process

Points in a manufacturing process that may be critical control points, as listed by the NACMCF, include cooking, chilling, specific sanitation procedures, product formulation control, prevention of cross contamination, and certain aspects of employee and environmental hygiene. For example, a cooking step that must be operated at a specific temperature and for a specified time in order to destroy microbiological pathogens is a critical control point. Likewise, refrigeration required to prevent hazardous microorganisms from multiplying or toxins from forming is a critical control point.

3. Establish Critical Limits for Preventive Measures Associated With Each Identified Critical Control Point

In essence, this step involves establishing a criterion that must be met for each preventive measure associated with a critical control point. Critical limits can be thought of as boundaries of safety for each critical control point and may be set for preventive measures such as temperature, time, physical dimensions, moisture level, water activity, Ph, available chlorine, or sensory information such as texture, aroma, or visual appearance. Critical limits may be derived from sources such as regulatory standards and guidelines, literature surveys, experimental studies, and experts.

4. Establish Procedures To Monitor Critical Control Points

Monitoring is a planned sequence of observations or measurements to assess whether a critical control point is under control and to produce an accurate record for future use in verification. NACMCF identifies three main purposes for monitoring: (1) It tracks the system's operation so that a trend toward a loss of control can be recognized, and corrective action can be taken to bring the process back into control before a deviation occurs; (2) it indicates when loss of control and a deviation has actually occurred, and corrective action must be taken; and (3) it provides written documentation for use in verification of the HACCP plan.

As NACMCF points out, continuous monitoring is possible with many types of physical and chemical methods. For example, temperature and time for a scheduled thermal process can be recorded continuously on temperature-recording charts. When it is not possible to monitor a critical limit on a continuous basis, monitoring intervals must be reliable enough to permit the manufacturer to determine whether the hazard is under control.

5. Establish the Corrective Action To Be Taken When Monitoring Shows That a Critical Limit Has Been Exceeded

While the HACCP system is intended to prevent deviations in a planned process from occurring, perfection is rarely, if ever, achievable. Thus, NACMCF states that there must be a corrective action plan in place to: (1) Determine the disposition of any food that was produced when a deviation was occurring; (2) fix or correct the cause of noncompliance to ensure that the critical control point is under control; and (3) maintain records of corrective actions.

6. Establish Effective Recordkeeping Systems That Document the HACCP System

This principle requires the preparation and maintenance of a written HACCP plan that sets out the hazards, critical control points, and critical limits identified by the firm, as well as the monitoring, recordkeeping, and other procedures that the firm intends to take to implement the plan. Secondly, this principle requires the maintenance of records generated during the operation of the plan.

Ultimately, it is the recordkeeping associated with HACCP procedures that makes the system work, both from the standpoint of the HACCP operator (industry) and the regulator. One conclusion in a study of HACCP performed by the Department of Commerce is that correcting problems without recordkeeping almost guarantees that problems will reoccur (Ref. 35, p. 85). The requirement to record events at critical control points on a regular basis ensures that preventive monitoring is occurring in a systematic way.

7. Establish Procedures to Verify That the HACCP System Is Working

This process involves: (1) Verifying that the critical limits are adequate to control the hazards; (2) ensuring that the HACCP plan is working properly, e.g., that it is being followed, and that appropriate decisions are being made about corrective actions; and (3) ensuring that there is documented, periodic revalidation of the plan to make sure that it is still relevant to raw materials as well as to conditions and processes in the plant. Government regulatory activities also help ensure that the HACCP system is working.

B. Specific Applications to Seafood

As NAS has pointed out, most health risks associated with seafood originate in the environment (Ref. 7, p. 1). Many of these risks are the subject of research by FDA, the National Oceanic and Atmospheric Administration (NOAA) of the Department of Commerce, the Environmental Protection Agency (EPA), and others. This research is designed both to produce information that will provide a better understanding of the toxins, bacteria, chemical contaminants, and other phenomena and to provide a basis for developing

more advanced types of controls for them. Within the limits of existing scientific knowledge, however, the industry can and should use HACCP to control the source and condition of raw materials based on an understanding of the likely hazards that need to be prevented.

The Pillsbury team that first applied HACCP to food production began with a systematic review of raw materials to ensure that they were not bringing hazards into the plant. As Bauman pointed out:

> This required the development of a familiarity with the raw materials that was not a normal process in food product development * * *. The areas of concern ranged from the potential presence of pathogens, heavy metals, toxins, physical hazards and chemicals, to the type of treatments the ingredients might have received such as pesticide applications or a pasteurization step. (Ref. 33, pp. 2 and 3.)

While all these areas that were of concern to Pillsbury are not germane to all seafoods, they certainly cover the range of hazards to which seafoods are susceptible.

Of the three most frequently reported seafood-related illnesses, two are environmentally related: ciguatera in warm water reef fish, as described previously, and water-borne viruses in molluscan shellfish consumed raw and partially cooked. While a rapid test to detect ciguatoxin in fish continues to be the target of research at FDA and elsewhere, processors and importers can exercise control by ensuring that they are obtaining fish from responsible sources that are not harvesting from waters where ciguatoxin is being found.

Ciguatera has been associated with recreational fishing. Processors and importers should address through HACCP any safety considerations that might exist with the commercial sale of recreational catch generally, depending upon species and locale.

For viruses from molluscan shellfish to be controlled, HACCP measures must be in place to ensure that molluscan shellfish harvested from polluted waters are not entering commerce. Other key safety controls relate to proper refrigeration to keep potentially harmful microbes from reaching dangerous levels.

The third seafood-related illness, scombroid poisoning, is caused by a toxin created as part of the process of decomposition after a fish has died. The formation of scombrotoxin can be triggered by time/temperature abuse anywhere in the commercial system and beyond, including as early as on the harvesting vessel if good handling controls are not followed.

FDA is considering whether to develop good handling practice requirements (not necessarily HACCP) specific to fishing vessels and invites comment on this matter. FDA has traditionally refrained from directly regulating fishing vessels, largely because of the huge number of such vessels in the U.S. fleet, even though it has authority to do so. FDA invites comment on whether those boats that harvest scombrotoxin-forming species, or any other specific component of the fleet, should be subject to mandatory HACCP controls.

Meanwhile, processors and importers of scombrotoxin-forming species can exercise HACCP controls aimed at ensuring that their incoming raw materials or imported shipments have not been time/temperature abused. Because any HACCP plans for such processors or importers would be clearly inadequate if scombrotoxin were not identified as a hazard and appropriate controls were not in place and systematically monitored, processors and importers should consider placing time/temperature requirements on vessel owners as a prerequisite to doing business.

HACCP can also be applied to control of hazards from chemical contaminants, even though the full range of possible chemical hazards is still imperfectly understood. Government and academia have important roles to play in researching the toxicities of these chemicals, in monitoring them, and in performing various forms of risk assessment. In some cases, these efforts may result in the establishment of national maximum limits. In other cases, regional advisories may be more appropriate. The seafood industry has a responsibility to know whether chemical hazards are associated with the species they are handling, whether the occurrence of such hazards depends on harvest site or other factors, and whether a sampling and analysis program on their part would be appropriate. Processors and importers should monitor the origin of raw materials and imported shipments to ensure, for example, that harvest did not occur in locations subject to public health advisories.

These are but a few examples of environmentally related hazards to which HACCP can be applied. HACCP controls can also ensure that hazards are not being created inside a processing facility through improper handling, cooking, or storing.

C. Regulatory Considerations

From a regulatory standpoint, inspections of processing facilities and of importers' plans and records would become more efficient and would be likely to have a much greater impact if HACCP controls were in place. A key feature of an inspection system tied to implementation of HACCP is access by Government investigators to the HACCP plan and to monitoring records kept under that plan. In contrast to the "snapshot" provided by current inspections, examination of HACCP records will enable an investigator to see how the processing facility or the importer operates over time. It will enable an investigator to determine whether problems have occurred, and how they were addressed. It will also enable an investigator to spot trends that could lead to problems, and thus to help prevent them from occurring. Additionally, it will enable the regulator to review the adequacy of the processor's or importer's preventive control system itself. Under such an inspection system, inadequate preventive controls would warrant remedial or regulatory action regardless of whether the processor's or importer's product is actually contaminated or unsafe.

HACCP is not a zero risk system, however. Problems in food production and processing will still occur. HACCP systems are designed to detect and document those problems, so that they can be corrected as quickly as possible. Thus, regulatory action would not be warranted on the basis of the mere occurrence of processing problems. It would be warranted, though, if the HACCP system is not functioning properly to detect and correct the problems, or if adulterated food is allowed to enter into commerce.

An inspection program tied to mandatory industry adoption of the HACCP system would not be industry self-certification, nor would it be deregulatory. An investigator under such a program would perform HACCP reviews but not to the exclusion of other inspection activities. Thus, it is highly doubtful whether any falsification of records would go undetected. Investigators are taught to recognize falsification of records, and the inspection techniques they use would likely reveal any instances in which the records do not reflect actual conditions and practices. Falsification of records carries strict penalties under Federal law.

Unlike the other inspection options discussed previously that would involve continuous or high-frequency inspection and commensurate costs, an inspection system tied to HACCP would not necessarily require an increase over current inspection frequencies.

Recordkeeping and record inspection will provide the inspector, however, with a broader view. Moreover, to the extent that States adopt equivalent inspection programs in response to these proposed regulations, the resultant network of consistent inspections would, in effect, increase the frequency of inspections at no additional cost. The value to the nation of such a network would be substantial.

FDA recognizes that many States are under considerable pressure to cut back funding in areas where a Federal presence also exists. For seafood, however, FDA urges that the States maintain their programs, strengthen them to the extent possible, and work with the agency to integrate them into a HACCP-based, Federal/State network. Such an approach would be consistent with recommendations relating to the role of States made by NAS in its 1991 report on seafood safety (Ref. 7, p. 16). FDA especially invites comment on how the proposed FDA program should mesh with an existing State HACCP program for seafood, such as the program that exists in Alaska, so that inconsistent Federal and State HACCP requirements are not imposed.

V. The Proposal

A. Decision To Propose To Make Use of HACCP Mandatory

For the foregoing reasons, FDA has tentatively concluded that a new system of regulatory controls for seafood is necessary, and that HACCP is the appropriate system. Therefore, FDA is proposing to add part 123 to establish procedures for the safe processing and importing of fish and fishery products. FDA is proposing these procedures under sections 402(a)(1), 402(a)(4), and 701(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 342(a)(1), 342(a)(4), and 371(a)), in conjunction with section 361 of the Public Health Service Act (the PHS Act) (42 U.S.C. 264). Section 402(a)(1) of the act states that food is adulterated if it bears or contains any poisonous or deleterious substance that may render it injurious to health. Section 402(a)(4) of the act was included in the act to provide additional control over insanitary and contaminated foods. (H.R. Rept. No. 2139, 75th Cong., 3d sess. 6 (1938).) Section 701(a) of the act authorizes the agency to adopt regulations for the efficient enforcement of the act. Section 361 of the PHS Act authorizes the agency to adopt regulations to prevent the spread of communicable diseases.

The proposed regulations set out those requirements that the agency tentatively has concluded are the minimum necessary to ensure that, to the extent possible, the processing and importation of fish and fishery products will not result in a product that is injurious to health. These requirements include the establishment of HACCP preventive controls that take into account the unique characteristics of seafood products. If a processor or an importer fails to adopt and implement an HACCP plan that complies with the requirements that FDA is proposing, or otherwise fails to operate in accordance with these proposed provisions, it will be preparing, packing, or holding the food under insanitary conditions under which the food may be rendered injurious to health. Thus the food will be adulterated under section 402(a)(4) of the act and subject to regulatory action by FDA. The agency has reflected this fact in proposed § 123.6(d).

FDA's tentative decision to adopt regulations that require the implementation of HACCP principles by the seafood industry is grounded in the statutory objective of preventing food safety and sanitation problems. Section 402(a)(4) of the act does not require that FDA demonstrate that food is actually hazardous or contaminated in order to deem the food adulterated and to exclude it from commerce. Instead, under section 402(a)(4) of the act, food producers must assure that the food is not "prepared, packed, or held under insanitary conditions whereby it *may have been* contaminated with filth, or whereby it *may have been* rendered injurious to health." [emphasis added.]

In enforcing section 402(a)(4) of the act, FDA has considered, among other things, prevailing industry standards and the technical state-of-the-art in determining on a case-by-case basis whether the conditions under which a company is processing or handling food satisfy section 402(a)(4) of the act. This proposed regulation would codify an appropriate state-of-the-art means of assuring seafood safety and of preventing sanitation problems under FDA's authority to promulgate regulations for the "efficient enforcement" of the act (section 701(a) of the act (21 U.S.C. 371(a))).

The factual record that FDA has developed concerning the safety and sanitation issues posed by seafood illustrates the need for codifying appropriate preventive methods consistent with the emerging technical state-of-the-art and explains why FDA's initial focus in implementing HACCP is on seafood. Proof that any particular process or set of manufacturing conditions in the production of seafood has in fact caused injuries or sanitation problems is not, however, a legal prerequisite to this rule.

The proposed adoption of this rule is supported by several additional factors. First, as stated above, the application of HACCP to the seafood industry has been the subject of a substantial amount of work, by the Federal government, some States, academia, and the seafood industry itself, to develop specific HACCP models and otherwise to apply HACCP to seafood processing and importation. The Model Seafood Surveillance Project (MSSP) was conducted by NOAA at the request of Congress in 1986 to design an inspection system for seafood consistent with HACCP principles. This project resulted in the development of 16 regulatory models for specific seafood products that describe the basis for a mandatory seafood inspection system. Each model applies many of the NACMCF principles described above in the context of a specific product, such as breaded shrimp, raw fish, and molluscan shellfish (Ref. 35, pp. 67 to 73).

The MSSP was conducted with significant industry involvement. The importance of industry participation in the development of HACCP systems was stressed by NAS in its 1985 study of HACCP (Ref. 36, pp. 13, 309, and 310). As part of the MSSP project, 49 workshops were conducted involving 1,200 industry, State, and university participants. HACCP controls were considered for economic fraud and plant sanitation/hygiene as well as for safety because economic fraud and sanitation have been problems in the seafood industry. The MSSP models cover nearly all the types of seafood products consumed in the United States except for low acid canned seafood, which is already subject to a mandatory HACCP control and inspection system under the low acid canned food regulations adopted by FDA.

Low acid canned seafood products represent about 25 percent of all seafoods consumed in the United States (Ref. 7, p. 23). The regulatory system in place for them represents the first formal application of HACCP principles to food by a regulatory agency. As with this proposal, the regulations for low acid canned foods were requested by industry, and they were developed through cooperation between Government and industry.

Although the low acid canned food regulations apply HACCP concepts to two hazards only, i.e., botulism in canned foods and contamination because of poor container integrity, they are regarded as a major success and demonstrate the benefits that HACCP

can provide. Botulism in canned goods has been effectively controlled under the low acid canned food regulations and is no longer a particular source of consumer concern. NAS recently concluded that canned fish is among the safest of seafood items. (Ref. 7, p. 320).

Seafood industry associations have been active in developing HACCP systems that their members could use. For the past several years, the New England Fisheries Development Association (NEFDA) has been assisting firms in the northeast to implement HACCP systems through Federal grants. NEFDA's activities include a pilot project for 15 processing firms and participation in a retail seafood HACCP pilot (Ref. 18, p. 26).

Academia has been active as well. For example, the Oregon Sea Grant, which services the Oregon marine community as part of the national Sea Grant extension service, has issued a publication, "Hazard Analysis & Critical Control Point Applications to the Seafood Industry" (Ref. 37). This publication explains the fundamentals of HACCP, inventories microbial hazards of seafoods, and describes model HACCP systems for specific types of seafood processing operations.

As a result of efforts like these by Government, industry, and academia, a considerable amount of literature and expertise now exist to facilitate the development of HACCP systems by seafood processors and importers, significantly more than for most other major segments of the food industry. Given the advanced state of knowledge about the application of HACCP to the seafood industry, FDA is proposing to make the use of HACCP mandatory for the seafood industry to ensure that there is compliance with section 402(a)(1) and 402(a)(4) of the act.

Second, seafood industry representatives have been urging the Federal Government to adopt a mandatory, HACCP-based system for years. The National Fisheries Institute, the largest seafood industry trade association, and others from the seafood industry testified repeatedly at congressional hearings from 1989 through 1992 in support of legislation that would mandate such a system.

Indeed, nearly all of the seafood bills introduced in the Congress since the late 1980's, including the bills that passed both chambers in 1990, contained HACCP elements. While there were different views on the merits of these legislative proposals, virtually all Government agencies, both Federal and State, that testified on these proposals—as well as most other witnesses—expressed support for the HACCP concept as it applies to seafood. The Chairman of the Interstate Shellfish Sanitation Conference (ISSC), an organization of States, Federal agencies, and industry that considers issues relating to molluscan shellfish safety, testified that a HACCP-type approach is now being used for aspects of the shellfish program and endorsed HACCP for all seafood.

Significant elements of the seafood industry continue to press for the Federal Government to institute a HACCP-based program. An article in a 1992 edition of a seafood trade publication on the advantages of HACCP concluded: "With the seafood industry under a continuing barrage of negative press regarding the wholesomeness and safety of product, the industry is impatient to get started with a seafood inspection program that will reassure consumers * * *" (Ref. 19, p. 39).

In February, 1993, the Executive Vice President of the National Fisheries Institute wrote to the Secretary of Health and Human Services asking that she "initiate a state-of-the-art program for seafood which would be of significant benefit to consumers * * *. HACCP-based regulation is very feasible for the seafood industry * * *. There is no reason to wait for congressional action to put this modern technology in place" (Ref. 38). As recently as April, 1993, the President of the Pacific Seafood Processors wrote to FDA expressing support for a mandatory seafood HACCP program (Ref. 39). The members of that organization process the majority of domestically harvested seafood. These requests provide further evidence of the appropriateness of this proposal.

B. Preparing for HACCP

FDA recognizes that this proposal involves a significant departure from current practices for most processors and importers and intends to work cooperatively with the industry in the establishment of this proposed system. The agency's experiences under both its HACCP-based low acid canned food regulations and the HACCP-based pilot programs for seafood that it conducted with NOAA in 1991 demonstrate the need for cooperation and technical support between the agency and the industry in order to establish HACCP and to make it work.

The FDA/NOAA joint pilot programs involved the development and implementation of HACCP-based systems by seafood processors and HACCP-based inspections by the two agencies. Even though the FDA/NOAA pilots involved highly motivated seafood firms that volunteered to adopt HACCP, the firms found it difficult initially to identify hazards and critical control points associated with their own products and processes (Ref. 40). As both the agencies and the firms discovered, HACCP involved new ways of thinking and behaving that were not readily understood or implemented. A considerable amount of consultation and assistance between the firms and the Government proved to be extremely helpful.

This experience reinforces the view that regulations that impose a HACCP-based system are needed for the seafood industry and thus represents a third factor supporting the appropriateness of this proposal. The systematic kind of preventive thinking that HACCP requires is not universal, but it can be adopted. Regulations will ensure that processors and importers do so. Significantly, once participants in the pilot programs made the transition to HACCP, they were able to identify benefits from using HACCP to themselves and to consumers in terms of product safety and quality, as well as plant sanitation and organization (Ref. 40).

VI. International Trade

Although not a public health issue, international trade is also a major consideration in determining the advisability and benefits of a new system of seafood regulation and therefore will be addressed here. It is estimated that close to 40 percent of the fish and shellfish harvested from the world's oceans, lakes, and other bodies of water entered international trade in 1991 (Ref. 41). This movement reflects the need to match supplies with demand. Nations often have species in their waters for which there is little or no demand among their consumers, while consumers in other countries may prefer these species. In addition, sometimes foreign markets are willing to pay higher prices than domestic markets.

Participation in the international trade in seafood is critical to U.S. consumers and industry. Approximately 55 percent of the U.S. supply of edible seafood is imported. In 1991, 3,014,819,000 pounds were imported, worth $5,617,887,000, making the United States the world's second largest seafood importing nation (Ref. 42).

At the same time, the United States is the world's largest exporter of fishery products. In 1991, the United States exported more than $3 billion worth of seafood, making a significant positive contribution to this country's balance of payments as well as to the many coastal State economies in which these

products are produced (Refs. 42 and 43). Our largest market is Japan, followed by the European Community (EC) and Canada. Both Canada and the EC have implemented or are in the process of implementing mandatory HACCP-based seafood inspection systems (Refs. 32 and 44).

Given the significance of both international and domestic trade, ongoing efforts to harmonize or make equivalent country inspection systems and requirements takes on great significance. The current multilateral round of trade negotiations under the General Agreement on Tariffs and Trade (GATT) has resulted in further focus on this area. The draft text on sanitary and phytosanitary measures acknowledges the desire of the contracting parties, including the United States, to support "the use of harmonized sanitary and phytosanitary measures between contracting parties, on the basis of international standards, guidelines, and recommendations developed by the relevant international organizations including the Codex Alimentarious Commission * * *" (Ref. 45, p. L.35). This move toward harmonization, coupled with the current recommendations of the Codex Committee on Food Hygiene encouraging the international use of the HACCP system (Ref. 46), clearly argue for the adoption of this approach in the United States for seafood. Failure by the United States to adopt a mandatory, HACCP-based inspection system may ultimately undermine its export success, with considerable economic consequences. For example, in addition to the EC, Canada, Iceland, Australia, and many other fishing nations have moved to a mandatory HACCP approach that could affect United States competitiveness in the major seafood markets.

The EC is the United States' second largest export market, purchasing $441 million worth of U.S. products in 1991. On July 22, 1991, EC Council Directive 91/493 was issued to set out the conditions for the production and placing on the EC market fish and fishery products (Ref. 44). This Directive requires, as of January 1, 1993, that both member States and third countries:

> * * * take all necessary measures so that, at all stages of the production of fishery products * * * persons responsible must carry out their own checks based on the following principles:
>
> —Identification of critical control points in their establishments on the basis of the manufacturing processes used;
>
> —establishment and implementation of methods for monitoring and checking such critical control points; * * *
>
> —keeping a written record * * * with a view to submitting them to the competent authority * * *.

While the directive provides some flexibility in terms of equivalence, it is clear that the EC is looking for a mandatory HACCP system along the lines proposed in this regulation. Maintaining and expanding this export market is likely to be facilitated if this proposal is adopted.

Similarly, ongoing discussions with Canada under the terms of section 708 of the U.S./Canada Free Trade Agreement (FTA) to harmonize or make equivalent the two nations' respective inspection systems and standards have made it clear that this proposed HACCP regulation will significantly facilitate the process (Ref. 47). Canada has recently completed implementation of a mandatory, HACCP-based seafood inspection program. Because Canada is the United States' third largest export market and largest supplier of imported seafood, adoption of an equivalent system would not only achieve the objectives of the FTA but potentially would save resources currently devoted to monitoring shipments between our two countries. Similar potential benefits could be expected under the proposed North American FTA, particularly at this formative stage in that process. Thus, facilitation of international trade is a fourth factor supporting the appropriateness, and thus providing a rational basis, for FDA's proposed course of action.

VII. The Proposed Regulations

These proposed regulations consist of a subpart of general applicability (subpart A) and one subpart that sets forth specific additional provisions for raw molluscan shellfish (subpart C). The agency is also setting forth guidelines, in the form of appendices, that will provide assistance to processors of cooked, ready-to-eat products (Appendix A), and to processors of scombrotoxin forming species (Appendix B), on how to meet various requirements in subpart A relating to the development and implementation of HACCP plans. The products addressed in the guidelines involve special considerations or special hazards for which additional guidance would be useful. Processors and importers that follow these guidelines will increase the likelihood that FDA will find their preventive controls acceptable. FDA requests comments on the need for, and the substance of, the guidelines that it has set forth. Comments should address whether it would be more appropriate for FDA to adopt the guidelines as regulations. If the comments provide a convincing basis for doing so, FDA will include some or all of the guidelines in the regulations in any final rule that results from this rulemaking.

FDA is also including a guideline on how to ensure product integrity relating to economic adulteration (Appendix D). FDA is including this guideline because economic adulteration is a particular problem in the seafood industry.

In Appendix 1 to this document, FDA is also providing samples from a package of general guidance, to be published separately, for processors to use in understanding and implementing HACCP principles in their operations. One of these samples is specific guidance on the processing of smoked and smoke-flavored fish. FDA requests comments on whether the latter guidance should remain as such, be provided as guidelines in an appendix to the regulations, or be made mandatory by incorporating them into any final rule that results from this proceeding.

A. Definitions

The agency is relying generally on the definitions contained in the act, in the umbrella good manufacturing practice guidelines in part 110, and in other agency regulations. The agency is using these definitions because it considers consistency in how it uses terms in its regulations to be necessary and appropriate. Thus, § 123.3(o) is derived from § 113.3(s), and § 123.3(r) is derived from § 110.3(q). Additional definitions are proposed in § 123.3 that are specific to the proposed HACCP program for fish and fishery products.

The agency is proposing to define "certification number" in § 123.3(a) as a unique combination of letters and numbers assigned to a shellfish processor by a shellfish control authority, usually the State. These numbers are used to identify the processor on tags and labels and in recordkeeping required under proposed § 123.28. States issue certification numbers to processors who receive shellfish from safe sources, keep requisite records of shellfish purchases and sales, and operate in accordance with CGMP and the other certification requirements of the State. This system of State issued numbers is used to identify the approximately 2,000 State certified shellfish dealers that are included on the Interstate Certified Shellfish Shippers List.

The agency is proposing in § 123.3(b) to define "cooked, ready-to-eat fishery product" as a fishery product that is subjected by a commercial processor to either a cooking process before being placed in a final container, or to

pasteurization in the final container, or to both. Cooked, ready-to-eat products undergo a heat treatment by a processor that results in the coagulation of the protein. Because their organoleptic qualities suggest that they are fully cooked, and thus ready-to-eat, these products will likely be eaten without any further heat treatment by the consumer sufficient to eliminate pathogenic microorganisms and preformed toxins.

As defined, cooked, ready-to-eat fishery products include products that must be stored either frozen or refrigerated. Products such as canned seafoods that are subjected to a cooking process after being placed in a final container, while technically considered cooked, ready-to-eat products, are not included in the definition because they are virtually sterile in the final container. As used in these proposed regulations, the term applies to cooked, ready-to-eat products that do not receive a heat treatment in the final container by the processor sufficient to destroy all pathogens and create a shelf-stable product that does not need refrigeration.

The agency is proposing in § 123.3(c) to define "critical control point" for purposes of these regulations as a point in a food process where there is a high probability that improper control may cause, allow, or contribute to a hazard in the final food. This is a modification of the definition of the same term in § 110.3(e). Under that definition, a "critical control point" is a point where an improper control could cause, allow, or contribute to "filth in the final food or decomposition in the final food" as well as to a "hazard" in the final food. Clearly, that definition is intended to apply both to human food safety and to certain quality issues that would not normally cause illness. In this document, FDA is proposing to require the identification of critical control points for safety only and is encouraging, but not requiring, the identification of certain critical control points for hazards not normally related to safety. The modification of the part 110 definition being proposed here represents the least revision necessary to achieve that purpose.

The agency is proposing to define "critical limit" in § 123.3(d) as a maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to minimize the risk of occurrence of the identified hazard. This definition is consistent with that of NACMCF, which defined "critical limit" as "a criterion that must be met for each preventive measure associated with a critical control point" (Ref. 34, p. 186), but FDA's proposed definition is somewhat more explanatory. Critical limits can be either maximum values, such as the maximum amount of histamine that can be allowed in a fish, or minimum values, such as the minimum temperature needed during a cooking step to kill pathogens.

The proposed definition states that control is for the purpose of minimizing risk. While complete prevention of a hazard is obviously the most desirable of all possible outcomes, the proposed definition recognizes that, in reality, complete prevention cannot always be ensured. A processor can minimize a microbiological hazard with a cooked, ready-to-eat product by proper cooking, but the hazard could still occur if the product is contaminated or otherwise abused elsewhere in the distribution system or in the home. This aspect of the definition is consistent with the view of NACMCF, which states that: "Each CCP [critical control point] will have one or more preventive measures that must be properly controlled to assure prevention, elimination or reduction of hazards to acceptable levels" (Ref. 34, p. 196).

The agency is proposing in § 123.3(e) to define "fish" and broadly to encompass the range of seafood products that are processed or marketed commercially in the United States. Thus, the term "fish" includes all fresh or saltwater finfish, molluscan shellfish, crustaceans, and other forms of aquatic animal life. Birds are specifically excluded from the definition because commercial species of birds are either nonaquatic or, as in the case of aquatic birds such as ducks, regulated by USDA. Mammals are also specifically excluded because no aquatic mammals are processed or marketed commercially in this country.

"Fishery products" in proposed § 123.3(f) are any edible human food product derived in whole or in part from fish, including fish that has been processed in any manner. This definition reflects the tentative conclusion of the agency to propose mandatory HACCP requirements at this time to control hazards associated with processing and importing seafood products intended for human consumption. The proposed definition includes products that contain ingredients other than seafood in keeping with the scope of FDA's regulatory authority. The control of hazards is as important for products that contain ingredients other than fish as it is for products consisting of fish alone.

The agency is proposing in § 123.3(g) to define "harvester" as a person who commercially takes molluscan shellfish from their growing waters, by any means. Harvester is defined because, under this proposal, this person has responsibility for tagging the product as to where it was harvested and when. Harvesters are expected to have an identification number issued by a shellfish control authority. Harvesting is generally illegal without such a number.

The agency is proposing to define the term "importer" in § 123.3(h) as the owner of the imported goods or his representative in the United States. This is the person who is responsible for ensuring goods being entered are in compliance with all laws affecting the importation. Importers may not always directly handle the imported food, but they are responsible for the safety and wholesomeness of products they offer for entry into the United States and therefore are subject to part 123.

The agency recognizes that the term "importer" is often used to describe not only the owner of the goods or his representative in the United States (that is, the importer of record) but also includes freight forwarders, food brokers, food jobbers, carriers, and steamship representatives. These other agents often represent the importer for legal and financial purposes that are not necessarily related to the safety of the product. Therefore, the agency has tentatively concluded that it is inappropriate to focus the HACCP requirements that bear on imports on these persons if they do not have authority to make decisions affecting the product's safety or wholesomeness.

FDA is proposing to define a "lot of molluscan shellfish" in § 123.3(i) as no more than one day's harvest from a single, defined growing area, by one or more harvesters. This definition establishes the quantity of shellfish that represents a single lot for tagging or labeling purposes. Lot distinctions are needed to differentiate shellfish harvested from different growing areas or at different times. The time limit of one day is imposed because the safety of a harvesting area can change daily as the result of rainfall, tides, winds, and other events that can bring contaminants into the area. The ultimate safety of raw molluscan shellfish is contingent on the water quality of the harvesting area. To ensure product safety, shellfish harvesting areas that are subject to appropriate state control are closed to harvesting within 24 hours of a finding of adverse conditions. The lot definition, coupled with the harvest date on the harvesting tag, provides evidence that the shellfish were harvested when the area was safe and open for harvesting.

The agency is proposing in § 123.3(j) that "molluscan shellfish" means any edible species, or edible portion of fresh or frozen oysters, clams, mussels, and scallops, except were the scallop product consists entirely of the shucked adductor mussel. The distinction between molluscan shellfish and crustacean shellfish, which include crabs, shrimp, and lobsters, is made because molluscan shellfish are commonly eaten whole and raw, while crustacean shellfish are not. The safety of molluscan shellfish therefore reflects the quality of the waters from which they are harvested and requires special public health controls. Furthermore, the agency is proposing to amend the definition of "shellfish" in § 1240.3(p) (21 CFR 1240.3(p)) to make it consistent with the proposed definition in § 123.3(j). The agency is proposing to amend the term "shellfish" in § 1240.3(p) to read "molluscan shellfish" to make the terms consistent between parts 123 and 1240. Because the term shellfish in its common usage, i.e., an edible mollusk or crustacean, includes crabs and lobsters, the agency believes that it is necessary to be more specific and accurate in its definition and consequent application of the requirements in its regulations. The proposed requirements for tagging do not apply to crabs and lobsters or to scallops when the final product is the shucked adductor muscle only. The agency is proposing to expand the definition in § 1240.3(p) to include scallops to make it consistent with the definitions in proposed part 123 and with requirements under NSSP.

The agency is proposing to define "potable water" in § 123.3(k) as water that meets EPA's primary drinking water regulations as set forth in 40 CFR part 141. Those regulations provide limits for certain microbiological, chemical, physical, and radiological contaminants that can render water unsafe for human consumption.

The proposed definition is slightly different from the definition of "potable water" in §§ 1240.3(k) and 1250.3(j) (21 CFR 1250.3(j). That definition also references the regulations of EPA in 40 CFR part 141 but further includes FDA sanitation requirements in 21 CFR parts 1240 and 1250. Those sanitation requirements apply to interstate travel conveyances that must take on water at watering points. Such requirements are not relevant to these proposed regulations and thus were not included in the proposed definition.

FDA is proposing to define "processing" and "processor" in § 123.3(m) and (n) broadly to ensure the safety of seafood through the application of HACCP principles throughout the seafood industry. The definition of "processor" is intended to include all seafood processors that handle products in interstate commerce, such as shuckers and other processors of raw molluscan shellfish, factory ships, packers, repackers, wholesalers, and warehouses. Those who process low acid canned foods are also included, even though they are subject to the HACCP controls of part 113. Those controls are targeted toward a limited number of safety hazards. These proposed regulations require that processors apply HACCP controls to all likely safety hazards.

Consistent with the regulations at part 113, the proposed definition of "processor" also includes persons engaged in the production of foods that are to be used in market or consumer tests. FDA has tentatively concluded that HACCP controls are needed for such products because the hazards associated with them are no different from those that can affect other commercial products.

There are, however, certain handlers of seafood that are not included in the coverage of the proposed definition. Fishing vessels that essentially only harvest are not covered by the proposed HACCP regulations. As explained earlier, FDA has traditionally refrained from directly regulating fishing vessels. The agency anticipates that the regulations being proposed here would affect vessels indirectly through processor and importer controls over raw materials and imported shipments, e.g., preventive controls such as the purchasing of raw materials only from fishing vessels that engage in proper sanitation and time/temperature practices and that harvest only from approved areas.

Transportation companies that carry, but do not otherwise process, fish and fishery products are also outside the scope of the proposed definition, although the agency expects that transporters will be affected indirectly in the same manner as fishing vessels (see also § 110.93). FDA invites comment on this aspect of the coverage of the proposed regulations. Proper refrigeration during transport is important for the safety of scombroid species products and of cooked, ready-to-eat products. Time and temperature conditions during shipment can also affect decomposition related to other factors bearing on seafood quality. These proposed regulations will affect transportation companies indirectly through the preventive controls the processor or importer will need to impose to ensure that the raw materials or imported shipments that it receives are free of relevant hazards and have been appropriately handled. FDA invites public discussion on whether this approach is adequate, and, if not, whether HACCP requirements should be applied directly to transportation companies. This issue is complex, especially because it is not unusual for transporters to deliver a variety of food products, including seafood, to several consignees during a single shipment.

The agency has also tentatively decided to exclude retail establishments from the definition of "processor." As with fishing vessels, FDA has traditionally exercised enforcement discretion with regard to retail establishments. The number of retail establishments in this country—literally in the hundreds of thousands—would totally overwhelm any rational Federal inspection system. FDA has traditionally provided training and other forms of technical assistance to States and local governments to inspect retail food establishments through the agency's retail Federal/State cooperative program. A major part of that cooperative program involves the development of model codes, some of which have been widely adopted by State and local governments. FDA is now consolidating those model codes into a single, updated food code for the retail sector. Appropriate HACCP-based controls are included to address seafood hazards at retail. Consequently, FDA will continue to operate through the Federal/State cooperative mechanism and has not included a retail component in proposed part 123. FDA requests comments on this tentative approach.

States are strongly encouraged, however, to consider how the principles in these regulations could be applied to seafood at retail and to shift to HACCP-type inspection systems as appropriate. Because of the high perishability of fresh seafood and the sometimes lengthy and complex distribution chain, these products can have relatively short shelf lives by the time they reach fresh fish counters and restaurants. In addition, seafood can be subject at retail both to cross-contamination because of poor handling practices and to species substitution.

Improper handling of seafood and other problems at retail have been documented in recent years. NAS has concluded that a significant number of reported acute health problems were likely linked to handling and preparation practices in food service establishments (Ref. 7, p. 27). The February, 1992 edition of Consumer Reports magazine reported on a number of such problems with regard to seafood

that were observed in retail establishments. A number of studies have found lack of adequate temperature controls in retail facilities (Ref. 48, p. 75).

The agency is proposing to define "shellfish control authority" in § 123.3(p) as the government entity responsible for implementing a comprehensive shellfish sanitation program. The shellfish control authority, among other things, is responsible for classifying shellfish growing waters, performing inspections of shellfish processors, and issuing certification numbers to shellfish processors. FDA relies on recognized governmental public health and food control agencies, both domestic and foreign, to carry out these functions.

The agency is proposing to define "shellstock" in § 123.3(q) as meaning raw, in-shell molluscan shellfish. This specific product form designation is needed because the applicability of the tagging, labeling, and recordkeeping requirements proposed in § 123.28(b) and (c) is determined by whether the product is shellstock or shucked product, respectively.

The agency is proposing to define "shucked shellfish" in § 123.3(s) as meaning molluscan shellfish that have one or both shells removed. The labeling and recordkeeping requirements proposed in § 123.28(c) apply to shucked shellfish.

The agency is proposing to define "tag" in § 123.3(t) as a record of harvesting information attached to a container of shellstock by the harvester or processor. Under proposed § 1240.60(b), the tag or bill-of-lading will identify the processor, harvester, date of harvest, and State, including the specific location of harvest. Most shellfish-producing States and countries currently require that shellfish harvested in their waters bear documentation with such information. This information is the minimum necessary to permit ready identification of site and time of harvest of the shellfish. Because raw molluscan shellfish directly reflect the quality of the harvesting area, this information is necessary to provide assurance that the shellfish were harvested from an area that was safe and open for harvesting.

B. Purpose and Criteria

Section 123.5(a) of the proposed regulations references the umbrella CGMP guidelines in part 110 as providing general guidance with regard to such matters as facility design, materials, personnel practices, and cleaning and sanitation procedures. Because part 110 provides guidance of general applicability to all foods, the agency intends that this guidance will continue to be valid for seafood processors when the proposed regulations at part 123 are issued in final form. Proposed § 123.5(b) makes clear that the purpose of subpart A of part 123 is to set forth requirements specific to the processing and importation of fish and fishery products.

C. HACCP Plans

1. Summary

FDA is proposing to require in § 123.6 that commercial processors and importers of fish and fishery products develop and implement HACCP plans in keeping with Principle 6 of the NACMCF discussed previously. Development and implementation of an HACCP plan requires that processors think through the entire process flow from raw materials to finished product shipping to ensure that safety hazards are controlled by design, and that they operate that process as a matter of daily routine. For importers, the thought process will begin with a decision from whom and from where to buy fishery products and follow through to arrangements for shipment to the United States, storage in the United States, and end when the product leaves the control of the importer. The plan provides the structure for the preventive controls, including the recordkeeping associated with those controls, that a processor or importer is to employ.

In summary, FDA has tentatively concluded that the essential elements of this structure must include: (1) The identification of hazards to ensure that the processor or importer knows what the hazards are, so that it controls them by design rather than by chance (proposed § 123.6(b)(1)); (2) the identification of critical control points to ensure that the processor or importer knows where to monitor to prevent or minimize the occurrence of the relevant hazard (proposed § 123.6(b)(2)); (3) the identification of critical limits that must be met at each critical control point, so that the processor or importer has objective standards in place by which to determine whether it is controlling the relevant hazard (proposed § 123.6(b)(3)); (4) the identification of procedures for how and when the processor or importer will monitor the critical control points to ensure both that monitoring is done as a matter of routine, and that it is done in an appropriate manner and with sufficient frequency to establish preventive control (proposed § 123.6(b)(4)); and (5) a recordkeeping system for that monitoring that will establish for the processor's or importer's benefit that it is effectively implementing a system of preventive controls, and record how those controls are operating over time (proposed § 123.6(b)(5)).

The recordkeeping system is the key to HACCP. As explained above, the records will enable the processor or importer, and ultimately the regulator, to see the operations of the processor or importer through time, rather than only how they are functioning at a particular moment in time. Among other things, HACCP records can reveal trends that might otherwise go undetected until significant problems occurred.

All of these requirements reflect the HACCP principles developed by NACMCF.

FDA is not proposing to require that the HACCP plan be signed by any official of a company, but invites comment on the merits of such a requirement in the final regulations as a means of both ensuring and demonstrating formal adoption of the plan by that company. FDA also invites comment on who in the firm would be the appropriate individual to sign the plan.

2. Guidelines and Other Assistance

FDA recognizes that HACCP plans will vary in complexity, from those having many critical control points, such as plans for multicomponent, ready-to-eat products, to those having only a few critical control points, such as a plan for a fish filleting plant. Plan development can be facilitated by technical assistance from many sources and by the detailed advice provided in the literature. NACMCF, for example, has recommended that, to facilitate the development of HACCP plans, processors should create an HACCP team, identify the intended use and likely consumers of the food, and prepare a flow diagram of the entire manufacturing process to help identify critical control points.

The agency favors simplicity and the rapid development of HACCP plans without undue expense. The appendices at the end of the proposed regulations are intended to facilitate plan development by setting forth certain critical control points, critical limits, controls, and records that, if incorporated into or prepared under a HACCP plan, would be acceptable to the agency for the types of products mentioned. To further facilitate the development of HACCP plans, FDA intends to issue separate HACCP guidance for seafood that will provide information on hazards and appropriate controls by species and by product type.

The guidance will provide a broad spectrum of information from which firms will be able to identify likely hazards and critical control points that apply to them. The agency believes that the number of critical control points will range, roughly, between 2 and 12 per product.

The guidance will also contain a fill-in-the-blank type of HACCP plan with instructions on how to complete the plan based on information in the guidance. The agency has tentatively concluded that a plan that follows this model is likely to be acceptable to FDA. The agency is including samples of the guidance it is developing in Appendix 1 to this document. FDA intends to issue a separate draft guidance document for public comment and to make the completed guidance available to the public at the time that the regulations are finalized.

In addition, seafood trade associations, university Sea Grant extension offices, and others have already developed work sheets and other aids to facilitate HACCP planning for seafood. Industry members are encouraged to contact their trade associations and state universities or Sea Grant extension offices on such matters.

3. Effective Date

Even with these forms of assistance, however, FDA recognizes that HACCP plans cannot be written and implemented overnight. As has already been discussed, the HACCP system of controls can involve new ways of thinking and performing on a routine basis. Consequently, FDA is proposing that these regulations will become effective 1 year after issuance of the final rule in this proceeding. The agency has tentatively concluded that this period of time is sufficient to permit the development and implementation of HACCP plans by the industry. FDA specifically invites comment on whether 1 year will be adequate. The agency's objective is to provide enough time to permit processors and importers to understand HACCP, analyze the relevant hazards, and develop an appropriate HACCP plan, but also to avoid unnecessary delay.

After the proposed effective date, inspection of HACCP plans will occur as part of routine, mandatory plant inspections and import examinations. FDA is not proposing to require that HACCP plans be submitted to FDA in advance, or that preapproval by FDA be a condition of their adoption or implementation. FDA is not requiring preapproval for two reasons. First, HACCP plans can only properly be judged in the context of the facility itself. Thus, while FDA investigators will consider the adequacy of the plan during their inspections, preapproval does not seem warranted. Second, the agency simply does not have the resources to make preapproval a requirement. Given the protections that are built into the HACCP approach, FDA tentatively finds that preapproval is not necessary to ensure that fish and fishery products are not produced under conditions whereby they may be adulterated under section 402(a)(4) of the act.

4. Location and Product Type

FDA is proposing in § 123.6(a) to require that every processor and importer have and implement an HACCP plan that is specific both to each location where that processor engages in processing and to each kind of fish and fishery product being processed. A plan should be specific to each location because the likely hazards, critical control points, critical limits, and monitoring procedures can vary from one facility to the next depending on such factors as type of equipment, conditions and procedures, and location. A plan also should be specific to each type of fish and fishery product for the same kinds of reasons. Hazards can vary depending on species, location of catch, and other factors.

FDA does not intend, however, to require a processor or importer to write a separate plan, or separate part of a plan, for each fish and fishery product it handles if the likely hazards, critical control points, critical limits, and monitoring procedures are identical for each of them. For example, the preventive controls necessary to ensure safety for most deep water species of finfish from the north Atlantic may be virtually identical. The agency has tentatively concluded that, in such cases, a processor or importer may group the fish or fish products together in an HACCP plan.

5. Safety Hazards Only

FDA is proposing to require at § 123.6(b)(1) that HACCP plans identify the human food safety hazards that must be controlled for each fish and fishery product being processed by a processor or importer. There exists a range of opinion on whether HACCP should apply solely to safety hazards, as this provision proposes to require, or whether HACCP should apply to other types of hazards, such as decomposition not normally associated with illness in humans. One school of thought holds that HACCP should apply to safety hazards only in order to keep it focused and to not overwhelm operators with an unnecessarily large number of critical control points that have no bearing on the primary concern of safety. Another view holds that, for seafood at least, HACCP-type controls can be applied to various consumer risks without generating an excessive number of critical control points. The Codex Committee on Food Hygiene came to the latter conclusion (Ref. 46), as did NOAA as a result of its experiences during the MSSP (Ref. 35, p. 70). Partly for that reason, the FDA/NOAA HACCP pilot programs involved HACCP controls for safety and HACCP-type controls for other hazards as well.

For purposes of these proposed regulations, however, FDA's application of HACCP is intended for the efficient enforcement of section 402(a)(1) and 402(a)(4) of the act, which applies to products that contain substances that may render the product injurious to health and to processing conditions that are insanitary and that could render a product injurious to health. Consequently, FDA is proposing to require that HACCP plans include identification of hazards that could affect human food safety only. To facilitate the production of such plans, FDA has listed in proposed § 123.6(b)(1) the types of hazards that have been associated with seafood (see section II.C. of this document for a discussion of these hazards). All of these hazards are identified and discussed in the NAS report on seafood safety (Ref. 7).

Processors and importers should identify in their written plans only those safety hazards that are reasonably likely to occur, rather than every conceivable hazard no matter how theoretical or remote. This view is in keeping with NACMCF's recommendation that firms conduct a hazard analysis and then give no further consideration to hazards that are unlikely to occur (Ref. 34, p. 189). FDA has tentatively concluded that processors and importers should not be required to establish controls and regularly monitor for hazards that are highly unlikely to occur in the absence of those controls. If, for example, chemical contaminants have never been found, or have only been found in amounts significantly below levels of public health concern in a species from a particular location, processors and importers need not identify chemical contaminants as a hazard that must be controlled for that fish.

As indicated earlier in this preamble, FDA intends to issue a guidance document that will cover possible environmental and processing hazards for fish and fishery products as well as

types of controls that can be applied to those hazards. The agency anticipates that it will update that guidance periodically as new controls (or new hazards) are identified or established.

FDA cannot reasonably expect processors and importers to exercise controls for hazards that are beyond the scope of current scientific knowledge. The agency does expect processors and importers to demonstrate that they are taking precautions that are reasonable in light of available information, and that they are adopting new controls as those controls are developed and accepted.

For example, the controls for *Vibrio* bacteria in raw molluscan shellfish, which can cause serious illness and death in certain at-risk populations, are the subject of continuing research at FDA and elsewhere. Short of a complete ban on harvesting, there is no known control that would prevent the presence of *Vibrios* in molluscan shellfish. Moreover, the infectious dose, that is, the number of *Vibrios* necessary to cause illness, is unknown. Because these bacteria occur naturally in the environment and are ubiquitous, controls that are employed to prevent sewage-related viruses from entering molluscan shellfish are not relevant to *Vibrios*. It is known, however, that proper temperature controls from the time of harvest onward can at least limit the growth of these bacteria (Ref. 49). FDA believes that such controls are reasonable and should be applied now. (In fact, temperature controls have long been a feature of the National Shellfish Sanitation Program (NSSP).)

Of the hazards listed in proposed § 123.6(b), pesticides and drug residues (proposed § 123.6(b)(1)(iv) and (b)(1)(v)) are forms of chemical contaminants (proposed § 123.6(b)(1)(iii)) but are listed separately because they can be of special concern in aquaculture-raised species. These fish generally have a greater likelihood of being exposed to agricultural run-off than wild ocean stocks (Ref. 50, pp. 11 and 12). Aquaculture-raised fish are known to be fed drugs for various purposes. Drug residues in edible tissues can be a public health concern.

Decomposition, listed in proposed § 123.6(b)(1)(vi), is a known hazard in those species that can generate scombrotoxin when they decompose; otherwise, it is regarded as a quality problem. Parasites (proposed § 123.6(b)(1)(vii)) are not a hazard if killed during cooking but can be a hazard in finfish consumed raw, unless that fish is commercially frozen. Unapproved direct and indirect food and color additives (proposed § 123.6(b)(1)(viii)) are a potential hazard with most any food.

6. Critical Control Points

Consistent with the HACCP principles identified by NACMCF, FDA is proposing to require in § 123.6(b)(2) that critical control points be identified for each of the hazards that the processor or importer has identified. Hazards may be caused by improper processing or by events outside the processor's or importer's direct control. To control the latter type of hazard, that is, environmental hazards and hazards that may be caused by poor handling prior to receipt of fish or fishery products by the processor or importer, the point of receipt by the processor or importer represents a critical control point. As indicated previously in this preamble, the processor or importer may need to ensure that it obtains imported shipments or raw materials only from harvesters, transporters, and others who can demonstrate that they also have exercised appropriate controls. The hazards that may be caused by both improper processing and events outside the plant are controlled by the critical limits, monitoring, control procedures, and recordkeeping that are done as part of HACCP.

7. Critical Limits

In § 123.6(b)(3), consistent with NACMCF principles, FDA is proposing that processors and importers identify critical limits in the plan that must be met at each critical control point. Critical limits must be met to ensure that the relevant hazard is avoided. Thus, some critical limits can be set to reflect regulatory levels established by FDA in the form of action levels, regulatory limits, and tolerances for such contaminants as pesticides, histamine, and other contaminants. FDA intends to compile all such levels in the guidance document described earlier.

Other critical limits can be set in consultation with outside experts, in keeping with the longstanding practice for low acid canned foods. For example, as explained later in this preamble with respect to cooked, ready-to-eat products, there exist a range of possible cooking time-temperature combinations that will deactivate pathogens during the cooking step, depending on the type of equipment being used by the processor and the size and species of fish being cooked. The existence of a range of effective cooking time-temperature combinations convinced FDA not to establish specific cooking time-temperatures for industry in the regulations for low acid canned foods. Rather, FDA decided to rely on outside experts and on research within the scientific community to establish cooking times and temperatures for these products. FDA is not proposing specific cooking time-temperature requirements for most seafood products (although FDA is providing guidance on time, temperature, and salinity parameters for smoked and smoke-flavored fish, as is fully explained in Appendix 1 to this document) for the same reason.

8. Monitoring and Control Procedures

Proposed § 123.6(b)(4) requires that the processor or importer identify in the HACCP plan the procedures that it will use to control and monitor each critical control point. Monitoring steps are necessary to ensure that the critical control point is in fact under control and to produce an accurate record of what has occurred at the critical control point (Ref. 34, p. 197). Among the procedures that are to be used under proposed § 123.6(b)(4) is monitoring of the consumer complaints received by the processor. While the goal of an HACCP system is to prevent all likely hazards from occurring, no system is foolproof. Consumer complaints may be the first alert that a processor has that deviations are occurring that are not being prevented or uncovered by the processor's HACCP controls. FDA has tentatively concluded, therefore, that each HACCP system should take advantage of consumer complaints as they relate to the operation of critical control points.

Proposed § 123.6(b)(4) also requires that procedures for controlling and monitoring critical control points must include calibration of process control instruments and validation of software for computer control systems, as appropriate. For a processor's preventive controls to work, the instruments and equipment that it relies upon in monitoring critical control points, such as thermometers, temperature-recording devices, and computer software, must be accurate and reliable. FDA has tentatively concluded that the best way to ensure such accuracy and reliability is to require that the processor's monitoring procedures include steps necessary to verify the reliability of these instruments and devices.

9. Recordkeeping

As explained above, a HACCP system will not work unless records are generated during the operation of the HACCP plan, and these records are maintained and are available for review (see section IV.A.6. of this document). Thus, FDA is requiring in proposed

§ 123.6(b)(5) that the HACCP plan provide for a recordkeeping system that will document the processor's or importer's monitoring of the critical control points. Proposed § 123.6(b)(5) also requires that HACCP records contain the actual values obtained during monitoring, such as the actual temperatures and times. FDA has tentatively concluded that it is not possible for the processor to derive the full benefits of its HACCP system, nor is it possible for FDA to verify the operation of the system, without actual values. Notations that refrigeration temperatures are satisfactory or unsatisfactory, without recording the actual temperatures, are vague and subject to varying interpretation and thus will not ensure that preventive controls are working. Also, it is not possible to discern trends without actual values.

In addition, proposed § 123.6(b)(5) requires that HACCP records include the actual consumer complaints that may have been received by the processor or importer relating to the operation of critical control points or possible critical limit deviations. FDA has tentatively concluded that it may be necessary on occasion for it to review these complaints in order to be able to validate whether the firm is taking necessary steps to review controls and correct deviations as necessary in response to consumer complaints.

It is not FDA's intent to gain unlimited access to industry's consumer complaint files through this proposal or to engage in "fishing expeditions" through consumer complaint files. Only those consumer complaints relating to the operation of the HACCP critical control points need be included as HACCP records. FDA's interest is solely in verifying that the HACCP system is working as it should. The agency understands the sensitivities associated with consumer complaint records and invites comments on this aspect of the proposal.

10. Nonsafety Hazards

Proposed § 123.6(c) encourages, but does not require, processors and importers to include in their plans controls for hazards other than hazards to health. Examples listed in § 123.6(c)(1)(i) and (ii) are decomposition not associated with human illness and economic adulteration. FDA is not requiring processors and importers to include nonsafety hazards in their HACCP plans for reasons stated previously. However, the agency is encouraging processors and importers to apply HACCP principles to these nonsafety hazards, and to control them in the same manner that processors and importers control safety hazards (see proposed § 123.6(c)(2)), because they are common problems in the seafood industry. FDA has included a guideline on economic adulteration with these proposed regulations (see Appendix D).

Despite the fact that these proposed regulations do not require HACCP controls for nonsafety hazards, such hazards as economic adulteration, decomposition not normally associated with human illness, general unfitness for food, and misbranding, constitute violations of the act and are subject to regulatory action by FDA (see sections 402(a)(3) and 403 of the act (21 U.S.C. 343). Inspections by FDA investigators will continue to consider and enforce these provisions of the act.

D. Corrective Actions

FDA is proposing in § 123.7 to require that deviations from critical limits trigger a prescribed series of actions by a processor or importer, including determining the significance of the deviation, taking appropriate remedial action, and documenting the actions taken. This proposed provision is consistent with the HACCP principles enunciated by NACMCF (Ref. 34). First, under proposed § 123.7(a)(1), any critical limit deviation will require the segregation and holding of the affected product until the significance of the deviation can be determined. This step is necessary to ensure that products that may be injurious to health do not enter commerce until the impact of the deviation on safety has been determined, and the safety of the product assured. Second, under proposed § 123.7(a)(2), the processor or importer must actually determine the effect of the deviation on safety, and third, under proposed § 123.7(a)(3), it must take whatever corrective actions are necessary with respect to both the affected product and the critical control point at which the deviation occurred, based on that determination.

Some deviations, especially if they are caught quickly, will not adversely affect safety. For example, if a refrigeration unit fails, but product being stored there is moved to a functioning unit before any appreciable warming of the product can occur, safety will not have been affected.

FDA is proposing to require in § 123.7(a)(2) that the safety determination be made by an individual who has successfully completed training in HACCP principles (see proposed § 123.9). FDA has tentatively concluded that this requirement is necessary to ensure that the person who is reviewing the significance of the deviation understands the possible consequences of a processing deviation and knows how to take appropriate measures in response to a deviation. FDA does not expect that a processor or importer will be able, without assistance, to determine the public health consequences of every possible deviation. The required training will, however, provide the processor or importer with information about when and how to obtain the assistance of an analytical laboratory, outside expert, State regulatory authority, or FDA district office in determining the proper course of action.

FDA is proposing to require in § 123.7(a)(4) and (a)(5) that the processor or importer review the process and the HACCP plan to determine whether the deviation reveals the need to modify the process or the plan, or both, and to make such modifications as may be needed. It is critically important that a processor or importer learn as much as possible from the occurrence of a deviation and take steps to ensure that it will not be repeated. The plan should be a living document that the processor or importer should modify and update as circumstances warrant. These proposed requirements will ensure that the processor and importer connect day-to-day processing and other operations to the plan. Each modification is required to be noted, dated, and maintained as part of their HACCP records.

FDA is proposing to require in § 123.7(b) that when a processor or importer receives a consumer complaint that may be related to the performance of a critical control point or that may reflect a critical limit deviation, it take appropriate steps to determine whether a deviation or other system failure has occurred that warrants remedial action and take such remedial action that appears to be warranted under § 123.7(a). The importance of consumer complaints has been discussed above.

FDA recognizes that segregation and holding of the affected product will not always be feasible or warranted in response to a consumer complaint. In many cases, there will be no product to hold because all of the product in question will already be in commerce. In other cases, a processor or importer may be able to determine very quickly whether a deviation has actually occurred.

FDA is proposing in § 123.7(c) to require that processors and importers clearly document all of the steps that they take in response to a critical limit deviation or a consumer complaint and include that documentation as part of

their HACCP records. FDA has tentatively concluded that the processor, the importer, and FDA will benefit from this requirement. Documentation helps processors and importers to think the whole process through in a thorough and methodical way and to establish to their own satisfaction that they have taken proper steps. Documentation enables the regulatory agency to determine whether the processor or importer is able to regain control once a deviation occurs and to ensure that potentially unsafe products are being prevented from entering commerce or at least quickly removed from commerce.

The documentation that FDA is proposing to require of the processor's or importer's response to the consumer complaints covered by § 123.7(b) will enable the processor, the importer, and FDA reviewers to determine whether those consumer complaints are receiving appropriate attention in a timely manner. The documentation should be clear enough to allow a determination of the nature of the complaint and of the time it took from the receipt of the complaint for processor or importer to review it and to take any necessary corrective actions. FDA may choose on occasion to review a limited number of consumer complaints to match against the documentation maintained by the processor or the importer.

There is a strong view in the HACCP literature (see e.g., Ref. 51), which is reflected in one of NACMCF's seven principles listed above, that processors should actually have a plan describing how they will handle deviations, and that this plan should be part of the overall HACCP plan. FDA believes that there is merit in this view and encourages processors and importers to think through how they will handle deviations that may occur. The agency has tentatively concluded, however, that the proposed requirements in § 123.7 represent the minimum requirements necessary to ensure that processors and importers respond effectively to deviations that could affect safety, and that given these provisions, it is not necessary to require that a specific plan be formulated and adopted. FDA requests comments on this tentative conclusion.

E. Records

As discussed above, maintenance of appropriate records is fundamental to the success of an HACCP system (see section IV.A.6. of this document). In recognition of this fact, FDA is proposing to require in § 123.8 that HACCP records contain certain necessary information; that processors review records of monitoring and related activities before distributing the products to which the records pertain; that processors and importers retain records for specific periods of time; and that FDA investigators be given access to HACCP records.

FDA is proposing in § 123.8(a) that records involving observations or measurements during processing, corrective actions, and related activities, contain the identity of the product, product code, and date that the record was made. The purpose of this provision is to ensure that both the processor or importer and the regulator can readily link a record to a product and to the timeframe in which the product was manufactured. The linkage of the record to product is especially important when there has been a deviation at a critical control point. The agency has tentatively concluded that including the identity of the product, product code, and date of the activity that the record reflects provide the minimum necessary information to enable the processor or the importer and, ultimately, the regulator to determine what product may have been affected and to take appropriate action, such as withholding the product from distribution or recalling it from distribution. Dates also help discern trends over time. Even when no deviation has occurred, the information will enable both the processor and the regulator to identify factors that may help prevent problems in the future.

In § 123.8(a), FDA is also proposing to require that information be recorded at the time that it is observed, and that each record be signed by the operator or observer. It is important that information relating to observations be recorded immediately to ensure accuracy. The record should be signed by the individual who made the observation to ensure responsibility and accountability. Also, if there is a question about the record, a signature ensures that the source of the record will be known.

FDA is proposing to require in § 123.8(b) that records receive a second review by an individual trained in accordance with § 123.9, for verification purposes, before the product is distributed into commerce. The purpose of this review is to ensure that the processor or importer verifies that employees are recording data in HACCP records, and that deviations from critical limits are being caught before products that may have been affected can enter commerce. The agency is proposing to require that this records verification be performed by a trained individual to ensure that the records are reviewed by a person who understands the HACCP system, understands the significance of a processing deviation, and knows how to respond if a deviation occurs.

FDA is proposing in § 123.8(c) to require that HACCP records be retained for at least 1 year after they are prepared for refrigerated products and for at least 2 years after they are prepared for frozen or preserved (i.e., shelf-stable) products. These timeframes are based on the length of time that these products can be expected to be in commercial distribution (Ref. 52; Ref. 53, pp. 72–73) plus a reasonable time thereafter to ensure that the records are there when the FDA inspector performs the next inspection. They are the same timeframes as now provided for in the Manual of Operations of the NSSP for the retention of records for raw molluscan shellfish.

Similarly, FDA is also proposing to require in § 123.8(c) that the processor retain any records relating to the general adequacy of the equipment or processes being used by the processor, including the results of scientific studies and evaluations to determine adequacy, for 1 year beyond the applicability of these records to refrigerated products being produced by the processor, and for 2 years beyond the applicability of the records to frozen or preserved products being produced by the processor. The processor may need to obtain a written scientific evaluation of a process, such as a cooking, pasteurization, or cooling process, to ensure that the process it is using is adequate to destroy pathogens or to prevent their growth. Such an evaluation may also be necessary to ensure the adequacy of the cooking, pasteurizing, or refrigerating equipment that the processor is using. (See the preamble discussion on cooked, ready-to-eat fishery products.) As with processing records, these records should be retained for a period of time that reflects the period that the products to which they relate can be expected to be in commercial distribution.

FDA recognizes that some processing plants may be closed on a seasonal basis. Given the nature of the HACCP system, however, FDA may choose to inspect at least the records of a plant even if the plant is not in operation. Therefore, FDA is providing in proposed § 123.8(c) that if a processing facility is closed between seasonal packs, the records may be transferred to some reasonably accessible location during the period of closure.

FDA is proposing to require in § 123.8(d) that HACCP plans and records be available for review and

copying by authorized agency employees at reasonable times. As already discussed, the agency's access to HACCP records is essential to ensure that the HACCP system is working, and that the safety of seafood is being ensured by design. FDA's authority to require maintenance of these records, and to provide for agency access to them, is fully supported by the holding in *National Confectioners Association* v. *Califano*, 569 F.2d 694–95 (D.C. Cir. 1978). In this case, the court recognized FDA's authority to impose recordkeeping requirements on firms that process foods when such requirements effectuate the goals of the act. See also *Toilet Goods Association* v. *Gardner*, 387 U.S. 158, 163–164 (1967). The importance of the records in ensuring that fish and fishery products will not be rendered injurious to health has been fully discussed. FDA access to these records will expedite the agency's efforts to ensure that the fish and fishery products in interstate commerce are not adulterated and to identify any such products that are.

FDA is aware that there is substantial public interest in the extent to which industry-generated HACCP records could or should be publicly available. As FDA understands it, the argument in favor of availability is that where an inspection system to protect the public health relies heavily on records, those records should be public to the maximum extent possible. The arguments in favor of protection of records, on the other hand, are based on concerns about advantages to competitors from disclosure and on the risk that the records will be otherwise misused if they become public. FDA invites comment on the general question of public disclosure of HACCP records and on the agency's preliminary analysis of their availability, as follows.

FDA has longstanding explicit statutory access to certain industry records during inspections involving infant formula, drugs, and devices and has access by regulation to certain processing records during inspections of low acid canned food processors. The agency has the right to copy and take possession of these records but does not routinely do so. FDA typically copies and takes possession of records only when they may be needed for regulatory purposes. As a preliminary matter, FDA expects to continue that practice with regard to seafood HACCP records.

The public availability of those HACCP records that FDA would possess as a result of copying during an inspection would be governed by section 301(j) of the act and by the Freedom of Information Act (FOIA) and regulations issued pursuant to it by the Department of Health and Human Services (DHHS) and FDA. Section 301(j) of the act expressly prohibits FDA from disclosing trade secret information obtained during the course of an inspection. The FOIA regulations also say that FDA will not divulge either trade secret or commercial confidential information. As a preliminary matter, HACCP plans and monitoring records appear to fall within these two categories of protected records. As a consequence, FDA may well have little discretion in this area. Moreover, under DHHS' FOIA regulations, processors may be entitled to challenge in court a pending disclosure of records on the grounds that the records to be disclosed are commercial confidential or trade secret.

As an additional matter, there are significant legal and practical questions as to whether FDA has the authority to require disclosure of industry records that are not in FDA's possession. As discussed elsewhere in this document, FDA does not contemplate the submission of HACCP plans or other records to FDA under these proposed regulations. The preapproval of HACCP plans by FDA (and thus the submission of HACCP plans to FDA) is simply not practical. The agency has tentatively concluded that HACCP plans and monitoring records will be reviewed on site by agency investigators as part of FDA's normal inspection regime.

FDA is proposing in § 123.8(e) to exempt tags as defined in § 123.3(t) from the recordkeeping requirements of § 123.8. While the information on tags must be saved in accordance with the proposed requirements of this section and § 123.28(d), the agency has tentatively concluded that it would be burdensome for processors to be required to retain the tags themselves for extended periods of time. NSSP now provides that processors are to retain tags for 90 days.

F. Training

Proposed § 123.9 requires that each processor and importer employ at least one individual who has successfully completed a training course on the application of HACCP to fish and fishery products processing. The agency has tentatively concluded that training is critical to the successful implementation of HACCP systems in the seafood industry. Based on experience obtained during the FDA/NOAA HACCP pilot programs in 1991–92, the agency believes that a significant portion of the seafood industry will be unprepared to meet the requirements of a mandatory HACCP program without some training. As discussed earlier, the pilot program revealed a general lack of understanding of the preventive nature of HACCP, including misunderstandings about how to establish critical limits, control measures, corrective actions, and recordkeeping procedures (Ref. 40).

A similar concern that the industry did not understand the application of HACCP principles formed the basis for the training requirements in the agency's regulations for low acid canned foods. Improvements in canning operations can be attributed in significant measure to the success of the training programs that were established to implement that requirement (Ref. 54). NAS concluded that the successful application of HACCP principles to low acid canned foods was substantially the result of the training requirement in the regulations for those products (Ref. 36, p. 309). The CGMP regulations for foods in part 110 also call for training in appropriate food protection principles (§ 110.10(c)).

The often seasonal nature, remote location, and small size of many seafood processors also support the need for formalized training. All of these conditions result in difficulty recruiting highly qualified management and supervisory staff. Thus, FDA has tentatively concluded that proposed § 123.9 is necessary to ensure that seafood processors and importers employ at least one person who is familiar with HACCP.

These regulations propose to require at § 123.9 that the person or persons at each importing and processing establishment who has received training be responsible for reviewing records of critical control point monitoring, recognizing critical limit deficiencies, and assessing the need for corrective actions relative to the product in question and the HACCP plan itself. While it is the intent of the agency to provide as much guidance as possible to assist processors and importers, these activities require specialized training in the principles of HACCP, various aspects of food science, and the criteria of existing regulations and guidelines.

The agency anticipates that 2- or 3-day training sessions, modeled after the Better Process Control Schools currently in place for low acid canned food and acidified food manufacturers, will be provided by various public and semiprivate institutions. The uniformity of this training can be assured by a review of their contents and by periodic onsite monitoring by the agency. Thus, FDA is proposing to require that the program of instruction be approved by the agency.

While 2- or 3-day courses may well become the norm, FDA invites comment on whether the training requirement could be satisfied by different gradations of training, depending on the complexity or size of the operation, or on the degree of risk posed by the product being produced, without compromising the purposes for which training is proposed to be required. For example, could training for a small business with few hazards be accomplished in a shorter time and at a lower cost through the use of a video? FDA also invites comment on whether training in HACCP received before these proposed regulations become effective as final regulations should be "grandfathered" as fulfilling the training requirement.

G. Sanitation Control Procedures

1. General

FDA is proposing to require in § 123.10 that processors and importers that engage in processing perform sanitation inspections at specified frequencies and maintain sanitation control records that document the results and frequency of those inspections. If these regulations are adopted, the sanitation control records will be subject to the recordkeeping requirements in § 123.8, including review by FDA investigators.

For seafood, sanitary practices affect most directly the safety of those products that do not receive any further cooking by the consumer. These products include raw molluscan shellfish; finfish destined to be consumed as sushi; cooked, ready-to-eat products; and certain smoked and salted products. Both finfish and shellfish are regarded as microbiologically sensitive foods based on the potential presence of pathogens, notably *L. monocytogenes* (Ref. 55, pp. 31 and 32).

L. monocytogenes is a pathogenic bacterium that is widespread in the environment. Thus, the likelihood of finding it on the exterior surfaces and viscera of fish is high. Since 1983, several large outbreaks of human listeriosis have been linked to contaminated foods. Although it is a relatively rare illness, the exceptionally high mortality rate among susceptible individuals makes this illness one of the leading fatal foodborne diseases in the United States.

Numerous seafood products have been shown to support growth of *L. monocytogenes* (Refs. 56 and 57), and seafoods have been epidemiologically linked to two outbreaks and one sporadic case of listeriosis (Ref. 58). Furthermore, several cooked seafood products have been recalled from the market in North America because of contamination with *L. monocytogenes* (Ref. 27). Seven of nine smoked fish processing facilities recently inspected by FDA in New York State had *L. monocytogenes* in the environment or in the products (Ref. 59).

Good sanitation practices are critical to the prevention of listeriosis and other microbiologically related foodborne illnesses. FDA's CGMP regulations for food in part 110 set out general principles of sanitation that should be followed in plants that manufacture, package, label, or hold human food. They address such matters as personal hygiene and cleanliness among workers who handle food, the suitability of the plant design to sanitary operations, and the cleaning of food-contact surfaces. FDA inspections of seafood processors apply the principles in part 110.

Nearly half of the consumer complaints relating to seafood that FDA receives in a typical year are related to plant or food hygiene (Ref. 60). The reasons, while not entirely clear, appear to be related to factors such as the age of processing facilities, the seasonal nature of operations that affect training, and the turnover of personnel.

A representative cross section of those FDA establishment inspection reports (EIR's) for domestic seafood manufacturers that revealed CGMP deficiencies for fiscal years 1988–90 demonstrates this point (Ref. 61). The cross section involves 795 EIR's covering 561 facilities. (The number of EIR's exceeds the number of facilities because followup visits were made to check on the status of corrective actions.) The following percentages refer to EIR's with deficiencies where at least some of the deficiencies involved sanitation:

(1) Twenty-three percent documented receiving area facilities that were not clean/orderly or in good repair.

(2) Twenty-six percent documented facilities lacking effective insect and rodent control measures in the receiving area.

(3) Sixteen percent documented failure to handle ice in a sanitary manner and to protect it properly.

(4) Thirty-five percent documented lack of adequate cleaning or sanitizing of processing equipment.

(5) Twenty-one percent documented processing equipment that was not constructed so that it could be easily cleaned and sanitized.

(6) Eighteen percent documented processing equipment that was not made of suitable materials.

(7) Fifteen percent documented hand sanitizers that were not kept at proper sanitizing levels.

(8) Eighteen percent documented failure to have hand sanitizers available in the processing area.

(9) Thirty percent documented processing areas that were not maintained in a clean and sanitary manner.

(10) Forty-two percent documented processing areas with exterior openings that were not sealed/covered properly to prevent the entrance of pests or insects.

(11) Sixteen percent documented waste material not being collected/covered in suitable containers or not being disposed of properly.

(12) Twenty-three percent documented handling of finished product in a manner that did not preclude contamination.

(13) Twenty-two percent documented employees not taking necessary precautions to avoid food contamination.

During fiscal years 1991–92, FDA conducted abbreviated inspections of nearly all domestic manufacturers in its seafood establishment inventory. These inspections provide data on sanitation practices and conditions that are generally consistent with the above findings (Ref. 62). Examples of these data are:

(1) Sixteen percent of firms had problems with the general sanitation condition of their processing areas. (This percentage is lower than for item 9 above because the universe is all firms, not just firms with deficiencies.)

(2) Nineteen percent of firms did not clean and sanitize their processing areas or equipment throughout the day's production. (This matches most closely with item 4 above but is lower, presumably for the reason stated in the previously numbered paragraph.)

(3) Twenty-eight percent of firms had employees that were not following proper sanitation practices in processing activities. (This figure does not precisely match any of the items listed above because the EIR's break employee practices down into specific categories, such as the wearing of hair nets. Some categories involve relatively minor matters, others are more significant. Findings with respect to these employee practices were not listed above for the sake of brevity.)

(4) Twenty percent had employees that were not following proper sanitation practices for packaging and finished product storage. (The parenthetical observations in the previously numbered paragraph apply here as well.)

(5) Thirty-six percent of firms either lacked hand sanitizers in their processing areas or had sanitizers that were not kept at proper sanitizing levels. (This finding is equivalent to a combination of items 7 and 8 above. Surprisingly, this finding is roughly the same as 7 and 8 added together, even though it includes all processors rather than processors with deficiencies.)

Sanitation problems found by NMFS during the operation of its fee-for-service inspection program for seafood manufacturers, as described earlier, are generally consistent with FDA's findings. Entrants into the NMFS program undergo initial sanitation surveys by NMFS and are checked for sanitation practices thereafter. NMFS' data show significant sanitation deficiencies during the initial surveys (Ref. 35, p. 40). Some of the most common for 1989 include:

(1) Sixty-four percent of plants had discrepancies relating to proper cleaning and sanitizing of product contact surfaces or equipment, containers, or utensils after use.

(2) Fifty-one percent of plants had discrepancies relating to design, materials, or construction that prevented their being maintained in a sanitary manner.

(3) Forty-five percent of plants had discrepancies relating to design of equipment, containers, and utensils so that they did not provide protection from contaminants and could not be readily cleaned and effectively sanitized.

(4) Forty-three percent of plants had discrepancies relating to improper storage of equipment, litter, waste, uncut weeds, and grass.

(5) Forty percent had discrepancies relating to storage facilities that were not clean, sanitary, or in good repair.

For established participants in the NMFS program (as opposed to entrants), the percentages with discrepancies in the above areas for 1989 were: 49 percent; 47 percent; 25 percent; 49 percent; and 33 percent (Ref. 35, p. 42).

FDA has tentatively concluded on the basis of all of these findings that HACCP-type controls for sanitation as proposed below are needed. The sanitation measures required under proposed § 123.10 are fundamental to good sanitation practices and can have a bearing on human safety. The agency recognizes, however, that depending on the conditions in a facility, additional measures may be necessary (see, e.g., part 110). FDA will expect processors to include those measures in their sanitation practices but tentatively concludes that it is not necessary to include them in the fundamental core of required steps.

FDA acknowledges the conclusion of the MSSP project that, for seafood at least, it is possible to include sanitation within an HACCP system without unduly overburdening that system with large numbers of critical control points. The FDA/NOAA HACCP-based seafood pilot program included critical control points for sanitation. For these regulations, however, FDA has tentatively decided to propose specific HACCP-type requirements for sanitation, rather than require that processors identify critical control points for sanitation in their HACCP plans. The proposed requirements in § 123.10 potentially relate to an entire facility, not just to a limited number of critical control points. FDA tentatively concludes that this step is necessary to fully implement section 402(a)(4) of the act and yet at the same time not overload the HACCP system. FDA invites comments on this approach.

In particular, FDA invites comment on whether sanitation requirements should be enumerated as in proposed § 123.10. The logical alternative would be to leave sanitation as one of the procedures that is to be identified and addressed in HACCP plans for the control of microbiological and physical hazards (see proposed § 123.6(b)(1)(ii), (b)(1)(ix), and (b)(4)), but not to have specific provisions in the regulations as to how sanitation is to be achieved. Good sanitation blocks avenues for the introduction of pathogens, harmful chemicals, and physical objects and is an essential preventive control for safety. Even if a product is to be cooked by the consumer, the load of microbiological pathogens on that product when received by the consumer is still relevant to safety. FDA's prescriptive approach to sanitation in proposed § 123.10 is intended to assist processors to provide the greatest protection for consumers. Nonetheless, FDA invites comment on whether an alternative approach as described above would ensure this protection at less cost.

FDA is proposing in § 123.10(a) to require that processors conduct sanitation inspections to ensure that the sanitation conditions in § 123.10(a)(1) through (a)(17) are met. FDA recognizes that the nature of the operations conducted by a processor affects the hazards that may be presented by the product. Processing other than storing usually involves manipulation of exposed, i.e., unpackaged, fish and fishery products. Both the manipulation and the exposure subject the product to all the hazards that can occur from unsanitary practices. Storage, on the other hand, can subject the product to some, but nowhere near all, of the hazards associated with insanitation. Consequently, FDA is proposing to require that processors of fish and fishery products inspect for those conditions in § 123.10(a)(1) through (a)(17) that are appropriate to their circumstances. FDA expects that, at a minimum, in, for example, storage facilities, such inspections will include ensuring against the presence of vermin, because this is a frequent problem in warehouses that can affect products even when they are being stored in a packaged state.

In § 123.10(a)(1), the agency is proposing to require that processors ensure that water that contacts the product or food-contact surfaces, or that is used in the manufacture of ice, is derived from a safe and sanitary source or is treated to render it of safe and sanitary quality. Water is used in virtually all fish and fishery product processing facilities for washing raw materials, product contact surfaces, and employees' hands. It is used to transport fish through the plant in water flumes. In addition, water is often an ingredient, as in soups and glazes. Contaminated water can serve as a vehicle for contamination of the product, both directly and indirectly (Refs. 63, 64; 65, p. 49; 66, 67, and 68, pp. 1 and 2). It can also serve as a vehicle for contamination as the ice in which the product is stored.

The safety and sanitary quality of water from United States and some foreign public water systems is generally ensured through public water treatment, chlorination, or monitoring and control by local health authorities. Where this assurance exists, FDA does not anticipate that processors will need to implement any additional controls.

Private sources of water, particularly surface waters or water from shallow wells, may be subject to microbiological, chemical, or radiological contamination attributable to the source itself or to surface contamination at the well head or intake. Private sources are also frequently untreated or minimally treated (Refs. 69, p. 15; and 70). Where the processor uses a private source of water, it will need to take steps to ensure that the water is of a safe and sanitary quality. These steps may include retaining a copy of the initial local health authority well design approval and copies of the local health authority fecal coliform test results; obtaining and maintaining copies of private coliform test results; performing and recording periodic inspections of the sanitary condition of the well head

or source intake; and performing and monitoring appropriate water treatment procedures, including filtration, sedimentation, and chlorination.

The type and frequency of controls exercised by the processor should be based upon the type of source water and its historic safety and sanitary quality. Consequently, the agency is proposing to require, in § 123.10(c)(3), that such controls be performed and documented at such frequency as necessary to ensure control. In § 123.10(a)(2), as a means of ensuring that potable water does not become contaminated, the agency is proposing to require that the processor ensure that there are no cross connections between the potable water system and any nonpotable systems. Nonpotable systems include waste water and sewage. Cross connections, which include situations that allow for back siphonage into a potable system from a nonpotable system under negative pressure conditions, can result in the chemical or microbiological contamination of the potable water system (Refs. 64; 65, pp. 50 and 51; 68, 71, and 72). For example, if a hose from a potable water system is left in a thawing tank with water and frozen fish, and if negative pressure occurs that draws water from the tank back through the hose to the potable water system, both the potable water line and the water source itself, i.e., the municipal or private water system, can become contaminated.

Cross connections can best be controlled by performing periodic inspections of the potable and nonpotable systems. These inspections should be performed at least every time that there is a change in the plumbing of the systems and with sufficient additional frequency to ensure that unintentional cross connections do not develop. Consequently, in § 123.10(c)(3), the agency is proposing to require that such inspections be performed and documented at such frequency as necessary to ensure control.

FDA is proposing in § 123.10(a)(3) to require that the processor ensure that all food-contact surfaces are designed, constructed, and maintained in a manner that minimizes the potential for chemical and microbiological contamination of the product. Utensils and equipment can be vehicles for microbial contamination of both the raw and finished products. Utensils, equipment, and other food-contact surfaces that are made of corrosive material or wood, or that contain breaks, pits, cuts, or grooves, may harbor pathogenic microorganisms that can migrate to the product and contaminate it. These kinds of surfaces are difficult to clean, with the pores and crevices shielding the microorganisms from the action of cleaning and sanitizing agents (Refs. 65, pp. 20, 36–48; 72, pp. 166 and 167; and 73).

Additionally, where food-contact surfaces are constructed of toxic materials (e.g., lead shucking blocks), the product may be directly contaminated with the toxic material (Ref. 74). Therefore, FDA tentatively concludes that it is necessary to require that processors take affirmative steps to minimize the possibility that any risks will be created by the utensils and equipment they use.

Proper construction of the equipment should be ensured at the time it is received, and whenever it is modified or repaired. The frequency of subsequent inspections necessary to ensure that the sanitary condition of the equipment has not declined with time will depend on the frequency of its use, the materials and construction methods, and the nature of its use. In § 123.10(c)(3) the agency is proposing to require that such controls be performed and documented with such frequency as is necessary to ensure control.

In § 123.10(a)(4), the agency is proposing to require that the processor ensure that food-contact surfaces are regularly cleaned and sanitized with cleaning and sanitizing preparations that are suitable for this purpose. Surfaces that are not adequately cleaned and sanitized can be a source of filth to subsequent products produced on the equipment, an attractant for vermin, and a reservoir for pathogenic microorganisms. Infrequent cleaning of equipment can result in the formation of biofilms, microscopic films in which microorganisms can be entrapped, shielded from the action of sanitizers, and physically bound to the food-contact surface of the equipment.

An effective cleaning compound is one that will lower the surface tension of water so that spills can be lifted and flushed away. Ordinary soap is generally ineffective for equipment washing because of its limited ability to solubilize fats, oils, and proteins. Mildly alkaline detergents are generally suitable for cleaning seafood processing plants, but high alkaline detergents are often necessary for heavy buildups of fats and proteins. Mineral deposits will frequently require the use of acid cleaners.

An effective sanitizing agent is one that has a good bacteriocidal effect on the types of pathogens normally present in the plant environment and is safe, stable, and convenient for use. Examples include hypochlorites, iodophors, and quaternary ammonium compounds (Refs. 73, 74, 75, 76, and 77).

To eliminate the product residue that accumulates on product contact surfaces during production, FDA is proposing in § 123.10(a)(4)(i) to require that utensils and surfaces of equipment that contact food during processing be thoroughly washed at the end of the day's operations. FDA is also proposing in § 123.10(a)(4)(iii) that sanitizing be performed on the same utensils and equipment immediately before the beginning of production, so that any recontamination that occurs between cleaning and production can be eliminated.

FDA is proposing to require in § 123.10(a)(4)(ii) that, in those operations in which microbiological contamination can adversely affect the safety of the product (e.g., the processing of cooked, ready-to-eat products), the equipment also be washed and sanitized at least every 4 hours during processing. Washing and sanitizing with this frequency is necessary to inactivate mesophilic pathogens, such as *Salmonella spp.*, before they leave the lag phase of growth and enter the rapid log phase (Ref. 23). Temperatures in fish and fishery product processing plants are generally not low enough to control the growth of such microorganisms and are certainly not low enough to control the growth of such psychrotropic pathogens as *L. monocytogenes* (Refs. 23, 78, 79, and 80). Therefore, FDA tentatively finds that washing and sanitizing equipment every 4 hours is necessary.

FDA is proposing to require both cleaning and sanitizing because neither step is fully effective without the other. When sanitizing occurs without benefit of cleaning, pathogenic microorganisms can be protected from the action of the sanitizer by food residue. Conversely, while cleaning can effectively remove product residue and a portion of the microorganisms, sanitizing is generally needed to remove the remaining microorganisms (Refs. 81 and 82).

FDA is proposing to require in § 123.10(c)(2) that the processor inspect the condition of the utensils and surfaces of equipment that contact food immediately after each cleaning and sanitizing. The purpose of the inspection is to ensure the adequacy of the cleaning and sanitizing operations, and to ensure that the equipment is in a condition that is suitable for further operations.

The agency is also proposing in § 123.10(c)(2) that the processor document the time of each cleaning and sanitizing, the concentration of the

sanitizer, and the condition of the equipment. Documentation of the time of each cleaning and sanitizing will facilitate an assessment of compliance with the frequency requirement of § 123.10(a)(4). Documentation of the concentration of the sanitizer will facilitate an assessment of the adequacy of the sanitizing operation. Sanitizers must be of sufficient strength to be effective, while excessive sanitizer concentrations can contaminate the product with indirect food additives (21 CFR part 178) (Ref. 82). Documentation of the condition of the equipment is necessary to ensure that it is examined after cleaning and sanitizing to make sure that these processes were done properly.

The agency is proposing in § 123.10(a)(5) to require that the processor ensure that gloves and outer garments that contact the food or food-contact surfaces are made of an impermeable material and are maintained in a clean and sanitary condition. Gloves or aprons that are made of cloth or other porous materials are difficult to clean and may serve as a reservoir for pathogenic microorganisms that can migrate to the food during processing, in much the same manner as previously described for processing equipment (Refs. 65 and 83). Gloves and aprons that are not maintained in a clean and sanitary condition can also house pathogens that can migrate to the food. Therefore, FDA tentatively finds that it is appropriate to require the measures set out in § 123.10(a)(5).

At § 123.10(c), the agency is proposing to require that, like most of the other sanitation measures that FDA is proposing, the sanitary condition and impermeability of gloves and outer garments that may contact the food or food-contact surfaces be checked at least daily while processing operations are occurring. Such checking will ensure that employees arriving for work are equipped with gloves and outer garments that will not serve as a source of contamination to the product. It will also ensure that employees are never using personally owned gloves and garments that are made of materials that are unsuitable for the processing environment. Proposed § 123.10(c) also requires that such checking be documented on a daily basis to provide a record that such checking has occurred.

Under proposed § 123.10(a)(6), the processor must ensure that employees' hands, gloves, outer garments, utensils, and food-contact surfaces that come into contact with insanitary objects are thoroughly cleaned and sanitized before contacting fish or fishery products. Under proposed § 123.10(a)(7), the processor must also ensure that employees' hands, gloves, outer garments, utensils, and food-contact surfaces that contact raw products are thoroughly cleaned and sanitized before they contact cooked product.

Employees and food-contact surfaces can serve as vectors in the transmission of filth and pathogenic microorganisms to the food. Filth and pathogenic microorganisms can be brought into the processing environment on the employees' hands from outside areas, restrooms, contaminated raw materials, waste or waste receptacles, floors, and other insanitary objects (Refs. 63, 64, 73, 74, 84, and 85).

Bacteria naturally present on fresh fish skin and gills and in the gastrointestinal tract reflect the microbial content of the water from which the fish were harvested. Typical microorganisms found on and in fresh fish include *C. botulinum*, enteric bacteria, *Vibrio parahaemolyticus*, salmonella, shigella, hepatitis A, and other microorganisms that pollute harvest waters (Ref. 7). These microorganisms contaminate the environment in processing plants and cannot, using reasonable methods, be completely eliminated.

Proper precautions, such as proper hand and equipment cleaning and sanitizing, must be taken to minimize opportunities for contamination of the finished product (Refs. 63, 64, 73, 74, and 84). Therefore, FDA is proposing in § 123.10 (a)(6) and (a)(7) that such precautions be taken with respect to hands, gloves, garments, utensils, and food-contact surfaces.

The agency recognizes that not all processing activities will require hand washing and sanitizing. Activities that would not require such steps include the handling of raw fish and fishery products prior to the initial washing step (i.e., directly from the fisherman) and the handling of finished products in shipping cases. These activities are exceptions, however, to the general rule that employees must thoroughly wash and sanitize their hands after each contact with an insanitary surface. Additionally, when insanitary objects come into contact with product contact surfaces, they must be thoroughly cleaned and sanitized.

In the processing of cooked products, the raw material may also serve as a reservoir of pathogenic microorganisms. For this reason, employees or equipment that handle or touch the raw material must be cleaned and sanitized before being used with cooked product or ice, or they could convey the microorganisms to these foods (Refs. 63, 64, 73, 74, 84, 87, and 88).

In § 123.10(c)(1), the agency is proposing to require that the sanitary practices of the employees, especially as they relate to hand washing, sanitizing practices, and the potential for cross contamination, be checked and recorded at least every 4 hours during processing. This monitoring will ensure that employees arriving for work and returning from the midshift break have properly washed and sanitized their hands. The concentration of hand sanitizing solutions tends to be reduced over the course of a production day because of the reaction of the sanitizer with organic matter and dissipation as a gas (Ref. 82). It will also cause a regular assessment of the adequacy of the normal operating procedures. Finally, recording will provide assurance that appropriate procedures are being followed.

In § 123.10(a)(8)(i), FDA is proposing to require that hand washing facilities be located in all processing areas in which washing and sanitizing is required by CGMP's so that these facilities are readily accessible to employees who work in processing areas. The agency has tentatively concluded that proper sanitization is such an important part of preventing the spread of disease as to warrant a requirement that hand washing equipment be conveniently located to facilitate their use. Where these facilities are not conveniently located, they may not be frequented by the employees.

FDA is proposing to require in § 123.10(a)(8)(ii) that these facilities be equipped with hand cleaning and effective sanitizing preparations and single-service towels or suitable hand drying devices. Ordinary soap is acceptable for hand washing. Hand sanitizers need to be fast acting because of the short contact time involved. In contrast to the sanitizing of equipment, which can involve leaving a sanitizing spray on the equipment for extended periods of time, hand sanitizing usually involves a quick dip in and out of the sanitizer. Of the sanitizers described previously (see discussion of proposed § 123.10(a)(4)), quaternary ammonium is not fast acting and is not suitable as a hand sanitizer. The others are appropriate as hand sanitizers.

The agency is proposing to require single-service towels or suitable hand drying devices to ensure that microbiological contamination does not occur though the repeated use of the same towel by several individuals. A hot-air blower is an example of a suitable hand drying device because

contamination from individual to individual is eliminated.

In § 123.10(c)(3), the agency is proposing to require that inspection and documentation of the location of hand washing facilities be performed at sufficient frequency to ensure that there is compliance with § 123.10(a)(8)(i). Generally, this procedure will be necessary only after construction or any significant building or process modification.

FDA is proposing to require in § 123.10(c) that the processor inspect, and document that it has inspected, the hand washing and hand sanitizing facilities to ensure that they are properly equipped no less than once per day. This procedure will ensure that cleaning and sanitizing preparations, as well as towels or hand drying devices, are present whenever needed by employees.

FDA is proposing to require at § 123.10 (a)(9) and (a)(10) that the processor protect the food, food-contact surfaces, and food packaging materials against adulteration by chemical and physical contaminants. Such protection is necessary to ensure that the food produced by the processor is safe. The use of toxic compounds (e.g., pesticides, cleaning and sanitizing agents, and lubricants) is frequently necessary in the processing environment. For example, lubricants and fuel are necessary to operate equipment. Improper use of these compounds is a frequent cause of product adulteration throughout the food industry (Ref. 74). Thus, it is necessary to ensure that food, food-contact surfaces, and food packaging materials are not contaminated by these toxic compounds. Food and food packaging material should be protected or removed from areas where pesticides are used, and caustic cleaning compounds should be thoroughly removed from food-contact surfaces before processing begins. Finally, as an additional protection, FDA is proposing to require in § 123.10(a)(10) that toxic compounds be labeled, held, and used in a manner that minimizes the risk of contamination of the product.

FDA is proposing to require in § 123.10(c) that the processing plant be inspected daily to ensure that the food is protected from toxic compounds, and that this inspection be documented. This check should normally be performed before the start of operations, at a time when the equipment can be effectively inspected, and in time to prevent adulteration of the product. Because processing conditions vary on a day-to-day basis, FDA has tentatively concluded that daily inspection is necessary.

FDA is proposing to require at § 123.10(a)(11) that the processor ensure that products are not exposed to contaminants that may drip, drain, or be drawn into the food. An example of such a contaminant is condensate, which may form on the ceilings and equipment in a processing plant. If the condensate forms on an insanitary surface and then falls on the product, it may carry with it filth and microbiological contaminants from that surface to the food (Ref. 65, pp. 24 and 25).

In § 123.10(c), the agency is proposing to require that the processing plant be inspected daily to ensure that the potential for such contamination is minimized, and that this inspection be documented. This check should normally be performed during the actual operations, at a time when condensate or other such contaminating conditions are likely to be present. As explained above, the agency has tentatively concluded that daily variations in processing and climatic conditions necessitate daily inspection.

In § 123.10(a)(12), the agency is proposing to require that the processor ensure that compressed gases that contact food or food-contact surfaces of equipment are filtered or treated in such a way that the food is not contaminated with unapproved indirect food additives or other chemical, physical, or microbiological contaminants. Compressed gases can be contaminated with oil from the compressor, filth and microbiological contaminants from the air intake, and rust or other physical contaminants from the compression, storage, and distribution equipment. Filtration at the air intake and after compression, storage, and distribution is an effective means of reducing the risk of such contaminants entering the food (Ref. 89).

FDA is proposing to require in § 123.10(c)(3) that the filtration and other equipment used to protect the food from such contaminants be inspected, and the inspection documented, with such frequency as is necessary to ensure control. Normally, this frequency will be directed by the manufacturer of the filtration equipment. FDA is not proposing to require daily inspection because the filter and related equipment do not normally need cleaning or replacement on a daily basis.

FDA is proposing to require in § 123.10(a)(13) that the processor take action to ensure that unprotected cooked, ready-to-eat fishery products, smoked fishery products, raw molluscan shellfish, and raw fish and fishery products are physically separated from each other during refrigerated storage. Cooked, ready-to-eat products are products that will not normally receive a cooking by the consumer adequate enough to kill pathogens. Therefore, any microbiological recontamination of the product after cooking can subject the consumer to health risks. Raw molluscan shellfish may contain pathogens that can cause severe illness to certain at-risk individuals, e.g., those who are immunocompromised. These individuals might know to avoid eating raw molluscan shellfish but would not expect the same health risk from cooked, ready-to-eat products. Similarly, raw fish and fishery products may contain filth and pathogenic microorganisms not normally associated with raw molluscan shellfish or cooked, ready-to-eat products (Refs. 63 and 84).

In § 123.10(c), the agency is proposing to require that refrigerated storage areas be inspected at least daily to ensure that the three types of products are physically separated from each other. This check should normally be performed during actual operations, at a time when commingling of these products is likely to take place. The agency has tentatively concluded that daily inspection is necessary because products are normally moved in and out of refrigerated storage areas on a regular basis, creating an ongoing threat that problems will occur.

FDA is proposing to require in § 123.10(a)(14) that refrigerated storage units operate at 40 °F (4.4 °C) or below when storing raw materials, in-process or finished cooked, ready-to-eat fishery products, smoked fishery products, and fish and fishery products made in whole or in part of scombroid toxin forming species. The purpose of this requirement is to ensure that processors control microbiological hazards associated with refrigerated storage for these products (Refs. 85 and 86). Cooked, ready-to-eat products as defined in proposed § 123.3(b) and smoked fishery products (see Appendix 1) are not shelf-stable and must be kept refrigerated to retard the growth of microorganisms. As stated above, these products will not normally be cooked by the consumer at a sufficient temperature to destroy any pathogens that may be present. Scombroid toxin forming species are addressed in considerable detail later in this document. These species can form a toxin harmful to humans if subjected to time/temperature abuse after capture.

Proper refrigeration is essential for fish and fishery products that include these species. Maintaining product temperatures during storage in a range that will minimize the growth of

mesophilic and psychrotropic pathogens is necessary to ensure product safety throughout the shelf life of these products (Ref. 85). It is uniformly more convenient to control refrigeration unit temperatures than to control and monitor the internal temperatures of the various products under refrigerated storage, particularly when these products are in sealed containers. For these reasons, FDA is proposing that refrigeration units be operated at or below 40 °F (4.4 °C). FDA tentatively finds that this temperature is appropriate because it is adequate to minimize the growth of pathogens (Refs. 85 and 86.) The agency also strongly recommends this temperature or lower for all fish and fishery products that need refrigeration, regardless of whether safety is an issue. The agency is also especially interested in obtaining comment on the appropriateness of this temperature.

In § 123.10(c)(4) the agency is proposing to require that the processor use instruments that monitor the temperature of refrigeration units on a continuous basis. The measurements from those instruments must be checked and documented with such frequency as is necessary to ensure control.

Continuous monitoring ensures that temperature fluctuations above 40 °F (4.4 °C), if any, as a result of circumstances such as heavy cooler loading, frequent cooler entry, or power failures, are quickly detected. The guideline for cooked, ready-to-eat products, in Appendix A, section 6, describes alternative ways to continuously monitor the temperature. A temperature-recording device can show both the high temperature and the length of time that refrigeration unit was operating at that temperature. Maximum-indicating thermometers and high temperature alarms also show that the critical limit has been exceeded but cannot show the duration of the deviation. Consequently, when a maximum-indicating thermometer or high temperature alarm reveals a deviation, the processor will need to assume loss of control since the last time that the measurements displayed by the instruments were checked, unless reasonable evidence exists to the contrary. The more frequent such checks are made, the lower the risk to which the processor is exposed. During periods when the refrigeration unit is not frequently entered and the load is constant, such as overnight, it is reasonable to reduce the frequency. However, during periods of heavy use and frequent entry, the frequency should be increased.

FDA is proposing to require in § 123.10(a)(15) that the processor ensure that persons with sores or illnesses that present an increased risk for product contamination are excluded from those areas of processing where such contamination is likely. Employees can serve as a reservoir of foodborne diseases, such as salmonellosis, shigellosis, and hepatitis, that can be passed on to the consumer through the fecal-oral route. Additionally, open sores, boils, or infected wounds present the potential for contamination of the food with such pathogenic microorganisms as *Staphylococcus aureus*. Employees with suspicious illnesses or sores can be effectively screened upon arrival at the processing facility with minimal personal intrusion (Refs. 22, 74, and 84).

In § 123.10(c), the agency is proposing to require that such screening, and documentation of the screening, take place daily. This frequency will ensure that changing health conditions of the employees are not missed.

In § 123.10(a)(16), the agency is proposing to require that the processor ensure that toilet facilities are available and maintained in a sanitary condition and in good repair, and that these facilities provide for proper disposal of the sewage. Toilet facilities eliminate from the processing environment pathogenic microorganisms shed in fecal material. Where fecal material is not properly conveyed from the processing plant to an acceptable treatment facility, restroom floors and grounds around the processing facility can become contaminated with pathogens. Foot traffic over the affected areas can introduce pathogens to the processing room and cause product contamination. Insanitary toilet facilities can also increase the potential for contamination of employees' hands and, ultimately, the product (Refs. 64 and 74).

FDA is proposing to require at § 123.10(c) that the toilet facilities be inspected, and the inspection be documented, to ensure that they function properly and are in a sanitary condition at least every day. Ordinarily this inspection should be performed before each day's operation to ensure that the facility is ready at the beginning of the day.

In § 123.10(a)(17), the agency is proposing to require that the processor ensure that no pests are present in the processing area. Pests, such as rodents, birds, and insects carry a variety of human disease agents, which they can introduce to the processing environment (Refs. 63, 64, 73, and 84). Additionally, their feces constitutes filth which can contaminate the food. A daily inspection of the processing facility, as proposed in § 123.10(c), serves to assess the effectiveness of the processor's pest control activities and redirect them where necessary.

In § 123.10(a)(18), the agency is proposing to require that the processor ensure that the plant is designed to minimize risk of contamination of the food. Proper construction is essential if the other sanitary measures that FDA is proposing to require are to be successful. It includes the isolation of incompatible operations, such as the handling of raw materials and the processing of cooked products (Refs. 71, 74, 87, and 88). A periodic inspection of the facility for structural defects, product flow, and general building condition is necessary to ensure that these attributes do not pose an increased potential for product contamination. In § 123.10(c)(3), the agency is proposing to require that such controls be performed and documented with sufficient frequency to ensure control.

FDA is proposing to require at § 123.10(b) that processors maintain sanitation control records that document the occurrence and findings of the inspections required by § 123.10(a) as well as the frequency required by § 123.10(c). FDA is also proposing to require that the problems found during these inspections be corrected, and the corrections recorded in accordance with proposed § 123.10(d). Such corrections are essential to the proper working of the HACCP system. The records that are produced are subject to the recordkeeping requirements of proposed § 123.8, including being subject to inspection by FDA investigators. FDA has tentatively concluded that HACCP-type preventive controls, including recordkeeping, will ensure that the hazards caused by insanitation are controlled by design. Recordkeeping is the key to an HACCP-type system. The agency's access to these records is essential to ensuring that the system is working.

In addition to these proposed requirements, FDA is encouraging processors in § 123.10(e) to have a written standard operating procedure for sanitation. The details of many sanitation procedures can differ from plant to plant depending upon the type of operation and other conditions. For example, how a piece of equipment should be cleaned can differ from plant to plant. In one plant, it may be necessary to disassemble all or part of the equipment in order to clean it. In other plants, breaking down the equipment may not be necessary.

Likewise, different cleaning compounds may be needed from one plant to another in order to solve specialized problems such as buildups of mineral deposits. FDA is therefore encouraging each processor to study its own plant and develop a procedure that is tailored to that processor's needs and circumstances.

2. Evisceration of Raw Fish

In 1988, following botulism outbreaks traced to consumption of kapchunka, FDA published compliance policy guide (CPG) 7108.17 for salt-cured, air-dried, uneviscerated fish (53 FR 44949 November 7, 1988). In this CPG, FDA stated that the processing and sale of smoked and salted uneviscerated fish products pose a potential health hazard, and that it would consider such products to be adulterated under section 402(a)(4) of the act in that they have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health (Ref. 175). FDA issued this CPG in an effort to prevent further outbreaks, as well as other potential health hazards, related to the consumption of ungutted fish products. The agency recognized only two exceptions: (1) Small species, such as anchovies and herring pieces (sprats), provided that they are processed by a method that will ensure a water-phase salt content of at least 10 percent, a water activity below 0.85, or a pH of 4.6 or less; and (2) fish that are fully cooked before further processing.

As previously noted, *C. botulinum*, as well as other microorganisms, are naturally present in the intestinal tract of both fresh-water fish and marine fish. Therefore, it is essential not only to remove the viscera but to do so in a manner that does not contaminate the fish flesh with viscera contents. It is the viscera that can contain the majority of the hazardous microorganisms (e.g., *C. botulinum* and *L. monocytogenes*) that pose the potential health hazard (Refs. 165 through 167). After the viscera is removed, it must be discarded immediately to a segregated area, using a method that minimizes the potential for contamination or cross-contamination of utensils, equipment, raw materials, and other processed products.

Uneviscerated fish that have been smoked, smoke-flavored, or salted, and that are intended to be filleted after processing, pose the same potential health hazard as those products sold as uneviscerated whole fish. The potential health hazard is created when the viscera is removed after processing. As the fish are being filleted, the viscera may be cut, and its contents may spill out, contaminating the processed fish. As a result, the opportunity arises for *C. botulinum* spore outgrowth and toxin production as well as for growth of other food spoilage microorganisms in these types of products.

Therefore, the agency is proposing to require in § 123.10(f) that, subject to the same limitations that were set forth in the CPG: (1) All fish for smoking or salting be eviscerated prior to processing, and (2) the process of evisceration must be performed in an area that is segregated and separate from other processing operations.

H. Imported Seafood

As stated earlier, imports make up over half of the seafood consumed in this country, in sharp contrast to meat and poultry, which are primarily domestically produced. Many of the hazards that can affect imported seafood are likely to occur before it enters the United States. These hazards include those that can be acquired from the environment before harvest and those that are process-induced. Detection of these hazards is the focus of the current regulatory system, and thus FDA tries to ensure safety by testing imported product.

However, product testing places a substantial burden on the agency. The system currently is overburdened because of limits on the number of government personnel available to collect and analyze samples of imported product. In addition, FDA is concerned because this system does not promote industry responsibility and accountability the way an HACCP-based problem prevention system would. Given when most problems with imported seafood occur, these problems can be more efficiently controlled if the seafood is subject to HACCP controls before it is offered for import into this country than if the product is simply tested at the time that it is offered for sale. Therefore, FDA has tentatively concluded that these HACCP regulations should cover imported products in the same manner, to the extent possible, that they cover domestic products.

Accordingly, FDA is proposing to make importers subject to the general provisions of subpart A. Thus, FDA is proposing in § 123.11(a) to require that products that are offered for import be produced under the same HACCP and sanitation controls that it is proposing to apply to domestically produced seafood. FDA is proposing to require that importers adopt an HACCP plan that includes the criteria for how they will decide to purchase and then handle seafood while it is under their control. They must also establish ways to determine that these requirements are being met.

More specifically, the plan must include hazard analysis, critical control points, and critical limits for each type of product imported as well as a copy of each supplier's HACCP plan for those products, as required in § 123.11(b). Under proposed § 123.11(b), these plans must be available on file at the importer's U.S. place of business. As stated above, the agency is developing a hazard analysis book to assist importers, as well as processors, in designing their individual plans.

Because of the proposed requirement of § 123.11(b) that importers must have on file an HACCP plan from each of their foreign suppliers, foreign processors who wish to offer their products for import into the United States after the implementation of this regulation will have to operate under valid HACCP plans and sanitation control procedures and furnish copies of those plans to the U.S. importers. The foreign processors should maintain appropriate monitoring records, as dictated by the principles of HACCP already discussed. These records should be kept at the foreign processors' places of business.

Importers will be required under proposed § 123.11(c) to take affirmative steps to monitor that their suppliers are in fact operating under their HACCP plans. Thus, under this proposal, the importer will need to take such steps as: (1) Obtaining records from the foreign processors' facilities; (2) obtaining certification from foreign governments that the suppliers are operating under valid HACCP plans or obtain certification lot by lot; (3) visiting the facilities to inspect them on a regular basis; or (4) taking some similar type of action, e.g., end product testing.

For example, importers of swordfish may specify to their suppliers that the mercury level in the swordfish that they purchase cannot exceed FDA's action level of 1 part per million methyl mercury. The importers may decide to require certificates of analysis for methyl mercury on a regular basis from their suppliers as a means of ensuring that the swordfish that they offer for import into the United States is not adulterated.

Section 123.11(d) provides an option for those importing from a country that has an active memorandum of understanding (MOU) or similar agreement with FDA. If the MOU is current, and if there is equivalency between the inspection system of the foreign country and the U.S. system, the importer will be able to rely on the

MOU in lieu of the actions required under § 123.11(c). An active MOU must accurately reflect the current situation between the signing parties and be functioning and enforceable in its entirety. It is the importer's responsibility to determine whether the MOU is in fact active, and whether it covers the products that the importer intends to receive from that country.

Finally, the agency strongly encourages importers (as reflected in proposed § 123.11(e)) to require their suppliers to obtain HACCP training such as is required in § 123.9.

Proposed § 123.12 provides that there must be evidence that seafood offered for import has been produced in accordance with part 123, subpart A. As stated previously, FDA is including this requirement to ensure that there is equivalent treatment of imported and domestic products. FDA can ensure that domestic product is being produced in accordance with the HACCP plan and the sanitation controls in § 123.10 through direct observation and review of records. Similar inspection of foreign processors would be prohibitively expensive. However, FDA tentatively finds that mere reliance on the existence of an HACCP plan is not enough, and that additional evidence of compliance must be provided. FDA tentatively finds that this evidence can be provided by the means listed in proposed § 123.12(a).

One of the ways that the agency contemplates obtaining this evidence would be by inspecting, at the importers' U.S. place of business, the importers' and foreign suppliers' HACCP plans, sanitation procedures, and records associated with the importers' plans. If these records demonstrate that the foreign processor and the importer are operating in accordance with adequate HACCP plans, agency will have assurance that the food is not adulterated under section 402(a)(4) of the act.

FDA also intends to pursue MOU's with countries that demonstrate that their inspection systems are and continue to be substantially equivalent to those in the United States (proposed § 123.12(a)(2)). The existence of an active MOU between FDA and the country of origin covering the seafood products being offered for import will provide assurance that these products covered by the MOU are being produced under appropriate conditions.

If there is no MOU, the agency will take into consideration, for purposes of verifying the compliance of imported seafood, knowledge that a foreign country has an advanced seafood inspection system that provides for plans that are HACCP based, as provided in proposed § 123.12(a)(3). The existence of such a regulatory system and its enforcement will provide assurance about the conditions under which products exported from that country are being produced.

Proposed § 123.12(a)(4) provides that inspection of foreign processors by the agency or other organization designated by FDA may also be used to establish compliance with these regulations.

Finally, the agency intends to use other measures as it finds appropriate to make determinations about the acceptability of the product being offered for import, including but not limited to end product testing, as in proposed § 123.12(a)(5).

If assurances do not exist, as described in § 123.12(a), that the product has been produced under an HACCP plan and under sanitation controls that are equivalent to those required of domestic processors, the agency will deny entry to the products as provided in proposed § 123.12(b) because the product will appear to be adulterated (see section 801(a) of the act).

I. Raw Molluscan Shellfish

FDA is proposing to require in part 123, subpart C that processors of raw molluscan shellfish include in their HACCP plans how they control the origin of the molluscan shellfish that they process. Proposed § 123.28 requires that these controls include obtaining raw shellfish only from approved growing waters through harvesters or processors licensed by a shellfish control authority. FDA is proposing to require that processors maintain records to document that each lot of raw molluscan shellfish meets these requirements. Under this proposal, these records will constitute HACCP records subject to the requirements of proposed § 123.8.

The agency is also proposing to establish a system of tagging or other labeling that provides information about the origin of all shellstock and shucked molluscan shellfish received by a processor. FDA is proposing to amend § 1240.60 (21 CFR 1240.60) to provide for such a tagging system.

Raw molluscan shellfish are molluscan shellfish that have not been subject to a treatment sufficient to kill pathogens of public health significance. Shellfish that have been subjected to any form of treatment, such as steam, hot water, or dry heat, for a short period of time before shucking to facilitate removal of the meat from the shell are still considered to be raw.

Molluscan shellfish consumed raw or partially cooked pose unique public health risks. They probably cause the majority of all seafood-related illnesses in the United States (Refs. 6; and 7, p. 330). The safety of raw molluscan shellfish directly reflects the cleanliness of its aquatic environment. Of all edible species of fish, molluscan shellfish are unique in that they are nonmotile, filter feeding organisms. They pump large quantities of water through their bodies during the normal feeding process (Refs. 7, p. 331; and 90, p. c-4). The positive relationship between harvesting areas contaminated by sewage pollution and shellfish-borne enteric disease has been demonstrated many times (Refs. 7, p. 76; 91 and 92). During feeding, the shellfish may concentrate pathogenic microorganisms, deadly toxins associated with naturally occurring marine plankton (Ref. 93), or forms of agricultural and industrial pollution (Ref. 94). Among the pathogenic microorganisms is the Norwalk virus, probably the most common cause of seafood-borne illness. This virus commonly occurs in waters contaminated by sewage effluent (Refs. 7, p. 76; 91, 92, and 95).

Before the adoption of the current public health controls in the United States, shellfish commonly transmitted many serious communicable diseases. Consumption of raw or undercooked seafood from polluted waters can be a mode of transmission for typhoid fever, infectious hepatitis, and cholera (Ref. 67). These diseases are still commonly associated with raw shellfish consumption in lesser developed countries (Ref. 7, p. 73). However, the incidence of these diseases in the United States has been largely controlled under section 361 of the PHS Act (42 U.S.C. 264). This statute was enacted to prevent the introduction, transmission, and spread of communicable disease. Under provisions of the PHS Act, FDA is empowered to accept assistance from the States to protect public health. Accordingly, FDA participates in a Federal/State cooperative program called NSSP.

Established in 1925, the NSSP provides water quality criteria for assessing the safety of shellfish growing areas. These criteria are applied by the States under the authority of their own laws. The NSSP "Manual of Operations" provides the basis (Refs. 90 and 96) for State regulation in 23 shellfish-producing States and 6 nations. Each participating State or nation classifies and monitors its shellfish growing waters, controls harvesting, inspects shellfish packing

and shucking facilities, and issues certificates to individual shellfish processors that meet the State or foreign government's shellfish control criteria.

To assist themselves in the implementation of their shellfish laws, the States have formed the ISSC. The ISSC is an organization of State officials, representatives of Federal agencies, and representatives of the shellfish industry. It provides guidance to the States and provides a forum for them to discuss their problems in attempting to ensure the sanitary control of shellfish handling and production (Ref. 97, p. 3).

FDA evaluates State and international shellfish sanitation programs (Ref. 98, part I, p. 2). When it finds that the program is consistent with the NSSP, FDA accepts the State's or country's shipper certifications. FDA publishes the "Interstate Certified Shellfish Shippers List" monthly, in which it lists the approximately 2,000 shellfish dealers that have been certified by participating States.

While FDA continues to believe in the cooperative partnership that it has established with the States, there is evidence that this system is not protecting the public health as well as it might (Refs. 7, p. 331; 99, p. iii; and 100). Problems can originate anywhere. As explained in the discussion above of the term "lot of molluscan shellfish," the water from which shellfish are harvested plays a significant role in determining their safety. If they are harvested from unclassified or polluted waters, shellfish can be a vector of communicable disease. Problems can also occur as a result of conditions under which the shellfish are held on the harvest vessel, in the processing plant, or by subsequent handlers or repackers of shucked products.

Given the current situation, FDA has tentatively determined that it is necessary for it to take steps to strengthen and provide additional support for the existing cooperative program. Thus, FDA is proposing two measures.

First, FDA is proposing to add § 1240.60(b), which will require that all shellfish offered for transport or transported in interstate commerce bear a tag that lists the date, place, type, and quantity of shellfish, and by whom it was harvested, including the harvester's identification number. FDA is proposing this requirement because it has determined that a tag is the only means by which the agency can ensure that it will be possible to determine whether the shellfish have been taken from safe water. FDA is proposing to require that the place where the shellfish were harvested be listed because it will enable a processor who receives the shellfish, or a regulatory official who inspects them, to determine whether they were taken from safe water.

FDA is proposing to require that the date when the shellfish were harvested be listed because, as discussed above, the shifting conditions in shellfish harvesting waters make shellfish safety virtually a day-to-day proposition. Therefore, when the shellfish are harvested becomes a critical factor.

FDA is proposing that the type of shellfish e.g., oysters, clams, mussels, or scallops, and quantity be shown on the tag or bill of lading to ensure that the tag is applied only to the product to which it was initially affixed. Information on type and quantity of shellfish describes that product. FDA is proposing to require that the person by whom the shellfish were harvested be listed because that person has the most direct knowledge of where and when the shellfish were harvested and should be readily identifiable in case there are problems with the shellfish, so that quick action can be taken to meet the effect of any problem.

Finally, FDA is proposing that the harvester identification number issued by the shellfish control authority be included to provide a means to confirm the harvester's identity and to obtain the harvester's local address in case of an illness investigation or followup to tagging and labeling discrepancies.

FDA is proposing this tagging requirement under section 361 of the PHS Act. Under this section, the Surgeon General and, by delegation, FDA, is authorized to make and enforce such regulations as in FDA's judgment are necessary to prevent the introduction, transmission, or spread of communicable disease. FDA tentatively finds that requiring a tag is a measure necessary to prevent the spread of communicable diseases because the tag will readily permit identification of those raw shellfish that were harvested from properly classified waters, and thus that will not be vectors of communicable disease in interstate commerce, and those that were not harvested from properly classified waters and thus that may be vectors of disease.

Under the PHS Act, FDA is also authorized to provide for such measures which in its judgment may be necessary to enforce the regulations that it adopts to prevent the spread of communicable diseases (section 361(a) of the PHS Act). Therefore, FDA is proposing to provide in § 1240.60(b) for the seizure and destruction of any shellfish that are not properly tagged. Without the assurances provided by the tag, the shellfish may bear a microorganism that may render them injurious to health. Thus, they are unfit for consumption and must be removed from the food supply.

FDA recognizes that all shellfish-producing States have laws that require the tagging of shellfish. This proposal is intended to support those laws, not supersede them. The proposed tagging requirement is necessary for two reasons. First, there is no assurance that untagged shellfish come from safe waters. Illegal harvesting of molluscan shellfish from contaminated or unclassified waters is known to occur (Ref. 7, p. 331). It is also known that illegally harvested shellfish find their way into commercial channels. States and FDA find untagged or improperly tagged shellfish during their inspections of shellfish processors under the cooperative program (Refs. 101 through 109). FDA frequently lacks a basis for taking action against untagged shellfish (Ref. 110). Proposed § 1240.60 will provide a basis. Second, State tagging requirements and sanctions are not uniform, and the sanctions provided under some State laws have little deterrent effect (Refs. 102, 103, and 109). The establishment of a Federal sanction will provide illegal harvesters with sure knowledge that if their catch enters interstate commerce and comes to the attention of FDA, it will be destroyed.

If § 1240.60(b) is adopted, as a practical matter, product identification will begin at the harvesting site. FDA is proposing to amend § 1240.60 to require that the first handler of live molluscan shellfish, be it the licensed harvester, licensed aquaculturist, or certified shellfish shipper, affix a tag to each container of shellfish. The tag will then provide the means for processors to ensure that the shellfish that they buy is from properly classified water.

Moreover, the tag will provide all information that is necessary to trace the product to its source, e.g., date of harvest, location of harvest, quantity and type of shellfish, and the harvester's name and identification number assigned by the shellfish control authority. The product traceability that results will enhance epidemiological investigations in the event of shellfish-borne illness. It will also facilitate prompt remedial actions necessary to reestablish public health controls.

The safety concerns about shucked molluscan shellfish are substantially the same as those discussed above for in-shell molluscan shellfish. Because shucked shellfish are packaged in a container that can be labeled, the agency is proposing to require in § 1240.60(c) that for these shellfish, a label may be

substituted that bears information equivalent to that found on the tag. Another reason for allowing labeling in lieu of a tag is the fact that one bag of unshucked molluscan shellfish bearing a single tag can typically be processed into more than one container of shucked molluscan shellfish.

The second measure that FDA is proposing is based on its experience with the NSSP and the ISSC. FDA has tentatively concluded that the system for protecting the safety of shellfish can be significantly strengthened if the agency were to require that certain limited steps be taken as part of the processing of shellfish that are intended for interstate commerce. FDA believes that these measures, like the proposed tagging requirement, will serve to strengthen the Federal-State cooperative program as well as the shellfish safety programs of each of the States and countries that participate in NSSP.

Many of the pathogens in shellfish, such as the Norwalk virus, are virtually undetectable. Moreover, from a technical and practical perspective, end product testing cannot be used in the processing of shellfish to ensure that they are not contaminated with one of the myriad of possible domestic, industrial, and agricultural contaminants that have been found in shellfish harvesting areas. Therefore, State classification of growing waters is a necessary first step to ensure the safety of shellfish. These classifications, as detailed in NSSP, address all actual and potential pollutants in deciding whether an area is suitable for harvesting (Ref. 90, pp. c–5 and c–6).

FDA is proposing in § 123.28(a) that each processor of shellfish have an HACCP plan that ensures that the molluscan shellfish that it processes come only from areas that have been classified by a shellfish control authority as satisfactory for harvesting. As noted above, the safety of molluscan shellfish consumed raw or partly cooked is predicated on the cleanliness of the growing area waters from which they are obtained. Ensuring that shellfish come from properly classified growing areas is where shellfish safety begins.

Under proposed § 123.28(b), processors are to process only shellfish that originate from growing waters that have been approved for harvesting by a shellfish control authority as shown by product tags or labels with specific information that establishes that they were harvested from appropriate waters. FDA is proposing this requirement under both section 361 of the PHS Act, to prevent the spread of communicable disease, and sections 402(a)(1), 402(a)(4), and 701(a) of the act to ensure that the food does not contain any added substances that may render it injurious to health and is not prepared, packed, or held under insanitary conditions whereby it may be rendered injurious to health.

Under proposed § 123.28(b)(2) and (b)(3), the shellstock tag from a licensed harvester or certified processor, or the bill of lading accompanying bulk shipments, will contain the information required under proposed § 1240.60(b) and thus document whether the shellfish are from an acceptable source.

The proposed requirement § 123.28(b) that only shellfish drawn from such acceptable sources can be processed will place a premium on properly tagged products from shellfish dealers that States or nations that participate in NSSP have certified.

The agency is further proposing to require in § 123.28(c) that shucked products be subject to the same requirements that apply to shellstock. FDA is doing so because the safety of shucked shellfish products, like shellstock, depends on the quality of the water where they are grown. Therefore, the same requirements are needed.

FDA is further proposing to require in § 123.28(d) that the processor maintain records that document that each lot of shellfish meets the tagging or labeling requirements in § 123.28 (b) or (c) (see Refs. 104 and 108). The information that FDA is proposing to require to be maintained in records simply reflects these requirements. Permanent records are needed to demonstrate that processors are controlling the origin of the shellfish they process. In addition, permanent records will facilitate epidemiological investigations by allowing complete product traceability to the source of origin.

The protection of shellfish consumers also requires that domestic and imported products be treated equally. While imported raw molluscan shellfish are subject to the same standards as domestic shellfish with regard to adulteration and misbranding, Federal law does not require that imported shellfish come from waters that were classified by a public health authority. This double standard is unfair to domestic processors, and both ISSC and industry representatives have urged the Federal Government to address this problem (Refs. 111 and 112). While virtually all States have chosen to reject imported shellfish that are not tagged as coming from classified waters (Ref. 113), it is known that such shellfish nonetheless enter interstate commerce (Ref. 107). Untagged imports originating from uncertified producers compromise the effectiveness of seafood safety programs (Ref. 7, p. 73) and product traceability. Therefore, FDA is proposing that all raw shellfish products either from domestic or foreign origin must comply with the requirements in part 123 and § 1240.60.

Thus, if § 123.28(b), for example, is adopted, it will mean that only those molluscan shellfish that are harvested in a foreign country that has a program that incorporates the type of measures set out in the NSSP for approving growing waters will be appropriate for processing. Such a program will need to include measures that provide for water classification, monitoring, and other related activities if it is to ensure that the growing waters that it approves are safe, and thus that the shellfish that are drawn from such waters are not adulterated. FDA has found that the best way to establish that a foreign country's program meets this standard is through the development of an MOU between the agency and that country. Currently, such agreements exist with Australia, Canada, Chile, England, Iceland, Japan, Republic of Korea, Mexico, and New Zealand.

In summary, FDA anticipates that these proposed requirements will improve the safety of raw molluscan shellfish by establishing uniform requirements for domestic and imported products and prohibiting interstate movement of shellfish that is not properly tagged to demonstrate that it came from an appropriate harvesting area.

The effectiveness of State shellfish sanitation programs and the NSSP will be strengthened by the proposed mandatory tagging, labeling, and recordkeeping requirements, which will allow complete product traceability to its source of origin. Should illnesses occur, product traceability will facilitate a rapid determination of when a problem occurred and allow immediate remedial actions to restore public health controls. Also, requiring proper tagging or labeling will place a premium on State and foreign shellfish sanitation and processor certification programs.

J. Guideline for Cooked, Ready-to-Eat Fishery Products

FDA is proposing a guideline in Appendix A for cooked, ready-to-eat fishery products. These products possess an elevated microbiological risk relative to most other seafood products because they are cooked as part of processing and do not normally receive any additional cooking by consumers before consumption. Consequently, to be safe, these products must be essentially pathogen-free by the time

they leave the processing facility. Immediate refrigeration at proper temperatures to prevent the growth of pathogens is also essential for these products, which are not shelf-stable.

The guideline addresses critical control points that apply to these products as a class and that thus will typically be identified in the HACCP plans of most processors of cooked, ready-to-eat products. The guideline also addresses ways of controlling hazards at each critical control point. Processors of cooked, ready-to-eat products that are also smoked and smoke-flavored fishery products should apply the controls set forth in Appendix 1. If FDA adopts that regulation, it will codify it in reserved subpart B of part 123.

This guideline is not relevant to most of the cooked, ready-to-eat products that are processed as low acid canned foods under part 113. However, the recommendations in Appendix A, section 4. a., b., and d. for cooling, processing after cooking, and refrigerated storage, will apply to those low acid canned foods that are cooked, processed, and then cooked again.

The guideline provides information on how to control the growth of *S. aureus* during the processing step between cooks. It also addresses the control of microbiological hazards that can occur within the processing environment for cooked, ready-to-eat products. It does not address nonprocessing hazards, because they are not relevant to this class of products. FDA intends to publish separate guidance that will, among other things, address nonprocessing hazards. Likewise, this guideline will not address the nonsafety hazards, such as decomposition that is not associated with human illness and economic adulteration, that FDA has suggested in proposed § 123.6(c) should be covered by the HACCP plan. These hazards will also be covered in the separately published guidance. Economic adulteration, for example, is addressed in Appendix D.

FDA has tentatively decided to address the processing controls for cooked, ready-to-eat products in a guideline, rather than by regulation, to permit flexibility in the face of changing processing technologies and knowledge. As stated earlier in this preamble, the guidelines are intended to advise processors about what FDA believes will be acceptable in a HACCP plan. The agency acknowledges, however, that there are basic processing norms to which conscientious processors adhere, and that these norms are not likely to change for the foreseeable future. FDA therefore invites comments on whether any or all of the guideline on the cooked, ready-to-eat products ought to be codified as requirements in part 123 if it is adopted as a final regulation.

1. Thermal Processing: Cooking and Pasteurization Processes and Equipment

The proposed guideline in Appendix A, section 4 advises processors on how to ensure that: (1) Their cooking and pasteurization processes are adequate to inactivate pathogens; and (2) their cooking and pasteurization equipment is adequate to deliver their cooking and pasteurization processes. A cooking process is, in essence, the temperature and time at that temperature that will both kill pathogens and create a marketable product. A pasteurization process is the temperature and time at temperature that is necessary to reduce the numbers of pathogens to the point where they will not cause harm over the shelf life of a refrigerated product. It is essential that *C. botulinum* type E not survive the pasteurization process for cooked, ready-to-eat products that are packed in hermetically sealed containers and held at refrigerated temperatures (Ref. 52). Such containers are typically vacuum or modified atmosphere packaged and thus can provide a good environment for the growth of *C. botulinum* type E.

To meet the requirements in part 123, subpart A, processors must have assurance that their cooking and pasteurization processes are adequate to inactivate pathogens and must document this assurance in their HACCP records. This approach is similar to that in the regulations for low acid canned foods, which require that processors of those products know that their thermal processes are adequate to destroy *C. botulinum*. The low acid canned food regulations do not specify to processors what their time/temperature parameters must be in order to destroy those pathogens. There are simply too many variables and possibilities with regard to thermal processing parameters for this kind of specificity in those regulations to be practical or appropriate. Rather, the regulations require that processors use a thermal process that is at least equivalent to one established by a competent process authority, i.e., a third party who has the expertise to determine the parameters of a thermal process that will destroy pathogens (Ref. 85).

This approach has served the consuming public, the agency, and the industry well over the years. FDA is therefore recommending in proposed Appendix A, section 4. a.1. and b.1. that processors utilize the services of process authorities to establish the parameters of their cooking and pasteurization processes.

A process authority could be a private individual, a member of academia, or an agency of government. Processors can find competent process authorities through their trade associations, local Sea Grant extension offices, or State universities.

The procedures that are used in establishing a cooking or pasteurization process should be generally recognized and accepted. Such procedures may include thermal death time, heat penetration, and inoculated pack studies, as necessary, to establish the minimum process necessary to destroy pathogens. In cases where the cooking process or pasteurization process is standardized and not unique to a specific processor, articles in journals; Federal, State, or local regulations and guidelines; or other appropriate vehicles could provide process parameters (Ref. 52). Whatever the source, processors must retain the documentation from the process authority that the process will be effective as part of their HACCP records, in accordance with proposed § 123.8(c).

The process established by a process authority should include values for those aspects of the process that can affect the destruction of pathogens. The most notable of these are cooking times and temperatures. Others may include the initial internal temperature of the cooking medium before the cooking, the product size and species, and the viscosity of formulated products such as soups.

FDA is already aware that the cooking processes necessary to create a marketable product for several types of cooked, ready-to-eat products are many times more lethal than necessary to inactivate pathogens (Ref. 114). The products are the several types of crabs listed in the guidelines at proposed Appendix A, section 4.a.4. FDA has tentatively concluded that, for these products, the adequacy of both the cooking process and cooking equipment can be assumed.

It is likely that other products could be added to this list. The agency invites comments on this point. Comments should be accompanied by data that will enable the agency to determine that the minimum cooking process necessary to achieve a marketable product, e.g., heat penetration data and data on the range of cooking processes (times and temperatures) applied to that product, will produce a safe product.

The same general principles also apply to the design of the cooking and

pasteurization equipment. It is necessary that this equipment be designed and operated so that every unit of product receives the established minimum cooking or pasteurization process proposed (Appendix A, section 4. a.2. and b.2.) (Ref. 85). FDA recommends that the equipment be evaluated for design and operation by a process authority who is familiar with the dynamics of temperature distribution in processing equipment. In some instances, temperature distribution studies may be necessary to establish the adequacy of the equipment. In other instances, existing literature should be sufficient. Processors must obtain and retain documentation that the equipment will provide the minimum process as part of their HACCP records in accordance with § 123.8.

2. Container Integrity

The proposed guidelines advise in Appendix A, section 3. c. and d. that HACCP plans prepared in accordance with part 123, subpart A will normally identify finished product container sealing for pasteurized products and postpasteurizing cooling as critical control points. Contamination with *C. botulinum* type E during the postpasteurization cooling step is a special food safety hazard that must be controlled for pasteurized products. Two potential causes of recontamination are poor container seams and contaminated cooling water. Consequently, the guidelines, at Appendix A, section 5, recommend controls that processors can utilize that are likely to meet the requirements of subpart A. Appendix A, section 5.a. advises processors how to inspect finished product containers of pasteurized products for container integrity to ensure a consistently reliable hermetic seal. At proposed Appendix A, section 5.b., the guidelines advise about testing for the presence of sanitizer in cooling water.

Seam inspections should determine whether the seams conform to the manufacturer's guidelines. Additionally, because of variations from seaming head to seaming head, from closing machine to closing machine, and over time for any one machine or head, FDA recommends that processors conduct inspections for each machine and head at least every 4 hours. Visual seam inspections are not adequate to fully assess the integrity of the seam. Physical testing and, in the case of double seams, seam teardown and measurement, are necessary parts of the inspection, as presently required for low acid canned foods in part 113.

The presence of sanitizer in cooling water provides a control for the risk of microbiologically contaminated water being drawn into the can. A vacuum created by a collapse in the cooling vat of the steam head in the container, generated during the heating step, can draw in a minute amount of cooling water and any pathogens contained in that cooling water. Seams are in a particularly stressed condition at that time. Sanitizer strength levels should be checked periodically because there is a tendency for variation in strength to occur, particularly in batch-type systems.

3. Time and Temperature

The guidelines advise, in proposed Appendix A, section 3. e., f., g., and h., that HACCP plans prepared in accordance with subpart A of part 123 will normally identify cooling after cooking, processing after cooking, final product cooling, and refrigerated storage, as critical control points. The potential exists for some pathogenic microorganisms to survive the cooking process, regardless of the controls that are in place at that step. Likewise, despite a processor's efforts to minimize recontamination of the cooked product with pathogens, the potential exists for some pathogens to be reintroduced. For these reasons, it is imperative that exposure of the product after the cooking process to temperatures that permit the growth of pathogens be kept to a minimum, since larger numbers are frequently associated with a greater potential for disease.

To control hazards as required by part 123, subpart A, the process must take steps to restrict time/temperature abuse of the cooked product to the point that pathogens such as *Salmonella spp.* do not enter the rapid (logarithmic) phase of growth. By restricting pathogen growth to the slow (lag) phase, pathogen numbers should remain constant or increase only slightly.

Proposed Appendix A, section 6.a. provides a way to control the growth of pathogens immediately after cooking. It advises that, after cooking, the product should be cooled from 140 °F (60 °C) to 70 °F (21.1 °C) within two hours. This time/temperature combination is based on the upper limit for growth (i.e., 140 °F) and the lower limit for rapid growth (i.e., 70 °F) of such mesophilic pathogens as *Salmonella spp.* and *S. aureus*, and the typical length of the lag phase for the former microorganism (Refs. 23, 85, and 115). However, 70 °F (21.1 °C) will not fully control the growth of psychrotrophic pathogens. Consequently, further cooling from 70 °F (21.1 °C) to 40 °F (4.4 °C) within 4 additional hours is advisable, based on the minimum growth temperatures of such psychrotropic pathogens as *L. monocytogenes*, *Salmonella spp.*, and *S. aureus*, and the lag time of *Salmonella spp.* (Refs. 23, 78, and 79).

These cooling recommendations are generally consistent with those of the Food Safety and Inspection Service (FSIS) of USDA (Ref. 115) and the National Food Processors Association (NFPA) (Ref. 78). FDA invites comments on the specifics in App. A, section 6.a.

In those instances where further processing takes place before the achievement of the 70 °F (21.1 °C) or the 40 °F (4.4 °C) temperatures, further reduction in temperature need not take place. There is no need for production delays when in-process storage times are normally less than the 2 or 6 hours needed to achieve each of these temperatures.

The time/temperature parameters employed to control the microbiological hazards associated with cooling after cooking can be confirmed by a program of routine time and temperature monitoring (Appendix A, section 6.a.1.). Real time documentation of this monitoring should be done to facilitate management and regulatory review.

Alternately, the ability of the firm's processing procedures to consistently achieve the appropriate time/temperature parameters can be confirmed through scientifically conducted time/temperature studies that take into consideration the range of processing variations encountered at the firm. Examples of processing variations include product size, e.g., the range of shrimp sizes that the firm typically processes; the temperature of the cooling medium, e.g., the highest temperature normally experienced in the firm's cooling unit; and the amount of product normally placed in the cooling unit.

In some instances in-process time/temperature monitoring may be impractical or needlessly redundant, particularly in continuous processing systems. A scientifically conducted study is especially appropriate for such situations, where it can be assured that in all plausible situations the time/temperature parameters will be met. Documentation and retention of the conduct and results of this study is required by § 123.8.

Appendix A, section 6.b. advises how processors can ensure that microbiological hazards associated with postcooking processing can be controlled. It advises that products not be exposed to ambient temperatures of 40 °F (4.4 °C) or higher for more than 4 hours during postcooking processing,

again based on the minimum growth temperature of such psychrotropic pathogens as *L. monocytogenes* and on the normal lag phase of such mesophilic pathogens as *Salmonella spp.* The agency recognizes that, for many products, manipulation of the product after cooking, while undesirable from the standpoint of microbiological recontamination, is necessary for many cooked, ready-to-eat products. It is often impractical to perform this manipulation under refrigerated conditions. Consequently, the product will be exposed to some combination of time and temperature that may allow for microbiological growth. The recommended conditions will minimize the growth of pathogenic microorganisms and the production of heat stable toxins (e.g., staphylococcal enterotoxin).

The ability of the firm's processing procedures to consistently achieve its time/temperature parameters can be confirmed by monitoring the length of time that the product is exposed to such ambient temperatures. Documentation of time/temperature monitoring must be in accordance with § 123.8. to facilitate management and regulatory review.

Appendix A, section 6.c. advises how processors can ensure that microbiological hazards associated with final product cooling can be controlled. Following the manipulation of the product during postcooking processing, it will be necessary for the processor to cool the product to a temperature that will not support the further growth of mesophilic or psychrotropic pathogens. This result can be achieved by cooling the finished product to an internal temperature of 40 °F (4.4 °C) within 4 hours of either placing it in the finished product container or completing pasteurization. Again, the recommendation is based on the minimum growth temperature of such psychrotropic pathogens as *L. monocytogenes* and on the normal lag phase of such mesophilic pathogens as *Salmonella spp.* Of specific concern to the pasteurization process is the reduction of the internal temperature of the product to a level that will not support the growth of any surviving spores of *C. botulinum*, type E.

The ability of the firm's processing procedures to consistently achieve its time/temperature parameters can be confirmed by a program of routine time and temperature monitoring designed to address the particulars of the firm's processing system. Real time documentation of this monitoring should be done to facilitate management and regulatory review.

Alternately, the firm's ability to consistently meet its parameters can be confirmed through scientifically conducted time/temperature studies that take into consideration the range of processing variations encountered at the firm. Examples of these processing variations include container size, the temperature of the cooling medium, and the amount of product normally placed in the cooling unit. In many instances, in-process time/temperature monitoring may be impractical and expensive for sealed finished product containers. A scientifically conducted study is especially appropriate in such situations, where it can be assured that in all plausible situations the time/temperature constraints will be met. Documentation of the conduct and results of the study is required under proposed § 123.8 to facilitate management and regulatory review.

Temperature control during refrigerated storage is best achieved through the use of temperature indicating and recording devices and recordkeeping, as stated in Appendix A, section 6.d.2. (Ref. 85). However, FDA recognizes that some processors may desire to manually monitor the temperature of the refrigeration unit, using only a temperature-indicating device and a logbook. When coupled with a high temperature alarm or a maximum-indicating thermometer, the agency feels that this practice represents an acceptable alternative.

The guideline advises, in Appendix A, section 3.i., that HACCP plans prepared in accordance with subpart A of part 123 will normally identify distribution as a critical control point. Distribution of perishable products encompasses the same hazards as associated with refrigerated storage. For this reason, in Appendix A, section 6.e., the agency is recommending a critical limit of an internal temperature maximum of 40 °F (4.4 °C) and is encouraging the shipper and consignee to arrange for appropriate control measures.

The agency recognizes that distribution patterns vary considerably from single shipments to pooled and multiple delivery shipments, from iced shipments to refrigerated shipments, and from shipments on the consignee's truck to shipments on the shipper's truck to common carrier shipments. Each mode presents different opportunities and impediments for control.

4. Temperature Monitoring Equipment

Processors must monitor and control the temperature of their refrigeration units in order to ensure that microorganisms of public health concern do not increase in numbers. Likewise, processors must control the times and temperatures of their thermal processes in order to ensure that the minimum thermal process is consistently delivered to the product. The guidelines address the outfitting of cooking, pasteurization, and refrigeration equipment with temperature indicating and recording devices (Appendix A, sections 4. a.2.ii. and b.2.ii., and section 6.d.2., respectively). A temperature-recording device provides a complete history of the temperature throughout the thermal process by continuously recording it on a chart. As has been demonstrated for low acid canned foods, the chart itself provides an excellent HACCP record for the benefit of both processor and regulator. For this record to be meaningful, it is critical that the temperature-recording device sensor be installed so as to accurately represent the temperature of the heating or cooling medium.

Temperature-recording devices are easily jarred and rendered inaccurate. They can be calibrated and corrected against a temperature-indicating device (e.g., a thermometer) quite easily, however. Processors should do so at least at the beginning and end of each production day in order to determine whether the instrument was accurate throughout the day's production. In this situation, the temperature-indicating device serves as reference instrument since it is much more reliable. Consequently, the temperature-recording device should never show a higher temperature than the temperature-indicating device.

Temperature-indicating devices are generally reliable and need only be calibrated upon installation and annually thereafter. Calibration should be against a standardized (i.e., traceable to the National Bureau of Standards) thermometer that is not subject to the rigors of the processing environment (Ref. 85). Temperature-indicating devices must often be read under less than ideal plant conditions, so they should be installed in a location that facilitates easy reading. As with the temperature-recording device, the sensor on the temperature-indicating device should be installed so as to accurately represent the temperature of the heating or cooling medium.

5. Corrective Actions

Appendix A, section 8. advises processors about corrective action steps that they should consider to comply with the proposed corrective action requirements in § 123.7 of subpart A.

Because the evaluation of critical limit failures relating to the cooking step and the terminal heat treatment step of cooked, ready-to-eat products may well require an understanding of the technical aspects of thermal process calculations, Appendix A, section 8. recommends additional controls to those required by § 123.7 in this regard. Of primary importance is the recommendation that any corrective action other than processing to eliminate the hazard or destruction must be assessed by a competent process authority. For this purpose, a process authority may be a representative of the firm or may be an outside source, so long as the process authority has a scientific background that is adequate to make the assessment.

6. Sanitary Zones

Section 123.10 of subpart A establishes requirements for all processors for sanitation within the processing environment. In addition to these requirements, this guideline recommends in Appendix A, section 8. that processors of cooked, ready-to-eat products establish sanitary zones in their facilities. The agency invites comments on the merits of this concept and on whether it should be codified in the regulations.

The importance of good sanitation in the processing of cooked, ready-to-eat products cannot be overemphasized. While, as has been stated earlier, plant sanitation has no real bearing on human food safety for many foods, the safety of cooked, ready-to-eat products can be easily jeopardized by pathogens that are introduced through poor sanitation practices. Consequently, FDA is recommending that processors establish sanitary zones around areas where products that have already been cooked are being handled or stored. The primary purpose of a sanitary zone is to physically separate insanitary objects from cooked products. Sanitary zones can also minimize the likelihood of airborne contamination through proper filtration and positive air pressure in the zone.

A sanitary zone is a separation of operations by location, partition, air flow, or enclosed systems. In most cases, it requires procedural changes to minimize the risk of contamination but not large-scale structural changes. Canada has successfully incorporated the concept of sanitary zones for seafood processing as part of its HACCP-based inspection program (Ref. 116).

K. Guideline For Scombroid Toxin Forming Species

FDA is proposing a guideline in Appendix B for handling of the species in which scombroid toxin can form. This problem is primarily, but not exclusively, associated with members of the family Scombridae. The fish involved contain significant levels of naturally occurring free histidine in their flesh, which certain bacteria can decarboxylate into histamine. Significant histamine levels occur when the fish are exposed after death to times and temperatures that permit the growth of these bacteria. Histamine can result in a mild to severe allergic response in humans. Scombrotoxin poisoning is one of the three most common seafood-related illnesses (Ref. 5, p. 24). The scombrotoxic species that have been associated with foodborne illness include tuna, bluefish, mahi, mackerel, sardines, herring, kahawai, anchovies, and marlin.

This HACCP guidance is intended to maximize the use of controls to ensure proper handling of scombrotoxic species and thus to minimize the possibility of a problem. It also recognizes the often complex pathways of movement and ownership through which such fish may pass. Failure to ensure safe handling at any point in the chain may render the fish injurious to health.

There is a basis for concern about the safety of the fish as soon as histamine begins to form. Once the histamine-forming process has begun, it is like a chain reaction. Lowering the temperature of, or freezing, the fish will slow or arrest the process, but only cooking and prevention of recontamination can stop it (Refs. 9 and 117).

The guideline describes a HACCP system that emphasizes reliance upon accurate recordkeeping to show continuity of proper handling. Accurate knowledge of the time/temperature history of the fish is very important in determining the likelihood that the fish are unsafe or may become unsafe. The guideline also calls for more stringent processor controls to be applied to lots for which records are inadequate. While this guideline is designed to prevent problems, nothing in it should be construed as meaning that the agency will not take regulatory action if it finds decomposed fish.

The guideline in Appendix B, section 2. identifies receipt of raw materials, which include imported shipments, as a critical control point for processors of scombroid toxin forming species. Time/temperature abuse by the fisherman can result in decomposition and the resultant production of histamine.

Decomposition can also occur before the fish are removed from the harvest water if the fish dies in capture nets or on long lines. In such an event, the degree of decomposition will reflect the sea temperature, time in the water, and particular species (Ref. 118). It is not uncommon to encounter water temperatures of 80 °F to 90 °F in tropical waters, which can produce rapid decomposition.

Thus, rapid cooling of fish when they are captured is very important to prevent initiation of the process by which histamine is produced. Fish subjected to 68 °F for periods as short as one day, a practice which can happen in warm climates on fishing vessels, will yield high levels of histamine, even if the fish are later stored at refrigerated temperatures (Ref. 117).

For these reasons, the guideline advises that processors of fish and fishery products from scombroid toxin forming species must ensure that their raw materials are essentially free of decomposition and histamine as a result of time/temperature abuse that occurred before the processor received them. The guideline provides for three interrelated controls for the processor to apply with regard to raw materials. For the first processor that takes ownership after harvest, these are: (1) Time/temperature records from the harvesting vessel (Appendix B, section 3.a.1.); (2) organoleptic examination of the fish from the harvesting vessel for decomposition (Appendix B, section 3.a.2.); and (3) histamine analysis, if warranted by the time/temperature history of the fish as revealed by the time/temperature record from the vessel or by the results of the organoleptic examination (Appendix B, section 3.a.3.), or both. Time/temperature records from the vessel indicate whether entire lots from the vessel may be suspect, and thus in need of a histamine examination, because of unusual events on the vessel. Such records would not normally reveal, however, whether there are individual fish in the lot that may have decomposition. An organoleptic examination for decomposition serves to screen individual fish. It also serves as a way to verify the time/temperature records from the vessel with regard to an entire lot. If organoleptic examination reveals an unusually high number of fish with decomposition, the entire lot should be considered suspect and subjected to histamine analysis.

Appendix B, section 3.a.1. provides for how the first processor can take measures to determine whether the fish were properly harvested and handled on

board the harvesting vessel. Certification of the mode of capture, including information on the time between physical capture and bringing the fish on board, handling techniques, and the use of temperature logs onboard the vessel that record that time/temperature history of the fish (for example, catch date and time, means and rate of cooling, storage temperature, and refrigerated brine or seawater temperature) provide documentation to the processor and to regulatory authorities that the fish were properly handled. Such records on the handling of the fish should be part of an HACCP system and can be used in the specific HACCP plans of processors.

The harvester's goal should be to bring the fish to an internal temperature of 40 °F (4.4 °C) or below as soon as possible after the fish dies to minimize the risk of histamine production. Cooling fish below 59 °F (15 °C), and preferably below 50 °F (10 °C), greatly reduces the growth of populations of the bacteria that are most likely to cause histamine formation (Ref. 7, p. 95). Once bacterial growth has begun, temperature at or below 41 °F (5 °C) halts bacterial growth, although enzymatic histamine formation may slowly continue (Ref. 7, p. 95). Consequently, in proposed Appendix B, section 3.a.1., the agency is recommending a slightly lower flesh temperature of 40 °F (4.4 °C) or below. This temperature is consistent with recommendations of safe temperatures in other sections of the proposed regulation. Nonetheless, FDA specifically invites comments on the appropriateness of this temperature.

Appendix B, section 3.a.1. recommends that the time/temperature history from the vessel be on a lot-by-lot basis and defines a lot as a discrete storage compartment on the vessel in keeping with industry practice. A lot typically reflects a day's catch. Because a boat's catch can be subject to varying conditions and treatment from day-to-day, the time/temperature records should be specific to each lot.

If the time/temperature records suggest that, for a particular lot, the conditions on the vessel were likely to cause, or significantly contribute to, the formation of histamine in the fish, or if no adequate time/temperature records exist for that lot, the guideline provides that a representative sample of fish from the lot be analyzed for histamine Appendix B, section 3.a.2.ii.B.). The samples should be collected on a statistically valid sample schedule because variations in time/temperature abuse are likely at various points in a ship's hold.

The second control, organoleptic examination by the processor for decomposition, should be performed regardless of what the time/temperature records show (Appendix B, section 3.a.2.). First, decomposition is a form of adulteration under 403(a)(3) of the act. Second, as indicated earlier, an organoleptic examination provides a screening mechanism for individual fish. It is possible for the conditions on the vessel to be good but for some fish to develop decomposition anyway. Third, also as stated earlier, an examination for decomposition provides a way to verify the time/temperature records.

FDA recognizes that an organoleptic examination of each fish can be highly impractical. Consequently, the guideline calls for an examination of a representative number of fish to achieve a 95 percent certainty that the total number of fish in the lot that exhibit decomposition does not exceed 2.5 percent. (The significance of 2.5 percent is addressed in the preamble discussion of Appendix B, section 3. a.2.iii. and a.2.iv.) Using this approach, the number of fish examined will be reasonably close to the total number of fish, so that the goal of screening individual fish is preserved to the maximum extent practicable. Additionally, FDA expects that this representative sample will be large enough so as to provide a sufficient verification of the time/temperature records for the entire lot.

Appendix B, section 3.a.2.i. provides that no fish flesh that exhibits any organoleptically detectable decomposition should be used for food. Aside from the clear violation of 402(a)(3) of the act presented by such decomposition, the public health risk presented by decomposition in scombrotoxin forming species is unacceptable. While the existence of decomposition does not mean that scombrotoxin is present, it does mean that a process has begun that can lead to the presence of scombrotoxin over the shelf life of the fish or fishery product.

In some instances, e.g., large fish such as tuna, isolated parts of the fish will exhibit decomposition but other parts will be free of decomposition. FDA recognizes that it is possible to remove those parts of a fish that have decomposition and salvage the remainder. Appendix B, section 3.a.2.i. provides for such reconditioning so long as a histamine examination is performed on the flesh that is free of decomposition. FDA believes that a histamine test is prudent under such circumstances to verify that scombrotoxin forming processes are not at work in that flesh.

The guideline also provides for how the processor should use organoleptic examination and time/temperature records in tandem to determine whether fish or fishery products from scombroid forming species are fit for further processing or should first be subject to a histamine examination. If no decomposition is found, and the time/temperature records show that conditions on the vessel were unlikely to cause, or significantly contribute to, the formation of histamine in the fish, all the fish from that lot may be further processed or directly entered into commerce (Appendix B, section 3.a.2.ii.). If, as stated earlier, the time/temperature records are inadequate or indicate conditions that could cause histamine, the processor should always conduct a histamine analysis on a representative sample regardless of the decomposition findings.

If decomposition is found in less than 2.5 percent of the lot, and the time/temperature records show that conditions on the vessel were unlikely to cause, or significantly contribute to, the formation of histamine in the fish, Appendix B, section 3.a.2.iii. provides that the decomposed fish should be removed in accordance with the procedure outlined in Appendix B, section 3.a.2.i., but that it is not necessary to subject the lot to a histamine examination. The agency has tentatively concluded that decomposition below 2.5 percent is not significant in terms of the acceptability of the entire lot. Under the best conditions, it is possible that some fish in a large lot will experience some minimal decomposition. Under these circumstances, so long as the fish with decomposition are culled from the lot, there is no reason to suspect that the lot has been subject to unusual conditions that could cause histamine or scombrotoxin to form. The agency is aware that the canned tuna industry uses the 2.5 percent value to determine whether special handling of a lot is warranted (Ref. 119). The canned tuna industry has concluded, just as FDA tentatively concludes, that levels above 2.5 percent represent likely exposure of the fish in a lot to conditions that are out of the ordinary and potentially dangerous.

For these reasons, if the processor finds decomposition in more than 2.5 percent of the fish from a lot, those fish must be removed from the lot, and a histamine examination needs to be performed on a representative sample of the remaining fish in that lot (Appendix B, section 3.a.2.iv.).

It is important to recognize that where the time/temperature records are

inadequate for all the fish on a vessel, or show poor conditions for all the fish from a vessel, histamine analyses should be performed on representative samples from each lot on the vessel. Although an appropriate number of fish for sampling could possibly be provided from a single lot, the results would not be representative of the vessel as a whole.

Appendix B, section 3.a.3. describes how fish should be disposed of depending on the results of a histamine examination. In keeping with current policy, the agency expects that any fish that is found to have histamine above a defect action level or other regulatory level or limit for histamine established by FDA will not be used for food. Moreover, the agency expects, as reflected in Appendix B, section 3.a.3.i., that a finding of histamine over such level or limit in any fish in a lot from the vessel will result in the destruction of that entire lot, regardless of the percentage of decomposition that was organoleptically detected or the conditions on the vessel as indicated by the time/temperature records. Such a histamine finding strongly indicates that neither the records from the vessel nor the decomposition test (if the results were below 2.5 percent) are reliable. Histamine may be present in the absence of organoleptically detectable decomposition.

Similarly, the agency expects, as reflected in Appendix B, section 3.a.3.ii., that a finding of histamine below the action level, but higher than is normally found in fresh fish (Refs. 120 and 121), in any fish in a lot will result in the immediate cooking of all the fish in the lot to ensure that scombrotoxin will not form over the shelf life of the fish. Cooking stops the histamine forming process once it has started. Without this cooking, any elevated temperatures later in the distribution system or in the home can result in a rapid elevation of histamine levels to hazardous levels (Ref. 117, p. 341).

Appendix B, section 3.b. addresses raw materials controls that can be exercised by subsequent processors, i.e., those other than the first processor to take possession of scombroid toxin forming fish and fish products from a harvester. Assuming that the first processor has met its responsibilities with regard to raw materials as explained above, and has not caused a problem through improper handling during processing, subsequent processors should determine whether decomposition occurred during transfer from the previous processor. Consequently, the guideline provides, at Appendix B, section 3.b.1., that subsequent processors that do processing other than simply storing, should subject a representative sample of fish or fish products from each lot to an organoleptic examination. Any finding of decomposition in that sample should lead to organoleptic examination of the entire lot. If decomposition is found in more than 2.5 percent of the fish in the lot, the processor should perform a histamine examination on a representative sample of fish from the lot. These gradations are consistent with the expectations reflected in the guidelines for first processors.

FDA has tentatively concluded these measures need not be taken by those who only store fish and fishery products. While time/temperature abuse can occur during storage, and thus scombroid toxin forming species must be held at appropriate temperatures (40 °F (4.4 °C) or below), the hazard of scombrotoxin in the finished product can be controlled by those who own the product or manipulate it during processing.

As suggested above, time/temperature abuse can occur during processing as well as before the raw materials are received. It is important that processors identify critical control points and suitable controls that will protect fish and fish products that can form scombrotoxin from time/temperature abuse. As the guideline for scombrotoxin states in Appendix B, section 5., many of the controls for time and temperature in the guideline for cooked, ready-to-eat products should be applicable to the processing of scombrotoxin forming species. Such handling conditions are necessary to control histamine production. In addition, Appendix B, section 4. provides that products that are undergoing processing not be exposed to ambient temperatures of 40 °F (4.4 °C) or higher for more than 4 hours during that processing. The agency recognizes that for many products, manipulation under unrefrigerated conditions is necessary. The processor must be aware, however, that during such periods the product will be exposed to conditions that can lead to histamine formation. Appendix B, section 4. describes how to minimize this possibility.

To comply with Appendix B, section 4., the processor should monitor the length of time that the product is exposed to ambient temperatures of 40 °F or higher. Documentation of the time/temperature monitoring controls will facilitate management and regulatory review.

L. Guideline for Product Integrity

1. Economic Adulteration

Economic adulteration occurs when a consumer is misled about the worth, amount, or identity of a food product and, therefore, unknowingly pays for value not received. Economically deceptive practices in the representation of a food's value may occur in a number of ways. Sections 402(b) and 403 of the act define the conditions and practices that result, respectively, in the economic adulteration and misbranding of a food. In addition, the Fair Packaging and Labeling Act, 15 U.S.C. 1451 *et seq.*, requires that food packages and their labeling provide consumers with accurate information about the identity and net quantity of the contents, so that consumers can make fair value comparisons among products.

While any food may be subjected to economic adulteration or to misbranding, fish and fishery products present distinctive characteristics and processing procedures that make them more susceptible to abusive economic practices than most foods. The great variety of finfish, shellfish, and crustacean species, as well as the multiplicity of products prepared from them, including fabricated surimi-based products that imitate actual seafoods, provide ample opportunity for both inadvertent and deliberate economic adulteration and misbranding practices that result in economic loss to the consumer.

Most important among the characteristics that make seafoods vulnerable to abuse is the similar appearance of many finfish, in the whole, raw state, in the form of fillets, or as ingredients. Unlike the situation with the limited types of red meats and fowl, it is very difficult for most consumers to detect the substitution of an economically inferior species for a more valuable one that is declared on the label or in labeling (e.g., the substitution of rockfish for red snapper).

Irrespective of the relative economic value of the substitute species, section 403(a)(1) of the act states that a food shall be deemed to be misbranded if its labeling is false and misleading in any particular. More specifically, a food is misbranded under section 403(b) of the act if it is offered for sale under the name of another food. If the substituted fish is less valuable than the species represented on the label or labeling, the product is also adulterated under section 402(b)(2) of the act, which states that a food shall be deemed to be adulterated if any substance has been substituted wholly or in part therefor. Consequently, it is a clear violation of

the act when a finfish, shellfish, or crustacean is not correctly identified on its label or in its labeling.

Furthermore, the misidentification of species may also have adverse public health consequences. Should an illness or outbreak occur from a seafood product, it is essential for proper diagnoses and treatment that public health investigators not be prevented from quickly identifying the exact cause or agent responsible in the food, and from tracing it back to the correct source of the food to prevent further sale and consumption.

For example, in a seafood related incident that occurred in 1982, in New York, two men became ill shortly after eating a fish dinner in a restaurant. Species substitution caused investigators to erroneously suspect that the illnesses were caused by ciguatoxin because the food was identified as being red snapper, a species which could cause that illness. The food actually was mahi, a fish which is often associated with scombroid poisoning (Ref. 122). Scombroid poisoning is associated with high levels of histamine.

FDA found that the fish mislabeled as red snapper had been shipped from Ecuador and processed in Panama. Had the fish been labeled as mahi, it would not have been permitted entry into the United States because FDA had an automatic detention for mahi from Ecuador at the time because of problems with high levels of histamine.

Another instance involving species substitution resulting in a negative public health consequence occurred in Hawaii in 1987. Fifty illnesses, 32 of which required medical attention, were attributed to the consumption of limpets misbranded as "Baby Abalone." The symptoms displayed were those of a histamine-type reaction. Because abalone is not one of the species expected to form histamine, substituting limpets for abalone put consumers at risk from a food that they had not intended to eat. Thus, accurate identification of species is essential to public health protection and prompt accurate diagnosis and treatment of illness when that protection fails.

Processing practices traditionally used in the seafood industry also are easily abused to increase a product's weight, in the form of ice or water. For instance, frozen fillets, shrimp, crab legs, and other products are normally protected from dehydration (freezer burn) while frozen by the application of a light glaze of ice. A packer then includes added product in the package to compensate for the weight of the glaze. Excessive amounts of glaze, however, not compensated for in this manner, can deliberately be used to increase the apparent weight, and therefore the apparent value, of the product delivered. Percentage weight increases from overglazing are most dramatic for foods with high surface area to volume ratios, such as shrimp. Overglazing is a practice that violates section 402(b)(4) of the act because a substance has been added to increase a food's weight or to make it appear of greater value than it is.

A similar type of fraud frequently results from oversoaking fish and shellfish meats in dip solutions. Dip solutions are customarily used to retard the natural loss of moisture (drip loss) from products such as scallops, which are particularly susceptible to drip loss. However, exposure to the dip may deliberately be prolonged to add weight in the form of water. Dip solutions may contain chemicals, such as sodium tripolyphosphate, that can greatly enhance the amount of water absorbed by the scallops. The net effect of such practices is to mislead the consumer into purchasing added water at scallop prices.

Seafoods generally represent a high dollar value per unit weight compared with other foods, particularly crab, lobster, shrimp, and certain shellfish. Thus, even relatively modest percentage weight increases from abusive glazing or water uptake from dip solutions represent a substantial loss of value to the consumer.

For the same reason, the potential fraudulent profit from similar practices of adding less valuable ingredients, such as breading on shrimp and fish sticks or water to shucked oysters, to increase the size or weight of products are enticing to unscrupulous processors.

The agency believes that economic adulteration occurs with sufficient frequency in various seafood products to result in substantial losses to the consumer. Evidence of such economic adulteration usually comes to light indirectly, as a result of investigations that are carried out for other purposes.

Fourteen and one-half percent of the samples of seafoods reported in 1986 as having adverse findings by eight FDA district offices were so listed because of product misrepresentation (Ref. 123).

Similarly, FDA found that in fiscal years 1991 and 1992, 14.8 and 11.7 percent, respectively, of all consumer complaints involved complaints of economic problems (Ref. 60).

Imported seafood products also are subject to significant levels of economic misrepresentation. In 1992, approximately 13 percent of all detentions of imported seafood involved some form of misbranding, such as false or misleading labeling, short fill, short weight, standard of identity, and omitted labeling (Ref. 124).

Specific data on species substitution are available from The National Seafood Inspection Laboratory (NSIL) of NMFS, Department of Commerce. Data gathered for the 3-year period of 1990–1992 by the laboratory in conducting species verification tests requested by industry show that 59 percent of the samples labeled as cod, 57 percent of the product labeled as haddock, 56 percent of the product labeled as flounder or sole, and 51 percent of the product labeled as red snapper were not the species claimed on the label. While these data cannot be regarded as representative of industry-wide misbranding practices because the testing was not random, the results indicate a remarkably high incidence of species substitution. Moreover, these findings are consistent with other surveys (Ref. 35, p. 45).

For example, a survey conducted in Florida to determine the extent of retail species substitution in the case of red snapper found that 64 percent of the fish fillets labeled for retail sale as red snapper were misbranded (Ref. 125). The prevalence of misbranding just this one desirable species is underscored by the observation: "If all of the red snapper sold in the United States were genuine, the seas would long since have been swept absolutely clean of this species" (Ref. 126, p. 41).

While most States' regulations follow FDA nomenclature policy and regulations, misbranding practices are exacerbated by the failure of some States to require these common names for some species sold within the State. Red snapper again provides a case study in the extent of variation in acceptable nomenclature allowed for a species. Although not permitted when sold in interstate commerce, California regulations allow 12 species of rockfish to be labeled as "Pacific red snapper" within the State. Similarly, Oregon and Washington regulations also allow rockfish to be called "snapper" (Ref. 126, p. 305). Moreover, an even greater variety of imported species may be misrepresented as "red snapper."

Many in the seafood industry believe that economic abuse is one its most significant problems. A survey conducted by the National Fisheries Institute found that the Institute's membership supported mandatory inspection as a means of overcoming practices that pose a threat to the reputation of processors and packers adhering to scrupulous practices in the representation of their products (Ref. 127). General agreement was found to exist among processors, distributors,

and importers, as well as retailers and restaurateurs, that abusive economic practices are widespread, including overglazing and overbreading of fishery products, inaccurate net weight measurement, and the substitution of inferior species for more valuable fish.

In a similar industry study by the Southeastern Fisheries Association, members ranked problems with economic fraud (such as species identification, overglazing, and the use of phosphates) above all other seafood industry problems, except vessel handling practices (Ref. 128).

2. Recommended Adoption of HACCP-Based Methods

Although the agency recognizes that HACCP was developed primarily to address safety, FDA believes that the proposed requirement in § 123.6, for seafood processors to adopt HACCP methods to ensure the safety of seafoods provides an opportunity for processors to develop and apply effective control point procedures that they can use to ensure that seafoods comply with the provisions of sections 402(b) and 403 of the act, The Fair Packaging and Labeling Act, the seafood standards of identity promulgated in 21 CFR, and applicable compliance policy guides issued by the agency (Compliance Policy Guides 7108.01, 7108.03, 7108.04, 7108.12, 7108.13, 7108.14, 7108.21, and 7108.23). Consequently, the agency is proposing in Appendix D to establish a guideline for HACCP-based procedures to avoid economic adulteration and misbranding of seafoods. Following this guideline will enable processors to develop procedures and records that will establish that they are not engaged in any practices that would render their products economically adulterated. Clearly, however, guidelines cannot prevent economic fraud.

The following guideline for product integrity lists critical control points covering raw material receipt, processing, and labels and labeling that processors and importers can incorporate in their HACCP plans. The agency believes that proper control begins with verification of the raw materials received by a processor. Therefore, in Appendix D, section 2.a., the agency is suggesting that, as part of their HACCP plan, processors and importers should include critical control points beginning with the receipt of raw materials. Ensuring that raw materials meet critical limits (e.g., correct species identification, net weight, additive identification) at the point they enter a processor's or importer's control is crucial.

There are a number of ways to ensure that species are properly identified. Physical examination, as indicated in Appendix D, section 2.a.1. is the typical method of determining the identity of a species. The agency believes that most seafood processors and importers are knowledgeable about the species that they handle and would have personnel available at the point of receipt who could monitor the incoming shipments for species substitution. Expert consultation is another option for correctly identifying species.

Processors or importers can also check the identity of seafood by employing laboratory services, as provided for in Appendix D, section 2.a.2. Protein chromatography is a laboratory method that can accurately establish the species of fish and fishery products (Ref. 50). Another option, Appendix D, section 2.a.3., is to receive raw materials certified by suppliers under either limited or general and continuing guaranties (section 303(c)(2) of the act (21 U.S.C. 333(c)(2)) and 21 CFR 7.12 and 7.13).

In Appendix D, section 2.b., the agency points out that processors must ensure that the labels, labeling, and invoices of their finished products accurately list weight, count, size, and product identity, as well as the content of valuable constituents (i.e., that ingredient that the consumer identifies as providing the reason to purchase the product, for example, the shrimp in breaded shrimp). The content of the valuable constituents must be maintained as required by FDA's standards of identity regulations (21 CFR part 161, including: oysters, Pacific salmon, canned wet packed shrimp in transparent or nontransparent containers, frozen raw breaded shrimp, frozen raw lightly breaded shrimp, and canned tuna) or in accordance with FDA's compliance policy guides.

More specifically, as in Appendix D, section 2.b.1., the species must be correctly identified by its common or usual name and be so represented on the label and labeling. To assist processors and consumers, FDA has developed both printed and database versions of the "FDA Fish List" to provide such guidance. Also specific requirements for such labeling are listed in Standards of Identity and the Common or Usual Name regulations (21 CFR, parts 161 and 102).

Appendix D, sections 2.b.2. through b.5. are based on section 402(b) of the act. Under Appendix D, section 2.b.2., the processor needs to ensure that valuable constituents of the product are not omitted or abstracted. For example, breaded shrimp must contain the required weight ratio of shrimp to breading. Similarly, shrimp must be of the size and/or weight specified on the label or labeling.

Under Appendix D, section 2.b.3., the processor needs to ensure that no substance is substituted wholly or in part for a valuable constituent. For example, substitution of crab flavored surimi cannot be used in whole or in part instead of crab meat in a product labeled as crab cake.

Under Appendix D, section 2.b.4., the processor needs to ensure that damage or inferiority is not concealed in any manner. This means, for example, that bleaching or coloring of product to conceal its true nature or condition of wholesomeness is not acceptable.

M. Additional Guidance—FDA Fish and Fishery Products Hazards and Controls Guide Including Specific Guidance on Smoked Fishery Products

As an adjunct to its rulemaking to require HACCP procedures in the seafood industry, FDA is drafting an extensive guidance for processors to use in understanding and implementing HACCP principles for their operations. This guidance will provide information that processors and importers can use in the development of their HACCP plans. This information consists largely of an identification of hazards that can affect the safety of seafood and a review of control measures that can keep the hazards from actually occurring, or that can at least minimize the likelihood of their occurrence.

FDA has included selected portions of the draft HACCP guidance as Appendix 1 to this proposal, so as to better inform the public about how this guidance will be structured and about the kinds of assistance that will be available to processors and importers who implement HACCP. The agency emphasizes, however, that this guidance is a work-in-progress and still being developed by FDA. Nonetheless, the agency seeks comment on the need for this guidance and the usefulness of the format the agency proposes to adopt.

In addition, FDA is including in Appendix 1 specific guidance on time-temperature and salinity parameters and other matters for use in the HACCP plans of processors of smoked and smoke-flavored fishery products. While FDA is seeking comment on the guidance generally, it particularly seeks comment on the guidance on smoked and smoke-flavored fishery products. Material relevant to the safe processing of smoked and smoke-flavored fishery products is found in various sections of the HACCP guidance because this general guidance is primarily organized

by hazard rather than by commodity type. However, the agency has gathered the materials relating to smoked and smoke-flavored fishery products into a single section of the guidance to facilitate use of this guidance by this industry, and to facilitate obtaining public comment on it. As stated above, FDA seeks public comment on the appropriateness of the materials relating to smoked and smoke-flavored fishery products as guidance, on their validity as guidelines, and on whether they should be made mandatory by incorporating them into any final regulation that results from this rulemaking.

While no known outbreaks of botulism attributed to smoked fish have been reported since 1963, FDA believes that the failure by manufacturers to obtain information about the composition of hot- and cold-process products represents a potential health hazard. Without analytical results from the testing for water-phase salt and sodium nitrite levels, a manufacturer cannot determine whether the fish have been adequately processed to inhibit *C. botulinum* spore outgrowth and toxin production. The agency's concerns are underscored by the diversity of processing temperatures and salt levels used in the manufacture of these products, particularly the lower range temperatures and water-phase salt levels (Ref. 24).

Finally, as stated above, the use of modified atmosphere and vacuum packaging with smoked and smoke-flavored fish products is also a source of concern. These types of packaging provide an anaerobic environment in which *C. botulinum* spores can grow out and produce botulin, the causative agent in botulism. When consumed, the toxin attacks the central nervous system and may cause death if untreated within 3 to 6 days.

For all these reasons, FDA has tentatively concluded that some type of guidance that defines the procedures for the safe processing of smoked and smoke-flavored fish is necessary.

Historically, fish have been smoked in order to preserve them. Today, the primary reason for smoking is to impart certain taste and texture qualities to the fish. There are essentially two types of smoked fish: (1) Those that are subjected to a "cold process" that leaves the fish soft and moist, with a delicate smoke flavor, such as lox, and (2) those that are subjected to a "hot process" that produces a less moist, firmer product with heavier smoke flavor, such as smoked whitefish.

The processing of these fish basically involves: (1) Cleaning and gutting followed by (2) immersion in a brine solution or dry salt in order to salt them, (3) drying in a cool temperature to avoid bacterial growth, (4) smoking in a smoking chamber at a temperature and for a time necessary to achieve the desired "cold process" or "hot process" effect, and (5) packaging and cooling. The taste and texture qualities attributable to "cold process" smoked fish require much lower temperatures during the smoking phase of the process than those attributable to "hot process." Salted fish may not be smoked at all.

As with virtually all fish, the species used to make smoked fish are exposed during their lives to *C. botulinum*, a spore- forming bacterium that is ubiquitous in the marine and freshwater environment. Type E is the predominant type of *C. botulinum* found in fish, other aquatic animals, water, and sediment, although other types such as A, proteolytic and nonproteolytic B, C, D, and F also have been found in fish (Refs. 148 through 152). The concentration of *C. botulinum* spores that may be expected in and on a naturally contaminated fish is unknown, although it is reported to vary from one spore per 16 g of fish to one spore per 200 g (Refs. 153 and 180).

Under certain conditions, *C. botulinum* can produce a toxin that causes botulism, a disease that attacks the central nervous system of humans and can cause death within 3 to 6 days of ingestion if not properly treated (Ref. 193). *C. botulinum's* ability to form spores means that in a dormant state, it can survive environments that are otherwise hostile to it. *C. botulinum* is "anaerobic," meaning that air constitutes a hostile environment. When conditions become favorable, that is, when no air is present, the spores experience "outgrowth" during which toxin can be produced. In fish, *C. botulinum* spores are found in the intestines and can also adhere to the surface of fish.

For these reasons, *C. botulinum* can be found in the environment of most any fish processor and cannot be totally eliminated using reasonable means. Moreover, even though a fish might be cleaned, gutted, and air packaged, some risk will still exist because *C. botulinum* spores can find their way into muscle tissue during processing. Muscle tissue below the surface of the fish can provide an anaerobic environment where outgrowth and toxin production can occur if time and temperature permit.

Although the processing procedures in Appendix 1 are based on studies of the time-temperature and salinity conditions required to prevent the outgrowth of botulinum spores, these practices are also effective in the elimination of risk from other pathogenic bacteria such as *L. monocytogenes*. *L. monocytogenes* is a pathogenic bacterium that is widespread in the environment and that is commonly isolated from surface waters and other environmental samples. Thus the likelihood of finding this pathogen on the exterior surfaces and viscera of fish is high. Since 1983, several large outbreaks of human listeriosis have been linked to the consumption of contaminated foods (Refs. 130, 131, and 132), thereby demonstrating the etiologic importance of foodborne transmission of this disease in humans.

Although listeriosis is a relatively rare illness (approximately 2,000 reported cases per year in the United States), the exceptionally high mortality rate, as high as 34 percent, makes this illness one of the leading fatal foodborne diseases in the United States. The highest incidence of listeriosis generally occurs in neonates, the elderly, pregnant women, and individuals suffering from compromised immune systems. However, there are instances in which apparently healthy individuals have contracted listeriosis (Refs. 130 and 133).

The incidence of *Listeria* species (including *L. monocytogenes*) in frozen raw and cooked seafood products is reportedly as high as 61 percent (Ref. 136). Indeed, numerous seafood products have been shown to support growth of *L. monocytogenes* (Refs. 137 and 138). *L. monocytogenes* is capable of prolific growth on smoked salmon stored at 4 °C, even when test inocula as low as 6 organisms per gram (g) are applied to the surface of fish samples (Ref. 139). Seafoods other than smoked or smoke-flavored fish have been epidemiologically linked to two outbreaks and one sporadic case of listeriosis (Ref. 140). Furthermore, several cooked seafood products have been recalled from the market in North America because of contamination with *L. monocytogenes*, but these crises did not involve smoked or smoke- flavored fish products.

A recent survey of smoked fish and smoked fish products in Iceland has shown that 29 percent of samples tested were contaminated with *Listeria* species, including *L. monocytogenes* (Ref. 141). Another survey revealed that 8.9 percent and 13.6 percent of hot- and cold-smoked fish, respectively, were contaminated with *L. monocytogenes* (Ref. 142). Cold-smoked fish may pose a significant health risk, particularly when stored for extended periods. When raw salmon was inoculated with known populations of *L. monocytogenes*

and smoked at 78.8 to 86 °F (26 to 30 °C) for 6 hours, and the finished product stored at 39.2 and 50 °F (4 and 10 °C) for up to 30 days, investigators observed substantial increases in *L. monocytogenes* populations at both incubation temperatures (Ref. 143). No known cases of listeriosis have been linked to smoked seafood consumption in the United States.

In contrast, studies have shown that properly controlled hot-smoking processes effectively eliminate *L. monocytogenes* contamination (Ref. 144). In raw trout inoculated with high doses of *L. monocytogenes*, stored for 12 hours in a marinade containing 10 percent NaCl, and then subjected to a hot-smoke process (dried for 30 minutes at 140 °F (60 °C), cooked at 230 °F (110 °C) until an internal temperature of 149 °F (65 °C) was maintained for 20 minutes, and finally smoked for 45 minutes at 140 °F), *L. monocytogenes* did not survive the smoking process. However, when fish were inoculated after smoking and stored at 46.4 to 50 °F (8 to 10 °C), a significant increase in *L. monocytogenes* populations was observed after up to 20 days of storage. These findings further emphasize the importance of preventing the contamination of processed fish.

Studies have also shown the importance of controlling the salt concentration in smoked fish. Although *L. monocytogenes* can survive in environments containing up to 20 percent NaCl (Ref. 145), it has been demonstrated that the organism becomes increasingly more sensitive to NaCl when it is exposed to heat processing (Ref. 146).

Because of the prevalence of *L. monocytogenes* in the environment, it may be impossible to completely eliminate the organism from all foods. However, use of the sanitary practices and processing practices proposed in this document should prevent cross-contamination and growth of the organism in smoked and smoke-flavored seafoods.

Smoking fish is a delicate process, involving a number of interrelated variables including times, temperatures, and exposure to smoke, salt, and sodium nitrite, when used. However, FDA believes that, by its very nature, this process involves certain inherent risks, risks that, if not attended to, can have very significant consequences.

For example, the times/temperatures involved in the "hot process" can injure but not kill *C. botulinum* spores while killing spoilage microorganisms. Thus, during the period when the spoilage microorganisms are becoming reestablished, surviving *C. botulinum* spores would be presented with an optimum growth environment because of the lack of competition. Yet, because of the absence of spoilage microorganisms, spoilage odors that would warn consumers away from potentially dangerous products would not be present. Botulism toxin alone is not detectable by sensory examination.

In addition, because of the number and types of steps involved, the processing of smoked fish involves an unusual amount of handling of the product relative to other seafood processing procedures. Increased handling presents increased opportunities for contamination during the process than would otherwise be the case.

The finished product also is inherently more risky than most other seafood products because it is a ready-to-eat product that is generally not cooked before eating. However, the present evidence indicates that smoked fish has caused no more cases of botulism in the United States than any other type of seafood product. In contrast, fresh fillets that are not smoked are intended to be cooked before consumption. Cooking is lethal to bacteria and will deactivate botulism toxin. Thus, smoked fish products usually do not get the benefit of an additional processing step that protects against most bacteriological risks.

In addition to these inherent characteristics, FDA believes that smoked fish present special risks because both domestic and foreign processors are now using vacuum packaging to a substantial extent—much more so than are other segments of the seafood industry. A 1988–1989 FDA and New York State survey of domestic processing plants, for example, showed that 45 percent of the firms visited vacuum-packaged smoked fish. However, there is no evidence to show a linkage between vacuum packaging of smoked fish and illness in the 5 years since this survey was completed.

An economic incentive for use of vacuum packaging is the extended shelf-life of the product, made possible by the anaerobic environment in the package that prevents the growth of some spoilage microorganisms and slows the growth of others. Because this anaerobic environment cannot prevent spoilage altogether, vacuum-packaged products must still be refrigerated.

Unfortunately, the anaerobic environment greatly favors the outgrowth of any *C. botulinum* spores that may be present over the development of telltale spoilage microorganisms. Thus, *C. botulinum* outgrowth can occur before spoilage if a vacuum-packaged product is temperature abused, i.e., not refrigerated. Moreover, as discussed elsewhere in this document, the growth of *L. monocytogenes* and *C. botulinum* type E and nonproteolytic type B is possible even at refrigeration temperatures below 40 °F (4.4 °C). FDA believes that strict controls are needed to overcome this risk.

In 1970, FDA issued a final rule for smoked fish in response to outbreaks of botulism attributed to vacuum-packaged smoked fish products (35 FR 17401, November 13, 1970). Among other things, the rule attempted to control the risk of botulism by setting conservative processing parameters for time, temperature, and salinity that would minimize the opportunity for *C. botulinum* spore outgrowth. These parameters were based on the relatively limited research that had been conducted up to that time with one species of fish. Many processors claimed that these parameters would have resulted in a product that was too salty and too dry in texture to be marketable.

The rule was overturned in court due to procedural problems (*United States* v. *Nova Scotia Food Products Corp.*, 568 F.2d 240 (2d Cir. 1977)). However, in rethinking this rule after the remand, FDA decided that research was needed into the relationships among time, temperature, and salinity to develop processing parameters that would provide safety without producing an undesirable product that consumers would not buy.

This research has been successfully conducted by FDA, the National Marine Fisheries Service, and the industry. FDA has prepared the time, temperature, and salinity parameters in the Hazard Assessment Guide based on the results of this research.

1. Need for Guidance

FDA routinely inspects smoked fish processing establishments for sanitary conditions using the guidance in 21 CFR part 110, "Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food" (Ref. 196) and in the FDA Inspection Operations Manual, Chapter 5, Establishment Inspection and section 616.6 Smoked Fish inspection methods (Ref. 197). In addition to the Establishment Inspection Reports (EIR's) discussed in section G, EIR's for smoked fish processing establishments over the past few years (1985 to the present) show evidence that the use of manufacturing procedures are not in line with CGMP's. The EIR's also show that processing parameters and controlled processing and storage

techniques, commonly recognized as appropriate in the industry (Ref. 182) are not being used (Ref. 169).

Typical observations by FDA officials in these inspections include: (1) Live flies in production areas providing a vehicle for contamination and recontamination of products; (2) standing water in production rooms providing a medium for microbial growth and contamination from splashed water; (3) utensils not sanitized prior to use; (4) open bags of raw materials in storage areas exposing products to flying insects and potential microbial contamination; (5) smoke racks encrusted with pieces of fish from previous processes, thus providing an opportunity for microbial growth; (6) refrigerators being used for both raw and finished products, thus providing an environment for microbial growth through cross-contamination between unprocessed and processed products; (7) overcrowded fish in brine tanks, whereby some fish are not fully submerged in brine, resulting in lower and uneven levels of salt uptake that would not be effective in inhibiting spore outgrowth; (8) salinity and microbiologic testing not performed on products; (9) low minimum water-phase salt levels (0.88 to 1.79 percent) that would not inhibit *C. botulinum* spore outgrowth and toxin production; and (10) poor employee practices that foster microbial contamination, including spitting into sinks adjacent to sinks used to thaw product, not washing or sanitizing hands, and street clothes in contact with product (Ref. 169). (See also Ref. 200.)

As part of its Fiscal Year (FY) 91 Domestic Fish and Fishery Products Inspection Assignment, FDA conducted food safety inspections of smoked fish establishments. These inspections revealed a continuing pattern of problems in these facilities. In over half of these inspections FDA found violations that required action, ranging from minor violations, which are normally handled by informing the firm's official during the inspection, to more serious violations that prompted some form of official agency action (Ref. 200).

In addition, several States, working through AFDO, have expressed concern that a potential health hazard exists with smoked and smoke-flavored fish products and have stated that a Federal regulation is necessary for uniform regulation of the production and distribution of these foods (Refs. 170 and 189). AFDO is an organization of Federal, State, and local regulatory officials with membership representing all 50 states, as well as FDA and other Federal agencies. AFDO's Central States Regional organization held a meeting in 1988, attended by public health officials from 6 states in which the smoked fish industry is concentrated, Canada, and NMFS, to discuss a Federal regulation governing the processing, storage, and distribution of smoked and smoke-flavored fish products. In December, 1989, AFDO first passed a resolution requesting that FDA expedite the rulemaking process to establish uniform Federal regulations to ensure that safe smoked fish processing methods are utilized for fish products sold in the United States. In December, 1990, AFDO passed resolution 8, which strongly encouraged FDA to "accelerate the promulgation of smoked fish CGMP's so that concerned States can move forward with their efforts to ensure the safety of smoked fish" (Ref. 170). FDA recognizes the need to address the hazards associated with smoked and smoke-flavored fishery products and therefore is setting forth the procedures in Appendix 1 in the interest of protecting the public health.

The need for some type of agency guidance on smoked fish is also evidenced by several other factors. First, the 1970 final rule, which covered only hot-process smoked and smoke-flavored fish and the processing parameters that they required, is still being used as a guideline by some States. These earlier parameters could result in commercially undesirable products. These parameters ought to be updated with the current technological understanding and processing flexibility for both hot and cold smoked products. The guidance in this document can provide the basis on which such updating can occur.

Second, the manufacture or sale of cold-processed fish products is not permitted in at least two States because there are no regulations or regulatory guidelines for these products (Ref. 170). There is some pressure, however, to permit the sale of these products. The Canadian Government, for example, has urged these States, Minnesota and Michigan, to permit the sale of these products so that Canadian products may be exported to the United States (Ref. 170). Some type of guidance that helps to define the processing parameters and techniques that reduce human health risks from cold-process smoked and smoke-flavored fish products would provide State, as well as federal, public health officials with the tools necessary to evaluate the safety of cold processed products manufactured in the United States, as well as those imported into the United States.

Third, in 1988 FDA conducted a survey of processing parameters used by fish smoking plants in the United States. Seventy five percent of the firms surveyed did not do final product testing to ascertain whether their products met commonly recognized (Ref. 182) parameters for their products (Ref. 24). The information collected in this survey augmented information obtained from the New York State Department of Agriculture and Marketing (Ref. 24), which had conducted a similar survey of fish smoking establishments in that State at approximately the same time. A total of 64 establishments were surveyed by FDA and New York State, representing over 90 percent of the smoked fish manufacturers in the United States. Among the species of fish included in the survey were chubs, bluefish, trout, carp, salmon, whitefish, and herring. Processing information was collected from manufacturers, and samples were collected for laboratory analysis.

The following chart summarizes the results of these surveys and compares them to proposed processing parameters:

1988–1989 DOMESTIC SURVEY DATA

Characteristic	FDA	New York	Proposal
Cold-Smoked Products:			
Temperature range	38 to 180 °F	34 to 90 °F	50 °F for 24 hours or 90 °F for 20 hours.
Water-phase salt	1.33 to 18.1 percent	1.4 to 7.4 percent	2.5 to 3.5 percent.[1]
Nitrite range	3.75 to 994 ppm		100 to 200 ppm.
Percentage of firms that do not know water-phase salt level.	40 percent	50 percent	
Hot-Smoked Products:			
Temperature range	90 to 210 °F	128 to 240 °F	145 °F.
Water-phase salt	0.88 to 27.5 percent	1.3 to 7.0 percent	3.0 percent.[1]

1988–1989 DOMESTIC SURVEY DATA—Continued

Characteristic	FDA	New York	Proposal
Nitrite range	15 to 239 ppm		
Percentage of firms that do not know water-phase salt level.	39 percent	72 percent	
Total number of firms that do not test their products (for 1 or more processing parameter).	76 percent	74 percent	

[1] Actual level depends on other processing factors.

Oven temperatures for hot processing ranged from 90 to 240 °F (32 to 116 °C) and from 38 to 125 °F (4.4 to 52 °C) for cold processing. Water-phase salt content in hot-process products ranged from 0.88 to 27.5 percent and in cold-process products from 1.33 to 18.1 percent. Twenty-eight firms (43.7 percent) vacuum packed cold-process products, but 60.7 percent of those firms did not test final products for water-phase salt content or for residual sodium nitrite. Twenty-five firms (39.1 percent) vacuum packed hot-process products, but 68 percent of those firms did not test final products for water-phase salt content or for residual sodium nitrite. Seventy-five percent of the firms surveyed did not test final products for water-phase salt content or for residual sodium nitrite, where used. Since this survey was conducted, the frequency of FDA inspections of smoked fish establishments has been increased over 50 percent each year.

Therefore, FDA is providing guidance on the appropriate parameters for processing smoked fishery products in Appendix 1 to this document.

The guidance addresses critical control points that apply to these products as a class and that will typically be identified in the HACCP plans of most processors of smoke and smoke-flavored products. The guidance also addresses ways of controlling hazards at these critical control points.

The key processing parameters that must be controlled to ensure the safety of these products involve time, temperature, and salinity. While a range of time-temperature-salinity (TTS) values will provide a safe product, there are now known safety minimums for these values that have been developed through years of research. Processors whose TTS values fall below these minimums do not produce a safe product and shift much of the burden of preventing botulism toxin outgrowth to those who take possession of these products after they leave the processing plant, including the ultimate consumer. This burden includes, among other things, maintaining strict temperature control at 40 °F or lower even though it is known that many commercial and home refrigerators are unable to maintain this temperature (Ref. 201).

These TTS minimums are known to produce a marketable product, because there are processors that operate in conformance with them. Moreover, because they are minimums, these values allow for the production of a variety of products, such as different types of lox with varying amounts of saltiness, to suit different tastes.

These minimum TTS values provide the only scientifically valid way developed to date of ensuring that no botulism toxin will be produced over the shelf life of the product under proper refrigeration conditions or under conditions of moderate temperature abuse. The minimum values, coupled with the sanitation practices proposed in this document, should also ensure against the presence of detectable *L. monocytogenes*.

These minimum TTS values are being issued at this time as proposed guidance to ensure maximum flexibility. If these values are reflected in the HACCP plans that are required by proposed subpart A of 21 CFR part 123, and are being effectively implemented by the processor, the agency is likely to find that the plan and its implementation are adequate with regard to those critical limits and critical control points. The same holds true for the other types of controls recommended in the guidance.

The agency is requesting comment on this approach, and on the following alternatives:

(1) Issue all or part of the materials relating to smoked and smoke-flavored fishery products in Appendix 1 as regulations, rather than guidance. Given the public health concerns associated with these products and the scientific basis for the TTS minimums, it may well be appropriate to issue them as regulations. Such regulations would take into account advances in knowledge and technology by allowing processors to use alternative processing parameters so long as these alternatives were scientifically demonstrated to produce an equivalent level of safety. (Section 11 of the guidance relating to smoked and smoke-flavored fishery products in Appendix 1 contains such a feature.)

(2) Issue a performance standard as a regulation, while leaving the materials in Appendix 1 as guidelines on how processors could meet the performance standard. The likely performance standard would be, as suggested above (and included in section 11 of the guidance relating to smoked and smoke-flavored fishery products in Appendix 1): (a) for botulism, zero toxin production in the product during a time period through—and slightly beyond—the shelf life of the product, demonstrated through inoculated pack studies under normal and moderate abuse conditions; and (b) no detectable *L. monocytogenes* in the final product.

(3) Maintain the guidance relating to smoked and smoke-flavored fishery products in the FDA Fish and Fishery Products Hazards and Controls Guide and control safety through the HACCP requirements for all seafood in proposed subpart A.

FDA requests comment on which of these alternatives is most likely to ensure that smoked fish will be safe and is most consistent with the agency's obligations under the act. In the absence of a regulation or guideline, how can the agency best ensure that the results of the research that it has conducted will be available for use by the industry? FDA solicits comments on these and the matters raised above.

N. Verification Issues

As described in section IV.A. of this document, one of the NACMCF's seven HACCP principles involves verification that the HACCP system is working. NACMCF recommends that HACCP plans include procedures for verification of the HACCP system (Ref. 34, p. 200). FDA advises processors to consider adopting this recommendation, but has not proposed to require it because the agency expects verification to occur through: (1) A firm's consistency with the controls and limits to be provided by FDA in the HACCP guidance described in section VII.C. and M. of this document; (2) third-party

technical assistance provided through trade associations, universities and government agencies; and (3) review of all HACCP monitoring records by trained individuals before distribution of product (see proposed § 123.8(b)); the proposed corrective action requirements (see proposed § 123.7), especially the provision for assessment of HACCP plans as a consequence of deviations (§ 123.7(a)(4)); the recommended use of process authorities for cooked, ready-to-eat products (see Appendix A); the proposed general training requirements (see proposed § 123.9); and inspector review during routine agency inspections. FDA invites comment on whether this approach is adequate to ensure that the NACMCF verification principle is being properly addressed, both for individual firms and for the overall HACCP program.

For individual firms, NACMCF specifically discourages the sole reliance on end-product sampling for verification purposes (Ref. 34, p. 201). FDA also has questions concerning the efficacy of end-product sampling as the only way to measure the success of HACCP. These caveats notwithstanding, FDA invites comment on what tests should be used to measure success, both in terms of individual firms and the program as a whole, and how frequently such tests should be administered.

VIII. Other Approaches to HACCP

This preamble has described in great detail the HACCP system that is being proposed and the reasoning behind each proposed provision. While the agency is inviting comment on the merits of each provision, FDA also invites comment on the overall system, including whether some other approach to HACCP or some variation of the proposed approach might be preferable. Variations on the proposed approach include, but are not limited to: (1) Requiring HACCP only for higher risk seafood products; (2) exempting small firms from HACCP requirements; (3) staggering the effective date for implementation based on size of firm or risk; and (4) deleting or altering some of the requirements in this proposal in order to facilitate implementation and lower costs. A brief discussion of each of these variations follows:

A. Higher Risk Only

An alternative to requiring HACCP for all commercial seafood products would be to require it for products or processes that have been linked to significant numbers reported seafood-borne illnesses. As section II.B. of this document explains in detail, many of the reported illnesses from seafood involve raw molluscan shellfish and certain species of finfish that can accumulate scombrotoxin and ciguatoxin. Other seafood products cause illness but are not as commonly reported. FDA invites comment on whether this proposed regulation should apply only to molluscan shellfish and the species responsible for scombrotoxin and ciguatoxin poisonings.

A variation on this approach would be to have the proposed regulation apply to those species and processes with a higher potential for harm, even if actual illnesses from them cannot be documented from the foodborne illness reporting system. As described earlier in the preamble, the fact that the system is not recording illnesses from a particular food does not mean that illnesses are not occurring. Also, potential for harm need not always be measured in terms of the number of illnesses that are actually occurring. For example, some problems, like botulism, may occur infrequently, but when they do, the consequences can be devastating. Based on the potential for harm, other candidates for inclusion would be: (1) Hot-process smoked and hot-process smoke-flavored fish, cold-process smoked and cold-process smoke-flavored fish, because of the hazards of botulism and listeria; (2) cooked, ready-to-eat products, because of the microbiological hazards associated with products that are not intended to be cooked by the consumer; (3) low acid canned foods, because of the hazard of botulism and general complexity of the processing operation; (4) raw, ready-to-eat products, because of the risk of parasites; and (5) species that require a judgment as to appropriate location of harvest to avoid unsafe pesticide or industrial contaminant levels.

FDA also invites comment on the effect of using a modified approach on the regulation of imports, especially with regard to the types of products described in item (5) above.

B. Exempting Small Firms

FDA invites comment on whether small firms should be exempt from the proposed regulation. Even if exempted, these firms would still be subject to the requirements of current food safety law and to inspection by FDA and State authorities.

As stated earlier in this preamble, small operations are the norm in the seafood industry. A significant majority of processors have total revenues of under 1 million dollars. If small firms are to be exempted, FDA invites comment on the criteria that should be used for exempting them, including how a small firm should be defined for purposes of an exemption.

The implementation of HACCP may be more burdensome for small firms than for large firms. Large firms tend to have quality control personnel already in place. In addition, many regulatory requirements are less burdensome for a large firm in proportion to output than they are for a small firm. On the other hand, FDA is taking steps, such as the preparation of its HACCP guidance, to minimize the cost of these regulations for small businesses. Thus, such an exemption may not be needed.

The agency also points out that, because many large firms already have quality control systems, an exemption for small business would appear to result in requiring HACCP for that segment of the industry (i.e., large firms) that needs it the least. Large processors, moreover, tend to process relatively low risk products, such as breaded fish and shrimp and raw fish blocks. Many high-risk processors, such as processors of cooked, ready-to-eat products, tend to be small, and processors of raw molluscan shellfish tend to be very small.

Nonetheless, an exemption for small business could be limited to those small businesses that produce low risk products, and FDA invites comment on this approach. As stated earlier, however, the criteria for determining low as well as high risk are not clear, due largely to the limitations of the U.S. foodborne illness reporting system. Moreover, a case can be made that risk also relates to the margin for error in a processing operation and to the consequences of failure as well as to the actual occurrence of illness.

With these points in mind, FDA invites comment on how to define "low risk." FDA also invites comment on what the nature of the exemption should be. Should a firm be exempt from all or part of the HACCP requirements? As circumstances change, a HACCP-based analysis of risk by a firm might reveal that the firm has become a high risk processor rather than a low risk processor. In addition, FDA invites comment on whether such an exemption should be obtained by petitioning the agency.

Finally, even if an exemption were to be adopted in the final rule based on the comments received, the agency would still encourage voluntary adoption of HACCP systems by exempted firms. The advantages that HACCP is expected to provide in terms of consumer confidence, control of process, and access to international markets warrant adoption of this system.

FDA also invites comment on the effect of a small business exemption on the regulation of imports. How would HACCP be applied to imports under a tiered approach? Would it be possible to treat domestic and imported products equally under such an approach?

C. Staggered Phase-in

The proposed regulations include an effective date of 1 year from the publication of a final rule. FDA has explained the reasoning behind this proposed effective date and has invited comment on it elsewhere in this preamble. In addition, comments are invited on the merits of a staggered phase-in instead of a single implementation date for all affected entities.

The two most obvious ways of accomplishing a staggered phase-in would be to differentiate on the basis of size or on the basis of risk. Differentiating on the basis of size would presumably allow small businesses to have a longer time or times for implementation than would be allowed for larger firms. As suggested earlier, large firms are probably much more able to implement a HACCP system than are small firms. Theoretically, the longer lead time for small firms would allow the private sector to develop an infrastructure that could help small firms implement HACCP. Such an infrastructure could include process authorities (see the preamble discussion on cooked, ready-to-eat products), testing facilities, and consulting services from trade associations, academia, and others.

As an additional consideration, FDA will likely learn lessons from its experiences in implementing the regulation that it could apply to the benefit of those that would have to implement it at a later date. For example, FDA is considering whether it should make the first review of HACCP plans by agency investigators a nonregulatory evaluation to facilitate plan development by the processor (although the overall inspection of the plant would be regulatory). The agency invites comment on this approach. Presumably, the more experience the agency has, the better this evaluation will be.

On the other hand, as noted above, small firms are involved in the processing of higher risk products. How does this fact bear on the possibility of longer implementation times for small firms?

Differentiation solely on the basis of risk appears to be more complex than differentiation on the basis of size. If high risk products were to be phased in first, it would appear that those with the most complex plans to develop and implement would receive the shortest lead time, while those with the simplest plans would receive the longest lead time.

Also, the criteria for determining risk would have to be carefully considered. FDA asks for comment on whether a staggered start should begin with raw molluscan shellfish and certain species of finfish that can accumulate scombrotoxin and ciguatoxin, or whether other criteria should apply, as discussed previously.

FDA invites comment on all these matters. FDA also invites comment on the effect of a phase-in approach on the regulation of imports. How could this approach be applied to imported products?

D. Deleting or Modifying Aspects of This Proposal, or Taking Some Other Step, to Reduce the Burden of Implementation

As has already been explained in this preamble, FDA has proposed only the basics of HACCP in order to keep the regulatory burden to a minimum. Several features of HACCP included within the NACMCF's seven principles, such as flow charts and the establishment of "HACCP teams," are noted in this preamble, but FDA has not proposed to require them. Nonetheless, FDA acknowledges that, theoretically, there are a number of ways in which this proposal could be scaled back even further. FDA invites comments on whether such scaling back would be desirable, and, if so, how it could be done. Possible areas for scale-back include, but are not limited to:

(1) Requiring only negative, rather than positive records. Negative records note only deviations from critical limits and how they are corrected. If a critical control point is under control, no record is made. Admittedly, FDA has reservations about such an approach. For example, it is virtually impossible for firms or for FDA to spot trends that could lead to problems if only negative records are being kept. Nonetheless, FDA invites comment on this approach.

(2) Developing generic plans by FDA that list critical control points and contain other information for various industry segments.

(3) Deleting some or all of the proposed specific sanitation requirements.

(4) Requiring HACCP only for the domestic industry. The HACCP requirements would become the basis for negotiating agreements with other countries relating to the equivalency of regulatory programs.

(5) Deleting or modifying the proposed training requirements.

(6) Requiring HACCP for processing hazards only. The Canadian HACCP system does not involve species-related safety hazards.

(7) Exempting warehouses.

(8) Although only in guidelines (Appendix B, Scombroid Toxin-Forming Species), sanctioning the receipt by a processor from a harvester of an assurance of good handling practices, rather than detailed time/temperature records. Such an assurance, without further verification, would be acceptable only from harvesters with histories of delivering acceptable products.

These four alternative approaches to implementing these regulations are not necessarily mutually exclusive. Comments are invited on them in combination as well as on them individually.

E. Information and Consumer Awareness

In addition to requesting comment on alternative approaches to HACCP, FDA is taking the opportunity to invite comment on the general subject of complementary risk reduction activities, primarily directed toward postprocessing handling. Elsewhere in this document, FDA invited comment on the advisability of applying HACCP or alternative regulatory approaches to commercial entities that are not directly subject to these proposed regulations, i.e., harvesting vessels, common carriers, and retail establishments (although not necessarily doing so as part of this rulemaking). In addition, FDA seeks comment on appropriate education and information that should be directed toward consumers and recreational fishermen. The commercial application of HACCP principles can mitigate somewhat the effects of poor consumer handling practices by helping to ensure that a safe product reaches the home, but no such program can prevent illnesses caused by improper home handling. Similarly, HACCP practiced by processors can have no effect on recreational fishermen who consume their own catch.

Education has always been an important part of FDA's comprehensive seafood safety program, but the agency believes that more can be done. Recent FDA education projects include the initiation of a seafood hotline, which has been consulted by over 26,000 individuals on a wide range of seafood safety issues since it began in October 1992. (The hotline can be reached by calling toll-free, 1–800–FDA–4010.) FDA also recently developed brochures aimed at advising certain medically

compromised populations that they should not eat molluscan shellfish without adequate cooking. FDA invites comment on other types of education and information activities that might be useful, including more information that might be made available through grocery stores, pharmacies, and other establishments, through the media, and through other means, including labeling. FDA is considering the merits of labeling information for consumers of molluscan shellfish, and will address this issue in proceedings separate from these regulations. FDA notes that several states have already mandated, or are in the process of mandating, point-of-purchase information for raw molluscan shellfish.

The agency also invites comment on whether FDA should consider proposing to require handling instructions for consumers on the labeling of seafood. The Department of Agriculture has proposed such requirements for meat and poultry (58 FR 58922, November 4, 1993).

FDA has a longstanding program to control the levels of microorganisms of public health concern in seafood. This program includes compliance policies on such levels, including zero levels (i.e., none detectable based upon official methods) for such pathogens as *Listeria monocytogenes* in cooked, ready-to-eat products and *Salmonella* in all foods. These proposed regulations require control of microbial pathogens through HACCP principles, including specific sanitation controls. Even so, FDA recognizes that no system can reduce all risks to zero. Because all foods in the home, including seafood, are subject to mishandling and cross contamination from other sources, FDA invites comment on the general subject of handling instructions. Should FDA decide to propose handling instructions, it would do so as a regulatory proposal separate from the proposed HACCP requirements for seafood.

IX. Paperwork Reduction Act

This proposed rule contains requirements for information collections which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980. The title, description, and respondent description of the information collection are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: Procedures for the Safe Processing and Importing of Fish and Fishery Products.

Description: The information requirements in this proposed rule are essentially monitoring and recordkeeping requirements encompassing critical control points in the production and inspection of fish and fishery products as established in the HACCP plans of processors and importers. The specific information collected and the frequency of collection will depend on such factors as the species and the processing conditions. It will include observations of processing parameters such as the time and temperature of processing and storage; the condition of raw materials; the results of chemical and microbiological tests; the sanitation conditions in a processing facility; the corrective actions taken in response to processing deviations, etc. Records identifying production lot codes and date of manufacture will also be maintained. Records will be maintained by the processing facility or at an importer's place of business for 1 year after the date of preparation in the case of refrigerated products and at least 2 years for frozen products.

This information will be used by FDA investigators during regularly scheduled inspections of processing plants, or at the time of entry of imports, to determine whether products were processed under sanitary conditions and processed, packaged, stored, and distributed using HACCP control techniques to avoid hazards that might cause the products to be adulterated. The information will also be used when necessary to trace and remove potentially hazardous products from the marketplace.

Records of processing conditions will also provide a means for processors to monitor the quality of their products and to alert them when a deviation from the critical limits established in the HACCP plan has occurred that may create a potential public health hazard in the final product.

The figures provided below reflect an FDA estimate of the annual hours of monitoring and recordkeeping based upon currently available data and assumptions about the effects of the requirements in proposed part 123. The estimate is based on data used to develop cost estimates for the economic impact analysis required by Executive Order 12866 and thus is subject to the same types of uncertainties described elsewhere in this preamble. For example, the agency has anecdotal evidence that the burden on firms that are operating under a mandatory HACCP system established by the State of Alaska is more nominal. Consequently, FDA acknowledges the possibility that the estimates provided here are conservatively high, indicating recordkeeping burdens that are higher than would customarily be the case. FDA specifically invites comments on this point.

Description of Respondents: Businesses.

ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

Number of respondents	Average annual burden per respondent (hours)	Total burden all respondents (hours)
4,349	650	2,826,850

The agency has submitted a copy of this proposed rule to OMB for its review of this information collection. Interested persons are requested to send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to FDA's Dockets Management Branch (address above), and to the Office of Information and Regulatory Affairs, OMB rm. 3208, New Executive Office Bldg., Washington, DC 20503, Attn: Desk Officer for FDA.

X. Economic Impact

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 compels agencies to use cost-benefit analysis as a component of decisionmaking. The Regulatory Flexibility Act requires regulatory relief for small businesses where feasible. FDA finds that this proposed rule constitutes a major rule under both Executive Order 12866 and the Regulatory Flexibility Act. A summary of the preliminary regulatory impact analysis (PRIA), which may be obtained from Dockets Management Branch (address above), is presented below.

Executive Order 12866 requires Federal agencies to justify the need for regulations by demonstrating that the problem that the regulation is designed to remedy cannot be adequately addressed by measures other than Federal regulation. In its review of such alternatives, FDA finds that the current system (periodic inspection plus sampling of a small proportion of seafood), coupled with the uncertainty in estimating the illnesses related to seafood, has not adequately ensured consumers that a minimum level of safety has been established. Although

the tort system is not able to provide remedies for unsafe seafood, the price system provides some differentiation between products based on brands and retail reputation. However, the price system works in conjunction with current Federal regulation which signals consumers as to a minimum level of seafood safety. As is argued in the preamble, countless public arguments and attempts at legislation imply that the minimum levels that some consumers believe they are getting (those that do not search for higher levels) is probably higher than the actual levels of seafood safety.

The tort system fails because consumers are often unable to trace either the source of their foodborne illness to seafood, and even where that is possible, it is often difficult to trace seafood to a specific company.

A. Regulatory Options

FDA has evaluated multiple options to address the compelling public interest in further ensuring seafood safety. These options include: (1) Maintaining the existing approach—"snapshot" inspections and sampling; (2) significantly increasing the frequency of both snapshot inspections and sampling under the existing approach; (3) beginning a voluntary HACCP program in addition to the existing approach; (4) beginning mandatory HACCP for high risk products only, in addition to the existing approach; (5) beginning mandatory HACCP for all seafood (the proposed approach); (6) beginning a more comprehensive mandatory HACCP program than that proposed, similar to the Model Seafood Surveillance Project (MSSP), which would include all CGMP's, quality factors, and economic fraud as critical control points; and (7) beginning a mandatory water-to-table HACCP program which would include all vessels, carriers, and retail food operators.

The existing approach does not adequately address the compelling public interest in further ensuring seafood safety because sampling the large volume of seafood with FDA's limited resources cannot detect many violative products. Increasing the frequency of sampling and inspections is also unlikely to resolve this problem without significant increases in funding. These options are discussed extensively in the preamble to the proposed regulations and in the PRIA. The third option, voluntary HACCP, has been in existence at NOAA and has very few participants. The forth option, risk-based HACCP, has been evaluated in the PRIA in several forms, including HACCP only for the highest risk products from a historical perspective and HACCP only for those products with the potential for catastrophic risk. For example, one possibility evaluated under this option would be to implement HACCP solely for molluscan shellfish, which NAS and other groups have concluded constitute most of the risk from seafood. The sixth option is more costly than the proposed option and includes more reliance on CGMP's. Finally, the last option involves mandatory HACCP for nearly 1 million establishments.

The options evaluated in the PRIA have both lower and higher costs than the proposed option. However, the benefits of all options are not equal to the proposed option. FDA has quantified net benefits of some of the high risk options and has found them to have been positive net benefits for those costs and benefits which have been quantified.

These options are not all equal in terms of costs and benefits. They differ significantly from one another in this regard, as well as from the option that FDA has selected to propose as new part 123. They are also not equal in their ability to meet all the regulatory objectives stated in the preamble, including effective treatment of imports and an appropriate alignment of industry and government responsibilities. FDA seeks comment on the costs and benefits as well as on the general pros and cons of all the stated options and on any options that the agency may have overlooked. It is extremely important that FDA's evaluation of regulatory options be as thorough as possible for purposes of developing a final rule, and that the agency be able to fully articulate the distinctions among them and the significance of those distinctions.

B. Costs

There is no single source of data that FDA has found to be entirely satisfactory for developing a preliminary estimate of the costs of the proposed regulations. Consequently, FDA has considered two sources of information, each with its own strengths and weaknesses. The results provide a range of possibilities, and FDA invites comment on them.

The first source is U.S. seafood processors that have actually implemented HACCP systems. The number of such firms may exceed 100. Understandably, many firms are reluctant to make public detailed information about the costs of operation; consequently, the information available to FDA from this source is incomplete. On the other hand, there is enough information from which some preliminary conclusions can be drawn that are relevant to an economic assessment.

The second source is a study of the costs of implementing a form of HACCP that was developed by the Department of Commerce for the congressionally mandated MSSP. That study was performed by an independent contractor for the National Fisheries Education and Research Foundation, Inc., and commissioned under a grant from NMFS. While these data are the most detailed available, fitting them to the proposed regulations required extensive adjustments and extrapolations. Thus, these data also fail to eliminate the considerable uncertainty of the results as they relate to these proposed regulations.

1. Costs: Actual Industry Experience

FDA has some information relevant to the actual costs of implementing HACCP experienced by a number of seafood firms. While this information is neither detailed nor complete enough to definitively answer the question of how much the proposed regulations will cost the industry, it does provide insight into the costs of the proposed regulations.

This information includes responses to a 1991 evaluation questionnaire from four of the eight firms that participated in the FDA/NOAA seafood HACCP pilot in 1990–1991 (Ref. 40). It also includes information more recently provided to FDA from seven firms through the assistance of NFPA, and from two trade associations. The trade associations, the NFI and the New England Fisheries Development Association (NEFDA) provided FDA with summary information about member firms that were implementing HACCP systems. NEFDA has operated a HACCP pilot with member firms through a Federal grant. The two trade associations provided information on 16 firms. The seven firms that provided information about themselves through NFPA operate a total of 44 processing plants, so FDA has information on at least 64 plants (Ref. 129).

The firms represent a good cross section of processing operation types, including canned, fresh, frozen, smoked/salted, and cooked, ready-to-eat products as well as molluscan shellfish. The majority of firms were involved in HACCP as participants in either pilot programs, the NOAA fee-for-service program, or the State of Alaska program, and therefore have been subject to some form of third party verification of their HACCP systems. Virtually all of them developed HACCP plans, and the

majority of these included critical control points for quality or economic fraud or both in addition to safety. In this respect, the majority of firms implemented a more extensive form of HACCP than is being proposed by FDA.

Presumably, start-up costs for HACCP are normally higher than operating costs in subsequent years. The majority of firms that could estimate their own start-up costs indicated costs in the $1,000 to $5,000 range. The remaining minority appear to be roughly equally divided between lower and higher costs. A few firms indicated costs in the $20,000 or higher range. These may be firms that decided to hire additional personnel in order to install or implement HACCP.

It should be noted that the cost figures that come from firms that operate more than one plant are for the total costs of their plants collectively; in order to calculate the average start-up cost per plant for these firms, their costs would have to be divided by the number of plants.

Nearly twice as many firms did not hire additional personnel or did not anticipate hiring additional personnel as a result of operating HACCP systems as those who did or felt the need to do so. The overwhelming majority of firms reported that they believed that the advantages they derived from HACCP were worth the costs to them in terms of better control over their operations, better sanitation, and greater efficiencies, such as reduced waste. Virtually all foresaw long-term benefits from operating under HACCP.

FDA notes that there are several uncertainties with this data. The first is that FDA does not know the extent of previous HACCP-type activities in these firms so that they may have different incremental costs than the industry average. In addition, these firms may have been relatively larger firms so that they may not be fully representative of the industry. Also, FDA does not know whether or not these firms would necessarily be in full compliance with the proposed regulations so that additional costs might have to be expended.

2. Costs: MSSP Study

The MSSP study provides FDA with survey data from which detailed cost estimates have been made in the PRIA, subject to numerous uncertainties. As this is the largest and only randomly selected data base available to FDA, the PRIA relied primarily on estimates based on these data. The contractor in the MSSP study sent teams into 130 processing plants, none of which were operating under HACCP systems, to project the costs to each plant to implement and operate a form of HACCP chosen for that study.

In areas where FDA had better data than that used in the contractor reports, the agency has used information available from its field surveys on current practices or conditions in the industry in general, and it has substituted that information for the information gathered from the sample plants in the contractor reports. Where gaps in the contractor estimates exist that could not be filled in by information from FDA field surveys, a number of assumptions have been made for the purposes of this economic assessment. FDA views the cost estimates extrapolated from the contractor reports and other sources as preliminary and requests comments on them.

From FDA's 1992 official establishment inventory, FDA has estimated that there are 4,846 domestic seafood manufacturing plants that will be affected by the proposed rule. Thirty-three percent of the first year costs can be attributed to expenditures necessary to comply with the HACCP-based sanitation provisions of the proposed rule. Another 36 percent are attributable to monitoring and recordkeeping requirements. In addition, approximately 31 percent of the first year costs are for equipment such as temperature indicators, temperature recorders, and can seam tear-down machines. Additional costs are for HACCP training, consulting by processing authorities, writing HACCP plans, instituting operational changes, responding to critical limit deviations, and analytical testing. The average expected cost of the proposed rule per domestic manufacturing plant is estimated to be $23,900 in the first year ($24,000 for small plants, $23,400 for large plants) and $15,000 in the following years ($14,700 for small plants and $15,700 for large plants). Total costs of the proposed rule for domestic manufacturers are estimated to be $117 million in the first year and $65 million in the following years.

In addition, FDA estimates that 924 importers will bear start-up costs of approximately $8 million, and 1,571 repackers and warehouses will bear annual recurring costs of $14 million. Therefore, based on these data, FDA estimates domestic costs for this rule to be $139 million in the first year and $79 million in succeeding years. Discounted domestic costs are estimated to be $676 million over 10 years (6 percent). FDA also estimates that 8,125 foreign processors will have initial costs of $96 million and recurring costs of $44 million.

Should smoked fish products be required to bear refrigeration statements on their labels, the maximum possible cost to this industry segment would be estimated to be $2.5 million for a label redesign for all products. A label redesign would be likely only in the case of extensive refrigeration instructions. If a simple statement such as "keep refrigerated" were to be required, then the cost to the smoked fish industry would be approximately $168,000 because approximately 75 percent of the products currently bear such statements.

These estimates are considerably higher than the estimates from data submitted to FDA from seafood plants as discussed above. These differences may be attributable to several factors. For example, the MSSP-based estimates also include estimated costs of compliance by processors with pre-existing sanitation requirements in part 110 and costs of complying with guidelines that are appended to these proposed regulations. Although these costs are not inherent to the operation of a HACCP system, they represent one-third of the total MSSP-based estimates. As indicated earlier in this document, compliance with CGMP's for sanitation has been a continuing problem across the industry. For this reason, FDA is proposing specific sanitation requirements in subpart A of part 123.

Moreover, the estimate of costs associated with complying with guidelines in the appendices may be overstated because, in actuality, FDA may find industry practices other than those stated in the guidelines to be acceptable. The guidelines are intended to provide the industry with information on how it could implement HACCP, not how it must do so.

Costs to importers and to foreign processors that ship to the United States were also estimated. In the absence of reliable data for estimating costs to foreign processors, FDA estimated the number of plants that export seafood to the United States and based their costs of implementing HACCP on MSSP-generated data on the costs to U.S. plants.

It is important to recognize that many of the United States major seafood trading partners are using, or have opted for, HACCP programs. For example, the EC will soon require HACCP or an equivalent system from over 100 nations that export to it. Consequently, with the current trend toward HACCP worldwide, the costs to many foreign processors of implementing HACCP may be incurred regardless of whether

FDA issued these proposed regulations. Moreover, in the near future, U.S. importers subject to this proposed rule should have little difficulty finding products produced under HACCP. FDA specifically invites comment on the estimated costs of the proposed regulations to importers and foreign processors, e.g., whether they are high due to the worldwide move toward HACCP or whether they are low due to other factors that have not been considered, and the potential effect on U.S. consumers of requiring that imports be produced under HACCP systems.

The PRIA presumes that most of the cost of compliance of the proposed regulations will be passed on to consumers. Estimating the magnitude of these price increases is difficult. U.S. consumers spent about $16.5 billion on domestically produced seafood in 1991 (Ref. 42). If the domestic industry passed on all of the estimated annual costs to consumers, prices for domestically produced seafood would increase by less than 1 percent in the first year and less than one-half of 1 percent in succeeding years. Price changes of such magnitude are unlikely to have a major impact on general seafood purchases. However, some regional price increases may considerably exceed this. In addition, this estimation of change in price does not address potential concentration effects. It is worth noting that the contractor that performed the MSSP study estimated a range of cost increases from negligible to 1.3 percent, depending on the type of product.

The effect on prices of imported products is impossible to estimate. While the PRIA uses MSSP data and a number of assumptions to estimate possible costs to foreign processors of complying with the proposed regulations, those costs will be spread among the consumers from all nations to which these processors export. FDA is unable to estimate what percentage of these costs would be passed on to U.S. consumers.

On the other side of the ledger, the MSSP-based estimates were not able to include costs associated with some features of the proposed rules because data were lacking. An inventory of these features is provided in the PRIA, and FDA invites comment on possible costs associated with them. They include prevention of cross contamination by the separation of food contact surfaces, storage at 40 °F of cooked, ready-to-eat products and products that are made in whole or in part of scombroid toxin forming species, and the costs of following the approach presented in the guidelines at Appendix B for scombroid toxin forming species.

C. Benefits

This proposed action will reduce the amount of illness that derives from consumption of seafood (safety benefits) and may have significant nutrition benefits that result from increased consumption of seafood. The increased consumption will result from a decrease in consumer anxiety associated with the consumption of seafood. In addition, there may be significant cost savings (benefits) in other areas as a result of adoption of this proposed rule.

The existence of a national, mandatory, HACCP-based inspection system for seafood should have a beneficial, although nonquantifiable effect on both the industry and the Federal government. FDA knows from experience that continuing concerns about the adequacy of the current Federal regulatory system for seafood place a financial stress on industry, which must constantly defend itself from criticism, and on regulatory agencies such as FDA, which must divert resources in order to respond to the Congress and the media. While public interest in food safety is healthy and desirable, the extreme interest in seafood safety, which has manifested itself in over 10 congressional hearings and over 20 pieces of legislation in the past 5 years, demonstrates how a system that is less than fully adequate from the public's standpoint can cause a steady diversion of both public and private resources that is likely to continue in the absence of a system that overcomes current inefficiencies and shortcomings.

Finally, there will be an additional benefit to firms wishing to export seafood to those countries which require federally monitored HACCP. The latter two benefits have not been quantified, and FDA requests comments on how this might be done.

The agency followed three steps to quantify the safety benefits of HACCP for processors: (1) Identify all significant hazards associated with seafood safety and establish the baseline number of incidents of each hazard in the U.S. population; (2) estimate the reduction in the number of incidents of each hazard that HACCP is expected to accomplish; and (3) quantify the benefit of the reduced illnesses and deaths. In all three steps, FDA acknowledges that there is substantial uncertainty.

First, to establish a baseline number of illnesses, FDA reviewed both reported data to the CDCP, which provides a lower bound on the actual number of cases, and an earlier FDA risk assessment that estimated an upper-bound number of cases. Using information about the probable amount of underreporting for each type of illness, FDA constructed a likely baseline number for each type of illness by inflating these numbers between zero and 1,000 times the amount reported. Thus, for example, while it is likely that nearly all cases of neurotoxic shellfish poisoning (NSP) are reported to CDCP, it is likely that *Campylobacter jejuni* is underreported by approximately 100 times the actual number of cases. This approach for estimating cases yielded an estimated 33,000 cases of illness from seafood per year. However, FDA acknowledges that even a reasonably precise estimate of the number of illnesses cannot be determined with the existing foodborne disease reporting mechanisms in this country.

In the second step, FDA used a panel of internal experts to determine the number of illnesses the proposed regulations are likely to reduce.[1] For example, it is not likely to reduce any cases of NSP because they are primarily associated with recreational fishing. On the other hand, it is likely to reduce over 50 percent of scombroid poisoning because most of the mishandling of seafood comes either at the catch or processing stages. This action will not reduce any cases that are a result of consumer or retailer mishandling but, as explained earlier in this document, problems at the retail level are addressed through mechanisms outside of this proposed regulation. FDA has estimated that between 5,000 and 19,000 cases of seafood illness and death will be reduced by the proposed action annually.

In the third step, FDA used economic valuation techniques to quantify the effect of reducing the range of cases of seafood illness. This technique combines costs of illness, such as hospital costs, with the costs of pain and suffering in a reduced health state to estimate the cost of each hazard. Thus, for example, NSP, with very mild symptoms, has a low cost per case ($270), whereas *Vibrio vulnificus*, with a high probability of death, has a very high cost ($1.3 million per case). Using this methodology, the total safety benefits of the proposed option are valued between $15 and $75 million per year.

FDA has also evaluated the potential health benefits associated with increased consumption of seafood. Because of the negative publicity concerning water pollution and seafood safety, consumer perception of seafood

[1] Memorandum to Richard A. Williams, Jr., November 17, 1993.

safety may overestimate actual risk. In addition, contamination scares cause drastic short-term drops in consumer demand for seafood products and undoubtedly contribute to the chronic level of consumer concern about seafood safety. Thus, safety concerns about seafood are a likely factor preventing wider consumer acceptance of seafood as part of the U.S. diet.

If this proposal is finalized, consumer concerns about seafood safety may be reduced which may, in turn, lead to increased consumption of seafood. FDA has evaluated the possibility that consumers may switch from higher fat flesh protein, such as meat and poultry, to seafood. The resulting reduced dietary fat in the diet of the general population would result in reduced incidence of coronary heart disease and cancer. Using the same methodology employed in an earlier analysis of the Nutrition Labeling and Education Act of 1990 (Pub. L. 101–535), FDA analyzed the benefits of a 1- and 5-pound per capita increase in consumption of seafood. These were estimated to decrease deaths by 673 and 2,782, respectively, over a 10-year period. The resulting benefits are valued at $3 and $14 billion.

D. Small Business Impact

The proposed rule will have a substantial impact on small seafood processors as defined by the Regulatory Flexibility Act. Eighty percent of the seafood processors covered by this proposed regulation are small, where small is defined for nonshrimp firms as less than $1 million in annual gross revenue and less than $2 million for shrimp firms. The provisions of this rule, such as monitoring and recordkeeping, are largely fixed costs (costs which do not vary significantly with the amount of the product produced) which will impose larger per unit costs on small rather than on large businesses. In addition, small firms may have as many critical control points as large firms because critical control points tend to be related to the complexity of the operation, not the size of the business. However, it may be that smaller firms are less complex than large firms, although the agency does not have sufficient data to determine if this is so.

In some cases the increase in cost will be large enough to cause some firms to go out of business. For example, estimates of firm failure have been as low as 2 percent (96 firms) of all firms (from the Canadian experience) to 334 firms (estimated for compliance with MSSP). However, FDA does not have enough information to estimate the number of firms that will close if the proposed rule becomes final.

There are several factors that affect the ability of small processors to comply with the proposed regulations. First, the basic HACCP requirements proposed in subpart A of part 123 deliberately include only the essentials of HACCP in order to keep fixed costs to a minimum. Second, FDA is developing considerable guidance in the form of a hazard guide and model HACCP plans to enable small processors to implement an effective HACCP system at the lowest possible cost. Third, FDA is also aware that academia and trade associations are available to assist processors to implement HACCP. Finally, for those small processors that have very simple operations requiring few critical control points, an inherent feature of HACCP is that it adjusts to the complexity and risks of an operation.

While any closure is regrettable, the agency strongly believes that firms that are unable to identify the likely hazards associated with their products and take reasonable preventive controls to prevent those hazards from occurring should not be selling food in interstate commerce. As described in the preamble, FDA is keenly interested in keeping the costs of implementing HACCP to a minimum and is issuing guidance documents and model HACCP plans to facilitate such implementation.

FDA is specifically requesting comment in areas where costs and benefit estimates are either very uncertain or potentially large. FDA will utilize answers received on these comments along with all other comments to help formulate the final rule.

1. Costs

FDA specifically requests comments on:

(1) The expected cost to retrofit plants as necessary for the proper operation of HACCP controls (e.g., enhance refrigerator capacity, water supply changes, etc.).

(2) The cost of taking corrective actions to respond to critical limit deviations on an annual basis. FDA has estimated an average of $1,000 per firm to take such actions as discarding product, buying new equipment, and changing the processing practice.

(3) The cost of training employees. FDA has estimated that there will be a cost per plant of $900 to train an employee to manage HACCP. This will include the cost of training, travel expenses, and loss of several days of productivity for that employee. Not all of these costs may be borne by manufacturers, however, because some training may be sponsored by academia, trade associations, and others.

(4) The cost of ensuring that cooking and pasteurizing equipment and processes are achieving the desired safety results (i.e., destroying microbiological pathogens). This ensurance may be obtained by having equipment and processes that are equivalent to those found effective by a processing authority. FDA estimated that this would cost $1,000 per plant in the first year and, on average, half that amount in the following years as processors change their processes and equipment. This cost may be offset, however, by reliance on literature that contains the necessary information from a processing authority.

(5) The cost of temperature indicators and thermometers for plants who do not now have this equipment. FDA estimated that the cost would be $1,000 per plant, initially, with replacement as necessary.

(6) The cost of creating a HACCP plan from the guidance provided by FDA. FDA estimated that it will take processors with simpler processes 24 hours of managerial time to adapt the guidance into a HACCP plan. FDA estimated that it will take processors with more complex processes 72 hours of managerial time to adapt the guidance into a HACCP plan.

(7) FDA requests comment on the recordkeeping burden associated with the proposed sanitation requirements in § 123.10 (b) and (c). If possible, such estimates should be provided in terms of hours spent and translated into dollars if staff compensation rates are known.

In addition, FDA was unable to provide cost estimates of the following provisions and requests specific comments on these areas:

(1) Section 123.10(a)(7), prevention of cross-contamination by the separation of food-contact surfaces;

(2) Section 123.10(a)(14), storage at 40 °F or below;

(3) Appendix A.6., cooling after cooking;

(4) Appendix B., scombroid toxin forming species;

(5) Appendix 1., specifically, the guidance on smoked and smoke-flavored fishery products;

(6) Increased short-term recall potential, if any, due to heightened industry awareness;

(7) Increasing time spent escorting Federal inspectors, particularly in the initial phases;

(8) The cost of restricting catch in certain areas and seasons if processors find it necessary.

2. Benefits

(1) FDA is reprinting two tables from the PRIA and requests comments on both the baseline number of illnesses due to seafood and the likelihood that HACCP for processors will reduce those illnesses. The baseline number of illnesses reflects an estimate of all cases (from any source, including recreational harvest, retail, and consumer mishandling). FDA considers the estimates in both tables as preliminary estimates.

TABLE 1.—SIGNIFICANT HAZARDS ASSOCIATED WITH SEAFOOD

[All Seafood Sources Combined—Recreational and Commercial]

Hazards	Reported cases (annual)	Upper-bound cases (annual)	Estimated cases (annual)
Anasakis	1	100	100
Campylobacter jejuni	2	200	200
Ciguatera	800	8,000	800
Clostridium botulinum	4	4	4
Clostridium perfringens	7	70	70
Diphyllobothrium latum	(1)	1,000	1,000
Giardia	3	50	30
Hepatitis A virus	9.2	6,700	92
Neurotoxic shellfish poisoning	48	48	48
Norwalk virus	12.4	30,000	12,400
Other *Vibrios*	43	10,000	10,000
Paralytic shellfish poisoning	13.4	13.4	13.4
Salmonella nontyphi	2	2,750	200
Scombrotoxin	796	21,500	7,960
Shigella	7	100	70
Vibrio vulnificus	24	48	48
Total	1,772	80,389	33,035

[1] Unknown.

TABLE 2.—PROJECTED NUMBER OF CASES AVERTED USING HACCP APPROACH

Hazards	FDA best estimate of the number of cases	Number of cases averted (lower)*	Number of cases averted (upper)**
Anasakis	100	10	75
Campylobacter jejuni	200	100	150
Ciguatera	800	50	100
Clostridium botulinum	4	0	1
Clostridium perfringens	70	53	70
Diphyllobothrum latum	1,000	250	750
Giardia	30	0	7.5
Hepatitis A virus	92	15	46
Neurotoxic shellfish poisoning	48	0	0
Norwalk virus	12,400	1,000	6,200
Other *Vibrios*	10,000	1,000	5,000
Paralytic shellfish poisoning	13	0	0
Salmonella nontyphi	200	100	150
Scombrotoxin	7,960	3,980	5,970
Shigella	70	18	35
Vibrio vulnificus	48	0	24
Total	33,035	6,575	18,679

*Estimates by Klontz and Altekruse.
**Estimates by Archer.
[1] Memorandum to Richard A. Williams, Jr., November 16, 1993.

(2) FDA also specifically requests comments on the number of cases of illness included in the baseline estimate (33,035) that may be due to factors outside the processors' control, such as those due to recreational harvests (that are not eventually sent to processors), those due to restaurants and supermarkets, and those due to consumer mishandling.

(3) As mentioned above, FDA has also estimated potential benefits associated with increased seafood consumption. These benefits will only be realized if the price increase resulting from this rule does not offset the effect of increased demand for seafood which will result from reduced consumer anxiety. FDA requests specific comment on the likelihood that seafood consumption will be increased as a result of this rule.

(4) FDA has identified but not quantified benefits to seafood exporters as well as reduced public anxiety associated with the safety of seafood.

FDA requests comments on these benefits (including how to quantify them) as well as other potential benefits such as how HACCP will help firms gain better control over their operations, better sanitation and greater efficiencies such as reduced product waste.

E. Tribal Governments

FDA is aware that some tribal governments are involved in the processing of seafood for interstate commerce. The agency expects that the proposed regulations will apply to them in such cases. Executive Order 12875 of October 26, 1993, requires, among other things, consultation with tribal governments before the formal promulgation of regulations containing unfunded Federal mandates. While FDA does not believe that the proposed regulations would impose an unfunded Federal mandate, the agency wishes to foster consultation on matters that might significantly affect tribal communities. Consequently, FDA specifically requests comment on the economic effect of the proposed regulations on tribal governments.

F Availability of PRIA/RFA

FDA acknowledges considerable uncertainty in both cost and benefit estimates of the proposed regulations and requests comment on all aspects of the PRIA and the RFA. The full PRIA/RIA is available at the Dockets Management Branch (address above).

XI. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

XII. Request for Comments

Interested persons may, on or before April 28, 1994, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

XIII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Committee on Diet and Health, Food and Nutrition Board, Commission on Life Sciences, National Research Council, "Diet and Health: Implications for Reducing Chronic Disease Risk," National Academy Press, Washington, DC, 1989.

2. National Heart, Lung, and Blood Institute, DHHS, "National Cholesterol Education Program: Report of the Expert Panel on Population Strategies for Blood Cholesterol Reduction, Executive Summary," NIH Publication No. 90–3047, National Institutes of Health, Bethesda, MD, 1990.

3. Hackney, C., and D. Ward, ed., "Microbiology of Marine Food Products," Van Nostrand Reinhold, 1991.

4. Roper, W.L. Director, Centers for Disease Control, letter to the Honorable John D. Dingell, May 2, 1990.

5. Otwell, W.S., "Seafood Safety in Question," *MTS Journal*, 25(1):23–29.

6. FDA, DHHS, "Seafood Safety," May 10, 1993.

7. Ahmed, F.E. ed., Committee on Evaluation of the Safety of Fishery Products, Food and Nutrition Board, Institute of Medicine, NAS, *Seafood Safety*, National Academy Press, 1991.

8. Rhodehamel, E.J., "Overview of Biological, Chemical, and Physical Hazards," *HACCP: Principles and Applications*, Van Nostrand Reinhold, 1992.

9. Colwell, R.R. ed., "Natural Toxins and Human Pathogens in the Marine Environment," Report of a Sea Grant-Sponsored Workshop, A Maryland Sea Grant Publication, undated.

10. Stone, R., ed., "Single-Celled Killer in Monterey Bay," *Science*, November 22, 1991.

11. Letter to John A. Sandor from Thomas J. Billy, March 22, 1993.

12. Bier, J.W., T.L. Deardorff, G.J. Jackson, and R.B. Raybourne, "Human Anisakiasis," *Bailliere's Clinical Tropical Medicine and Communicable Diseases*, 2(3):723–733, 1987.

13. Liston, J., Statement before the Senate Committee on Commerce, Science, and Transportation, U.S. Senate, June 30, 1992.

14. Mayer, B.K., and D.R. Ward, "Microbiology of Finfish and Finfish Processing," *Microbiology of Marine Food Processing*, Van Nostrand Reinhold, 1991.

15. Spitzig, P., memorandum, "Decomposition Data From the Seafood Regulatory Action Database," May 14, 1992.

16. FDA, DHHS, "The Fish List: FDA Guide to Acceptable Market Names for Food Fish Sold in Interstate Commerce," 1988.

17. Letter From Skip Widtfeldt, Seafood Permit Coordinator, State of Alaska Department of Environmental Conservation, to Alaska Seafood Processors, January 17, 1992.

18. Nardi, G., "HACCP: A View From the Inside," American Seafood Institute Report, April 1992.

19. Coons, K., "HACCP is Here," *Seafood Supplier*, May/June 1992.

20. Kraemer, D.W., memorandum, "Unique Nature of Seafood Processing Industry," May 6, 1993.

21. Kraemer, D.W., memorandum, "High Risk Survey—Cooked Ready to Eat Results," March 1, 1993.

22. Bryan, F.L., "What the Sanitarian Should Know About Staphylococci and Salmonellae in Non-Dairy Products: I. Staphylococci," *Journal of Milk and Food Technology*, 31(4):110–116, April 1968.

23. Golden, D.A., E.J. Rhodehamel, and D.A. Kautter, "Growth of *Salmonella* spp. in Cantaloupe, Watermelon, and Honeydew Melons," *Journal of Food Protection*, 56(3):194–196, 1993.

24. FDA Smoked or Salted Fish Assignment (FY 89), and compilation of data, dated December 19, 1988.

25. New York State Good Manufacturing Practices Regulation for Smoked Fish Products, 1990.

26. Eklund, M.W. et al., "Inhibition of *Clostridium Botulinum* Types A and E Toxin Production by Liquid Smoke and NaCl in Hot- Process Smoke-Flavored Fish," *Journal of Food Protection*, 45(10):935, 1982.

27. Program Evaluation Branch, Office of Regulatory Affairs, FDA, DHHS, "Field Summary Seafood Accomplishments/ Expenditures FY 1984–FY 1992," November 1992.

28. FSIS, USDA, "Meat and Poultry Inspection 1991: Report of the Secretary of Agriculture to the U.S. Congress."

29. Snyder, M.I., memorandum, "FDA Rejection Insurance," May 7, 1993.

30. Sunde, S., "A Sea of Uncertainties," *Seattle Post-Intelligencer*, February 25, 1993.

31. Wilms, H.G., memorandum, "State Seafood Resources," May 17, 1993.

32. Spencer, H., "The Role of Government in a Mandatory HACCP Based Program," *Dairy, Food and Environmental Sanitation*, July 1992.

33. Bauman, H.E., "Introduction to HACCP," *HACCP: Principles and Applications*, Van Nostrand Reinhold, 1992.

34. NACMCF, "National Advisory Committee on Microbiological Criteria for Foods, Hazard Analysis and Critical Control Point System Adopted March 20, 1992," *HACCP: Principles and Applications*, Van Nostrand Reinhold, 1992.

35. NMFS, NOAA, U.S. Department of Commerce, "The Report of the Model Seafood Surveillance Project: A Report to the Congress," draft dated February 5, 1993.

36. Subcommittee on Microbiological Criteria, Committee on Food Protection, Food and Nutrition Board, National Research Council, *An Evaluation of the Role of Microbiological Criteria for Foods and Food Ingredients*, National Academy Press, 1985.

37. Lee, J.S., and K.S. Hilderbrand, Jr., "Hazard Analysis & Critical Control Point Applications to the Seafood Industry," Oregon Sea Grant, ORESU-H–92–001, 1992.

38. Weddig, L.J., letter to the Honorable Donna E. Shalala, February 25, 1993.

39. Iani, L.J., letter to Tom Billy, April 1, 1993.

40. Peeler, T., "Review of the FDA/NOAA Seafood Pilot," undated.

41. Food and Agriculture Organization of the United Nations, "Fishery Statistics: Commodities 1990," vol. 71, Rome, 1992.

42. NMFS, NOAA, U.S. Department of Commerce, "Fisheries of the United States, 1991," Silver Spring, MD, 1992.

43. NMFS, NOAA, U.S. Department of Commerce, "Current Fisheries Statistics No. 9202: Imports and Exports of Fishery Products Annual Summary, 1992."

44. The Council of the European Communities, "Council Directive of 22 July 1991 Laying Down the Health Conditions for the Production and the Placing on the Market of Fishery Products," *Official Journal of the European Communities*, No. L 268/15.

45. GATT Secretariat, "Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations," December 20, 1991.

46. Codex Alimentarius Commission, Food and Agriculture Organization of the United Nations, "Joint FAO/WHO Food Standards Programme, Codex Alimentarius Commission, 20th Session, Geneva 28 June–7 July 1993, Report of the 25th Session of the Codex Committee on Food Hygiene Washington D.C., 28 October–1 November 1991."

47. "Communication From The President of the United States Transmitting the Final Legal Text of the U.S.–Canada Free-Trade Agreement, The Proposed U.S.–Canada Free-Trade Agreement Implementation Act of 1988, and a Statement of Administrative Action, Pursuant to 19 U.S.C. 2112(e)(2), 2212(a)," House Document 100–216, July 26, 1988.

48. Rhodehamel, E.J., "FDA's Concerns With Sous Vide Processing," *Food Technology*, 46(12) 73–76, 1992.

49. Cook, D.W., and Ruple, A.D., "*Vibrio Vulnificus* and Indicator Bacteria in Shellstock and Commercially Processed Oysters From the Gulf Coast," *Journal of Food Protection*, 55(9):667–671, 1992.

50. FDA, DHHS, "Food and Drug Administration Pesticide Program: Residue Monitoring 1991," *Journal of the Association of Official Analytical Chemists International*, Vol. 75, September/October 1992.

51. Corlett, D.A., Jr., and Pierson, M.D., ed., *HACCP: Principles and Applications*, Van Nostrand Reinhold, 1991.

52. Duersch, J.W., Paparella, M.W., and Cockey, R.R., "Processing Recommendations for Pasteurizing Meat from the Blue Crab," Advisory Report, Maryland Sea Grant Program, Publication No. UM–SG–MAP–81–02, 1981.

53. Gorga, C., and Ronsivalli, L.J., "Quality Assurance of Seafood," Van Nostrand Reinhold, New York.

54. Schaffner, R.M., "Introduction to Canned Foods: Principles of Thermal Process Control, Acidification and Container Closure Evaluation" The Food Processors Institute, 1982.

55. Corlett, D.A., Jr., and Pierson, M.D., "Hazard Analysis and Assignment of Risk Categories," *HACCP: Principles and Applications*, Van Nostrand Reinhold, 1991.

56. Farber, J.M., "*Listeria Monocytogenes* in Fish Products," *Journal of Food Protection*, 54:922–924, 1991.

57. Lovett, J., Francis, D.W., and Bradshaw, J.G., "Outgrowth of *Listeria Monocytogenes* in Foods," *Foodborne Listeriosis*, Society for Industrial Microbiology, Elsevier Science Publishers, New York, 1990.

58. Farber, J.M., and Peterkin, P.I., "*Listeria Monocytogenes*, a Food-borne Pathogen," *Microbiology Reviews*, 55:476–511, 1991.

59. Warner, E.T., memorandum, "New York District Smoked Fish Inspection Results," May 24, 1993.

60. Wilson, B.F., memorandum, "Seafood Consumer Complaint Data," April 15, 1993.

61. Data summary sheets.

62. Wilson, B., memorandum, "Sanitation Data from 1991–1992 Abbreviated Inspections," April 13, 1993.

63. Bryan, F.L., "Microbiological Food Hazards Today—Based on Epidemiological Information," *Food Technology*, pp. 52–64, September 1974.

64. FDA, DHHS, "FDA Fact Sheet: Shigella in Food," December 1969.

65. FDA, DHHS, "Food Service Sanitation Manual Including a Model Food Service Sanitation Ordinance," DHEW Publication No. (FDA) 78–2081, 1976.

66. Koren, H., "Handbook of Environmental Health and Safety Principles and Practices," Vol. I, 2d ed., Lewis Publishers, pp. 116–117, 1991.

67. Benenson, A.S., ed., "Control of Communicable Diseases in Man," 15th ed., American Public Health Association, pp. 170–177, 197–8, 210–11, 491–2, 1991.

68. Cross Connection Control Committee, Pacific Northwest Section, American Water Works Association, With the Assistance of EPA, "Cross Connection Control Manual, Accepted Procedures and Practice," 5th Ed., May, 1990.

69. National Sanitation Foundation, "Reference Guide: Sanitation Aspects of Food Service Facility Plan Preparation and Review," January 1978.

70. EPA, "Drinking Water; Substitution of Contaminants and Priority List of Additional Substances which May Require Regulation under the Safe Drinking Water Act," 52 FR 25720, July 8, 1987.

71. National Sanitation Foundation, Ann Arbor, Michigan, "Sanitation Aspects of Installation of Food Service Equipment," undated.

72. The National Food Safety Certification Program, Applied Food Service Sanitation, A Certification Coursebook, 4th ed., John Wiley & Sons, Inc., pp. 176–179, 1992.

73. Surkiewicz, B.F., Hyndman, J.B., and Yancey, M.V., "Bacteriological Survey of the Frozen Prepared Foods Industry: II. Frozen Breaded Raw Shrimp," *Applied Microbiology*, 15(1):1–9, January 1967.

74. Bryan, F.L., "Emerging Foodborne Diseases: II. Factors that Contribute to Outbreaks and Their Control," *Journal of Milk and Food Technology*, 35(11):632–638, November 1972.

75. Brown, J.L., "Fundamentals of Cleaning Multi-Use Utensils," National Sanitation Foundation Testing Laboratory, Ann Arbor, Michigan, undated.

76. "Carbon Dioxide Treatment Destroys Biofilms: NFPA *Food Chemical News*, p. 22, November 11, 1991.

77. Surkiewicz, B.F., Groomes, R.J., and Shelton, L.R. Jr., "Bacteriological Survey of the Frozen Prepared Foods Industry: IV. Frozen Breaded Fish," *Applied Microbiology*, 16(1): 147–150, January 1968.

78. Food Safety Committee, NFPA, "Guidelines for the Development of Refrigerated Foods," NFPA Bulletin 42–L, 1989.

79. Kornacki, J.L., and Gabis, D.A., "Microorganisms and Refrigeration Temperatures," *Dairy, Food and Environmental* Sanitation, 10(4):192–195, April 1990.

80. Phillips, F.A., and Peeler, J.T., "Bacteriological Survey of the Blue Crab Industry," *Applied Microbiology*, pp. 958–966, December 1972.

81. Moody, M.W., "How Cleaning Compounds Do the Job," Seafood Technology Cooperative Extension Service, Louisiana State University, undated.

82. Lentsch. S., "Sanitizers for an Effective Cleaning Program," Klenzade Division, Economics Laboratories, St. Paul, MN.

83. Codex Alimentarius Commission, Food and Agriculture Organization of the United Nations, "Recommended International Code of Practice for Fresh Fish," 2d ed., CAC/RCP 9–1976.

84. Bryan, F.L., "Emerging Foodborne Diseases: I. Their Surveillance and Epidemiology," *Journal of Milk and Food Technology*, 35(10):618–625, October 1972.

85. Refrigerated Foods and Microbiological Committee, NFPA, "Factors to be Considered in Establishing Good Manufacturing Practices for the Production of Refrigerated Foods," *Dairy and Food Sanitation*, 8(6):288–291, June 1988.

86. Schmidt, C.F., Lechowich, R.V., and Folinazzo, J.F., "Growth and Toxin Production by Type E *Clostridium Botulinum* Below 40 °F," *Journal of Food Science*, 26:626, 1961.

87. Bott, T.L. et al., "*Clostridium Botulinum* Type E in Fish from the Great Lakes," *Journal of Bacteriology*, 91(3):919, 1966.

88. Bott, T.L., et al., "Possible Origin of the High Incidence of *Clostridium Botulinum* Type E in an Inland Bay (Green Bay of Lake Michigan), *Journal of Bacteriology*, 95(5):1542, 1968.

89. Milk Safety Branch, Center for Food Safety and Applied Nutrition, FDA, "FDA's Dairy Product Safety Initiatives: Preliminary Status Report," September 1986.

90. FDA, DHHS, "National Shellfish Sanitation Program—Manual of Operations Part I Sanitation of Shellfish Growing Areas," 1992.

91. Richards, G.P., "Outbreaks of Shellfish-Associated Enteric Virus Illness In The United States: Requisite For Development Of Viral Guidelines," *Journal of Food Protection*, 48:815–823; 1985.

92. Richards, G.P., 1987, "Shellfish-associated Enteric Virus Illness in the United States," 1934–1984, *Estuaries* 10(1):84–85.

93. McFarren, E.C., et al., 1960, "Public Health Significance of Paralytic Shellfish Poison," *Advances in Food Research*, 10:135–179.

94. Farrington, J.W., et al., "U.S. 'Mussel Watch' 1976–1978: An Overview Of The Trace-Metal, DDE, PCB, Hydrocarbon, And Artificial Radionuclide Data," *Environmental Science Technology*, 17:490–496; 1983.

95. Kaplan, J.E., et al., 1982, "Epidemiology of Norwalk Gastroenteritis and the Role of Norwalk Virus in Outbreaks of Acute Nonbacterial Gasteroenteritis," *Annals of Internal Medicine*, 96(1):756–761.

96. FDA, PHHS "National Shellfish Sanitation Program—Manual of Operations, Part II, Sanitation of The Harvesting, Processing and Distribution of Shellfish, 1992."

97. FDA, Compliance Policy Guide, Chapter 58—Non-Government Agreements, 7158.04, April 1, 1984.

98. FDA, Compliance Program Guidance Manual, Compliance Program 7318.004 (TN 92–41, 01/01/92), 1992.

99. General Accounting Office, "Problems in Protecting Consumers From Illegally Harvested Shellfish (Clams, Mussels, and Oysters)," HRD–84–36, Report to the Honorable Thomas J. Downey, House of Representatives, 1984, U.S. Government Printing Office, Washington, DC.

100. New York Department of Environmental Conservation, "Improved Procedures for Source Identification of Shellfish by State Government," 1988.

101. Goza, M., memorandum, "Arizona Ban of Shellfish," February 19, 1993.

102. Veazey, J., memorandum, "Louisiana and Mississippi Seizures for Tagging Violations," March 29, 1993.

103. Steele, E.A., memorandum, "Shellfish Summons and Arrests—South Carolina," April 9, 1992.

104. Letter from David G. Field, Director, State Program Branch, Northeast Region, FDA, to Mr. John Volk, Director, Aquaculture Division, Connecticut Department of Agriculture, December 10, 1992.

105. Letter from David G. Field, Director, State Program Branch, Northeast Region, FDA to Mr. John Volk, Director, Aquaculture Division, Connecticut Department of Agriculture, December 18, 1992.

106. Letter from David G. Field, Director, State Program Branch, Northeast Region, FDA, to Mr. John Volk, Director, Aquaculture Division, Connecticut Department of Agriculture, December 31, 1992.

107. Hesselman, D., memorandum, "Imported Shucked Frozen Mussels from Thailand," March 4, 1993.

108. Letter from Donald M. Hesselman, Shellfish Specialist, Southeast Region, FDA, to Mr. Robert G. Benton, Chief, Shellfish Sanitation Program, North Carolina Department of Environment, Health and Natural Resources, February 11, 1993.

109. Glatzer, M., memorandum, "Tagging/Labeling Violations/Actions," March 24, 1993.

110. Letter from Joseph P. Hile, Associate Commissioner for Regulatory Affairs, FDA, to Dr. Robert L. Flentge, Chief, Division of Food, Drugs and Dairies, State of Illinois, November 5, 1985.

111. Moore, K., Statement before the House Merchant Marine and Fisheries Committee, Subcommittee on Fisheries and Wildlife Conservation and the Environment, U.S. House of Representatives, May 15, 1991.

112. Smith, T., Statement before the House Merchant Marine and Fisheries Committee, Subcommittee on Fisheries and Wildlife Conservation and the Environment, U.S. House of Representatives, May 15, 1991.

113. Banks, A., memorandum, "Model Food Codes Provisions Requiring that Shellfish be Obtained from U.S. PHS Listed Sources, and Status of Adoptions," May 17, 1993.

114. Kraemer, D.W., "Processing Methods for Ready-To-Eat Seafood Products and Control and Inactivation of *Listeria monocytogenes*," December 1989.

115. FSIS, USDA, "Time/Temperature Guidelines for Cooling Heated Products," FSIS Directive 7110.3.

116. Department of Fisheries and Oceans, Canada, "Good Manufacturing Practices, Lobster Processing, Annex A: Sanitary Zone(s)," Revision No. 1 900601, pp. 49–51.

117. Stratton, J.E., and Taylor, S.L., "Scombroid Poisoning," *Microbiology of Marine Food Products*, Van Nostrand Reinhold, pp. 331–351, 1991.

118. Frank, H.A., and Yoshinaga, D.H., "Histamine Formation in Tuna," *Seafood Toxins*, Regelis, E.P., ed., ACS Symposium Series No. 262, American Chemical Society, Washington, D.C., pp. 443–451, 1984.

119. Barnett, J.D., memorandum, "Scombrotoxin Regulation," May 14, 1993.

120. Yoshinaga, D.H., and Frank, H.A., "Histamine-Producing Bacteria in Decomposing Skipjack Tuna (*Katsuwonus pelamis*)" *Applied and Environmental Microbiology*. 44(2):447–452, 1982.

121. Baranowski, J.D., Frank, H.A., Brust, P.A., Chongsiriwatana, M., and Premaratne, R.J., "Decomposition and Histamine Content in Mahimahi (*Coryphaena Hippurus*)," *Journal of Food Protection*, 53(3):217–222, 1990.

122. Association of Food and Drug Officials Quarterly Bulletin, 49(3):129, July 1985.

123. General Accounting Office, "Seafood Safety: Seriousness of Problems and Efforts to Protect Consumers," GAO/RCED–88–135, 1988.

124. Brunetti, A.P., memorandum, "Import Detentions Related to Misbranding for FY 1992," May 26, 1993.

125. Hsieh, Y., Kirsh, P., and Woodward, B., "Species identification of retail snapper fillets in Florida," *Proceedings of the 14th Annual Conference of the Tropical and Subtropical Fisheries Technological Society of the Americas*, Florida Sea Grant Program, SGR–101, University of Florida, Gainesville, September, 1990.

126. Ian Dore, "Fresh Seafood, The Commercial Buyers Guide," Van Nostrand Reinhold, New York, 1984.

127. National Fisheries Institute, Inc., "Seafood Quality: Inspecting the Issue: A Study of the U.S. Fisheries Inspection System Conducted by the National Fisheries Institute in Cooperation With the National Marine Fisheries Service," Washington, DC, 1985.

128. Jones, B., and Doolin, C., "Industry and Regulatory Interface to Address Concerns for Seafood Product Quality and Safety," Federal Saltonstall-Kennedy Project NA88–WC–H–06065, Southeast Fisheries Association, Inc., Tallahassee, FL, June, 1990.

129. Spiller, P., Memorandum, "Industry Costs of HACCP," September 13, 1993.

130. Schlech, W.F. et al., "Epidemic Listeriosis—Evidence for Transmission by Food," *New England Journal of Medicine*, 308:203–206, 1983.

131. Fleming, D.W. et al., "Pasteurized Milk as a Vehicle of Infection in an Outbreak of Listeriosis," *New England Journal of Medicine*, 312:404–407, 1985.

132. James, S.M. et al., "Listeriosis Outbreak Associated With Mexican-style Cheese—California," *Morbidity and Mortality Weekly Report*, 34:358–359, 1985.

133. Azadian, B.S., G.T. Finnerty, and A.D. Pearson, "Cheeseborne *Lister* Meningitis in Immunocompetent Patient," *The Lancet*, i:322–323, 1989.

134. Buchanan, R.L., H.G. Stahl, M.M. Bencivengo, and F. Del Corral, "Comparison of Lithium Chloride-Phenylethanol-Moxalactam and Retail-Level Meats, Poultry, and Seafood," *Applied and Environmental Microbiology*, 55:599–603, 1989.

135. Johnson, J.L., M.P. Doyle, and R.G. Cassens, "*Listeria Monocytogenes* and Other *Listeria* Spp. in Meat and Meat products: A Review," *Journal of Food Protection*, 53:81–91, 1990.

136. Weagant, S.D. et al., "The Incidence of *Listeria* Species in Frozen Seafood Products," *Journal of Food Protection*, 51:655–657, 1988.

137. Farber, J.M., "*Listeria Monocytogenes in Fish Products*," *Journal of Food Protection*, 54:922–924, 1991.

138. Lovett, J., D.W. Francis, and J.G. Bradshaw, "Outgrowth of *Listeria Monocytogenes* in Foods," p. 183–187, *In* A.J. Miller, J.L. Smith, and G.A. Somkuti (eds.), "Foodborne Listeriosis," *Society for Industrial Microbiology*, Elsevier Science Publishers, New York, 1990.

139. Rorvik, L.M., M. Yndestad, and E. Skjerve, "Growth of *Listeria Monocytogenes* in Vacuum-packed, Smoked Salmon, During Storage At 4 °C, *International Journal of Food Microbiology*, 14:111–118, 1991.

140. Farber, J.M., and P.I. Peterkin, "*Listeria Monocytogenes*, a Food-borne Pathogen, *Microbiology Reviews*, 55:476–511, 1991.

141. Hartemink, R., and F. Georgsson, "Incidence of *Listeria* Species in Seafood and Seafood Salads," *International Journal of Food Microbiology*, 12:189–196, 1991.

142. Jemmi, T., "Occurrence of *Listeria Monocytogenes* in Imported Smoked and Fermented Fish," *Food Science and Technology Abstracts*, 23(9):226, 1990.

143. Guyer, S., and T. Jemmi, "Behavior of *Listeria Monocytogenes* During Fabrication and Storage of Experimentally Contaminated Smoked Salmon, *Applied Environmental Microbiology*, 57:1523–1527, 1991.

144. Jemmi, T., and A. Keusch, "Behavior of *Listeria Monocytogenes* During Processing and Storage of Experimentally Contaminated Hot-smoked Trout," *International Journal of Food Microbiology*, 15:339–346, 1992.

145. Shahamat, M., A. Seaman, and M. Woodbine, "The Survival of *Listeria Monocytogenes* in High Salt Concentrations," Zentral Blatt for Bakteriologie, Mikrobiologie and Hygiene I.ABT.Originate, A, 246:506–511, 1980.

146. Golden, D.A., L.R. Beuchat, and R.E. Brackett, "Inactivation and Injury of *Listeria Monocytogenes* as Affected by Heating and Freezing," *Food Microbiology*, 5:17–23, 1988.

147. Pace, P.J., and E.R. Krumbiegel, "*Clostridium Botulinum* and Smoked Fish Production: 1963–1972," *Journal of Milk and Food Technology*, 36(1):42, 1973.

148. Craig, J.M., and K.S. Pilcher, "*Clostridium Botulinum* Type F: Isolation

From Salmon From the Columbia River," *Science*, 153:311, 1966.

149. Kautter, D.A. et al., "Incidence of *Clostridium Botulinum* in Crabmeat From the Blue Crab," *Applied Microbiology*, 28(4):722, 1974.

150. Ward, B.Q. et al., "Survey of the U.S. Atlantic Coast and Estuaries From Key Largo to Staten Island for the Presence of *Clostridium Botulinum*," *Applied Microbiology*, 15(4):964, 1970.

151. Ward, B.Q. et al., "Survey of the U.S. Gulf Coast for the Presence of *Clostridium Botulinum*," *Applied Microbiology*, 15(3):629, 1970.

152. Huss, H.H., A. Pedersen, and D.C. Cann, "The Incidence of *Clostridium Botulinum* in Danish Trout Farms," *Journal of Milk and Food Technology*, 9(4):445, 1974.

153. Pace, P.J., E.R. Krumbiegel, and H.J. Wisniewski, "Interrelationship of Heat and Relative Humidity in the Destruction of *Clostridium Botulinum* Type E Spores on Whitefish Chubs," *Applied Microbiology*, 23(4):750, 1972.

154. Graikoski, J.T., "Effect of Heat and Environmental Conditions on the Survival and Outgrowth of *Clostridium Botulinum* Type E in Smoked Fish," unpublished, May 12, 1967.

155. Bott, T.L. et al., "*Clostridium Botulinum* Type E in Fish From the Great Lakes," *Journal of Bacteriology*, 91(3):919, 1966.

156. Bott, T.L. et al., "Possible Origin of the High Incidence of *Clostridium Botulinum* Type E in an Inland Bay (Green Bay of Lake Michigan)," *Journal of Bacteriology*, 95(5):1542, 1968.

157. Craig, J.M., and K.S. Pilcher, "The Natural Distribution of *Cl. Botulinum* Type E in the Pacific Coast Areas of the United States" *In* M. Ingram, and T.A. Roberts, (eds.), "Botulism 1966, Proceedings of the Fifth International Symposium on Food Microbiology: Moscow, July 1966," Chapman and Hall Ltd., London, 1967.

158. Craig, J.M., S. Hayes, and K.S. Pilcher, "Incidence of *Clostridium Botulinum* Type E in Salmon and Other Marine Fish in the Pacific Northwest," *Applied Microbiology*, 16(4):553, 1968.

159. Eklund, M.W., and F. Poysky, "Incidence of *Cl. Botulinum* Type E From the Pacific Coast of the United States," *In* M. Ingram, and T.A. Roberts, (eds.), "Botulism 1966, Proceedings of the Fifth International Symposium on Food Microbiology: Moscow, July 1966," Chapman and Hall Ltd., London, 1967.

160. Hayes, S., J.M. Craig, and K.S. Pilcher, "The Detection of *Clostridium Botulinum* Type E in Smoked Fish Products in the Pacific Northwest," *Canadian Journal of Microbiology*, 16(3):207, 1970.

161. U.S. Department of the Interior and U.S. Department of Health, Education, and Welfare, "Sanitation Standards for Smoked-Fish Processing; 1967 Recommendations," Public Health Service Publication No. 1587, 1967.

162. Guthrie, R.K., "Sanitation in Food Production and Processing," *In* R.K. Guthrie, "Food Sanitation," p. 131, AVI Publishing Co., Inc., Westport, CT, 1980.

163. Christiansen, L.N. et al., "Survival and Outgrowth of *Clostridium Botulinum* Type E Spores in Smoked Fish," *Applied Microbiology*, 16(1):133, 1968.

164. *United States* v. *Nova Scotia Food Products Corp.*, U.S. Court of Appeals, Second Circuit, 1977, 568 F.2d 240.

165. Anonymous, Monthly Epidemiological Bulletin, State of Israel Ministry of Health, December 1987.

166. Centers for Disease Control, "International Outbreak of Type E Botulism Associated With Ungutted, Salted Whitefish," *Morbidity and Mortality Weekly Report*, 36(49):812, 1987.

167. Centers for Disease Control, "Botulism Associated With Commercially Distributed Kapchunka—New York City," *Morbidity and Mortality Weekly Report*, 34(35):546, 1985.

168. Badhey, H. et al., "Two Fatal Cases of Type E Adult Food-borne Botulism With Early Symptoms and Terminal Neurologic Signs," *Journal of Clinical Microbiology*, 23(3):616, 1986.

169. EIR's conducted by FDA.

170. Letter to D.A. Kautter from Alan L. Hoeting, July 31, 1987.

171. Codex Alimentarius Commission, "Thirteenth Session of the Codex Committee on Fish and Fishery Products, RCP–25, Recommended International Code of Practice for Smoked Fish," 1979.

172. Codex Alimentarius Commission, "Thirteenth Session of the Codex Committee on Fish and Fishery Products, RCP–26, Recommended International Code of Practice for Salted Fish," 1979.

173. Eklund, M.W., "Significance of *Clostridium Botulinum* in Fishery Products Preserved Short of Sterilization," *Food Technology*, 35(12):107, 1982.

174. Schmidt, C.F., R.V. Lechowich, and J.F. Folinazzo, "Growth and Toxin Production by Type E *Clostridium Botulinum* Below 40 °F," *Journal of Food Science*, 26:626, 1961.

175. CPG No. 7108.17; Salt-cured, Air-Dried, Uneviscerated Fish (53 FR 44949, November 7, 1988), Docket No. 88D–0306.

176. Graham, P.P., R.S. Hamilton, and M. D. Pierson, "Influence of Bringing Procedures on Salt Content and Distribution in Smoked Whitefish Chubs," *Journal of Food Processing and Preserving*, 10:295, 1986.

177. Deng, J., R.T. Toledo, and D.A. Lillard, "Effect of Smoking Temperatures on Acceptability and Storage Stability of Smoked Spanish Mackerel," *Journal of Food Science*, 39:596, 1974.

178. Chan, W.S., R.T. Toledo, and J. Deng, "Effect of Smokehouse Temperature, Humidity, and Air Flow on Smoke Penetration into Fish Muscle," *Journal of Food Science*, 40:240, 1975.

179. Pelroy, G.A. et al., "Inhibition of *Clostridium Botulinum* Types A and E Toxin Formation by Sodium Nitrite and Sodium Chloride in Hot-process (Smoked) Salmon," *Journal of Food Protection*, 45(9):833, 1982.

180. Eklund, M.W., testimony presented at New York State Department of Agriculture and Markets' hearing, May 13, 1989.

181. Newberry, R.E., Letter to City Smoked Fish Co., Use of Colors in Smoked Salmon, March 11, 1985.

182. National Fisheries Institute, Inc., "Techniques For Smoking Fish," Washington, DC.

183. Borgstrom, G., "Smoking," in "Fish as Food, Processing: Part I, Vol. 3," p. 88, Academic Press, New York, 1965.

184. Kautter, D.A., memorandum, "Aqueous Phase Salt Concentration for Vacuum Packaged Cold-smoked Fish," April 6, 1990.

185. Eklund, M.W. et al., "Feasibility of a Heat-pasteurization Process for the Inactivation of Nonproteolytic *Clostridium Botulinum* Types B and E in Vacuum-packaged, Hot-process Smoked Fish," *Journal of Food Protection*, 51(9):720, 1988.

186. Eklund, M.W., D.I. Wieler, and F.T. Poysky, "Outgrowth and Toxin Production of Nonproteolytic Type B *Clostridium Botulinum* at 3.3 to 5.6 °C," *Journal of Bacteriology*, 93(4):1461, 1967.

187. Solomon, H.M. et al., "Effect of Low Temperatures on Growth of *Clostridium Botulinum* Spores in Meat of the Blue Crab," *Journal of Food Protection*, 40(1):5, 1977.

188. Ohye, D.F., and W.J. Scott, "Studies in the Physiology of *Clostridium Botulinum* Type E," *Australian Journal of Biological Science*, 10:85, 1956.

189. National Research Council, "An Evaluation of the Role of Microbiological Criteria for Foods and Food Ingredients," p. 249, National Academy Press, Washington, DC.

190. Federal Standard, "Sanitation Standards For Fish Plants," FED-STD–369, Academy of Health Sciences, U.S. Army, Fort Sam Houston, Houston, TX, August 2, 1977.

191. Masso T.W., letters to T. Schwarz With AFDO Resolution No. 8, June 8, 1990.

192. Bryan, F.L., "Application of HACCP to Ready-to-eat Chilled Foods," *Food Technology*, 44(7):70, 1990.

193. Tartakow, I.J., and J.H. Vorperian, (eds.), "Foodborne and Waterborne Diseases: Their Epidemiologic Characteristics," p. 50–52, AVI Publishing Co., Westport, CN, 1981.

194. Rhodehamel, J.E., N.R. Reddy, and M.D. Pierson, "Botulism: The Causative Agent and its Control in Foods: A Review," *Food Control*, 3(3):125–143, 1992.

195. FDA, "Human Foods; Current Good Manufacturing Practice (Sanitation) in Manufacturing, Processing, Packing, or Holding Smoked Fish," 34 FR 17176, October 23, 1969.

196. FDA, Part 110—Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food (21 CFR part 110).

197. FDA, FDA Inspections Manual, Chapter 5, Establishment Inspection, Subchapter 530, Food.

198. Center for Disease Control, "Fish Botulism—Hawaii, 1990," *Morbidity and Mortality Weekly*, 40(24):412–414, June 21, 1991.

199. FDA, "Studies in Food Sanitation Control—Year Five, Contract No. 223–80–2295, Task XVI, Effect of Controlled Humidity of Processing Ovens at High Operating Temperatures on Production of Smoked Fish," June 14, 1984.

200. Printout of FDA FY 90/91 Domestic Fish and Fishery Products Assignment Inspection Data as of August 6, 1991.

201. Daniels, Richard W., "Applying HACCP to New Generation Refrigerated Foods at Retail and Beyond," *Food Technology*, June 1991.

List of Subjects

21 CFR Part 123

Fish, Fishery products, Imports, Reporting and recordkeeping requirements, Seafood.

21 CFR Part 1240

Communicable diseases, Public health, Travel restrictions, Water supply.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR chapter I be amended as follows:

1. Part 123 is added to read as follows:

PART 123—FISH AND FISHERY PRODUCTS

Subpart A—General Provisions

Sec.
123.3 Definitions.
123.5 Current good manufacturing practice (sanitation).
123.6 Hazard Analysis Critical Control Point (HACCP) plan.
123.7 Corrective actions.
123.8 Records.
123.9 Training.
123.10 Sanitation control procedures.
123.11 Obligations of importers.
123.12 Imports—determination of compliance.

Subpart B—[Reserved]

Subpart C—Raw Molluscan Shellfish

123.20 General.
123.28 Source controls and records.
Appendix A to Part 123—Cooked, Ready-to-eat Fishery Products
Appendix B to Part 123—Scombroid Toxin Forming Species
Appendix C to Part 123—[Reserved]
Appendix D to Part 123—Product Integrity

Authority: Secs. 201, 402, 403, 406, 409, 701, 704, 721, 801 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321, 342, 343, 346, 348, 371, 374, 379e, 381]; secs. 301, 307, 361, 1702 of the Public Health Service Act [42 U.S.C. 241, 242], 264, 300u–1).

Subpart A—General Provisions

§ 123.3 Definitions.

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act and in part 110 of this chapter are applicable to such terms when used in this part. The following definitions shall also apply:

(a) *Certification number* means a unique combination of letters and numbers assigned by a shellfish control authority to a molluscan shellfish processor.

(b) *Cooked, ready-to-eat fishery product* means a fishery product that is subjected by a commercial processor to either a cooking process before being placed in a final container, or to pasteurization in the final container, or to both.

(c) *Critical control point* means a point in a food process where there is a high probability that improper control may cause, allow, or contribute to a hazard in the final food.

(d) *Critical limit* means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to minimize the risk of occurrence of the identified hazard.

(e) *Fish* means fresh or saltwater finfish, molluscan shellfish, crustaceans, and other forms of aquatic animal life other than birds or mammals.

(f) *Fishery product* means any edible human food product derived in whole or in part from fish, including fish that has been processed in any manner.

(g) *Harvester* means a person who has an identification number issued by a shellfish control authority for commercially taking molluscan shellfish by any means from a growing area.

(h) *Importer* means a person, or his representative in the United States, who is responsible for ensuring that goods being offered for entry into the United States are in compliance with all laws affecting the importation.

(i) *Lot of molluscan shellfish* means a collection of shellstock or containers of shellstock of no more than 1 day's harvest from a single, defined growing area harvested by one or more harvesters.

(j) *Molluscan shellfish* means any edible species of fresh or frozen oysters, clams, mussels and scallops or edible portions thereof, except when the scallop product consists entirely of the shucked adductor muscle.

(k) *Potable water* means water which meets the U.S. Environmental Protection Agency's Primary Drinking Water Regulations as set forth in 40 CFR part 141.

(l) *Process control instrument* means an instrument or device used to monitor conditions during processing at a critical control point.

(m) *Processing* means, with respect to fish or fishery products, handling, storing, preparing, heading, gutting, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, or holding. Practices such as heading or gutting intended solely to prepare a fish for holding on board a harvest vessel are excluded. This regulation does not cover the operation of a retail establishment.

(n) *Processor* means any person engaged in commercial, custom, or institutional processing of fish or fishery products, either in the United States or in a foreign country. Persons engaged in the production of foods that are to be used in market or consumer tests are also included. Persons who only harvest or transport seafood, without otherwise engaging in processing, are not covered by these regulations.

(o) *Shall* is used to state mandatory requirements.

(p) *Shellfish control authority* means a Federal or State health authority, or foreign government health authority, legally responsible for the administration of a program that includes classification of molluscan shellfish growing areas, enforcement of harvesting controls, and certification of molluscan shellfish processors.

(q) *Shellstock* means raw, in-shell molluscan shellfish.

(r) *Should* is used to state recommended or advisory procedures or to identify recommended equipment.

(s) *Shucked shellfish* means molluscan shellfish that have one or both shells removed.

(t) *Tag* means a record of harvesting information attached to a container of shellstock by the harvester or processor.

§ 123.5 Current good manufacturing practice (sanitation).

(a) The criteria in part 110 of this chapter apply in determining whether the facilities, methods, practices, and controls used to process fish and fishery products are safe, and whether these products have been processed under sanitary conditions.

(b) The purpose of subpart A of this part is to set forth requirements specific to the processing of fish and fishery products.

§ 123.6 Hazard Analysis Critical Control Point (HACCP) plan.

(a) Every processor and importer shall have and implement a written HACCP plan that is specific to:

(1) Each location where fish and fishery products are processed by that processor; and

(2) Each kind of fish and fishery product processed by the processor. The plan may group kinds of fish and fishery products together if the hazards, critical control points, critical limits, and procedures required to be identified in paragraph (b) of this section are identical for all fish and fishery products so grouped.

(b) The HACCP plan shall:

(1) Identify the safety hazards that are reasonably likely to occur and that thus must be controlled for each fish and

fishery product, including, as appropriate:

(i) Natural toxins;

(ii) Microbiological contamination;

(iii) Chemical contamination;

(iv) Pesticides;

(v) Drug residues;

(vi) Decomposition;

(vii) Parasites;

(viii) Unapproved direct and indirect food and color additives; and

(ix) Physical hazards;

(2) Identify the critical control points for each of the identified hazards;

(3) Identify the critical limits that must be met at each of the critical control points;

(4) Identify the procedures, and frequency thereof, including the use of consumer complaints received by the processor or importer, that will be used to control and monitor each of the critical control points to ensure compliance with the critical limits. Such procedures shall include the calibration of process control instruments and validation of software for computer control systems as appropriate;

(5) Provide for a recordkeeping system that will document the monitoring of the critical control points. The records shall contain the actual values obtained during monitoring. The records shall also include consumer complaints that relate to the operation of critical control points or possible critical limit deviations.

(c) In addition, the HACCP plan should:

(1) Identify other consumer hazards not related to the safety of the product, including, but not necessarily limited to:

(i) Decomposition not associated with human illness; and

(ii) Economic adulteration.

(2) Provide for control of these hazards in the manner described by paragraphs (b)(2) through (b)(5) of this section.

(d) Failure of a processor or importer to have and implement an HACCP plan that complies with this section or to operate in accordance with the requirements of this part, shall render the products of that processor or importer adulterated under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act.

§ 123.7 Corrective actions.

(a) Any critical limit deviation shall require:

(1) Segregation and holding of the affected product, at least until the requirements of paragraphs (a)(2) and (a)(3) of this section are met;

(2) Immediate review by an individual or individuals who have been trained in accordance with § 123.9, to determine the acceptability of the lot in question for distribution, based on a judgment as to whether the deviation may have rendered the product in that lot injurious to health or otherwise adulterated;

(3) Corrective action, when necessary, with respect to the affected product and the critical control point at which the deviation occurred;

(4) Timely assessment by an individual or individuals who have been trained in accordance with § 123.9, to determine whether the process or Hazard Analysis Critical Control Point (HACCP) plan needs to be modified to reduce the risk of recurrence of the deviation; and

(5) Modification when necessary as it applies to the process or HACCP plan.

(b) When a processor or importer receives a consumer complaint that may be related to the performance of a critical control point or that may reflect a critical limit deviation, it shall determine whether corrective action as described by paragraph (a) of this section is appropriate and, if so, it shall take such action.

(c) All actions required by paragraphs (a) and (b) of this section shall be documented in records that are subject to the requirements of § 123.8.

§ 123.8 Records.

(a) Records required by this part that involve observations or measurements during processing or related activities, including corrective actions taken in accordance with § 123.7, shall include the identity of the product, product code, and date of activity that the record reflects. Processing and other information shall be entered at the time that it is observed. Each record shall be signed by the operator or observer, except that corrective action records need only be signed in accordance with paragraph (b) of this section.

(b) Records required by this part shall be reviewed, signed, and dated by an individual who has been trained in accordance with § 123.9, before distribution of the product for completeness and compliance with the established critical limits.

(c) The records required by this part shall be retained at the processing facility or the importer's place of business in the United States for at least 1 year after the date they were prepared in the case of refrigerated products and for at least 2 years after the date they were prepared in the case of frozen or preserved products. Records that relate to the general adequacy of equipment or processes being used by a processor, including the results of scientific studies and evaluations, shall be retained at the processing facility for at least 2 years after their applicability to the product being produced at the facility. If the processing facility is closed between seasonal packs, the records may be transferred to some other reasonably accessible location during the period of closure.

(d) All records required by this part, including HACCP plans required in § 123.6 and consumer complaints that may be related to a critical limit deviation, shall be available for review and copying at reasonable times by duly authorized officers and employees.

(e) Tags as defined in § 123.3(t) are not subject to the requirements of this section.

§ 123.9 Training.

Each processor and importer shall employ at least one individual who has successfully completed a prescribed course of instruction in the application of Hazard Analysis Critical Control Point (HACCP) principles to fish and fishery product processing at a program of instruction approved by the Food and Drug Administration. At a minimum, this individual shall be responsible for developing and modifying the plan as required by § 123.6, evaluating critical limit deviations and corrective actions as required by § 123.7, and performing record review as required by § 123.8(b).

§ 123.10 Sanitation control procedures.

(a) Every processor and importer who takes physical possession of fish or fishery products and engages in the processing of such fish or fishery products, including storing such products, shall perform sanitation inspections and ensure at a minimum that, to the extent applicable to the operations conducted by the processor or importer, the following conditions apply:

(1) Water that directly comes into contact with a product or with food contact surfaces, or is used in the manufacture of ice, is derived from a safe and sanitary source or is being treated to render it of safe and sanitary quality.

(2) There are no cross connections between the potable water system and any nonpotable system.

(3) All food contact surfaces of plant equipment and utensils, including equipment used for ice production and storage, are so designed and of such material and workmanship as to be easily cleanable, and are maintained in a sanitary condition. Such surfaces shall be constructed of nontoxic materials and designed to withstand the environment of its intended use and the

action of the food, cleaning compounds, and sanitizing agents.

(4) All utensils and surfaces of equipment that contact food during processing are cleaned and sanitized with effective cleaning and sanitizing preparations with the following frequency:

(i) Cleaned at the end of the day's operations;

(ii) Cleaned and sanitized at least every 4 hours during the processing of cooked, ready-to-eat fishery products; and

(iii) Sanitized before the beginning of the day's operations.

(5) Gloves and outer garments that contact food or food contact surfaces are made of an impermeable material and are maintained in a clean and sanitary condition.

(6) Employees' hands, gloves, outer garments, utensils and food contact surfaces of equipment that come into contact with waste, the floor, or other insanitary objects, do not contact fish or fishery products without first being adequately cleaned and sanitized.

(7) Where applicable, employee's hands, gloves, outer garments, utensils and food contact surfaces of equipment that come into contact with raw product shall not contact cooked product or ice used on cooked product, without first being adequately cleaned and sanitized.

(8) Hand washing and hand sanitizing facilities are:

(i) Located in all processing areas in which good sanitary practice requires employees to wash and sanitize their hands; and

(ii) Equipped with hand-cleaning and effective sanitizing preparations and single service towels or suitable hand drying devices.

(9) Food, food contact surfaces, and food-packaging materials shall be protected from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, metal fragments, or other chemical or physical contaminants.

(10) Toxic compounds shall be identified, held, used, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.

(11) Food, food-contact surfaces, and food-packaging materials shall be protected from contaminants that may drip, drain, or be drawn into the food.

(12) Compressed gases that contact food or food contact surfaces of equipment shall be filtered or treated in a way that ensures that they will not contaminate the food with unapproved indirect food additives or other chemical, physical, or microbiological contaminants.

(13) Unprotected cooked, ready-to-eat fishery products, smoked fishery products, raw molluscan shellfish, and raw fish and fishery products shall be physically separated from each other during refrigerated storage.

(14) Refrigeration units that store raw materials, in-process, or finished fish or fishery products that are cooked, ready-to-eat, smoked, or made in whole or in part from scombroid toxin forming species shall be operated at a temperature of 40 °F (4.4 °C) or below.

(15) Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other source of microbial contamination by which there is a reasonable possibility that food, food-contact surfaces, or food-packaging materials will become contaminated, shall be excluded from any operations that may be expected to result in such contamination until the condition is corrected.

(16) Adequate, readily accessible toilet facilities that provide for proper sewage disposal shall be available and maintained in a sanitary condition and in good repair.

(17) No pests are in any area of a food plant.

(18) The plant is designed to minimize the risk of contamination of the food, food-contact surfaces, and food-packaging material.

(b) Each processor shall maintain sanitation control records that document that the steps required under paragraph (a) of this section are performed with requisite frequency.

(c) Sanitation control measures shall be taken on a daily basis, and the sanitation control records shall be prepared according to the requirements of paragraph (a) of this section, except that:

(1) The hand sanitizer strength and sanitary practices of the processing employees, especially as these relate to hand washing and sanitizing practices and the potential for cross contamination, shall be checked and recorded at least every 4 hours during processing.

(2) All utensils and food-contact surfaces of equipment shall be inspected immediately after each cleaning and sanitizing operation under paragraph (a)(4)(ii) of this section. Each such cleaning and sanitizing shall be documented, and such documentation shall at a minimum record the time of each cleaning, the concentration of the sanitizer, and the condition of the equipment.

(3) The requirements of paragraphs (a)(1), (a)(2), (a)(3), (a)(8)(i), (a)(12), and (a)(18) of this section shall be performed and documented with such frequency as is necessary to ensure control.

(4) The requirement of paragraph (a)(14) of this section shall be ensured by the continuous monitoring of the refrigeration unit with an accurate process control instrument. The instrument shall be checked and the measurements documented with such frequency as is necessary to ensure control.

(d) Where deviations from the requirements of paragraph (a) of this section are noted during these inspections, appropriate corrective actions shall be taken and documented on the sanitation control record.

(e) Every plant should have a written standard operating procedure (SOP) for assuring the maintenance of proper sanitary conditions and practices during processing that is specific to each fish and fishery product produced at that location. The SOP should include, at a minimum, requirements as described in paragraph (a) of this section.

(f)(1) All fish to be smoked or salted shall be eviscerated and free of residual viscera, except for:

(i) Small species of fish, such as anchovies and herring sprats, provided that they are processed in a fashion so that they contain a water-phase salt level of at least 10 percent, a water activity below 0.85, or a pH of 4.6 or less; and

(ii) Fish that are fully cooked before further processing.

(2) Evisceration shall be conducted in an area that is segregated and separate from other processing operations. Evisceration shall be performed with minimal disturbance of the intestinal tract contents. The fish, including the body cavity, shall be washed thoroughly with a vigorous water spray or a continuous water flow system.

§ 123.11 Obligations of importers.

This section sets forth the specific obligations of importers of fish and fishery products into the United States.

(a) An importer of fish or fishery products shall have and implement a Hazard Analysis Critical Control Point (HACCP) plan in accordance with § 123.6 that describes how the fish will be prepared, packed, or held while it is in the control of the importer.

(b) The importer of fish or fishery products shall have on file the HACCP plans of each of its foreign processors.

(c) The importer shall take affirmative steps to ensure that the fish and fishery products that it offers for import were produced under the HACCP plan that it has in its possession and subject to the sanitation controls listed in § 123.10.

Such steps may include, but would not be limited to:

(1) Obtaining from the foreign processor the HACCP monitoring records that relate to the specific fish or fishery products being offered for import.

(2) Obtaining a certificate from a foreign government inspection authority certifying that the firm is operating under a valid HACCP plan or certification on a lot-by-lot basis.

(3) Regularly inspecting its suppliers' facilities to ensure that they are being operated in compliance with the applicable HACCP plan and § 123.10.

(4) Periodic end-product testing by the importer or a private laboratory hired by the importer; or

(5) Other such verification measures as appropriate.

(d) An importer's obligation under paragraph (c) of this section will be satisfied if the importer imports product from a country that has an active memorandum of understanding (MOU), or similar agreement, with FDA that documents the equivalency of the inspection system of the foreign country with the U.S. system. The active MOU will be expected to accurately reflect the current situation between the signing parties and be functioning and enforceable in its entirety.

(e) Importers should encourage foreign processors to obtain HACCP training similar to that required by § 123.9.

§ 123.12 Imports—determination of compliance.

(a) There must be evidence that seafood that is offered for import has been produced under conditions that comply with subpart A of this part. Such evidence can be provided by:

(1) Examination, at the U.S. importer's place of business, of the importer's Hazard Analysis Critical Control Point (HACCP) plan, the foreign processor's HACCP plan and sanitation procedures and records associated with the importer's plan that demonstrate that the plan and procedures were followed.

(2) An active memorandum of understanding (as defined in § 123.11(d)) with an exporting country that provides that the country will impose regulatory controls equivalent to those established in this part for domestic processors.

(3) Evidence that an exporting country has in place and is enforcing an HACCP-based regulatory system.

(4) Inspection of foreign processors by FDA or some other organization designated by FDA.

(5) Any other measures that FDA deems appropriate, including, but not limited to, end-product testing.

(b) If assurances do not exist that the product has been produced under an HACCP plan and sanitation controls that are equivalent to those required of domestic processors, the product will appear to be adulterated and will be denied entry.

Subpart B—[Reserved]

Subpart C—Raw Molluscan Shellfish

§ 123.20 General.

This subpart augments subpart A of this part by setting forth specific requirements for processing fresh or frozen molluscan shellfish.

§ 123.28 Source controls and records.

(a) In order to meet requirements of subpart A of this part as they apply to microbiological contamination, natural toxins, and related hazards, processors shall include in their Hazard Analysis Critical Control Point (HACCP) plans how they are controlling the origin of the molluscan shellfish they process.

(b) Processors shall only process molluscan shellfish that originate from growing waters approved for harvesting by a shellfish control authority. To meet this requirement, processors shall only receive shellstock:

(1) From a harvester that is licensed or a processor that is certified by a shellfish control authority; and

(2) That has affixed a tag on each container of shellstock received by the processor that bears, at a minimum, the information required in § 1240.60(b) of this chapter.

(3) Bulk shellstock shipments may be identified by a bill of lading or similar document that contains the same information.

(c) The same requirements that apply to shellstock shall apply to shucked molluscan shellfish received by a processor except that, in lieu of a tag, the body of the container of shucked molluscan shellfish shall bear a label that complies with § 1240.60(c) of this chapter.

(d) Processors shall maintain records that document that each lot of molluscan shellfish meet the requirements of paragraphs (b) and (c) of this section.

(1) For shellstock these records shall document:

(i) The date of harvest;

(ii) The location of harvest by State and site;

(iii) The quantity and type of shellfish;

(iv) The date of receipt by the processor; and

(v) The name of the harvester and identification number.

(2) For shucked shellfish these records shall document:

(i) The date of receipt;

(ii) The quantity and type of shellfish; and

(iii) The name and certification number of the shipper.

Appendix A to Part 123—Cooked, Ready-to-Eat Fishery Products

1. General guidelines for cooked, ready-to-eat fishery products.
2. Definitions in Appendix A.
3. Critical control points.
4. Thermal processing critical control points.
5. Container integrity critical control points.
6. Time and temperature critical control points.
7. Temperature monitoring equipment.
8. Corrective actions.
9. Sanitary zones.

1. General Guidelines for Cooked, Ready-to-Eat Fishery Products

This Appendix provides guidance on how to meet the requirements of 21 CFR part 123, subpart A for the processing of cooked, ready-to-eat fishery products. Cooked, ready-to-eat fishery products are those that are subjected by a commercial processor to either a cooking process before being placed in a final container, or to pasteurization in the final container, or to both. This guidance involves processing procedures that are common to most of these products for the control of the microbiological hazards to which they are particularly susceptible. The guidance does not apply to environmental or other hazards that might occur before the processor takes possession of the product or raw materials. (Guidance on these hazards may be found in a separate guidance document for all fish and fishery products to be issued by FDA.) This guidance also does not apply to cooked, ready-to-eat fishery products covered by 21 CFR part 123, subpart B.

2. Definitions in Appendix A

a. *Cooking process* means the application of sufficient heat for a sufficient period of time to a fish or fishery product to coagulate the protein throughout the product.

b. *Hermetically sealed package* means a container that is designed and intended to be secure against the entry of microorganisms.

c. *Microorganisms of public health significance* means bacteria, fungi, and viruses capable of producing illness if they or their toxins are ingested by humans.

d. *Pasteurization* means a process applied to a fish or fishery product after that fish or fishery product has been placed in a final, hermetically sealed package, which involves the application of sufficient heat or other processes for a sufficient period of time to result in the reduction of microorganisms of public health concern to levels that, under normal conditions of storage, are unlikely to cause disease.

e. *Process authority* means a person having expert knowledge of commercial processing of fish and fishery products based on a combination of education, training and experience.

f. *Raw materials* means fish and fishery products that are received for processing and include fishery products that have been processed elsewhere and that are received for further processing.

g. *Temperature-indicating device* means a mercury-in-glass thermometer or equivalent device, such as a resistance temperature device or thermocouple.

h. *Temperature-recording device* means a device that is capable of providing a continuous record of the temperature conditions being monitored.

3. Critical Control Points

Hazard Analysis Critical Control Point (HACCP) plans prepared in accordance with 21 CFR part 123, subpart A will typically identify and address the following critical control points:

a. Cooking;
b. Pasteurization;
c. Finished product container sealing for pasteurized products;
d. Post-pasteurization cooling;
e. Cooling after cooking;
f. Processing after cooking;
g. Final product cooling;
h. Refrigerated storage; and
i. Distribution.

In accordance with 21 CFR part 123, subpart A, processors shall identify in their HACCP plans how they will control hazards at critical control points. The measures in sections 4. through 6. of this Appendix are suitable for HACCP plans.

4. Thermal Processing Critical Control Points

a. Cooking

1. *The Cooking Process.* The processor must be able to demonstrate to itself and to FDA that its cooking process ensures the destruction of vegetative cells of microorganisms of public health concern. This may be accomplished by having a cooking process that is at least equivalent to a process established by a process authority. To demonstrate equivalence, a processor should have on file in its Hazard Analysis Critical Control Point (HACCP) records a document that:

i. Describes the results of a scientific evaluation, conducted by a process authority, of the adequacy of the cooking process; and

ii. Identifies and establishes values for key aspects of the process or of the product that may affect the adequate destruction of microorganisms of public health concern. At a minimum, these values should include cooking times and temperatures.

Such a document may consist of, but should not be limited to, a letter from a process authority, articles in scientific journals, or Federal, State, or local government regulations or advisories. Failure to have documentation that the cooking process will achieve its goal will violate 21 CFR 123.8 and will mean that the product produced by the processor will be produced under insanitary conditions whereby it may be rendered injurious to health.

2. *Cooking Equipment Design.*

i. The processor must be able to demonstrate to itself and to FDA that its cooking equipment can deliver the cooking process that ensures the destruction of vegetative cells of microorganisms of public health concern. One way to accomplish this is for the processor to have on file in its HACCP records a document that describes the results of a scientific evaluation, conducted by a process authority, of the design and operation of the type of equipment and the operational procedures used by the processor. The engineering specifications for the equipment used by the processor (e.g., pipe sizes, flow rates, loading configuration, and, whenever a steam process is used, venting parameters) should meet or exceed those for the equipment evaluated by the process authority. Failure to have documentation that the cooking equipment will achieve its goal will violate 21 CFR 123.8 and will mean that the product produced by the processor will be produced under insanitary conditions whereby it may be rendered injurious to health.

ii. Cooking equipment should be equipped with both a temperature-indicating device and temperature-recording device. The temperature-indicating device should be the reference instrument for determining conformance to the established process temperatures.

3. *Records.*

Monitoring records made by the processor should record both the actual values that are occurring for those key aspects of the process identified by the process authority in section 4.a.1. of this Appendix and the actual values that are occurring for operational procedures identified by the process authority in section 4.a.2.i. of this Appendix.

4. *Special Considerations.*

For the cooking of blue crab (*Callinectes sapidus*), dungeness crab (*Cancer magister*), or king crab (*Paralithodes camtschatica*), the known lethality of the cooking process necessary to make the product generally acceptable for human consumption, or to enable further processing, is sufficient so that the adequacy of the process and the equipment can normally be assumed.

b. Pasteurization

1. *The Pasteurization Process.* The processor must be able to demonstrate to itself and to FDA that its pasteurization process ensures the adequate reduction of numbers of viable spores of microorganisms of public health concern. One way to accomplish this is to have a pasteurization process that is equivalent to a process established by a process authority. To demonstrate equivalence, a processor should have on file in its HACCP records a document that:

i. Describes the results of a scientific evaluation conducted by a process authority of the adequacy of the pasteurization process; and that

ii. Identifies and establishes values for those key aspects of the process, or of the product, that may affect the adequate reduction in numbers of microorganisms of public health concern. At a minimum, these values should include pasteurization times and temperatures.

Such document may consist of, but should not be limited to, a letter from a process authority, articles in scientific journals, or Federal, State or local government regulations or advisories. Failure to have documentation that the pasteurization process will achieve its goal will violate 21 CFR 123.8 and will mean that the product produced by the processor will be produced under insanitary conditions whereby it may be rendered injurious to health.

2. *Pasteurization Equipment Design.*

i. The processor must be able to demonstrate to itself and to FDA that its pasteurization equipment can deliver the pasteurization process that ensures the adequate reduction of viable spores of microorganisms of public health concern. One way to accomplish this is to have on file a document that describes the results of a scientific evaluation conducted by a process authority, of the design and operation of the type of equipment used by the processor. The engineering specifications for the equipment used by the processor (e.g., pipe sizes, flow rates, loading configuration) should meet or exceed those for the equipment evaluated by the process authority. Failure to have documentation that the pasteurization equipment will achieve its goals will violate 21 CFR 123.8 and will mean that the product produced by the processor will be produced under insanitary conditions whereby it may be rendered injurious to health.

ii. Pasteurization equipment should be equipped with both a temperature-indicating device and temperature-recording device. The temperature-indicating device should be the reference instrument for determining conformance to the established process temperatures.

3. *Records.* Monitoring records made by the processor should record the actual values that are occurring for those key aspect of the process identified by the process authority in section 4.b.1.ii of this Appendix.

5. Container Integrity Critical Controls Points

a. Finished Product Container Sealing

Finished product containers must be inspected, and the results recorded, for container integrity to assure a consistently reliable hermetic seal. FDA recommends that:

1. Visual seam inspection of one container from each seaming head occur every 30 minutes; and

2. Testing by qualified personnel of one container from each seaming head occur at least every 4 hours. As applicable, these tests should be performed in accordance with 21 CFR 113.60(a)(1) and (a)(2).

b. Post-pasteurization Cooling

Container cooling water must contain a measurable residual of chlorine or other sanitizer. Tests to determine the presence of a measurable residual of chlorine or other sanitizer in the container cooling water should be made, and the results recorded, at sufficient frequency to ensure control.

6. Time and Temperature Critical Control Points

a. Cooling After Cooking

After cooking, the product must be rapidly cooled to minimize recontamination. Continuous cooling from 140 °F (60 °C) to achieve an internal temperature of 70 °F (21.1 °C) or below within 2 hours and an internal temperature of 40 °F (4.4 °C) or below within an additional 4 hours, unless processing after

cooking, as described in section 6.b. of this Appendix, occurs during either of these time periods, will effectively minimize recontamination. Other time/temperature parameters may also be effective. Processors should ensure that the cooling parameters are met by either:

1. *Monitoring.* Monitoring and recording internal product temperatures at least every 2 hours; or

2. *Studies.*

i. Conducting or obtaining a study that establishes that appropriate cooling temperatures are always met under prescribed processing conditions. The study should establish the limits of significant variables that could affect the rate of cooling. These variables may include product size, ambient air temperature, and amount of product in the cooler. An adequate study should consist of at least three processing runs under the prescribed processing conditions; and

ii. Monitoring and recording the prescribed processing conditions as identified by the study in section 6.a.2.i. of this Appendix at least every 2 hours.

b. Processing After Cooking

Products that will receive processing after cooking should not be exposed to ambient temperatures of 40 °F (4.4 °C) or higher for longer than a cumulative total of 4 hours after cooking. If they are exposed to such temperatures for more than 4 hours, unacceptable recontamination is the likely result. Processors are required to regularly monitor and record the length of time that the product is exposed to temperatures above 40 °F (4.4 °C) under 21 CFR 123.8. FDA recommends that such monitoring and recording be done at least every 2 hours.

c. Final Product Cooling

To avoid microbiological hazards for perishable finished products, the internal temperature of the finished product should be 40 °F (4.4 °C) or below within 4 hours of either placement in a finished product container or the completion of pasteurization. Processors should either conduct:

1. *Monitoring.* Monitor and record internal product temperatures at least every 2 hours; or

2. *Studies.*

i. Conduct or obtain a study that establishes that the internal temperature of the finished product will always be 40 °F (4.4 °C) or below within 4 hours of either placement in a finished product container or completion of pasteurization under prescribed processing conditions. The study should establish the limits of significant variables that could affect the rate of cooling. These variables may include product size, ambient air temperature, and amount of product in the cooler. An adequate study should consist of at least three processing runs under the prescribed processing conditions; and

ii. Monitoring and recording the prescribed processing conditions as identified by the study in section 6.c.2.i. of this Appendix at least every 2 hours.

d. Refrigerated Storage

1. *In-process products.* Refrigeration units that are being used to store in-process products or finished products shall operate at a temperature of 40 °F (4.4 °C) or below in accordance with 21 CFR 123.10(a)(14).

2. *Temperature devices.* Units should be equipped with both a temperature-indicating device and a temperature-recording device. In lieu of a temperature-recording device, a processor may equip a refrigeration unit with a high temperature alarm or a maximum-indicating thermometer and maintain a temperature log that notes temperature with such frequency as is necessary to achieve control.

e. Distribution

All perishable finished products should be distributed in a manner that ensures that the internal temperature is maintained at 40 °F (4.4 °C) or below.

7. Temperature Monitoring Equipment

Where reference is made in this Appendix to temperature-indicating devices and temperature-recording devices, the following conditions should apply:

a. Temperature-Indicating Devices

Temperature-indicating devices should be installed where they can be easily read and located to ensure that they accurately measure the warmest temperature of the refrigeration equipment and the coldest temperature of the heating equipment, as appropriate. Temperature-indicating devices should be calibrated at the routine operating temperature of the refrigeration, cooling, or heating equipment against a known accurate standard thermometer upon installation and at least once a year thereafter, or more frequently, if necessary, to ensure their accuracy. Records required to be maintained under 21 CFR 123.8 of accuracy checks for temperature-indicating devices should specify the date, standard used, method used, results, and person performing the test. A temperature-indicating device that has a divided fluid column or that cannot be adjusted to the standard should be immediately repaired or replaced.

b. Temperature-Recording Devices

Temperature-recording devices should be installed where they can be easily read and the sensors for such devices should be installed to ensure that they accurately measure the warmest temperature of the refrigeration equipment and the coldest temperature of the heating equipment, as appropriate. Computerized storage of temperature data may be used in place of recorder thermometer charts if the use of such a system has been validated and can be shown to be substantially equivalent to the use of a temperature-recording device. Each temperature-recording device should be checked for accuracy at the beginning and end of each production day and adjusted as necessary to agree as nearly as possible with the reference temperature-indicating device. A record of these accuracy checks should be maintained that specifies the time, date, temperatures indicated by both devices before adjustment, corrective action taken, where applicable, and person performing the accuracy check.

8. Corrective Actions

Under 21 CFR 123.7, whenever a deviation occurs at a critical control point, the processor shall segregate and hold the product until a review can be made to determine the effect of that deviation, and shall take corrective action as necessary. For cooked, ready-to-eat products, when a deviation occurs at a cooking or pasteurization critical control point, the processor should meet the requirements of § 123.7 either by destroying the product; by fully reprocessing, where possible, that portion of the production involved, keeping full records of the reprocessing conditions; or by setting aside that portion of the product involved for further evaluation as to any potential public health significance. Such an evaluation should be made by a process authority and should be in accordance with procedures recognized by process authorities as being adequate to detect any unacceptable hazard to public health. Unless this evaluation demonstrates that the product had been given a thermal process that rendered it free of microorganisms of potential public health significance or, in the case of pasteurization, that resulted in the adequate reduction in numbers of microorganisms, the product set aside should be either fully reprocessed to correct the deficiency or destroyed. A record should be made of the evaluation procedures used and the results. Either upon completion of full reprocessing or after the determination that no significant public health hazard exists, that portion of the product involved may be shipped in normal distribution. Otherwise, the portion of the product involved should be destroyed.

9. Sanitary Zones

In addition to the requirements of 21 CFR 123.10, sanitary zones should be established around areas in which cooked product is handled or stored. In such areas, objects and employees that have come into contact with waste, raw product, or other insanitary objects are excluded. Packaging material, equipment, employees, and in-process materials that enter a sanitary zone should be treated in a manner that will minimize the risk of the introduction of microorganisms. Air handling systems should be designed to minimize the risk of airborne contamination and to provide positive air pressure in the sanitary zone relative to the surrounding areas.

Appendix B to Part 123—Scombroid Toxin Forming Species

1. General guidelines for Scombroid Toxin Forming Species.
2. Critical control points.
3. Receipt of raw materials critical control point.
4. Processing critical control point.
5. Additional critical control points.

1. General Guidelines for Scombroid Toxin Forming Species

This Appendix provides guidance on how to meet the requirements of 21 CFR part 123, subpart A for fish and fishery products that consist in whole or in part of scombroid toxin forming species. These include tuna, bluefish, mahi mahi, mackerel, sardines,

herring, kahawai, anchovies, marlin, and other species, whether or not of the family Scombridae, in which significant levels of histamine may be produced in the fish flesh by decarboxylation of free histidine as a result of exposure of the fish after capture to temperatures that permit the growth of mesophilic bacteria. The guidance focuses on preventing the formation of scombrotoxin, which can be harmful to humans, as a consequence of improper handling after capture, i.e., time and temperature abuse.

2. Critical Control Points

Every processor who engages in processing other than, or in addition to, storing of fish or fishery products that consist in whole or in part of scombroid forming species, must ensure that neither decomposition leading to histamine formation, nor histamine formation, has occurred before receipt of such fish or fishery products. Processors must also ensure that neither decomposition leading to histamine formation, nor histamine formation, occurs as a result of inadequate handling practices by the processor. In order to prevent these hazards from occurring, Hazard Analysis Critical Control Point (HACCP) plans prepared in accordance with 21 CFR part 123, subpart A will typically identify and address the receipt of raw materials, as well as processing, as critical control points. In accordance with 21 CFR part 123, subpart A, processors shall identify in their HACCP plans how they will control hazards at critical control points. This appendix provides guidance on how to do so with respect to scombroid toxin forming species.

3. Receipt of Raw Materials Critical Control Point

a. First Processor

1. *On-board handling.* The first processor to take ownership after harvest of fish and fishery products of scombroid toxin forming species should ensure that vessels supplying such fish have in place measures to ensure that the fish were rapidly brought to, and maintained at, an internal temperature of 40 °F (4.4 °C) or below, and were not held for a period of time sufficient to allow histamine formation to begin at the temperature at which they were held. The processor may determine the time and temperature history of the fish by requiring certification of the fishing method and on-board handling practices, and a time/temperature log from the harvesting vessel. The time/temperature log should record, for each lot of fish, the date of harvest, fishing method, temperature of the harvest water, and temperature history of the fish relating to the lowering of the internal temperature. The temperature history of the fish may be documented by controlling and recording the key aspects of the cooling and storage operation (e.g., refrigerated brine or seawater temperature, fish size, and container packing). For purposes of this guideline, a lot of fish is the fish in a vessel storage compartment (i.e., well, tote, or other container). The log should be sufficient to enable the processor to determine whether the fish were subject to conditions in the water after capture, on the harvesting vessel, or in storage, that could cause, or significantly contribute to, the formation of histamine in the fish.

2. *Sampling and examination.* The first processor, as described in section 3.a.1. of this Appendix, should subject a representative sample of fish in each lot from the vessel to an external organoleptic examination for decomposition and should record the results of the examination. A representative sample should provide at least 95 percent confidence that decomposition does not exist in more than 2.5 percent of the fish in the lot. If the number of fish from a vessel is small enough to permit an examination of each fish, e.g., because the weight of each fish is typically greater than 10 pounds, the processor is encouraged to examine each fish.

i. Any fish that exhibits decomposition should either be rejected and not used for food, or reconditioned according to the processor's established procedures. Reconditioning should include, at a minimum, removal of all parts of the fish that exhibit any decomposition, organoleptic reexamination of the remaining fish flesh, and the performance of a histamine analysis on the remaining fish flesh.

ii. If no decomposition in any fish in a lot is detected through organoleptic examination, the following should apply:

A. If the time/temperature log as described in section 3.a.1. of this Appendix indicates that the conditions on the vessel were unlikely to cause, or significantly contribute to, the formation of histamine in the fish, all the fish from that lot may be further processed or enter commerce.

B. If the time/temperature log as described in section 3.a.1. of this Appendix indicates that the conditions on the vessel were likely to cause, or significantly contribute to, the formation of histamine in the fish in a lot, or if no adequate time/temperature log is available, a histamine analysis should be made on a representative sample of fish from that lot.

iii. If decomposition is detected in less than 2.5 percent of the fish from a lot, the following should apply:

A. If the time/temperature log as described in section 3.a.1. of this Appendix indicates that the conditions on the vessel were unlikely to cause, or significantly contribute to, the formation of histamine in the fish in a particular lot, those fish from that lot found to have decomposition should be treated in accordance with section 3.a.2.i. of this Appendix. Other fish from that lot may be further processed or enter commerce.

B. If the time/temperature log as described in section 3.a.1. of this Appendix indicates that the conditions on the vessel were likely to cause, or significantly contribute to, the formation of histamine in the fish in a particular lot, or if no adequate time/temperature log is available, the processor should perform a histamine analysis on a representative sample of organoleptically acceptable fish from that lot. (However, if the processor elects to perform a histamine analysis on a representative sample of each lot of fish from the vessel before conducting an organoleptic analysis for decomposition because, for example, the processor received the fish in a frozen state, the histamine analysis does not have to be repeated based on results of subsequent organoleptic analysis.)

iv. If decomposition is detected in more than 2.5 percent of the fish from a particular lot, the processor should perform a histamine analysis on a representative sample of organoleptically acceptable fish from that lot.

3. *Histamine Findings.*

i. If any fish from a particular lot is found to have histamine above a defect action level or other regulatory level or limit for histamine established by FDA, the fish in that lot may not be used for food.

ii. If any fish from a particular lot is found to have histamine below the defect action level or other regulatory level or limit for histamine established by FDA but above levels expected of fresh fish, the fish from that lot should enter commerce only if first immediately cooked to prevent histamine from increasing to unacceptable levels.

b. Subsequent Processors

1. *Processor evaluations.* All subsequent processors who take ownership of fish and fish products of scombroid toxin forming species and who engage in processing other than, or in addition to, storage, should subject a representative sample each lot of such fish and fishery products to organoleptic evaluation for decomposition to determine whether decomposition occurred during transfer from the previous processor. Any fish that exhibits decomposition should be treated in accordance with section 3.a.2.i. of this Appendix.

2. *Decomposition.* A finding of any organoleptically detectable decomposition should result in the organoleptic examination of the entire lot. If decomposition is detected in more than 2.5 percent of the fish in the lot, the processor should perform a histamine analysis on a representative sample of fish from the lot. The results should be treated in accordance with section 3.a.3. of this Appendix.

4. Processing Critical Control Point.

Products that are undergoing processing should not be exposed to ambient temperatures of 40 °F (4.4 °C) or higher for more than a cumulative total of 4 hours. Processors should ensure that this requirement is met by monitoring and recording, at least every 2 hours, the length of time that the product is exposed to temperatures of 40 °F (4.4 °C) or higher.

5. Additional Critical Control Points.

The guidelines relating to cooked ready to eat fish and fishery products specified by Appendix A, sections 6 and 7 should also be applied to scombroid toxin forming species, where applicable.

Appendix C to Part 123—[Reserved]

Appendix D to Part 123—Product Integrity

1. General guidelines for product integrity.
2. Product integrity critical control points.

1. General Guidelines for Product Integrity

This Appendix provides guidance on how a processor can use an HACCP-based approach to ensure that all fish and fishery products are in compliance with the economic adulteration and misbranding provisions of the Federal Food, Drug, and

Cosmetic Act (sections 402(b) and 403, respectively). This guidance applies to controlling economic factors including the identity of species, weight, count and size, and the percentage of valuable constituents. These factors must be accurately represented on the label and labeling of a food.

2. Product Integrity Critical Control Points

Hazard Analysis Critical Control Point (HACCP) plans prepared in accordance with subpart A of 21 CFR part 123 will typically include the following critical control points, as appropriate, that can be used to ensure the economic integrity of the product:

a. Receipt of Raw Material

A processor must ensure that the fish and fishery products that it receives are correctly identified as to species at the point of receipt into its processing facility. Methods used for identification upon receipt may include, but are not limited to:

1. *Exams.* Physical examination of the seafood species by qualified personnel;

2. *Evaluations.* Laboratory evaluation (e.g., protein chromatography); and

3. Acceptance of species identity as certified by a supplier under either a Limited or a General and Continuing Guaranty, as provided for by section 303(c)(2) of the Federal Food, Drug, and Cosmetic Act (21 CFR 7.12 and 7.13).

b. Labeling-Economic Value

A processor must ensure that the finished product labels, labeling, and invoices accurately represent the weight, count, and size of the product, as well as the presence and amount of any valuable constituents. An example would be the handling of shrimp and breading material to make breaded shrimp. The processor must ensure that the shrimp has not been adulterated by the addition of water, and that the valuable constituents are present at levels that are consistent with FDA standards of identity (21 CFR part 161) and compliance policy guides. The processor thus should provide for monitoring of the level of the valuable constituents throughout receipt, processing, and distribution to ensure that:

1. *Identification.* The species is correctly identified by its common or usual name and is so represented on the label and labeling. Guidance in selecting the correct common or usual name of a species is provided by the FDA Fish List. Specific requirements are given in 21 CFR 101.18 and 21 CFR part 161.

2. *Valuable constituents.* The valuable constituents of the product are not omitted or abstracted from the product (e.g., breaded shrimp contains the required weight ratio of shrimp to breading and, if appropriate, shrimp of the size and weight specified on the label or labeling).

3. *Substitution.* No substance is substituted wholly or in part for the valuable constituent (e.g., through added water or glazing, or substitution of crab flavored surimi for crab meat in a product labeled as crab cake).

4. *Damage or inferiority.* Damage or inferiority is not concealed in any manner (e.g., through bleaching or coloring of product to conceal its true nature or condition of wholesomeness).

5. *Product adulteration.* No substance is added to, or mixed with, the product to increase its bulk or weight or to reduce its quality, or make it appear of better or greater value than it is (e.g., through adding water to a product by chemical or other means).

PART 1240—CONTROL OF COMMUNICABLE DISEASES

2. The authority citation for 21 CFR part 1240 continues to read as follows.

Authority: Secs. 215, 311, 361, 368 of the Public Health Service Act (42 U.S.C. 216, 243, 264, 271).

3. Section 1240.3 is amended by revising paragraph (p) to read as follows:

§ 1240.3 General definitions.

* * * * *

(p) *Molluscan shellfish.* Any edible species of fresh or frozen oysters, clams, mussels, and scallops or edible portions thereof, except when the scallop or scallop product consists entirely of the shucked adductor muscle.

4. Section 1240.60 is amended by revising the section heading; by designating the existing text as paragraph (a) and adding the word "molluscan" before the word "shellfish" the two times that it appears; and by adding new paragraphs (b) and (c) to read as follows:

§ 1240.60 Molluscan shellfish.

* * * * *

(b) All unshucked raw molluscan shellfish, that is all unshucked molluscan shellfish that has not been subject to a treatment sufficient to kill pathogens of public health significance, shall bear a tag that discloses the date and place they were harvested, type and quantity of shellfish, and by whom they were harvested, including the number assigned to the harvester by the shellfish control authority. Any raw molluscan shellfish that are found by FDA in interstate commerce without such a tag or label, or with a tag or label that does not bear all the required information, will be subject to seizure and destruction.

(c) Shucked molluscan shellfish shall be subject to the same requirements as apply to molluscan shellfish that has not been shucked as provided in paragraph (b) of this section, except that, in lieu of a tag, the body of the container of shucked molluscan shellfish, shall bear a label that identifies the name, address, and certification number of the processor of the molluscan shellfish.

Dated: January 21, 1994.

David A. Kessler,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

Note: The following appendix will not appear in the annual Code of Federal Regulations.

Appendix 1—FDA Fish Fishery Products Hazard and Controls Guide Including Guidance on Smoked Fish

FDA is in the process of developing guidance to, among other things, assist the seafood industry develop and implement HACCP systems. The guidance will be titled the "FDA Fish and Fishery Products Hazard and Controls Guide." When a draft of the entire Guide is completed in the near future, FDA will publish a notice of availability in the **Federal Register** and invite public comment. FDA will revise the draft as warranted and then issue the first edition of the Guide.

I. The Information Presented

The selected portions of the draft Guide that are provided below are:

Example 1. The Table of Contents.

Example 2. One page each from the "Vertebrate" and "Invertebrate Hazard and Control Lists." Together, these lists contain about 350 species of commercially marketed fish. Each list is in the form of a chart that directs the reader to one or more of the 10 numbered hazard and control descriptions elsewhere in the Guide for species-related hazards. For purposes of the Guide, species-related hazards are those that can occur in the environment or during harvest. Processors should find in the appropriate list the species they handle, then turn to those numbered hazard and control descriptions that are relevant to that species.

Example 3. A sample of a species-related hazard and control description (Species-related Hazard and Control #1 (Chemical Contamination)). Each description explains a hazard and the measures available to control it, with an emphasis on HACCP controls such as critical control points, critical limits, monitoring procedures and frequencies, recordkeeping, and corrective actions. Some descriptions contain several control options.

Example 4. One page from the "Process-related Hazards and Controls List." For purposes of this Guide, process-related hazards are those that can occur because of the nature of the processing procedures and the finished product form. This list includes 20 types of finished products (e.g., cooked shrimp) and directs the reader to one or more of the 22 process-related hazard and control descriptions, which are located in the next part of the Guide.

The process-related hazard and control descriptions are numbered. Some of them are further subdivided into lettered portions. Where the reader need only refer to a portion of a process-related hazard and control description, the list directs the reader to that portion by referring to a lettered part of the description. See below.

Example 5. A sample of a process-related hazard and control description ("Process-

related Hazard and Control #11" (pathogen survival during pasteurization)). As with the species-related descriptions discussed above, each process-related description explains a hazard and the measures available to control it, with an emphasis on HACCP controls. Some of these descriptions are subdivided. For example, "Process-related Hazard and Control No. 8," which is about temperature abuse, is subdivided into "8a: Histamine," "8b: Pathogens," and "8c: Decomposition." Where the list in 4. above directs a reader to a number-letter combination, e.g., "8b," it is to one of the subdivided portions of a description, in this case to the "Pathogens" material in Process-related Hazards and Controls #8.

Example 6. A consolidated section for smoked and smoke-flavored fishery products.

Example 7. A model HACCP plan. This is essentially a fill-in-the-blank model. Processors can use the materials in the hazards and controls descriptions and this model plan, to develop much if not all of their HACCP plans, depending on their circumstances.

It must be remembered that these materials reflect a work in progress and are published to provide the public with a preview of the document. When the entire document is made available to the public in the near future, the selected portions published here may have been revised.

To help processors and other interested persons to understand the guidance presented in the consolidated section on smoked fishery products, FDA will explain that guidance in the section that follows.

II. Smoked Fishery Products

Research conducted since FDA proposed the 1970 final rule shows that less stringent processing temperatures and lower water-phase salt content, with or without use of other inhibiting factors such as sodium nitrite, can provide an adequate margin of safety for hot-process products held in refrigerated storage (40 °F (4.4 °C) or lower). FDA has considered this research, and based on it, the agency is proposing a guidance setting forth what it tentatively finds are the minimum time, temperature, and salinity requirements to make a safe and marketable smoked fish product. Proposed TTS parameters are found in example 6 of this appendix.

A. Raw Materials/Handling of Unprocessed Fish.

The presence of microorganisms, including *C. botulinum* and *L. monocytogenes*, cannot be avoided in fresh-water fish and marine fish because they are present in the aquatic environment. Under certain conditions, the potential exists for the outgrowth of *C. botulinum* spores and toxin production (Refs. 148 through 152), as well as for an increase in the *L. monocytogenes* population (Ref. 143).

To minimize microbial growth, fresh fish should be maintained at refrigerated temperatures close to 38 °F (3.3 °C) (Refs. 173 and 175). Although certain strains of *C. botulinum* are capable of growth at temperatures as low as 38 °F (3.3 °C), favorable growth media are necessary for a significant growth rate to occur at this temperature. For example, it has been shown that *C. botulinum* Type E requires 31 to 35 days before outgrowth and toxin production occurs in a beef stew media held at 38 °F. However, outgrowth and toxin production in a cooked meat medium held at 41 °F does not occur until after 56 days, demonstrating that less favorable growth media can significantly lower the rate of growth. Even in those cases where *C. botulinum* does grow and produce toxin, the laboratory conditions are generally more ideally suited to growth than those found in nonexperimental situations where less favorable growth environments prevail. Thus, while the growth of *C. botulinum* is not completely inhibited at 40 °F (4.4 °C), under the less than ideal conditions for its growth that are generally encountered in the processing of smoked fish, FDA has tentatively concluded that maintaining fresh fish at a maximum temperature of 40 °F, only 2 degrees above the temperature of complete growth inhibition, before and during processing will provide adequate protection against *C. botulinum* outgrowth. Moreover, 40 °F (4.4 °C) is consistent with the maximum temperature FDA has proposed in various guidelines, such as the Unicode (now called the Food Code) (53 FR 16472, May 9, 1988). Therefore, under proposed § 123.10(a)(14), all raw fish that is to be smoked must be refrigerated until needed for processing (Ref. 175).

Similarly, fish that are initially frozen need to remain in the frozen state until needed for processing (Refs. 161 and 25). When frozen fish are needed for processing, the thawing procedure must be carried out in a way that minimizes the opportunity for microbial growth (Refs. 161 and 171). The method used to thaw the fish must provide an environment that will inhibit the growth of *C. botulinum* and other microorganisms that pose a potential health hazard (Refs. 171 and 172). Thus, the fish should be thawed in a way that ensures that the internal temperature at the core of the fish does not exceed 40 °F (4.4 °C) (Refs. 171 and 172). Therefore, section 4.a. of Example 6 of this appendix, the agency suggests that this procedure be used in the thawing process.

B. Manufacturing Operations

Reduction of the potential health hazard from *C. botulinum* spore outgrowth and toxin production in smoked and smoke-flavored fish relies on the interrelationship of processing time, processing temperature, water-phase salt concentration in the loin muscle, and smoke (or constituents of smoke) deposition, combined with refrigerated storage (40 °F (4.4 °C) or lower) (see proposed § 123.10(a)(14)) (Ref. 173). At one time, smoking and associated brining may have been an effective preservation method. With the changes in processing techniques that have occurred since the advent of refrigeration and in response to consumers' demands for products with certain organoleptic qualities, however, smoked fish products, either hot- or cold-process, have become perishable products that must be refrigerated and cannot be considered preserved foods (Ref. 173). The changes that have occurred, both in processing techniques and in organoleptic qualities, have resulted in products that are more moist and contain less salt. As a result, the two critical processing factors that affect the overall preservation and safety of the product have been altered. The processing time-temperature parameters have been decreased, and the water-phase salt content has been reduced (Ref. 173). Therefore, these products need to be maintained at refrigerated temperatures (40 °F (4.4 °C) or lower) or frozen immediately after processing to ensure the overall quality of these products (Ref. 173).

1. *Brining/dry salting.* Salt, as a preservative in smoked and smoke-flavored fish, is somewhat limited in its effectiveness because of the variability in salt uptake by fish flesh, even among fish in the same brining tank. Ventral muscle, which is thin, absorbs high levels of salt, while the thicker dorsal muscles absorb less salt, limiting the effectiveness of salt as a deterrent against spore outgrowth in that part of the fish. Equilibration techniques, such as two-stage brining, reduce variation in salt content within a fish and increase the preservative effect (Ref. 176).

It is possible that salt-tolerant microorganisms of public health concern (such as strains of *Staphylococcus*) may grow during brining or after the dry salting process. Therefore, FDA is providing in section 5.c. and 5.e. in example 6 of this appendix that the brining and dry salting of fish be carried out at refrigerated temperatures, i.e., 40 °F (4.4 °C) or lower. Doing so will ensure that the environment in which brining is done, and in which fish are held after dry-salting, will inhibit the growth of salt-tolerant microorganisms that can cause a potential health hazard (Ref. 173).

FDA recognizes that when fish are initially added to the brine, the temperature of the brine may increase. It is essential to this process that the brine be returned to refrigerated temperatures 40 °F (4.4 °C) or lower to reduce the opportunity of microbial growth and to ensure the overall quality of the product during the brining process (Refs. 175 and 182). Therefore, the agency is suggesting in section 5.d. of Example 6 of this appendix that the temperature of the brine not exceed 60 °F (16 °C) at the start of brining.

To minimize the variation in salt content of the fish, the agency is recommending in section 5.f. of Example 6 of this appendix that only fish of the same species and of similar size and similar weight be brined in the same tank (Refs. 171 and 199). Because reuse of brine solutions is a possible route of microbial contamination of raw fish, the agency is providing in section 5.g. of Example 6 of this appendix that brines not be reused unless they have been processed in some way to return them to a microbiological quality equivalent to the original, unused brine made with potable water and food-grade salt. The agency is also providing in section 5.h. of Example 6 of this appendix that a processor may rinse the brined fish with fresh water to remove any unwanted excess salt on the exterior of the fish.

2. *Drying.* Fish that are to be processed as smoked or smoke-flavored fish are dried after brining to remove excess water and prevent

dripping during smoking. The drying process, usually of several hours in duration, provides another opportunity for microbial growth. Therefore, to minimize the opportunity for microbial growth by reducing those conditions that would provide a favorable environment for such growth, the agency is providing in section 5.i. of Example 6 of this appendix that the presmoking drying step should be conducted in a refrigerated room (Ref. 46).

3. *Smoking.* Smoke deposition, like water-phase salt content, is very difficult to control. Constituents of smoke called "inhibitory compounds" (such as phenolic compounds) are reported to have a bactericidal effect (Ref. 177). Factors that affect the quantity of inhibitory compounds deposited on the fish surface and the degree of penetration by those compounds into the fish are the humidity in the smoking chamber, the temperature of smoking, and the air flow in the smoking chamber (Ref. 178). Decreased levels of inhibitory compounds reduce the preservative effect of the smoke and make dependence on these compounds inadvisable (Ref. 178). In general, smoked products are not shelf stable and must be either refrigerated at a temperature of 40 °F (4.4 °C) or lower or frozen immediately after processing (Refs. 43, 45, and 178).

To promote uniform deposition of smoke, heat exposure, and dehydration, and to ensure that on completion of these processes, the fish do not contain any raw or wet sections that would create an environment favorable for microbial growth and spoilage, the agency is providing in section 5.j. of Example 6 of this appendix that fish should be arranged in the smokehouse chamber or oven so that they are not overcrowded or touching each other, and that only fish of like size and weight should be included in a single batch of fish for smoking.

Liquid smoke, a solution of wood smoke that, when diluted, may be used to impart a smoke flavor to fish products, is often used as an alternative to generated smoke. Liquid smoke has been reported to have similar antibacterial properties to, and some advantages over, generated smoke (Ref. 26). It is easier to apply uniformly, and the inhibitory compounds penetrate further into the fish flesh (Ref. 26). Liquid smoke, generated smoke, or a combination of liquid smoke and generated smoke needs to be applied to all surfaces of fish to be smoked. Liquid smoke may be applied to the product before, at the commencement of, or during the process, while generated smoke needs to be applied to the fish during the first half of the process and longer if necessary (Refs. 178 and 179). If a combination of liquid smoke and generated smoke is used, the method for use of liquid smoke may be followed, and the generated smoke may be applied at any stage of the process (Ref. 26). The agency is providing for the use of liquid smoke alone or in combination with generated smoke in section 3.c.2. of Example 6 of this appendix to impart smoke flavor and antibacterial properties to the products.

4. *Use of sodium nitrite.* Use of sodium nitrite in smoked and smoke-flavored fish products is limited to the species listed in § 172.175 (21 CFR 172.175) and to chubs in § 172.177 (21 CFR 172.177). Section 172.175 permits the use of sodium nitrite as a preservative and color fixative in cured, smoked sablefish, salmon, and shad. However, it requires that the level of sodium nitrite in the final product not exceed 200 ppm. Use of sodium nitrite substantially reduces the level of salt necessary to inhibit outgrowth of *C. botulinum* type A and type E spores, although the levels vary because of the difference in heat resistance between the two types of spores (Ref. 179). The quantity of sodium nitrite necessary to achieve inhibition is affected by both the level of contamination and the resistance of the spores (Refs. 179 and 180). Refrigeration of the finished product at temperatures of 40 °F (4.4 °C) or below is necessary to retain the inhibitory characteristic gained through use of sodium nitrite (Ref. 179). Therefore, in accordance with the provisions of §§ 172.175 and 172.177, the agency is proposing to provide for the use of sodium nitrite in the processing and packaging of smoked and smoke-flavored fish in section 5.a. and section 5.b. of Example 6 of this appendix.

5. *Vacuum- and modified atmosphere-packaging.* Vacuum packaging and other types of modified atmosphere-packaging (those in which the air in the package or container is replaced by one or more gases, in various concentrations, before the package is sealed) extend the shelf life of foods markedly. However, the anaerobic environment created in these types of packaging favors the outgrowth of *C. botulinum* spores and subsequent toxin production, and it inhibits growth of aerobic microorganisms that might otherwise serve as organoleptic indicators of spoilage (Refs. 180 and 182). Consequently, use of vacuum- or modified atmosphere-packaging demands strict adherence to temperature-controlled storage and distribution to reduce the opportunity for spore outgrowth and toxin production and to reduce the potential growth of other microorganisms of public health significance (such as *L. monocytogenes*).

Two methods of reducing the potential public health hazard of vacuum or modified atmosphere packaged smoked, smoke-flavored, and salted fish products are: (1) To store and distribute the products frozen or, alternatively, (2) to use in-package heat processing followed by refrigeration. At freezer temperatures, outgrowth of spores of *C. botulinum* types B, E, and F is retarded (Refs. 171, 173, and 180). Type A does not grow below 50 °F (10 °C) (Refs. 179 and 180). Storage and distribution in the frozen state reduces the possibility that temperature abuse will occur.

In-package heat processing, sometimes referred to as "heat pasteurization," at temperatures in the range of 185 °F (85 °C) for 85 minutes to 198 °F (92 °C) for 55 minutes, inhibits outgrowth and toxin production by type E spores (Ref. 185). Longer exposure to processing temperatures is required for more heat resistant spores, such as types B and A (Ref. 185). In a study examining this method of packaging, samples of hot-process salmon steaks were injected with spores of nonproteolytic strains of *C. botulinum* types B and E (Ref. 185). The steaks were vacuum packaged, heat pasteurized, then incubated using different time-temperature combinations. The results of this research showed that closely controlled in-package heat processing extends the shelf life of the product, inactivates nonproteolytic *C. botulinum* types B, E, and F and other vegetative pathogens, and maintains product quality attributes. However, this process is more suitable for pieces, fillets, and steaks than for whole eviscerated fish because this process causes the flesh to separate from the backbone (Ref. 185).

C. Specific Processing Conditions

The various processing techniques used to produce smoked and smoke-flavored fish are affected by the interrelationship of the smoking, the method of smoke application, the time-temperature combinations used, and the water-phase salt content. A critical factor in determining alternative processing methods is the type of packaging utilized, specifically whether the product is air-packaged or vacuum-packaged. The following discussion sets out the various processing procedures that the agency has tentatively concluded will ensure the safety of hot-process smoked and smoke-flavored fish, and cold-process smoked and smoke-flavored fish.

1. *Hot-process smoked and smoke-flavored fish.* a. *Air-packaged.* Research data and industry practice show that a lower minimum water-phase salt content (3.5 percent or lower), in combination with lower processing temperatures (lower than 180 °F (82 °C)) than cited in the 1970 final rule for hot-process products are effective in inhibiting spore outgrowth and toxin production when the products are not vacuum-packaged and are held at refrigerated temperatures (40 °F (4.4 °C) or lower) (Refs. 24, 163, and 177). Research studies from the National Marine Fisheries Service and testimony presented at a public hearing held by the New York State Department of Agriculture and Markets on May 3, 1989, to establish a CGMP for the manufacture of smoked and smoke-flavored fish products, show that *C. botulinum* type E is inhibited in air-packaged smoked fish products when the water-phase salt content is at least 3.0 percent, and the processing internal temperature of the product is maintained at a minimum of 145 °F (63 °C) for at least 30 minutes (Ref. 180). In light of these findings, FDA is setting forth these processing parameters in Example 6 of this appendix to provide guidance on the safe manufacturing of these products.

The agency is setting forth the following minimum T-T-S parameters for air-packed, hot-process smoked and smoke-flavored fish in section 5.a.1. of Example 6 of this appendix: Heating at an internal temperature of 145 °F (63 °C) for 30 minutes with a water-phase salt content of 3.0 percent in the finished product.

b. *Vacuum-packaged/modified atmosphere.* For vacuum-packaged products, National Marine Fisheries Service research shows that processing temperatures in the range of 145 to 175° F (63 to 80 °C) for hot-process smoked fish will inhibit *C.*

botulinum type E when the water-phase salt content is greater than 3.5 percent (Refs. 26, 173, and 180). Based on this evidence, New York's CGMP included a procedure for processing vacuum-packaged smoked fish that specifies heating the fish to an internal temperature of 145 °F (63 °C) for 30 minutes, with a water-phase salt content of 3.5 percent (Ref. 25).

The use of sodium nitrite in combination with sodium chloride significantly inhibits the outgrowth and toxin production of *C. botulinum* type E. Research data show that when the water-phase salt content and sodium nitrite content are at least 3.1 percent and 100 ppm, respectively, and the internal temperature of the fish is not less than 145 °F, the inhibitory effect on *C. botulinum* growth and toxin production greatly increases (Refs. 173 and 179). At higher processing temperatures, e.g., 180 °F (82 °C), a water-phase salt content of 3.0 percent or more inhibits toxin formation by *C. botulinum* type E (Ref. 163).

Based on this information, the agency is setting forth the following T-T-S parameters for vacuum-packaged hot-process smoked and smoke-flavored fish in section 5.a.2. of Example 6 of this appendix: (1) Heating at an internal temperature of at least 145 °F (63 °C) for 30 minutes with a minimum water-phase salt content of 3.5 percent in the finished product, or (2) heating at an internal temperature of at least 145 °F (63 °C) for 30 minutes, with a minimum water-phase salt content of 3.0 percent, and a sodium nitrite content of 100 to 200 ppm (as permitted by the food additive regulations in § 172.175) in the finished product, or (3) as described in § 172.177 for smoked chub containing sodium nitrite.

The agency points out that these processing parameters for vacuum-packaged hot-process smoked and smoke-flavored fish are minimums. Unless the comments on Example 6 of this appendix convince the agency otherwise, fish that have been processed at a lower temperature or with a lower water-phase salt level could provide the basis for regulatory action on the grounds that the product has been processed under conditions whereby it may have been reduced injurious to health and thus could represent a hazard for consumers.

2. *Cold-process smoked and smoke-flavored fish.* Cold-process smoked and smoke-flavored fish, by virtue of the temperatures used in processing, are not cooked because they are processed at temperatures lower than those that coagulate protein, i.e., 100 °F (38 °C) or lower. Because these temperatures are not high enough to inactivate *C. botulinum* spores, and because they provide a favorable environment for other food spoilage microorganisms, other inhibitive factors, such as higher salt content and sodium nitrite (where permitted by food additive regulations in § 172.175) need to be used.

The time and temperature relationship in the processing of cold-smoked and smoke-flavored fish is a critical factor in yielding a microbiologically safe and high quality finished product (Ref. 182). Modern establishments that cold-smoked fish generally process between 40 °F (5 °C) and 100 °F (38 °C) for 18 to 24 hours (Refs. 171 and 182). Based on the research data that are available and the requirements in the New York CGMP, the agency is proposing the following requirements for air-packaged and vacuum-packaged/modified atmosphere cold-process smoked and smoke-flavored fish (Refs. 25, 180, and 184).

a. *Air-packaged products.* The agency is providing in section 5.a.3. of Example 6 of this appendix that air-packed, cold-process smoked and smoke-flavored fish should have a minimum water-phase salt content of: (1) 3.5 percent, or (2) 3.0 percent and contain 100 to 200 ppm of sodium nitrite in the finished product, or (3) 2.5 percent in the finished product if the product is frozen immediately after processing and cooling and is kept frozen throughout holding and distribution. The agency is providing that the finished product that contains a water-phase salt content of 2.5 percent should be frozen immediately and kept frozen to ensure the microbiological safety of the product, as well as to maintain the shelf-life of the finished product.

As stated above, because these products are not cooked and contain a low water-phase salt content, these products may present a potential public health hazard because they provide an ideal environment for the outgrowth of *C. botulinum* spores and toxin production. Therefore, based on the discussion above, the agency is suggesting that air-packaged cold-process smoked and smoke-flavored fish be processed under one of the following sets of conditions: (1) A maximum 20-hour drying and smoking period with the temperature in the smoking chamber not exceeding 90 °F (32 °C) (section 5.a.3.i. of Example 6 of this appendix), or (2) a maximum 24-hour drying and smoking period with the temperature in the smoking chamber not exceeding 50 °F (10 °C) (section 5.a.3.ii. of Example 6 of this appendix) except that sablefish needs to be heated to a temperature not to exceed 120 °F (49 °C) for a period not to exceed 6 hours (section 5.a.3.iii. of example 6 of this appendix) (Refs. 25, 180, and 184).

b. *Vacuum-/modified atmosphere-packaged products.* FDA is providing in section 5.a.4. of Example 6 of this appendix that cold-process smoked and smoke-flavored fish to be vacuum- or modified atmosphere-packaged should have a minimum water-phase salt content of: (1) 3.0 percent and contain 100 to 200 ppm of sodium nitrite in the finished product, or (2) 3.5 percent in the finished product when no sodium nitrite is used. The agency is also providing that vacuum-/modified atmosphere-packaged cold-process smoked and smoke-flavored fish should be processed under one of the following sets of conditions: (1) A maximum 20-hour drying and smoking period with the temperature in the smoking chamber not exceeding 90 °F (32 °C) (section 5.a.3.i. of Example 6 of this appendix), or (2) a maximum 24-hour drying and smoking period with the temperature in the smoking chamber not exceeding 50 °F (10 °C) (section 5.a.3.ii. of Example 6 of this appendix) (Refs. 25, 180, and 184).

The agency again points out that these processing parameters for vacuum-/modified atmosphere-packaged cold-process smoked and smoke-flavored fish are minimums. Failure to adhere to these parameters could provide the basis for regulatory action because the product that results may be injurious to health and thus could represent a hazard to consumers.

The agency believes that the proposed processing requirements for cold-process smoked and smoke-flavored products, air-packed and vacuum- or modified atmosphere-packaged, will produce a safe and commercially acceptable product. However, because less data and information are available for these products than for hot-process products, the agency is requesting specific comments, data, and information about these processing parameters and any alternative processing parameters that should be included in the guideline.

3. *Cooling and storage of finished products.* Rapid cooling and storage at temperatures of 40 °F (4.4 °C) or below are essential for all smoked, smoke-flavored, and salted fish products to minimize microbial growth. The exceptions are cold-process air-packaged products that contain a water-phase salt content of 2.5 percent, which should be frozen immediately after processing and remain frozen throughout distribution because of the lower water-phase salt content and lower processing temperatures that may provide an opportunity for food spoilage microorganisms to flourish during storage (see section 5.a.3. of Example 6 of this appendix) and the discussion above).

Outgrowth of *C. botulinum* spores, types A and proteolytic B, and toxin production are inhibited at temperatures of 50 °F (10 °C) and lower. Spore types E and nonproteolytic B are completely inhibited at temperatures of 38 °F (3.3 °C) and lower (Refs. 174 and 185 through 188).

At section 6 of Example 6 of the appendix, the agency is recommending specific time/temperature controls for processing after smoking. These proposed controls are the same as those proposed for after cooking in the cooked, ready-to-eat section of this document (Appendix A, section 6). A full discussion of the controls is provided in section VII.J.3. of this document.

4. *Alternative processing parameters.* As this preamble indicates, FDA has tentatively concluded that the TTS processing parameters reflected in this appendix are the minimum necessary to ensure that these products are free from botulinum toxin over their shelf life. FDA has also tentatively concluded that the T-T-S parameters, coupled with good sanitation practices, will also render these products listeria free. Nonetheless, the agency does not wish to discourage the development and use of alternative procedures that are capable of achieving the same outcome.

Consequently, section 11 of Example 6 of this appendix calls for the use of alternative processing parameters when the user can demonstrate the following: (1) For botulism, zero toxin production slightly beyond the expected shelf life of the product, demonstrated through inoculated pack studies under normal and moderate abuse conditions and (2) for listeria, no detectable *L. monocytogenes* in the final product. The

data demonstrating these outcomes would have to be available to FDA to enable the agency to determine whether they have been achieved.

Example 6 of this appendix states that those data should be part of a processor's HACCP records. FDA asks for comment on whether a third-party scientific expert, or processing authority, should be involved in the development of the data that demonstrate the effectiveness of the alternative procedure.

5. *Use of vacuum- and modified atmosphere-packaging.* As explained above, vacuum- or modified atmosphere-packaged smoked, smoke-flavored, and salted fish products represent an increased public health hazard over conventionally packaged products because these types of packaging provide the ideal environment for spore outgrowth and toxin production. Based on the discussion above, the agency states in section 3 of Example 6 of this appendix that these types of packaging should be used only when: (1) As provided in section 5.a.2. of Example 6 of this appendix the product is a hot-process smoked or smoke-flavored product, is vacuum-packed or modified atmosphere-packed, and contains at least 3.5 percent water-phase salt in the finished product, or 3.0 percent salt and 100 to 200 ppm of sodium nitrite in the finished product (section 4.a.1. of Example 6 of this appendix); (2) as provided in section 5.a.4. of Example 6 of this appendix, the product is a cold-process smoked or smoke-flavored product, is vacuum-packed or modified atmosphere-packed, and contains at least 3.5 percent water-phase salt in the finished product or 3.0 percent salt and 100 to 200 ppm of sodium nitrite.

The agency is providing in Appendix C, section 8.a. that all vacuum- or modified atmosphere-packaging should be conducted within the processing plant where the product is manufactured (Ref. 180). FDA considers this limitation appropriate to prevent any postprocessing contamination of the product from bacterial pathogens and to ensure that the fish will be packaged immediately after processing to protect its overall quality.

6. *Process monitoring.* Section 7 of Example 6 of this appendix, the agency is recommending specifications for temperature indicating and recording devices where they are recommended elsewhere in this appendix. These proposed specifications are the same as those proposed in Appendix A for cooked, ready-to-eat fishery products (Appendix A, section 7). A full discussion of these controls is provided in section VII.J.4. of the preamble to this document. Temperature indicating and recording devices are specifically recommended in section 5.j. and 5.k. of Example 6 of this appendix for the control of the smoking temperature.

At section 5.b. of Example 6 of this appendix, the agency is recommending specific controls to ensure that the appropriate water-phase salt and sodium nitrate levels are achieved. The significance of these attributes has already been discussed in this document. In section 5.b. of Example 6 of this appendix, the agency recommends that a processor perform or obtain a study that shows that under certain processing conditions the desired water phase salt or sodium nitrite level will reliably be achieved. The processor should monitor those processing conditions identified by the study as having an impact on the ability of the product to achieve the desired level. The study should provide critical limits for each of the relevant processing conditions (e.g. maximum fish size, minimum soak time, minimum salt to product ratio).

Because of the existence of numerous variables that affect the ability of fish to uniformly take up salt and sodium nitrite, it may be appropriate for a processor to perform periodic finished product water phase salt or sodium nitrite analyses as a verification step. The purpose of such analyses would be to identify any variables that have an impact on salt or nitrite absorption that were not identified by the study.

7. *Corrective actions.* At section 9 of Example 6 of this appendix, the agency is recommending corrective action procedures. These proposed procedures are the same as those proposed in the cooked, ready-to-eat section of this document (Appendix A, section 8). A full discussion of the procedures is provided in section VII.J.5 of the preamble to this document.

8. *Sanitary zones.* At section 10 of Example 6 of this appendix, the agency is recommending the institution of sanitary zones. This proposed control procedure is the same as that proposed in the cooked, ready-to-eat section of this document (Appendix A, section 9). A full discussion of the control procedure is provided in section VII.J.6 of the preamble to this document.

To further ensure the safety of the product during distribution and storage, FDA is considering adopting specific package labeling requirements for smoked and smoke-flavored fish products to reduce the opportunity of temperature abuse of the finished product. The agency requests comments on whether it should require that the label of all shipping containers and retail packages state that the product is perishable, and, more specifically, that the product must be kept refrigerated. FDA tentatively finds that such labeling is extremely important to ensuring the safe handling of these products, and, therefore, it considers it likely that it will require this labeling in the final rule. The agency requests comment on whether it should do so. The agency also requests comment on whether, if it decides to require such a label statement, the statement should specify a temperature at which the product should be refrigerated (e.g. 40 °F (4.4 °C) or below). The agency is also considering requiring that the label of all frozen smoked products state that the product must remain frozen, that if the product needs to be thawed, it must be thawed at refrigerated temperatures, and that the product must not be refrozen.

FDA has authority to adopt these labeling requirements under sections 201(n), 403(a), and 701(a) of the act because these sections require the inclusion of facts on the food label that are material with respect to consequences that may result from use of the product under conditions of use prescribed in the label or that are otherwise customary or usual. The agency requests comments on whether it is necessary to do so.

EXAMPLE 1.—FDA Fish And Fishery Products Hazards And Controls Guide

Table of Contents

Section I:
Status
Purpose
HACCP
This Guide and How to Use It
Section II:
Table 1—Vertebrate Hazard and Control List
Table 2—Invertebrate Hazard and Control List
Species Related Hazards and Controls Nos. 1–10
No. 1 (Safety)—Chemical contamination other than methyl mercury
No. 2 (Safety)—Methyl mercury
No. 3 (Safety)—Natural toxins
3a Paralytic shellfish poisoning (PSP)
3b Neurotoxic shellfish poisoning (NSP)
3c Diarrheic shellfish poisoning (DSP)
3d Amnesic shellfish poisoning (ASP)
3e Ciguatera food poisoning (CFP)
3f Clupeotoxin
3g Chondrichthytoxin
3h Tetrodotoxin
3i Gempylotoxin
No. 4 (Nonsafety)—Filth, extraneous materials or noxious substances
No. 5 (Nonsafety)—Decomposition
No. 6 (Safety)—Histamine
No. 7 (Safety)—Food and color additives
No. 8 (Nonsafety/safety): Parasites
No. 9 (Safety)—Animal drugs
No. 10 (Safety)—Pathogenic Microorganisms
Section III:
Table 3—Process Related Hazards and Controls List
Process Related Hazards and Controls Nos. 1–22
No. 1 (Nonsafety)—Filth in dry ingredients
No. 2 (Nonsafety)—Processing of dead crustaceans and mollusks
No. 3 (Nonsafety)—Temperature abuse during raw material storage
No. 4 (Safety)—Excessive water activity
No. 5 (Safety)—Inadequate salt, sugar, and/or nitrite concentration
No. 6 (Safety)—Pathogen survival during cook
No. 7 (Safety)—Cross-contamination
No. 8 (Safety/nonsafety)—Temperature abuse during processing of cooked products and raw molluscan shellfish
No. 9 (Safety/nonsafety)—Temperature abuse during processing of noncooked products
No. 10 (Safety)—Microbiological growth in batter
No. 11 (Safety)—Pathogen survival during pasteurization
No. 12 (Safety): Recontamination after pasteurization
No. 13 (Safety/nonsafety)—Temperature abuse during final cooling
No. 14 (Safety/nonsafety)—Temperature abuse during finished product storage
No. 15 (Safety/Nonsafety)—Temperature abuse during finished product distribution
No. 16 (Safety)—Metal inclusion

No. 17 (Safety)—Food and color additives
No. 18 (Nonsafety)—Short weight
No. 19 (Nonsafety)—Species substitution
No. 20 (Nonsafety)—Grade size misrepresentation
No. 21 (Nonsafety)—Incorrect proportions
No. 22 (Nonsafety)—Over breading
Section IV:
Finished Product Standards for Use in Verification
Section V:
Smoked and Smoke-Flavored Fishery Products
Cooked, Ready-to-Eat Fishery Products
Scombroid Toxin Forming Species
Section VI:
Model HACCP Plan

EXAMPLE 2.—SECTION II

[Table 1—Vertebrate Hazard and Control List]

Market names	Scientific names	Safety hazards	Non safety hazards [1]
Aholehole	*Kuhlia spp.*	.....	4, 5
Alewife/river herring	*Alosa spp.*	1	4, 5, 8
Alfonsino/red bream	*Beryx spp.*	.....	4, 5
	Trachichthodes spp.	.....	4, 5
Amberjacks/yellowtail	*Seriola spp.*	3e, 6	4, 5, 8
Anchovy/anchoveta	*Anchova spp.*	1, 3f,	4, 5
	Anchoviella spp.	6	4, 5
	Cetengraulis spp.	1, 6	4, 5
	Engraulis spp.	1, 6	4, 5
	Stolephorus spp.	1, 6	4, 5
Aquaculture species	Aquatic species, (Including invertebrates, fishes, amphibians and reptiles)	1, 7, 8, 9	4, 5, 8
Angelfish	*Holacanthus spp.*	3e	4, 5
	Pomacanthus spp.	.....	4, 5
Argentine/queenfish	*Argentina elongata*	.....	4, 5
Barracouta	*Thrysites atun*	.....	4, 5
Barracuda	*Sphyraena spp.*	3e	4, 5
Bass	*Ambloplites spp.*	1, 9	4, 5, 8
	Micropterus spp.	1, 9	4, 5, 8
	Morone spp.	1, 9	4, 5, 8
	Stereolepis gigas	1, 9	4, 5, 8
	Synagrops bellus	1, 9	4, 5, 8
Bass, sea	*Acanthistius*	8	4, 5, 8
	Brasilianus	.....	4, 5, 8
	Centropristis spp.	.....	4, 5, 8
	Dicentrachus labrax	.....	4, 5, 8
	Lateolabrax	.....	4, 5, 8
	Japonicus	.....	4, 5, 8
	Paralabrax spp.	.....	4, 5, 8
	Pranthias furcifer	.....	.....
	Polyprion spp.	.....	.....

[1] See Table of Contents for key to hazards.
Reminder: See process hazard tables beginning on p. 70 for hazards that apply to your product.

TABLE 2.—INVERTEBRATE HAZARD AND CONTROL LIST

Market names	Scientific names	Safety hazards [1]	Non safety hazards [1]
Abalone	*Haliotis spp.*	1, 3a, 3b, 3c, 3d	4, 5
Aquacultured invertebrates	All species (Coelenterates, Molluscs, Crustacea, and Echinoderms).	1, 3a, 3b, 3c, 3d, 7, 9, 10	4, 5, 8
Arkshell	*Anadara subcrenata Arca spp.*	1, 3a, 3b, 3c, 3d, 10	4, 5
Clam, Carpet Shell	*Tapes spp*	1, 3a, 3b, 3c, 3d, 10	4, 5
Clam, Bentnose	*Macoma nasuta,*	1, 3a, 3b, 3c, 3d, 10	4, 5
Clam, Butter	*Saxidomus spp*	1, 3a, 3b, 3c, 3d, 10	4, 5
Clam, Calico	*Macrocallista maculata*	1, 3a, 3b, 3c, 3d, 10	4, 5
Clam, Clovis	*Tapes virginea*	1, 3a, 3b, 3c, 3d, 10	4, 5
Clam, Geoduck	*Panopea spp*	1, 3a, 3b, 3c, 3d, 10	4, 5
Clam, Hard	*Arctica islandica, Meretricinae spp. Venus mortoni.*	3a, 3b, 3c, 3d, 10	4, 5
Clam, Hardshell/Quahog	*Protothaca thaca*	1, 3a, 3b, 3c, 3d, 10	4, 5
Clam, Littleneck	*Protothaca staminea Protothaca tenerrima, Tapes philippinarum.*	1, 3a, 3b, 3c, 3d, 10	4, 5
Clam, Manila	*Tapes semidecussata*	1, 3a, 3b, 3c, 3d, 10	4, 5
Clam, Pismo	*Tivela stultorum*	1, 3a, 3b, 3c, 3d, 10	4, 5

[1] See Table of Contents for key to hazards.
Reminder: See process hazard tables beginning on p. 70 for hazards that apply to your product.

Example 3

Species-Related Hazards and Controls No. 1

Hazard No. 1 (Safety)—Chemical Contamination Other Than Methyl Mercury

Contamination of Raw Material at Receipt with Pesticides, Radioactivity, Toxic Elements, and Industrial Chemicals, Derived From the Harvest Area.

Hazard Statement

Fish and molluscan shellfish may be harvested from waters that are exposed to varying amounts of environmental contaminants. Industrial chemicals, pesticides, and many toxic elements may accumulate in fish at levels that can cause public health problems. Concern for these contaminants primarily focuses on fish and shellfish harvested from fresh water, estuaries, and near-coastal waters rather than from the open ocean. Pesticides and herbicides used near aquaculture operations or for other purposes may contaminate fish and fishery products.

Federal tolerances or action levels are established for some of the most toxic and persistent contaminants that are found in fish and fishery products shipped in interstate commerce. (These contaminants and their corresponding limits are listed below.) When products exceed these limits, FDA can seize the contaminated fish and fishery products.

States often use the limits for deciding whether to issue consumption advisories or to close or classify waters for harvesting. Molluscan shellfish waters are controlled by the State Shellfish Control Agency (SSCA) or the equivalent in foreign countries that have Memoranda of Understanding with the United States that permit them to export molluscan shellfish to this country. If local or regional contaminants are not covered by federal limits, contact local health departments to decide if contaminant levels in fish and fishery products are of public health concern.

The control measures provided in this section are appropriate for the control of methyl mercury contamination in fish, where such contamination is the result of industrial contamination in a harvest area. Recommended controls for the problem of open ocean species, such as swordfish and shark, concentrating methyl mercury from their diet and its diffuse presence in the environment are provided in the "Mercury" hazard section.

Critical Control Point: Receiving

There are five options for control at this critical control point.

Option 1

Where the firm receives wild caught fish, other than molluscan shellfish, directly from the fisher or from a supplier that has credible knowledge of the harvest area location (e.g., a tender or related company that pools fish from various fishers), the following applies:

Control Measures

1. Find out the harvest area location for each lot or batch from the fisher upon receipt.

2. Find out whether the harvest area is closed to fishing by foreign, Federal, State or local health authorities due to known instances of chemical contamination.

3. Reject fish that have been caught in a closed area.

Example

ABC Fish Co. has contacted the State Department of Health and learned that the Long River is closed to commercial harvest above Lookout Point, including its tributaries, due to the presence of chlordecone (Kepone™). The species affected are croaker, bluefish, and striped bass. ABC Fish Co., which processes these species, will reject any of the listed species originating from the area.

Frequency

1. For finding out the location: each lot or batch.

2. For finding out whether the harvest area is closed: before accepting fish from a new area and after that at least quarterly.

3. For rejecting fish: each lot or batch that does not meet the critical limit.

Critical Limits

Zero tolerance for fish (i.e., accept no fish) harvested from areas closed by foreign, State, or local health authorities due to chemical contamination.

Records

A record for each lot or batch that shows the harvest area for the fish. Record may be the receipt from the fisher, if it shows the harvest area, or it may be a notation on another record of the location of harvest for each lot or batch. The description of the location should be clear enough to show that the fish were harvested from an area that is open to harvesting. Longitude and latitude may be necessary (e.g., for open ocean harvesting).

Corrective Actions

Destroy or recall product that fails to meet the critical limit.

Any critical limit deviation should cause a timely assessment by management to: Decide whether the process or HACCP plan needs changing to reduce the risk of recurrence of the deviation, and to take appropriate followup action.

Option 2

Where the firm receives raw fish, other than molluscan shellfish, directly from the aquacultural or maricultural producer or from a supplier that has credible knowledge of the harvest area location (e.g., a tender or related company that pools fish from various aquaculturists), the following applies:

Control Measures

1. Find out the harvest area location for each lot or batch of aquacultured fish.

2. Find out the potential for chemical contamination before receipt of the product. This can be done by obtaining or reviewing the results of analysis of soil, water, and raw fish samples, as needed. Monitor agricultural and industrial practices in the aquacultural or maricultural production area.

3. Reject fish that have been grown in an area where uses of agricultural or industrial chemicals are likely to have caused contamination of the growing and harvesting environment or where soil, water, or fish sample results show chemical contamination.

Example

ABC Fish Co., which receives pond-raised catfish from the Long River delta area, screens potential pond sites either directly or by obtaining results of the aquaculturists' analyses of soil and water samples.

The samples are analyzed for pesticides, PCB's, dioxins, and petrochemicals. Either ABC Fish Co. representatives visit each pond to assess the potential for ongoing chemical contamination, or information is obtained from the U.S. Department of Agriculture Extension Service about the use of pesticides and herbicides near each pond. Where there is a potential for pond contamination, annual samples are collected and analyzed for the same contaminants. Fish that come from contaminated or suspect ponds are rejected.

Frequency

1. For finding out the location: each lot or batch.

2. For learning the potential for contamination: before accepting fish from a new growing area, and annually, after that if there is a potential for ongoing contamination of the growing area.

3. For rejecting fish: each lot or batch that does not meet the critical limit.

Critical Limits

Zero tolerance for fish (i.e., accept no fish) produced in an area where uses of agricultural or industrial chemicals are likely to have caused contamination of the growing and harvesting environment.

Records

Record that shows the production area for each lot of raw material. Records describing the assessed risk of chemical contamination for all producers.

Corrective Actions

Destroy or recall product that fails to meet the critical limit.

Any critical limit deviation should cause a timely assessment by management to: Learn whether the process or HACCP plan needs modification to reduce the risk of recurrence of the deviation, and take appropriate followup action.

Option 3

Where the firm receives fish, other than molluscan shellfish, from someone other than the fisher, aquacultural producer, or a supplier that has credible knowledge of the harvest area location (e.g., a transportation company that pools fish from various fishers or aquaculturists), the following applies:

Control Measures

1. Periodically monitor the incoming fish for environmentally persistent organochlorine pesticides which have the potential to be present in the fish. These should include, but are not limited to: DDT and its degradation products (DDE, TDE), chlordane, and heptachlor, also similar chlorinated industrial chemicals, such as PCB's and dioxins. Sampling should represent all suppliers (i.e., three samples per supplier per year).

2. Reject all shipments from suppliers that provide fish that exceed the critical limits unless convincing evidence can be obtained that only acceptable harvest or growing areas are now being used.

Example

ABC Fish Co. receives brown shrimp from an interstate seafood transportation company. The carrier, which buys the shrimp directly from the fishers, makes no effort to learn the harvest location. ABC Fish Co. collects three samples per supplier per year and sends them to a contract laboratory for pesticide screening. When positive test results are obtained, the firm stops using that supplier.

Frequency

1. For sampling incoming fish: three times per supplier per year.
2. For rejecting fish: each lot or batch that does not meet the critical limit.

Critical Limits

All limits are for the edible portion of the fish product, and are based on wet weight:

- Aldrin plus dieldrin, chlordane, endrin, heptachlor plus heptachlor epoxide, and chlordecone (Kepone™): 0.3 ppm in edible portion (except chlordecone in crabmeat 0.4 parts per million(ppm)) (CPG 7141.01);
- DDT plus TDE plus DDE: 5 ppm (CPG 7141.01);
- Mirex: 0.1 ppm (CPG 7141.01);
- Toxaphene: 5.0 ppm in edible portion (CPG 7141.01);
- PCB's: 2 ppm [CPG 7108.19 and CFR 109. 30 (A)];
- Methyl mercury: 1 ppm (CPG 7108.07).

Records

Records of analytical results from the firm's own laboratory or contract laboratory(s).

Corrective Actions

Destroy or recall product that fails to meet the critical limit.

Any critical limit deviation should cause a timely assessment by management to: Learn whether the process or HACCP plan needs changing to reduce the risk of recurrence of the deviation, and take appropriate followup action.

Option 4

Where the firm receives inshell molluscan shellfish, the following applies:

Control Measures

1. Find out the harvest area location from the harvester's tag on the containers of shellfish for each lot or batch of shellfish.
2. Check the harvester's state commercial fishing license or compare the dealer's certification number to those listed in the most current edition of the "Interstate Certified Shellfish Shippers List (ICSSL)." If the dealer is not listed, check for certification with the SSCA or equivalent.
3. Find out whether the harvest area is closed (i.e. classified as prohibited) to fishing by a SSCA or equivalent due to chemical contamination.
4. Reject molluscan shellfish harvested from a closed (i.e., classified as prohibited) area, or delivered by an unlicensed harvester or uncertified dealer, or those not properly tagged.

Example

The ABC Fish Co. distributes clams, muscles, and oysters to restaurants. The shellfish are received from other processors. The firm examines the labels of the containers in each lot to learn the name, address, and certification number of the last processor. This information is compared to the ICSSL to confirm that the product is from a certified processor. Containers from uncertified processors and inadequately labeled containers are rejected. Contact the State Department of Health to confirm certification for unlisted processors.

Frequency

1. For finding out the location: each lot or batch.
2. For checking licenses and certification: each lot or batch.
3. For finding out whether the harvest area is closed: before accepting shellfish from a new area and as often after that as necessary to ensure accuracy.
4. For rejecting molluscan shellfish: each lot or batch that does not meet the critical limit.

Critical Limits

Zero tolerance for molluscan shellfish (i.e., accept no molluscan shellfish) harvested from areas closed (i.e. classified as prohibited) by a SSCA or equivalent due to chemical contamination.

Zero tolerance for molluscan shellfish (i.e., accept no molluscan shellfish) delivered by a harvester that is unlicensed or a processor that is not certified by a SSCA or equivalent.

Zero tolerance for molluscan shellfish (i.e., accept no molluscan shellfish) that do not bear a tag on each container that contains the following information, at a minimum: harvester's name, address, the harvester number assigned by the SSCA or equivalent; date of harvest; location of harvest by state and site; type and quantity of shellfish. Bulk shipments should be identified by a bill-of-lading that contains the same information.

Records

A record for each lot or batch that shows the information from the harvester tag or bill of lading, including: name of harvester, address, identification number, the date of harvest, location of harvest by state and site, quantity and type of shellfish.

Corrective Actions

Destroy or recall product which fails to meet the critical limit.

Any critical limit deviation should cause a timely assessment by management to: learn whether the process or HACCP plan needs changing to reduce the risk of recurrence of the deviation, and take appropriate followup action.

Option 5

Where the firm receives shucked molluscan shellfish, the following applies:

Control Measures

1. Find out the name, address, and certification number of the last processor from the containers of shucked molluscan shellfish in each lot or batch.
2. Compare the dealer's certification number to those listed in the most current edition of the "Interstate Certified Shellfish Shippers List" (ICSSL), which is published monthly. If the dealer is not listed, check for certification with the SSCA or equivalent.
3. Reject molluscan shellfish not from a dealer certified by a SSCA or equivalent, packed in containers not bearing the name, address, and certification number of the last processor.

Example

ABC Fish Co. receives shucked oysters from other processors. The firm examines the labels of the containers in each lot to learn the name, address, and certification number of the last processor. This information is compared to the current ICSSL to confirm that the product is from a certified processor. Containers from uncertified processors and inadequately labeled containers are rejected. The firm contacts the State Department of Health to confirm certification for unlisted processors.

Frequency

1. For finding the certification number: each lot or batch.
2. For finding out if the processor is certified: each lot or batch.
3. For rejecting uncertified molluscan shellfish: each batch that does not meet the critical limit.

Critical Limits

Zero tolerance for molluscan shellfish (i.e., accept no molluscan shellfish) from an uncertified processor.

Zero tolerance for molluscan shellfish (i.e., accept no molluscan shellfish) packed in containers that do not list the name, address, and certification number of the last processor.

Records

Record for each lot or batch that shows the date of receipt, type and quantity of shellfish, and name and certification number of the last processor.

Corrective Actions

Destroy or recall product that does not meet the critical limit.

Any critical limit deviation should cause a timely assessment by management to: Learn whether the process or HACCP plan needs changing to reduce the risk of recurrence of the deviation, and take appropriate followup action.

Example 4

Section III

TABLE 3.—PROCESS-RELATED HAZARDS AND CONTROLS LIST PRODUCTS

Finished product	Safety hazards	Nonsafety hazards
Cooked crustacean meat, cooked crustacean sections, whole crustaceans (except shrimp).	3b[1], 6[2], 7, 8b, 13b, 14b, 15b 16[3], 17	2[4], 3c[1], 8c, 13c, 14c, 15c, 18, 19
Cooked shrimp	6, 7, 8b, 13b, 14b, 15b, 16[3], 17	3c, 8c, 13c, 14c, 15c, 18, 20
Surimi-based analog products	6, 7, 8b, 13b, 14b, 15b, 16, 17	1, 8c, 13c, 14c, 15c, 18, 21
Pasteurized crustacean meat and pasteurized surimi-based analog products (in addition to hazards identified above).	11, 12	
Coldsmoked fish (including spreads and dips)	3a[5]b, 5, 7, 9a[5]b, 13a[5]b, 14a[5]b, 15a[5]b, 16[3], 17.	3c, 9c, 13c, 14c, 15c, 18, 19
Hotsmoked fish (including spreads, dips, sausages, and jerkies)	3a[5], 5, 6, 7, 8a[5]b, 13a[5]b, 14a[5]b, 15a[5]b, 16[3], 17.	3c, 8c, 13c, 14c, 15c, 18, 19

[1] This hazard applies only if a cooked raw material or molluscan shellfish is used.
[2] This hazard does not apply to blue crab (*Callinectes sapidus*), dungeness crab (Cancer magister), or king crab (*Paralithodes spp.*) and golden crab (*Lithodes aequispina*).
[3] This hazard applies only to those products that are mechanically produced.
[4] This hazard applies only to live raw material.
[5] This hazard applies only for scombriod-type species. See Vertebrate Hazard List (Hazard 6-Histamine).

Example 5

Process-Related Hazard and Control No. 11

Hazard No. 11 (Safety)—Pathogen Survival During Pasteurization

Hazard Statement

Survival of *Clostridium botulinum* (*C. botulinum* type E) or other microorganisms of public health concern, through the pasteurization process is a food safety hazard for cooked, ready-to-eat products packed in hermetically sealed containers and held refrigerated. Pasteurization is a process applied to a fish or fishery product after that fish or fishery product has been placed in a final, hermetically sealed package. The process involves the application of sufficient heat (or other processes) for a sufficient time to cause the reduction of microorganisms of public health concern to levels that, under normal conditions of storage, are unlikely to cause disease. *C. botulinum* type E is a pathogenic microorganism that may be found in fish and fishery products.

Botulism is a severe type of food poisoning caused by the ingestion of foods containing the potent neurotoxin formed during the growth of *C. botulinum*. *C. botulinum* type E can grow and produce toxin at temperatures as low as 3.3 °C (38 °F), and must, therefore, be eliminated from the hermetically sealed container during the pasteurization process. Pasteurized products that are stored, distributed, and displayed in the frozen state, and are so labeled, are not similarly at risk, and need not be subjected to the constraints of these control measures.

For there to be assurance that the pasteurization step effectively eliminates the microorganisms of public health significance (e.g., *C. botulinum* type E), a minimum acceptable process should be scientifically established. This requires expert knowledge of thermal process calculations. Procedures used in establishing the minimum thermal process should be those that are generally recognized and accepted. Sometimes, thermal death time, heat penetration, and inoculated pack studies will be necessary to establish the minimum process. In other instances, existing literature is sufficient to provide the processor with a minimum process.

In either case, characteristics of the process and/or the product will necessarily affect the ability of the cook step to effectively eliminate the microorganisms of public health significance. Such factors should be considered in the establishment of the process. Where control of those factors is necessary to consistently achieve that goal, the process authority should specify these to the processor.

It is necessary that the pasteurizing equipment be designed and operated so that every unit of product receives the established minimum process. This will require that a competent process authority, who is thoroughly familiar with the dynamics of heat transfer in processing equipment, evaluate the design and operation of the type of equipment used by the processor. Sometimes temperature distribution studies will be necessary to establish the adequacy of the equipment. In other instances existing literature will be sufficient to establish the adequacy of the equipment.

Critical Control Point: Pasteurization Control Measures

1. Make sure that the pasteurization process that is being used was designed to ensure an appropriate reduction in the numbers of viable microorganisms of public health concern. The adequacy of the pasteurization process should be established by a process authority. The pasteurization process that is being used should meet any factors of the process or of the product that are identified by the process authority as critical to achieving pathogen destruction. At a minimum, these critical factors should include pasteurizing times and temperatures.

2. Make sure that the pasteurization equipment being used is properly designed and operated to deliver the process established by the process authority. The engineering specifications of the equipment being used (e.g., pipe sizes, flow rates, loading pattern) should meet or exceed that of the equipment evaluated by a process authority.

3. Deliver the pasteurization process in a way that there is no deviation from the minimum established pasteurization critical factors.

4. Monitor the pasteurization temperature with a temperature recording device (i.e., temperature recorder). The temperature recorder should be installed where it can be easily read and the sensor for the device should be installed to ensure that it accurately measures the coldest temperature of the pasteurizing equipment. The temperature recorder must show a continuous record of the process. Computerized storage of temperature data may be used for a temperature recorder chart if the use of such a system has been validated and can be shown to be equivalent to the use of a temperature recorder.

5. Check the accuracy of each temperature recorder at the beginning and end of each production day and adjust it as necessary to agree as nearly as possible with a temperature indicating device (mercury-in-glass thermometer or equivalent device). The thermometer should be installed where it can be easily read and placed to ensure that it accurately measures the coldest temperature of the pasteurizing equipment.

6. Calibrate the thermometer at the pasteurizing temperature against an accurate standard thermometer. This should be done when the thermometer is installed and at least once a year after that, or more frequently, if necessary, to ensure its accuracy.

7. Monitor the length of the pasteurization cycle.

8. Monitor other critical factors (e.g., initial temperature, container size, product formulation) at the start of each shift or when the product changes during a shift.

Example

The ABC Crab Co. produces pasteurized crabmeat. The pasteurization process being used has been established by the university extension service (a process authority). The process provided by the extension service includes limits on how to stack the canned product into the pasteurizer, the process

temperature, and the length of time needed to achieve proper pasteurization.

The pasteurization equipment being used by ABC Crab Co. is at least equivalent to that described by the information received from the extension service. It is equipped with both a mercury-in-glass thermometer and a recording thermometer. The recording thermometer is compared to the mercury-in-glass thermometer during each pasteurization cycle. It is adjusted as necessary to meet the critical limit. The mercury-in-glass thermometer is calibrated at an independent laboratory every 6 months. The temperature of each pasteurization cycle is controlled to meet the critical limits using the mercury-in-glass thermometer and the length of each cycle is controlled using a wall clock. The loading of the cans is checked before starting each batch.

Frequency

1. For making sure that the pasteurization process was properly established: before using a pasteurization process.
2. For making sure that the pasteurizing equipment is properly designed: before using pasteurizing equipment.
3. For properly delivering the process: each lot or batch.
4. For monitoring the temperature: each lot or batch.
5. For checking the accuracy of the temperature recorder: at the beginning and end of each production day.
6. For calibrating the thermometer: at installation and at least annually after that.
7. For monitoring the length of the pasteurizing cycle: each lot or batch.
8. For monitoring other critical factors: as often as necessary to achieve control.

Critical Limits

Zero tolerance for product produced with a deviation from the minimum established pasteurization process, including such critical factors as time, temperature, initial temperature, container size, and product formulation.

The temperature-indicating device should agree within 1 °C (±2 °F) of the National Institute of Standards and Technology (NIST) traceable thermometer.

The temperature recording device should be adjusted to agree as nearly as possible, but never to be higher, than the temperature indicating device.

Records

A record that describes the results of a scientific evaluation, conducted by a process authority, of the adequacy of the pasteurizing process. Such document may consist of, but is not limited to, a letter from a process authority, articles in scientific journals, or Federal, State, or local government regulations or advisories.

A record that describes the results of a scientific evaluation, conducted by a process authority, which applies to the design and operation of the type of equipment used by the processor.

A record for each lot or batch that shows the results of the pasteurization process. The records should include: the time of day that the pasteurization temperature is achieved; the time of day that the pasteurization cycle ends; the time of day that the product is placed in the water; and, as appropriate, the product size, belt speed (continuous pasteurizer), the temperature at the time that the processing starts, and any other factors of the process or of the product that are identified by the process authority as being critical to achieving pathogen reduction.

Temperature recorder charts or computerized temperature data storage. A record of calibration for thermometers that specify the date, standard against which the thermometers were compared (NIST-traceable thermometer), procedure used, results, and person performing the test.

A record of accuracy checks for the temperature recorder that specifies the time, date, temperatures shown by the thermometer and temperature recorder before adjustment, the corrective action taken, and person performing the accuracy check.

Records of process evaluation by the process authority, where deviations from critical limits occurred.

Corrective Actions

When there has been a failure to maintain appropriate temperature, time, or other critical factors of the process or of the product, within the critical limits, the affected product should be:

- destroyed;
- reprocessed to eliminate the hazard, keeping full records of the processing conditions; or,
- segregated and held until an evaluation can be made to determine the effect of a deviation. The evaluation should be made by a process authority following recognized procedures. Unless the evaluation shows that the product has received adequate pasteurization, the product should be destroyed or reprocessed to eliminate the hazard.

Indicating or recording thermometers that cannot be adjusted to within the critical limits should be repaired or replaced. A thermometer that has a divided fluid column should be immediately repaired or replaced.

Any critical limit deviation should cause a timely assessment by management to: Learn whether the process or HACCP plan needs changing to reduce the risk of recurrence of the deviation, and take appropriate followup action.

Example 6

General Guidance for Smoked and Smoke-Flavored Fishery Products

1. General guidance for smoked and smoke-flavored fishery products
2. Definitions
3. Critical control points
4. Thawing
5. Brining and smoking
6. Post-smoking
7. Temperature monitoring equipment
8. Packaging
9. Corrective actions
10. Sanitary zones
11. Alternative parameters

1. General guidance for smoked and smoke-flavored fishery products

This section provides consolidated guidance on how to meet the requirements of subpart A of 21 CFR part 123, for the processing of smoked and smoke-flavored fishery products. This guidance involves processing procedures for the control of the microbiological hazards to which these products are particularly susceptible. The guidance does not apply to finnan haddie, smoked cod fillets, smoked scotch kippers, or other smoked fish that are cooked before being consumed, because these products will be heated to destroy any potential toxins or pathogens. The guidance also does not apply to smoked fishery products that are packaged in hermetically sealed containers, processed to destroy spores of nonproteolytic *C. botulinum* types B, E, and F, and stored and distributed refrigerated, in the same container. These products are covered by Appendix A relating to Cooked, Ready-to-Eat fishery products. In addition, the guidance does not cover environmental or other hazards that might occur before the processor takes possession of its product or raw materials. (Guidance on these hazards may be found in a separate guidance document for all fish and fishery products issued by FDA.)

2. Definitions

a. *Cold-process smoked or cold-process smoked-flavored fish* means the finished food prepared by subjecting forms of smoked fish and smoke-flavored fish to heat for a period of time that does not coagulate the protein.

b. *Hot-process smoked or hot-process smoke-flavored fish* means the finished food prepared by subjecting forms of smoked fish and smoke-flavored fish to sufficient heat for a sufficient period of time to coagulate protein throughout the fish.

c. *Liquid smoke* means an aqueous solution of wood smoke which, when suitably diluted, may be used to impart a smoke flavor to fish products.

d. *Loin muscle* means the longitudinal quarter of the great lateral muscle of the fish that is free from skin, scales, visible blood clots, bones, gills, and from the nonstriated part of such muscle, which part is known anatomically as "the median superficial muscle."

e. *Modified atmosphere-packaging* means the food-packaging technique in which the air in a package or container is replaced by one or more gases, in various concentrations, before sealing. The purpose of this type of packaging is to extend the refrigerated shelf life of the product by limiting microbial growth or detrimental chemical changes in the food.

f. *Smoked-flavored fish* means fish that is prepared by treating it with salt (sodium chloride) and then imparting to it the flavor of smoke by other than the direct action of smoke, such as immersing it in a solution of liquid smoke. This paragraph does not alter the labeling requirements under § 101.22 of this chapter.

g. *Smoked fish* means fish that is prepared by treating it with salt (sodium chloride) and then subjecting it to the direct action of smoke from burning wood, sawdust, or similar material.

h. *Sodium nitrite content* means the concentration in parts per million of sodium nitrite in the loin muscle of the finished product as determined by the method of

analysis for sodium nitrite in the "Official Methods of Analysis of the Association of Official Analytical Chemists," 15th ed. (1990).

i. *Vacuum-packaged* means the food-packaging technique in which the air in a package or container is removed before sealing.

j. *Water-phase salt content* means the percent salt (sodium chloride) in the finished product as determined by the method of analysis for water-phase salt on the "Official Methods of Analysis of the Association of Official Analytical Chemists," 15th ed. (1990). It is measured in the loin muscle of whole, dressed fish and in the thickest part of cuts of fish.

3. Critical Control Points

Hazards Analysis Critical Control Point (HACCP) plans prepared in accordance with subpart A of 21 CFR part 123, will typically identify and address the following critical control points:

a. Raw material thawing
b. Brining or dry salting
c. Drying
d. Smoking
e. Cooling after smoking
f. Post-smoke processing, if any
g. Final product cooling
h. Refrigerated storage
i. Distribution

In accordance with subpart A of 21 CFR part 123, processors shall identify in their HACCP plans how they will control hazards at critical control points. The measures in sections 4 through 11 of this guidance are suitable for HACCP plans.

4. Thawing

Thawing should be carried out in as rapid a manner as possible, so that the internal temperature at the core of the fish does not exceed 40 °F (4.4 °C).

5. Brining and smoking

a. Products covered by this guidance should be subjected to one of the following processes:

(1) Hot-process smoked or hot-process smoke-flavored fish to be air packaged needs to be heated to a continuous internal temperature of at least 145 °F (63 °C) throughout each fish for a minimum of 30 minutes, and brined to contain not less than 3.0 percent water-phase salt in the finished product (except that smoked chub containing sodium nitrite as provided for in § 172.177 of this chapter must be processed as described in that section); or

(2) Hot-process smoked or hot-process smoked-flavored fish to be vacuum packaged, modified atmosphere packaged, or controlled atmosphere packaged, needs to be heated to a continuous internal temperature of at least 145 °F (63 °C) throughout each fish for a minimum of 30 minutes. It also needs to be brined to contain not less than 3.5 percent water-phase salt in the finished product. However, where sodium nitrite is present at not less than 100 parts per million (as permitted by §§ 172.175 and 172.177 of this chapter) the water-phase salt content in the finished product should not be less than 3.0 percent; or

(3) Cold-process smoked fish and cold-process smoke-flavored fish to be air-packaged should be brined or dry salted to contain at least 3.5 percent water-phase salt in the finished product. However, when such fish contains not less than 100 parts per million sodium nitrite, it should contain not less than 3.0 percent water-phase salt in the finished product. When cold-process smoked fish or cold-process smoked-flavored fish to be air-packaged is frozen immediately after smoking and cooling, and remains frozen throughout subsequent storage and distribution, it should contain not less than 2.5 percent water-phase salt in the finished product. Cold smoked and cold smoke-flavored fish to be air packaged should be processed under one of the following sets of conditions:

(i) The temperature in the smoking chamber does not exceed 90 °F (32 °C) during a drying and smoking period that does not exceed 20 hours, or

(ii) The temperature in the smoking chamber does not exceed 50 °F (10 °C) during a drying and smoking period that does not exceed 24 hours.

(iii) For sablefish, the temperature in the smoking chamber does not exceed 120 °F (49 °C) during a drying and smoking period that does not exceed 6 hours; or

(4) Cold-process smoked fish and cold-process smoke-flavored fish, to be vacuum packaged, modified atmosphere packaged, or controlled atmosphere packaged should be brined to contain at least 3.0 percent water-phase salt in the finished product and not less than 100 parts per million of sodium nitrite (where permitted by §§ 172.175 and 172.177 of this chapter) and should be processed as described in section 5(a)(3)(i) or (a)(3)(ii) of this Appendix. If sodium nitrite is not used, the water-phase salt content in the finished product should be at least 3.5 percent.

b. Brining and dry salting operations should be conducted in a manner that will consistently result in the water phase salt content or sodium nitrite level (where permitted by §§ 172.175 and 172.177 of this chapter) recommended by section 5.a. of this Appendix. This should be achieved by conducting or obtaining a study that establishes that the appropriate salt content or sodium nitrite level is always met under prescribed processing conditions. The study should establish the limits of significant variables that could affect the ability of the product to reach the appropriate levels. These variables may include product size, product condition, soak time, soak temperature, salt-to-water ratio, and product-to-brine ratio. An adequate study should consist of at least three processing runs under the prescribed processing conditions. In this case, the processor should monitor and record the prescribed processing conditions identified by the study at least every 2 hours.

c. The brining of all fish should take place in a refrigerated area at 40 °F (4.4 °C) or lower.

d. The temperature of the brine should not exceed 60 °F (15.6 °C) at the start of brining. The temperature of the brine at the start of the each brining process should be determined and recorded.

e. For dry salting, the fish should be returned to a refrigerated area of 40 °F (4.4 °C) or lower immediately after the application of the salt.

f. Different species of fish and fish of dissimilar size and weight should not be mixed in the same brining tank.

g. Brines should not be reused unless they are subject to a process that effectively returns them to a microbiological condition equivalent to the original, unused brine made with potable water and food-grade salt.

h. Fish may be rinsed with potable water after brining.

i. Drying of a product to be cold-smoked should be carried out in a refrigerated area at 40 °F (4.4 °C) or below.

j. Smoking operation.

(1) Fish should be arranged without overcrowding and without touching each other within the smokehouse oven or chamber to permit uniform smoke absorption, heat exposure, and dehydration. Fish smoked in the same smoke chamber load should be of relatively uniform size and weight.

(2) Liquid smoke, generated smoke, or a combination of liquid smoke and generated smoke needs to be applied to all surfaces of the product. Liquid smoke may be applied to the product before, at the beginning, or during the process. If only generated smoke is to be used, it needs to be applied to the fish during the first half of the process. If a combination of liquid smoke and generated smoke is used, the generated smoke may be applied at any stage of the process.

k. Each smoking chamber should be equipped with a temperature recording device to indicate the temperature of the air and of the fish within the smoking chamber. Additionally, each chamber should be equipped with a temperature indicating device to indicate the temperature of the air within the smoking chamber.

l. During hot-smoking or cold-smoking, a temperature recording device should be used to monitor both the internal temperature of the fish and the ambient temperature of the smoking chamber. The internal temperature readings should be obtained by inserting probes from the temperature recording device into the thickest flesh portion of three or more of the largest fish in the smoking chamber. The temperature from the slowest heating fish should be considered the processing temperature.

6. Post-Smoking

a. *Cooling after smoking.* After smoking, the product needs to be rapidly cooled to minimize recontamination. Continuous cooling from 140 °F (60 °C) to achieve an internal temperature of 70 °F (21.1 °C) or below within 2 hours and an internal temperature of 40 °F (4.4 °C) or below within an additional 4 hours, unless processing after smoking as described in section 6.b. of this Appendix, occurs during either of these time periods, will effectively minimize recontamination. Other time/temperature parameters may also be effective. Processors should ensure that the cooling parameters are met by either:

(1) *Monitoring.* Monitoring and recording internal product temperatures at least every 2 hours; or

(2) *Studies.*

i. Conducting or obtaining a study that establishes that appropriate cooling temperatures are always met under prescribed processing conditions. The study should establish the limits of significant variables that could affect the rate of cooling. These variables may include product size, ambient air temperature, and amount of product in the cooler. An adequate study should consist of at least three processing runs under the prescribed processing conditions; and

ii. Monitoring and recording the prescribed processing conditions as identified by the study in section 6.a.2.i. of this Appendix at least every 2 hours.

b. *Processing after smoking.* Products that will receive processing after smoking should not be exposed to ambient temperatures of 40 °F (4.4 °C) or higher for longer than a cumulative total of 4 hours after smoking. If they are exposed to such temperatures for more than 4 hours, unacceptable recontamination is the likely result. Processors are required to regularly monitor and record the length of time that the product is exposed to temperatures above 40 °F (4.4 °C) under 21 CFR 123.8. FDA recommends that such monitoring and recording be done at least every 2 hours.

c. *Final product cooling.* To avoid microbiological hazards for perishable finished products, the internal temperature of the finished product should be 40 °F (4.4 °C) or below within 4 hours of placement in a finished product container. Processors should either conduct:

(1) *Monitoring.* Monitor and record internal product temperatures at least every 2 hours; or

(2) *Studies.*

i. Conduct or obtain a study that establishes that the internal temperature of the finished product will always be 40 °F (4.4 °C) or below within 4 hours of placement in a finished product container under prescribed processing conditions. The study should establish the limits of significant variables that could affect the rate of cooling. These variables may include product size, ambient air temperature, and amount of product in the cooler. An adequate study should consist of at least three processing runs under the prescribed processing conditions; and

ii. Monitoring and recording the prescribed processing conditions as identified by the study in section 6.c.2.i. of this Appendix at least every 2 hours.

d. *Refrigerated storage.*

(1) *In-process products.* Refrigeration units that are being used to store in-process products or finished products must operate at a temperature of 40 °F (4.4 °C) or below in accordance with 21 CFR 123.10(a)(14).

(2) *Temperature devices.* Units should be equipped with both a temperature-indicating device and a temperature-recording device. In lieu of a temperature-recording device, a processor may equip a refrigeration unit with a high temperature alarm or a maximum-indicating thermometer and maintain a temperature log that notes temperature with such frequency as is necessary to achieve control.

e. *Distribution.* All perishable finished products should be distributed in a manner that ensures that the internal temperature is maintained at 40 °F (4.4 °C) or below.

7. Temperature Monitoring Equipment

Where reference is made in this Appendix to temperature-indicating devices and temperature-recording devices, the following conditions should apply:

a. *Temperature-indicating devices.* Temperature-indicating devices should be installed where they can be easily read and located to ensure that they accurately measure the warmest temperature of the refrigeration equipment and the coldest temperature of the smoking equipment, as appropriate. Temperature-indicating devices should be calibrated at the routine operating temperature of the refrigeration, cooling, or smoking equipment against a known accurate standard thermometer upon installation and at least once a year thereafter, or more frequently, if necessary, to ensure their accuracy. Records of accuracy checks for temperature-indicating devices required to be maintained under 21 CFR 123.8 should specify the date, standard used, method used, results, and person performing the test. A temperature-indicating device that has a divided fluid column or that cannot be adjusted to the standard should be immediately repaired or replaced.

b. *Temperature-recording devices.* Temperature-recording devices should be installed where they can be easily read and the sensors for such devices should be installed to ensure that they accurately measure the warmest temperature of the refrigeration equipment and the coldest temperature of the smoking equipment, as appropriate. Computerized storage of temperature data may be used in place of recorder thermometer charts if the use of such a system has been validated and can be shown to be substantially equivalent to the use of a temperature-recording device. Each temperature-recording device should be checked for accuracy at the beginning and end of each production day and adjusted as necessary to agree as nearly as possible with the reference temperature-indicating device. A record of these accuracy checks should be maintained that specifies the time, date, temperatures indicated by both devices before adjustment, corrective action taken, where applicable, and person performing the accuracy check.

8. Packaging

a. Vacuum- or modified atmosphere-packaging should be conducted only within the facilities in which the product is produced.

b. Permanently legible code marks should be placed on each finished product package and shipping container. These marks should identify the plant where the product was packed and the date of packing.

9. Corrective Action

Under 21 CFR 123.7, whenever a deviation occurs at a critical control point, the processor is required to segregate and hold the product until a review can be made to determine the effect of that deviation and take corrective action as necessary. For smoked and smoke-flavored fishery products, when a deviation occurs at a brining or smoking critical control point, the processor should meet the requirements of § 123.7 either by destroying the product; by fully reprocessing, where possible, that portion of the production involved, keeping full records of the reprocessing conditions; or by setting aside that portion of the product involved for further evaluation as to any potential public health significance. Such an evaluation should be made by a process authority and should be in accordance with procedures recognized by process authorities as being adequate to detect any unacceptable hazard to public health. Unless this evaluation demonstrates that the product had been rendered safe for its intended use, the product set aside should be either fully reprocessed to correct the deficiency or destroyed. A record should be made of the evaluation procedures used and the results. Either upon completion of full reprocessing or after the determination that no significant public health hazard exists, that portion of the product involved may be shipped in normal distribution. Otherwise, the portion of the product involved should be destroyed.

10. Sanitary Zones

In addition to the requirements of 21 CFR 123.10, sanitary zones should be established around areas in which a smoked product is handled or stored. In such areas, objects and employees that have come into contact with waste, raw product, or other insanitary objects are excluded. Packaging material, equipment, employees, and in-process materials that enter a sanitary zone should be treated in a manner that will minimize the risk of the introduction of microorganisms. Air handling systems should be designed to minimize the risk of airborne contamination into sanitary zones and to provide positive air pressure in the sanitary zone relative to the surrounding areas.

11. Alternative Parameters

A processor of smoked or smoke-flavored fishery products may use parameters other than those provided in Appendix C, section 5.a., if those parameters will achieve the following, as demonstrated by adequate scientific studies:

(1) For botulism, zero toxin production in the product through a time period slightly beyond the shelf life of the product, demonstrated through inoculated pack studies under normal and moderate abuse conditions, and

(2) For listeria, no detectable *Listeria monocytogenes* in the final product. A processor using alternative parameters should have on file, subject to the requirements of 21 CFR 123.8(d), a description, including the results of, the scientific studies.

Example 7

Section VI

Model HACCP Plan

Establishment Name _____
Establishment Address _____
Mailing Address _____

Date and Authorization of HACCP Plan(s) Activation:

Product _____
Critical Control Point _____

1. What is the hazard at this critical control point?
2. Describe your control measures.
3. What is your frequency of control?
4. What are your critical limits?
5. What records are kept of control measures?
6. What corrective action will you take when the product fails to meet the critical limits?

[FR Doc. 94–1592 Filed 1–21–94; 4:31 pm]
BILLING CODE 4160–01–P

federal register

Friday
January 28, 1994

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 310, et al.

Amendment of Final Monograph for Over-the-Counter Antihistamine Drug Products; Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 310, 341, and 369

[Docket No. 76N–052H]

RIN 0905–AA06

Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Amendment of Final Monograph for OTC Antihistamine Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the final monograph for over-the-counter (OTC) antihistamine drug products to include the ingredient doxylamine succinate. FDA is issuing this final rule after considering extensive information concerning this ingredient and the recommendations of its Nonprescription Drugs Advisory Committee (NDAC), which met on June 28, 1993, to consider potential labeling for doxylamine succinate regarding the results of toxicology testing conducted under the National Toxicology Program (NTP). This final rule is part of the ongoing review of OTC drug products conducted by FDA.

EFFECTIVE DATE: January 30, 1995.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD–810), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 9, 1976 (41 FR 38312), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking for OTC cold, cough, allergy, bronchodilator, and antiasthmatic drug products. In that notice, the Advisory Review Panel on OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products (the Panel) recommended that doxylamine succinate be generally recognized as safe and effective (Category I) as an OTC antihistamine at a dosage level of 7.5 to 12.5 milligrams (mg) (41 FR 38312 at 38385 through 38387). At that time, the agency concluded that doxylamine succinate should remain a prescription drug at dosage levels above 7.5 mg because it causes a high incidence of drowsiness compared to other OTC antihistamines (41 FR 38312 at 38313). Subsequently, after evaluating extensive data on the safety of doxylamine succinate, the agency determined that doxylamine succinate could be marketed OTC at the Panel's recommended dosage. In the **Federal Register** of August 24, 1987 (52 FR 31892 at 31893 through 31903), the agency proposed monograph status at dosages of 7.5 to 12.5 mg. No comments were received in response to this proposal.

In 1991, the agency received a report of a study on doxylamine succinate conducted by the National Center for Toxicological Research (NCTR) (Ref. 1). The results of this study were under consideration when the agency published the final monograph on OTC antihistamine drug products on December 9, 1992 (57 FR 58356). Accordingly, the agency deferred a decision on doxylamine succinate at that time.

The NCTR technical report concerns a 2-year carcinogenicity and chronic toxicity study of doxylamine succinate in Fischer 344 rats and B6C3F1 mice. The study was conducted under the auspices of the NTP. The study was prompted by the National Cancer Institute's finding that methapyrilene, a similar antihistamine, is a potent liver carcinogen in the rat (Ref. 2). Methapyrilene was removed from the market in 1979. The NCTR study on doxylamine succinate was reviewed by the agency's Pulmonary-Allergy Drugs Advisory Committee (the P-A Committee) on June 13 and 14, 1991 (Ref. 3).

In the NCTR study (Ref. 1), doxylamine succinate was administered, ad libitum, as an admixture in the feed to male and female rats at dose levels of 0, 500, 1,000, or 2,000 parts per million (ppm) for 2 years. Mice of both sexes received food containing dose levels of 0, 190, 375, or 750 ppm. Each group contained 48 weanling animals per sex; the animals were scheduled for sacrifice at the end of 104 weeks. An additional group of animals (9 rats and 12 mice per sex) in each dose group was sacrificed at the end of 65 weeks. There were no significant treatment-related differences in survival in either rats or mice. In rats, the highest doxylamine succinate dose group had final body weights that were 22.8 percent (females) and 8.4 percent (males) lower than controls. A number of nonneoplastic lesions was observed in rats, including fatty change, degeneration, and hyperplasia of the liver and increased cytoplasmic alteration in the salivary glands. In mice, there was evidence of hepatotoxicity including hypertrophy, clear and mixed cell foci, and, in females, fatty change. There also was a treatment-related increase in "atypical" hepatocytes in male mice. Both male and female mice had a dose-related increase in thyroid follicular cell hyperplasia. There was a positive trend for increased incidence with increasing dose for both hepatocellular adenomas and carcinomas in male rats. When the incidence of adenomas and carcinomas was combined, the statistical test was positive ($p < 0.01$) and the incidence in the highest dose group was significantly ($p < 0.05$) increased over that of controls. No treatment-related increase in neoplasms was found in female rats. Although not statistically significant, one rat in each of the high dose groups of male and female rats was found to have a pineal gland tumor, which is an extremely rare neoplasm in rats. In mice, doxylamine succinate administration produced an increased incidence of hepatocellular adenoma in both males ($p < 0.001$) and females ($p < 0.001$). Also, there was an increased incidence of follicular cell adenoma of the thyroid gland in male ($p < 0.05$) and female ($p < 0.0001$) mice.

Although the rodent tumorigenicity studies were positive, doxylamine succinate tested negative overall in in vitro tests for genotoxic activity (causing damage to deoxyribonucleic acid (DNA)). Based on the overall assessment, the tumorigenic responses observed in the rodent bioassays may relate to secondary mechanisms involving the induction of liver microsomal enzymes, cytotoxicity, cell proliferation, promotion of tumor potential in pre-existing susceptible cells, or other processes. Such mechanisms may represent species-specific effects or threshold phenomena applicable to rodents (under the conditions of the bioassay), but these mechanisms are considered of questionable significance in humans.

Due to uncertainty concerning the relevance of these findings to human use, the agency asked its P-A Committee and a number of consulting experts to evaluate the data and to advise the agency on whether doxylamine succinate should continue to be marketed OTC. By a vote of five to one, the P-A Committee concluded at its June 13 and 14, 1991, meeting that doxylamine succinate is not likely to have human carcinogenic potential. Again, by the same vote, the P-A Committee recommended that doxylamine succinate could remain OTC, but that consumers should be alerted that these data exist. The P-A Committee discussed labeling as a preferred means of providing this

information (Ref. 3, pp. 175 through 182).

FDA subsequently developed possible labeling that could be used. This labeling included the warning: "Use of this product may be hazardous to your health. This product contains doxylamine succinate which has been determined to produce tumors in laboratory animals." The agency requested the views of a national trade association of OTC drug manufacturers on this suggested warning (Ref. 4). In response, the association asserted that such a warning would be inappropriate (Ref. 5). The association stated that such a warning: (1) Would not ensure safe and effective product use by consumers; (2) is not based on sound scientific data known to be relevant to the human condition; (3) is not understood and actionable, in a meaningful way, by consumers; and (4) might reduce the impact of other warnings and occupy scarce label space.

The association argued that the proposed warning does not meet the criteria of section 502(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(c)). This part of the statute requires labeling information to be presented in "terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use." The association contended that the proposed warning effectively shifts the burden of determining product safety from the agency to the consumer and then does not tell the consumer what action to take. In a subsequent communication (Ref. 6), the association further argued that a warning statement in the labeling of doxylamine products is not justified because the scientific data do not suggest a significant risk to humans, that such a warning would be unprecedented, and that a label warning is not the appropriate means for disclosing this information.

In 1992, the agency established a new advisory committee specifically for the review of OTC drugs, the Nonprescription Drugs Advisory Committee (NDAC). The agency asked NDAC to consider the issue of a tumor statement in the labeling of OTC drug products containing doxylamine succinate at its June 28, 1993, meeting. The agency presented a summary of the NCTR data, possible labeling, and legal and compliance issues (Ref. 7). Other interested parties presented their positions. The agency asked NDAC to consider the following questions: (1) Should a labeling statement be used to inform consumers in place of other alternative approaches (no warning, prescription only status, removal from all marketing, etc.)? (2) Is there a desirable risk-to-benefit relationship for labeling? (3) If the answer to both questions is yes, what information should be included in the labeling and what language should be used that would be easily understood by the average consumer? (4) How should information be presented to the consumer (i.e., under the "Warning" or some other heading, visible at the point of purchase, on the immediate container, or in a package insert) and should the information indicate that the product could be "hazardous" to health?

After considering the available evidence, NDAC voted unanimously (10 to 0) to reaffirm the P-A Committee's recommendation that doxylamine succinate remain OTC. NDAC also recommended (10 to 0) that there be no specific statement about tumors in the labeling and urged FDA to write a fully descriptive article on the subject in the "FDA Consumer" magazine.

The agency has considered the two advisory committees' recommendations and concludes that doxylamine succinate is safe and effective for OTC use as an antihistamine. Accordingly, the agency is including doxylamine succinate in the final monograph for OTC antihistamine drug products. The agency is also developing an "FDA Consumer" article and has issued a talk paper concerning the NCTR findings in animals to inform consumers of these data and the uncertainty of their relevance to humans.

References

(1) Department of Health and Human Services, NCTR, "Technical Report for Experiments 406 and 407; Chronic Study of Doxylamine in Fischer 344 Rats and B6C3F1 Mice," 1991, in OTC vol. 04HFM, Docket No. 76N–052H, Dockets Management Branch.

(2) Lijinsky, W., M. D. Reuber, and B. N. Blackwell, "Liver Tumors Induced in Rats by Chronic Oral Administration of the Common Antihistamine Methapyrilene Hydrochloride," Science, 209:817–819, 1980.

(3) Transcript of the June 13 and 14, 1991, meeting of the FDA Pulmonary–Allergy Drugs Advisory Committee, coded RPT 5, Docket No. 76N–052H, Dockets Management Branch.

(4) Letter from W. E. Gilbertson, FDA, to R. W. Soller, NDMA, coded LET 91, Docket No. 76N–052H, Dockets Management Branch.

(5) Letter from R. W. Soller, NDMA, to W. E. Gilbertson, FDA, coded C216, Docket No. 76N–052H, Dockets Management Branch.

(6) Letter from R. W. Soller, NDMA, to W. E. Gilbertson, FDA, coded C224, Docket No. 76N–052H, Dockets Management Branch.

(7) Transcript of the June 28, 1993, meeting of the FDA Nonprescription Drugs Advisory Committee, vol. I, pp. 6–89, coded TR 2, Docket No. 76N–052H, Dockets Management Branch.

The agency has examined the economic consequences of this final rule and has determined that it does not require either a regulatory impact analysis, as specified in Executive Order 12866, or a regulatory flexibility analysis, as defined in the Regulatory Flexibility Act (Pub. L. 96–354). This rulemaking for OTC antihistamine drug products is not expected to have an impact on small businesses. Doxylamine succinate remains available OTC. No product reformulations will be required. Some minor relabeling will be necessary to meet the conditions of the final monograph. Manufacturers will have 1 year to implement this relabeling. Thus, the impact of the final rule appears to be minimal. Therefore, the agency concludes that the final rule is not a major rule as defined in Executive Order 12866. Further, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act.

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

The agency is removing the exemption for certain drugs limited by new drug applications (NDA) to prescription sale in § 310.201(a)(13) (applicable to doxylamine succinate preparations) because most portions of that exemption are superseded by the requirements of the antihistamine final monograph (21 CFR part 341). Section 310.201(a)(13) does not apply to the use of doxylamine succinate as a nighttime sleep-aid, for which an NDA is required for marketing.

List of Subjects

21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 341

Labeling, Over-the-counter drugs.

21 CFR Part 369

Labeling, Medical devices, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 310, 341, and 369 are amended as follows:

PART 310—NEW DRUGS

2. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 512–516, 520, 601(a), 701, 704, 705, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 360b–360f, 360j, 361(a), 371, 374, 375, 379e); secs. 215, 301, 302(a), 351, 354–360F of the Public Health Service Act (42 U.S.C. 216, 241, 242(a), 262, 263b–263n).

§ 310.201 [Amended]

2. Section 310.201 *Exemption for certain drugs limited by new-drug applications to prescription sale* is amended by removing paragraph (a)(13) and reserving it.

PART 341—COLD, COUGH, ALLERGY, BRONCHODILATOR, AND ANTIASTHMATIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

3. The authority citation for 21 CFR part 341 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).4. Section 341.12 is amended by adding new paragraph (h) to read as follows:

§ 341.12 Antihistamine active ingredients.

* * * * *

(h) Doxylamine succinate.

* * * * *

5. Section 341.72 is amended by revising the heading of paragraphs (c)(4) and (c)(6)(iii) and by adding new paragraph (d)(8) to read as follows:

§ 341.72 Labeling of antihistamine drug products.

* * * * *

(c) * * *

(4) *For products containing diphenhydramine citrate, diphenhydramine hydrochloride, or doxylamine succinate identified in § 341.12(f), (g), and (h).* * * *

* * * * *

(6) * * *

(iii) *For products containing diphenhydramine citrate, diphenhydramine hydrochloride, or doxylamine succinate identified in § 341.12(f), (g), and (h).* * * *

(d) * * *

(8) *For products containing doxylamine succinate identified in § 341.12(h).* Adults and children 12 years of age and over: oral dosage is 7.5 to 12.5 milligrams every 4 to 6 hours, not to exceed 75 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: oral dosage is 3.75 to 6.25 milligrams every 4 to 6 hours, not to exceed 37.5 milligrams in 24 hours, or as directed by a doctor. Children under 6 years of age: consult a doctor.

* * * * *

6. Section 341.90 is amended by adding new paragraph (l) to read as follows:

§ 341.90 Professional labeling.

* * * * *

(l) *For products containing doxylamine succinate identified in § 341.12(h).* Children 2 to under 6 years of age: oral dosage is 1.9 to 3.125 milligrams every 4 to 6 hours, not to exceed 18.75 milligrams in 24 hours.

* * * * *

PART 369—INTERPRETATIVE STATEMENTS RE WARNINGS ON DRUGS AND DEVICES FOR OVER-THE-COUNTER SALE

7. The authority citation for 21 CFR part 369 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 371).

§ 369.21 [Amended]

8. Section 369.21 Drugs; warning and caution statements required by regulations is amended by revising the introductory text of the entry for "ANTIHISTAMINICS, ORAL (PHENYLTOLOXAMINE DIHYDROGEN CITRATE, DOXYLAMINE SUCCINATE, AND CHLOROTHEN CITRATE PREPARATIONS)" to read "ANTIHISTAMINICS, ORAL (PHENYLTOLOXAMINE DIHYDROGEN CITRATE AND CHLOROTHEN CITRATE PREPARATIONS). (See § 310.201(a)(4) and (a)(24) of this chapter.)"

* * * * *

Dated: January 24, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 94–1792 Filed 1–27–94; 8:45 am]

BILLING CODE 4160–01–F

federal register

Friday
January 28, 1994

Part IV

Department of Education

34 CFR Part 692

State Student Incentive Grant Program; Rule

DEPARTMENT OF EDUCATION

34 CFR Part 692

RIN 1840–AB72

State Student Incentive Grant Program

AGENCY: Department of Education.

ACTION: Final regulations.

SUMMARY: The Secretary amends the State Student Incentive Grant (SSIG) Program regulations to clarify them, to make minor technical changes, and to implement statutory changes made by the Higher Education Amendments of 1992 to the Higher Education Act of 1965, as amended (HEA).

EFFECTIVE DATE: These regulations take effect either 45 days after publication in the **Federal Register** or later if the Congress takes certain adjournments. If you want to know the effective date of these regulations, call or write the Department of Education contact person. A document announcing the effective date will be published in the **Federal Register.**

FOR FURTHER INFORMATION CONTACT: Dan Sullivan, U.S. Department of Education, 400 Maryland Avenue, SW., room 4018, ROB–3, Washington, DC 20202–5447. Telephone: (202) 708–4607. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The Secretary is revising the existing SSIG Program regulations to implement statutory changes required by the Higher Education Amendments of 1992, enacted July 23, 1992 (Pub. L. 102–325) (1992 amendments), which amend the HEA. These revised regulations also change the SSIG Program regulations to reduce burden and clarify existing rules.

The SSIG Program provides financial incentives for States to establish and to maintain financial assistance programs that make grants and provide work-study assistance to students with substantial financial need.

The SSIG Program supports National Education Goal 5, which calls for every adult American to be literate and possess the knowledge and skills necessary to compete in a global economy and exercise the rights and responsibilities of citizenship.

On July 2, 1993, the Secretary published a notice of proposed rulemaking (NPRM) for this program in the **Federal Register** (58 FR 36110). The major issues addressed by the proposed regulations are discussed in the preamble to the NPRM. There are two major differences between the NPRM and the final regulations. The first change is to revise the allotment formula above the "hold-harmless" allotment of Federal funds each State received in fiscal year 1979 under the SSIG Program. The "hold-harmless" amount of Federal funds is the SSIG Program allotment each State received in fiscal year 1979. Under section 415B(a)(1) of the program statute, if an appropriation exceeds the fiscal year 1979 appropriation, each State still would continue to receive at least its "hold-harmless" amount regardless of the results of the allotment formula. Based on the comments received, a change was made in the final regulations to revise the allotment formula above the "hold-harmless" level by redefining the term "deemed eligible." The Secretary determines the number of students "deemed eligible" to participate in a State's SSIG Program by dividing the amount of each State's SSIG expenditures, including both its Federal allotment and the State-appropriated funds matching the allotment, by the average grant award per student of all participating States. The Secretary determines the "average grant award per student" by dividing the total number of student recipients for all States into the total amount of SSIG expenditures for all States, including both the Federal allotment and the State-appropriated funds matching the allotment. In making this determination, the Secretary uses the most recently available data reported by each State. The Secretary will allot additional SSIG funds to States above their "hold-harmless" amounts by using the following steps:

(1) Calculate the States' number of students "deemed eligible" to participate in a State's SSIG Program by dividing the amount of each State's SSIG funds expenditures, including both its Federal allotment and the State-appropriated funds matching the allotment, by the average grant award per student of all participating States.

(2) Calculate the States' projected allotments by dividing each State's number of students "deemed eligible" by the total number of students "deemed eligible" for all States, and then multiply that number by the appropriation.

(3) Compare each State's projected allotment calculated in step 2 to its "hold-harmless" amount and select only States where the projected allotment exceeds the "hold-harmless" amount.

(4) For the States selected in step 3, calculate the amount the Secretary will allot above the "hold-harmless" amount to each of these States by dividing each of the selected State's number of students "deemed eligible" by the total "deemed eligible" students for all of the selected States and then multiply that number by the amount of the appropriation above the total "hold-harmless" amount.

The other change under § 692.41(b) provides that, upon a showing of good cause, the Secretary may approve a State's definition for "independent student" that varies from that term as defined in section 480(d) of the HEA.

Analysis of Comments and Changes

Fifteen commenters responded to the Secretary's invitation to comment on the NPRM. The following is an analysis of comments and changes in the regulations since publication of the NPRM. Substantative issues are discussed under the section of the regulations to which they pertain. Technical and other minor changes to the language published in the NPRM—and requests for changes the Secretary is not legally authorized to make under the applicable statutory authority—may not be addressed.

Section 692.10 How Does the Secretary Allot Funds to the States?

Comment: Three commenters agreed with the revision in § 692.10(b) of the proposed regulations to redefine students who are "deemed eligible" to participate in the SSIG Program as students who were reported by the State as SSIG recipients in the most recently available performance report data.

Several commenters objected to the use of State-reported SSIG recipients in the most recently available performance report data as students who are "deemed eligible" to participate in the SSIG Program. These commenters believed that the number of recipients could be easily manipulated by States by inflating the number of awards to students. Rather than provide substantial awards to the most needy students, States could inflate the number of students deemed eligible by providing smaller awards to a larger number of students in order to receive a larger share of program funding above the hold-harmless amount.

A few commenters believed that the current allotment formula for awarding SSIG funds above the hold-harmless amount should not be amended. These commenters felt that the current allotment formula based on the enrollment data for each State is more objective and meaningful in distributing funds for the SSIG Program.

Two commenters recommended that the allotment formula above the hold-

harmless level should be based on the amount of funds actually expended by each State to match its Federal allotment.

Discussion: The Secretary is amending the current allotment formula for awarding funds above the hold-harmless level because it does not conform to section 415B(a)(1) of the HEA. Section 415B(a)(1) was amended by the Higher Education Amendments of 1986 (Pub. L. 99–498), but the SSIG Program regulations were not amended to conform with this statutory change.

The Secretary is changing the allotment formula for funds above the hold-harmless level to one that counts, for purposes of making allotments to States, the number of students "deemed eligible" to participate in a State's SSIG Program as determined by the following formula. The Secretary divides the amount of each State's SSIG expenditures, including both its Federal allotment and the State-appropriated funds matching the allotment, by the average grant award per student of all participating States in the most recent award year as reported by the State. The Secretary determines the "average grant award per student" by dividing the total number of student recipients for all States into the total amount of SSIG expenditures for all States, including both the Federal allotment and the State-appropriated funds matching the allotment.

In the past, the Secretary has provided extreme flexibility to States in implementing the SSIG Program statute. It is the Secretary's experience that mere head counts do not accurately reflect the participation of States in the joint Federal-State SSIG Program. Moreover, this change responds to the concerns raised by some commenters that States might manipulate a head-count of recipients and the concerns raised by other commenters that funding should be based on the actual matching expenditures of the States. Furthermore, the Secretary collects the Federal and State SSIG funding data and average grant award per student from each State's most recent SSIG Program performance report. By using the most recently available performance report data, the States will not be required to conduct a new data collection.

Under section 415B(a)(1) of the program statute, this formula would be used only if an appropriation exceeds the fiscal year 1979 appropriation. Each State still receives at least its "hold-harmless" amount. The Secretary believes that by considering the amount of State SSIG expenditures in the calculation of the number of students "deemed eligible," States are provided with incentive to increase the amount of funds they allocate to their SSIG Programs. In this way, States that provide more State dollars will receive more Federal SSIG funds above the "hold-harmless" amount, the allotment each State received in fiscal year 1979 under the SSIG Program. For States to exceed the allotment of funds beyond the "hold harmless" amount, States would have to elect to include more of their State grant funds under the SSIG Program in their calculation under § 692.10(b).

The Secretary believes that the change encourages the inclusion of additional State funds in the SSIG Program and, as a result, would stabilize the grant funds available to students from the States. The Secretary also believes that the revised formula provides for the best use of Federal funds under the program by: (1) Rewarding States that have made a strong commitment of their State grant funds to the SSIG Program as reflected by the States' amount of State grant funds; and (2) encouraging States to maintain or expand their commitment of their level of expenditures for State grant programs.

Changes: A change has been made. The Secretary has amended § 692.10(b) to provide that the Secretary determines the number of students "deemed eligible" to participate in a State's SSIG Program by dividing the amount of each State's SSIG expenditures, including both its Federal allotment and the State-appropriated funds matching the allotment, by the average grant award per student of all participating States. The Secretary determines the "average grant award per student" by dividing the total number of student recipients for all States into the total amount of SSIG expenditures for all States, including both the Federal allotment and the State-appropriated funds matching the allotment. In making this determination, the Secretary uses the most recently available data reported by each State.

Section 692.21 What Requirements Must Be Met by a State Program?

Comment: One commenter stated that the Secretary should clarify § 692.21(e) concerning whether fees may or may not be collected in the case of decentralized State grant programs under which institutions award State grant funds as well as institutional aid.

Discussion: If there is a fee for submitting and processing the State information on a form to make a determination of financial need under the SSIG Program, the fee must be payable to the State regardless of whether the information may also be used for institutional aid. In the case of a decentralized State grant program under which institutions participating in the State's SSIG Program award State grant funds, funds awarded under these programs are still considered to be State aid and not institutional aid. It is the responsibility of each State to ensure that institutions participating in the State's SSIG Program conform with this requirement.

Changes: None.

Comment: Two commenters stated that the term "reasonable" as listed in § 692.21(g) should be clearly defined by the Secretary with some specific parameters provided.

Discussion: Section 692.21(g) provides that, if a State awards grants to independent students or to students who are less-than-full-time students enrolled in an institution of higher education, a reasonable portion of the State's allocation must be awarded to those students. The Secretary believes that in order to provide the States with the maximum amount of flexibility under this provision, no specific parameters for the term "reasonable" should be provided. The Secretary on a case-by-case basis, if necessary, will determine the reasonableness of the allocation.

Changes: None.

Comment: A few commenters believed that under § 692.21(g), the Secretary requires that a State must award SSIG Program grants to independent students or to students who are less-than-full-time students in reasonable proportion to the State's allocation of SSIG Program funds.

One commenter believed it was unwise to reserve a portion of very limited need-based grant aid for less-than-full-time students because of the overwhelming numbers of very needy full-time students who cannot be served due to lack of adequate funding.

Discussion: Section 692.21(g) provides that, if a State awards grants to independent students or to students who are less-than-full-time students enrolled in an institution of higher education, a reasonable portion of the State's allocation must be awarded to those students. Neither the program statute nor § 692.21(g) requires a State to award grants to independent students or students who are less-than-full-time. If the State's allocation from the Secretary is based on a formula that includes the financial need of students who are independent or attend an institution less-than-full-time, then the State must ensure that those students receive a reasonable proportion of SSIG funds.

Changes: None.

Section 692.21 What Requirements Must be met by a State Program? and Section 692.41 What Standards May a State Use to Determine Substantial Financial Need?

Comment: Several commenters objected to the proposed requirement in § 692.41(b) that States use the term "independent student" as defined by section 480(d) of the HEA in a State's own need-analysis system or a need-analysis system combining the State's system with the Federal system under part F of title IV of the HEA in order to obtain the Secretary's approval of the State's system.

Some commenters believed that the use of the Federal definition infringes upon the State's right to set priorities for administering State grant funds and would limit the State's flexibility in awarding these funds.

Some commenters also believed that they should have the flexibility to use their own State statutory or regulatory definition of "independent student" and report any variance with the Federal definition on the State's annual application to participate in the program.

One commenter was concerned that, if the regulations are adopted as proposed, the States should be given an opportunity to amend their statutory or regulatory definitions of "independent student" to conform with the Federal definition by making the effective date of the provision begin with the 1995–96 award year. This effective date would provide the States with time to amend their statutory or regulatory independent student definitions to conform with the Federal definition.

One commenter was concerned regarding whether the students selected for SSIG matching purposes by a State would reflect the proportion of independent students in the State program. The commenter believed that the Secretary could achieve the intent of the Higher Education Amendments of 1992 by allowing States to submit changes to their applications and programs. Each State's application would specify the proportion of independent students as defined in the State's approved need-analysis system which are in the base used to allocate funds and the means by which the State would ensure a proportionate distribution of SSIG Program funds to independent students.

Discussion: The Secretary agrees with the concerns raised by commenters who believed that the proposed requirement in § 692.41(b) would create difficulties for some States in administering the SSIG Program. The Secretary, therefore, is revising § 692.41(b) to provide that, upon the review and approval of the Secretary, a State may use its own definition for "independent student" that varies from the Federal definition of the term as defined in section 480(d) of the HEA. The Secretary will approve a variant definition on a case-by-case basis. States that wish to use a variant definition of "independent student," other than the Federal definition, must provide information concerning their "independent student" definition at the time of application for program funds that includes a justification, with accompanying supporting documentation, demonstrating "good cause" as to why the Secretary should approve the variant definition.

The Secretary believes that States that have a valid reason to use a different independent student definition should be accommodated, as long as the use of a different definition is reasonably justified and does not place significant additional reporting burdens on applicants. The Secretary believes that a valid reason for requesting a variance might include that excessive costs to the State are incurred in implementing the Federal definition. The Secretary will also take into consideration in approving a definition the extent to which the new definition imposes additional data requirements beyond those provided for by the Federal definition and the Federal Need Analysis Methodology authorized under part F of title IV of the HEA. For example, a State, rather than adopt a new definition, may decide, with the Secretary's approval, to use the Federal definition except for the professional judgment provision in section 480(d)(7) of the HEA.

The Secretary also agrees with the concerns raised by a commenter regarding whether a State, in selecting students for the SSIG Program matching purposes, would accurately reflect the proportion of independent students to all students in the State program. The Secretary believes that the State SSIG Program student funding should be comparable to the overall State program, if the entire State program is not contained in the State SSIG Program. However, the Secretary does not wish to place any unnecessary burdens on States. Therefore, the Secretary is providing a new paragraph (j) in § 692.21. Under § 692.21(j) the proportion of SSIG Program funds awarded to independent students, including both the Federal allotment and the State funds matching the allotment, must be, to the extent practicable, the same proportion of funds awarded independent students as is in the State program or programs of which the State's SSIG Program is a part.

Changes: Two changes have been made. The Secretary amends § 692.41(b) to provide that he may approve, on a case-by-case basis, the use of a definition of "independent student" that varies from the term defined in section 480(d) of the HEA if a State demonstrates "good cause" as to why a variance should be approved.

The Secretary also amends § 692.21 by adding a new paragraph (j) to provide that, to the extent practicable, the proportion of the funds awarded to independent students in the SSIG Program shall be the same proportion of funds awarded to independent students as is in the State program or programs of which the State's SSIG Program is a part.

Assessment of Educational Impact

In the notice of proposed rulemaking, the Secretary requested comments on whether the proposed regulations in this document would require transmission of information that is being gathered by or is available from any other agency or authority of the United States.

Based on the response to the proposed regulations and on its own review, the Department has determined that the regulations in this document do not require transmission of information that is being gathered by or is available from any other agency or authority of the United States.

List of Subjects in 34 CFR Part 692

Grant programs—education, Postsecondary education, State administered—education, Student Aid—education, Reporting and recordkeeping requirements.

(Catalog of Federal Domestic Assistance Number 84.096, State Student Incentive Grant Program)

Dated: January 14, 1994.

Richard W. Riley,

Secretary of Education.

The Secretary amends part 692 of title 34 of the Code of Federal Regulations as follows:

PART 692—STATE STUDENT INCENTIVE GRANT PROGRAM

1. The authority citation for part 692 is revised to read as follows:

Authority: 20 U.S.C. 1070c through 1070c–4, unless otherwise noted.

* * * * *

2. Section 692.3 is amended by revising paragraphs (b) and (d) to read as follows:

§ 692.3 What regulations apply to the State Student Incentive Grant Program?

* * * * *

(b) The Education Department General Administrative Regulations (EDGAR) as follows:

(1) 34 CFR 75.60–75.62 (Ineligibility of Certain Individuals to Receive Assistance).

(2) 34 CFR part 76 (State-Administered Programs).

(3) 34 CFR part 77 (Definitions That Apply to Department Regulations).

(4) 34 CFR part 79 (Intergovernmental Review of Department of Education Programs and Activities).

(5) 34 CFR part 80 (Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments).

(6) 34 CFR part 82 (New Restrictions on Lobbying).

(7) 34 CFR part 85 (Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants)).

(8) 34 CFR part 86 (Drug-Free Schools and Campuses).

* * * * *

(d) The Student Assistance General Provisions in 34 CFR part 668.

(Authority: 20 U.S.C. 1070c–1070c–4)

3. In § 692.4, paragraph (a) is amended by removing the terms, "Academic year (§ 668.2)", "Campus-based programs (§ 668.2)", "Guaranteed Student Loan Program (§ 668.2)", "Income Contingent Loan Program (§ 668.2)", "Pell Grant Program (§ 668.2)", "PLUS Program (§ 668.2)", and "Postsecondary vocational institution (§ 668.5)"; by redesignating paragraph (b) as paragraph (c); and by adding a new paragraph (b) to read as follows:

§ 692.4 What definitions apply to the State Student Incentive Grant Program?

* * * * *

(b) *Definitions in the HEA.* The following terms used in this part are defined in section 481(a), (b), (c), and (d) of the HEA:

Academic year
Institution of higher education
Postsecondary vocational institution
Proprietary institution of higher education

* * * * *

4. Section 692.10 is amended by revising paragraph (b) to read as follows:

§ 692.10 How does the Secretary allot funds to the States?

* * * * *

(b) For the purpose of paragraph (a)(1) of this section, the Secretary determines the number of students "deemed eligible" to participate in a State's SSIG Program by dividing the amount of that State's SSIG expenditures, including both its Federal allotment and the State-appropriated funds matching the allotment, by the average grant award per student of all participating States. The Secretary determines the "average grant award per student" by dividing the total number of student recipients for all States into the total amount of SSIG expenditures for all States, including both the Federal allotments and the State-appropriated funds matching those allotments. In making this determination, the Secretary uses the most current available data reported by each State.

5. Section 692.21 is amended by removing the periods after paragraphs (a) and (d); adding semi-colons after paragraphs (a) and (d); redesignating paragraphs (e), (f), (g), (h), and (i) as paragraphs (f), (g), (h), (i), and (k), respectively; adding new paragraphs (e) and (j); revising paragraphs (b), (c), and redesignated pargraphs (g), and (i); and revising the Office of Management and Budget control number at the end of the section to read as follows:

§ 692.21 What requirements must be met by a State program?

* * * * *

(b) Provides assistance only to students who meet the eligibility requirements in § 692.40;

(c) Provides that assistance under this program to a full-time student will not be more than $5,000 for each academic year;

* * * * *

(e) Provides that no student or parent shall be charged a fee that is payable to an organization other than the State for the purpose of collecting data to make a determination of financial need in accordance with paragraph (d) of this section;

* * * * *

(g) Provides that, if a State awards grants to independent students or to students who are less-than-full-time students enrolled in an institution of higher education, a reasonable portion of the State's allocation must be awarded to those students;

* * * * *

(i) Provides for State expenditures under the State program of an amount that is not less than—

(1) The average annual aggregate expenditures for the preceding three fiscal years; or

(2) The average annual expenditure per full-time equivalent student for those years;

(j) Provides that, to the extent practicable, the proportion of the funds awarded to independent students in the SSIG Program shall be the same proportion of funds awarded to independent students as is in the State program or programs of which the State's SSIG Program is a part; and

* * * * *

(Approved by the Office of Management and Budget under control number 1840–0660)

* * * * *

6. Section 692.30 is amended by removing the first of the duplicate paragraphs (e)(2).

7. Section 692.41 is amended by redesignating paragraphs (a), (b), and (c) as paragraphs (a) (1), (2), and (3), respectively; by designating the introductory text as the introductory text of paragraph (a); by revising paragraph (a)(1); and by adding a new paragraph (b), to read as follows:

§ 692.41 What standards may a State use to determine substantial financial need?

(a) * * *

(1) A system for determining a student's financial need under part F of title IV of the HEA;

* * * * *

(b) The Secretary generally approves a need-analysis system under paragraph (a) (2) or (3) of this section only if the need-analysis system applies the term "independent student" as defined under section 480(d) of the HEA. However, for good cause shown, the Secretary may approve, on a case-by-case basis, a State's need analysis system that uses a definition for "independent student" that varies from that term as defined in section 480(d) of the HEA.

* * * * *

[FR Doc. 94–1692 Filed 1–27–94; 8:45 am]
BILLING CODE 4000–01–P

federal register

Friday
January 28, 1994

Part V

Department of Defense

Department of the Army

Corps of Engineers

33 CFR Part 334
Restricted Area, Pacific Ocean Offshore of Camp Pendleton, CA; Rule

DEPARTMENT OF DEFENSE

Department of the Army

Corps of Engineers

33 CFR Part 334

Restricted Area, Pacific Ocean Offshore of Camp Pendleton, San Diego County, CA

AGENCY: Army Corps of Engineers, DoD.
ACTION: Final rule.

SUMMARY: This rule adopts as final, the Corps regulations contained in 33 CFR 334.905 Pacific Ocean, offshore of Camp Pendleton, California, Fallbrook restricted area, which were published in the **Federal Register** as an interim final rule on October 15, 1993.

EFFECTIVE DATE: October 15, 1993.

ADDRESSES: HQUSACE, CECW–OR, Washington, DC 20314–1000.

FOR FURTHER INFORMATION CONTACT: Ms. Elizabeth White at (619) 455–9422 or Mr. Ralph Eppard at (202) 272–1783.

SUPPLEMENTARY INFORMATION: The Commanding Officer of the Naval Weapons Station requested the Corps to establish a restricted anchorage area (identified as Fallbrook), offshore of Camp Pendleton, San Diego County, California. In accordance with Naval Sea Systems Command, OPS Volume 1 Manual, Ammunition and Explosives Ashore Safety Regulations for Handling, Storing, Production, Renovation, and Shipping, a safety distance of 9,000 feet to inhabited structures is required for the anticipated net explosive weight of 5,500,000 pounds. During loading/unloading, vessel traffic and anchorage would be restricted to a distance not closer than 5,400 feet from the vessel. The Fallbrook anchorage site has been intermittently utilized in the past and its use needs to be continued in support of replenishment operations associated with the transfer of ordnance from the Fallbrook Annex to and from naval combatants and ammunition ships. The Navy's utilization of this anchorage is expected to grow to a maximum of 10 days per month. This planned long-term utilization for replenishment operations necessitates establishment of the restricted anchorage. The Corps Los Angeles District Engineer issued a public notice on June 2, 1993, which solicited comments on this proposed restricted area to all known interested parties. The District did not receive any objections to the establishment of the restricted anchorage area. There also were no comments received in response to the interim final rule and accordingly, the rule is adopted without change.

Economic Assessment and Certification

This final rule is issued with respect to a military function of the Defense Department and the provisions of E.O. 12866 do not apply. These rules have been reviewed under the Regulatory Flexibility Act (Pub. L. 96–354), which requires the preparation of a regulatory flexibility analysis for any regulation that will have a significant economic impact on a substantial number of small businesses (i.e., small businesses and small government) jurisdictions. There is no anticipated navigational hazard or interference with existing waterway traffic. There are no recreational or commercial fishery operations presently in or using the waters within this area because of ongoing military operations. Therefore, no loss of resources or use of resources would be borne by the public. Therefore, it has been determined that this rule will not have a significant economic impact on a substantial number of small entities and that preparation of a regulatory flexibility analysis is not warranted.

List of Subjects in 33 CFR Part 334

Danger zones, Navigation (water), Transportation.

In consideration of the above, the Corps is amending part 334 of title 33 to read as follows:

PART 334—DANGER ZONE AND RESTRICTED AREA REGULATIONS

1. The authority citation for part 334 continues to read as follows:

Authority: 40 Stat. 266; (33 U.S.C. 1) and 40 Stat. 892; (33 U.S.C. 3)

2. Accordingly, the interim final rule amending 33 CFR part 334 which was published at 58 FR 53426 on October 15, 1993, is adopted as a final rule without change.

Dated: January 14, 1994.

Stanley G. Genega,

Major General, USA, Director of Civil Works.

[FR Doc. 94–1838 Filed 1–27–94; 8:45 am]
BILLING CODE 3710–92–M

federal register

Friday
January 28, 1994

Part VI

Environmental Protection Agency

National Emission Standards for Radionuclide Emissions From Facilities Licensed by the Nuclear Regulatory Commission and Federal Facilities Not Operated by the Department of Energy; Notice

ENVIRONMENTAL PROTECTION AGENCY

[FRL–4830–7]

RIN 2060–AE39

National Emissions Standards for Radionuclide Emissions From Facilities Licensed by the Nuclear Regulatory Commission and Federal Facilities Not Operated by the Department of Energy

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: This notice confirms that 40 CFR part 61, subpart I, is presently in effect for two categories: (1) Facilities licensed by the Nuclear Regulatory Commission (NRC) or NRC Agreement States except for commercial nuclear power reactors and (2) all federal facilities not operated by the Department of Energy (DOE). The effectiveness of Subpart I is presently stayed for commercial nuclear power reactors. The previous stay of Subpart I for NRC and Agreement State licensees other than nuclear power reactors expired on November 15, 1992, and has not been extended or renewed. All NRC and Agreement State licensees other than nuclear power reactors, as well as federal facilities not operated by DOE, are now subject to all applicable provisions of subpart I. Each affected facility must demonstrate compliance for calendar year 1993 with the annual emission standard set forth in 40 CFR 61.102, utilizing the procedures specified in 40 CFR 61.103. Those facilities which are not exempt from reporting requirements under 40 CFR 61.104(b) must submit the annual report concerning emissions for calendar year 1993 required by 40 CFR 61.104(a) to EPA by March 31, 1994. Facilities that are unable to gather the necessary information and report to EPA by March 31, 1994 should request an extension from the appropriate EPA regional office. EPA will consider extensions of up to 60 days.

DATES: 40 CFR part 61, subpart I became effective for NRC and Agreement State licensees other than commercial nuclear power reactors on November 16, 1992. Those facilities which are not exempt from reporting requirements under 40 CFR 61.104(b) must submit the annual report concerning emissions required by 40 CFR 61.104(a) for calendar year 1993 to EPA by March 31, 1994. Facilities that are unable to gather the necessary information and report to EPA by March 31, 1994 should request an extension from the appropriate EPA regional office. EPA will consider extensions of up to 60 days.

FOR FURTHER INFORMATION CONTACT: David P. O'Very, Air Standards and Economic Branch, Criteria and Standards Division (6602J), Office of Radiation and Indoor Air, Environmental Protection Agency, Washington, DC 20460, (202) 233–9762.

SUPPLEMENTARY INFORMATION:

I. Background

On October 31, 1989, EPA promulgated National Emission Standards for Hazardous Air Pollutants (NESHAPS) to control radionuclide emissions to the ambient air from several source categories. This rule was published in the **Federal Register** on December 15, 1989 (54 FR 51654).

Subpart I limits radionuclide emissions to the ambient air from NRC-licensed facilities to that amount which would cause any member of the public to receive in any year an effective dose equivalent (ede) of 10 millirem, of which no more than 3 millirem ede may be from radioiodines. These limits involved application to radionuclide emissions of the Agency's policy for regulating section 112 pollutants which was first announced in the benzene NESHAP (54 FR 38044 September 14, 1989), and utilized the two-step process outlined in *NRDC* v. *EPA*, 824 F.2d at 1146 (1987) (the *Vinyl Chloride* decision).

At the time of promulgation of the radionuclide NESHAPS rule, EPA granted reconsideration of subpart I based on information received late in the rulemaking from the NRC and the National Institutes of Health (NIH). The NRC was concerned about duplicative regulation of its licensees by NRC and EPA, while the NIH was concerned with the potential negative effects of the standard on the use of nuclear medicine in patient treatment. EPA subsequently extended the stay of the effective date of subpart I on several occasions, pursuant to the authority provided by section 10(d) of the Administrative Procedure Act (APA), 5 U.S.C. 705, and section 301(a) of the Clean Air Act, 42 U.S.C. 7601(a). (55 FR 10455, March 21, 1990; 55 FR 29205, July 18, 1990; and 55 FR 38057, September 17, 1990).

In 1990, Congress enacted legislation comprehensively amending the Clean Air Act, which included a section addressing the issue of regulatory duplication between EPA and NRC. Section 112(d)(9) of the CAA provides, that no standard for radionuclide emissions from any category or subcategory of facilities licensed by the Nuclear Regulatory Commission (or an Agreement State) is required to be promulgated under Section 112 if the Administrator determines, by rule, and after consultation with the Nuclear Regulatory Commission, that the regulatory program established by the Nuclear Regulatory Commission pursuant to the Atomic Energy Act for such category or subcategory provides an ample margin of safety to protect the public health. This provision enables EPA to eliminate duplication of effort between EPA and NRC so long as public health is protected with an ample margin of safety.

On April 24, 1991, EPA issued a final rule staying until November 15, 1992 the effectiveness of subpart I for all categories of facilities licensed by the NRC or NRC Agreement States except nuclear power reactors (56 FR 18735). The purpose of this stay was to avoid the costs and disruption associated with formal implementation of subpart I while EPA was collecting additional information necessary to make the substantive determination for these facilities contemplated by CAA Section 112(d)(9). NESHAPS Rulemaking on Nuclear Regulatory Commission and Agreement State Licensees Other Than Nuclear Power Reactors, EPA 430–R–92–011 (November 1992). (On August 5, 1991, EPA proposed to rescind subpart I for commercial nuclear power reactors (56 FR 37196) and issued a final rule staying the effectiveness of subpart I for nuclear power reactors during the pendency of the substantive rulemaking on rescission (56 FR 37158)).

The Natural Resources Defense Council (NRDC) petitioned for judicial review of the rule staying subpart I for NRC and Agreement State licensees other than nuclear power reactors. On September 25, 1992, the DC Circuit Court of Appeals issued a decision holding that EPA had exceeded its authority by staying subpart I while it was collecting the information required to make a finding under CAA section 112(d)(9). *NRDC* v. *Reilly*, 976 F.2d 36 (DC Cir. 1992).

EPA completed its investigation of radionuclide emissions by NRC and Agreement State licensees other than nuclear power reactors while the litigation in the DC Circuit Court concerning the rule staying subpart I for these facilities was still pending. On September 18, 1992, EPA announced that it intended to propose rescission of subpart I for these facilities and proposed a rule which would further stay subpart I during the pendency of the substantive rulemaking on rescission (57 FR 43173). Although EPA did propose to rescind subpart I for NRC and Agreement State licensees other

than nuclear power reactors on December 1, 1992 (57 FR 56877), EPA did not adopt the proposed stay. EPA concluded that the Court's ruling in *NRDC* v. *Reilly* had left substantial doubt concerning the legality of any further stay of subpart I for these facilities and decided not to issue any further stay. As a result, the rule staying subpart I for NRC and Agreement State licensees other than nuclear power reactors expired by its own terms on November 15, 1992, and subpart I took effect for these facilities on November 16, 1992 (the official mandate implementing the DC Circuit Court's decision in *NRDC* v. *Reilly* was not transmitted until after the stay had already expired).

II. Implementation of Subpart I as Applied to NRC-Licensed Facilities Other Than Nuclear Power Reactors

Subpart I became effective on November 16, 1992 for all categories of facilities licensed by NRC or Agreement States except for commercial nuclear power reactors. Subpart I was already in effect prior to that time for federal facilities not operated by DOE.

At this time, EPA has not taken final administrative action concerning the rule to rescind subpart I for NRC and Agreement State licensees other than commercial nuclear power reactors which it proposed on December 1, 1992. EPA is recommending that NRC make certain changes in its regulatory program in order to fully support the substantive finding which is required by CAA Section 112(d)(9) before EPA may rescind subpart I for NRC licensees other than commercial nuclear power reactors. EPA and NRC are presently engaged in consultations concerning specific actions which would strengthen the basis for rescission of subpart I for this category, but it is unlikely that any agreement between EPA and NRC concerning additional measures could be implemented quickly. While the rulemaking concerning rescission is still pending, EPA advises all facilities not to presume that EPA will take any particular action in that rulemaking and to proceed in the meantime with all legally required compliance activities.

Because subpart I first took effect for NRC and Agreement State licensees other than nuclear power reactors near the end of 1992, EPA has determined that affected facilities were not required to demonstrate compliance with subpart I for calendar year 1992. However, each NRC or Agreement State licensee, as well as each federal facility not operated by DOE, is now subject to all provisions of subpart I. Each affected facility must demonstrate compliance for calendar year 1993 with the annual emission standard set forth in 40 CFR 61.102, utilizing the procedures specified in 40 CFR 61.103. Those facilities which are not exempt from reporting requirements under 40 CFR 61.104(b) must submit the annual report concerning emissions for calendar year 1993 required by 40 CFR 61.104(a) to EPA by March 31, 1994. Facilities that are unable to gather the necessary information and report to EPA by March 31, 1994 should request an extension from the appropriate EPA regional office listed below. EPA will consider extensions of up to 60 days.

As required by 40 CFR 61.04, all requests, reports, applications, submittals, and other communications to EPA pursuant to the standards in subpart I should be submitted in duplicate to the appropriate Regional Office of the EPA to the attention of the Director of the Division indicated in the following list of EPA Regional Offices:

Region I (Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont), Director, Air, Pesticides, and Toxics Management Division, U.S. Environmental Protection Agency, John F. Kennedy Federal Building, Boston, MA 02203.

Region II (New Jersey, New York, Puerto Rico, Virgin Islands), Director, Air and Waste Management Division, U.S. Environmental Protection Agency, Federal Office Building, 26 Federal Plaza, New York, NY 10278.

Region III (Delaware, District of Columbia, Maryland, Pennsylvania, West Virginia), Director, Air, Toxics and Radiation Management Division, U.S. Environmental Protection Agency, 841 Chestnut St., Philadelphia, PA 19107.

Region IV (Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee), Director, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, 345 Courtland Street NE, Atlanta, GA 30365.

Region V (Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin), Director, Air and Radiation Division, U.S. Environmental Protection Agency, 77 West Jackson Blvd., Chicago, IL 60604–3590.

Region VI (Arkansas, Louisiana, New Mexico, Oklahoma, Texas), Director, Air, Pesticides, and Toxics Division, U.S. Environmental Protection Agency, 1443 Ross Avenue, Dallas, TX 75202.

Region VII (Iowa, Kansas, Missouri, Nebraska), Director, Air and Toxics Division, U.S. Environmental Protection Agency, 726 Minnesota Avenue, Kansas City, KS 66101.

Region VIII (Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming), Director, Air, Radiation, and Toxics Division, U.S. Environmental Protection Agency, 999 18th Street, Suite 500, Denver, CO 80202–2460.

Region IX (American Samoa, Arizona, California, Guam, Hawaii, Nevada), Director, Air & Toxics Division, U.S. Environmental Protection Agency, 75 Hawthorne Street, San Francisco, CA 94105.

Region X (Alaska, Oregon, Idaho, Washington), Director, Air & Toxics Division, U.S. Environmental Protection Agency, 1200 Sixth Avenue, Seattle, WA 98101.

Facility operators and owners desiring further information should write to Eleanor Thornton, Air Standards and Economic Branch, Criteria and Standards Division (6602J), Office of Radiation and Indoor Air, Environmental Protection Agency, Washington, DC 20460 to obtain a copy of EPA's Guide for Determining Compliance with the Clean Air Act Standards for Radionuclide Emissions from NRC-Licensed and Non-DOE Federal Facilities, the COMPLY computer code, and the User's Guide for the COMPLY Computer Code.

Dated: January 20, 1994.

Carol M. Browner,

Administrator.

[FR Doc. 94–1960 Filed 1–27–94; 8:45 am]

BILLING CODE 6560–50–P

federal register

Friday
January 28, 1994

Part VII

Congressional Budget Office

Transmittal of Sequestration Preview Report for Fiscal Year 1995 to Congress and the Office of Management and Budget; Notice

CONGRESSIONAL BUDGET OFFICE

Notice of Transmittal of Sequestration Preview Report for Fiscal Year 1995 to Congress and the Office of Management and Budget

Pursuant to section 254(b) of the Balanced Budget and Emergency Deficit Control Act of 1985 (2 U.S.C. 904(b)), the Congressional Budget Office hereby reports that it has submitted its Sequestration Preview Report for Fiscal Year 1995 to the House of Representatives, the Senate, and the Office of Management and Budget.

Stanley L. Greigg,

Director, Office of Intergovernmental Relations, Congressional Budget Office.

[FR Doc. 94–2188 Filed 1–27–94; 11:57 am]

BILLING CODE 4107–02–M

Reader Aids

Federal Register

Vol. 59, No. 19

Friday, January 28, 1994

INFORMATION AND ASSISTANCE

Federal Register

Index, finding aids & general information	202–523–5227
Public inspection desk	523–5215
Corrections to published documents	523–5237
Document drafting information	523–3187
Machine readable documents	523–3447

Code of Federal Regulations

Index, finding aids & general information	523–5227
Printing schedules	523–3419

Laws

Public Laws Update Service (numbers, dates, etc.)	523–6641
Additional information	523–5230

Presidential Documents

Executive orders and proclamations	523–5230
Public Papers of the Presidents	523–5230
Weekly Compilation of Presidential Documents	523–5230

The United States Government Manual

General information	523–5230

Other Services

Data base and machine readable specifications	523–3447
Guide to Record Retention Requirements	523–3187
Legal staff	523–4534
Privacy Act Compilation	523–3187
Public Laws Update Service (PLUS)	523–6641
TDD for the hearing impaired	523–5229

ELECTRONIC BULLETIN BOARD

Free **Electronic Bulletin Board** service for Public Law numbers, and Federal Register finding aids. **202–275–1538, or 275–0920**

FEDERAL REGISTER PAGES AND DATES, JANUARY

1–240.....3
241–498.....4
499–652.....5
653–946.....6
947–1262.....7
1263–1446.....10
1447–1616.....11
1617–1888.....12
1889–2280.....13
2281–2518.....14
2519–2724.....18
2725–2924.....19
2925–3312.....20
3313–3512.....21
3513–3632.....24
3633–3650.....25
3651–3770.....26
3771–3980.....27
3981–4232.....28

CFR PARTS AFFECTED DURING JANUARY

At the end of each month, the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

3 CFR

Proclamations:
6644.....1261
6645.....2722
6646.....2925
6647.....2927

Executive Orders:
11063 (Revoked in part by EO 12892).....2939
12259 (Revoked by EO 12892).....2939
12864 (Amended by EO 12890).....499
12890.....499
12891.....2935
12892.....2939

Administrative Orders:
Memorandums:
January 1, 1994.....653
Presidential Determinations:
No. 94–7 of December 18, 1993.....1
No. 94–9 of January 5, 1994.....2929
No. 94–10 of January 5, 1994.....2931
No. 94–12 of January 16, 1994.....2933

5 CFR

Ch. LXIII.....3771
110.....2945
1620.....1889

7 CFR

2.....2725
16.....3981
25.....2686
54.....1890
58.....1263
201.....655
210.....1890
215.....1890
220.....1890
253.....1447
254.....1447
272.....2725
273.....2725
276.....2725
277.....2725
301.....2281, 3313
322.....656
703.....3772
906.....1266, 1449, 1450
907.....241, 1268
908.....241, 1268
910.....1269
925.....3316
928.....1266
932.....1270
944.....1270
955.....1894
959.....1452
966.....1453
984.....1453
1106.....1273
1464.....1274
1468.....2283
1710.....494, 3982
1717.....3982
1773.....657
1902.....3776
1930.....3776
2018.....3651

Proposed Rules:
13.....2307
51.....1490
319.....3002
273.....2779
701.....1293
723.....1493
1005.....1305
1007.....1305
1011.....1305
1030.....260
1046.....1305
1065.....260
1068.....260
1076.....260
1079.....260
1094.....1307
1210.....4013
1941.....2307
1943.....2307
1945.....2307
1951.....2307

8 CFR

3.....1896
103.....1455, 1896
204.....501
212.....1467, 1992
214.....1455, 1468
223.....1455
223a.....1455
238.....1617
242.....1896
245a.....1470
248.....1455
264.....1455
292.....1455, 1896

Proposed Rules:
103.....1308, 1317
211.....1317
216.....1317
235.....1317
242.....1317

9 CFR

94.....2285
78.....2649

Proposed Rules:
Ch. III.....1499
78.....2312

94.....3029
318.....550
381.....551

10 CFR

20.....1900
26.....502
30.....1618
34.....1900
40.....1618
50.....1618
70.....1618
72.....1618
73.....661

Proposed Rules:

50.....979
51.....2542

12 CFR

325.....3779
615.....3785
935.....2945
1102.....1900

Proposed Rules:

213.....3796
230.....1921
960.....1323

13 CFR

Proposed Rules:

116.....2782
121.....1360

14 CFR

27.....3988
39.....3, 4, 507, 509, 511, 514, 1471, 1903, 1904, 1905, 1906, 1907, 1909, 1910, 1912, 1913, 2519, 2950, 2952, 3651, 3787, 3988
71.....662, 947, 1472 1619, 1620, 1621, 1623, 2953, 2954, 3409, 3788
73.....3990
91.....2918
97.....1623, 1625, 3789, 3791
121.....1780, 3936, 3990
125.....1780
127.....3936
135.....1780, 3936
145.....3936

Proposed Rules:

Ch. I.....31, 554, 1362, 2783, 3796
21.....2783
23.....2784
27.....554
29.....554
33.....703, 704, 984, 4140
39.....35, 265, 266, 555, 556, 1500, 1501, 1503, 1505, 1676, 3527, 3636, 3797, 3798
71.....706, 1677, 1679, 1680, 1681, 1683, 1684, 1686, 1687, 2316, 2454, 3032, 3409, 3801, 3802
91.....3409

15 CFR

295.....663
1180.....6

Proposed Rules:

290.....3803
990.....1062, 1189, 1190

16 CFR

Ch. I.....2955

305.....1626, 1627
453.....1592
500.....1862

17 CFR

30.....1915
1.....2286
5.....2286
239.....242

Proposed Rules:

1.....1506
30.....1506
33.....1506
190.....1506
201.....1509
202.....1509
229.....1509
240.....1509
275.....3033
279.....3033

18 CFR

161.....243
250.....243
284.....516
341.....12
342.....12
343.....12
344.....12
345.....12
347.....12
360.....12
361.....12
375.....12, 1917
385.....1628

Proposed Rules:

141.....1687, 1690
161.....268
250.....268
375.....1687
385.....1687
388.....1690

19 CFR

4.....1918
12.....110
102.....110
123.....1918
175.....1992, 2292
134.....110
356.....228

Proposed Rules:

4.....141
10.....141
12.....141
102.....141
134.....141
177.....141

20 CFR

209.....2292
266.....3990
336.....3996
404.....670, 1274, 1416, 1629
416.....1274, 1629
617.....906
621.....874
655.....874

Proposed Rules:

Ch. III.....3040
200.....2317, 2318
422.....1363

21 CFR

20.....350, 395, 531
74.....3998
76.....2293
100.....536
101.....350, 354, 378, 395, 423, 436
109.....1638
178.....2733, 3653
310.....4216
330.....3998
341.....4216
358.....4000
369.....4216
510.....1918, 1919
520.....1918, 1919, 3317
1308.....671

Proposed Rules:

Ch. I.....3040, 3042, 3043
20.....3944
101.....427
123.....4142
176.....3322
178.....3322
211.....2542
347.....2319
358.....4015
1240.....4142

22 CFR

171.....2521
41.....1473

23 CFR

Proposed Rules:

1204.....2320
1205.....2337

24 CFR

44.....2735
45.....2735
85.....2735
92.....2735
104.....1642
207.....2735
213.....2735
221.....2735
232.....2735
236.....2735
242.....2735
251.....1474
252.....1474
255.....1474
277.....2735
280.....2735
570.....2735
572.....2735
575.....2735
576.....2735
577.....2735
578.....2735
579.....2735
597.....2700
880.....2735
881.....2735
883.....2735
884.....2735
885.....2735
886.....2735
889.....2735
890.....2735
907.....3626
3280.....2456
3282.....2456

Proposed Rules:

945.....1244
960.....1244

25 CFR

23.....2248
67.....3290

Proposed Rules:

163.....3952
900.....3166

26 CFR

1.....12, 947, 1476, 2956, 2958, 3318, 4140
40.....4140
48.....4140
602.....12, 2958, 3318, 4140

Proposed Rules:

1.....807, 1690, 3045

27 CFR

9.....537
70.....2521

Proposed Rules:

4.....2548
9.....1510

28 CFR

36.....2674
301.....2666
570.....3510
571.....1238
572.....1238

Proposed Rules:

65.....558
68.....2548
81.....37
540.....2668
543.....2668
545.....1240
550.....1240
570.....3512

29 CFR

504.....874
1650.....23
1915.....146
1926.....146
1952.....2294
2610.....2295
2619.....2296
2622.....2295
2644.....2299
2676.....2296

Proposed Rules:

2530.....1692

30 CFR

904.....540
906.....2739
914.....1919
936.....2300
950.....3513, 3521

Proposed Rules:

870.....278
886.....278
887.....278
888.....278
914.....3528
917.....1921
935.....3325
944.....3530

32 CFR

40a.....1645
312.....2745
806b.....2746

Proposed Rules:

199.....3046

323.....2786

33 CFR

2.....947
3.....947
100.....673
147.....674
155.....3749
165.....675, 676, 948, 949
334.....2916, 4226
402.....2985

Proposed Rules:

117.....986

34 CFR

319.....1651
429.....1651
462.....1418
472.....1418
644.....2658
674.....1651
682.....1651
685.....472
692.....4220

Proposed Rules:

75.....2480, 2549
76.....2480
600.....2714
601.....2714
602.....3578
667.....3604
682.....2486

36 CFR

200.....2986

Proposed Rules:

292.....2787

37 CFR

2.....256

Proposed Rules:

251.....2550
252.....2550
253.....2550
254.....2550
255.....2550
256.....2550
257.....2550
258.....2550
259.....2550
301.....2550
302.....2550
303.....2550
304.....2550
305.....2550
306.....2550
307.....2550
308.....2550
309.....2550
310.....2550
311.....2550

38 CFR

4.....677, 2523, 2529

Proposed Rules:

3.....278, 3532
13.....3659

39 CFR

962.....2987

Proposed Rules:

111.....1512

40 CFR

13.....650
52.....1476, 1485, 2530, 2532, 2535, 2537, 2540, 2649, 2747, 2988, 2991, 2994, 4001, 4003
61.....542
63.....1992
152.....2748
180.....950, 951, 1652, 2751, 3654, 3655
260.....458
261.....458
271.....1275, 2752, 2998, 3792
305.....25
600.....677
707.....2999
799.....1992

Proposed Rules:

Ch. I.....1923, 3047
52.....278, 707, 988, 1513, 1693, 1695, 1698, 2795, 3047, 3534, 3540, 3544, 3804, 3808, 3809, 4016
55.....994
63.....1515
72.....3660
73.....3660
81.....707
131.....810, 3829
180.....1700, 1702, 1704, 2799, 2800
186.....2800
261.....709
300.....714, 2568
372.....1788
430.....1515
438.....4019
721.....38
761.....3660
799.....3661

41 CFR

105–57.....1277
201–17.....952
201–20.....952

Proposed Rules:

201–1.....39
201–3.....39
201–20.....39
201–39.....39

42 CFR

60.....3409
401.....108
405.....1278
410.....1278
412.....1654
413.....1278, 1654
414.....1278
421.....679
435.....1659
436.....1659
488.....108
489.....108
493.....682

Proposed Rules:

Ch. I.....3040
Ch. II.....3040
Ch. III.....3040
Ch. IV.....3040
Ch. V.....3040
406.....714

43 CFR

4.....1486

Public Land Orders:

6986.....108
7025.....2301
7026.....1489
7027.....3000

Proposed Rules:

12.....2343
403.....40
426.....997
3160.....718

44 CFR

10.....953
59.....2754
64.....4004

45 CFR

233.....3319

Proposed Rules:

Ch. II.....3040
Ch. III.....3040
Ch. IV.....3040
Ch. X.....3040
Ch. XIII.....3040
2510.....1194
2513.....1194
2515.....1194
2516.....1194
2517.....1194
2518.....1194
2519.....1194
2520.....1194
2521.....1194
2522.....1194
2523.....1194
2524.....1194
2530.....1194
2531.....1194
2532.....1194
2540.....1194

46 CFR

501.....954

Proposed Rules:

25.....2575
67.....725
114.....1994
115.....1994
116.....1994
117.....1994
118.....1994
119.....1994
120.....1994
121.....1994
122.....1994
123.....1994
124.....1994
125.....1994
126.....1994
127.....1994
128.....1994
129.....1994
130.....1994
131.....1994
132.....1994
133.....1994
134.....1994
135.....1994
136.....1994
137.....1994
138.....1994
139.....1994
160.....2575
170.....1994
171.....1994
173.....1994
175.....1994
176.....1994
177.....1994
178.....1994
179.....1994
180.....1994
181.....1994
182.....1994
183.....1994
184.....1994
185.....1994
514.....1515
571.....1923
572.....1923
580.....1515
581.....1515

47 CFR

Ch. I.....3633
0.....542
1.....542
13.....3794
22.....1285
25.....1285
73.....2301, 2302, 4007, 4008
80.....1285
87.....1285
90.....1285
95.....1285
97.....542
99.....1285

Proposed Rules:

1.....3050
15.....280
73.....41, 42, 43, 44, 726, 1365, 1366, 2343, 2344, 4020
76.....1706
90.....280
97.....558

48 CFR

5.....544
14.....544
15.....544
17.....544
25.....544
52.....544
225.....1288
252.....1288
538.....3657
552.....3657

Proposed Rules:

Ch. III.....3040
519.....2345
552.....2345

49 CFR

173.....1784
180.....1784
391.....1366
392.....1366
396.....1366
571.....2755, 3164
1051.....2303
1053.....2303
1056.....2304
1312.....2303

Proposed Rules:

195.....2802
212.....3051
234.....3051
393.....1706, 2811
571.....281
1312.....2347

50 CFR

222.....440
227.....440

611.....685
625.....257, 3320
641.....966, 3749
642.....257
650.....2757, 2777
651.....26
663.....258, 685, 698
675.....3000, 4009
676.....701
678.....3321

Proposed Rules:
17.....44, 48, 53, 288, 852, 862, 869, 997, 3067, 3326, 3811, 3824, 3825, 3829, 3830
23.....3832
222.....3068
227.....3067, 3068, 3662
285.....2813, 3838
301.....2649
630.....3328, 3838
638.....2347
661.....3327
672.....2817
675.....2817
678.....3838

LIST OF PUBLIC LAWS

Note: The list of Public Laws for the first session of the 103d Congress has been completed and will resume when bills are enacted into law during the second session of the 103d Congress, which convenes on January 25, 1994.

A cumulative list of Public Laws for the first session of the 103d Congress was published in Part IV of the **Federal Register** on January 3, 1994.

Printed on recycled paper