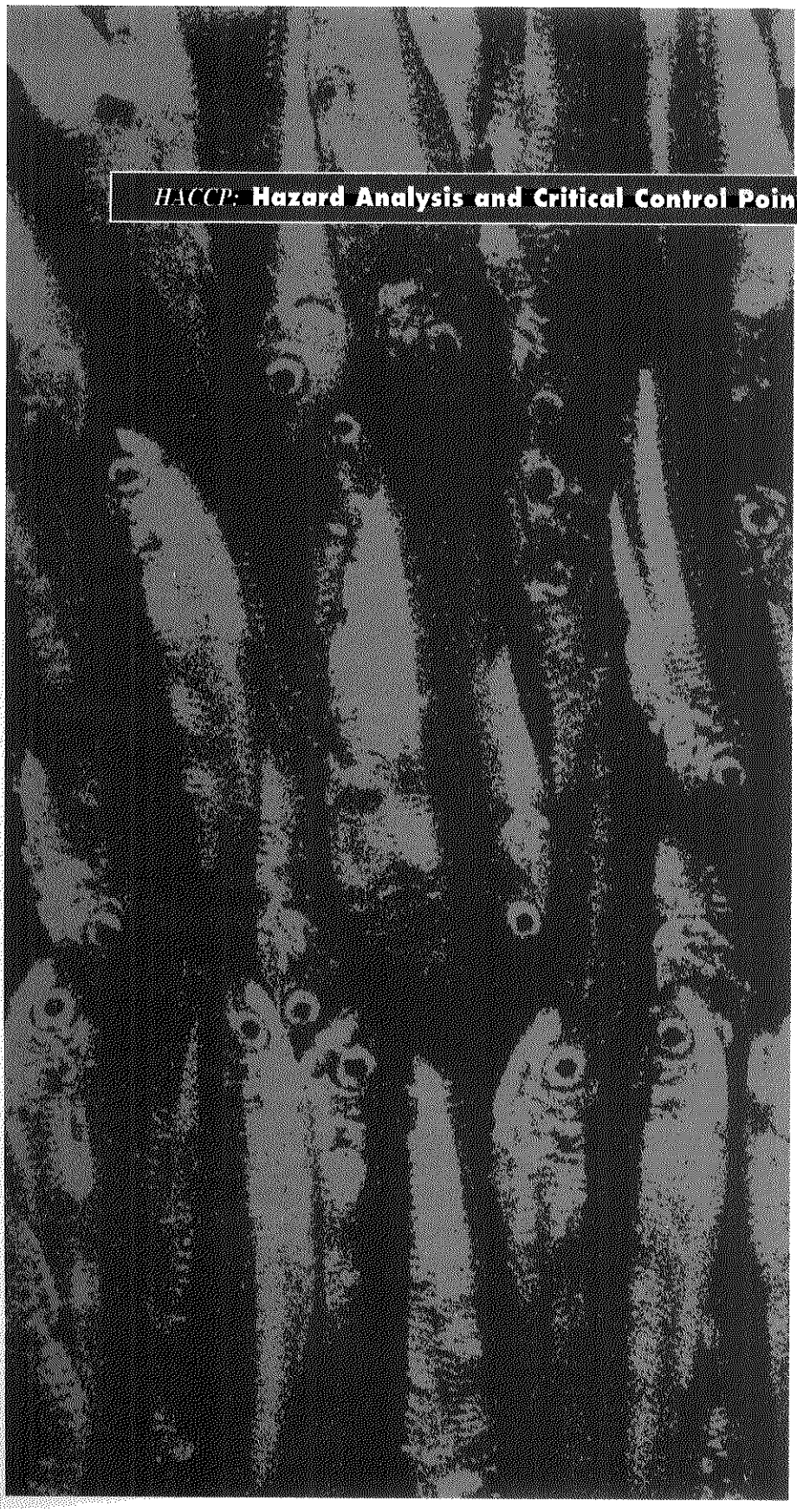
HACCP: Hazard Analysis and Critical Control Point Training Curriculum

Developed by the
National Seafood
HACCP Alliance
for Training
and Education



HACCP: Hazard Analysis and Critical Control Point Training Curriculum

Developed by the
National Seafood
HACCP Alliance
for Training
and Education

Edited by
Donn Ward,
North Carolina
State University
Kathy Hart,
North Carolina
Sea Grant

Technical Editors:
Dane Bernard,
National Food
Processors Association
Bob Collette,
National Fisheries
Institute
Don Kraemer,
U.S. Food and Drug
Administration
Steve Otwell,
University of Florida
Donn Ward,
North Carolina
State University

Introduction: National Seafood HACCP Alliance

The National Seafood HACCP Alliance for education and training began as an idea during the April 1993 National Sea Grant Forum on Seafood Safety and Quality. In conjunction with the Association of Food and Drug Officials of the Southern States (AFDOSS), the board of directors passed a resolution to advance a seafood HACCP training program. The Council of Sea Grant Directors supported a joint meeting between a selection of industry, regulatory and academic experts to explore financial support for a partnership in HACCP education. The National Sea Grant College Program approved two years of support and the first meeting of the National Seafood HACCP Alliance was held in December 1993. The alliance steering committee decided to:

- organize an alliance for HACCP training based on existing programs and established educational networks;
- produce a standard core HACCP training manual to be complemented with the U.S. Food and Drug Administration's Fish and Fishery Products Hazard and Control Guide;
- adopt a protocol to assure a uniform education program that would be recognized by state and federal regulatory agencies;
- train a national cadre of qualified instructors recognized by the Association of Food and Drug Officials (AFDO) that reflect regional needs; and
- assist with HACCP education and implementation by developing a compendium of methods, maintaining a list of research needs and enhancing public awareness.

The alliance approach recognizes the essential role of state regulatory authorities, the educational networks of Sea Grant and the Cooperative Extension Service, and the need for regional programs due to seafood diversity. The alliance does not plan to set or recommend policy. They will strive to provide uniform education for the seafood and aquaculture industry and federal, state and local food inspectors. The plan is not intended to be private, institutional and/or government-based. Those completing this program will be recognized by "Certificates of HACCP Course Completion" to be issued and recorded by AFDO.

Table of Contents: **HACCP Training Curriculum**

Contributors: HACCP Training Curriculum iv

Introduction: About this Course. v

National Seafood HACCP Alliance: Course Agenda. vii

Chapter 1: Introduction to Course and HACCP 1

Chapter 2: Hazards – Biological, Chemical, Physical 11

Chapter 3: Preliminary Steps and Prerequisite Programs 27

Chapter 4: Commercial Processing Example: IQF Cooked Shrimp. 33

Chapter 5: Principle 1: Hazard Analysis and Preventive Measures 49

Chapter 6: Principle 2: Identification of Critical Control Points 59

Chapter 7: Principle 3: Establish Critical Limits 71

Chapter 8: Principle 4: Critical Control Point Monitoring 79

Chapter 9: Principle 5: Corrective Actions 89

Chapter 10: Principle 6: Record-Keeping Procedures 97

Chapter 11: Principle 7: Verification Procedures 113

Chapter 12: The Seafood HACCP Regulation 123

Appendix I: FDA's Seafood HACCP Rule. 141

Appendix II: NACMCF Questions and Sample Worksheets 157

Appendix III: Hazards Found in Seafood. 163

Appendix IV: More Information on HACCP 181

Appendix V: Models 189

Contributors: HACCP Training Curriculum

- Association of Food and Drug Offtcials
- Association of Food and Drug Officials of Southern States
- Central Atlantic States Association of Food and Drug Officials
- Mid-Continental Association of Food and Drug Officials
- North Central Association of Food and Drug Officials
- Northeast Association of Food and Drug Offtcials
- Western Association of Food and Drug Officials
- U.S. Food and Drug Administration
- National Fisheries Institute
- National Food Processors Association
- National Marine Fisheries Service
- Interstate Shellfish Sanitation Conference
- U.S. Department of Agriculture Cooperative Research, Education and Extension Service
- National Sea Grant College Program
- Virginia Polytechnic Institute and State University
- Oregon State University
- University of Alaska
- Louisiana State University
- University of Florida
- University of California at Davis
- North Carolina State University

About the Course Manual

This course manual and accompanying HACCP models and overheads were developed by the National Seafood HACCP Alliance — a group comprised of federal and state food-inspection officials, university food science educators and seafood industry representatives. The course was designed to meet the HACCP training requirements established under 21 CFR Part 123.10 of the Food and Drug Administration's mandatory seafood HACCP inspection program

Part 123.10 requires that certain HACCP activities must be completed by a "HACCP-trained individual." A HACCP-trained individual is one who has successfully completed FDA-recognized training in the application of HACCP to fishery products (at least equivalent to that received under a "standardized curriculum" recognized by FDA) or has acquired the knowledge through job experience. The National **Seafood HACCP Alliance course is the standardized curriculum by which FDA will evaluate other training courses.**

Maintaining Course Integrity

Because this course will be used to evaluate HACCP-training equivalency, it is imperative that course instructors adhere to the course format and material to the extent possible. The course is divided into three segments. The first teaches the student the seven principles of HACCI? The second segment explains the seafood HACCP regulations and guidance materials available to help develop a HACCP plan. The last segment is a class exercise where students are divided into small groups and asked to conduct a hazard analysis and develop a HACCP plan for one more of the six seafood processing models found in Appendix V. Each of these segments is necessary to give students an adequate foundation to establish their firm's HACCP mandate. Instructors are urged not to delete the material in the course because this defeats the course objective of standardizing the training experience. But instructors may wish to augment the course with examples pertinent to their region.

It is noteworthy that segment one, dealing with the seven principles, was designed to address the HACCP training needs for any FDA-regulated food product. In some instances, nonfishery product examples are used to demonstrate the application of HACCP principles. A discussion on seafood-specific hazards will be provided later in the course.

Continued

Tools for Developing HACCP Plans

The course material incorporates teaching tools to assist students in conducting a hazard analysis and developing a HACCP plan. A fictional seafood processing firm (the ABC Shrimp Co.) that produces IQF cooked shrimp is used to illustrate how a HACCP plan may be developed. It is important that instructors understand (and that they help students understand) that the model developed for ABC Shrimp Co. as well as other models are illustrative. The National Seafood HACCP Alliance does not suggest that the models represent the only way or necessarily the best way to develop HACCP plans for the products in question

A hazard-analysis worksheet is introduced in Chapter 5. In Chapter 6, a decision tree is used to help determine which steps in the production of IQF cooked shrimp are critical control points (CCPs). It must be remembered that tools such as the decision tree are not perfect since not all products and processes fit neatly into the tree. In some circumstances, the decision tree may not lead to an appropriate answer. Students must be taught to factor in all pertinent data and information about the plant operation and the characteristics of the product to determine if and where a CCP exists.

The development of ABC Shrimp Co.'s HACCP plan continues in Chapters 7 to 11. A HACCP plan form is used to identify critical limits, monitoring activity, corrective actions, records and verification procedures associated with the CCPs.

The forms and worksheets are completed step-by-step as the instructor covers each chapter. The manual provides the forms and worksheets with the answers provided. Instructors are urged to have students use the blank worksheets and forms found in Appendix II to fill in their own answers before turning to the completed forms in the manual. Students may then be instructed to check their answers against those found at the end of each chapter.

Convening the Course

Instructors may wish to begin the program by introducing themselves and asking each student to give his/her name, title, affiliation or the nature of their company or organization. Students may be from the private sector or from government agencies. If the student is from industry, the types of products they process and handle might be discussed briefly.

After the introduction, the instructors should cover meeting logistics: directions to bathrooms, phones, food establishments, smoking areas, etc. Students should be informed that the course is designed to provide a morning and afternoon break each day. Instruction should proceed with the introduction provided in Chapter 1.

Course Agenda: National Seafood HACCP Alliance

Day One

8:00 - 8:30	Welcome and Course Objectives	Chapter 1
8:30 - 9:45	Hazards (Biological, Chemical, Physical)	Chapter 2
9:45 - 10:15	Prerequisite Programs and HACCP Preliminary Steps	Chapter 3
	Commercial Processing Example: IQF Cooked Shrimp	Chapter 4
10:15 - 10:30	*Break*	
10:30 - Noon	Hazard Analysis and Preventive Measures	Chapter 5
Noon - 1:00	*Lunch*	
1:00 - 2:oo	Identification of Critical Control Points	Chapter 6
2:00 - 3:00	Establish Critical Limits	Chapter 7
3:15 - 3:30	*Break*	
3:30 - 4:30	Critical Control Point Monitoring	Chapter 8
4:30 - 5:30	Corrective Actions	Chapter 9

Day Two

8:00 - 9:00	Record-Keeping Procedures	Chapter 10
9:00 - l0:OO	Verification Procedures	Chapter 11
l0:00 - 10:15	*Break*	
10:15 - Noon	The Seafood HACCP Regulation	Chapter 12
Noon - 1:00	*Lunch*	
1:00 - 2:30	Overview of the Regulation (continued)	Chapter 12
2:30 - 2:45	*Break*	
2:45 - 3:30	Seafood-Specific Hazards	Appendix III
3:30 - 4:00	Where To Go For Help	Appendix IV
4:00 - 5:00	Review and Preparation for Developing HACCP Plans Work Session	Appendix V

Day Three

8:00 - Noon	Work Sessions on Developing HACCP Plans (break into groups)
Noon - 1:00	*Lunch*
1:00 - 4:oo	Work Session Reports (discussions, questions and answers)
4:00	*Adjourn*

Notes:

Overhead *1*

Objective:
In this module, you will learn the:
- Objective of the course,
- Format of the course,
- Expectations of the participant and,
- Meaning and importance of HACCP.

Course Objective

In December 1995, the Food and Drug Administration (FDA) issued seafood regulations based on the principles of Hazard Analysis and Critical Control Point (HACCP). The FDA issued these regulations to ensure safe processing and importing of fish and fishery products. These regulations specify that certain critical jobs in seafood processing be performed by someone trained in HACCP. This person is responsible for developing and modifying the HACCP plan and reviewing records. This course contains the information necessary for you, or a team, to meet the HACCP-training requirements. It is also designed to provide inspectors with the knowledge they need to evaluate HACCP plans and practices.

Course Format

This seafood HACCP course is divided into three distinct segments:
- HACCP fundamentals,
- Relationship of HACCP and FDA's regulation to the seafood industry, and
- Work session to develop a seafood HACCP plan.

The first segment defines the seven principles of HACCP. Learning these principles will give a clear understanding of the fundamentals on which HACCP is based. As each principle is discussed, the class will develop a HACCP plan for cooked shrimp using the fictional ARC Shrimp Co. as a model. This will help you understand HACCP principles and how they interrelate.

The second segment explains the seafood HACCP regulations and guidance materials that are available to help you develop a HACCP plan. The manual also presents information about seafood-specific hazards.

The third segment demonstrates how to develop a seafood HACCP plan. During this part of the course, the class will be divided into teams to write a HACCP plan based on a narrative and flow chart.

Continued

Notes:

What is Expected of the Participant

HACCP is a common sense technique used to control food-safety hazards. It is an important safety management system and can be integrated into any operation. However, HACCP can seem complicated and demanding until its concepts are understood. Therefore, you are encouraged to ask questions and to contribute first-hand experiences to discussions. This manual includes exercises that require class participation throughout the training. Keep in mind that the more you contribute to these exercises, the less complicated the HACCP system will seem and the easier it will be to implement a HACCP plan later.

How to Use This Manual

This manual is yours. Become familiar with it. Learn where the definitions are, where the forms are that will help you develop a HACCP plan, and where to find other basic information. Make as many notes and marks in the text as needed for assisting in creating and understanding a HACCP plan. Use the manual as a reference. This manual does not have a copyright. Make as many copies of its forms as necessary or copy the whole manual to share with others in your company.

Meaning and Importance of HACCP

Many people may not have heard the term "HACCP" until recently. However, it is neither a new term nor a new concept.

Overhead 2

HACCP stands for:
Hazard **A**nalysis and **C**ritical **C**ontrol **P**oint

HACCP is merely an acronym that stands for Hazard Analysis and Critical Control Point. But the concept behind this term is important.

Overhead 3

HACCP is:
- Preventive, not reactive.
- A management tool used to protect the food supply against microbiological, chemical and physical hazards.

HACCP is a preventive system of hazard control rather than a reactive one. Food processors can use it to ensure safer food products for consumers. To ensure safer food, the HACCP system is designed to identify hazards, establish controls and monitor these controls. Hazards can be harmful microorganisms, or chemical and/or physical contaminants.

Notes:

Overhead 4

Origins of HACCP:
- Pioneered in the 1960s.
- First used when foods were developed for the space program.
- Adopted by many food processors and the U.S. government.

The Pillsbury Co. pioneered the application of the HACCP concept to food production during its efforts to supply food for the U.S. space program in the early 1960s. Pillsbury decided that their existing quality control techniques did not provide adequate assurance against contamination during food production. The company found that end-product testing necessary to provide such assurance would be so extensive that little food would be available for space flights.

Overhead 5

HACCP is not a zero-risk system.
It is designed to minimize the risk of food-safety hazards.

The only way to ensure safety, Pillsbury concluded, would be to develop a preventive system that kept hazards from occurring during production. Since then, Pillsbury's system has been recognized worldwide as the state-of-the-art measure for food-safety control. It is not a zero risk system, but it is designed to minimize the risk of food-safety hazards. The FDA first required HACCP controls for food processing in 1973 for canned foods to protect against *Clostridium botulinum,* which causes botulism.

Overhead 6

Recommendation:
"The HACCP approach be adopted by all regulatory agencies and that it be mandatory for food processors."
1985 National Academy of Sciences

Continued

Notes:

In an assessment of the effectiveness of food regulation in the United States, the National Academy of Sciences (NAS) recommended in 1985 that the HACCP approach be adopted by all regulatory agencies and that it be mandatory for food processors.

Overhead 7

National Academy of Sciences recommendation
led to formation of the National Advisory Committee
on Microbiological Criteria for Food (NACMCF) in 1988.

This recommendation led to the formation of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) in 1988. This committee standardized the HACCP principles used by industry and regulatory authorities. The committee's work is the basis of this core curriculum.

Overhead 8

Seven principles of HACCP:

1. Conduct hazard analysis and identify preventive measures.
2. Identify critical control points (CCP).
3. Establish critical limits.
4. Monitor each CCP.
5. Establish corrective action to be taken when a critical limit deviation occurs.
6. Establish a record-keeping system.
7. Establish verification procedures.

In 1989, NACMCF developed the seven HACCP principles. They are:

1. Conduct hazard analysis. Prepare a list of steps in the process where significant hazards occur and describe the preventive measures.
2. Identify the critical control points (CCP) in the process.
3. Establish critical limits for preventive measures associated with each CCP identified.
4. Establish CCP monitoring requirements. Establish procedures for using monitoring results to adjust the process and maintain control.
5. Establish corrective actions to be taken when monitoring indicates that there is a deviation from an established critical limit.
6. Establish effective record-keeping procedures that document the HACCP system.
7. Establish procedures for verification that the HACCP system is working correctly.

These principles will be explained in more detail in the following sessions. The seafood HACCP regulation and other domestic and international HACCP control systems are based on these principles.

Notes:

Overhead 9

International use:
- Codex
- European Union
- Canada

HACCP has been endorsed worldwide by organizations such as Codex Alimentarius (a commission of the United Nations) and the European Union and by several countries including Canada, Australia, New Zealand and Japan.

Overhead *10*

HACCP:
A System for Food-Safety Control

HACCP is a preventive system for ensuring food-safety, but it is not a stand-alone system. HACCP must be built upon current food-safety programs such as Good Manufacturing Practices (GMPs) (e.g., sanitation and personal hygiene programs) to make it work.

Overhead *11*

Traditional Inspection Methods for Food-Safety Control
versus
The HACCP Approach

The HACCP concept is used by regulators during inspections of food processors to focus their attention on the parts of the process that are most likely to affect the safety of the product.

The inspection of plants operating under HACCP plans differs from traditional inspection methods of food-safety control. Traditional methods evaluate processing practices on the day or days of inspection. The HACCP approach allows regulators to look at what happens in the plant through time by examining the firm's monitoring and corrective action records.

Continued

Notes:

Overhead 12

Inspecting (verifying) HACCP complements traditional inspection methods. HACCP:

- Emphasizes process control.
- Concentrates on the points in the process that are critical to the safety of the product.
- Stresses communication between the regulator and industry.

With HACCP, the emphasis is to understand the process system. This requires the regulator and industry to communicate and to work with one another. The inspector will be verifying the HACCP plan by determining that critical hazards have been properly identified and that industry is consistently controlling these hazards. The inspector will accomplish this by first surveying the plant and then reviewing the HACCP plan and records. Regulatory inspections will continue to look for compliance in areas such as sanitation, economic fraud, food standards, etc.

Overhead 13

"Our safety inspections should focus on preventing problems rather then chasing the horses after they're out of the barn. HACCP is a system that will make that possible."

FDA Commissioner David Kessler
announcing Seafood HACCP Regulation, December 18, 1995

As FDA Commissioner David Kessler stated in his announcement of the seafood HACCP regulation in 1995, "Our safety inspections should focus on preventing problems rather than chasing the horses after they're out of the barn. HACCP is a system that will make that possible."

HACCP is receiving positive comments from the industry.

Overhead 14

"Ensuring food safety is a top priority for Campbell, and HACCP is one of the best management tools to accomplish this goal."

Campbell Soup Company

Overhead 15

"HACCP doesn't necessarily require a big investment. A company can keep it simple yet effective."

Gerber Products Company

Overhead 16

"As far as product is concerned, you can see the difference; both in-house bacteriological tests and bacteriological reports from inspection agencies have noticeably improved since implementation of HACCP."

Elgin Voisin
Motivatit Seafood, Houma, La

In defining the roles of industry and the regulatory agencies in HACCP, the NACMCF document indicates: "It is the responsibility of the food industry to develop and implement HACCP plans and for regulatory agencies to facilitate this process." Or, in other words, the role of the government is to ensure that industry adheres to their role.

Overhead *17*

"It is the responsibility of the food industry to develop and implement HACCP plans and for regulatory agencies to facilitate this process."

NACMCF, June 1993

As you learn more about HACCP, there will be many new definitions that you will need to understand. To assist you, the most common HACCP definitions are found in the following two pages. Refer back to these pages as needed and add other terms, as appropriate, which will help you in developing and implementing your own HACCP plan.

The next sessions will explain the basics of HACCP. We will start by first defining the types of hazards.

Notes:

Notes:

Definitions

- Continuous Monitoring: Uninterrupted collection and recording of data such as temperature on a strip chart.
- Control:(a) (verb) To manage the conditions of an operation to maintain compliance with established criteria.
  (b) (noun) The state in which correct procedures are being followed and criteria are being met.
- **Control Point:** Any point, step or procedure at which biological, physical or chemical factors can be controlled.
- Corrective Action:Procedures followed when a deviation from a critical limit occurs at a critical control point.
- Critical Control Point (CCP):A point, step or procedure at which control can be applied and a food-safety hazard can be prevented, eliminated or reduced to acceptable levels.
- CCP Decision Tree:A sequence of questions asked to determine whether a control point is a CCP.
- Critical **Limit:** A criterion that must be met for each preventive measure associated with a critical control point.
- Deviation:Failure to meet a critical limit.
- **HACCP:** Hazard Analysis and Critical Control Point.
- **HACCP Plan:** The written document based upon principles of HACCP that delineates the procedures to be followed to ensure the control of a specific process or procedure.
- HACCP System:The result of the implementation of the HACCP plan.
- **HACCP Team:** The group of people who are responsible for developing a HACCP plan.
- **HACCP Plan Validation:** The initial review by the HACCP team to ensure that all elements of the HACCP plan are accurate.
- **Hazard:** A biological, chemical or physical property that may cause a food to be unsafe for consumption.
- **Monitor:** To conduct a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification.

- **Operating limits:** Criteria that are more stringent than critical limits and that are used by an operator to reduce the risk of a deviation.

- **Prerequisite Programs:** Steps or procedures that control the in-plant environmental conditions which provide a foundation for safe food production

. **Preventive Measure:** Physical, chemical or other factors that can be used to control an identified health hazard. (In some documents, referred to as a control measure.)

- **Risk:** An estimate of the likely occurrence of a hazard.

- **Severity: The** seriousness of a hazard (if not properly controlled).

- **Verification: The** use of methods, procedures or tests, in addition to those used in monitoring, that determine if the HACCP system is in compliance with the HACCP plan and/or whether the plan needs modification and revalidation.

Notes:

Notes:

Acronyms

- CCP: Critical control point
- CL: Critical limit
- FDA: Food and Drug Administration
- **GMP:** Good Manufacturing Practice
- **HACCP:** Hazard analysis and critical control point
- **MIG:** Mercury-in-glass thermometer
- **NAS:** National Academy of Science
- **NACMCF:** National Advisory Committee on Microbiological Criteria for Foods
- **PPM:** Parts per million
- **SOP:** Standard operating procedure
- **SSOP:** Sanitation operating procedure

Chapter 2: Hazards - Biological, Chemical and Physical

Overhead *1*

Objective:
- Awareness of:
  - Biological hazards
  - Chemical hazards
  - Physical hazards
- Characteristics of certain microorganisms

To perform a hazard analysis for the development of a HACCP plan, food processors must gain a working knowledge of potential hazards. The HACCP plan is designed to control all reasonably likely food-safety hazards. Such hazards are categorized into three classes: biological, chemical and physical.

Overhead *2*

Definition:
Hazard: a biological, chemical or physical property that may cause a food to be unsafe for consumption.

Biological hazards include harmful bacteria, viruses or parasites (e.g., salmonella, hepatitis A and trichinella). Chemical hazards include compounds that can cause illness or injury due to immediate or long-term exposure. Physical hazards include foreign objects in food that can cause harm when eaten, such as glass or metal fragments.

It is important to understand that, for the purposes of HACCP, hazards only refer to the conditions or contaminants in food that can cause illness or injury to people. Many conditions are highly undesirable in food, such as the presence of insects, hair, filth or spoilage. Economic fraud and violations of regulatory food standards are equally undesirable. All of these defects must be controlled in food processing. However, they often are not directly related to the safety of the product. Unless these conditions directly affect food safety, they are not included in a HACCP plan.

Continued

Explanatory Note:

Whether a particular hazard listed in this chapter will need to be addressed in a HACCP plan will depend on an evaluation of the actual risk and severity of the hazard in the food. This evaluation is explained in the next chapter.

This chapter is intended as a general discussion on hazards. For information on seafood-specific hazards, refer to Appendix III.

Notes:

Overhead 3

In HACCP, "hazards" refer to conditions or contaminants in foods that can cause illness or injury. It does not refer to undesirable conditions or contaminants such as:

- Insects,
- Hair,
- Filth,
- Spoilage,
- Economic fraud, and
- Violations of regulatory food standards not directly related to safety.

It is not within the scope of this course to go into detail on foodbome hazards. That topic is too large and would be covered better in separate microbiology, toxicology and food-processing courses. However, this chapter will increase awareness of the kinds of hazards that may occur in foods. This awareness will prepare participants for recognizing what is and is not appropriate to control with HACCP. Food processors may find it necessary to work with technical experts to develop a HACCP plan.

Biological Hazards

Foods can contain biological hazards. These hazards can come from raw materials or from food-processing steps used to make the final product. Table A (at the end of the chapter) provides a list of biological hazards.

- *Microorganisms*

Organisms too small to be seen with the naked eye are called microorganisms. Microorganisms live everywhere: air, dirt, fresh and salt water, skin, hair, animal fur and plants.

Microorganisms are classified into various groups. A few groups important in foods include yeasts, molds, bacteria, viruses and protozoa. Since microorganisms are so widespread, it is important to understand when to be concerned about them and how to deal with them.

Although thousands of kinds of microorganisms exist, only a few pose hazards to humans. These hazardous microorganisms, or pathogens, will be discussed in more detail later.

Many microorganisms are beneficial. Certain kinds of yeast, molds and bacteria help make cheese, sour cream, yogurt and other fermented dairy products. Particular kinds of yeast are used in making beer, wine and other fermented beverages. We add these microorganisms to our foods intentionally, and they cause no harm. In fact, studies show that some of these microorganisms contribute to good health.

People may come into contact with thousands of kinds of yeasts, molds, bacteria, viruses and protozoa daily without ill effect. Therefore, when foods are processed and preserved, food processors and regulators need only be concerned with some microorganisms, particularly pathogens.

Notes:

Overhead 4

Microorganisms can be beneficial, even essential.
Some can be pathogenic. It is this class about which
food operations and public health officials are concerned.

Although microorganisms are too small to be seen without a microscope, they are alive and have certain needs to live and grow. Without adequate food, water and temperature, microorganisms stop growing and multiplying. Some die; others stop functioning until they get the elements they need. Some preservation methods, such as drying or smoking, control the water or nutrients in food, making these essential elements unavailable to microorganisms.

Overhead *5*

What do microorganisms need?
- Food
- Water
- Proper temperature
- Air, no air, minimal air

Different microorganisms respond differently to air. Like most plants and animals, many microorganisms need oxygen to live and will die or stop growing if deprived. However, many microorganisms can function without oxygen. Some are poisoned by it. Unfortunately, pathogens exist in each of these categories. Although some microorganisms can be controlled by the amount of air they receive, it is not an effective way of controlling all pathogens.

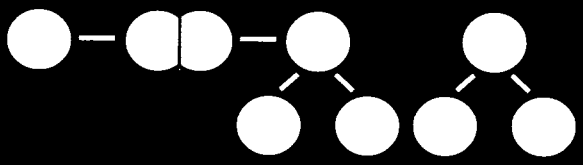
Microorganisms multiply in different ways. The most common method, especially for yeasts, bacteria and protozoa, is to grow large and divide. One microorganism splits into two, two into four, four into eight, eight into sixteen, and so on. By doubling, microorganisms multiply quickly. Under ideal conditions, some bacteria double every 20 minutes. Potentially, one microorganism can multiply to more than 30,000 in five hours and to more than 16 million in eight hours. Fortunately, most microorganisms grow more slowly than this, and we can slow them even more by controlling the food, water and temperature that they need to grow and multiply.

Continued

Notes:

Overhead 6

How do pathogenic microorganisms reproduce?
By dividing in two:



When they grow, microorganisms produce by-products.
- Yeast — bread, beverages, fruit
- Lactic acid bacteria — yogurt, cheese, meats
- *Staphylococcus aureus* — enterotoxin

Most spoiled foods do not present a health risk, and not all food that appears normal is safe to consume.

When microorganisms grow, they often produce by-products. The more they grow, the more by-products they produce. Some of the by-products are desirable in the right foods. For example, when yeasts grow in dough, they produce carbon dioxide, acids and flavors. The dough rises and we make bread. However, when the same yeasts grow and produce the same by-products in another food, such as fruit juice, it may not be desirable. Then we call it spoilage. Such spoilage is undesirable, and processors strive to avoid it in food. In addition, some by-products produced by pathogens are toxic and can cause disease.

Overhead *7*

Food spoilage or decomposition that can result in a food-safety problem should be prevented or controlled by a HACCP program.

Spoiled food may not look, smell or taste good, but only food spoiled by pathogens or contaminated by toxic microbial by-products can make a person sick. Food spoilage or decomposition that can result in food-safety problems should be prevented or controlled by a HACCP program.

During the processing of foods, the amounts and types of microorganisms can be increased, held constant, reduced or destroyed. Even though processing can be used to destroy harmful microorganisms, many safe microorganisms can survive the treatment and continue to live.

Example: **Milk is pasteurized, or heat-treated, to destroy pathogens. After pasteurization, milk is safe to drink even though nonpathogenic microorganisms survive.**

Overhead 8

Microbiological hazards include harmful:
- Bacteria,
- Viruses, and
- Protozoa

Among the five groups of microorganisms described above, only bacteria, viruses and protozoa include the kinds of microorganisms that can make food unsafe. Generally, yeast and molds do not pose a biological hazard in food. Some molds produce hazardous toxins, but these toxins are considered chemical hazards.

- *Bacterial Hazards*

Bacterial hazards are defined as those bacteria that, if they occur in food, may cause illness in humans, either by infection or intoxication. Food-borne infections are caused by swallowing live pathogens that grow within the body, usually in the intestinal tract. They differ from food-borne intoxication, which is a condition caused by swallowing preformed toxins (i.e., toxins produced by microorganisms in the food before it is eaten).

Overhead 9

Bacterial Hazards:
- Food infection and food intoxication
- Sporeforming and nonsporeforming bacteria

Bacterial hazards can also be grouped into sporeformers and non-sporeformers. Certain types of bacteria (e.g., *Clostridium* and *Bacillus* spp.) pass through a dormant stage in their life cycle called a spore. Although the microorganism exists as a spore, it is very resistant to chemicals, heat and other treatments that would normally be lethal to nonsporeforming bacteria. Because they are dormant, spores are not hazardous as long as they stay spores. Unfortunately, if they survive a processing step designed to kill nonsporeforming bacteria, they may become a hazard in the food if they are allowed to grow. When sporeformers are a concern, the process steps used to control them are often much more severe than if only nonsporefotmers need to be controlled.

Continued

Explanatory Note:

Students may ask why some hazards are classified as chemical rather than biological. The best answer is tradition. It is important to stress, however, that the significant issue is not the actual classification of a hazard, but accurate identification and control.

Notes:

Overhead *10*

Sporeforming Bacteria (Pathogens):
- *Clostridium botulinum*
  - Proteolytic
  - Nonproteolytic
- *Clostridium perfringens*
- *Bacillus cereus*

Overhead *11*

Nonsporeforming Bacteria:
- *Brucella abortis, B. suis*
- *Campylobacter* spp.
- Pathogenic *Escherichia coli* (e.g., *E. coli* 0157:H7)
- *Listeria monocytogenes*
- *Salmonella* spp. (e.g., *S. typhimurium, S. enteriditis)*
- *Shigella* spp. (e.g., *S. dysenteriae)*
- *Staphylococcus aureus*
- *Streptococcus pyogenes*
- *Vibrio* spp. (e.g., *V. cholerae, V. parahaemolyticus, V. vulnificus)*
- *Yersinia enterocolitica*

Example:
The following are examples of bacterial hazards found in food and why they are considered hazards:

Microorganism	**Why a hazard?**
Clostridium botulinum (sporeformer)	Causes an intoxication that affects the central nervous system and causes shortness of breath, blurred vision, loss of motor capabilities and death.
Listeria monocytogenes (nonsporeformer)	Causes an infection with mild flulike symptoms. Severe forms of listeriosis are possible in people with weakened immune systems, causing septicemia, meningitis, encephalitis and stillbirths.
Salmonella spp. (nonsporeformer)	Causes an infection with the following symptoms: nausea, vomiting, abdominal cramps, diarrhea, fever and headache. Death is possible in people with weakened immune systems.

See Appendix III (Hazards in Seafood) for growth characteristics.

• *Viral Hazards*

Like other microorganisms, viruses exist everywhere. They are very small particles that cannot be seen with a light microscope and cannot reproduce by themselves. Although they are alive, viruses differ from other microorganisms in what they need to live and how they multiply. Viruses exist in foods without growing, so they need no food, water or air to survive. They do not cause spoilage. Viruses cause illness by infection. They can infect living cells and reproduce inside the host cell using material from it. Vises only grow once they enter a suitable host. Only some viruses consider humans a suitable host. Viruses can survive in human intestines, contaminated water and frozen foods for months.

Overhead *12*

Hazards from viruses in foods
- What are viruses?
- Where do they come from?
- How do they reproduce?
- How can they be controlled?
- What are some examples? (Table A)

Viruses can be found in people who were previously infected but are no longer ill. Viruses can also be present in people who show no outward signs of illness (carriers). Transmission of viruses to foods is usually related to poor hygienic practices. People who have viruses shed the particles when they defecate. Food handlers with viruses can transmit them to food if they forget to wash and sanitize their hands properly. This route can also result in contamination of food with bacterial hazards.

Example:
The following are examples of viral hazards found in food:

Microorganism	**Why a hazard?**
Hepatitis A virus	Causes fever and abdominal discomfort, followed by jaundice.
Norwalk virus	Causes nausea, vomiting, diarrhea and abdominal pain (gastroenteritis). Headache and low-grade fever may also occur.

Continued

Notes:

Notes:

Overhead *13*

Viruses:
- Hepatitis A and E
- Norwalk Virus Group
- Rotavirus

- ***Parasitic Hazards (Worms and Protozoa)***

Parasites are organisms that need a host to survive, living on or within it. Thousands of kinds of parasites exist worldwide. Only about 20 percent can be found in food or water, and less than 100 are known to infect people through consumption. There are two types of parasites that can infect people through food or water: parasitic worms and protozoa. Parasitic worms include roundworms (nematodes), tapeworms (cestodes) and flukes (trematodes). These worms vary in size from barely visible to several feet in length. Protozoa are single-cell animals, and most cannot be seen without a microscope.

Table A at the end of the chapter lists the parasitic protozoa and worms most likely to be found in the U.S. food supply. For most foodbome parasites, the food is part of their natural life cycle (e.g., nematode worms in fish and meat). They have the opportunity to infect humans when people eat them along with the food. The two factors most important to parasitic survival are a proper host (i.e., not all organisms can be infected by parasites) and a suitable environment (i.e., temperature, water, salinity, etc.).

Overhead *14*

Parasites in Foods
- Parasites are organisms that need a host to survive.
- Thousands of kinds exist worldwide but only about 100 types are known to infect people through food consumption.
- Two types of concern from food or water:
  - Parasitic worms [e.g., roundworms (nematodes), tapeworms (cestodes), flukes (trematodes)]
  - Protozoa
- Role of fecal material in transmission of parasites.

Some parasites may be transmitted through food or water that is contaminated by fecal material shed by infected hosts. Methods of preventing transmission of parasites to foods by fecal contamination include:
- good personal hygiene practices by food handlers,
- proper disposal of human feces,
- elimination of insufficiently treated sewage to fertilize crops, and
- proper sewage treatment.

Consumer exposure to parasites depends on food selection, cultural habits and preparation methods. Most parasites do not harm humans but may be aesthetically unpleasant. Parasitic infections are normally associated with raw or undercooked foods because thorough cooking of foods eliminates all foodborne parasites. In specific instances, freezing can be used to destroy parasites in food. However, consuming raw foods containing infective parasites can pose a hazard.

Example:
The following are examples of parasite hazards found in food:

Organism	**Why a hazard?**
Giardia lamblia	This protozoa causes diarrhea, abdominal cramps, fatigue, nausea, flatulence (intestinal gas) and weight loss. Illness may last for one to two weeks, but chronic infections can last months to years.
Entamoeba histolytica	*This* protozoa causes dysentery (severe, bloody diarrhea).
Ascaris lumbricoides	*This* roundworm causes intestinal and lung infection.
Diphyllobothrium latum	*This* tapeworm attaches itself to the intestinal wall and can grow to 3 to 7 feet. Symptoms include abdominal pain, cramping, flatulence and diarrhea.

Overhead *15*

Parasitic Protozoa and Worms:
- *Cryptosporidium parvum*
- *Diphyllobothrium latum*
- *Entamoeba histolytica*
- *Giardia lamblia*
- *Anasakis simplex*
- *Ascaris lumbricoides*
- *Taenia solium, T. saginata*
- *Trichinella spiralis*
- *Pseudoterranova dicepiens*

Notes:

Continued

Explanatory Note:

Some of these limits (such as for aflatoxin, lead and histamine) can be found in Title 21 of the Code of Federal Regulations and in the FDA Compliance Policy Guides.

Chemical Hazards

Chemical contamination can happen at any stage in food production and processing. Chemicals can be helpful and are purposefully used with some foods, such as pesticides on fruits and vegetables. Chemicals are not hazardous if properly used or controlled. Potential risks to consumers increase when chemicals are not controlled or the recommended treatment rates are exceeded. The presence of a chemical may not always represent a hazard. The amount of the chemical may determine whether it is a hazard or not. Some may require exposure over prolonged periods to have a toxic effect. Regulatory limits are set for some of those contaminants.

Chemical hazards can be separated into three categories:
- Naturally occurring chemicals.
- Intentionally added chemicals.
- Unintenionally or incidentially added chemicals.

The types of chemicals included in these categories are listed in Table B at the end of the chapter.

Explanatory Note:

Allergic reactions are caused by proteins (allergens) that react with the body's natural immune system. This type of chemical hazard is of concern to individuals who are sensitive to the allergen.*

- **It *is particularly important that* foods *formulated with components that* *are known to* produce these types of *reactions* clearly identify these ingredients on the *label. HACCP-type* controls may be necessary when it may not be obvious *that* the food contains the allergen.**

- *Naturally Occurring Chemicals*

These chemicals are derived from a variety of plants, animals or microorganisms. In most cases, these naturally occurring chemicals are found prior to or during harvest. Although many naturally occurring toxins are biological in origin, they are traditionally categorized as chemical hazards.

Example:
The following are examples of foods containing naturally occurring chemical hazards:

Source	Why a hazard?
Certain fish species (e.g., tuna, mahi-mahi)	Spoilage of certain species of fish can result in production of toxic levels of histamine and related compounds.
Nuts	Certain varieties produce an allergic reaction in sensitive people.
Corn	Certain molds that grow on corn can create toxins (e.g., aflatoxin).
Molluscan shellfish	Some of the microscopic organisms and plants upon which they feed can produce a toxin, such as domoic acid, that affect people but not shellfish.

Overhead *16*

Types of Naturally Occurring Chemical Hazards:
- Mycotoxins (e.g., aflatoxin)
- Scombrotoxin
- Ciguatoxin
- Shellfish toxins
  - Paralytic shellfish poisoning (PSP)
  - Diarrheic shellfish poisoning (DSP)
  - Neurotoxic shellfish poisoning (NSP)
  - Amnesic shellfish poisoning (ASP)/Domoic Acid
- Pyrrolizidine alkaloids
- Phytohemagglutinin

Notes:

- ***Intentionally Added Chemicals***

These chemicals are intentionally added to food at some point during the food's growth and distribution. Intentionally added chemicals are safe when used at established safe levels but can be dangerous when those levels are exceeded.

Example:
The following are examples of food additives that may be chemical hazards if used improperly:

Source	Why a hazard?
FD&C *Yellow No. 5* (food coloring)	*Can* produce an allergic reaction in sensitive people.
Sodium nitrite (preservative)	Can be toxic in high concentrations.
Vitamin A (nutrient supplement)	Can be toxic in high concentrations.
Sulfiting *agents* (preservative)	Can cause allergic-type reaction in sensitive people.

Explanatory Note:

Certain food additives must have prior approval before they can be used in foods. Before using a new food additive, food processors should review the appropriate regulations for approval status and any limitations on its use.

Chemicals such as lubricants, cleaning compounds, sanitizers and paints must have prior approval.

Notes:

Overhead 17

Intentionally Added Chemicals — Food Additives:
- Direct (allowable limits under GMPs)
  - Preservatives (e.g., nitrite and sulfiting agents)
  - Nutritional additives (e.g., niacin)
  - Color additives

Overhead 78

Unintentionally or Incidentially Added Chemicals:
- Agricultural chemicals (e.g., pesticides, fungicides, herbicides, fertilizers, antibiotics and growth hormones)
- Prohibited substances (Code of Federal Regulations, Chapter 21, Section 189)
- Toxic elements and compounds (e.g., lead, zinc, arsenic, mercury, cyanide)
- Secondary direct and indirect
  - Plant chemicals (e.g., lubricants, cleaning compounds, sanitizers, paint)

. Unintentionally or Incidentially Added Chemicals

Chemicals can become part of a food without being intentionally added. These incidental chemicals might already be in a food ingredient when it is received. For example, certain seafood may contain small but legal residues of approved antibiotics. Packaging materials that are in direct contact with ingredients or the product can be a source of incidental chemicals, such as sanitizers or inks. Most incidental chemicals have no effect on food safety, and others are only a concern if they are present in too high an amount. Incidental chemicals also include accidental additions of prohibited substances such as poisons or insecticides that may not be allowed at any level.

Example:
The following are examples of incidental contaminants that may be chemical hazards:

Source	Why a hazard?
Agricultural chemicals (e.g., pesticides, herbicides)	Can be acutely toxic if present in the food at high levels and may cause health risks with long-term exposure.
Cleaning chemicals (e.g., acids, caustics)	Can cause chemical bums if present in the food at high levels.
Maintenance chemicals (e.g., lubricants, paint)	Chemicals that are not approved for food use and may be toxic.

Explanatory Note:

A partial list of prohibited substances can be found in Title 21, part **189 of the Code** of Federal Regulations, "Substances Prohibited from Use in Human Food."

Physical Hazards

Physical hazards include any potentially harmful extraneous matter not normally found in food. When a consumer mistakenly eats the foreign material or object, it is likely to cause choking, injury or other adverse health effects. Physical hazards are the most commonly reported consumer complaints because the injury occurs immediately or soon after eating, and the source of the hazard is often easy to identify. Table C at the end of the chapter lists the types of materials that can be physical hazards in foods.

Example:
The following are examples of materials that may be physical hazards:

Material	**Why a hazard?**
Glass	Cuts, bleeding; may require surgery to find or remove.
Metal	Cuts, broken teeth; may require surgery to remove.

Explanatory Note:

Exercise caution in listing bone fragments as physical hazards. The presence of bone should be kept as low as possible, which would be product and process dependent. However, in many products (especially seafood), bone fragments are uncontrollable quality defects and not consumer-safety hazards.

Overhead *19*

Physical Hazard:
Any potentially harmful extraneous matter
not normally found in food

Notes:

TABLE A

Biological Hazards

I. Bacteria

A. Sporeformers

Clostridium botulinum

Clostridium *perfringens*

Bacillus cereus

B . Nonsporeformers

Brucella *abortis,* ***B. suis***

Campylobacter spp.

pathogenic ***Escherichia*** *coli* ***(e.g. E.*** *coli* O157:H7)

Listeria monocytogenes

Salmonella spp. (e.g., S. ***typhimurium, S. enteriditis)***

Shigella spp. (e.g., S. ***dysenteriae)***

Staphylococcus aureus

Streptococcus pyogenes

Vibrio spp. (e.g., *V. cholerae, V.* ***parahaemolyticus,*** *V.* ***vulnificus)***

Yersinia enterocolitica

II. Viruses

Hepatitis A and E

Norwalk virus group

Rotavirus

III. Parasitic Protozoa and Worms

Anasakis simplex

Ascaris lumbricoides

Cryptosporidium parvum

Diphyllobothrium latum

Entamoeba histolytica

Giardia lamblia

Pseudoterranova dicepiens

Taenia solium, *T. saginata*

Trichinella spiralis

TABLE B

Types of Chemical Hazards

I. Naturally Occuring Chemicals

- Mycotoxins (e.g., aflatoxin)
- Scombrotoxin (histamine)
- Ciguatoxin
- Mushroom toxins
- Shellfish toxins
  - Paralytic shellfish poisoning (PSP)
  - Diarrheic shellfish poisoning (DSP)
  - Neurotoxic shellfish poisoning (NSP)
  - Amnesic shellfish poisoning (ASP)/Domoic acid
- Pyrrolizidine alkaloids
- Phytohemagglutinin

II. Intentionally Added Chemicals

- Food additives
  - Direct (allowable limits under GMPs)
    - Preservatives (e.g., nitrite and sulfiting agents)
    - Nutritional additives (e.g., niacin)
    - Color additives

III. Unintentionally or Incidentially Added Chemicals

- Agricultural chemicals
  (e.g., pesticides, fungicides, herbicides, fertilizers, antibiotics and growth hormones)
- Prohibited substances
  (Code of Federal Regulations, chapter 21, section 189)
- Toxic elements and compounds
  (e.g., lead, zinc, arsenic, mercury and cyanide)
- Polychlorinated biphenyls (PCBs)
- Plant chemicals
  (e.g., lubricants, cleaning compounds, sanitizers and paints)

Notes:

Notes:

TABLE C
Physical Hazards and Common Sources

Material	Sources
Glass	Bottles, jars, light fixtures, thermometers, gauge covers
Wood	Fruit/vegetables/grain, pallets, boxes, buildings
Stones	Fruit/vegetables/grain, buildings
Metal	Machinery, agricultural fields, buckshot, birdshot, wire, staples, buildings, employees
Plastic	Agricultural fields, production area, packaging materials, pallets, employees

Overhead *1*

Objective:
In this module, you will learn:
- Prerequisite programs to have in place before starting HACCP, and
- Preliminary steps involved in developing a HACCP plan.

Prerequisite Programs

HACCP is not a stand-alone program but is one part of a larger system of control procedures. For HACCP to function effectively, it should be accompanied by the prerequisite programs discussed in this chapter.

Overhead *2*

GMP — Good Manufacturing Practices
SSOP — Sanitation Standard Operating Procedure
HACCP — Hazard Analysis and Critical Control Point

HACCP systems are designed to prevent and control food-safety hazards associated with food from the time a company receives raw material through production to distribution to the consumer. HACCP systems must be built upon a firm foundation of compliance with current Good Manufacturing Practices (GMPs) (Code of Federal Regulations, Title 21, Part 110) and acceptable sanitation standard operating procedures (SSOPs). GMPs and sanitation procedures affect the processing environment and should be considered prerequisite programs to HACCP.

Overhead *3*

Definition:
Prerequsite Programs: Steps or procedures that control the in-plant environmental conditions that provide a foundation for safe food production. Examples include:
- Sanitation,
- GMPs,
- Training,
- Recall program,
- Preventive maintenance, and
- Product identification program and coding.

Continued

Explanatory Note:

This chapter is not intended to be an exhaustive discussion of all elements of what could be included in prerequisite programs.

Notes:

When sanitation SSOPs are in place, HACCP can be more effective because it can concentrate on the hazards associated with the food or processing and **not** on the processing plant environment. If sanitation controls are included as part of a HACCP plan, they must lend themselves to all aspects of a critical control point (CCP) such as establishing critical limits, monitoring, corrective actions, record keeping and verification procedures.

A Clean-in-Place (CIP) system for equipment is a good example of sanitation controls that could be handled as a CCP within a HACCP plan. A CIP system's effectiveness can be monitored, critical control points can be established, monitoring records can be maintained, and appropriate corrective actions can be established when the critical limits are not met. On the other hand, a processor's pest-control program should be included in its SSOP rather than its HACCP plan.

Even without HACCP, the level of plant sanitation and GMPs must comply with the law. Contrary to popular perception, sanitation control is not limited to cleaning equipment. Although clean equipment and a clean working area are essential for producing safe foods, so are personnel practices, plant facilities, pest control, warehouse practices, and equipment and operation design. Each should be addressed in a complete written sanitation program designed to comply with existing regulations. An important component in any sanitation program is monitoring. A system of monitoring should be designed to ensure that the conditions and practices specified in the SSOP are consistently met. An example of an SSOP is given in Chapter 4.

Preliminary Steps in Developing a HACCP Plan

HACCP is often thought of in terms of its seven basic principles. However, it also includes five preliminary steps. Failure to properly address the preliminary steps may lead to ineffective design, implementation and management of the HACCP plan.

In preparation for developing a HACCP plan, a firm must have a solid foundation.

Overhead 4

This foundation includes:
- Management commitment,
- HACCP training,
- HACCP team assembly,
- Description and intended use of product, and
- Development and verification of the product's flow diagram.

- *Management Commitment*

For a HACCP plan to work, it is extremely important to have the support of top company officials such as the owner, director and chief executive officer. Without it, HACCP will not become a company priority or be effectively implemented.

- *HACCP Training*

Education and training are important elements in developing and implementing a HACCP program. Employees who will be responsible for the HACCP program must be adequately trained in its principles. This course is designed to meet that need.

- *HACCP Team Assembly*

Assembling a HACCP team is an important step in building a HACCP program. The team should consist of individuals with different specialties. The team may include personnel from maintenance, production, sanitation, quality control and laboratory. The HACCP team should include members who are directly involved with the plant's daily operations.

The team develops the HACCP plan, writes SSOPs, and verifies and implements the HACCP system. The team should be knowledgeable about food-safety hazards and HACCP principles. When issues arise that cannot be resolved internally, it may be necessary to enlist outside expertise.

Although one person may be able to analyze hazards and develop a HACCP plan successfully, many industries find it helpful to build a HACCP team. When only one person develops the HACCP plan, some key points can be missed or misunderstood in the process. The team approach minimizes risk that key points will be missed or that aspects of the operation will be misunderstood. It also encourages ownership of the plan, builds company involvement and brings in different areas of expertise.

In small companies, the responsibility for writing the HACCP plan may fall to one person. If it is possible to build a HACCP team in a small company, employees knowledgeable of various divisions, including owners, should be members. Universities, cooperative extension, consulting groups, Sea Grant programs, model plans and published guidance can provide additional assistance.

Notes:

Continued

Notes:

- *Description and Intended Use of Product*

Once a HACCP team is established, the members first describe the product, the method of distribution, the intended customer (e.g, general public, infants, elderly) and consumer use of the product (e.g., consumed without further cooking, heat and serve, cooked).

Example:
Frozen, cooked, ready-to-eat breaded shrimp, distributed and sold frozen, to be heated and used by the general public.

In this example, the presence of certain pathogens is likely to be a significant hazard in cooked, ready-to-eat shrimp because the product may not be heated by the consumer. However, growth of the same pathogens is unlikely to be a significant hazard in raw shrimp because it will be cooked by the consumer before consumption.

- *Development and Verification of the Product's Flow Diagram*

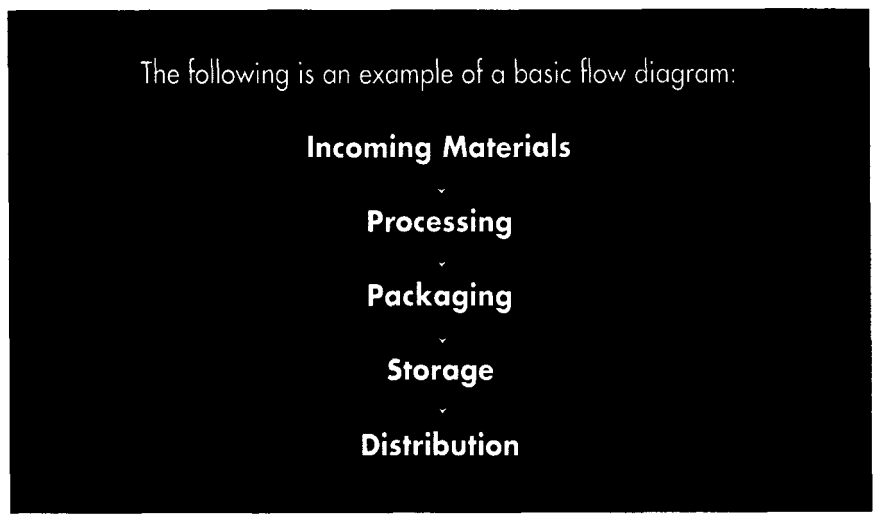
A flow diagram shows in simple block or symbol form the steps required to manufacture and distribute a food product. This step provides an important visual tool that the HACCP team can use to complete the remaining steps of the HACCP plan development. Only a clear, simple, but complete, description of the process is needed.

It is important to include all the steps within the facility's control, including receiving and storage steps for all raw materials. The flow diagram should be clear and complete enough so that people unfamiliar with the process can quickly comprehend your processing stages.

Overhead *5*

Explanatory Note:

This depicts a generic flow diagram. An actual flow diagram needs to be much more detailed.



Since the accuracy of the flow diagram is critical to conduct a hazard analysis, the steps outlined in the diagram must be verified at the plant. If a step is missed, a significant safety issue may not be addressed

The HACCP team should walk through the facility and make any changes required in the flow chart. The walk-through allows each team member to gain an overall picture of how the product is made. It may be helpful to invite additional plant personnel to review the diagram during the walk-through.

Notes:

Chapter 4: Commercial Processing Example: IQF Cooked Shrimp

Notes:

To facilitate our discussion of HACCP, we are introducing the ABC Shrimp Co. With this fictitious company as a base, we will discuss and illustrate the evolution of a HACCP plan for cooked shrimp. Keep in mind that the HACCP plan developed for ABC Shrimp Co. is primarily intended to demonstrate the procedures used in plan development. **Since HACCP plans are very product, process and plant specific, ABC Shrimp Co.'s plan may not be suitable for firms actually processing cooked shrimp.**

Processing narratives can help explain the current processing steps needed to produce a product covered by a particular HACCP plan. They offer a historical, working reference for the processor and facilitate communication with the staff and inspectors. For these reasons, a written narrative should accompany a HACCP plan.

IQF Cooked Shrimp Processing Narrative

Company: ***ABC Shrimp Co.***

Final Product: ***IQF cooked, headless, peeled and deveined shrimp***

Procedures/Steps:

INCOMING MATERIALS

- Frozen, raw shrimp is received in-block form from international and domestic sources. The standard block is 5 lbs. (2.27 kg) in a polybag packed with eight to 10 blocks to the master container. Depending on production requirements, product size (count of individual shrimp) can range from less than 15 to more than 500 per pound. The shrimp are received shell-on. Following acceptance, the frozen, raw shrimp is assigned an individual storage lot number and placed in frozen inventory. Buying specifications for all frozen shrimp states that they must not contain any sulfite residual. Furthermore, a supplier certification must accompany each shipment attesting to the absence of sulfites.
- Fresh, raw shrimp are purchased directly from local boats. The shrimp are headed at sea and are often treated with sulfiting agents (i.e., sodium bisulfite and/or sodium metabisulfite dips) to inhibit black spot formation (melanosis). Shrimp/ice mixtures from the boats are emptied into tanks containing potable water. The shrimp are placed in plastic totes for fresh ice and refrigeration. Ice is refreshed daily by topping the totes.
- Packaging materials are delivered in clean, well-maintained and covered vehicles. All materials are checked for integrity and order specifications. Then they are assigned lot numbers and placed into a dry-storage warehouse/room.

Continued

Notes:

PROCESSING

- The thawing process for the block frozen shrimp uses potable water in a thaw tank maintained at 50 F to 65 F. The tank water is circulated with aeration and through worker stirring. The frozen blocks are removed from the master case, opened and placed in the thaw tank. As blocks rotate through the tank, workers remove any foreign debris. The thawed shrimp are conveyed from the tank directly to a size grader.
- The size grader mechanically size the shrimp by passing them over a series of inclined rollers set to segragate individual shrimp by differences in width and/or bulk. As the shrimp cascade through the rollers, the various sizes are diverted by shoots into baskets. The various sizes are placed in separate totes for icing. These totes are rolled to the peeling room.
- The firm's peeling process uses Laitram machinery. The shrimp are conveyed onto a series of inclined spinning rollers where the shell of the shrimp is cracked/split and peeled. As the shrimp pass down the rollers, they move through a series of cleaning sluices that lead to the deveining process.
- The deveining process occurs on a razor slide set at approximately 45 degrees. The razor edges are set to cut the shrimp, exposing the vein as they slide toward the tumbler/deveiner.
- The tumbler/deveiner is a large cylinder with interior ridges or flanges that tumble the product and pull the exposed vein from the razor-cut shrimp. The deveined product is conveyed to a culling table.
- Workers on either side of the conveyor/cull table will remove defective product (i.e., broken shrimp, pieces, unpeeled or undeveined shrimp, blackspot, crushed material). The properly sized, peeled and deveined, and culled material is iced in totes before being returned to cold storage.
- Before cooking, the cold product is deiced. The raw shrimp will then pass through a steam injection cooker. The cooker is equipped with an auger to tumble the shrimp, ensuring a thorough, uniform cook. The cook time and temperature is based on a pre-established schedule.
- As cooked shrimp exit the cooker, they fall into a shuffler that moves the product toward a final cull table. At the same time, the shuffler exposes the shrimp to a cold-water spray to stabilize and cool the product.

- The final cull **table** is a conveyer leading to the spiral freezing unit. Workers on either side of the table remove defective product (i.e., clumps, pieces, mutilated material, blackspot, improperly peeled shrimp) before it enters the freezer.
- **The spiral freezer** is a continuous freezing process based on product exposure to air cooled by standard ammonia refrigeration. As the frozen shrimp exit the freezer, they are conveyed immediately to the glazing station.
- The **glazing operation** consists of a stainless steel table equipped with an adjustable water spray to impart a uniform frozen-water glaze.

PACKAGING

- Following freezing and glazing, the finished product is conveyed to the **weigh/pack/and label station.** At this point, a computerized system weighs the correct amount of product and bags it in prelabeled bagging material. Each primary container will be identified by the production date code and lot number.
- Following weigh/pack/label, all primary containers or packages are **mastercased** as required by the customer or the company. Each mastercase is marked with identical production date codes and lot numbers as used on the primary containers or packages. As each mastercase is packed, it is palletized immediately in accordance with customer or company criterion. Once a pallet load is completed, it is conveyed to the storage freezer.

STORAGE

- All finished product is placed into frozen storage without delay. All product is stored on a first-in, first-out basis.

SHIPPING

- All shipping transports are prechilled to 0 F or below.

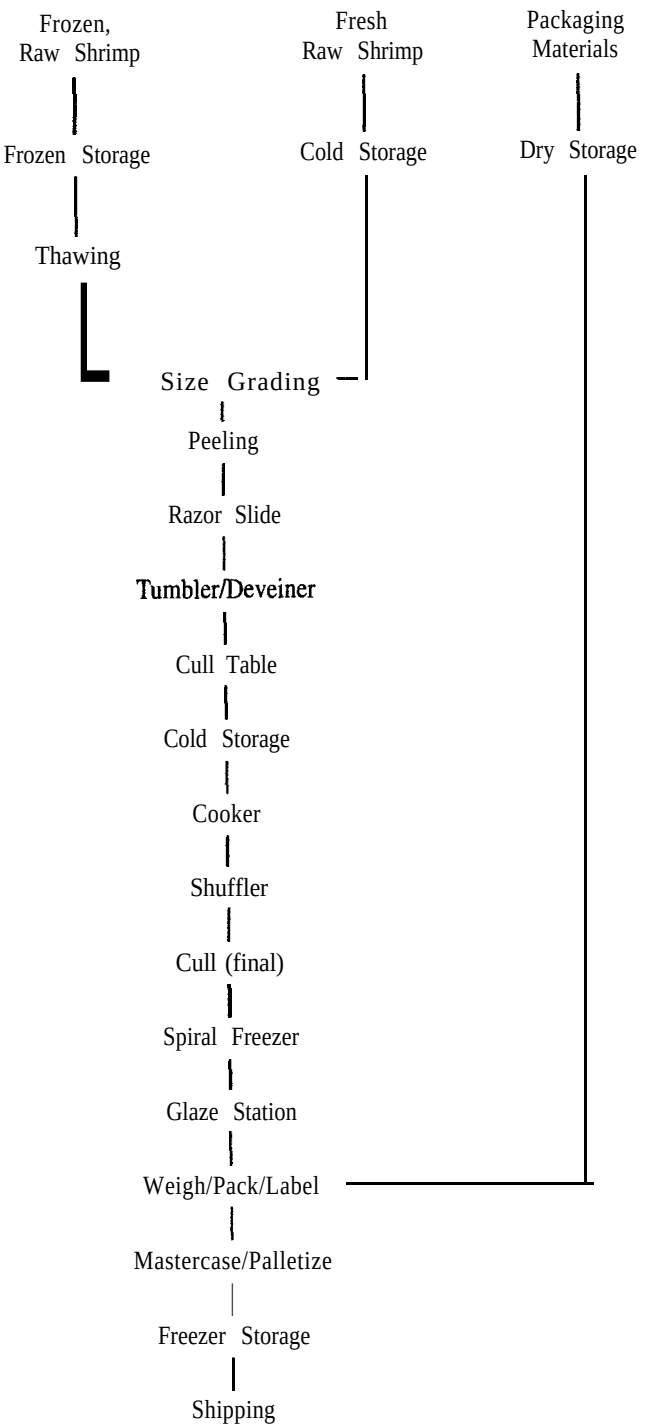
Notes:

Continued

Instructor's Notes:

Example of a Process Flow Diagram for ABC Shrimp Co.

ABC Shrimp Co.
IQF Cooked Shrimp Production Flow



Model Sanitation Standard Operating Procedure (SSOP)

The following model SSOP addresses the sanitation concerns for a fictitional shrimp company, the ABC Shrimp Co. SSOP designs will vary from facility to facility because each is designed differently. In this model, the ABC Shrimp Co. has distinct quality assurance, maintenance and production departments.

1. Goal: Water that comes into direct contact with food or food-contact surfaces or is used in the manufacturing of ice is derived from a safe and sanitary source or is treated to make it safe.

   Procedure: ABC Shrimp Co. will use city water throughout processing, including the manufacture of ice. The company's quality-control supervisor will request verification of the water quality from the city and maintain it on file.

2. Goal: There are no cross-connections between the potable water system and any nonpotable system.

   Procedure: The quality-control supervisor will perform a monthly inspection to determine that no cross connections exist between potable and waste systems. The results of theinspections will be recorded on the monthly sanitation audit form.

3. Goal: All food-contact surfaces of plant equipment and utensils, including equipment used for ice production and storage, are designed of such material and workmanship to be easily cleaned and maintained in a sanitary condition. Such surfaces will 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.

   Procedure: Presently, all plant equipment and utensils meet current recommended state and federal standards. Prior to replacing any major piece of equipment, the quality assurance, production and maintenance departments will meet to evaluate the equipment. The evaluation will determine whether replacing the equipment will impact adjacent processing steps. Specifications of all equipment will be reviewed to ensure it is capable of withstanding the intended use and can be easily cleaned. The same evaluation will be conducted on materials used in the modification of the physical plant. Orders of minor equipment and utensils used in the process will be reviewed by the line supervisor making the order and the quality assurance department. If necessary, the supervisor of the contracted cleaning company will be contacted to consider the impact of present methods of cleaning and sanitizing plant equipment and utensils. The results of these evaluations will be kept on file. The quality-control supervisor will evaluate the condition of plant equipment and utensils monthly. The results of these evaluations will be recorded on the monthly sanitation audit form.

Continued

Notes:

Explanatory Note:

FDA's regulation requires records of several key sanitation operations. ABC Shrimp Co. meets many of these requirements through daily preoperational checks.

Notes:

4. Goal: All utensils and surfaces of equipment that contact food during processing are cleaned and sanitized with effective cleaning and sanitizing preparations in the following frequencies:
   a. Cleaned at the end of the day's operations;
   b. Cleaned and sanitized at least every four hours during processing of cooked, ready-to-eat fishery products;
   c. Sanitized before the day's operations begin.

   Procedure: All process lines, regardless of the intended purpose, will be cleaned during:
   a. Each break and lunch break, but at least every four hours, following the start of production. This will consist of sweeping the area and removing any buildup of debris or other materials. The equipment will be inspected by the quality-control supervisor prior to start-up and the results recorded on a daily sanitation audit form.
      NOTE: Processing will not resume until the plant conditions are determined to be satisfactory.
   b. In addition, process lines for ready-to-eat products will be broken down every four hours after production starts. These lines will be thoroughly cleaned and sanitized. Food-grade alkaline detergent will be used for cleaning, followed by a 100 parts per million (ppm) chlorine rinse. The equipment will be inspected before start-up by the quality-control supervisor. The concentration of the chlorine sanitizer will be checked by the quality-control supervisor before it is used. The results will be recorded on a daily sanitation audit form.
      NOTE: Processing will not resume until the plant conditions are determined to be satisfactory.
   c. At the end of the production day, the **XYZ Cleaning and Sanitizing Co.** will clean and sanitize all equipment, utensils and the facility for the next production day. A food-grade alkaline detergent will be used for cleaning, followed by a 100-ppm chlorine rinse. The concentration of the chlorine sanitizer will be checked by the quality-control supervisor before it is used. The results will be recorded on a daily sanitation audit form. Before the production day begins, a quality-assurance representative will conduct a preoperational sanitary inspection. A representative of the cleaning company will be present and, if necessary, immediately eliminate any discrepancy noted. The observations will be recorded on a daily sanitation audit report.
      NOTE: Processing will not resume until the plant conditions are determined to be satisfactory.

5. Goal: Gloves and outer garments that contact food or food-contact surfaces are made of an impermeable material and are kept clean and sanitary.

   Procedure: The company will issue line workers rubber aprons and work gloves. The line supervisor will ensure that his or her employees are issued this gear. Employees are not allowed to use personal gear in place of these items unless authorized by the line supervisor and foreman. Employees are required to maintain this gear in a sanitary and operable condition and, if necessary, must replace it through the line supervisor. Supervisors must require all employees to comply. In addition, the quality-control supervisor will check this gear at the beginning of each day's operations. Observations will be recorded on a daily sanitation audit form.

6. Goal: Employees' hands, gloves and outer garments; utensils; food-contact surfaces of equipment that come into contact with waste; the floor; or other unsanitary objects do not touch food products without first being adequately cleaned and sanitized.

   Procedure:

   a. Employees will be trained on how and when to properly wash and sanitize hands. Training will be documented and kept on file.
   b. The foreman will maintain hand-washing stations and hand dips at the start and end of process lines. Hand-dip stations are to be maintained at or above 25 ppm iodine.
   c. The foreman will maintain separate utensil wash stations and dips for shovels, stirrers, buckets and other utensils used in the process.
   d. Should the process line become contaminated by any form of waste or floor splash, the supervisor or designated person will immediately stop the process line. The section affected will be cleaned, sanitized and inspected before production starts again. Results will be recorded on the daily sanitation audit form.
   e. Supervisors, maintenance workers, quality-control and production personnel, including those who handle waste, touch the floor or other insanitary objects, must clean and sanitize their hands and gloves before handling product. These practices will be observed every four hours by the quality-control supervisor and the results will be recorded on the daily sanitation audit form.
   f. Utensils and equipment food-contact surfaces that have come in contact with the floor, waste or other insanitary objects must be washed and sanitized before being used in contact with product. These practices will be observed every four hours by the quality-control supervisor and the results will be recorded on the daily sanitation audit form.

Continued

Notes:

Notes:

7. **Goal:** Where applicable, employee's hands, gloves and outer garments; utensils; and food-contact surfaces of equipment that come into contact with raw product will not contact cooked product or ice used on cooked product without first being adequately cleaned and sanitized.

   Procedure: Employees working on the raw-product production line (i.e., a breaded product) or on the raw side of the cooker on the cooked, ready-to-eat shrimp line will not be assigned to work on the cooked side of the cooker. If such an assignment becomes necessary, supervisors must ensure that those employees clean and sanitize their hands, gloves and outer garments before working in the ready-to-eat process line. Raw production is not allowed on ready-to-eat process lines. These practices will be observed every four hours by the quality-control supervisor and recorded on a daily sanitation audit form. Supervisors, maintenance workers and others that are required to move from the raw side to the cooked side must first clean and sanitize their hands, gloves and outer garments.

8. Goal: Hand-washing and hand-sanitizing facilities are located in all processing areas where good sanitary practices require employees to wash and sanitize their hands. These facilities must be equipped with hand-cleaning and effective sanitizing preparations and disposable towels.

   Procedure:

   a. Hand-washing stations and hand dips will be located at all entrances to the process floor, including entrances from the administrative offices. These will be used upon entry to the process floor. In addition, line employees will use foot dips for their boots, which will also be located at each entrance to the production floor.

   b. Hand-washing stations and hand dips will also be located at the beginning and end of each process line. These will be used each time an employee contaminates hands or gloves and upon return to the process line.

   c. Restrooms will be equipped with foot-activated hand-washing facilities, soap dispensers stocked with antibacterial soap and disposable towels.

   d. The hand-washing stations will be checked by the quality-control supervisor for adequate supplies before operation begins and every four hours during operation. The concentration of the chlorine hand dips will be checked before operation and every four hours during operation by the quality-control supervisor. They are to be maintained at or above 25 ppm iodine. The results of these will be recorded on a daily sanitation audit form.

9. Goal: 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.

   Procedure:

   a. All cleaning compounds and sanitizing agents used by XYZ Cleaning and Sanitizing Co. will be clearly identified and stored away from the process area and any other lubricants or chemicals. The cleaning company will provide the quality-assurance department with a material-safety data sheet for all compounds and agents stored at the plant.
   b. All food-grade lubricants will be stored separately from nonfood-grade lubricants and will be properly labeled.
   c. The Stun'em Pesticide Co. will not store any pesticides in the plant. The company will provide a material-safety data sheet for any pesticides or traps used for pest control.
   d. The maintenance department will store and properly label all nonfood lubricants within the maintenance area. No fuels will be stored within the facility. All gas fuels (i.e., oxygen and acetylene) shall be stored in portable tanks outside the plant and will be brought inside only when production is stopped. If it becomes necessary to use such fuels during production, maintenance personnel will raise barriers to ensure that the process is not contaminated. When finished, the area will be thoroughly cleaned, sanitized and inspected before production starts again.
   e. The quality-control supervisor will inspect the processing area daily during operation for possible contamination sources and to make sure toxic compounds are labeled and stored properly. The results will be documented on the daily sanitation audit form.

10. Goal: Any toxic compounds allowed in the plant shall be identified, held, used and stored in a manner that protects against contamination of food, food-contact surfaces or packaging materials.

    Procedure: The quality-control supervisor will inspect the processing area daily during operations for possible contamination sources and to make sure toxic compounds are labeled and stored properly. The results will be documented on the daily sanitation audit form.

Notes:

Continued

Notes:

11. Goal: Food, food-contact surfaces and food-packaging materials will be protected from contaminants that may be sprayed, dripped, drained or drawn into food.

    Procedure:

    a. The maintenance department is responsible for establishing a regular maintenance program for the facility's ventilation system. This ensures adequate ventilation, airflow and air pressure that prevents or inhibits the formation of condensates in the processing and storage areas. Condensates can lead to contamination of product, product-contact surfaces or packaging materials.
    b. Supervisors must also ensure that no floor splash occurs in processing areas during cleaning or sanitizing during production hours. They must also make sure that the area is cleaned, sanitized and inspected before restarting production. The food-processing area will be inspected for possible sources of contamination, including condensate, by the quality-control supervisor each day during operations and the results recorded on a daily sanitation audit form.

12. Goal: Ready-to-eat fishery products, including raw molluscan shellfish, will be physically separated from raw fishery products during refrigerated storage.

    Procedure:

    a. Under normal conditions, cooked, ready-to-eat product is not stored in the cooler unpackaged. If this becomes necessary, it must be physically separated from any raw product by a minimal distance of three feet. No **exceptions allowed.** In addition, all ready-to-eat product -raw or cooked, packaged or unpackaged — will be clearly identified by lot number, species and intended final-product form.
    b. Coolers will be inspected daily for product separation during operations by the quality-control supervisor. Observations will be recorded on the daily sanitation audit form.

13. Goal: Anyone who has or may have, by medical examination or supervisory observation, an illness, infected wound, an open lesion such as a boil or sore, or any other problem that might contaminate food, food-contact surfaces or packaging materials shall be excluded from any operations until the condition is healed or corrected.

Procedure:

a. As a part of new employee orientations, staff will be briefed on the need to notify immediate supervisors of any illness or injury that may lead to contamination of any part of the process. Employees must notify immediate supervisors if they have been exposed to a confirmed disease outbreak of *Salmonella* (such as typhoid), Hepatitis A or *Shigella,* especially when employees are asymptomatic. In addition, employees will be informed that, if at all possible, they will be assigned duties that will not compromise the process. The results of the training will be documented and kept on file.

b. It is the responsibility of all supervisory personnel to observe the apparent well-being of their personnel. Employees will be reviewed for signs of medical problems daily before operations begin by the quality-control supervisor. At any indication of injury or illness that may compromise the process due to contamination, the supervisor will remove that person from the line and report to the plant manager. If that employee cannot be assigned other duties, he or she will be sent home until the situation is alleviated or a medical authority states that he or she may return to work. Observations will be recorded on the daily sanitation audit form.

14. Goal: Adequate, readily accessible toilet facilities that provide for proper sewage disposal shall be available and maintained in a sanitary condition and in good repair.

Procedure:

a. Separate toilet facilities are provided for male and female employees in the break area and adjacent to the processing area. Each restroom is equipped with double doors opening inward and is well-ventilated. The number of toilets provided is based on the number of employees, with consideration to gender given separately. ABC Shrimp Co. has 125 male and 135 female employees. There are eight toilets for males and nine toilets for females. Extra toilets will be installed if an increase in employees occurs.

b. During production hours, line supervisors check, on a rotational basis, that toilet facilities are sanitary and well-stocked. Following production, the **XYZ Cleaning and Sanitizing Co.** is responsible for cleaning and sanitizing toilet facilities and for restocking them.

c. The maintenance department keeps toilet facilities operable and in good repair.

d. The condition of the restrooms will be inspected daily by the quality-control supervisor. The results will be recorded on the daily sanitation audit form.

Continued

Notes:

Notes:

15. Goal: No pests are in any area of a food plant.

    Procedure: The presence of rodents, insects, birds or other pests in the plant is unacceptable. The **Stun'em Pesticide Co.** has been contracted and is responsible for all facets of pest control within the plant as well as the grounds. Material data sheets for all pesticides used by the company are on file. A representative of the company will meet monthly with the quality-control supervisor and discuss facility pest control. In addition, the quality-control supervisor will inspect the facility for the presence of pests daily, before operation. Observations will be recorded on the daily sanitation audit form.

16. Goal: The plant is designed to minimize the risk of contamination of the food, food-contact surfaces and food-packaging material.

    Procedure:

    a. The quality-control supervisor and representatives from the maintenance department will schedule a monthly review of the plant layout and structure to ensure that contamination of any aspect of the process does not occur from internal or external sources. Observations will be recorded on the monthly sanitation audit form.
    b. Any modification to the physical facility requires the consultation of a certified sanitarian.

ABC Shrimp Co.
Daily Sanitation Audit Form

Sanitation Condition	Time Pre-Op Pass/Fail	Time Pass/Fail	Time Pass/Fail	Comments
1. Equipment cleaning and sanitizing				
a. Equipment cleaned and sanitized before start-up.				
b. Product residue removed from equipment during breaks.				
c. Ready-to-eat product equipment cleaned and sanitized during breaks.				
d. Concentration of chlorine used for sanitizing equipment (ppm)				
2. Employee attire				
a. Gloves and aprons clean and in good repair				
3. Cross contamination				
a. Employees' hands, gloves, equipment and utensils that contact unsanitary objects are washed and sanitized before contacting product.				
b. Employees on raw side wash and sanitize hands, gloves and aprons before moving to cooked side.				
4. Hand washing and sanitizing facilities				
a. Adequate supplies				
b. Concentration of iodine in hand dips (ppm).				
Front entrance				
Rear entrance				
Side entrance				
Start of line 1				
End of line 1				
Start of 2				
End of line 2				

Firm Name: _____

Date: _____ Supervisor: _____

ABC Shrimp Co.
Daily Sanitation Audit Form

Sanitation Condition	Time Pre-Op Pass/Fail	Time Pass/Fail	Time Pass/Fail	Comments
5. Protection from adulterants				
a. Cleaning compounds labeled and stored properly				
b. Lubricants labeled and stored properly				
c. Pesticides labeled and stored properly				
d. Product protected from condensate				
e. Product protected from floor splash				
6. Cooler storage				
a. Unpackaged, cooked product separated from raw product.				
7. Employee health				
a. Employees do not show signs of medical problems that could compromise product.				
8. Toilet facilities				
a. Toilets are clean and properly functioning.				
9. Pests				
a. No pests in the processing area				

Firm Name: _____

Date: _____ Supervisor: _____

ABC Shrimp Co.
Monthly Sanitation Audit Form

Sanitation Condition	Time Pass/Fail	Comments
No cross connections between potable and wastewater systems		
Processing equipment and utensils in suitable condition		
Physical condition of plant and layout of equipment suitable to minimize risk of contamination		

Firm Name: _____

Date: _____ Supervisor: _____

Overhead *1*

Objective:
In this module you will learn:
- What hazard analysis is.
- How to conduct a hazard analysis.
- How to identify significant hazards.
- What preventive measures are.
- How to identify preventive measures.

The hazard-analysis step is fundamental to the HACCP system. To establish a plan that effectively prevents food-safety hazards, it is crucial that all significant safety hazards and the measures to control them be identified.

Overhead *2*

Principle 1:
Conduct a hazard analysis. Prepare a list of steps in the process where significant hazards occur and describe the preventive measures.

As previously stated, a hazard is a biological, chemical or physical property that may cause a food to be unsafe for consumption. The term hazard, when used in the context of HACCP, is limited to safety.

- *Considerations for the HACCP Team*

During the hazard analysis, the potential significance of each hazard should be assessed by considering risk (likelihood of occurrence) and severity. The estimate of risk is usually based upon a combination of experience, epidemiological data and information in the technical literature. Severity is the seriousness of a hazard.

During the hazard analysis, factors that may be beyond the immediate control of the processor must be considered. For example, product distribution may be beyond direct control of your firm, but information on how the food will be distributed could influence how the food will be processed and/or packaged.

Continued

Explanatory Note:

As students gain experience and confidence in understanding hazard analysis, they should identify preventive measures at the same time as they perform the hazard analysis. However, for the sake of instruction, these will be discussed separately. Ultimately they will be linked together.

Explanatory Note:

HACCP traditionally deals only with food-safety hazards. Participants may realize that issues associated with GMPs — sanitation, economic fraud and wholesomeness — are important and must be properly handled by the processor. However, unless these issues specifically affect food safety, they should not be part of a company's HACCP program.

Explanatory Note:

Smoked fish offers an example of considering factors beyond the immediate control of the processor. Due to the possibility of temperature abuse during distribution and/or retail sales of smoked fish, the potential exists for germination, growth and toxin production of *Clostridium botulinum* type E. The hazard is controlled by brining fish to achieve salt concentrations at some specified level (e.g., 3.5 percent water-phase salt in the finished product).

Notes:

For some processors, the expertise necessary to properly assess the risk of occurrence and severity of the various hazards is available within the company. However, others may need to seek outside assistance to address this issue correctly.

The HACCP team has the initial responsibility to decide which hazards are significant and must be addressed by the HACCP plan. Keep in mind that there may be differences of opinion, even among experts, as to the significance of a hazard. The HACCP team may rely on available guidance materials and the opinions of experts who assist in the development of HACCP plans. During the hazard analysis, safety concerns must be differentiated from quality concerns.

Hazard Analysis

One approach to hazard analysis divides it into two activities — brainstorming and risk assessment. Brainstorming should result in a list of potential hazards at each operational step (use flow diagram) in the process from the receipt of raw materials to the release of the finished product. During brainstorming, the team need not be confined by the hazard's likelihood of occurence or its potential for causing disease.

All potentially significant hazards must be considered. To assist in this, the following list of hazards will be valuable.

Overhead 3

Hazards List

Biological Hazards:
- Pathogenic microorganisms (e.g., bacteria, viruses)
- Parasites

Chemical Hazards:
- Natural toxins
- Chemicals
- Pesticides
- Drug residues
- Unapproved food and color additives
- Decomposition (safety only, e.g., histamine)

Physical Hazards:
- Metal, glass, etc.

Explanatory Note:

The list of hazards and FDA's Fish and Fishery Products Hazards and Controls Guide can be very useful, especially for firms that do not have strong technical expertise. These firms may also need to seek technical assistance in developing their HACCP programs.

After brainstorming, the team conducts an analysis of the risks and severity of each of the hazards to determine the significance of the food-safety hazards. This can be confusing, since it is easy to suggest that any hazard that compromises food safety should be controlled. However,

HACCP focuses solely on significant hazards that are **reasonably likely to occur and likely to result in an unacceptable health risk to consumers.** Without this focus, it would be tempting to try to control too much and thus lose sight of the truly relevant hazards.

Overhead *4*

Hazard Analysis
A significant hazard must be controlled if it is
- reasonably likely to occur, and
- likely to result in an unacceptable risk to consumers.

• *Hazard-Analysis Worksheet*

A hazard-analysis worksheet can be used to organize and document the considerations in identifying food-safety hazards. In the cooked-shrimp example, each step in the process flow diagram should is first listed in Column 1. The results of the hazards brainstorming is recorded in Column 2. The results of the risk assessment should be recorded in Column 3, with the justification for accepting or rejecting the listed potential hazards stated in Column 4.

Preventive Control Measures

Preventive measures are actions and activities that can be used to prevent or eliminate a food-safety hazard or reduce it to an acceptable level. In practice, preventive measures encompass a wide array of measures.

On the hazard-analysis worksheet, please note the significant hazards that are identified for IQF cooked shrimp. At the receiving step, bacterial pathogens and chemicals have been identified as significant hazards for the two raw material forms (fresh and frozen) used by this company. Bacterial pathogens (e.g., Vibrios) are known to be associated with raw (fresh and frozen) shrimp, hence they must be identified as significant hazards. Additionally, sulfiting agents used to inhibit the development of blackspot are considered significant hazards.

As ABC Shrimp Co. analyzed its process, it did not identify any preventive measures at the receiving step for bacterial pathogens on incoming product. However, it did determine preventive measures for chemicals. Previously sulfited product will be labeled. For raw product received from boats, the company will test for sulfiting agents. For frozen shrimp received from other suppliers, ABC Shrimp Co. will rely on supplier declarations. ABC Shrimp Co. also has identified mislabeling as a significant hazard at the weigh/pack/label stage because of sulfiting use. ABC Shrimp Co. resolved this hazard by training weigh/pack/label personnel to identify and use the correct label.

Continued

Explanatory Note:

First time HACCP writers, more often than not, identify **too** many hazards! This is a problem because the potential exists to dilute a processor's ability to focus efforts and control the truly significant hazards. Therefore, it is essential that only the genuinely significant safety hazards be identified and controlled with the HACCP system. The dilemma is deciding what is significant. A hazard must be controlled if it is: **1) reasonably likely** to occur **AND 2)** if not properly controlled, it is likely to result as an unacceptable health risk to consumers. In the case of hazards for which regulatory action levels, tolerances or other limits have been established for safety concerns (e.g., pesticides, animal drugs), an unacceptable health risk is the risk that the limit has been exceeded, not the mere presence of the substance at a detectable level. Therefore, if violation of an action level in that type of food is reasonably likely to occur, then the processor's hazard analysis should identify that hazard as one to be controlled through its HACCP system.

Explanatory Note:

Verification procedures will be discussed later, but at this point, ABC Shrimp Co. may verify the results of the supplier testing by randomly conducting its own tests.

Notes:

Cold storage is identified in the hazard analysis as potentially important in terms of food safety. Unless temperatures are properly maintained, bacterial pathogens can increase. Therefore, maintaining refrigerated storage conditions is a preventive measure.

ABC Shrimp Co. also noted a significant hazard at the cooking step. At this step, where it is most concerned about the survival of pathogens that may contaminate the finished product, ABC Shrimp Co. has determined three measures that are important in controlling this hazard. First, an adequate cook time and temperature will be established that ensures the destruction of bacterial pathogens. Second, cook time and temperature are monitored to assure they meet the requirements of the established process. Third, cooker personnel will be trained to operate all cooking equipment, including monitoring devices (timers and temperature recorders).

Examples of Preventive Measures

The following are examples of preventive measures that could be used to control the three types of hazards.

A. Biological Hazards

Bacteria

1. Time/temperature control (e.g., proper control of refrigeration and storage time minimizes the growth of pathogens).
2. Heating and cooking processes (e.g., thermal processing).
3. Cooling and freezing (e.g., cooling and freezing retard the growth of pathogenic bacteria).
4. Fermentation and/or pH control (e.g., lactic acid-producing bacteria in yogurt inhibit the growth of some pathogenic bacteria that do not grow well in acidic conditions).
5. Addition of salt or other preservatives (e.g., salt and other preservatives inhibit growth of some pathogenic bacteria).
6. Drying (e.g., the drying process may use enough heat to kill pathogenic bacteria, but even when drying is conducted at lower temperatures, it may remove enough water from the food to prevent some pathogens from growing).
7. Source control (e.g., the presence or amount of pathogens in raw materials may be controlled by obtaining them from non-contaminated sources).

Viruses

1. Cooking methods (e.g., adequate cooking will destroy viruses).

Parasites

1. Dietary control (e.g., preventing the parasite from having access to the food. For example, infection from *Trichinella spiralis* in pork has decreased due to better control of pigs' diets and environments. However, this control method is not always practical for all species of animals used for food. The diet and environment of wild fish cannot be controlled, for instance).
2. Inactivation/removal (e.g., some parasites are resistant to chemical disinfection but can be inactivated by heating, drying or freezing. In some foods, visual examination may detect parasites. A procedure called "candling," enables processors to examine fish on a brightly lit table. Over the light, worms, if present, are easy to see and remove. This procedure cannot ensure 100 percent detection. Therefore, it should be combined with other means of control, such as freezing.)

B. Chemical Hazards

1. Source control (e.g., vendor certification and raw-material testing).
2. Production control (e.g., proper use and application of food additives).
3. Labeling control (e.g., finished product properly labeled with ingredients and known allergens).

C. Physical Hazards

1. Source control (e.g., vendor certification and raw-material testing).
2. Production control (e.g., use of magnets, metal detectors, sifter screens, destoners, clarifiers, air tumblers, and x-ray equipment).

NOTE: Preventive measures for each significant hazard should be recorded in column 5 of the hazard-analysis worksheet.

Notes:

Continued

Hazard-Analysis Worksheet

ABC Shrimp Co.

IQF Cooked Shrimp Production

Example: For Illustrative Purposes Only*

Note: The ABC Shrimp Co. will serve as our model seafood processing firm. Following the discussion of each HACCP principle, that principle will be applied to the ABC Shrimp Co. Please become familiar with the process flow diagram and process narrative associated with the model.

(1) Ingredient/processing step	(2) Identify potential hazards introduced, controlled or enhanced at this step.	(3) Are any potential food-safetv hazards significant? (Yes/No)	(4) Justiy your decision for column 3.	(5) What preventative measure(s) can be applied to prevent significant hazards?	(6) Is this step a critical control point ? (Yes/No)
Receiving Fresh Shrimp	BIOLOGICAL Bacterial Pathogens	Yes	Raw seafoods can be natural reservoirs for marine vibrios and, depending on the quality of the harvest, can harbor terrestrial pathogens such as *Salmonella*.	A cook step follows that assumes a high bacterial load.	
Note: If this product were marketed raw, the answer in column 3 would be no because the product is highly unlikely to be used by a consumer without adequate cooking. In this case, this would not be a significant hazard.					
	CHEMICAL Sulfiting agent	Yes	Sulfiting agents may cause an allergic-type reaction.	Product screening	
Note: If shrimp were aquacultured, hazards could include chemicals such as pesticides, herbicides and heavy metals. Additionally, drugs used to prevent disease, control parasites and affect growth should be considered.					
	PHYSICAL None				
Cold Storage	BIOLOGICAL None CHEMICAL None PHYSICAL None				

Firm Name: _____ Product Description: _____

Firm Address: _____

Method of Storage and Distribution: _____

Signature: _____ Intended Use and Consumer: _____

Date: _____

Models may not be fully consistent with guidance contained in FDA's Fish and Fishery Products Hazards and Control Guide.

IQF Cooked Shrimp

(1) Ingredient/processing step	(2) Identify potential hazards introduced, controlled or enhanced at this step?	(3) Are any potential food-safety hazards significant? (Yes/No)	(4) Justify your decision for column 3.	(5) What preventative measure(s) can be applied to prevent the significant hazard?	(6) Is this step a critical control point? (Yes/No)
Receiving Frozen Shrimp	BIOLOGICAL Bacterial Pathogens	Yes	Frozen seafoods can be natural reservoirs for marine vibrios and, depending on the quality of the harvest, can harbor terrestrial pathogens such as *Salmonella.*	A cook step follows that assumes a high bacterial load.	
	CHEMICAL Sulfiting agent	Yes	Sulfiting agents may cause an allergic-type reaction.	Supplier declaration	
	PHYSICAL None				
Frozen Storage	BIOLOGICAL None				
	CHEMICAL None				
	PHYSICAL None				
Receiving Packaging Material	BIOLOGICAL Bacterial pathogen contamination	No	Not likely to occur		
	CHEMICAL Chemical contaminants	No	• Not likely to occur • No history of occurrence		
	PHYSICAL None				
Dry Storage	BIOLOGICAL None				
	CHEMICAL None				
	PHYSICAL None				
Thawing	BIOLOGICAL • Bacterial pathogen growth	Yes	If not properly controlled, bacterial pathogens can grow during thawing.	Control of time and temperature	
	• Bacterial pathogen contamination	No	Controlled by SSOP		
	CHEMICAL None				
	PHYSICAL None				

IQF Cooked Shrimp

(1) Ingredient/processing step	(2) Identify potential hazards introduced, controlled or enhanced at this step?	(3) Are any potential food-safety hazards significant? (Yes/No)	(4) Justify your decision for column 3.	(5) What preventative measure(s) can be applied to prevent the significant hazard?	(6) Is this step a critical control point? (Yes/No)
Size Grading	BIOLOGICAL • Bacterial pathogen growth	No	Not likely to occur because of the continuous process		
	• Bacterial pathogen contamination	No	Controlled by SSOP		
	CHEMICAL Sanitizer residues	No	Controlled by SSOP		
	PHYSICAL None				
Peeling	BIOLOGICAL • Bacterial pathogen growth	No	Not likely to occur (See size grading)		
	• Bacterial pathogen contamination	No	(See size grading)		
	CHEMICAL Sanitizer residues	No	Controlled by SSOP		
	PHYSICAL None				
Razor Slide	BIOLOGICAL • Bacterial pathogen growth	No	Not likely to occur (See size grading)		
	• Bacterial pathogen contamination	No	(See size grading)		
	CHEMICAL Sanitizer residues	No	Controlled by SSOP		
	PHYSICAL None				
Tumbler/Deveiner	BIOLOGICAL • Bacterial pathogen growth	No	Not likely to occur (See size grading)		
	• Bacterial pathogen contamination	No	(See size grading)		
	CHEMICAL Sanitizer residues	No	Controlled by SSOP		
	PHYSICAL None				
Cull Table	BIOLOGICAL • Bacterial pathogen growth	No	Not likely to occur (See size grading)		
	• Bacterial pathogen contamination	No	(See size grading)		
	CHEMICAL Sanitizer residues	No	Controlled by SSOP		
	PHYSICAL None				

IQF Cooked Shrimp

(1) Ingredient/processing step	(2) Identify potential hazards introduced, controlled or enhanced at this step.	(3) Are any potential food-safety hazards significant? (Yes/No)	(4) Justiy your decision in column 3.	(5) What preventative measure(s) can be applied to prevent the significant hazards?	(6) Is this step a critical control point? (Yes/No)
Cold Storage	BIOLOGICAL Bacterial pathogen growth	Yes	without controlled temperatures, bacterial pathogens may increase in numbers.	Monitor cold storage temperatures	
	CHEMICAL Sanitizer residues	No	Controlled by SSOP		
	PHYSICAL None				
Cooker	BIOLOGICAL Bacterial pathogen survival	Yes	Without proper processing time and temperature, bacterial pathogens such as *Listeria monocytogenes*, *Salmonella* spp. and *Vibrio* spp. may survive.	Adequate cooking time and temperature	
	CHEMICAL Sanitizer residues	No	Controlled by SSOP		
	PHYSICAL None				
Shuffler	BIOLOGICAL • Recontamination with bacterial pathogens	No	Controlled by SSOP		
Note: Companies that DO NOT have SSOPs in place would need to control post-processing contamination with appropriate HACCP sanitation CCPs.					
	• Bacterial pathogen growth	No	Not likely to occur because of the continuous process		
Note: Under different conditions where time and temperature abuse may occur, controls must be sufficient to minimize the growth of bacterial pathogens in the product. Remember, this product does not have to be heated by the consumer.					
	CHEMICAL Sanitizer residues	No	Controlled by SSOP		
	PHYSICAL None				
Cull	BIOLOGICAL • Recontamination with bacterial pathogens	No	Controlled by SSOP		
	• Bacterial pathogen growth	No	(See remarks for shuffler)		
	CHEMICAL Sanitizer residues	No	Controlled by SSOP		
	PHYSICAL None identified				
Spiral Freezer	BIOLOGICAL Bacterial pathogen growth	No	Not likely to occur due to rapid freezing rate		
	CHEMICAL Sanitizer residues	No	Controlled by SSOP		
	PHYSICAL None identified				

IQF Cooked Shrimp

(1) Ingredient/processing step	(2) Identify potential hazards introduced, controlled or enhanced at this step?	(3) Are any potential food-safet hazards significant (Yes/No)	(4) Justify your decision for column 3.	(5) What preventative measure(s can be applied to prevent the significant hazard?	(6) Is this ste a critical control point? (Yes/No)
Glaze Station	BIOLOGICAL • Recontamination with bacterial pathogens	No	Use potable water and equipment cleaned per SSOP		
	• Bacterial pathogen growth	No	(See shuffler)		
	CHEMICAL Sanitizer residues	No	Controlled by SSOP		
	PHYSICAL None				
Weigh/Pack/Label	BIOLOGICAL • Recontamination with bacterial pathogens	No	(See shuffler)		
	• Bacterial pathogen growth	No	(See shuffler)		
	CHEMICAL Sulfiting agent	No	Potential allergic-type reaction (accurate label declaration)	Accurate label declaration	
	Sanitizer Residues	No	Controlled by SSOP		
	PHYSICAL None identified				
Mastercase/Palletize	BIOLOGICAL Bacterial pathogen growth	No	Not likely to occur because frozen		
	CHEMICAL None				
	PHYSICAL None				
Freezer Storage	BIOLOGICAL Bacterial pathogen growth	No	Not likely to occur because frozen		
	CHEMICAL None				
	PHYSICAL None				
Shipping	BIOLOGICAL Bacterial pathogen growth	No	Not likely to occur because frozen		
	CHEMICAL None				
	PHYSICAL None				

Notes:

Overhead *1*

Objective:
In this module, you will learn:
- The definition of a critical control point (CCP).
- The relationship between a significant hazard and a CCP.
- A CCP may change for product formulations and processing lines.
- The use of a decision tree to select a CCP.
- Examples of CCPs.

For every significant hazard identified during the hazard analysis (Principle 1), there must be one or more CCPs where the hazard is controlled. The CCPs are the points in the process where the HACCP control activities will occur.

Overhead *2*

Definition:
Critical Control Point: A point, step or procedure at which control can be applied and a food-safety hazard can be prevented, eliminated or reduced to acceptable levels.

A CCP should be a specific point in the process flow where application of a preventive measure effectively controls the hazard.

Overhead *3*

Points may be identified as CCPs when hazards can be prevented.

In some products and processes, the following may be true:
- Introduction of pathogens or drug residue can be prevented by control at the receiving step (e.g., supplier declaration).
- A chemical hazard can be prevented by control at the formulation or ingredient-addition step.
- Pathogen growth in the finished product can be prevented by control at the formulation or ingredient-addition step (e.g., pH adjustment or addition of preservatives).
- Pathogen growth can be controlled by refrigerated storage or chilling.

Continued

Notes:

Overhead 4

Points may be identified as CCPs when hazards can be eliminated.

In some products and processes, the following may be true:

- Pathogens can be killed during cooking.
- Metal fragments can be detected by a metal detector and eliminated by removing the contaminated product from the processing line.
- Parasites can be killed by freezing (e.g., *Anisakis* in fish destined for raw consumption).

Overhead 5

Points may be identified as CCPs when hazards are reduced to acceptable levels.

In some products and processes, the following may be true:

- The occurrence of foreign objects can be minimized by manual sorting and automatic collectors.
- Some biological and chemical hazards can be minimized by obtaining shellfish from approved waters.

It may not be possible to fully eliminate or prevent a significant hazard. In some processes and with some hazards, minimization may be the only reasonable goal of the HACCP plan. For example, when producing a product that will be consumed raw or partially cooked, no lethal treatment may exist to eliminate a pathogen hazard, or no technology may exist to detect and prevent a chemical or physical hazard. In these cases, it may be necessary to select CCPs that allow significant hazards to be reduced to acceptable levels.

Although hazard minimization is acceptable in some instances, it is important that all significant hazards be addressed and that any limitations of the HACCP plan to control those hazards be understood.

Overhead 6

Definition:
Control Point: Any point, step or procedure at which biological, physical or chemical factors can be controlled.

Overhead 7

CCPs vs. Control Points

. ***CCPs*** *vs. Control Points*

Any points in the flow diagram not identified as CCPs are considered control points. A HACCP plan can lose focus if points are unnecessarily identified as CCPs.

Only points at which significant food-safety hazards can be controlled are considered to be CCPs. A tendency exists to control too much and to designate too many CCPs. A CCP should be limited to that point or those points at which control of the significant hazards can best be achieved. For example, a metal hazard can be controlled by ingredient sourcing, magnets, screens and a metal detector, all in one line. However, sourcing, magnets and screens would not be considered CCPs if the metal hazard is best controlled by use of metal detection and product rejection.

Overhead 8

Multiple CCPS and Hazards

• ***Multiple CCPs*** *and* ***Hazards***

A CCP can be used to control more than one hazard. For example, refrigerated storage might be a CCP to control pathogen growth and histamine formation. Likewise, more than one CCP may be needed to control a hazard. In controlling pathogens in cooked hamburger patties, the cook and the patty-forming steps could both be identified as CCPs if cooking time is based on a maximum patty thickness.

Continued

Notes:

Explanatory Note:

Reintroduce the IQF cooked shrimp example. Use the decision tree to fill in the sixth column in the hazard-analysis worksheet. On this worksheet, we previously noted for receiving of fresh (and frozen) shrimp in column 5 that a subsequent step can be applied to control the hazard of bacterial pathogens on raw shrimp. Thus the answer to question 1 on the decision tree is yes.

Explanatory Note:

In the IQF cooked-shrimp example, bacterial pathogens were identified as a significant hazard at the receiving-fresh-shrimp step. In some cases, supplier guarantees or raw material handling can minimize pathogen levels at a receiving step. However, those measures are not likely to reduce the hazard of pathogens, such as *Salmonella* or *Listeria,* to acceptable levels in the finished product. Therefore, the receiving step cannot be used in this plant to "eliminate or reduce the likely occurrence of a hazard to an acceptable level." The answer to Question 2 is no.

Overhead 9

CCPS are Product- and Process-Specific.

- ***CCPs are Product- and Process-Specific***

CCPs identified for a product on one processing line may be different for the same product on another line. This is because the hazards and the best points for controlling them may change with differences in:

- plant layout,
- formulation,
- process flow,
- equipment,
- ingredient selection and
- sanitation and support programs.

Although HACCP models and generic HACCP plans can be useful in considering CCPs, the HACCP requirements of each formulation and processing line must be considered separately.

- ***CCP Decision Tree***

In Principle One, you learned how to determine where hazards enter a process or may be enhanced during the process. Often the best place to control a hazard is at the point of entry. But this is not always true. The CCP can be several process steps away from the point where the significant hazard is introduced. A series of four questions can help to identify CCPs for a process (see ***Figure I). The*** questions are referred to as the CCP Decision Tree and are asked at each process step identified in Principle 1 with a significant hazard. Properly used, the CCP decision tree can be a helpful tool in identifying CCPs, but it is not a perfect tool. Although application of the CCP decision tree can be useful in determining if a particular step is a CCP for a previously identified hazard, it is merely a tool and not a mandatory element of HACCP The CCP decision tree is not a substitute for expert knowledge, since complete reliance on the decision tree can lead to false conclusions.

Question 1. Does a preventive measure(s) exist at this step or subsequent steps in the process flow for the identified hazard?

If your answer is yes, ask Question 2.

If you cannot identify a preventive measure in the process that controls the hazard, answer no. If the answer is no, then ask: Is control at this step necessary for safety? If this answer is no too, the step is not a CCP for that hazard. Move to the next hazard at that step or to the next step with a significant hazard. If the answer is yes, then you have identified a significant hazard that is not being controlled. In this case, the step, process or product must be redesigned to include a preventive measure. Sometimes there is no reasonable preventive measure available. In such cases, HACCP does not provide assurance that food products are 100 percent safe.

Question 2. Does this step eliminate or reduce the likely occurrence of a significant hazard to an acceptable level?

To answer this question, consider if this is the **best** step at which to control the hazard? If the answer is yes, then the step is a CCP; move to the next significant hazard. If the answer is no, ask Question 3.

Question 3. Could contamination with an identified hazard or hazards occur in excess of acceptable levels, or could these increase to unacceptable levels?

The question refers to contamination that exists, occurs or increases at this step. If the answer is no, then the step is not a CCP for that hazard. Move to the next hazard at that step or the next step with a significant hazard.

If the answer is yes, then ask the fourth question.

Question 4. Will a subsequent step eliminate the identified hazard or hazards or reduce the likely occurrence to an acceptable level?

If you answer no, then this step is a CCP. If you answer yes, then this step is not a CCP for this hazard. In this case, be sure the hazard is controlled by a subsequent processing step.

In Chapter 5, eight significant hazards were identified for the IQF cooked shrimp. In Table 1, the CCP decision tree is applied for these hazards.

Continued

Explanatory Note:

In the cooked shrimp example, pathogenic microorganisms can be introduced at the receiving-fresh-shrimp step in excess of acceptable levels. The answer to Question 3 is yes.

Explanatory Note:

In the cooked-shrimp example, the cook step will reduce pathogen occurrence to an acceptable level and will be the best point to control the hazard. For the receiving-fresh-shrimp step, the answer to Question 4 is yes. The receiving-fresh-shrimp step is, therefore, not a CCP for bacterial pathogens.

Explanatory Note:

Review the answers to the CCP decision tree questions. Note that once the answers make it clear that a step is or is not a CCP, it is not necessary to continue with the questions for that step (e.g., cooker).

Explanatory Note:

For the hazard due to sulfite residuals in fresh shrimp, the preventive measure is to screen each lot of product with a malachite green test to determine the presence of any chemical residual in excess of **10** ppm, which requires appropriate product labeling. Similarly, supplier declarations are required to determine any residuals and labeling requirements for frozen shrimp.

Notes:

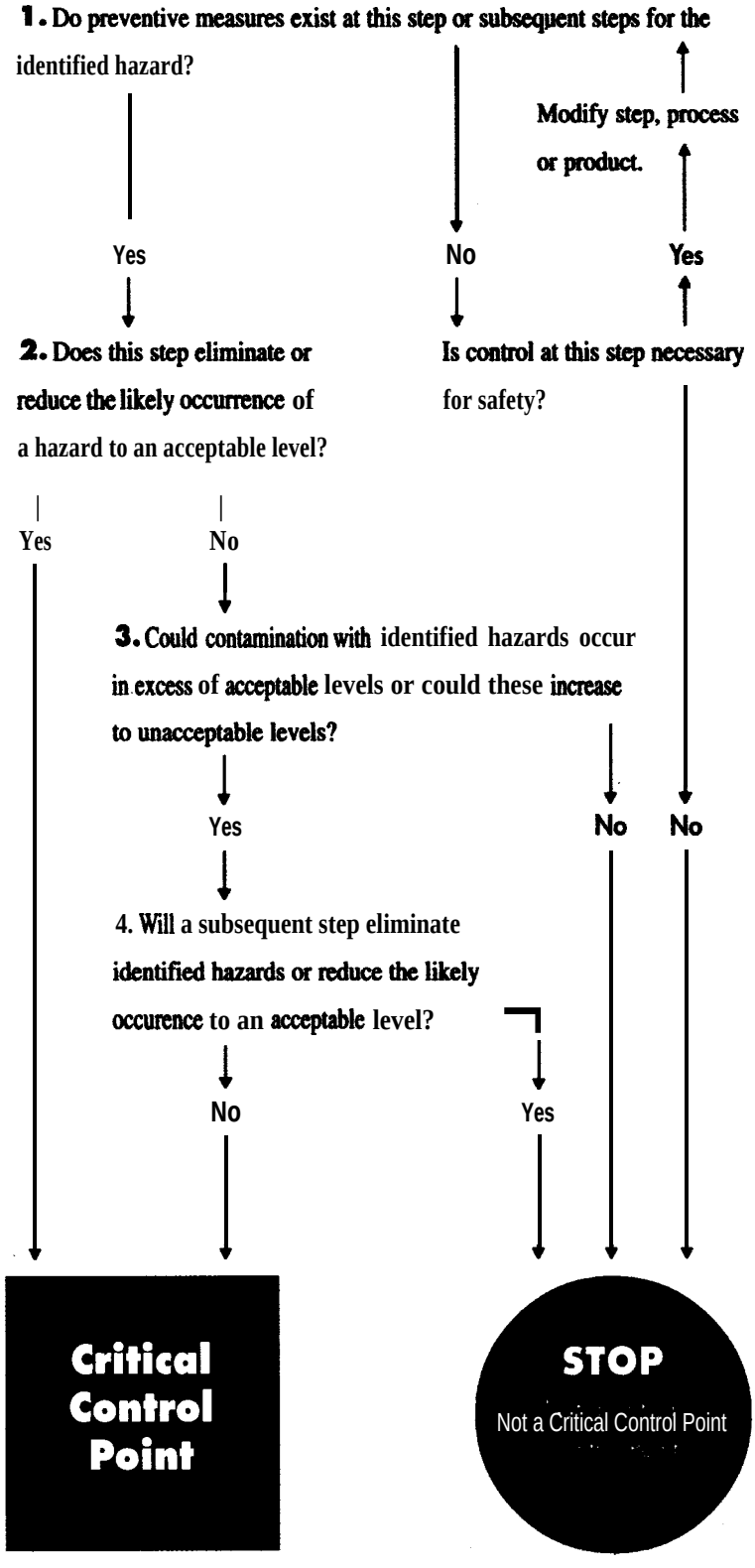
Table 1

CCP Decision Tree Table for IQF Cooked Shrimp Example

Process Step/Hazard	Q1	Q2	Q3	Q4	CCP
Receiving Fresh Shrimp: bacterial pathogens	Yes	No	Yes	Yes	No
Receiving Fresh Shrimp: sulfiting agent	Yes	No	Yes	Yes	No
Receiving Frozen Shrimp: bacterial pathogens	Yes	No	Yes	Yes	No
Receiving Frozen Shrimp: sulfiting agent	Yes	No	Yes	Yes	No
Thawing: bacterial pathogens	Yes	No	Yes	Yes	No
Cold Storage: bacterial pathogens	Yes	No	Yes	Yes	No
Cooker: pathogen survival	Yes	Yes			Yes
Weigh/Pack/Label: sulfiting agent	Yes	Yes			Yes

Notes:

Figure 1: CCP Decision Tree Table



Decision Tree adapted from NACMCF.

Hazard Analysis Worksheet

ABC Shrimp Co.

IQF tied Shrimp Production

*Example: For illustrative Purposes Only**

Note: The ABC Shrimp Co. will serve as our model seafood processing firm. Following the discussion of each HACCP principle, that principle will be applied to the ABC Shrimp Co. Please become familiar with the process flow diagram and process narrative associated with the model.

(1) **Ingredient/processing** step	(2) Identify potential hazards introduced, **controlled** or enhanced at this step.	(3) **Are any** potential fowl-safety hazards significant? **(Yes/No)**	(4) **Justiy your decision** for **column 3.**	(5) What preventative measure(s) can be applied to prevent **significant** hazards?	(6) Is this step a critical **control** point ? **(Yes/No)**
Receiving Fresh Shrimp	BIOLOGICAL Bacterial pathogens	Yes	Raw seafoods can be natural reservoirs for marine vibrios and, depending on the quality of the harvest, can harbor terrestrial pathogens such as ***Salmonella.***	A cook step follows that assumes a high bacterial load.	No
	Note: If this product is marketed raw, the answer in column 3 would be no because the product is highly unlikely to be used by a consumer without adequate cooking. In this case, this would not be a significant hazard.				
	CHEMICAL Sulfiting agent	Yes	Sulfiting agents may cause an allergic-type reaction.	Product screening	No
	Note: If shrimp were aquacultured, hazards could include chemicals suck as pesticides. herbicides and heavy metals. Additionally, drugs used to prevent disease, control parasites and affect growth should be considered.				
	PHYSICAL None				
Cold Storage	BIOLOGICAL None CHEMICAL None PHYSICAL None				

Firm Name: _____ Product Description: _____

Firm Address: _____

Method of Storage and Distribution: _____

Signature: _____ Intended Use and Consumer: _____

Date: _____

Models may not be fully consistent with guidance contained in FDA's Fish and Fishery Products Hazards and Control Guide.

IQF Cooked Shrimp

(1) Ingredient/processing step	(2) Identify potential hazards introduced, controlled or enhanced at this step?	(3) Are any potential food-safety hazards significant? (Yes/No)	(4) Justify your decision for column 3.	(5) What preventative measure(s) can be applied to prevent the significant hazard?	(6) Is this step a critical control point? (Yes/No)
Receiving Frozen Shrimp	BIOLOGICAL Bacterial pathogens	Yes	Frozen seafoods can be natural reservoirs for marine vibrios and, depending on the quality of the harvest, can harbor terrestrial pathogens such as Salmonella.	A cook step follows that assumes a high bacterial load.	No
	CHEMICAL Sulfiting agent	Yes	Sulfiting agents may cause an allergic-type reaction.	Supplier declaration	No
	PHYSICAL None				
Frozen Storage	BIOLOGICAL None				
	CHEMICAL None				
	PHYSICAL None				
Receiving Packaging Material	BIOLOGICAL Bacterial pathogen contamination	No	Not likely to occur		
	CHEMICAL Chemical contaminants	No	• Not likely to occur • No history of occurrence		
	PHYSICAL None				
Dry Storage	BIOLOGICAL None				
	CHEMICAL None				
	PHYSICAL None				
Thawing	BIOLOGICAL • Bacterial pathogen growth	Yes	If not properly controlled, bacterial pathogens can grow during thawing.	Control of time and temperature	No
	• Bacterial pathogen contamination	No	Controlled by SSOP		
	CHEMICAL None				
	PHYSICAL None				

IQF Cooked Shrimp

(1) Ingredient/processing step	(2) Identify potential hazards introduced, controlled or enhanced at this step?	(3) Are any potential food-safety hazards significant? (Yes/No)	(4) Justify your decision for column 3.	(5) What preventative measure(s) can be applied to prevent the significant hazard?	(6) Is this step a critical control point? (Yes/No)
Size Grading	BIOLOGICAL • Bacterial pathogen growth	No	Not likely to occur because of the continuous process		
	• Bacterial pathogen contamination	No	Controlled by SSOP		
	CHEMICAL Sanitizer residues	No	Controlled by SSOP		
	PHYSICAL None				
Peeling	BIOLOGICAL • Bacterial pathogen growth	No	Not likely to occur (See size grading)		
	• Bacterial pathogen contamination	No	(See size grading)		
	CHEMICAL Sanitizer residues	No	Controlled by SSOP		
	PHYSICAL None				
Razor Slide	BIOLOGICAL • Bacterial pathogen growth	No	Not likely to occur (See size grading)		
	• Bacterial pathogen contamination	No	(See size grading)		
	CHEMICAL Sanitizer residues	No	Controlled by SSOP		
	PHYSICAL None				
Tumbler/Deveiner	BIOLOGICAL • Bacterial pathogen growth	No	Not likely to occur (See size grading)		
	• Bacterial pathogen contamination	No	(See size grading)		
	CHEMICAL Sanitizer residues	No	Controlled by SSOP		
	PHYSICAL None				
Cull Table	BIOLOGICAL • Bacterial pathogen growth	No	Not likely to occur (See size grading)		
	• Bacterial pathogen contamination	No	(See size grading)		
	CHEMICAL Sanitizer residues	No	Controlled by SSOP		
	PHYSICAL None				

IQF Cooked Shrimp

(1) Ingredient/processing step	(2) Identify potential hazards introduced, controlled or enhanced at this step.	(3) Are any potential food-safety hazards significant? (Yes/No)	(4) Justiy your decision in column 3.	(5) What preventative measure(s) caa be applied to prevent the significant hazards?	(6) Is this step a critical control point? (Yes/No)
Cold Storage	BIOLOGICAL Bacterial pathogen growth	Yes	Without controlled temperatures, bacterial pathogens may increase in numbers.	Monitor cold storage temperatures	No
	CHEMICAL Sanitizer residues	No	Controlled by SSOP		
	PHYSICAL None				
Cooker	BIOLOGICAL Bacterial pathogen survival	Yes	Without proper processing time and temperature, bacterial pathogens such as *Listeria monocytogenes,* *Salmonella* spp. and *Vibrio* spp. may survive	Adequate cooking time and temperature	Yes
	CHEMICAL Sanitizer residues	No	Controlled by SSOP		
	PHYSICAL None				
Shuffler	BIOLOGICAL • Recontamination with bacterial pathogens	No	Controlled by SSOP		
Note: Companies that DO NOT have SSOPs in place would need to control post-processing contamination with appropriate HACCP sanitation CCPs.					
	• Bacterial pathogen growth	No	Not likely to occur because of the continuous process		
Note: Under different conditions where time and temperature abuse may occur, controls must be sufficient to minimize the growth of bacterial pathogens in the product. Remember, this product does not have to be heated by the consumer.					
	CHEMICAL Sanitizer residues	No	Controlled by SSOP		
	PHYSICAL None				
Cull	BIOLOGICAL • Recontamination with bacterial pathogens	No	Controlled by SSOP		
	• Bacterial pathogen growth	No	(See remarks for shuffler)		
	CHEMICAL Sanitizer residues	No	Controlled by SSOP		
	PHYSICAL None identified				
Spiral Freezer	BIOLOGICAL Bacterial pathogen growth	No	Not likely to occur due to rapid freezing rate		
	CHEMICAL Sanitizer residues	No	Controlled by SSOP		
	PHYSICAL None identified				

IQF Cooked shrimp

(1) Ingredient/processing step	(2) Identify potential hazards introduced, controlled or enhanced at this step?	(3) Are any potential food-safety hazards significant? (Yes/No)	(4) Justify your decision for column 3.	(5) What preventative measure(s) can be applied to prevent the significant hazard?	(6) Is this step a critical control point? (Yes/No)
Glaze Station	BIOLOGICAL • Recontamination with bacterial pathogens	No	Use potable water and equipment cleaned per SSOP		
	• Bacterial pathogen growth	No	(See shuffler)		
	CHEMICAL Sanitizer residues	No	Controlled by SSOP		
	PHYSICAL None				
Weigh/Pack/Label	BIOLOGICAL • Recontamination with bacterial pathogens	No	(See shuffler)		
	• Bacterial pathogen growth	No	(See shuffler)		
	CHEMICAL Sulfiting agent	No	Potential allergic-type reaction (accurate label declaration)	Accurate label declaration	Yes
	Sanitizer Residues	No	Controlled by SSOP		
	PHYSICAL None identified				
Mastercase/Palletize	BIOLOGICAL Bacterial pathogen growth	No	Not likely to occur because frozen		
	CHEMICAL None				
	PHYSICAL None				
Freezer Storage	BIOLOGICAL Bacterial pathogen growth	No	Not likely to occur because frozen		
	CHEMICAL None				
	PHYSICAL None				
Shipping	BIOLOGICAL Bacteria1 pathogen growth	No	Not likely to occur because frozen		
	CHEMICAL None				
	PHYSICAL None				

Notes:

Overhead *1*

Objective:
In this module, you will learn:
- How to define critical limits.
- How to set critical limits for a CCP.
- How to find sources of critical limit information.
- How to determine the relationship between critical limits and operating limits.

Critical limits must be established for each CCP identified in the hazard analysis.

Overhead *2*

Principle 3:
Establish critical limits for preventive measures associated with each CCP.

Overhead *3*

Definition:
Critical limit: A criterion that must be met for each preventive measure associated with a CCP.

A critical limit represents the boundaries that are used to ensure that an operation produces safe products. Each CCP must have one or more critical limits for each significant hazard. When the process deviates from the critical limit, a corrective action must be taken to ensure food safety. Examples of critical limits are listed in Table 1.

Establishing Critical limits

In many cases, the appropriate critical limit may not be readily apparent or available. Tests may need to be conducted or information gathered from sources such as scientific publications, regulatory guidelines, experts or experimental studies (Table 2).

Continued

Overhead 4

Table 1. Examples of Critical Limits

Hazard	*CCP*	*Critical Limit*
bacterial pathogens (biological)	pasteurizer	161 F for 15 seconds for elimination of pathogens from milk
bacterial pathogens (biological)	drying oven	Drying schedule — oven temperature: 200 F, drying time: 120 min., air flow rate: 2 cuft/min, product thickness: 0.5 inches (to achieve $a_w \leq$ to 0.85 to control pathogens in dried foods)
bacterial pathogens (biological)	acidification	Batch schedule — product weight: 100 lbs., soak time: 8 hrs., acetic acid concentration: 3.5 percent, volume 50 gal. (to achieve maximum pH of 4.6 to control *Clostridium botulinum* in pickled foods)

Explanatory Note:

These critical limits are for illustrative purposes only. They do not relate to any specific product but demonstrate how critical limits could apply at CCPs utilizing different control parameters for bacterial pathogens.

Overhead 5

Table 2. Sources of Information on Critical Limits

General Source	*Examples*
scientific publications	journal articles, food science texts, microbiology texts
regulatory guidelines	state and local guidelines, tolerances and action levels; USDA guidelines, tolerances and action levels; FDA guidelines, tolerances and action levels
experts	NACMCF (National Advisory Committee on Microbiological Criteria for Foods), thermal process authorities; consultants, food scientists/microbiologists, equipment manufacturers, sanitarians, university extension, trade associations
experimental studies	in-house experiments; contract labs

If the information needed to define the critical limit is not available, a conservative value should be selected. The rationale and reference material used to establish a critical limit should become part of the support documentation for the HACCP plan.

Often a variety of options exist for controlling a particular hazard. The control options usually necessitate the establishment of different critical limits. The selection of the best control option and the best critical limit is often driven by practicality and experience. The following examples suggest control options and critical limits that could be applied at the fryer step to control bacterial pathogens in fried fish patties.

Notes:

Overhead 6

Option No. 1
Monitoring for Pathogens
Hazard — presence of pathogens (microbiological)
CCP — fryer
Critical limit — no pathogens detected

(Not typically the best option)

Setting a microbial limit as a critical limit for an in-process CCP is rarely practical. Microbiological limits are difficult to monitor, and testing to determine critical limit deviations may require several days. Therefore, microbiological limits cannot be monitored on a timely basis. Microbiological contamination is often sporadic, and samples may need to be large to be meaningful. In this example, sampling and microbiological tests of the fish patties are unlikely to be sensitive enough or practical.

Overhead *7*

Option No. 2
Controlling Internal Temperature
Hazard — presence of pathogens (microbiological)
CCP — fryer
Critical limit — minimum internal temperature of 150 F

Setting a microbial critical limit is not necessary in this example as long as an appropriate critical limit can be set that is based on the conditions needed to inactivate the microorganisms of concern. Pathogens of concern in fish patties are destroyed by cooking the patties to an internal temperature of 150 F. In this option, the product temperature at the end of frying is used as a critical limit. This option is typically more practical and sensitive than finished-product pathogen testing.

Continued

Notes:

Overhead 8

Option No. 3
Controlling Factors that Affect Internal Temperature
Hazard — presence of pathogens (microbiological)
CCP — fryer
Critical limit — minimum fryer oil temperature of 350 F
Critical limit — maximum patty thickness of 1/4 inch
Critical limit — minimum cook time in the oil of 1 minute

In many cases, it is not practical to continually monitor the internal temperature of the food product to ensure conformance with a critical limit. As an alternative, critical limits may be set that establish conditions necessary to assure that the cooking process achieves the necessary minimum product temperature. In this option, the oil temperature, the fish patty thickness and the time that the patty stays in the hot oil are all factors that affect the final patty temperature. Tests must be performed to ensure that controlling these factors within the critical limits will always result in an internal product temperature that will inactivate the microorganisms of concern. Typically, this option is easier to control and to monitor than the other two. In addition, the cooker temperature and cooking time can be monitored continually, which gives greater confidence that every item has been adequately cooked.

The process should be capable of operating within the bounds set by the critical limit. The parameters for the fryer — minimum fryer-oil temperature, maximum patty thickness and minimum cook time — become the critical limits for the CCP. The critical limits should not be confused with the operating parameters of the equipment.

Establishing Operating limits

Overhead *9*

Definition:
Operating Limits: Criteria that are more stringent than critical limits and that are used by an operator to reduce the risk of a deviation.

If monitoring shows a trend toward lack of control at a CCP, operators should take action to bring the CCP under control before the critical limit is exceeded. The point where operators take such an action is called the operating limit. Operating limits should not be confused with critical limits. Operating limits are established at a level that would be reached before the critical limit is violated.

Overhead 10

Notes:

Definition:
Process adjustment: An action taken by the firm to bring the process back within operating limits.

The process should be adjusted when the operating limit is exceeded to avoid violating critical limits. These actions are called process adjustments. A processor may use these adjustments to avoid loss of control and the need to take corrective action. Spotting a trend toward loss of control early and acting on it can save product rework, or worse yet, product destruction. Corrective action is only required when the critical limit is exceeded.

Operating limits may be selected for various reasons:

- For quality reasons (e.g., higher cooking temperatures for flavor development or to control organisms that can cause spoilage).
- To avoid exceeding a critical limit (e.g., a cooking temperature higher than the critical limit could be used as an alarm point to warn the operator that the temperature is approaching the critical limit and needs adjusting).
- To account for normal variability (e.g., a fryer with a 5 F variability should be set at least 5 F above the critical limit to avoid violating it).

Figures 1 and 2 are graphical representations of several important points: 1) operating limits and process adjustments, 2) critical limits and corrective actions, and 3) implications of lot size. In this example of a generalized cooking process, an operating limit is established at 200 F and a critical limit at 190 F. Somewhere in the 10 F range between these two points, wise processors will make a process adjustment to bring the cook temperature back above 200 F. Because an adjustment is made before the temperature drops below the critical limit of 190 F, no HACCP record is required. However, if an adjustment is not taken until after the temperature drops below the critical limit, appropriate corrective actions must be taken and a corrective action report must be placed in the HACCP records file (corrective actions and records will be discussed in subsequent chapters).

When a corrective action is necessary, processors must be able to identify and segragate the affected lots. If lot sizes are big, large quantities of product may require segregation and corrective action despite the fact that only a small amount of product was produced when critical limits were exceeded. Coding production into smaller lots means far less product may be involved when violation of a critical limit occurs. Therefore, wise processors should change codes often during the production day and match monioring frequency with code changes.

Notes:

Figure 1

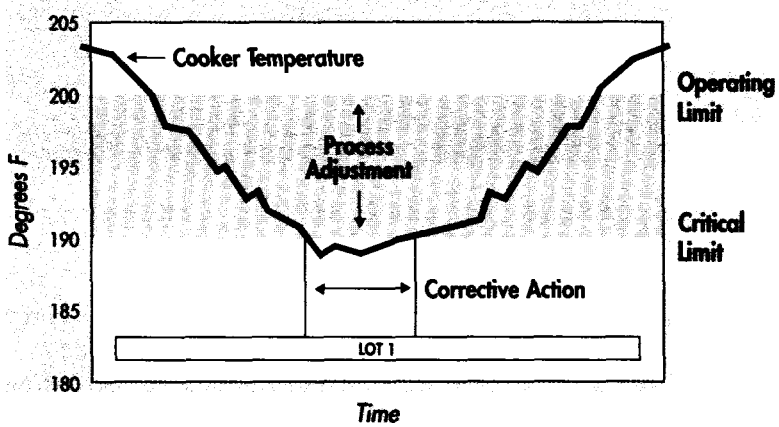
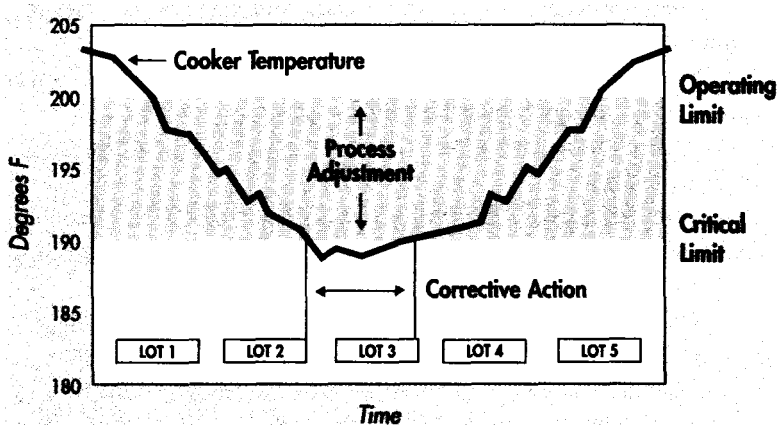


Figure 2



Critical Limits for ABC Shrimp Co.

The hazard-analysis worksheet for the IQF cooked-shrimp example identifies two CCPs: cooker and weigh-pack-label. The following table lists examples of critical limits for these CCPs.

Overhead *11*

Table 4. Establishment of Critical Limits

Critical Control Point	*Critical Limit*
CCP — Cooker	Cook at 212 F for 3 minutes (to achieve minimum internal temperature of 145 F.)
CCP — Weigh/Pack/Label	All product containing sulfiting agent must declare presence

Overhead *12*

HACCP Plan Form

Critical Limits:

1. CCP	2. Hazard	3. Critical Limits	4. 5. 6. 7. Monitoring (What How Frequency Who)	8. Corrective Action(s)	9. Records	10. Verification

The CCP, hazards and critical limits should be recorded in columns 1, 2 and 3 on the HACCP plan form.

Notes:

Explanatory Note:

For the purpose of this example, we have assumed that a study was performed to determine the worst case (e.g., largest shrimp, lowest initial temperature). The shrimp would be heated to an internal temperature of 140 F and cooked for three minutes at 212 F. In practice, processors may choose to vary process times depending on shrimp size. Therefore, shrimp size grading would likely become a CCP.

Explanatory Note:

Sulfite labeling is required when shrimp have a residual sulfite concentration in excess of the regulatory limit.

EXAMPLE: For Illustrative Purposes Only* - HACCP Plan Form

ABC Shrimp Co.

Cooked Shrimp

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Preventive Measure	(4) Monitoring				(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
Cooker	Survival of bacterial pathogens	Cook at 212 F for three minutes (to achieve minimum internal temperature of 145 F)							
Weigh/Pack/ Label	Allergic-type reaction for undeclared sulfiting agent	All product containing residual sulfiting agent must declare presence							

Firm Name: ABC *Shrimp Co.*

Firm Address: *Anywhere, USA*

Product Description: ***Cooked and frozen, headless, peeled and deveined shrimp***

Method of Storage and Distribution: Frozen

Signature:

Intended Use and Consumer: ***Thaw and serve, general public***

Date:

Models may not **be fully consistent with guidance contained in **FDA's** Fish **and** Fishery Products **Hazards** and Control Guide.*

Notes:

Overhead 1

Objective:
In this module, you will learn:
- How monitoring is defined.
- Why monitoring is needed.
- How to design a monitoring system.
- What methods and equipment are used for monitoring critical limits.
- How often monitoring should be performed.
- Who should monitor.

Monitoring is important to ensure that the critical limits are consistently met.

Overhead 2

Principle 4:
Establish CCP monitoring requirements. Establish procedures for using the results of monitoring to adjust the process and maintain control.

Overhead 3

Definition:
Monitor: to conduct a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification.

Continued

Notes:

- *Purpose for Monitoring*

Overhead 4

MONITORING

Purpose of Monitoring:

- To track the operation of the process and enable the identification of trends toward a critical limit that may trigger process adjustments,
- To identify when there is loss of control (a deviation occurs at a CCP), and
- To provide written documentation of the process control system.

Monitoring is the process that the operator relies upon to maintain control at a CCP. Accurate monitoring indicates when there is a loss of control at a CCP and a deviation from a critical limit. When a critical limit is compromised, a corrective action is needed. The extent of the problem needing correction can be determined by reviewing the monitoring records and finding the last recorded value that meets the critical limit.

Monitoring also provides a record that products were produced in compliance with the HACCP plan. This information is useful in the verification of the HACCP plan as discussed in Principle 7.

- *Design of a Monitoring System*

The preventive measures discussed in Principle 1 and the critical limits discussed in Principle 3 are intended to control the hazards at each CCP. The monitoring procedures are used to determine if the preventive measures are being enacted and the critical limits are being met. Monitoring procedures must identify:

- What will be monitored. (Column 4)
- How the critical limits and preventive measures will be monitored. (Column 5)
- How frequently monitoring will be performed. (Column *6)*
- Who will perform the monitoring. (Column 7)

Overhead *5*

HACCP Plan Form

Monitoring:

1. CCP	2. Hazard	3. Critical Limits	4. 5. 6. 7. Monitoring (What, How, Frequency, Who)	8. Corrective Action(s)	9. Records	10. Verification

Specify the monitoring procedures for each CCP.

Overhead *6*

MONITORING

- **What:** usually a measurement or observation to assess if the CCP is operating within the critical limit.
- **How:** usually physical or chemical measurements (for quantitative critical limits) or observations (for qualitative critical limits). Needs to be real-time and accurate.
- **When (frequency):** can be continuous or intermittent.
- **Who:** someone trained to perform the specific monitoring activity.

Overhead *7*

What will be Monitored?

- ***What will be Monitored***

Monitoring may mean measuring a characteristic of the product or of the process to determine compliance with a critical limit.

Examples include:

- Measurement of cold-storage compartment temperature when critical for temperature-sensitive ingredients.
- Measurement of the pH of an acidifying ingredient when critical for the production of an acidified food.
- Measurement of line speed when critical to adequate cooking or chilling processes.

Continued

Notes:

Notes:

Monitoring may also involve observing if a preventive measure at a CCP is being performed.

Examples include:
- Checking that a vendor's certificate accompanies a lot of raw material.
- Checking the harvest area listed on a tag attached to a container of raw molluscan shellfish to assure harvest from approved waters.

What will be monitored is listed in column 4 of the HACCP plan form.

Overhead 8

How Critical Limits and Preventive Measures will be Monitored

Explanatory Note:

The length of time between monitoring checks will directly affect the amount of rework or product loss when a critical-limit deviation is found.

- ***How Critical Limits and Preventive Measures will be Monitored***

Monitoring must be designed to provide rapid (real-time) results. There is no time for lengthy analytical testing because critical limit failures must be detected quickly and an appropriate corrective action instituted before distribution.

Microbiological testing is seldom effective for monitoring CCPs. Very often the analytical methods are lengthy. Additionally, to do a statistically adequate job of finding pathogenic organisms at levels that may cause illness, large sample sizes are usually needed.

Physical and chemical measurements are preferred monitoring methods because testing can be done rapidly. Physical and chemical measurements (e.g., pH, time, temperature) can often be related to the microbiological control as illustrated by the fried-fish example in Principle 3. Examples of physical- and chemical-measurement monitoring at a CCP follow:

- Time and temperature. This combination of measurements is often used to monitor the effectiveness for destroying or controlling the growth of pathogenic bacteria. By processing a food at a set temperature for a set time, pathogenic bacteria can be destroyed. For example, pasteurized crabmeat (in a 401 x 301 can) should be heated to a container-core temperature of 185 F for one minute. This is usually assured by monitoring the temperature of a heated water bath and by monitoring the time that the product is held therein. In addition, pathogens can be controlled by minimizing exposure of a food to the critical pathogen growth temperatures between 40 F and 140 F. This can be achieved through rapid heating and/or cooling of the product through these critical temperatures and maintaining temperatures below 40 F or above 140 F during storage. For example, monitoring should be performed to determine the cumulative exposure of crabmeat to temperatures between 40 F and 140 F during the processing.

- Water Activity (a_w). Pathogen growth can be controlled by limiting water activity — the amount of water available for microbial growth. For example, drying products to a water activity below 0.85 stops pathogen growth. In this case, samples may be collected during the drying process and tested for water activity. The process is completed when a_w falls below 0.85. Processors may monitor temperature, time and flow if the rate of drying under these conditions is known to achieve an 0.85 a_w at the end of the process.
- Acidity (pH). Pathogen growth can be controlled by limiting the pH of the product to a level that does not allow growth. For instance, the growth of *Clostridium botulinum*, which leads to botulism, is controlled in acidified products by adding acid to lower the pH to 4.6 or below. In this case, the pH of an acidifying agent may be monitored before it is added to a batch. Recording the pH of the finished product is not a good monitoring tool because a few days must pass before the finished product's pH reaches equilibrium.
- Sensory examination. This is a means of testing for decomposition that may result in food-safety hazards such as histamine development. The type and intensity of the odor gives the examiner an indication of the time/temperature abuse that could result in histamine development.

The selection of the monitoring equipment is a major consideration during development of a HACCP plan. Equipment used for monitoring CCPs varies with the attribute being monitored. Examples of monitoring equipment include:

- thermometers,
- clocks,
- scales,
- pH meters,
- water activity meters and
- chemical analytical equipment.

The equipment chosen for monitoring at the CCP must be accurate to assure control of the hazard. The variability of the monitoring equipment should be considered when setting the critical limit. For example, a minimum internal temperature of 145 F is necessary to kill pathogens in a product. If the thermometer has an accuracy off 2 F, then the critical limit should be set no lower than 147 F. Periodic calibration or standardization is necessary to ensure accuracy. This is further discussed in Chapter 11.

How monitoring will be performed is recorded in column 5 of the HACCP plan form.

Notes:

Continued

Notes:

Overhead 9

Monitoring Frequency

- *Monitoring Frequency*

Monitoring can be continuous or noncontinuous. Where possible, continuous monitoring should be used. Continuous monitoring is possible for many types of physical and chemical parameters. Examples of continuous monitoring include:

- The time and temperature of a batch pasteurization process for crabmeat may be continuously monitored and recorded on a temperature-recording chart.
- Each package of frozen, mechanically chopped spinach may be passed under a metal detector.
- The container closures on glass jars may be monitored by passing each jar under a dud detector to reject jars that have not formed a vacuum.

A monitoring instrument that produces a continuous record of the measured value will not control the hazard on its own. The continuous record needs to be observed periodically and action taken when needed. This too is a component of monitoring. The length of time between checks will directly affect the amount of rework or product loss when a critical-limit deviation is found. In all cases, the checks must be performed in time to ensure that irregular product is isolated before shipment.

When it is not possible to monitor a CCP on a continuous basis, it is necessary for the monitoring interval to be short to detect possible deviations from critical limits or operating limits.

The frequency of noncontinuous monitoring should be partially determined from historical knowledge of the product and process. Questions that will help determine the correct frequency include:

- How much does the process-normally vary (i.e., how consistent is the data)? If the data varies considerably, the time between monitoring checks should be short.
- How close are the normal values to the critical limit? If the normal values are close to the critical limit, the time between monitoring checks should be short.
- How much product is the processor prepared to risk if the critical limit is exceeded?

Examples of potential noncontinuous monitoring include:

- Temperature checks of batter on a breading line at specified time intervals.
- Temperature checks of the core temperature of a pasteurized product at specified time intervals.
- Periodic sensory examination for decomposition in histamine-forming seafood

Overhead 10

Who will Monitor?

- ***Who will*** *Monitor?*

Assignment of the responsibility for monitoring is an important consideration when developing a HACCP plan.

Individuals assigned to CCP monitoring can be:
- Line personnel;
- Equipment operators;
- Supervisors;
- Maintenance personnel; or
- Quality-assurance personnel.

Monitoring by line personnel and equipment operators can be advantageous since they are continuously viewing the product and/or equipment and can readily observe changes from the norm. Also, including line personnel in HACCP activities has the advantage of building a broad base of understanding and commitment to the HACCP program.

Those responsible for monitoring a CCP must:
- Be trained in the CCP monitoring techniques.
- Fully understand the importance of CCP monitoring.
- Have ready access to the monitoring activity.
- Accurately report each monitoring activity.
- Immediately report critical-limit infractions so that immediate corrective actions (Principal 5) can be taken.

The monitor's duties should require that all unusual occurrences and deviations from critical limits be reported immediately to make sure adjustments and corrective actions are made in a timely manner. All records and documents associated with CCP monitoring must be signed or initialed by the person doing the monitoring.

The monitoring procedures for each of the critical limits identified in Principle 3 for the IQF cooked-shrimp are contained in the attached HACCP plan.

Who will perform the monitoring will be recorded in column 7 of the HACCP plan form.

Notes:

EXAMPLE: For Illustrative Purposes Only* - HACCP Plan Form

ABC Shrimp Co.

Cooked Shrimp

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Preventive Measure	(4) Monitoring				(8) Corrective Action(s)	(9) Records	(10) Verification
			What	(5) How	(6) Frequency	(7) Who			
Cooker	Survival of bacterial pathogens	Cook at 212 F for three minutes (lo achieve minimum internal temperature of 140 F)	Cook time and temperature	• Monitor temperature with a continuous temperature recorder and visual checks using a MIG thermometer • Monitor time of cook by timing the movement of a block placed on belt through cooker.	• Temperature monitored continuously. • MIG thermometer monitoret hourly. • Cook time monitored hourly.	• Cook will perform the hourly checks. • Quality-control supervisor will program the continuous-recording thermometer.			

Firm Name: *ABC Shrimp Co.*

Firm Address: *Anywhere, USA*

Product Description: *Cooked and frozen, headless, peeled and deveined shrimp*

Method of Storage and Distribution: Frozen

Signature:

Date:

Intended Use and Consumer: *Thaw and serve, general public*

**Models may not be fully consistent with guidance contained in FDA'S Fish and Fishery Products Hazards and Control Guide.*

EXAMPLE: For Illustrative Purposes Only* - HACCP Plan Form

ABC Shrimp Co.

Cooked Shrimp

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Preventive Measure	(4) Monitoring				(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
Weigh/Pack Label	Allergic-type reaction from undeclared sulfiting agent	All product containing residual sulfiting agent must declare presence	• At weigh/pack/ label stage, check for "contains sulfite" declaration. • At receiving, sample each lot of fresh shrimp to test for presence of sulfites. • At receiving, receive supplier declaration for absence of sulfites.	Examine all labels issued at packing line and match declaration with product identity.	One label each time a label roll is replaced	Packing supervisor			

Note: In this example, results from product screening at the receiving step are a portion of the monitoring necessary to assure compliancy with weigh/pack/label critical limits.

**Models may not be fully consistent with guidance contained in FDA's Fish and Fishery Products Hazards and Control Guide.*

Overhead *1*

Objective:
In this module, you will learn:
- The definition of corrective actions,
- Procedures for corrective action, and
- Record-keeping requirements for corrective actions.

Overhead *2*

Principle 5:
When a deviation from a critical limit occurs, a corrective action must be taken.

Corrective actions must be taken when critical limits at a CCP have been compromised. When possible, these actions must be predetermined when developing the HACCP plan.

Overhead *3*

Definition:
Corrective Action: Procedures to be followed when a deviation, or failure to meet a critical limit occurs.

When critical limits are violated at a CCP, the predetermined, documented corrective actions should be instituted. These corrective actions should state procedures to restore process control and determine the safe disposition of the affected product. It may be possible, and is always desirable, to correct the problem on the spot.

Corrective action options include:
- isolating and holding product for safety evaluation.
- diverting the affected product or ingredients to another line where deviation would not be considered critical.
- reprocessing.
- rejecting raw material.
- destroying product.

Continued

Explanatory Note:

Corrective actions are implemented when monitoring results indicate a deviation from critical limits. Effective corrective actions depend heavily on an adequate monitoring program.

Notes:

The primary objective is to establish a HACCP program that permits rapid identification of deviations from a critical limit. The sooner the deviation is identified, the more easily corrective actions can be taken and the greater the potential for minimizing the amount of noncompliant product. An individual who has a thorough understanding of the process, product and HACCP plan and who has the authority to make decisions needs to be assigned the responsibility of making corrective actions.

Effective corrective action plans must:

- Correct and eliminate the cause of the noncompliance to assure that the CCP is brought back under control.
- Segregate, assess and determine the disposition of the noncompliant product.

All corrective actions taken should be documented. Documentation will assist the firm in identifying recurring problems so that the HACCP plan can be modified. Additionally, corrective action records provide proof of product disposition.

Components of Corrective Actions

There are two components of corrective actions: 1) to correct and eliminate the cause of the deviation and restore process control and 2) to identify the product that was produced during the process deviation and determine its disposition.

Overhead 4

Corrective Action Components:

- To correct and eliminate the cause of the deviation and restore process control.
- To identify the product that was produced during the process deviation and determine its disposition.

- *Correct and Eliminate the Cause of the Deviation and Restore Process Control*

Corrective actions must bring the CCP back under control. A corrective action should take care of the immediate (short-term) problem as well as provide long-term solutions. The objective is to implement a short-term fix so that control can be re-established and the process started again as soon as possible without further process deviation.

It may be necessary to determine the cause of the deviation to prevent future recurrence. A critical limit failure that was not anticipated or reoccurs should result in an adjustment to the product or process, or a re-evaluation of the HACCP plan.

One outcome of the re-evaluation may be a decision to modify the HACCP plan. A permanent solution to eliminating or minimizing the initial cause or causes for the process deviation should be implemented if necessary. Specific instructions for corrective actions must be available to plant workers and should be part of the documented HACCP plan.

- ***Identify*** *the Product that* ***was*** *Produced During the Process Deviation and Determine the Disposition*

When a deviation occurs, identify nonconforming product. There are four steps that may be used for determining product disposition and developing a corrective action plan.

Overhead *5*

Four Steps:

A. Step One: Determine if the product presents a safety hazard:
   a. Based on expert evaluation.
   b. Based on physical, chemical or microbiological testing.
B. Step Two: If no hazard exists based on the evaluations in Step 1, the product may be released.
C. Step Three: If a potential hazard exists (based on the evaluations in Step 1), determine if the product can be:
   a. Reworked/reprocessed.
   b. Diverted for a safe use.
D. Step Four: If potentially hazardous product cannot be handled as described in Step 3, the product must be destroyed. This is usually the most expensive option and is usually regarded as the last resort.

Notes:

Explanatory Note:

If a product is to be tested and released, the sampling method is highly important. The use of a faulty sampling protocol can result in accepting, rather than rejecting, an undesirable product. The limits of sampling plans must be understood. It may be prudent to consult an expert.

Explanatory Note:

It is important to ensure that any reworking does not result in the creation of a new hazard. Of primary concern are toxic materials, including heat-stable biological toxins. It must be realized that reworked product is still subject to regulatory scrutiny and that reworking must result in a safe product.

Continued

Notes:

Corrective Action Format Examples

Corrective actions are usually written in an "if/then" format. The "if' part of the corrective action describes the condition and the "then" part describes the action taken. For example:

Overhead 6

IF *deviation:*	Temperature of milk at pasteurizer drops below critical limit.
THEN *corrective action:*	Milk flow is diverted until temperature recovers. Diverted product is repasteurized. Check the operation of the heating/cooling units to determine the reason for the temperature deviation that caused the flow diversion. Repair if necessary, re-establish control and resume production.

Overhead 7

IF *deviation:*	Product (e.g., hot smoked fish) does not reach required internal temperature at the end of the process.
THEN *corrective action:*	Extend cook until the internal temperature has been met. Check the operation of the smoker or heating unit. Repair if necessary.

Overhead *8*

Notes

IF *deviation:*	Mahi-mahi held at elevated temperature for excess time period (temperature limit exceeded, possible elevated histamine level).
THEN *corrective action:*	Bury product in ice, place on hold and conduct sensory analysis and histamine test. Determine the reason for the process delay. Prevent future occurrences.

Corrective Action Records

Predetermined corrective actions are written into the HACCP plan. When critical limits are exceeded and a corrective action occurs, it is recorded. A corrective-action report form is helpful.

The corrective-action report should contain the following:

a. Product identification (e.g., product description, amount of product on hold).
b. Description of the deviation.
c. Corrective action taken including final disposition of the affected product.
d. Name of the individual responsible for taking the corrective action.
e. Results of the evaluation when necessary.

HACCP plan records should contain a separate file in which all deviations and corresponding corrective actions are maintained in an organized fashion. Corrective actions are recorded in column 8 of the HACCP plan form. Following is the corrective actions for the IQF cooked shrimp example.

Overhead 9

HACCP Plan Form

Corrective Actions:

1. CCP	2. Hazard	3. Critical Limits	4. 5. 6. 7. Monitoring (What, How, Frequency, Who)	8. Corrective Action(s)	9. Records	10. Verification

Specify the corrective-action procedures for each CCP.

Continued

EXAMPLE: For Illustrative Purposes Only* - HACCP Plan Form

ABC Shrimp Co.

Cooked Shrimp

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Preventive Measure	(4) Monitoring				(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
Cooker	Survival of bacterial pathogens	Cook at 212 F for three minutes (to achieve minimum internal temperature of 140 F)	Cook time and temperature	• Monitor temperature with a continuous temperature recorder and visual checks using a MIG thermometer. • Monitor time of time of cook by timing the movement of a block placed on belt through cooker.	• Temperature monitored continuously. • MIG thermometer monitored hourly. • Cook time monitored hourly.	• Cook will perform the hourly checks. • Quality-control supervisor will program the continuous-recording thermometer.	• If temperature or time parameters are not met, then processing line will be stopped and required adjustments made. • All product produced during the deviation will be recooked.		

Firm Name: *ABC Shrimp Co.*

Firm Address: *Anywhere, USA*

Product Description: *Cooked and frozen, headless, peeled and deveined shrimp*

Method of Storage and Distribution: Frozen

Signature:

Date:

Intended Use and Consumer: *Thaw and serve, general public*

**Models may not be fully consistent with guidance contained in FDA's Fish and Fishery Products Hazards and Control Guide.*

EXAMPLE: For Illustrative Purposes Only* - HACCP Plan Form

ABC Shrimp Co.

Cooked Shrimp

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Preventive Measures	(4) Monitoring	(5) Monitoring	(6) Monitoring	(7)	(8) Corrective Action(s)	(9) Records	(10) Verification
			What	**How**	**Frequency**	Who			
Weigh/Pack Label	Allergic-type reaction from undeclared sultiting agent	All product containing residual sultiting agent must declare presence	• At weigh/pack/ label stage, check for "contains sulfite" declaration. • At receiving, sample each lot of fresh shrimp to test for presence of sulfites. • At receiving, receive supplier declaration for absence of sulfites.	Examine all labels issued at packing line and match declaration with product identity.	One label each time a label roll is replaced	Packing supervisor	Relabel as necessary.		

Note: In this example, results from product screening at the receiving step are a portion of the monitoring necessary to assure compliancy with weigh/pack/label critical limits.

Models may not **be fully consistent** with **guidance** contained in FDA's *Fish and Fishery Products* **Hazards** and Control Guide.

Notes:

Overhead *1*

Objective:
In this module, you will learn:
- What kinds of records are needed in a HACCP system.
- When to record monitoring information.
- How computerized records can be used.
- How to conduct a record review.

Accurate record keeping is an essential part of a successful HACCP program. Records provide documentation that the critical limits have been met or that appropriate corrective actions were taken when the limits were exceeded. Likewise, they provide a means of monitoring so that process adjustments can be made to prevent a loss of control.

Overhead *2*

Principle 6:
Establish effective record-keeping procedures that document the HACCP system.

Types of **Records** Needed

Overhead *3*

Four kinds of records are kept as part of the HACCP system.
1. HACCP plan and support documentation used in developing the plan
2. Records of CCP monitoring
3. Records of corrective action
4. Records of verification activities

Continued

Explanatory Note:

Although not required by the seafood HACCP regulation, it is advisable to maintain HACCP plan supporting documentation described in this chapter.

. *HACCP Plan and Support Documents*

HACCP support documents include the information and dam used to develop the HACCP plan. This includes the written hazard-analysis worksheet (Chapter 5) and records of any information used in performing the hazard analysis and establishing the critical limits.

Support documents may include: sufficient data used to establish the adequacy of any barriers to bacterial pathogen growth, to establish the safe shelf life of the product (if age of the product can affect safety), and to establish the adequacy of a heating process in destroying bacterial pathogens. In addition to data, support documents may also include correspondence with consultants or other experts.

Support documents should also include:

- A list of the HACCP team and their responsibilities.
- A summary of the preliminary steps taken in the development of the HACCP plan.
- Prerequisite programs.
- *Monitoring Records*

HACCP monitoring records are primarily kept to demonstrate control at CCPs. HACCP records provide a useful way to determine if critical limits have been violated. Timely record review by a management representative ensures that the CCPs are being controlled in accordance with the HACCP plan. This will be discussed further in Chapter 11. Monitoring records also provide a means by which regulators can determine whether a firm is in compliance with its HACCP plan.

By tracking the values recorded on monitoring records, an operator or manager can determine if a process is approaching its critical limit. Trends can be identified through record review to make necessary process adjustments. If timely adjustments are made before the critical limit is violated, processors can reduce or eliminate the labor and material costs associated with corrective actions.

Overhead 4

All HACCP monitoring records should be on forms that contain the following information:

- Form title,
- Firm name,
- Time and date,
- Product identification (including product type, package size, processing line and product code, where applicable),
- Actual observation or measurement,
- Critical limits,
- Operator's signature or initials,
- Reviewer's signature or initials, and
- Date of review.

Examples of CCP monitoring records may include:

- Storage temperature records for temperature-sensitive ingredients, in-process materials and finished products where temperature control is necesssary to ensure product safety.
- Container-seal examination records where the hermetic seal affects product safety.
- Salometer-measurement records where salt brine is used to establish a barrier to bacterial pathogen growth in the finished product

• 3. Corrective *Action Records*

Corrective action records were discussed in Chapter 9.

• 4. ***Verification*** *Records*

Verification records (Chapter 11) should include:

- Modifications to the HACCP plan (e.g., changes in ingredients, formulations, processing, packaging and distribution);
- Processor audit records verifying supplier compliance with guarantees or certifications;
- Verification of the accuracy and calibration of all monitoring equipment;
- Results of microbiological challenge tests, environmental microbiological tests, and periodic in-line and finished-product microbiological, chemical and physical testing if applicable;
- Results of in-house, on-site inspections; and
- Results of equipment evaluation tests.

Examples of verification records include:

- Temperature distribution studies for thermal processes.
- Metal detector challenges.
- Dud detector (used in canning industry) challenges.

Continued

Notes:

Explanatory Note:

Figure 1 also includes information for a variety of nonsafety attributes in addition to the sulfiting agent information. It exemplifies the use of existing forms for HACCP purposes. Some firms may choose to separate their HACCP records from nonsafety control records. Note the critical limits at the bottom of the form.

Explanatory Note:

Figure 3: Continuous temperature monitoring is performed by a recording thermometer. Manual time and temperature checks are performed every hour. Time checks are performed by determining how long it takes a block to move through the steam tunnel using a stopwatch. A comparison between the mercury-in-glass (MIG) thermometer and the recording thermometer is made daily. Note that during the 4:28 p.m. and 5:01 p.m. temperature checks, the recording thermometer was reading lower than the MIG thermometer. This condition is acceptable as long as the two instruments are as close as reasonably possible. However, it would not be acceptable for the recording thermometer to read higher than the MIG thermometer.

Explanatory Note:

Figure 7: Emphasize that all thermal processing equipment should be tested to verify that it will perform the required process.

Record Monitoring Information

Monitoring information should be recorded at the time the observation is made. False or inaccurate records filled out before the operation takes place or ones that are completed later are inappropriate for a HACCP system.

Computerized Records

Computerized records are an option to record keeping. When using computerized records, include controls to ensure that records are authentic, accurate and protected from unauthorized changes.

Record Review

Monitoring records for CCPs and critical-limit deviations should be reviewed in a timely manner by a representative of plant management. All records should be signed or initialed and dated by the reviewer. This subject is discussed further in Chapter 11.

ABC Shrimp Company IQF Cooked-Shrimp Example

- *Monitoring Records*

Sample records are included for each of the monitoring activities identified in columns 4 to 7 of the HACCP plan for IQF cooked shrimp. The names of these forms should be entered in column 9 of the form. These records include:

Figure 1. Raw material evaluation sheet.
This form records the presence or absence of sulfiting agents detected in incoming raw shrimp at the receiving-raw-shrimp step. It is also used to record the vendor's name and the presence or absence of a supplier's certificate for incoming frozen shrimp at the receiving-frozen-shrimp step.

Figure 2. Supplier's guarantee.
This document indicates that the shrimp from this vendor does not contain sulfiting agents.

Figure 3. Shrimp cooker log.
This form is used to record the time and temperature of cooking at the cooker step.

Figure 4. Pack-room inspection record.
The form is used to note that shrimp treated with sulfiting agents are appropriately labeled.

- ***Additional Records***

Figure 5. Laboratory results - sulfite residuals.
This document indicates the results of a laboratory analysis for sulfite residual, which is used as a quarterly verification of the supplier's certification.

Figure 6. Cooking process validation letter.
This document confirms that the cooking critical limits are scientifically sound.

Figure **7.** Cooking equipment validation letter.
This document confirms that the temperature throughout the cooking equipment is at or above the critical limit when the equipment is properly operated.

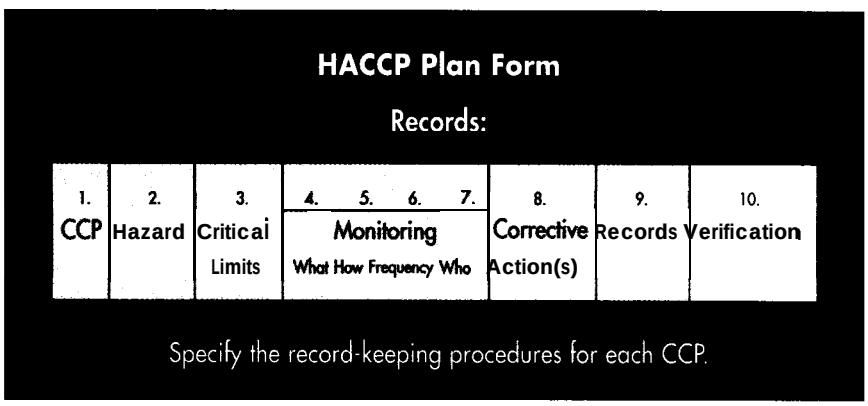
Figure 8. Equipment calibration log.
This form records the results of the quarterly calibration of the MIG thermometers used on the cookers.

Figure **9.** Laboratory report - product microbiology.
This document indicates the results of finished product laboratory analyses for total plate count (TPC), coliform bacteria, *Escherichia coli,* ***Staphylococcus aureus*** and ***Salmonella.***

Figure 10. Sample corrective action record.
This record relates to the cooking process records that have been previously discussed. This form is used to document the action taken when a critical limit is exceeded.

Figure 11. Employee Training Record.
This document indicates the training courses completed by each employee.

Overhead 5



Continued

Explanatory Note:

Figure 8: Emphasize that all monitoring equipment such as thermometers and scales should be checked against a standard. In some cases, this standard may be a boiling-water bath and an ice slush or a known weight, depending upon the instrument and the accuracy requirements for the critical limit being monitored. Note that on the 6/12/89 calibration, the thermometer was 1 F above the standard. This could have an impact on the previously produced product and could have resulted in critical limit deviations. These should be evaluated, and appropriate corrective action should be taken and recorded.

Explanatory Note:

Figure 9: Finished product analyses may often be included as part of a firm's periodic verification efforts. Firms should establish specifications for the microbiological tests that are performed as part of verification.

Explanatory Note:

Figure 10: The critical limit failure in the first corrective action report would not likely have been noted without the continuous monitoring provided by the recording thermometer. In a continuous cooker, when a temperature drop occurs, the product in the cooker at the time of the deviation must be held and evaluated, recooked, destroyed or shifted to some other acceptable use unless the line can be stopped to give a still cook.

Notes:

Figure 7 *and* Overhead 5.

Raw Material Evaluation Sheet

ABC Shrimp Co.

Date: _____ **Time of Examination:** _____

Lot Number: _____ **Declared Wt:** _____

Actual Wt: _____

Brand: _____ **Country** of origin: _____

Packer: _____ Shrimp Type: _____

Vendor: _____ **Process Type:** _____

Sample No.	*1*	2	3	4	5	*6*
Actual Color						
Frozen Wt.						
Drained wt.						
No./Pkg.						
Ct./Lb.						
% Peel						
% Pieces						
% Shell Spots						
Foreign Mat.						
% Meat Spots						
Dehydrated						
% swimmerets						
% Missing Tail						
Sulfites						
Veins						
Phosphate						
% spines						
Bleaching						
% Discolored						
salt						
Bilge Odor						
Stale						

Certificate for Sulfite Use (Yes/No): _____

Reviewed By: _____ **Date:** _____

(Items in bold are part of HACCP record.)

Notes:

Figure 2 and Overhead 6:
Supplier's Guarantee
East Bay Fishing Co.
Yourtown, LA

December 25, 1995

ABC Shrimp Co.
P.O. Box 54
Smithville, GA 43898

Dear Mr. smith,

This certifies that, in accordance with your purchasing specification, this shipment of frozen shrimp has not been treated with any sulfite compounds.

Yours truly,
Ira M. Honest
QC Director, East Bay Fishing Co.

Figure 3 and *Overhead* 7
Shrimp Cooker Log
ABC Shrimp Co.

Date: 3/4/96 Critical Limits: 212 F for 3 minutes

Line: Number 2 Product: IQF cooked shrimp

Operator: Jamie Good

Line Number	Lot Number	Time of Day	Steam Temp. MIG (F)	Steam Temp. Recorder (F)	Cook Time (Min.)	Critical Limits Met	Comments
1	034	2:34 p.m.	214	214	3.2	Yes	
1	043	3:30 p.m.	214	214	3.2	Yes	
1	053	4:28 p.m.	211	210	3.1	No	See *corrective actions*
1	053	4:29 p.m.	212	212		Yes	steam value adjusted
1	053	5:01 p.m.	213	212	3.1	Yes	

Temperature/time to be checked hourly during operation.

Reviewer: _____ Date: _____

If critical limits are exceeded, notify the shift supervisor, and separate and identify the batch involved

Notes:

Figure 4 and Overhead 8
Pack Room Inspection Record
ABC Shrimp Co.

Date: 3/4/95

Line: Number 2 Product: IQF cooked shrimp

Label Room Supervisor: Betty Smith

Lot Number	Time of Day	Presence of Sulfiting Agents Yes/No	Sulfite Statement on Label Yes/No	Label Type & Comments
043	3:45 p.m.	Yes	Yes	ABC 8 oz.
044	4:45 p.m.	Yes	Yes	Smith Brothers 12 oz.

Reviewer: _____ Date of Review: _____

Critical Limits: *AIl* ***shrimp treated with sulfiting agents must be accurately labeled.***

Figure 5 **and Overhead *9***
A-One Laboratory Report
ABC Shrimp Co.

Date: 3/5/95 Sample Number: ABC Shrimp 002

Vendor: East Bay Sulfites, ppm: 60 ppm found

Examined by: Sheila Good

Remarks:

The above ***sample was analyzed for the presence of sulfites using official AOAC recognized methods.***

Irvine R. Wright
Laboratory Director
A-One Laboratories
Jonestown, PA 25418

Figure 6 and Overhead 70
Cooking Process Validation Letter
Seafood Processing Research and Extension Unit
Your State University

January 5, 1996

ABC shrimp co.
P.O. Box **54**
Smithville, GA 43898

Dear Mr. smith:

Various published studies document that a process which provides an internal temperature of 145 F in shrimp is adequate for pasteurization. This supports our studies revealing that pathogenic organisms are destroyed by processing the shrimp at 212 F for three minutes. This process provides an internal temperature above 145 F.

Sincerely,
I.M. Helpful
Seafood Processing Research and Extension Unit
Your State University

Notes:

Notes:

Figure 7 and Overhead 11:
Cooking Equipment Validation Letter
Seafood Processing Research and Extension Unit
Your State University

January 5, 1996

ABC shrimp Co.
P.O. Box 54
Smithville, GA 43898

Dear Mr. Smith:

On Dec. 20, 1995, during a visit to your firm, temperature distribution tests were performed in your shrimp steam cooker on line number one using a portable data logger and 12 thermocouple leads. Test results from three production runs indicated that the temperature distribution in your batch steam cooker, when operated at a mercury-in-glass reading of 212 F, ranges from 212 F to 214 F. These studies indicate that your steam cooker continues to operate as designed.

On this same date, the internal temperature of six shrimp from individual lots of large (3.5 to 5.0 shrimp per oz.), medium (5.0 to 9.0 shrimp per oz.) and small (9.0 to 17.0 shrimp per oz.) shrimp were measured in the cooker during production runs at 212 F for three minutes. The internal temperahue of the large shrimp exceeded 150 F; the medium shrimp, 160 F; and the small shrimp, 165 F. The internal temperatures noted during these tests exceedyour firm's HACCP critical limits of an internal temperature of 145 F.

Sincerely,
I.M. Helpful
Seafood Processing Research and Extension Unit
Your state University

Notes:

Figure 8 *and* Overhead 72
Equipment Calibration log
Temperature Measurement
Instrument/Equipment
ABC Shrimp Co.

Instrument/Equipment: Mercury-in-glass thermometer

Location in Plant: Shrimp Cooker Line Number One

Serial Number: B546

Model Number: Always Right 140 F to 260 F

Date Received in Plant: 3/2/95

Date Calibrated	Calibration Results	Method of Calibration	Employee
3/15/95	Thermometer was in calibration.	Tested in steam flow 215 F using certified thermometer S.N. 07569	Sam Smith
6/12/95	Thermometer scale adjusted 1 F down to match standard thermometer.	Tested in steam flow 215°F using certified themometer S.N. 07569	Stan Jones
9/10/95	Thermometer was in calibration.	Tested in steam flow 215 F using certified themometer S.N. 56432	Sam Smith
12/2/95	Thermometer was reading 5 F below the standard themometer scale. Adjusted.	Tested in steam flow 215 F using certified themometer S.N. 56432	Sam Smith
2/30/96	Thermometer was in calibration.	Tested in oil bath 2 15 F by laboratory using certified tbemometer S.N. 56432	Jean Jones

Explanatory Note:

There are situations when the results of a verification activity would necessitate a corrective action. If, for example, one of these *Salmonella* results had been positive, it would be appropriate for the processor to hold any of the affected lot still in storage and recall any of the product that was no longer under the processor's control. Then the processor could recook or destroy the lot. It would also be appropriate to re-evaluate the HACCP plan and its implementation to determine how the defect could have occurred.

Figure 9 and Overhead 13

A-One Laboratory Report

ABC Shrimp Co.

Date: 4/5/96 Sample No.: ABC shrimp 0112

Vendor: East Bay Analysist: Sheila Good

The results of the analyses of sample 0112 consisting of 6/8 oz. samples of shrimp identified as batch 1 to 6 are as follows:

Batch	T.P.C.	Coliforms	E. Coli	Staph	Salmonella
1	40	0	0	Negative	Positive
2	48	0	0	Negative	Negative
3	20	0	0	Negative	Negative
4	56	0	0	Negative	Negative
5	40	0	0	Negative	Negative
6	20	2	0	Negative	Negative

Remarks:

The above sample was analyzed using methods found in the FDA Bacteriological Analytic Manual, 7th Edition.

Irvine R. Wright
Laboratory Director
A-One Laboratories
Jonestown, PA 254 18

Figure 7 0 and Overhead 74
Corrective Action Report
ABC Shrimp Co.

Date: 314196 Lot I.D.: 053

Description of Problem:

At 4:28 p.m., the temperature dropped to 210 F for 30 seconds, according to the recorder.

Action Taken:

Temperature drop was noted immediately. Steam valve was adjusted and the product exiting the cooker for the next five minutes was destroyed.

Date Problem Solved: 3/4/96

Current Status:

Remainder of lot is acceptable.

Supervisor: Ollie K. Fellows

Reviewer: Seymour Samples Date: 3/4/96

Explanatary Note:

See Figure 3 for corresponding monitoring record showing process deviation.

Notes:

Figure I 7 and Overhead 15
Employee Training Record
ABC Shrimp Co.

Employee: Richard J. Smith

Training Course	Date of Course
Sanitation in the processing plant, 4-hour course, state inspection service.	July 6, 1994
Computer operation of the pasteurizer, Best Yet Pasteurizer Co., John Jones, customer representative. three days on-the-job training.	Feb. 2-5, 1995
Sanitation in the processing plant, 4-hour course, state inspection service, update.	Aug. 3, 1995

EXAMPLE: For Illustrative Purposes Only* - HACCP Plan Form

ABC Shrimp Co.

Cooked Shrimp

(1) Critical Contml Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Preventive Measure	(4) Monitoring	(5) Monitoring	(6) Monitoring	(7) Monitoring	(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
Cooker	Survival of bacterial pathogens	Cook at 212 F for three minutes (to achieve minimum internal temperature of 140 F)	Cook time and temperature	• Monitor temperature with a continuous temperature recorder visual checks using a MIG thermometer. • Monitor time of cook by timing the move. ment of a block placed on belt through cooker.	• Temperature monitored continuously. • MIG thermometer monitored hourly. • Cook time monitored hourly.	• Cook will perform the hourly checks. • Quality-control supervisor will program the continuous-recording thermometer.	• If temperature or time parameters are not met, then processing line will be stopped and required adjustments made. • All product produced during the deviation will be recooked.	• Cooker log • Recording charts	

Firm Name: ABC *Shrimp Co.*

Firm Address: *Anywhere, USA*

Product Description: *Cooked and frozen, headless, peeled and deveined shrimp*

Method of Storage and Distribution: Frozen

Signature:

Date:

Intended Use and Consumer: *Thaw and serve, general public*

**Models may not be fully consistent with guidance contained in FDA's Fish and Fishery Products Hazards and Control Guide.*

EXAMPLE: For Illustrative Purposes Only*- HACCP Plan Form

ABC Shrimp Co'.

Cooked Shrimp

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Preventive Measure	(4) Monitoring				(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
Weigh/Pack Label	Allergic-type reaction from undeclared sulfiting agent	All product containing residual sulfiting agent must declare presence	• At weigh/pack/label stage, check for "contains sulfite" declaration. • At receiving, sample each lot of fresh shrimp to test for presence of sulfites • At receiving, receive supplier declaration for absence of sulfites.	Examine all labels issued at packing line and match declaration with product identity.	One label each time a label roll is replaced	Packing supervisor	Relabel as necessary	• Raw-material evaluation sheets • Supplier guarantees • Pack-room inspection sheet	

Note: In this example, results from product screening at the receiving step are a portion of the monitoring necessary to assure compliancy with weigh/pack/label critical limits.

**Models may not be fully consistent with guidance contained in FDA's Fish and Fishery Products Hazards and Control Guide.*

Overhead *1*

Objective:
In this module, you will learn:
- How to define verification.
- What functions are part of HACCP plan verification.
- How to define validation.
- What functions are part of validation.

Having a carefully designed HACCP plan with all the necessary items clearly defined does not guarantee the plan's effectiveness. Verification is a means of assessing the effectiveness of the HACCP plan and providing confirmation that the system works.

Overhead *2*

Principle 7:
Establish procedures to verify that the HACCP system is working correctly.

Overhead *3*

Definition:
Verification: The use of methods, procedures or tests, in addition to those used in monitoring, to determine if the HACCP system is in compliance with the HACCP plan and/or whether the plan needs modification and revalidation.

- ***Verification Procedures***

Each HACCP plan should include verification procedures for individual CCPs and for the overall plan. HACCP plans are expected to evolve and to improve with experience and new information. Periodic verification helps the processor to improve the plan by identifying weaknesses in the HACCP system. The processor can then eliminate unnecessary or ineffective control measures.

As part of verification, audits are performed to compare actual practices and procedures with what is written in the plan.

Continued

Explanatory Note:

Routine monitoring activities for critical limits should not be confused with verification methods, procedures or activities. This could be a point of confusion, and the instructor should keep this in mind while addressing this chapter.

Notes:

- ***Audits***

Audits are an important component of verfication. They are systematic evaluations. These evaluations include on-site observations and record reviews. They are usually performed by an unbiased person who is not responsible for performing the monitoring activities.

Overhead 4

On-site verification activities include:
- Checking accuracy of the product description and flow chart.
- Checking that CCPs are monitored as required by the HACCP plan.
- Checking that processes are operating within established critical limits.
- Checking that records are completed accurately and at the time intervals required.

Overhead *5*

Record-review verification activities include:
- Monitoring activities have been performed at the locations specified in the HACCP plan.
- Monitoring activities have been performed at the frequencies specified in the HACCP plan.
- Corrective actions have been performed whenever monitoring indicated that critical limits had been exceeded.
- Equipment has been calibrated at the frequencies specified in the HACCP plan.

Audits should occur at a frequency that ensures the HACCP plan is being followed continuously. This frequency depends on a number of conditions, such as the variability of the process and product.

. *Calibration*

Verification also includes calibration of monitoring devices or review of calibration records to assure accuracy of measurements taken.

Calibration is conducted to provide assurance that monitoring results are accurate.

Overhead 6

Calibrations are performed:
- On appropriate equipment and instruments used in monitoring or verification.
- At a frequency sufficient to assure continuous accuracy.
- By checking accuracy against a recognized standard at or near the conditions that the instrument or equipment will be used.

Calibration of CCP monitoring equipment is important. If the equipment is out of calibration, then monitoring results will not be accurate. Significant deviations could render monitoring results completely unreliable. If this happens, the CCP could be considered out of control since the last documented acceptable calibration. This condition should be considered when establishing the frequency of calibration.

Examples of calibration activities:

1. A MIG thermometer used to monitor temperature at a cook CCP may be checked for accuracy by comparing it against a certified thermometer in a hot-water bath.
2. The continuous temperature chart recorder on a pasteurizer is compared during each batch against a MIG thermometer.
3. A pH meter is calibrated against pH buffer standards of 7.0 and 4.0 when it is used to test products with a final pH of 3.8 to 4.2.

. *Calibration Record Review*

Reviewing the equipment calibration records involves checking the dates and methods of calibration, and the test results (e.g., equipment passing or failing). Calibration records are kept and reviewed as part of an audit.

Example:

1. An audit of the MIG-thermometer records show that the thermometer was checked for accuracy against a certified thermometer at a frequency required in the HACCP plan. The records indicate that the thermometer performed within established limits and did not need adjustment. This audit disclosed no problems in the MIG calibrations.

Continued

Notes:

Notes:

- *Targeted Sampling and Testing*

Verification may also include targeted sampling, testing and other periodic activities. Vendor compliance may be checked by targeted sampling when receipt of material is a CCP and purchase specifications are relied on as critical limits.

Examples:

1. In the cooked-shrimp example, the firm may purchase frozen shrimp under a supplier's guarantee for a sulfite-free product. A quarterly sample is then collected for laboratory analysis to assure the product is sulfite-free.
2. In the cooked shrimp example, verification of sulfite residual control at receiving of fresh shrimp would involve quarterly analysis of samples to ensure the results obtained through the original monitoring procedures (e.g., malachite green test) are accurate. Records should indicate any deviations.

When critical limits are set for equipment operation, product samples may be taken to ensure that the equipment settings are appropriate for the product safety.

Examples:

1. In the cooked-shrimp example, the firm may collect in-line samples of selected product after cooking to measure internal temperature.
2. When hamburger thickness is critical to assuring a proper cook, patties may be periodically collected and measured to verify that the equipment is producing the proper patty thickness.

- *The Role of Microbiological Testing in HACCP **Verification***

Overhead *7*

The Role of Microbiological Testing in HACCP Verification

As explained in Chapter 2, microbiological testing is ineffective for routine monitoring. But it can be used as a verification tool. Microbiological testing can be used to determine (i.e., verification audits) that the overall operation is under control.

Example:

Egg white is used as an ingredient in meringue-pie topping. Historically, egg whites have been associated with a risk of ***Salmonella.*** Since the meringue is not cooked or otherwise treated to kill ***Salmonella,*** the preventive measure could be to assure that all egg whites received are ***Salmonella-free. The*** CCP would be egg-white receiving, and the critical limit would be "every lot has a guarantee assuring it is pasteurized and ***Salmonella-free." The*** adequacy of the supplier's certificate could be periodically verified by collecting samples from a lot and testing for ***Salmonella.***

- ***Verification Frequency***

Overhead 8

Verification Frequency

Verification activities should be performed according to a pre-established schedule described in the HACCP plan. They should also be performed whenever there are indications that the process may be out of control. These indications may include:

- on-line observations that CCPs are not operating within critical limits.
- record reviews that indicate inconsistent monitoring.

Verification procedures should be scheduled at a frequency that assures the HACCP plan is being followed. Therefore, the length of time between scheduled verifications should match the level of confidence in the performance of the HACCP plan.

Example:

> In the meringue example, sampling and microbiological testing to verify the supplier's guarantee could be performed monthly at first. The frequency would then increase to every lot or decrease to quarterly, depending on what the verification or audit history indicates as a safe period.

- ***Validation Procedures***

Overhead 9

Validation Procedures

Validation is a part of overall verification. Validation involves an assessment of whether the HACCP plan adequately identifies and controls all significant safety hazards associated with the particular product and process. HACCP plan validation should include a review to determine that the following activities have been done correctly:

- Hazard analysis,
- CCP determination
- Critical-limit determination
- Monitoring, corrective-action, record-keeping and verification activities.

Continued

Explanatory Note:

The frequency of verification activities will likely change over time. A history of audit findings that indicate that the processes are consistently in control may justify safely reducing the frequency of audits. On the other hand, adverse audit findings, such as inconsistent monitoring activities, inconsistent record keeping and improper corrective actions warrant correcting the problems and more frequent audits. Adverse audit findings may indicate a need for revalidation of the HACCP plan.

Notes:

Validation is a more involved procedure than a HACCP plan audit. Validation can be performed by the HACCP team or by an individual qualified by training or experience. Validation activities are similar in scope and time commitment to the original HACCP plan development. An in-plant validation should be performed initially, before reliance on the HACCP plan and periodically thereafter. Validation involves a scientific and technical review of the rationale behind each part of the HACCP plan, from hazard analysis through each verification strategy.

A review is performed to determine how and on what basis (scientific and technical information) are identified hazards being controlled. This could include a review of the hazard analysis and critical limits to incorporate new scientific information and data gathered as part of verification. This can be performed for the overall HACCP plan as well as for individual CCPs.

The process of validating an existing HACCP plan should include a review of HACCP audit reports, changes to the HACCP plan, the reasons behind those changes and past validation reports. Validation of an existing HACCP plan should also include a review of deviation reports and an assessment of corrective action effectiveness. The validation study should provide a review of linkages between the HACCP plan and the prerequisite programs (e.g., any sanitation SOP programs, training programs, preventive maintenance programs and pest-control programs). An independent HACCP authority may be called upon to review the study findings for the HACCP plan's initial validation or to validate an existing plan.

Examples of Validation Activities:

One approach to controlling vegetative pathogens as a hazard in cooked hamburgers is to assure that the hamburgers are cooked to an internal temperature that destroys pathogens. In the HACCP plan, maximum patty thickness, maximum belt speed and minimum oven temperature could be the critical limits to assure that an adequate temperature is reached at the cook step. These criteria would be established after collecting enough data on-line to assure that controlling those points would also control the minimum internal temperature reached during the cook. With those criteria in place, there would be no need to measure or monitor the internal temperature of every hamburger patty as it is cooked. However, periodically the effectiveness of these criteria should be validated by actually determining that pathogens are eliminated.

An internal temperature of 145 F was determined to be critical to destroy pathogens in cooked shrimp. The firm uses a process of 212 F for four minutes to provide an internal temperature of 145 F. The ability of the process time and temperature to achieve the internal temperature of the cooked shrimp should be validated by measuring the center temperature of a representative number of cooked shrimp. The cooking equipment should also be validated using temperature distribution tests to determine that uniform temperatures are delivered throughout the cooker during processing.

• ***Validation*** *Frequency*

Overhead 10

Validation Frequency

Like verification, HACCP plan validation is an ongoing, periodic procedure. Validations may be scheduled to occur at a preset frequency. However, other factors may trigger a review of the plan to determine if changes are necessary. These factors could include: changes to the raw materials, product or process; adverse audit findings; recurring deviations; new scientific information about potential hazards or control measures; on-line observations; or new distribution or consumer-handling practices.

• *The Role of Regulatory Agencies in HACCP* ***Plan Verification***

Overhead *11*

The Role of Regulatory Agencies in HACCP Plan Verification

The major role of regulatory agencies in a HACCP system is to verify that HACCP plans are effective and are being followed. Verification normally will occur at the inspected facility. However, some aspects of verification may be conducted at other appropriate locations.

HACCP plans are unique documents prepared by a processor to assure the control of a specific process or procedure. The plans may contain proprietary information and must be protected by the regulatory agency. Agency personnel must have access to records that pertain to CCP's, deviations, corrective actions and other information pertinent to the HACCP plan that may be required for verification.

Verification procedures by an agency include:

a. Review of the HACCP plan and any modifications.
b. Review of CCP monitoring records.
c. Review of corrective action records.
d. Review of the verification records.
e. Visual inspections of operations to determine if the HACCP plan is followed and records are properly maintained.
f. Random sample collection and analysis.

Notes:

EXAMPLE: For Illustrative Purposes Only - HACCP Plan Form

ABC Shrimp Co.

Cooked Shrimp

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Preventive Measure	(4) Monitoring				(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
Cooker	Survival of bacterial pathogens	Cook at 212 F for three minutes (to achieve minimum internal temperature of 140 F)	Cook time and temperature	• Monitor temperature with a continuous temperature recorder and visual checks using a MIG thermometer. • Monitor time of cook by timing the movement of a block placed on belt through cooker.	• Temperature monitored continuously. • MIG thermometer monitored hourly. • Cook time monitored hourly.	• Cook will perform hourly checks. • Quality-control supervisor will program the continuous-recording thermometer.	• If temperature or time parameters are not met, then processing line will be stopped and required adjustments made. • All product produced during the deviation will be destroyed.	• Cooker log • Recording charts	• Daily record review • Quarterly calibration of MIG thermometer • Semi-annual finished-product microbial testing • Process validation study of time and temperature of cook and its effect on the final internal temperature of various sizes of shrimp and initial temperature (on file) • Cooking equipment validation study (on file)

Firm Name: *ABC Shrimp Co.*

Product Description: *Cooked and frozen, headless, peeled and deveined shrimp*

Firm Address: Anywhere, USA

Method of Storage and Distribution: Frozen

Signature:

Intended Use and Consumer: *Thaw and serve*

Date:

**Models may not be fully consistent with guidance contained in FDA'S Fish and Fishery Products Hazards and Control Guide.*

EXAMPLE: For Illustrative Purposes Only - HACCP Plan Form

ABC Shrimp Co.

Cooked **Shrimp**

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Preventive Measure	(4) Monitoring	(5) Monitoring	(6) Monitoring	(7) Monitoring	(8) Corrective Action(s)	(9) Records	(10) Verification
			What	HOW	Frequency	Who			
Weigh/Pack Label	Allergic-type reaction from undeclared sulfiting agent	All product containing residual sulfiting agent must declare presence	• At weigh/pack/ label stage, check for "contains sulfite" declaration. • At receiving, sample each lot of fresh shrimp to test for presence of sulfites. • At receiving, receive supplier declaration for presence of sulfites.	Examine all labels issued at packing line and match declaration with product identity.	One label each time a label roll is replaced	Packing supervisor	Relabel as necessary	• Raw material evaluation sheets • Supplier guarantees • Pack room inspection sheet	• Lab reports for sulfites • Daily packing record review

Firm Name: *ABC Shrimp Co.*

Product Description: *Cooked and frozen, headless, peeled and deveined shrimp*

Firm Address: *Anywhere, USA*

Method of Storage and Distribution: Frozen

Signature:

Intended Use and Consumer: *Thaw* and *serve*

Date:

Models may not be fully consistent with guidance contained in** FDA's Fish and **Fishery Products Hazards and Control Guide.

Notes:

Overhead *1*

Objective:
In this module, you will learn:
- What are the requirements of the seafood HACCP regulation.
- How to reference the specific requirements.

On Dec. 18, 1995, FDA published a seafood regulation based on the seven principles of HACCP called "Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products." This regulation has become known as "the seafood HACCP regulation." It will be referred to in this chapter as "the regulation." A copy of the regulation is provided in Appendix I.

. *Regulation Format*

The regulation is part of Title 21 of the Code of Federal Regulations (CFR), Part 123, and is subdivided into three subparts and 13 sections.

Overhead *2*

Regulation Format

Subpart A — General provisions
- 123.3 Definitions
- 123.5 Current GMPs
- 123.6 HACCP plan
- 123.7 Corrective actions
- 123.8 Verification
- 123.9 Records
- 123.10 Training
- 123.11 Sanitation control procedures
- 123.12 Special requirements for imported products

Subpart B — Smoked and smoke-flavored fishery products
- 123.20 General
- 123.16 Process controls

Subpart C — Raw molluscan shellfish
- 123.20 General
- 123.28 Source controls

Continued

Explanatory Note:

The terms "fish" and "fishery product" together define the products that are subject to this regulation.

• ***Definitions 123.3***

Twenty important terms are used throughout the regulation. They are:

Overhead 3

Definitions 123.3

- certification number
- critical control point
- critical limit
- fish
- fishery product
- hazard
- importer
- molluscan shellfish
- preventive measure
- process-monitoring instrument
- processing
- processor
- scombroid toxin-forming species
- shall
- shellfish-control authority
- shellstock
- should
- shucked shellfish
- smoked or smoke-flavored fishery products
- tag

Of the terms listed above, a few definitions need to be emphasized.

Fish means freshwater or saltwater finfish, crustaceans, aquatic life (including alligators, frogs, aquatic turtles, jellyfishs, sea cucumbers, sea urchins and roe), other than birds or mammals, and all mollusks, where such animal life is intended for human consumption.

Fishery product means any human food product where fish is a characterizing ingredient. [Note: This definition exempts products from the mandatory HACCP requirements that contain inconsequential amounts of fish. For example, Worcestershire sauce contains some anchovy paste but is not characterized by that ingredient.]

Overhead 4

Who must comply?

Importer

Processor — domestic and foreign

Importer means either the U.S. owner/consignee or the U.S. agent/representative of the foreign owner/consignee at the time of the product's entry into the United States. This person is responsible for ensuring that goods being offered for entry are in compliance with all laws affecting the importation. Ordinarily, the importer is not the custom house broker, freight forwarder, carrier or steamship representative. [Note: The ownership of an imported product can change many times in a short period of time after entry into the United States. However, the person who is the owner or consignee at the time that the product is offered for entry is identified as the importer because: 1) that person has the ability to decide whether to offer the product for entry; and 2) that person is in a position to ensure that the product is processed under appropriate controls and to demonstrate this to FDA.]

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.

Processing means handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading or holding fish or fishery products. [Note: Eviscerating done by an aquaculture grower before delivery to a processing plant would make it necessary for the grower to comply with the requirements of this regulation. Fishing vessels and carriers may be affected by this regulation indirectly through the controls that processors may impose on them to meet HACCP obligations. However, vessels are not directly affected by the regulation, except for factory trawlers and similar vessels. Retail establishments must follow state and local government regulations. The Food Code (FDA's model food ordinance that many state and local regulatory authorities use in developing their food laws and regulations) requires that raw materials for retail establishments come from approved sources.]

Overhead 5

This regulation does not apply to:

- The harvest or transport of fish or fishery products.
- Practices such as heading, eviscerating or freezing intended solely to prepare a fish for holding on a harvest vessel.
- The operation of a retail establishment.

Shall is used to state mandatory requirements.

Should is used to state recommended or advisory procedures or to identify recommended equipment.

Continued

Explanatory Note:

The terms importer, processor and processing together define who is subject to this regulation.

Notes:

- ***Current Good Manufacturing Practices (CGMP's) 123.5***

Overhead ***6***

Current Good Manufacturing Practices 123.5

- Regulations found in Title 21, Part 110 of the Code of Federal Regulations
- Proper practices for the safe and sanitary handling of all foods

The Food Drug and Cosmetic Act deems food to be adulterated if processed under insanitary conditions. The Current Good Manufacturing Practices describe the conditions and practices that must be followed to avoid producing adulterated food product. Part 110 applies to the processing of fish and fishery products because it is the basis for determining whether the facilities, methods, practices and controls used to process these products are safe and whether the products have been processed under sanitary conditions. The purpose of the seafood HACCP regulation is to set out requirements specific to the processing of fish and fishery products.

- ***Hazard Analysis 123.6(a)***

Overhead *7*

Hazard Analysis 123.6(a)

Every processor shall conduct or have conducted a hazard analysis.

The regulation requires that every processor perform a hazard analysis. It outlines two major steps in a hazard analysis:

- Determine whether there are hazards that are reasonably likely to occur.
- Identify preventive measures to control the identified hazards.

Overhead *8*

Hazards that are "reasonably likely to occur:"

Those "for which a prudent processor would establish controls"

This means a prudent processor would establish controls because there is a reasonable possibility that a hazard will occur. To make this decision, examine:

- Experience,
- Illness data,
- Scientific reports, and
- Other information.

The criteria for including a food-safety hazard in a processor's HACCP plan should be the likelihood that the hazard will develop in that product without proper controls (e.g., based on the processing technique, the harvest location, the species).

An example of a hazard that is reasonably likely to occur is histamine. Histamine reaction is one of the most frequently reported illnesses from seafood. The relationship between time and temperature abuse after harvest and the formation of the toxin is well-established.

It is the end product of the hazard analysis — the HACCP plan and its implementation — that will be judged by the regulator and not the hazard analysis itself. For this reason, the regulation does not require that the hazard analysis be performed in any particular way or that it be documented in writing for regulatory review. However, a written hazard analysis will help the processor remember the thought process used to identify the hazards and develop the HACCP plan. This will be useful when periodic plan reassessments are conducted and when the plan is reviewed by regulators.

Overhead 9

HACCP Plan 123.6(b)

Every processor shall have and implement a written HACCP plan whenever a hazard analysis reveals one or more food-safety hazards that are reasonably likely to occur.

Overhead *10*

A HACCP plan shall be specific to:

- Each processing location.
- Each species of fish and type of fishery product.

When HACCP plan components are similar, some fish and fishery products may be grouped under a single HACCP plan.

Notes:

Continued

Notes:

- *HACCP **Plan** Contents 123.6(c)*

Overhead 11

The HACCP plan shall:

- List the food-safety hazards that are reasonably likely to occur.
- List the CCPs.
- List the critical limits.
- List the monitoring procedures.
- List predetermined corrective-action plans.*
- List the verification measures.
- Provide for a system of monitoring records.

* *Processors are not required to predetermine corrective actions.*

Food-safety hazards can include: natural toxins, microbiological contamination, chemical contamination, pesticides, drug residues, decomposition that is related to safety (e.g., scombroid toxin-forming species), parasites that are related to safety (e.g., fish used for raw consumption), unapproved food and color additives, and physical hazards. They can be hazards that are introduced inside the processing plant or hazards that occur before, during or after harvest.

The frequencies of the monitoring and verification procedures must be included in the HACCP plan. Monitoring records must provide the actual values or observations noted during monitoring.

- *Signing and Dating the HACCP **Plan** 123.6(d)*

Overhead 12

The HACCP plan shall be signed and dated by:

The most responsible individual at the processing facility or a higher level official of the processor.

This signature shall signify that the HACCP plan has been accepted for implementation by the firm.

Overhead *13*

The HACCP plan shall be signed and dated:

- Upon initial acceptance.
- Upon any modification.*
- At least annually.*

* *This is a verification requirement.*

- ***Low Acid Canned Foods and Acidified Foods 123.6(e)***

Processors who must comply with the requirements of part 113 or 114 (acidified and low-acid canned foods) of the CFR do not need to address the hazard of *Clostridium botulinum* in their HACCP plans. Their HACCP plans do not need to include controls to prevent that hazard, but they must continue to comply with 113 or 114. Other hazards may be reasonably likely to occur in an acidified or low-acid canned fishery product (e.g., histamine in canned tuna), and these must be addressed in the HACCP plan as appropriate.

- ***Sanitation Controls and the HACCP Plan 123.6(f)***

FDA recognizes that sanitation controls may be troublesome to manage in a HACCP plan. It is often difficult to determine appropriate critical limits and corrective actions for sanitation controls, particularly those relating to personnel hygiene (e.g., hand washing). For this reason, the regulation does not require that sanitation controls be included in the HACCP plan. However, sanitation controls that are not in the plan must be monitored according to the sanitation provisions of the regulation. Sanitation is discussed in section 123.11.

- ***Legal Basis 123.6(g)***

FDA's application of HACCP is primarily based on the Federal Food Drug and Cosmetic Act. This section of the act makes it unlawful to process food under conditions that may render it injurious to health. Any fish or fishery products processed or imported in violation of this regulation can be considered adulterated and subject to regulatory action.

Continued

Notes:

Explanatory Note:

HACCP plans will not be preapproved by FDA before they are implemented by the processor. They should not be submitted to the agency for review. FDA reached this decision because:

- HACCP plans should be evaluated on-site, a process best accomplished during inspections of processing facilities.
- FDA does not have sufficient resources to review HACCP plans from all domestic and foreign seafood processors in advance of HACCP implementation by processors.

Notes:

- *Corrective Action 123.7*

Overhead 14

Corrective Action 123.7

Whenever a deviation from a critical limit occurs, a processor shall take corrective action.

The regulation requires that a corrective action take place whenever a critical limit is not met at a CCP.

Overhead *15*

Corrective Actions — Two Choices

- Predetermined
- Alternate Procedure
  - Segregate and hold product.
  - Determine product acceptability.
  - Apply corrective action to product and process.
  - Reassess the HACCP plan.

Processors have a choice of developing a predetermined corrective-action plan in advance as part of their HACCP plans or of following the alternate procedure for corrective actions provided in the regulation. When a processor develops a plan in advance, he/she follows the plan that is appropriate when the deviation occurs. These corrective-action plans become part of their HACCP plans as previously described in section 123.6(c).

A predetermined corrective-action plan provides a processor with benefits such as faster action when a deviation occurs and less need to justify to management the appropriateness of the corrective action after it has been taken. But unusual situations may arise that may not be addressed in predetermined corrective-action plans. Processors may choose not to predetermine their corrective actions. In these cases, the alternate corrective-action procedure must be followed.

A proper corrective-action plan describes the steps that are to be taken and assigns responsibility for taking those steps. It is designed to ensure that:

- No product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation.
- The cause of the deviation is corrected.

The alternate corrective-action procedure involves:

- Segregating and holding the affected product until the next two requirements are met.
- Determining whether the product is safe for distribution. This decision must be made by someone who has suitable training or experience. This training or experience must be in the field(s) of science that is necessary for the person to understand the public health consequences of the critical limit deviation.
- Take corrective action, as necessary, to ensure no unsafe product enters commerce.
- Take corrective action, as necessary, to fix the problem that caused the deviation.
- Determine whether the HACCP plan needs to be modified to reduce the risk that the deviation will happen again and modify the HACCP plan as necessary. This decision must be made by someone who has met the training requirements covered in section 123.10.

All corrective actions must be fully documented in records.

- ***Verification*** 123.8

Overhead 76

Every processor shall verify:

- That the HACCP plan is adequate to control the food-safety hazards that are reasonably likely to occur.
- That the HACCP plan is implemented effectively.

The HACCP plan must be reassessed at least once per year and whenever any changes occur that could affect the hazard analysis or the HACCP plan in any way. This could include changes in:

- Raw materials or source of raw materials.
- Product formulation.
- Processing methods or systems.
- Finished product distribution systems.
- The intended use or consumers of the finished product.

The purpose of the reassessment is to ensure that the HACCP plan is adequate to control the food-safety hazards which are reasonably likely to occur. It must be performed by an individual who meets the training requirements described in section 123.10. If a processor has no HACCP plan because no significant hazards were identified, then the hazard analysis must be reassessed at the frequency just described.

Continued

Notes:

Notes:

The regulation requires ongoing verification activities in addition to periodic reassessment. These ongoing activities are in keeping with the HACCP principle that verification must ensure that the HACCP plan is being implemented on a day-to-day basis. These ongoing verification procedures must be listed in the HACCP plan.

Overhead 17

Ongoing verification:
- Consumer complaint review.
- Calibration of process-monitoring instruments.
- Periodic end-product and in-process testing (processor's option).

Records must be kept of the calibration procedures and end-product or in-process testing that is performed as part of a processor's HACCP activities.

Consumer complaints must be reviewed by the processor to determine whether they relate to problems at a CCP The regulation does not give regulators access to consumer complaints but does give them access to corrective action records that relate to problems identified by consumer complaints.

Overhead 18

Review of records:
- CCP monitoring records.
- Corrective-action records.
- Calibration records.
- In-process and end-product testing records.

The regulation requires that processors review certain records as part of verification. The purpose of these reviews is to ensure that the records are complete and that the activities occurred in accordance with the processor's written procedures. The records must be reviewed by someone who meets the training requirements described in section 123.10.

Monitoring and corrective-action records must be reviewed within one week of when the record was made. Calibration and in-process or end-product testing records must be reviewed in a timely manner.

Sometimes the review of a consumer complaint or the performance of verification procedure will indicate a potential public health problem. When this happens, the processor must follow the corrective-action procedures described in section 123.7.

- *Records 123.9*

Overhead 19

Records required by the regulation:
- Monitoring records.
- Corrective-action records.
- Verification records.
- Sanitation-control records.
- Importer-verification records.

The records required by the regulation must:
- Contain certain information.
- Be completed at the time of the activity.
- Be signed or initialed by the operator or observer.
- Be retained for specified periods of time.
- Be available for review and copying by regulatory authorities.

Overhead 20

Required information on each record:
- Name and location of the processor or importer.
- Date and time of the activity being recorded.
- Signature or initials of the person making the record.
- Identity of the product and the production code if any.

Overhead 21

Record retention:
- One year for refrigerated products.
- Two years for frozen or preserved products.

If permanent storage at the processing facility is not practical (e.g., a remote processing site or a processing vessel), the records may be transferred to some other facility at the end of the season. But the records must be able to be promptly returned when requested by a regulatory agency.

Notes:

Continued

Notes:

A key feature of the HACCP verification process is access by government inspectors to the the HACCP plan, monitoring records and corrective-action records. Examination of HACCP records enables an inspector to see how the processing facility operates over time rather than just on the day of the inspection. Additionally, it enables the inspector to review the adequacy of the processor's preventive-control system.

FDA has concluded that records and plans should be protected to the extent possible to promote the implementation of HACCP across the seafood industry. The regulation states that HACCP plans and records that come into FDA's possession will be treated as either trade secrets or commercial confidential materials.

- ***Training 123.10***

The regulation requires that certain activities and functions be performed by an individual trained in HACCP

Overhead *22*

The HACCP-trained individual shall:
- Develop the HACCP plan.
- Reassess and modify the HACCP plan and hazard analysis.
- Review HACCP records.

Processors can use a trained employee or a trained third party to perform these functions. The jobs may be done by one person or by several as long as they have been properly trained. The regulation defines a "HACCP-trained individual" as one "who has successfully completed training in the application of HACCP principles to fish and fishery product processing that is at least equivalent to that received under a standardized curriculum recognized as adequate by the U.S. Food and Drug Administration or who is otherwise qualified through job experience to perform these functions. Job experience will qualify if it has provided knowledge at least equivalent to that provided through the standardized curriculum." This course material, developed by the National Seafood HACCP Allicance, is the standadized curriculum that has been recognized by FDA.

- ***Sanitation 123.11***

Sanitation is a prerequisite program that is necessary for the effective implementation of HACCP. In writing the seafood HACCP regulation, FDA concluded that the GMP regulations (21 CFR 110) had not proven fully effective at encouraging seafood processors to take full responsibility for ensuring that sanitation in their plants consistently met minimum standards. For these reasons, the regulation requires that processors take certain actions to control sanitation conditions and practices.

These actions must be taken even if a processor determines there is no need for a HACCP plan. The sanitation requirements of the regulation may be made part of the processor's HACCP plan or may be managed separately. Some processors may choose to use a combination of these approaches.

Notes:

Overhead 23

General Requirement
- Current GMP regulations are the standard for proper sanitation conditions and practices.
- Eight key sanitation conditions and practices.
- Mandatory sanitation monitoring with record keeping.
- Mandatory corrections with record keeping.
- Recommended SSOP.

The regulation encourages, but does not require, that each processor develop an SSOP. The SSOP should describe how the processor will ensure that certain key sanitation conditions and practices will be met. It should also describe how the plant operations will be monitored to ensure that the conditions and practices will be met.

Whether or not a processor chooses to write an SSOP, the key sanitation conditions and practices that are relevant to the plant must be monitored.

Overhead 24

Eight key sanitation conditions and practices:
- Safety of water.
- Condition and cleanliness of food-contact surfaces.
- Prevention of cross-contamination.
- Maintenance of hand-washing, hand-sanitizing and toilet facilities.
- Protection from adulterants.
- Labeling, storage and use of toxic compounds.
- Employee health conditions.
- Exclusion of pests.

The purpose of the monitoring is to ensure that the requirements of the current GMP regulations are met. Monitoring frequencies are not specified but must be sufficient to ensure that the current GMP requirements are met.

Continued

Notes:

When the conditions and practices contained in the current GMP regulations are not met, they must be corrected in a timely manner. Records must be kept of the monitoring and the corrections. These records are subject to the same requirements as the HACCP records, except plant-verification review.

- *Imported Products 123.12*

It has always been the importer's responsibility to offer for entry into this country products that are not adulterated under U.S. law. FDA's surveillance system for imports has traditionally consisted of: reviews of customs entry forms for fish and fishery products being offered for entry into the United States, sensory analyses (wharf examinations) and sample collections for laboratory anlysis of products awaiting entry, and automatic detention of products with a history of problems. As with traditional processing plant inspections, this method is a "snapshot" approach that is not preventive.

Under the seafood HACCP regulation, HACCP controls are required for imported fish and fishery products as well as for domestic products. The definition of processor explicitly includes those who process seafood in foreign countries. Additionally, the regulation requires that importers take certain steps to verify that their foreign suppliers meet the requirements of the regulation.

Overhead 25

Importer Verification:
- Import from countries with a memorandum of understanding (MOU) or
- Implement verification procedures.

Importers may meet their obligation in one of two ways. They may import fish and fishery products that are covered by a memoranda of understanding between the United States and a foreign country. In this case, they do not need to take any other action to meet the requirements of the regulation.

Otherwise, the importer must have and implement written verification procedures for ensuring that the fish and fishery products offered for import into the United States were processed in accordance with the requirements of the regulation.

Overhead 26

Notes:

Importer Verification Procedures:
- Product specifications and
- Affirmative steps.

Product specifications should cover those characteristics of the product that would be useful in providing assurance that the product is not adulterated under section 402 of the Federal Food, Drug and Cosmetic Act. This section relates to contaminants that may render the food injurious to health and to insanitary processing conditions. It may be appropriate for a specification for frozen tuna steaks to include a maximum limit for histamine of 50 ppm.

Overhead 27

Importer Verification Procedures

Affirmative steps may include any of the following:
- Obtain foreign processor's HACCP and sanitation monitoring records for the lot being entered.
- Obtain continuing or lot-by-lot certificate from competent third party.
- Regularly inspect foreign processor.
- Obtain foreign processor's HACCP plan and written guarantee that regulation is being met.
- Test the product and obtain written guarantee that regulation is being met.
- Perform other verification procedures that provide equivalent level of assurance.

An importer may hire a competent third party to perform verification activities. However, the importer remains responsible for demonstrating to FDA that the requirements have been met.

The importer must keep records in English that document that the affirmative steps have been performed. The records must describe the results of the steps. These records are subject to the records requirements described in section 123.9. Importers that also process fish or fishery products must also meet the HACCP and sanitation requirements of the regulation for their processing operations.

Continued

Notes:

- ***Smoked and Smoke-Flavored Fishery Products 123.15 and 123.16***

Overhead ***28***

Smoked and Smoke-Flavored Fishery Products
- HACCP plan must include controls for *Clostridium botulinum* toxin formation for the shelf life of the product under normal and moderate abuse conditions.
- Where product is subject to 21 CFR 113 or 114, the HACCP plan need not include such controls.

Smoked fish has been linked to a few cases of botulism. ***Clostridium botulinum***, the bacteria that causes botulism, is prevented from growing in properly smoked fish by a combination of barriers, including salt, smoke, nitrite and, in the case of hot-smoked fish, heat. Careful control of these parameters is necessary to ensure the safety of the finished product. Such controls must be included in the HACCP plans of these products, unless the product is preserved by the addition of acid or heat under the controls required by the acidified or low-acid canned food regulations (21 CFR 113 and 114).

It is important to note that if there are other significant hazards that must be included in the HACCP plan.

- ***Raw Molluscan Shellfish 123.20 and 123.28 and Control of Communicable Diseases 1240.60***

Overhead 29

Raw Molluscan Shellfish 123.20
- HACCP plans must include a means for controlling the origin of the raw molluscan shellfish.
- Where processing includes a treatment that ensures the destruction of vegetative cells of microorganisms of public health concern, the HACCP plan need not include such controls.

The largest number of reported illnesses from consumption of seafood is caused by raw molluscan shellfish (oysters, clams and mussels). These hazards are primarily introduced before the molluscan shellfish are harvested. The risk of occurrence of these hazards is reduced by ensuring that the molluscan shellfish come from sanitary growing waters. In most cases, the sanitary quality of molluscan-shellfish growing waters is determined by a state or national agency called a shellfish-control authority.

The regulation provides very specific requirements for controlling the source of origin for raw molluscan shellfish. It is important to note, however, that other hazards may also be reasonably likely to occur in these products, and they must be identified in the HACCP plan.

Notes:

Overhead *30*

Raw Molluscan Shellfish 123.28
Processors shall only process molluscan shellfish from:
- Growing waters approved by a shellfish-control authority.
- Federal growing waters not closed by an agency of the federal government.

Overhead 31

Raw Molluscan Shellfish 123.28
Shellstock Receiving
- If source is a harvester, harvester must be in compliance with any license requirement.
- If source is another processor, processor must be certified by a shellfish-control authority.
- Containers of shellstock must be properly tagged.

Overhead 32

Raw Molluscan Shellfish 1240.60
Required information on tag:
- Date and place shellfish were harvested (state and site).
- Type and quantity of shellfish.
- Harvester identification number, name of harvester or name or registration number of harvester's vessel.

Continued

Notes:

Overhead 33

Raw Molluscan Shellfish 123.28
Records for shellstock receiving must document:
- Date of harvest.
- Location of harvest by state and site.
- Quantity and type of shellfish.
- Date of receipt by the processor.
- Name of harvester, name or registration number of the harvester's vessel or harvester's identification number.

Overhead 34

Raw Molluscan Shellfish 123.28
Shucked molluscan shellfish containers must bear a label that contains:
- Name of packer or repacker.
- Address of packer or repacker.
- Certification number of packer or repacker.

Overhead *35*

Raw Molluscan Shellfish 123.28
Records for shucked product must document:
- Date of receipt.
- Quantity and type of shellfish.
- Name and certification number of the packer or repacker.

Appendix I: FDA's Seafood HACCP Rule

Notes:

Subpart A — General Provisions

§ 123.3 *Definitions*

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) and in part 110 of this chapter are applicable to such terms when used in this part, except where they are herein redefined. 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) Critical control point means a point, step or procedure in a food process at which control can be applied, and a food-safety hazard can be prevented, eliminated, or reduced to acceptable levels.

(c) 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 prevent, eliminate or reduce to an acceptable level the occurrence of the identified food-safety hazard.

(d) Fish means fresh or saltwater finfish, crustaceans, other forms of aquatic animal life (including, but not limited to alligators, frogs, aquatic turtles, jellyfishs, sea cucumbers, sea urchins and roe of such animals) other than birds or mammals, and all mollusks, where such animal life is intended for human consumption.

(e) Fishery product means any human food product in which fish is a characterizing ingredient.

(f) Food-safety hazard means any biological, chemical or physical property that may cause a food to be unsafe for human consumption.

(g) Importer means either the U.S. owner or consignee at the time of entry into the United States or the U.S. agent or representative of the foreign owner or consignee at the time of entry into the United States. The person is responsible for ensuring that goods being offered for entry into the United States are in compliance with all laws affecting the importation. For the purposes of this definition, ordinarily the importer is not the custom-house broker, the freight forwarder, the carrier or the steamship representative.

(h) Molluscan shellfish means any edible species of fresh or frozen oysters, clams, mussels, scallops or edible portions of such species, except when the product consists entirely of the shucked adductor muscle.

(i) Preventive measure means physical, chemical or other factors that can be used to control an identified food safety hazard.

(j) Process-monitoring instrument means an instrument or device used to indicate conditions during processing at a critical control point.

(k) (1) Processing means, with respect to fish or fishery products:
Handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading or holding.
(2) The regulations in this part do not apply to:
(i) Harvesting or transporting fish or fishery products, without otherwise engaging in processing.
(ii) practices such as heading, eviscerating or freezing intended solely to prepare a fish for holding on a harvest vessel.
(iii) The operation of a retail establishment.

(l) 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. A processor includes any person engaged in the production of foods that are to be used in market or consumer tests.

(m) Scombroid toxin-forming species means tuna, bluefish, mahi mahi, and other species, whether or not in 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.

(n) Shall is used to state mandatory requirements.

(o) Shellfish control authority means a federal, state or foreign agency, or sovereign tribal government, legally responsible for the administration of a program that includes activities such as classification of molluscan shellfish growing areas, enforcement of molluscan shellfish harvesting controls, and certification of molluscan shellfish processors.

(p) Shellstock means raw, in-shell molluscan shellfish.

(q) Should is used to state recommended or advisory procedures or to identify recommended equipment.

(r) Shucked shellfish means molluscan shellfish that have one or both shells removed.

(s) Smoked or smoke-flavored fishery products means the finished food prepared by:
(1) Treating fish with salt (sodium chloride), and
(2) Subjecting it to the direct action of smoke from burning wood, sawdust or similar material and/or imparting to it the flavor of smoke by a means such as immersing it in a solution of wood smoke.

(t) Tag means a record of harvesting information attached to a container of shellstock by the harvester or processor.

Notes:

Continued

Notes:

§ *123.5 Current Good Manufacturing Practice*

(a) Part 110 of this chapter applies 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 this part is to set forth requirements specific to the processing of fish and fishery products.

$123.6 *Hazard Analysis and Hazard Analysis Critical Control Point (HACCP) **Plan***

(a) Hazard analysis. Every processor shall conduct or have conducted a hazard analysis to determine whether there are food-safety hazards that are reasonably likely to occur for each kind of fish and fishery product processed by that processor and to identify the preventive measures that the processor can apply to control those hazards. Such food-safety hazards can be introduced both within and outside the processing plant environment, including food-safety hazards that can occur before, during and after harvest. A food-safety hazard that is reasonably likely to occur is one for which a prudent processor would establish controls because experience, illness data, scientific reports or other information provide a basis to conclude that there is a reasonable possibility that it will occur in the particular type of fish or fishery product being processed in the absence of those controls.

(b) The HACCP plan. Every processor shall have and implement a written HACCP plan whenever a hazard analysis reveals one or more food-safety hazards that are reasonably likely to occur as described in paragraph (a) of this section. A HACCP plan shall be 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 or group kinds of production methods together if the food-safety hazards, critical control points, critical limits and procedures required to be identified and performed in paragraph (c) of this section are identical for all fish and fishery products so grouped or for all production methods so grouped.

(c) The contents of the HACCP plan. The HACCP plan shall, at a minimum:

(1) List the food-safety hazards that are reasonably likely to occur as identified in accordance with paragraph (a) of this section, and that must be controlled for each fish and fishery product. Consideration should be given to whether any food-safety hazards are reasonably likely to occur as a result of the following:

(i) Natural toxins;

(ii) Microbiological contamination;

(iii) Chemical contamination;

(iv) Pesticides;

(v) Drug residues;

(vi) Decomposition in scombroid toxin-forming species or in any other species where a food-safety hazard has been associated with decomposition;

(vii) Parasites, where the processor has knowledge or has reason to know that the parasite-containing fish or fishery product will be consumed without a process sufficient to kill the parasites, or where the processor represents, labels or intends for the product to be so consumed;

(viii) Unapproved use of direct or indirect food or color additives; and

(ix) Physical hazards;

(2) List the critical control points for each of the identified food-safety hazards, including as appropriate:

(i) Critical control points designed to control food-safety hazards that could be introduced in the processing plant environment; and

(ii) Critical control points designed to control food-safety hazards introduced outside the processing plant environment, including food-safety hazards that occur before, during and after harvest;

(3) List the critical limits that must be met at each of the critical control points;

(4) List the procedures, and frequency thereof, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;

(5) Include any corrective action plans that have been developed in accordance with § 123.7(b), to be followed in response to deviations from critical limits at critical control points;

(6) List the verification procedures, and frequency thereof, that the processor will use in accordance with § 123.8(a);

(7) Provide for a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.

Continued

Notes:

Notes:

(d) **Signing and dating he HACCP plan.**

(1) The HACCP plan shall be signed and dated, either by the most responsible individual onsite at the processing facility or by a higher level official of the processor. This signature shall signify that the HACCP plan has been accepted for implementation by the firm.

(2) The HACCP plan shall be dated and signed:

(i) Upon initial acceptance

(ii) Upon any modification and

(iii) Upon verification of the plan in accordance with §123.8(a)(1).

(e) **Product subject to other regulations.** For fish and fishery products that are subject to the requirements of part 113 or 114 of this chapter, the HACCP plan need not list the food-safety hazard associated with the formation of *Clostridium botulinum* toxin in the finished, hermetically sealed container, nor list the controls to prevent that food-safety hazard. A HACCP plan for such fish and fishery products shall address any other food-safety hazards that are reasonably likely to occur.

(f) Sanitation. Sanitation controls may be included in the HACCP plan. However, to the extent that they are monitored in accordance with § 123.1 l(b) they need not be included in the HACCP plan and vice versa.

(g) Legal basis. Failure of a processor to have and implement a HACCP plan that complies with this section whenever a HACCP plan is necessary, otherwise operate in accordance with the requirements of this part, shall render the fish or fishery products of that processor adulterated under section 402(a)(4) of the act. Whether a processor's actions are consistent with ensuring the safety of food will be determined through an evaluation of the processors overall implementation of its HACCP plan, if one is required.

§ 123.7 Corrective *Actions*

(a) Whenever a deviation from a critical limit occurs, a processor shall take corrective action either by:

(1) Following a corrective action plan that is appropriate for the particular deviation, or

(2) Following the procedures in paragraph (c) of this section.

(b) Processors may develop written corrective action plans, which become part of their HACCP plans in accordance with §123.6(c)(5), by which they predetermine the corrective actions that they will take whenever there is a deviation from a critical limit. A corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that:

(1) No product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation; and

(2) The cause of the deviation is corrected.

(c) When a deviation from a critical limit occurs and the processor does not have a corrective-action plan that is appropriate for that deviation, the processor shall:

(1) Segregate and hold the affected product, at least until the requirements of paragraphs (c)(2) and (c)(3) of this section are met;

(2) Perform or obtain a review to determine the acceptability of the affected product for distribution. The review shall be performed by an individual or individuals who have adequate training or experience to perform such a review. Adequate training may or may not include training in accordance with § 123.10;

(3) Take corrective action, when necessary, with respect to the affected product to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation;

(4) Take corrective action, when necessary, to correct the cause of the deviation;

(5) Perform or obtain timely reassessment by an individual or individuals who have been trained in accordance with § 123.10, to determine whether the HACCP plan needs to be modified to reduce the risk of recurrence of the deviation, and modify the HACCP plan as necessary.

(d) All corrective actions taken in accordance with this section shall be fully documented in records that are subject to verification in accordance with §123.8(a)(3)(ii) and the recordkeeping requirements of § 123.9.

§ 123.8 *Verification*

(a) Overall verification. Every processor shall verify that the HACCP plan is adequate to control food-safety hazards that are reasonably likely to occur and that the plan is being effectively implemented. Verification shall include, at a minimum:

(1) Reassessment of he HACCP plan. A reassessment of the adequacy of the HACCP plan whenever any changes occur that could affect the hazard analysis or alter the HACCP plan in any way or at least annually. Such changes may include changes in the following: raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been trained in accordance with § 123.10. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan is no longer adequate to fully meet the requirements of § 123.6(c).

Continued

Notes:

Notes:

(2) Ongoing verification activities. Ongoing verification activities including:

(i) A review of any consumer complaints that have been received by the processor to determine whether they relate to the performance of critical control points or reveal the existence of unidentified critical control points;

(ii) The calibration of process-monitoring instruments; and,

(iii) At the option of the processor, the performing of periodic end-product or in-process testing.

(3) **Records review.** A review, including signing and dating, by an individual who has been trained in accordance with § 123.10, of the records that document:

(i) The monitoring of critical control points. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that they document values that are within the critical limits. This review shall occur within 1 week of the day that the records are made;

(ii) The taking of corrective actions. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that appropriate corrective actions were taken in accordance with § 123.7. This review shall occur within one week of the day that the records are made; and

(iii) The calibrating of any process control instruments used at critical control points and the performing of any periodic end-product or in-process testing that is part of the processor's verification activities. The purpose of these reviews shall be, at a minimum, to ensure that the records are complete, and that these activities occurred in accordance with the processor's written procedures. These reviews shall occur within a reasonable time after the records are made.

(b) **Corrective actions.** Processors shall immediately follow the procedures in § 123.7 whenever any verification procedure, including the review of a consumer complaint, reveals the need to take a corrective action.

(c) **Reassessment of the hazard analysis.** Whenever a processor does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur, the processor shall reassess the adequacy of that hazard analysis whenever there are any changes that could reasonably affect whether a food-safety hazard now exists. Such changes may include, but are not limited to changes in: raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been trained in accordance with § 123.10.

(d) Recordkeeping. The calibration of process-monitoring instruments, and the performing of any periodic end-product and in-process testing, in accordance with paragraphs (a)(2)(ii) through (iii) of this section shall be documented in records that are subject to the recordkeeping requirements of § 123.9.

§ 123.9 ***Records***

(a) General requirements. All records required by this part shall include:

(1) The name and location of the processor or importer;
(2) The date and time of the activity that the record reflects;
(3) The signature or initials of the person performing the operation; and
(4) Where appropriate, the identity of the product and the production code, if any. Processing and other information shall be entered on records at the time that it is observed.

(b) Record retention.

(1) All records required by this part shall be retained at the processing facility or importer's place of business in the United States for at least one year after the date they were prepared in the case of refrigerated products and for at least two years after the date they were prepared in the case of frozen, preserved or shelf-stable products.
(2) 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 or the importer's place of business in the United States for at least two years after their applicability to the product being produced at the facility.
(3) If the processing facility is closed for a prolonged period between seasonal packs, or if record storage capacity is limited on a processing vessel or at a remote processing site, the records may be transferred to some other reasonably accessible location at the end of the seasonal pack but shall be immediately returned for official review upon demand.

(c) Official review. All records required by this part and all plans and procedures required by this part shall be available for official review and copying at reasonable times.

Notes:

Continued

Notes:

(d) Public disclosure.

(1) Subject to the limitations in paragraph (d)(2) of this section, all plans and records required by this part are not available for public disclosure unless they have been previously disclosed to the public as defined in § 20.81 of this chapter or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in § 20.61 of this chapter.

(2) However, these records and plans may be subject to disclosure to the extent that they are otherwise publicly available, or that disclosure could not reasonably be expected to cause a competitive hardship, such as generic-type HACCP plans that reflect standard industry practices.

(e) Tags. Tags as defined in § 123.3(t) are not subject to the requirements of this section unless they are used to fulfill the requirements of § 123.28(c).

(f) Records maintained on computers. The maintenance of records on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.

§ 123.10 *Training*

At a minimum, the following functions shall be performed by an individual who has successfully completed training in the application of HACCP principles to fish and fishery product processing at least equivalent to that received under standardized curriculum recognized as adequate by the U.S. Food and Drug Administration or who is otherwise qualified through job experience to perform these functions. Job experience will qualify an individual to perform these functions if it has provided knowledge at least equivalent to that provided through the standardized curriculum.

(a) Developing a HACCP plan, which could include adapting a model or generic-type HACCP plan, that is appropriate for a specific processor, in order to meet the requirements of § 123.6(b);

(b) Reassessing and modifying the HACCP plan in accordance with the corrective action procedures specified in §123.7(c)(5), the HACCP plan in accordance with the verification activities specified in § 123.8(a)(l), and the hazard analysis in accordance with the verification activities specified in § 123.8(c); and

(c) Performing the record review required by § 123.8(a)(3);
The trained individual need not be an employee of the processor.

§ *123.11 Sanitation Control Procedures*

Notes:

(a) Sanitation SOP. Each processor should have and implement a written sanitation standard operating procedure (herein referred to as SSOP) or similar document that is specific to each location where fish and fishery products are produced. The SSOP should specify how the processor will meet those sanitation conditions and practices that are to be monitored in accordance with paragraph (b) of this section.

(b) Sanitation monitoring. Each processor shall monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with those conditions and practices specified in part 110 of this chapter that are both appropriate to the plant and the food being processed and relate to the following:

(1) Safety of the water that comes into contact with food or food-contact surfaces, or is used in the manufacture of ice;
(2) Condition and cleanliness of food-contact surfaces, including utensils, gloves and outer garments;
(3) Prevention of cross-contamination from insanitary objects to food, food-packaging material and other food-contact surfaces, including utensils, gloves and outer garments, and from raw product to cooked product;
(4) Maintenance of hand washing, hand sanitizing and toilet facilities;
(5) Protection of food, food-packaging material and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate and other chemical, physical and biological contaminants;
(6) Proper labeling, storage and use of toxic compounds;
(7) Control of employee health conditions that could result in the microbiological contamination of food, food-packaging materials and food-contact surfaces; and
(8) Exclusion of pests from the food plant.

The processor shall correct in a timely manner, those conditions and practices that are not met.

(c) Sanitation control records. Each processor shall maintain sanitation control records that, at a minimum, document the monitoring and corrections prescribed by paragraph (b) of this section. These records are subject to the requirements of § 123.9.

(d) Relationship to HACCP plan. Sanitation controls may be included in the HACCP plan, required by § 123.6(b). However, to the extent that they are monitored in accordance with paragraph (b) of this section, they need not be included in the HACCP plan and vice versa.

Continued

Notes:

§ *123.12 Special Requirements for Imported Products*

This section sets forth specific requirements for imported fish and fishery products.

(a) **Importer verification.** Every importer of fish or fishery products shall either:

(1) Obtain the fish or fishery product from a country that has an active memorandum of understanding (MOU) or similar agreement with the Food and Drug Administration, that covers the fish or fishery product and documents the equivalency or compliance of the inspection system of the foreign country with the U.S. system, accurately reflects the current situation between the signing parties, and is functioning and enforceable in its entirety; or

(2) Have and implement written verification procedures for ensuring that the fish and fishery products that they offer for import into the United States were processed in accordance with the requirements of this part. The procedures shall list at a minimum:

(i) Product specifications that are designed to ensure that the product is not adulterated under section 402 of the Federal Food, Drug and Cosmetic Act because it may be injurious to health or have been processed under insanitary conditions, and,

(ii) Affirmative steps that may include any of the following:

(A) Obtaining from the foreign processor the HACCP and sanitation monitoring records required by this part that relate to the specific lot of fish or fishery products being offered for import;

(B) Obtaining either a continuing or lot-by-lot certificate from an appropriate foreign government inspection authority or competent third party certifying that the imported fish or fishery product is or was processed in accordance with the requirements of this part;

(C) Regularly inspecting the foreign processor's facilities to ensure that the imported fish or fishery product is being processed in accordance with the requirements of this part;

(D) Maintaining on file a copy, in English, of the foreign processor's HACCP plan, and a written guarantee from the foreign processor that the imported fish or fishery product is processed in accordance with the requirements of the part;

(E) Periodically testing the imported fish or fishery product, and maintaining on file a copy, in English, of a written guarantee from the foreign processor that the imported fish or fishery product is processed in accordance with the requirements of this part or,

(F) Other such verification measures as appropriate that provide an equivalent level of assurance of compliance with the requirements of this part.

(b) Competent third party. An importer may hire a competent third party to assist with or perform any or all of the verification activities specified in paragraph (a)(2) of this section, including writing the importer's verification procedures on the importer's behalf.

(c) Records. The importer shall maintain records, in English, that document the performance and results of the affirmative steps specified in paragraph (a)(2)(ii) of this section. These records shall be subject to the applicable provisions of § 123.9.

(d) Determination of compliance. There must be evidence that all fish and fishery products offered for entry into the United States have been processed under conditions that comply with this part. If assurances do not exist that the imported fish or fishery product has been processed under conditions that are equivalent to those required of domestic processors under this part, the product will appear to be adulterated and will be denied entry.

Subpart B-Smoked and Smoke-Flavored Fishery Products

§ 123.15 *General*

This subpart augments subpart A of this part by setting forth specific requirements for processing smoked and smoke-flavored fishery products.

§ 123.16 Process *Controls*

In order to meet the requirements of subpart A of this part, processors of smoked and smoke-flavored fishery products, except those subject to the requirements of part 113 or 114 of this chapter, shall include in their HACCP plans how they are controlling the food-safety hazard associated with the formation of toxin by *Clostridium botulinum* for at least as long as the shelf life of the product under normal and moderate abuse conditions.

Notes:

Continued

Notes:

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, where such processing does not include a treatment that ensures the destruction of vegetative cells of microorganisms of public health concern.

§ 123.28 Source *Controls*

(a) In order to meet the requirements of subpart A of this part as they apply to microbiological contamination, chemical contamination, natural toxins, and related food safety hazards, processors shall include in their HACCP plans how they are controlling the origin of the molluscan shellfish they process to ensure that the conditions of paragraphs (b), (c), and (d) of this section are met.

(b) Processors shall only process molluscan shellfish harvested from growing waters approved for harvesting by a shellfish control authority. In the case of molluscan shellfish harvested from U.S. federal waters, the requirements of this paragraph will be met so long as the shellfish have not been harvested from waters that have been closed to harvesting by an agency of the federal government.

(c) To meet the requirements of paragraph (b) of this section, processors who receive shellstock shall accept only shellstock from a harvester that is in compliance with such licensure requirements as may apply to the harvesting of molluscan shellfish or from a processor that is certified by a shellfish control authority, and that has a tag affixed to each container of shellstock. The tag shall bear, at a minimum, the information required in §1240.60(b) of this chapter. In place of the tag, bulk shellstock shipments may be accompanied by a bill of lading or similar shipping document that contains the information required in § 1240.60(b) of this chapter. Processors shall maintain records that document that all shellstock have met the requirements of this section. These records shall document:

(1) The date of harvest;
(2) The location of harvest by state and site;
(3) The quantity and type of shellfish;
(4) The date of receipt by the processor; and
(5) The name of the harvester, the name or registration number of the harvester's vessel, or an identification number issued to the harvester by the shellfish control authority.

(d) To meet the requirements of paragraph (b) of this section, processors who receive shucked molluscan shellfish shall accept only containers of shucked molluscan shellfish that bear a label that complies with §1240.60(c) of this chapter. Processors shall maintain records that document that all shucked molluscan shellfish have met the requirements of this section. These records shall document:

(1) The date of receipt,

(2) The quantity and type of shellfish, and

(3) The name and certification number of the packer or repacker of the product.

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 (r), and by adding new paragraphs (s), (t), and (u) to read as follows:

§ 1240.3 *General Definitions*

(r) Molluscan shellfish. Any edible species of fresh or frozen oysters, clams, mussels, and scallops or edible portions thereof, except when the product consists entirely of the shucked adductor muscle.

(s) Certification number means a unique combination of letters and numbers assigned by a shellfish control authority to a molluscan shellfish processor.

(t) Shellfish control authority means a federal, state, or foreign agency, or sovereign tribal government, legally responsible for the administration of a program that includes activities such as classification of molluscan shellfish growing areas, enforcement of molluscan shellfish harvesting controls, and certification of molluscan shellfish processors.

(u) Tag means a record of harvesting information attached to a container of shellstock by the harvester or processor.

Notes:

Continued

Notes:

4. Section 1240.60 is amended by revising the section heading, by redesignating 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), (c), and (d) to read as follows:

§ 1240.60 ***Molluscan Shellfish***

(b) All shellstock shall bear a tag that discloses the date and place they were harvested (by state and site), type and quantity of shellfish, and by whom they were harvested (i.e., the identification number assigned to the harvester by the shellfish control authority, where applicable or, if such identification numbers are not assigned, the name of the harvester or the name or registration number of the harvester's vessel). In place of the tag, bulk shellstock shipments may be accompanied by a bill of lading or similar shipping document that contains the same information.

(c) All containers of shucked molluscan shellfish shah bear a label that identifies the name, address and certification number of the packer or repacker of the molluscan shellfish.

(d) Any molluscan shellfish without such a tag, shipping document, or label, or with a tag, shipping document or label that does not bear all the information required by paragraphs (b) and (c) of this section, shall be subject to seizure or refusal of entry, and destruction.

Appendix II: National Advisory Committee on Microbiological Criteria in Foods Questions and Sample Worksheets

Notes:

Examples of Questions to be Considered in a Hazard Analysis

- Questions *Adapted from the NACMCF*

A. Ingredients

1. Does the food contain any sensitive ingredients that may present microbiological hazards (e.g. ***Salmonella, Staphylococcus aureus***), chemical hazards (e.g., aflatoxin, histamine, antibiotic or pesticide residues, ciguatera, shellfish toxins) or physical hazards (stones, glass, metal)?
* 2. Is potable water used in formulating or handling the food?

B. Intrinsic factors - physical characteristics and composition (e.g., pH, type of acidulants, fermentable carbohydrate, water activity and preservatives of the food during and after processing.

1. Which intrinsic factors of the food must be controlled to ensure food safety?
2. Does the food permit survival or multiplication of pathogens (microbial) or toxin formation during processing?
3. Will the food permit survival or multiplication of pathogens or toxin formation during subsequent steps in the food-handling chain?
4. Are there similar products in the marketplace? What has been the safety record of these products?

C. Procedures used for processing

1. Is there a controllable processing step that destroys pathogens?
2. Is the product subject to recontamination between processing (e.g., cooking, pasteurizing) and packaging?
3. Does the process include steps to remove chemical or physical hazards?

D. Microbial content of food

1. Is the food commercially sterile (e.g., low-acid canned food)?
2. Is it likely that the food will contain viable sporeforming or nonsporeforming pathogens?
3. What is the normal microbial content of the food?
4. Does the microbial population change during food storage prior to consumption?
5. Does the subsequent change in microbial population alter the safety of the food?

E. Facility design

* 1. Does the layout of the facility provide adequate separation of raw materials from the ready-to-eat food. Is this important to food safety?
* 2. Is positive air pressure maintained in product packaging areas? Is this essential for product safety?
* 3. Is the traffic pattern for people and movable equipment a significant source of contamination?

F. Equipment Design

1. Will the processing equipment provide the time-temperature control that is necessary?
2. Is the equipment the proper size for the volume of food that will be processed?
3. Can the equipment be sufficiently controlled so that the variation in performance will be within the tolerances required to produce a safe food product?
4. Is the equipment reliable or is it prone to frequent breakdowns?
* 5. Is the equipment designed so that it can be cleaned and sanitized?
6. Is there a chance for product contamination with hazardous substances such as glass?
7. What product safety devices are used to enhance consumer safety?
   - Metal detectors?
   - Magnets?
   - Sifters?
   - Filters?
   - Screens?
   - Thermometers?
   - Deboners?
   - Dud detectors?

G. Packaging

1. Does the method of packaging affect the multiplication of microbial pathogens or formation of toxins?
2. Is the packaging clearly labeled "Keep Refrigerated" if this is required for safety?
3. Does the package include instructions for the safe handling and preparation of the food by the consumer?
4. Is the packaging material appropriately resistant to damage and able to prevent the entrance of microbial contamination?
5. Is tamper-evident packaging used?
6. Is each package and case legibly and accurately coded?
7. Does each package contain the proper label?

H. Sanitation

* 1. Can sanitation affect the safety of the food being processed?
* 2. Can the facility and equipment be cleaned and sanitized to permit safe food handling?
* 3. Is it possible to provide sanitary conditions consistently and adequately to ensure safe food?

I. Employee health, hygiene and education

* 1. Can employee health or personal hygiene practices affect the safety of the food being processed?
2. Do employees understand the process and the factors they must control to ensure the preparation of safe foods?
3. Do employees understand they need to inform management of a problem that could affect food safety?

Continued

Notes:

Notes:

J. Conditions of storage between packaging and use
   1. What is the likelihood that the food will be improperly stored at the wrong temperature?
   2. Would an error in improper storage lead to a microbiologically unsafe food?

K. Intended use
   1. Will the food be heated by the consumer?
   2. Will there be leftovers?

L. Intended Consumer
   1. Is the food intended for the general consumer?
   2. Is the food intended for consumption by a population with increased susceptibility to illness (e.g., infants, the aged, the infirmed, people with weakened immune systems)?

* *If these items are critical to the manufacture of safe food, then it may be more appropriate for processors to address them in a prerequiste sanitation program.*

Hazard Analysis Worksheet

(1) Ingredient/ processing step	(2) Identify potential hazards introduced, controlled or enhanced at this step.	(3) Are any potential food-safety hazards significant? (Yes/No)	(4) Justify your decision for column 3	(5) What preventative measure(s) can be applied to prevent the significant hazards?	(6) Is this step a critical control point? (Yes/No)
	BIOLOGICAL CHEMICAL PHYSICAL				
	BIOLOGICAL CHEMICAL PHYSICAL				
	BIOLOGICAL CHEMICAL PHYSICAL				
	BIOLOGICAL CHEMICAL PHYSICAL				
	BIOLOGICAL CHEMICAL PHYSICAL				
	BIOLOGICAL CHEMICAL PHYSICAL				

HACCP Plan Form

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Preventive Measure	(4) Monitoring				(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			

Appendix III: **Hazards Found in Seafood**

Notes:

Overhead 1

Objective:
In this module, you will learn:
- The identity and characteristics of biological, chemical and physical safety hazards commonly identified with seafood.
- Control measures for hazards in seafood.

Biological Hazards

Biological safety hazards commonly found in seafood include bacterial pathogens, viral pathogens and parasites.

- *Bacterial Pathogens*

Pathogen growth is often an important factor in food-borne illness. For this reason, the maximum and minimum pH and temperature, the minimum water activity (aw), and the maximum salt that will permit the growth of the described pathogens are listed in Table 1. The oxygen conditions required for the growth of the bacteria are also provided.

Overhead 2

Bacterial Pathogens:
- *Campylobacter jejuni*
- *Clostridium botulinum*
- *Escherichia coli*
- *Listeria monocytogenes*
- *Salmonella spp.*
- *Shigella spp.*
- *Staphylococcus aureus*
- *Vibrio cholerea*
- *Vibrio parahaemolyticus*
- *Vibrio vulnificus*
- *Yersinia enterocolitica*

Table 1: Factors Affecting Growth of Selected Pathogens

Pathogen	Minimum a_w	Minimum pH	Maximum pH	Maximum salt (%)	Minimum temperature (F)	Maximum temperature (F)	Oxygen requirement
Campylobacfer jejuni	.99	4.9 - 5.5	8.0	1.5 -2	86 - 90	108 - 113	microaerophilic*
Clostridium botulinurn Type A	.93 - .96	4.7	9.0	10	50	118 - 122	anaerobe* *
Clostridium botulinum Type E	.93 - .96	4.7 - 4.8	9.0	4.5 - 6	38	86	anaerobe**
Escherichia coli	.93 - .95	3.6 - 4.7	9.5	7.5 - 8	33 - 37	113	facultative anaerobe***
Listeria monocytogenes	.92 - .95	4.8	9.6	8 - 12	36	113	facultative anaerobe***
Salmonella spp.	.92	4.0	9.0	8	41	115-117	facultative anaerobe***
Shigella spp.	.96	3.5 - 4.5	<10	6	>46	<113	facultative anaerobe***
Staphylococcus aureus	.83 - .86	4.0	10.0	18-20	41-43	113 - 118	facultative anaerobe***
Vibrio cholerae	.95	3.6 - 6.0	9.6	6-8	46	108	facultative anaerobe***
Vibrio parahaemolyticus	.94	4.8 - 5.0	9.6	8 - 10	41	109	facultative anaerobe***
Vibrio vulnificus	.95	6.3	9.0	6	41	111	facultative anaerobe***
Yersinia enterocolitica	.95 - ,966	4.1 - 4.4	9.0	6-7	30 - 34	111	facultative anaerobe***

* *requires limited levels of oxygen* ** *requires the absence of oxygen* *** *grows either with or without oxygen*

Notes:

Notes:

Campylobacter jejuni

C. jejuni is widely distributed in the intestinal tract of poultry, livestock, and warm-blooded domestic animals. It is a very common and important cause of diarrhea1 illness in humans. Symptoms include profuse diarrhea (sometimes bloody), abdominal pain (intensity and duration can be somewhat severe), headache, weakness and fever. Many infections occur without symptoms. C. jejuni is transmitted through: contaminated foods, including raw clams, mussels and oysters; person-to-person contact; and contaminated water. Cross-contamination of foods by dirty food-contact surfaces, including cutting boards and hands, may be the most frequent route of transmission.

Hazards from *C.* jejuni can be controlled by thoroughly cooking seafood and by stressing the importance of proper (and frequent) hand and equipment washing and sanitary food-handling practices. Since the infective dose of C. jejuni is thought to be small, time/temperature abuse of food products could result in this illness.

Clostridium botulinum

C. *botulinum* is found throughout the environment and has been isolated from soil, water, vegetables, meats, dairy products, ocean sediments, the intestinal tracts of fish, and the gills and viscera of crabs and other shellfish. C. *botulinum* is a spore-forming bacteria that grows in the absence of air. These characteristics allow it to survive normal cooking temperatures and to grow in a vacuum-packaged and modified-atmosphere environment. C. *botulinum* produces a powerful neurotoxin that causes botulism. Growth is necessary for C. *botulinum* to produce toxin. Symptoms include diarrhea, vomiting, abdominal pain, nausea and weakness. These are followed by double, blurred vision and dilated, fixed pupils. In severe cases, paralysis of the muscles responsible for breathing can cause death.

The type of C. *botulinum* Type E that is most common in fish and fishery products is of particular concern because it grows at temperatures as low as 38 F and produces little noticeable evidence of spoilage. C. *botulinum* Type A, is the form of this bacteria that is most common in land-based products. It is a common contaminant on processing equipment. It will grow at temperatures no colder than 50 F and produces a putrid odor in products in which it grows. However, its spores are much more heat-resistant than the Type E form of the bacteria.

Because C. *botulinum* produces heat-resistant spores and requires the absence of oxygen for growth, botulism has been most commonly associated with improperly canned food (usually home canned). Semi-preserved seafood, including smoked, salted and fermented fish, have also been identified as causes of botulinurn.

Hazards from *C. botulinum* can be controlled by inhibiting growth of the bacteria or by destroying it in seafood. Proper thermal processes for canned seafood destroy the bacteria. Heavy salting or drying to reduce the water activity below 0.93 and fermentation or acidification to below pH 4.7 are effective means of preventing C. ***botulinum*** growth. Maintaining proper storage temperatures alone is not considered an adequate control measure for C. ***botulinum*** Type E because of its ability to grow at low temperatures and because of the severity of the illness. Nonetheless, in many products, it is an important second barrier to growth.

Escherichia coli

E. coli are naturally found in the intestinal tracts of all animals, including humans. Most forms of the bacteria are not pathogenic and serve useful functions in the intestine. Pathogenic strains of ***E. coli are*** transferred to seafood through sewage pollution of the coastal environment or by contamination after harvest. ***E. coli*** food infection causes abdominal cramping, water or bloody diarrhea, fever, nausea and vomiting.

Hazards from ***E. coli*** can be prevented by: heating seafood sufficiently to kill the bacteria, holding chilled seafoods below 40 F, preventing post-cooking cross-contamination and prohibiting people who are ill from working in food operations. The infective dose of ***E. coli*** is dependant upon the particular strain, from only a few organisms to millions. For this reason, time/temperature abuse of food products may or may not be necessary to result in illness.

Listeria monocytogenes

L. monocytogenes is widespread in nature and has been isolated from soil, vegetation, marine sediments and water. In the early 1900s, ***L. monocytogenes*** was recognized as a bacterium that caused illness in farm animals. More recently, it has been identified as the cause of listeriosis in humans. Most healthy individuals are either unaffected by ***L. monocytogenes*** or experience only mild flulike symptoms. Victims of severe listeriosis are usually immunocompromised. Those at highest risk include: cancer patients, individuals taking drugs that affect the body's immune system, alcoholics, pregnant women, persons with low stomach acidity and individuals with AIDS. Severe listeriosis can cause meningitis, abortions, septicemia and a number of other maladies, some of which may lead to death.

The greatest threat of listeriosis is from ready-to-eat products that do not require further cooking at home. ***L. monocytogenes*** in raw food that will be cooked before consumption is less of a concern to the food industry since the bacteria are killed during cooking. ***L monocytogenes*** has been isolated from raw fish, cooked crabs, raw and cooked shrimp, raw lobster, surimi and smoked fish. One of its most significant characteristics is its ability to grow at temperatures as low as 36 F.

Continued

Notes:

Notes:

Hazards from ***L. monocytogenes can*** be prevented by thoroughly cooking seafood and by preventing cross-contamination once the seafood is cooked. Since the infective dose of ***L. monocytogenes*** is thought to be small, time/temperature abuse of food products may not be necessary to result in illness.

Salmonella *spp.*

Salmonella are naturally found in the intestinal tracts of mammals, birds, amphibians and reptiles but not in fishes, crustaceans or mollusks. *Salmonella* is transferred to seafood through sewage pollution of the coastal environment or by contamination after harvest.

Salmonella food infection causes nausea, vomiting, abdominal cramps and fever. Outbreaks of ***Salmonella*** food infection have been associated with raw oysters, salmon, tuna salad, shrimp cocktail, stuffed sole and gefilte fish.

Hazards from ***Salmonella can*** be prevented by: heating seafood sufficiently to kill the bacteria, holding chilled seafood below 40 F, preventing post-cooking cross-contamination and prohibiting people who are ill or are carriers of ***Salmonella*** from working in food operations. The infective dose of ***Salmonella*** is thought to be extremely variable, relatively high for healthy individuals and very low for at-risk individuals, such as the elderly or medically compromised. For this reason, illness could result even without time/temperature abuse, but abuse has been a contributing factor in many outbreaks.

Shigella spp.

Shigella are naturally found in the intestinal tract of humans. ***Shigella*** is transferred to seafood through sewage pollution of the coastal environment or by contamination after harvest. ***Shigella*** produces an illness called Shigellosis, which causes mild diarrhea, fever, abdominal cramps and severe fluid loss.

Hazards from ***Shigella*** can be prevented by preventing human waste contamination of water supplies and by improved personal hygiene for people who are ill or are carriers of ***Shigella*** and work in food operations.

Staphylococcus aureus

Humans and animals are the primary reservoirs for S. ***aureus. S. aureus can be*** found in the nose and throat and on the hair and skin of 50 percent of healthy individuals. However, the bacteria can be found in air, dust, sewage and surfaces of food-processing equipment. S. ***aureus can*** produce a toxin if allowed to grow in food. The toxin is not destroyed by the cooking or canning processes. S. ***aureus*** has the ability to grow in food with very little available water (.86 a,, 18 percent salt), which would prevent the growth of other pathogens.

S. aureus food poisoning causes nausea, vomiting, abdominal cramping, watery or bloody diarrhea and fever.

Hazards from S. aureus can be prevented by: minimizing time/temperature abuse of seafood, especially after cooking, and requiring that food handlers engage in proper hygiene.

Vibrio *cholerae*

*V. **cholerae*** is found in estuaries, bays and brackish waters. It is naturally occurring and is not necessarily related to sewage contamination. *V. cholerae* tends to be more numerous in the environment during warmer months.

There are a number of types of *V. **cholerae,*** and these produce very different symptoms. One type, *Vibrio **cholerae*** 01, initially causes abdominal discomfort and mild diarrhea. As the illness progresses, the symptoms may include: watery diarrhea, abdominal cramps, vomiting and dehydration. Death can occur. Susceptibility to cholerea is enhanced in people who have had gastric surgery, take antacids or have type 0 blood. Outbreaks of this type of cholera have been associated with oysters, crabs and shrimp from the Gulf of Mexico. *V. **cholerae*** 01 has also been recovered from Chesapeake Bay waters, although no illness has been reported from that area.

Another type of *V. **cholerae,*** non-01, causes diarrhea, abdominal cramps and fever. Nausea, vomiting and bloody diarrhea have also been reported. The severity of the symptoms is dependant, in part, upon the specific strain. In its most severe form, *V. **cholerae*** non-01 has resulted in septicemia (blood poisoning) in individuals with medical conditions that weaken their immune systems. The illness has been associated with consumption of raw oysters, but the bacterium has also been found in crabs.

Hazards from *V. **cholerae*** 01 can be prevented by cooking seafood thoroughly and by preventing cross-contamination once the seafood is cooked. Freezing is ineffective in killing the bacteria.

Vibrio parahaemolyticus

V. parahaemolyticus is naturally occurring in estuaries and other coastal areas throughout most of the world. In most areas, *V. **parahaemolyticus*** is more numerous in the environment during the warmer months, and as a result, most outbreaks in the United States occur during the summer.

The most commonly experienced symptoms of *V. parahaemolyticus* illness include: diarrhea, abdominal cramps, nausea, vomiting and headache. Fever and chills are less frequently reported. The illness has been associated with consuming contaminated crabs, oysters, shrimp and lobster.

Notes:

Continued

Notes:

Hazards from *V. parahaemolyticus can be* controlled by thoroughly cooking seafood and preventing cross-contamination after cooking. Because of its high infective dose, control of time/temperature abuse is also an important preventative measure.

Vibrio vulnificus

V. vulnificus is a naturally occurring marine bacterium. *Vibrio vulnificus* requires salt for survival and is commonly isolated at salinities of 7 to 16 ppt. It is primarily found in the Gulf of Mexico, but it has also been isolated from the Atlantic and Pacific oceans. The numbers of the bacterium in the environment are highest during the warmer months of April through October.

The most common symptoms include: skin lesions, septic shock, fever, chills and nausea. Abdominal pain, vomiting and diarrhea are less frequently reported. Death occurs in about 50 percent of the cases. A number of medical conditions make individuals more susceptible to the life-threatening affects of this bacterium, including: liver disease, alcohol abuse, cancer, diabetes, chronic kidney disease, immunosuppressive drug or steroid usage, low stomach acidity and AIDS. *V. vulnificus* sepsis has been associated with the consumption of oysters, clams and blue crabs.

Hazards from *V. vulnificus* can be controlled by thorough cooking of shellfish and by preventing cross-contamination once the seafood is cooked. The risk of *V. vulnificus* infection can also be reduced by rapidly refrigerating oysters from the Gulf Coast during warm-weather months. Individuals in the "high risk" groups should not consume raw molluscan shellfish.

Yersinia enterocoliticu

Y. enterocoliticu is naturally found in soil, water and domesticated and wild animals. Yersiniosis causes diarrhea, vomiting, abdominal pain and fever, often mimicking appendicitis. Outbreaks have been associated with oysters and fish.

Hazards from *Y. enterocolitica can* be prevented by: heating seafood sufficiently to kill the bacteria, holding chilled seafoods below 40 F and preventing post-cooking cross-contamination.

- *Viral Pathogens*

Overhead *3*

Viral Pathogens:

- Hepatitis A Virus
- Norwalk Virus

Hepatitis A Virus

Viruses survive better at low temperatures and are killed at high temperatures. As a result, most outbreaks of hepatitis occur during winter and early spring. Vises can remain alive for long periods of time in seawater and have been shown to survive over one year in marine sediments.

Both raw and steamed clams, oysters and mussels have been implicated in outbreaks of hepatitis A, including shellfish from approved harvest waters. Symptoms of hepatitis A include weakness, fever and abdominal pain. As the illness progresses, the individual usually becomes jaundiced. The severity of the illness ranges from very mild (young children often experience no symptoms) to severe, requiring hospitalization. The fatality rate is low, and deaths primarily occur among the elderly and individuals with underlying diseases.

Hazards from hepatitis A can be prevented by thoroughly cooking seafood and by preventing cross-contamination of cooked seafood. But hepatitis A appears to be more resistant to heat than other viruses. A laboratory study showed that hepatitis A viruses in infected oysters were inactivated after heating at 140 F for 19 minutes. Therefore, mollusks steamed only until the shells open (a common cooking practice) are not exposed to heat long enough to inactivate hepatitis A viruses.

Notes:

Continued

Notes:

Norwalk Virus

Norwalk virus is considered a major cause of nonbacterial intestinal illness (gastroenteritis). From 1976 to 1980, the CDC reported that 42 percent of the outbreaks of nonbacterial gastroenteritis were caused by Norwalk virus.

Illness from Norwalk virus has been associated with eating clams (raw and steamed), oysters and cockles. Norwalk virus causes nausea, vomiting, diarrhea, abdominal cramps and occasionally fever in humans.

Hazards from Norwalk virus can be prevented by thoroughly cooking seafood and by preventing cross-contamination of cooked seafood. Additionally, a recent outbreak has demonstrated that controlling overboard discharge of untreated sewage from shellfish harvesting vessels would reduce the incidence of illness attributable to Norwalk virus.

• *Parasites*

Overhead *4*

Parasites:

- *Anisakis simplex*
- *Pseudoterranova decipiens*
- *Diphyllobothrium latum*

Anisakis simplex

Anisakis simplex, commonly called herring worm, is a parasitic nematode or roundworm. Its final hosts are dolphins, porpoises and sperm whales. The larval (wormlike) stage in fish and squid is usually 18 to 36 millimeters in length, 0.24 to 0.69 millimeters in width and pinkish to whitish in color.

Anisakiasis, the human illness caused by *Anisakis simplex,* is associated with eating raw fish (sushi, sashimi, lomi lomi, ceviche, sunomono, Dutch green herring, marinated fish and cold-smoked fish) or undercooked fish.

Parasites in fish are considered a hazard only in fish that the processor knows or has reason to believe will be served raw or undercooked. In other products, parasites are considered filth but not hazardous. The FDA has established two freezing processes to kill parasites, blast freezing to -35 C (-31 F) or lower for 18 hours and freezing to -20 C (-4 F) or lower for 168 hours (7 days).

Pseudoterranova decipiens

Pseudoterrunova decipiens, commonly called "codworm" or "sealworm." is another parasitic nematode or roundworm. The usual final hosts of *Pseudoterranova are* gray seals, harbor seals, sea lions and walruses. The larval stage in fish are 5 to 58 millimeters in length, 0.3 to 1.2 millimeters in width and yellowish, brownish or reddish in color.

These nematodes are related to *Anisakis simplex* and the disease associated with infections is also termed anisakiasis. These nematodes are also transmitted to humans through raw or undercooked fish. Control of *Pseudoterrunova* is the same as for *Anisakis simplex.*

Diphyllobothrium latum

Diphyllobothrium latum is a cestode, or tapeworm, which parasitizes a variety of fish-eating mammals of the northern latitudes. A similar species is found in the southern latitudes and is associated with seal hosts. Cestodes have a structure that allows them to attach to the intestinal wall of their host and have segmented bodies. Cestode larvae found in fish range from a few millimeters to several centimeters in length and are white or gray in color.

Diphyllobothrium tapeworms primarily infect freshwater fish. But salmon and related fish can also carry the parasite. *Diphyllobothrium* tapeworms are usually found unencysted and coiled in musculature or encysted in viscera. These tapeworm can mature and cause disease in humans. These cestodes are also transmitted to humans through raw or undercooked fish. Control of *Diphyllobothrium* is the same as for *Anisakis simplex.*

CHEMICAL HAZARDS

- *Marine Biotoxins*

Marine biotoxins (natural toxins) represent a significant threat to human health when humans consume fish and fishery products contaminated with them. The marine biotoxins comprise many distinct compounds, all produced by species of naturally occurring marine algae. The algae are at the bottom of the marine food chain. Consequently, the biotoxins produced by some algae are collected and concentrated through levels of the food chain (e.g., mollusks, crustaceans and finfish) and ultimately are consumed by humans.

There are five recognized marine biotoxins in the United States: paralytic, neurotoxin, diarrhetic and amnesic shellfish poisonings and ciguatera fish poisoning. Molluscan shellfish waters are classified by state shellfish control agencies to reduce the risk that these toxins will be carried by shellfish in commercial channels. Processors should obtain molluscan shellfish only from those waters that have been approved for harvest.

Continued

Notes:

Notes:

Overhead *5*

Marine Toxins:

- Amnesic Shellfish Poisoning (ASP)
- Diarrhetic Shellfish Poisoning (DSP)
- Neurotoxic Shellfish Poisoning (NSP)
- Paralytic Shellfish Poisoning (PSP)
- Ciguatera Fish Poisoning (CFP)
- Gempylotoxin
- Scombroid Toxin
- Tetrodotoxin

FDA has established action levels for all of the marine biotoxins except CFP. None of these toxins can be fully destroyed by normal cooking, freezing, salting, acidification or smoking processes. However, there is some evidence that PSP levels, and perhaps levels of other shellfish toxins, can be reduced to safe levels through commercial canning processes.

Amnesic Shellfish Poisoning (ASP)

ASP is caused by contaminated molluscan shellfish, primarily from the U.S. Northeast and Northwest and imports from similar climates. The shellfish become contaminated with domoic acid produced by dense growths of an algae in the genus *Pseudonitzschia*. It should be assumed that all filter-feeding mollusks are capable of accumulating domoic acid. However, the only shellfish implicated in cases of ASP have been mussels. ASP has recently been identified as a problem in the viscera of Dungeness crabs and anchovies along the U.S. West Coast.

In the early stages of ASP, the individual usually experiences intestinal distress. Severe ASP can cause a facial grimace or chewing motion, short-term memory loss and difficulty breathing. Death can occur.

Diarrhetic Shellfish Poisoning (DSP)

DSP is caused by contaminated molluscan shellfish, primarily from the U.S. Northeast and Northwest and imports from similar climates. Filter-feeding mollusks can accumulate toxins even at algae concentrations below that necessary to discolor the water. Mussels, oysters, hard clams and soft-shell clams have been implicated in cases of DSP. Contaminated scallops have caused cases of DSP in Japan, but the likelihood of scallops causing illness in this country is reduced because roe-on scallops are not typically consumed in the United States. A number of algae species in the genus *Dinophysis* and *Prorocentrum* have been associated with DSP These algae are responsible for the production of a number of toxins (okadaic acid and its derivatives).

The symptoms of diarrhetic shellfish poisoning are diarrhea, nausea, vomiting, moderate to severe abdominal pain and cramps, and chills. No known fatalities have occurred, and total recovery is expected within three days, with or without medical assistance.

Notes:

Neurotoxic Shellfish Poisoning (NSP)

Gymnodinium **breve was** first recognized as causing NSP in the mid 1960s. Blooms of this algae usually result in fish kills and can make shellfish toxic to humans. The blooms generally begin offshore and move inshore. G. ***breve*** produces three known toxins (brevetoxins).

NSP is caused by contaminated shellfish from the Southeast. Oysters and clams are the only shellfish associated with NSP illness. However, all filter-feeding mollusks are capable of accumulating neurotoxic shellfish toxins.

NSP resembles a mild case of ciguatera or PSP Symptoms begin within three hours of consuming contaminated shellfish and include: tingling of the face that spreads to other parts of the body, cold-to-hot sensation reversal, dilation of the pupils and a feeling of inebriation. Less commonly, victims may experience: prolonged diarrhea, nausea, poor coordination and burning pain of the rectum.

Paralytic Shellfish Poisoning (PSP)

There are many species of toxic algae that cause paralytic shellfish poisoning. These include algae in the genus *Alexandrium, Pyrodinium* and *Gymnodinium*. PSP can be caused by a combination of any of 18 toxins (saxitoxins), depending on the species of algae, geographic area and type of shellfish involved.

PSP is caused by contaminated shellfish primarily from the U.S. Northeast and Northwest and imports from similar climates. All filter-feeding mollusks accumulate paralytic shellfish toxins. Mussels become highly toxic within a few hours to a few days of the onset of a red tide but also lose their toxin load rapidly. Clams and oysters generally do not become as toxic as mussels. They require more time to accumulate high levels of toxins and also require longer to cleanse themselves. Scallops can become extremely toxic, even during periods when blooms are not evident. However, scallops generally do not pose a PSP threat because the adductor muscle, the only part of the scallop traditionally consumed in Western society, does not accumulate toxin. PSP has recently been reported in the liver of Atlantic mackerel.

Continued

Notes:

Symptoms of PSP initially involve numbness and a burning or tingling sensation of the lips and tongue that spreads to the face and fingertips. This leads to general lack of muscle coordination in the arms, legs and neck. A variety of other less commonly reported symptoms also exist. Severe cases of PSP have resulted in respiratory paralysis and death.

Ciguatera Fish Poisoning (CFP)

By eating toxic algae, certain species of tropical and subtropical fish can become toxic to humans. The algae species most often associated with CFP is *Gambierdiscus toxicus*, but others are occasionally involved. Toxic algae populations tend to fluctuate, influenced by the turbidity and nutrient content of the water. There are at least four known toxins that concentrate in the viscera, head or central nervous system of affected fish. Ciguatoxin is the principal toxin.

CFP is carried to humans by contaminated finfish from the extreme southeastern United States, Hawaii and the tropics worldwide (between 35N and 34S latitude). In the south Florida, Bahamian and Caribbean regions, barracuda, amberjack, horseye jack, black jack, other large species of jack, king mackeral, large groupers and snappers are likely to contain ciguatoxin. Many other species of large fish-eating fish may be suspect. In Hawaii and throughout the central Pacific, barracuda, amberjack and snapper are frequently ciguatoxic, and many other species, both large and small, may be suspect. Mackerel and barracuda from mid to northeastern Australian waters are frequently ciguatoxic.

The incidence of poisonous fish is sporadic. Not all fish of the same species and caught in the same area will necessarily be toxic. A study done in Hawaii indicated that if fish in one location are toxic, other fish in the vicinity are 60 percent likely to be toxic. Both plant-eating and fish-eating fish can become toxic. Plant-eating fish become toxic by eating the toxic algae itself. Fish-eating fish become toxic by consuming toxic plant-eating fish. Large fish are more likely to be poisonous than small fish because they consume greater amounts of the toxins.

Ciguatera causes: diarrhea, abdominal pain, nausea, vomiting, abnormal or impaired skin sensations, vertigo, lack of muscle coordination, cold-to-hot sensation reversal, muscular pain and itching. Some of the symptoms may recur for as long as six months. Death occasionally results.

Currently, the principal test method is a mouse bioassay that is not suitable for commercial use. There is no validated method suitable for shipboard or dockside testing of large catches of fish. However, some such tests are being evaluated and may soon be available. In the meantime, for those in the fish industry to avoid ciguatoxic fish, they must rely on local knowledge of safe harvest areas.

Notes:

Gempylotoxin

The gempylids, escolars or pelagic mackerels are a small group of fish-eating oceanic fish. Important species in this group include: *Lepidocybium flavobrunneum* (escolar — California, Peru, Hawaiian Islands, Australia, South Africa, Cuba, Aru Islands, Madeira), *Ruvettus pretiosus* (oilfish, castor oil fish, purgative fish — tropical Atlantic and Indo-Pacific oceans), and *Thyrsites atun* (snek — west coast of South America, Indo-Pacific, South Africa).

Gempylids produce an oil which has a purgative effect. The diarrhea caused by eating the oil contained in the flesh and bones of gempylid fish develops rapidly and is pronounced but generally without pain or cramping. No other untoward effects have been reported. Gemphylid fish, including escolar, should not be imported or marketed in the United States.

Scombroid Toxin (Histamine)

Scombroid poisoning, also known as histamine poisoning, is caused by eating fish of certain species that have undergone spoilage by types of bacteria. These bacteria produce an enzyme that reacts with natural components of the fish flesh to produce histamine. Fish that have been involved in scrombroid poisonings include tuna, mahi mahi, bluefish, sardines, amberjack and mackerel. The toxin is not eliminated by cooking or canning.

Scombroid toxicity is a common illness associated with seafood. From 1973 to 1986, 178 outbreaks, affecting 1,096 individuals, were reported to the Center for Disease Control. No deaths have been reported in the United States. Symptoms of scombroid poisoning begin within four hours of eating contaminated fish. The most common symptoms include: a metallic, sharp or peppery taste; nausea; vomiting; abdominal cramps; diarrhea; swelling and flushing of the face; headache; dizziness; heart palpitations; hives; rapid and weak pulse; thirst; and difficulty in swallowing.

The histamine-forming bacteria usually grow rapidly only at high temperatures. At 90 F (32.2 C), unsafe levels of histamine may appear within six hours; at 70 F (21 C), 24 hours. Because wide variations occur between individual fish even under the same conditions, it is necessary to consistently remove heat rapidly from the freshly harvested fish and maintain a low temperature until the fish are prepared for consumer use. Particularly for large fish, special precautions and equipment are required for the rapid removal of heat. Periodic increases in product temperature during storage can result in more histamine being formed. Histamine may form without the usual odors of decompositon. Sensory analysis is an

Continued

Notes:

effective screening method that reduces the risk of accepting histamine-containing fish. Chemical analysis for histamine is also possible. A detailed knowledge of the temperature history of the product provides the best control measure.

Tetrodotoxin (puffer fish)

Puffer fish, also called fugu or blowfish, contain the potent toxin, tetrodotoxin. It is unclear whether the fish itself produces the toxin, or like ciguatera, it is introduced to the fish by eating toxic algae. There are approximately 80 species of puffer fish that are known to contain tetrodotoxin in the Pacific, Atlantic and Indian oceans. The domestic species of puffer, sometimes called sea squab, is much less poisonous than the Japanese species.

Symptoms of poisoning usually begin within 10 minutes of consuming puffer fish. The victim first experiences numbness and tingling of the mouth. This is followed by weakness, paralysis, decreased blood pressure, and quickened and weakened pulse. Death can occur within 30 minutes. Puffer fish may not be imported into the United Sates except under strick certification requirements and specific authorization from FDA.

Other Chemical Hazards

Overhead 6

Other Chemical and Physical Hazards:

- Aquaculture Drugs
- Chemical Contaminants
- Food Additives
- Metal Fragments

- ***Aquaculture*** *Drugs*

Animal drugs are used in the raising of fish: 1) to treat and prevent disease, 2) to control parasites and 3) to affect reproduction and growth. Residues of unapproved drugs may occur in aquacultured fish because there are few approved drugs for aquaculture, resulting in pressure on growers to use unapproved drugs. Additionally, producers often use general purpose chemicals that are not labeled for drug use or use approved drugs in ways that are not approved. FDA premarket approval is required for animal drugs to ensure that when an animal is treated in accordance with the labeled directions (e.g., dosage, route of administration, type and life stage of animal and withdrawal times), the flesh will not contain unsafe levels of drug residues. The withdrawal period is the time from the last drug treatment until the animal may be sold for processing.

The hazard of unsafe levels of animal drugs in aquacultured fish can be controlled by processors performing on-site audits of the animal drug controls used by their growers. Where this is not possible, processors can also take advantage of rapid screening methods that are designed to detect the presence of a wide variety of approved and unapproved drugs.

- *Chemical Contaminants*

Fish are 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. Of greatest concern are fish harvested from fresh water, estuaries and near-shore waters rather than from the open ocean. Pesticides and herbicides used near aquaculture operations are also of concern. Federal tolerances or action levels are established for some of the most toxic and persistent contaminants. States often use limits for deciding whether to close waters for harvesting. Processors should be aware of these closures and should not purchase fish that have been harvested in closed areas.

- *Food Additives*

Food and color additives are used in many fish and fishery products, including some usage by fishermen and aquaculturists. Many additives are acceptable in such products when used in conformity with GMPs and established limits. Other additives are not permitted in fish or fishery products. Before using a food additive, the processor should become familiar with the applicable legal limitations for its use. The processor should be especially aware of food additives that are known to cause allergic-type reactions or are otherwise linked to adverse health consequences if not properly used. These reactions can be severe (e.g., anaphylactic shock induced by sulfites or yellow 5 and 6 can be fatal). The use of color additives that are permitted should be carefully controlled to ensure that they remain within established limits. Correct listing of food and color additives on the product label is necessary.

PHYSICAL HAZARDS

- *Metal Fragments*

Metal-to-metal contact, especially in mechanical cutting and blending operations and with equipment that has parts that can break or fall off, such as wire-mesh belts, can introduce metal fragments into products. Such fragments serve as a hazard to the consumer. This hazard can be controlled by subjecting the product to metal detection devices or by regular inspection of at-risk equipment for signs of damage.

Notes:

Appendix IV: More Information on HACCP

Explanatory Note:

Although not required by the seafood HACCP regulation, it is advisable to maintain HACCP plan supporting documentation described in this chapter.

Overhead 1

Objective:
In this module, you will learn:
- What sources of information exist to help you identify seafood safety hazards and establish control measures.
- How to use the *Fish and Fishery Products Hazards and Controls Guide* to identify hazards and establish control measures.

Overhead 2

Sources of Information:
- Seafood processors
- Government inspectors
- Trade associations
- Suppliers and buyers
- Sea Grant/Cooperative Extension
- Publications
  - *Fish and Fishery Products Hazards and Control Guide*
  - Compliance policy guides
  - Import alerts
  - National Shellfish Sanitation Program manuals
  - U.S. Department of Agriculture
  - Model Seafood Surveillance Project (National Marine Fisheries Service)
  - Seafood Safety (National Academy of Sciences)
  - Morbidity and Mortality Weekly Report (Centers for Disease Control and Prevention)
  - Recommended International Code of Practice (CODEX)
  - Food Safety Enhancement Program (Agriculture Canada)
  - Quality Management Program (Fisheries and Oceans Canada)

Sources of Information on Seafood Hazards and Control Measures

Appendix III introduced the hazards that are common in fish and fishery products. It also provided some information about how these hazards can be controlled. You will need to perform a hazard analysis to decide whether these or other hazards are reasonably likely to occur in your products. Also, control measures need to be devised that make sense for your operations. To do this, gather information from a variety of sources and choose the information that best applies to your situation. Some of the most useful sources are described in this chapter.

- ***The Seafood Processor***

You and your employees know your operation better than anyone. Experience is an excellent source of information. You may already have knowledge about hazards that can affect your product, and you may have already implemented suitable controls.

- ***Government Inspectors***

Federal, state and local inspectors that visit your plant can be a good source of information. Inspectors may point out potential hazards, but it will usually be your responsibility to implement effective control measures.

- ***Trade Associations***

Trade associations can also provide useful information. Trade journals often provide general information on potential hazards and controls. Articles on specific processes or products also can be useful. Some trade organizations provide services such as consulting, educational programs and publications that can help identify hazards and control measures.

- ***Suppliers and Buyers***

Suppliers of cleaning materials, processing equipment and packaging materials can provide information on potential hazards and control measures. A buyer's specification may point to a hazard in one of your products. For example, a buyer may require a Salmonella-free product. It is important to note, however, that not all buyer's specifications relate to safety.

- ***Sea Grant/Cooperative Extension***

Many universities have Sea Grant or Cooperative Extension programs. These programs provide continuing education and technical assistance to industry. Extension specialists and agents can assist in identifying potential hazards and control measures.

- ***Publications***

Textbooks, government publications and scientific literature provide general and specific HACCP information. These publications usually include a list of references that can be used to get further information.

Scientific journals are available in most libraries, especially university libraries. Summaries of information from scientific journals are also available in FDA, Sea Grant and other publications. Following is a listing of organizations that produce publications that may be helpful.

Continued

Notes:

- *U.S. FDA Fish and Fishery Products Hazards and Controls Guide*

This guide was developed to help seafood processors identify and control hazards in their operations. The guide provides information on seafood hazards and suggested control measures that can be incorporated into seafood HACCP plans. The guide was also developed as a tool that regulators can use to assist them in evaluating seafood processors' HACCP plans.

- *FDA Compliance Policy Guides (CPGs) and Import Alert*

The FDA CPGs provide information on FDA compliance policy. The FDA Import Alerts are notices from FDA headquarters to district offices concerning new or unusual problems affecting import products. The CPGs and import alerts can be obtained by contacting: FDA, Freedom of Information (HFI-35), 5600 Fishers Lane, Rockville, MD 20857. Alternately, you may purchase the Import Alerts Manual and the Compliance Policy Guides Manual from: U.S. Department of Commerce, Technology Administration, National Technical Service (NTIS), Sales Desk, 5285 Port Royal Road, Springfield, VA 22161 (Phone: 703/487-4650). In addition, the import alerts can be obtained on the World Wide Web at HTTP://VM.CFSAN.FDA.GOV/INDEX.HTML (then click on the following: Food & Drug Administration/Inspections and Imports/Access to Import Program/Current Import Alerts).

- *FDA National Shellfish Sanitation Program (NSSP) Manuals*

The NSSP is a cooperative federal/state/industry program established in 1925 to ensure the safety of molluscan shellfish. The program is described in the *National Shellfish Sanitation Program Manual of Operations,* Parts I and II. Part I is entitled "Sanitation of Shellfish Growing Areas," and Part II is entitled "Sanitation of the Harvesting, Processing and Distribution of Shellfish." The manuals are available from FDA regional offices.

- U.S. *Department of Agriculture (USDA) HACCP*

The USDA Food Safety and Inspection Service conducted a 1990 study to determine how to implement the HACCP system in meat and poultry inspection operations. The project resulted in the development of model HACCP plans. Two generic HACCP models deal with refrigerated foods and cooked sausage. They are available from: USDA, Food Safety and Inspection Service, Washington, DC 20250.

- *National Marine Fisheries Service (NMFS) Model Seafood Surveillance Program (MSSP)*

The NMFS developed the MSSP in response to a Congressional mandate to "design a program of certification and surveillance to improve the inspection of fish and seafood consistent with the hazard analysis critical control point system." As a result of this project, NOAA/NMFS developed HACCP models for 14 types of products and for wholesalers/distributors/seafood auctions and fishing vessels. These models include

product safety, plant/food hygiene and economic fraud hazards. They may be obtained from: National Marine Fisheries Service, PO. Box 1207, Pascagoula, MS 39568.

Notes:

- ***National Academy of Sciences (NAS)***

The NAS received its congressional charter in 1863, which established it as a private, nonprofit organization designated as an official advisor to the federal government on science and technology matters. Its members include experts from many disciplines, including scientists, engineers, doctors, lawyers and corporate executives. The NAS Seafood *Safety* publication provides a good source of information about seafood hazards. NAS publications can be obtained from the National Academy Press (phone:800/624-6242).

- ***Centers for Disease Control and Prevention (CDC)***

The CDC is responsible for characterizing risk factors and prevention strategies for diseases that impact on public health. In addition, the CDC assists local health agencies in epidemiologic investigations of foodborne illness outbreaks. Certain diseases are reported to the CDC by state epidemiologists. The *Morbidity and Mortality Weekly Report* contains summaries of this information. It can be obtained by contacting CDC at: *Morbidity and Mortality Weekly Report,* Mailstop C-08, CDC, 1600 Clifton Road N.E., Atlanta, GA 30333 (Phone: 404/332-4555).

- ***Codex Alimentarius (CODEX)***

The Codes Alimentarious Commission is sponsored by the Food and Agriculture Organization and the World Health Organization of the United Nations. Its purpose is to facilitate international trade by establishing uniform food standards. The commission has developed many standards and guidelines, including *Recommended International Code of Practice* **for** *Fresh Fish.* Information may be obtained: U.S. Coordinator for Codex Alimentarious, USDA, Food Safety and Inspection Service, Washington, D.C. 20250.

- ***Agriculture Canada Food Safety Enhancement Program (FEP)***

Agriculture Canada has developed FEP, a HACCP-based program for food manufacturing operations. Guidance manuals for the FEP, including *Guidelines and Principles for the Development of HACCP Generic Models,* are available from Agriculture Canada, Food Protection and Inspection Branch, 59 Camelot Dr., Nepean, Ontario, Canada K18 0Y9.

- ***Fisheries and Oceans Canada Quality Management Program (QMP)***

This HACCP-based program is designed for seafood processing plants. Publications are available from Fisheries and Oceans Canada, Inspection Directorate, 200 Kent St., 7th Floor, Ottawa, Canada K1A OE6 (phone: 613/993-6930).

Continued

Notes:

Computer-Accessible Information Sources

- *FDA's Home Page*

The FDA home page Internet address is: http://www.fda.gov. From there, you can easily locate consumer education materials, industry guidance, bulletins for health professionals and other documents and data from FDA's centers and offices. The World Wide Web enables you to download and print the documents you want.

FDA seafood information is located on the Center for Food Safety and Applied Nutrition (CFSAN) home page. Use the search option found on the FDA home page to find CFSAN.

If you don't have access to Internet, you may access the FDA home page by using a free dial-up modem connection: 800/222-0185. At the login prompt, type bbs. If you experience a problem, call 301/443-4908.

- *FDA's Prime Connection*

The FDA Prime Connection is a free on-line, computer-based technical information source for retail food protection, milk safety and seafood safety. It is a regulatory program information system that provides electronic access to technical materials issued by the FDA Center for Food Safety and Applied Nutrition's Division of Cooperative Programs. Information on the Prime Connection can be obtained from: FDA Prime Connection, Center for Food Safety and Applied Nutrition, FDA, 200 C St. SW. (FM-625), Washington, DC 20204.

- *AquaNIC*

AquaNIC (Aquaculture Network Information Center) is a gateway to electronic resouces on aquaculture. AquaNIC is maintained at Perdue University, West Lafayette, Indiana. Access to AquaNIC is free. Information on AquaNIC can be viewed on your computer monitor, downloaded via modem or sent to your e-mail address. AquaNIC also contains an image directory that holds hundreds of pictures, short videos and slides in a variety of common image formats. AquaNIC is linked to other aquaculture databases on the Internet. Information on accessing AquaNIC can be obtained from Perdue University, 317/494-4862/6264.

- *Seafood **Listserve***

An Internet mailbox has been established to facilitate seafood technology information exchange. The National Seafood HACCP Alliance sends network subscribers new information on seafood HACCP implementation, upcoming seafood technology meetings and other seafood technology information. Subscriptions are free and available to anyone with access to e-mail. Information on the listserve can be obtained from: Robert J. Price, Extension Specialist, Seafood Products, Food Science and Technology, University of California, Davis, CA 95616 (916/752-2194).

- ***SeafoodNIC***

SeafoodNIC (Seafood Network Information Center) is a database containing information on the National Seafood HACCP Alliance, seafood guidelines and regulations, seafood organizations, seafood publications and upcoming seafood meetings. SeafoodNIC is linked to other seafood-related databases on the Internet. SeafoodNIC is maintained on a gopher server at the University of California, Davis. Information on Seafood NIC can be viewed on your computer monitor, downloaded or sent to your e-mail address. Information on SeafoodNIC can be obtained from: Robert J. Price, Extension Specialist, Seafood Products, Food Science and Technology, University of California, Davis, CA 95616 (916/752-2194).

- ***Selected Additional References***

FDA/DHHS. 1994. "Proposal to Establish Procedures for the Safe Processing and Importing of Fish and Fishery Products," Government Printing Office, Washington, DC 20402 (202/512-2357), January 28, 1994 Federal Register, pages 4 142-42 14.

Food Safety Committee, National Food Processors Association (NFPA). 1989. "Guidelines for the Development of Refrigerated Foods," NFPA Bulletin 42-L, 1989. Hackney, C. and D. Ward, eds., Microbiology of Marine Food Products, Van Nostrand Reinhold.

Huss, H.H. 1994. Assurance of Seafood Quality, Food and Agriculture Organization of the United Nations, FAO Fisheries Technical Paper 334, ISBN 92-5-103446-X.

Lee, J.S. and K.S. Hilderbrand Jr., 1992. "Hazard Analysis and Critical Control Point Applications to the Seafood Industry," ORESU-H-92-001, Oregon Sea Grant, Oregon State University, Corvallis, OR.

NACMCF. 1992. National Advisory Committee on Microbiological Criteria for Foods, Hazard Analysis and Critical Control Point System Adopted March 20, 1992, (NAS), "HACCP: Principles and Applications," Van Nostrand Reinhold.

Subcomittee on Microbiological Criteria, Committee on Food Protection, Food and Nutrition Board, National Research Council, NAS. 1985. "An Evaluation of the Role of Microbiological Criteria for Foods and Food Ingredients," National Academy Press.

Continued

Notes:

Notes:

How to Use the Fish and Fishery Products Hazards and Controls Guide

The guide is designed so that a processor or regulator can look up the fish species and finished-product form of interest and identify potential food-safety hazards. It is structured around the same hazard-analysis worksheet and HACCP plan form that has been used throughout this course. In this way, the user is lead through a series of decisions such as: whether a potential hazard is a significant hazard; what is the proper CCP; what critical-limits monitoring programs, corrective-action procedures and verification procedures are appropriate; and what records are necessary.

The recommendations included in the guide are not, for the most part, binding FDA requirements. Use of the guide in developing HACCP plans is not mandatory. The guide provides useful guidance, but seafood processors and importers are free to choose other control measures that provide an equivalent level of safety assurance to those listed in the guide. There may also be circumstances where a hazard identified in the guide may not apply to a product or species because of conditions specific to the processor.

Food -safety hazards can be introduced to a product because of the nature of the product (e.g., the species) or because of the way it is processed. The guide refers to the first type as species-related hazards. It refers to the second type as process-related hazards. The guide is set up in a way that lets you look up the species of interest (among the more than 350 listed) in a table. The table lists the potential species-related hazards that FDA has reason to believe exist for each species. You can also find the finished product of interest in another table. This table lists the potential process-related hazards that FDA has reason to believe exist for each finished product form. Processors must control both types of hazards.

The guide then provides information to help processors and regulators decide if these potential hazards are reasonably likely to occur in any given circumstance. It further provides information about how the hazard might be controlled. These control options are not intended to be all inclusive. Rather they represent the mechanisms that FDA is aware of that should prove effective in eliminating or minimizing the risk of a hazard developing in a product. In particular, the guide provides information about critical limits that may be appropriate in certain circumstances. In some cases, the suggested critical limits are derived from existing tolerances or action levels. In other cases, they are derived from a review by FDA of the scientific and technical literature, conducted for the specific purpose of assisting in the development and review of HACCP plans.

You have been provided a copy of the latest edition of the guide along with your other training materials. You should use it as a reference tool during the practical exercise on the last day of the course.

Appendix V: **Models**

Examples For Illustrative Purposes Only
(Models may not be fully consistent with guidance contained in FDA's Fish and Fishery Products Hazards and Control Guide.)

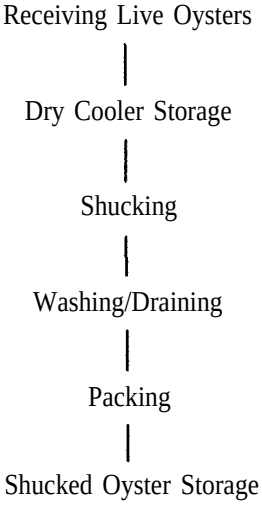
Raw Oysters: Description of the Process

Example: For Illustrative Purposes Only
(Models may not ***be*** *fully consistent with guidance contained in FDA's Fish and Fishery Products Hazards* and Control Guide.)

Live Chesapeake Bay oysters are received from harvesters sacked and tagged. Shellstock are delivered to the processing facility within 24 hours of harvesting.

Upon delivery to the processing facility, the shellstock is refrigerated at 45 F until shucked. This is dry storage. Oysters may be kept several days before shucking. Shellstock is placed on tables for hand shucking into buckets. Buckets of shucked oyster meat are given to the packing room for washing, draining and placing into containers. Shucked meats are stored at 46 F.

shucked Oyster Process Flow Chart



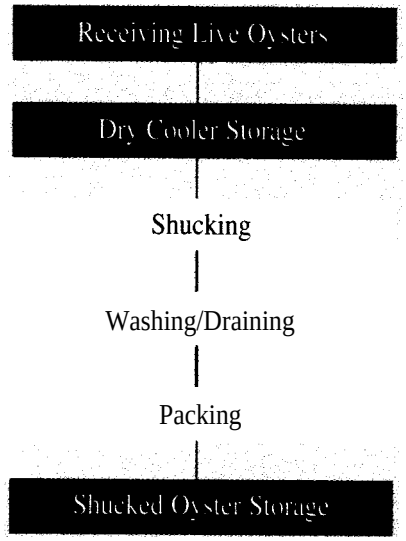
Notes:

Continued

Notes:

Shucked Oyster Process Flow Chart

Shaded step is critical control point



*Example: For Illustrative Purposes Only**
Hazard-Analysis Worksheet

(1) Ingredient/processing step	(2) Identify potential hazards introduced, controlled or enhanced at this step	(3) Are anv potential food-safety hazards significant: (Yes/No)	(4) Justify your decision for column 3.	(5) What preventative measures :an he applied to prevent the significant hazards?	(6) Is this step a critical control point? (Yes/No)
Receiving Live Oysters	BIOLOGICAL Pathogens	Yes	Oysters are assumed to be eaten raw. Oysters are easily contaminated with pathogens from harvesting waters.	• Only accept shellstock from waters open to harvest. • Require proper tagging. • Require proper harvester license.	Yes
	CHEMICAL Chemical contamination	Yes	Industrial pollution frequently occurs in estuarine waters. Oysters may become contaminated with these pollutants.	• Only accept shellstock from waters open to harvest. • Require proper tagging. • Require proper harvester license.	Yes
	Natural toxins	Yes	Natural toxins and organisms that produce them can be filtered and concentrated by oysters.	• Only accept shellstock from waters open to harvest. • Require proper tagging. • Require proper harvester license	Yes
	PHYSICAL None				
Dry Cooler Storage	BIOLOGICAL Bacterial pathogens	Yes	Pathogens may increase in number if oysters are not properly cooled during storage.	Maintain coolers at temperatures below 45 F.	Yes
	CHEMICAL None				
	PHYSICAL None				
Shucking	BIOLOGICAL Bacterial pathogens	Yes	Excessive time in shucking room can promote pathogen growth.	Time of exposure is being controlled at shucked oyster storage.	No
	CHEMICAL None				
	PHYSICAL Bits of shell	No	Hazard analysis indicates that this inherent defect is not "reasonably likely" to result in the food being unsafe for consumption.		No

Firm Name: ABC *Oyster* Co

Product Description: *Shucked oysters in plastic one-gallon containers*

Firm Address: *Anvwhere, USA*

Method of Storage and Distribution: *Shipped on ice and refrigerated; stored at retail under refrigeration.*

Signature: _____

Intended Use and Consumer: *Raw consumption*

Date: _____

**Models may not be fully consistent with guidance contained in FDA'S Fish and Fishery Products Hazards and Control Guide.*

*Example: For Illustrative Purposes Only**
Hazard-Analysis Worksheet

(1) Ingredient/processing step	(2) Identify potential hazards introduced, controlled or enhanced at this step(1)	(3) Are any potential food-safety hazards significant? (Yes/No)	(4) Justify your decisions for column 3.	(5) What preventative measures can be applied to prevent the significant hazards?	(6) this step critical control point? (Yes/No)
Washing/Draining	BIOLOGICAL Bacterial pathogen CHEMICAL None PHYSICAL None	Yes	Excessive time at washing/ draining step can promote pathogen growth.	lime of exposure is being controlled at shucked oyster storage.	*No*
Packing	BIOLOGICAL Bacterial pathogens CHEMICAL None PHYSICAL None	Yes	Excessive time at packing step can promote pathogen growth.	Time of exposure is being controlled at shucked oyster storage.	No
Shucked Oyster Storage	BIOLOGICAL Bacterial pathogens CHEMICAL None PHYSICAL None	Yes	Pathogens may increase in number if oysters are- not properly cooled during storage.	Maintain cooler temperature below 40 F. Limit the exposure time of oysters to ambient temperatures.	Yes

**Models may not be fully consistent with guidance contained in FDA's Fish and Fishery Products Hazards and Control Guide.*

*Example: For Illustrative Purposes Only** – HACCP Plan **Form**

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4) Monitoring	(5) Monitoring	(6) Monitoring	(7) Monitoring	(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
Receiving live oysters	Pathogens	• Must have properly tagged containers. . Must be licensed harvester. • No oysters from closed areas.	• Harvester tag • Harvester license	*Visual check	• Every container • Every delivery	Quality-control person	Reject if untagged. improperly tagged, from closed areas or from unlicensed harvester.	Receiving record	Daily record review
	Chemical contamination	• Must have properly tagged containers. • Must be licensed harvester. • No oysters from closed areas.	• Harvester tag • Harvester license	Visual check	Every container	Quality-control person	Reject if untagged. improperly tagged, from closed areas or from unlicensed harvester.	Receiving record	Daily record review
	Natural toxins	• Must have properly tagged containers. • Must be licensed harvester. • No oysters from closed areas.	• Harvester tag • Harvester license	Visual check	Every container	Quality-control person	Reject if untagged, improperly tagged, from closed areas or from unlicensed harvester..	Receiving record	Daily record review

Firm Name: ABC Oyster Co.

Firm Address: Anywhere, *USA*

Product Description: *Shucked oysters in plastic one-gallon containers*

Method of Storage and Distribution: *Shipped on ice and refrigerated; stored at retail under refrigeration.*

Signature:

Date:

Intended **Use** and **Consumer:** *Raw consumption*

**Models may not be fully consistent with guidance contained in FDA's Fish and Fishery Products Hazards and Control Guide.*

*Example: For Illustrative Purposes Only** – HACCP Plan Form

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measures	(4) Monitoring				(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
Dry cooler storage	Bacterial pathogen growth	Coolers not to exceed 45 F for more than two hours.	Cooler temperature	Visual check of continuous thermometer every 4 hours during operation.	Visual check of continuous thermometer	Quality-control person	• Adjust cooler temperature. • Hold and evaluate product based on total time of exposure to abusive temperatures.	• Cooler temperature record • Recorder chart	• Daily record review • Thermometer calibration weekly
Shucked Oyster Storage	Bacterial pathogen growth	• Cooler temperature must not exceed 40 F for a time greater than two hours. • No more than three hours from removal of product from dry storage cooler to placement in the shucked oyster storage	• Cooler temperature • Time from dry storage cooler to shucked oyster storage	• Visual checks of continuous thermometer • Check progress of marked product	• Visual check of continuous thermometer every 4 hours during operation	Quality-control person	• Ice product and/or return shell-stock to cooler • Adjust cooler temperature • Hold and evaluate based on time and exposure by competent authority	• Cooler temperature record • Recorder chart calibration • Product time of exposure log	• Daily record review • Weekly thermometer calibration • Weekly recorder calibration

Models may not be fully consistent with guidance contained in FDA's Fish and Fishery Products Hazards and Control Guide.

Dried Shrimp: Description of the Process

Example: For Illustrative Purposes Only
(Models may not be fully consistent wiht guidance contained in FDA's Fish and Fishery Products Hazards and Control Guide.)

Shrimp received for drying are head-on, small and fresh. They are delivered on ice by fishermen. The drying process is seasonal.

Head-on shrimp are kept on ice until processed. Shrimp are washed and weighed to remove ice and damaged shrimp. Shrimp are boiled in seasoned (salt) water. The amount of salt used to season the shrimp may vary and is determined by desired flavor of the end product.

After boiling each batch of shrimp, additional salt is added to the cook water to maintain a constant concentration. Cooked shrimp are placed in forced-air drying units until the shrimp are properly dried, usually six to seven hours.

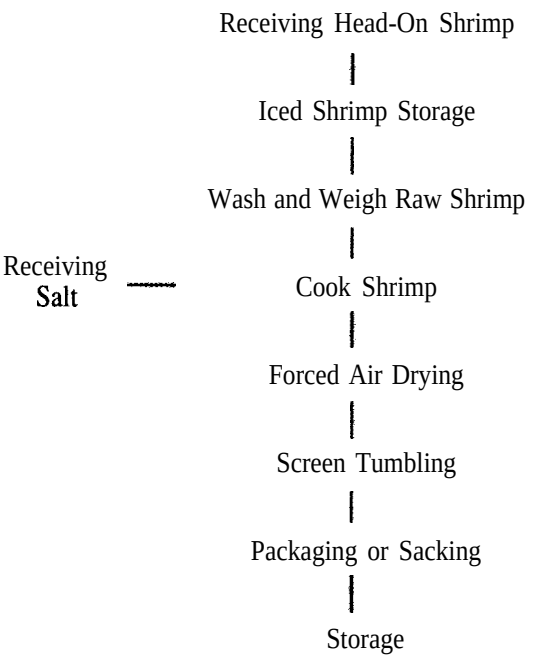
The dried shrimp are rotated in a screen drum to remove shells and heads from the dried meat. Dried shrimp tails are sacked and stored. Sulfite is not declared on the label because sulfited shrimp are not used. The shrimp may be stored under refrigeration, although this is not necessary.

Continued

Notes:

Notes:

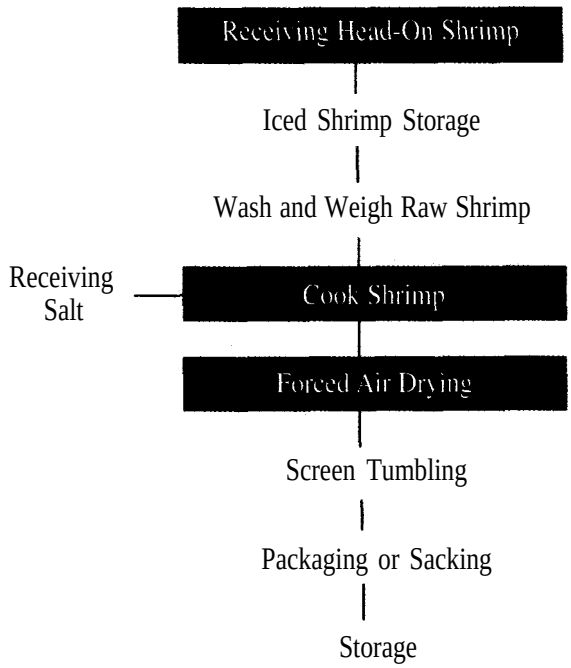
Dried Shrimp Process Flow Chart



Notes:

Dried Shrimp Process Flow Chart

Shaded step is critical control point



Example: For Illustrative Purposes Only*

Hazard-Analysis Worksheet

(1) **Ingredient/processing** step	(2) Identify potential hazard introduced, controlled or enhanced at this step.	(3) Are anv potential food-safety hazards significant? **Yes/No)**	(4) **Justify your decisions** for **column 3.**	(5) What pwentative measures can be applied to prevent the significant hazards?	(6) Is this ste a critical control point? **(Yes/No)**
Receiving Shrimp	BIOLOGICAL Bacterial pathogens CHEMICAL Sulfiting agent PHYSICAL **None**	Yes Yes	Raw seafood can be natural reservoirs for pathogens. Potential for allergic-type reaction.	Cooking will destroy prior to consumption. Reject shrimp containing sulfite residuals.	No Yes
Iced Shrimp Storage	BIOLOGICAL Bacterial pathogens CHEMICAL None PHYSICAL None	Yes	Pathogen growth if temperature abused.	Cooking will destroy prior to consumption.	No
Receiving Salt	BIOLOGICAL None CHEMICAL None PHYSICAL None				
Wash Raw Shrimp	BIOLOGICAL None CHEMICAL None PHYSICAL None				
Cook Shrimp	BIOLOGICAL Pathogen growth CHEMICAL None PHYSICAL None	Yes	Improper cooking will allow survival of pathogens.	Control time/temperature during cooking.	Yes

Firm Name: ABC *Shrimp Drying Co.* Product Description: *Dried shrimp in cloth sacks*

Firm Address: *Anywhere. USA*

Method of Storage and Distribution: *Dry storage, unrefrigerated*

Signature: Intended Use and Consumer: *Ready to eat without further processing*

Date:

Models* may ***not be fully* *consistent with guidance contained in FDA's Fish and Fishery* ***Products Hazards and Control*** *Guide.*

*Example: For Illustrative Purposes Only**

Hazard-Analysis Worksheet

(1) Ingredient/processing step	(2) Identify potential hazard introduced, controlled or enhanced at this step.	(3) Are any potential food-safety hazards significant? Yes/No)	(4) Justify your decisions for column 3.	(5) What preventative measures can he applied to prevent the significant hazards?	(6) Is this step a critical control point? (Yes/No)
Drying	BIOLOGICAL Pathogen growth CHEMICAL None PHYSICAL None	Yes	Improperly dried shrimp will have a wet spot, allowing pathogen growth.	Reduce water activity to acceptable levels.	Yes
Tumbling	BIOLOGICAL • Pathogen recontamination • Pathogen growth CHEMICAL None PHYSICAL None	No No	Controlled by SSOP Low water activity		
Packing	BIOLOGICAL Pathogen recontamination Pathogen growth CHEMICAL None PHYSICAL None	No No	Controlled by SSOP Low water activity		
Storage	BIOLOGICAL Pathogen growth CHEMICAL None PHYSICAL None	No	Low water activity		

*Models may *not be fully* consistent *with guidance contained in FDA'S Fisland* Fishery *Products Hazards and Control Guide.*

*Example: For Illustrative Purposes Only** – HACCP Plan Form

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4) Monitoring What	(5) Monitoring How	(6) Monitoring Frequency	(7) Monitoring Who	(8) Corrective Action(s)	(9) Records	(10) Verification
Receiving bead-on shrimp	Sulfite residuals	No detectable sulfite residuals	Presence of sulfite residuals	Malachite green procedures	Every boat	Dockmaster	Reject if present	Receiving record	• Daily record review . Lab reports with official AOAC tests seasonally
Cook Shrimp	Survival of pathogens	212 F for three minutes	Water temperature and time of cook	Visual check of boiling and time check	Every batch	Cooking operator	Hold and evaluate or recook	Cooking log	• Daily record review
Drying	Pathogen growth	Water activity .85 or less achieved within eight hours	Water activity and drying time	Water activity meter and drying cycle timer	Every batch	Quality-control person	If .85 water activity is not achieved within eight hours. continue drying cycle and hold and evaluate by competent authority	Drying record	• Daily record review • Calibration of water activity meter

Firm Name: ABC *Shrimp Drying Co.*

Product Description: Dried *shrimp in cloth sacks*

Firm Address: *Anywhere, USA*

Method of Storage and Distribution: *Dry storage, unrefrigerated*

Signature:

Intended Use and Consumer: *Ready to eaf without further processing*

Date:

**Models may not be* fully *consistent with guidance contained* in *FDA's Fish and Fishery Products Hazards and Control Guide.*

Pasteurized Blue Crabmeat: Description of Process Flow

Notes:

Example: For Illustrative Purposes Only
(Models may not be fully consistent wiht guidance contained in FDA's Fish and Fishery Products Hazards and Control Guide.)

Blue crabs are caught and transported live to processing facilities by either boat or truck. On arrival, the crabs are inspected for physical damage, chemical contamination and mortality. Those crabs that are not immediately processed are placed in a cooler (55 F to 65 F) for a maximum of 24 hours.

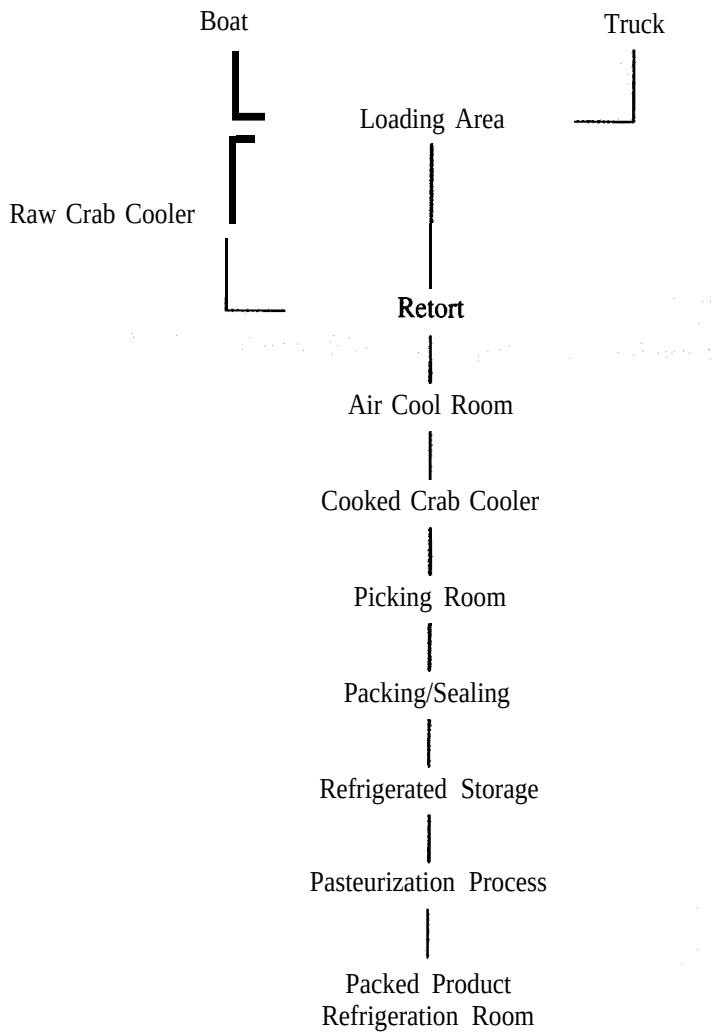
The crabs are cooked in a retort for 10 minutes at 250 F (15 psig). Cooked crabs are placed in an air-cool room for a maximum of two hours or until steam is not visible from the crabs. The crabs are then placed in a refrigerated room at 45 F until processed.

The cooled crabs are picked by hand into metal cans. In the packing rooms, cans are check-weighed and hermetically sealed. The sealed containers are refrigerated. Within 48 hours of picking, meat is pasteurized. During the pasteurization process, the can of picked meat is heated in a water bath followed by cooling in ice slush. Finished product containers are stored under refrigeration.

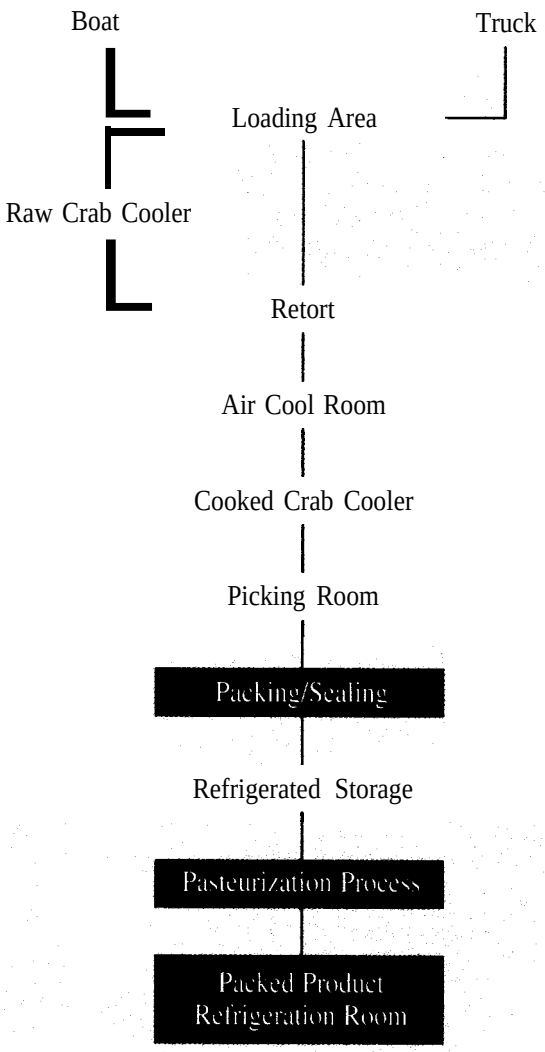
Continued

Notes:

Pasturized Blue Crabmeat Processing Flow Chart



Pasturized Blue Crabmeat Processing Flow Chart
Shaded step is **Critical *Control Point***



Notes:

Continued

*Example: For Illustrative Purposes Only**

Hazard-Analysis Worksheet

(1) Ingredient/prows&g step	(2) Identify potential hazards **introduced, controlled** or enhanced at this step.	(3) Are any potential food-safety hazards significant? **Yes/No)**	(4) Justify your decision for **column 3.**	(5) What preventative measure(s) can be applied to prevent the significant **hazards?**	(6) Is this **step** a critical control **point? (Yes/No)**
Receipt	BIOLOGICAL Bacterial pathogens CHEMICAL Environmental contaminants PHYSICAL None	Yes No	Raw crabs can be a reservoir for pathogens. No history of problems with crabs	Pasteurization elimiates pathogens.	No
Raw Crab Cooler	BIOLOGICAL Bacterial pathogens CHEMICAL None PHYSIC AL None	Yes	Raw crabs contain human pathogens that can grow under refrigerated conditions.	Pasteurization eliminates pathogens.	No
Retort	BIOLOGICAL Pathogens CHEMICAL Boiler chemicals PHYSICAL None	Yes No No	Improper cook will not kill or inactivate human pathogens. SSOP	Pasteurization eliminates pathogens.	No
If this product was sold as fresh crabmeat, then the **retort** *process may be a critical* control **point.**					
Air Cool Room	BIOLOGICAL Pathogens CHEMICAL None PHYSICAL None	No	• Recontamination controlled by SSOP. • Bacterial growth controlled by hot crab temperature and short holding time.		No

Firm Name: ABC *Crab Co.*

Product Description: *Pasteurized crabmeat in hermetically sealed steel cans*

Firm Address: *Anywhere, USA*

Method of Storage and Distribution: *Refrigerated*

Signature:

Intended Use and Consumer: *Ready to eat without further processing*

Date:

***Models** may **not be** filly consistent with **guidance** contained in **FDA's** Fish and **Fishery** Products **Hazards** and Control Guide.*

Example: *For Illustrative Purposes Only**

Hazard-Analysis Worksheet

(1) Ingredient/processing step	(2) Identify potential hazards introduced, controlled or enhanced at this step.	(3) Are any potential food-safety hazards significant? Yes/No)	(4) Justify your decision for column 3.	(5) What preventative measure(s) can be applied to prevent the significant hazards?	(6) Is this step a critical control point? (Yes/No)
Cooked Crab Cooler	BIOLOGICAL Bacterial pathogens CHEMICAL None PHYSICAL None	Yes	Time/temperature abuse could allow pathogen growth.	Pasteurization eliminates the pathogens.	No
Picking Room	BIOLOGICAL • Bacterial pathogen growth • *Staphylococcus aureus* • Bacterial pathogen recontamination CHEMICAL None PHYSICAL Shell	Yes *No* No No	Excessive time in processing room will promote pathogen growth. Although humans are natural reservoirs, using USDA's pathogen modeling program, it was determined that the temperature abuse conditions necessary for growth of *S. aureus* to levels sufficient for toxin production were not reasonably likely to occur. SSOP Hazard analysis indicates that this inherent defect is not "reasonably likely" to result in the food being unsafe for consumption.	Pasteurization will eliminate the pathogens.	No
Packing/Sealing	BIOLOGICAL Bacterial pathogen recontamination tbrougb can seams CHEMICAL None PHYSICAL None	Yes	Defective seams may allow entry of *Clostridium botulinum type* E.	Proper can seams	Yes
Refrigerated Storage	BIOLOGICAL Bacterial pathogen growth CHEMICAL None PHYSICAL None	No	Not likely to occur		

***Models may not be fully consistent** with **guidance contained** in **FDA's** Fish and **Fishery Products Hazards** and **Control** Guide.*

*Example: For Illustrative Purposes Only**

Hazard-Analysis Worksheet

(1) Ingredient/processing step	(2) Identify potential hazards introduced, controlled or enhanced at this step.	(3) Are any potential food-safety hazards significant? (Yes/No)	(4) Justify your decision for column 3.	(5) What preventative measure(s) can be applied to prevent the significant hazards?	(6) Is this step a critical control point? (Yes/No)
Pasteurization	BIOLOGICAL Pathogen survival CHEMICAL None PHYSICAL None	Yes No No	Pathogens will survive an improper thermal process.	Apply proper thermal process.	Yes
Packed Product Refrigeration Room	BIOLOGICAL Bacterial pathogens CHEMICAL None PHYSICAL None	Yes	Human pathogens (*Clostridium botulinum*, *Type* A) could grow if product is temperature abused.	Proper refrigeration	Yes

**Models may not be fully consistent with guidance contained in FDA's Fish and Fishery Products Hazards and Control Guide.*

*Example: For Illustrative Purposes Only** -- HACCP Plan Form

(1) 'ritical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measures	(4) Monitoring	(5) Monitoring	(6) Monitoring	(7) Monitoring	(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
Packing/Sealing	Bacterial pathogen recontamination through can seams	Container seams meet manufacturer's specifications	Can seams	• Can-seam tear-down evaluation • Visual seam examination	* Monitor one can at start-up and when an adjust-ment is made to sealing machine. • One can every half hour	Quality-control person	Readjust can seaming machine	Can-seam evaluation from visual checks of seams twice per hour.	Daily record review
Pasteurization	Survival of pathogens	For401 X 301 can, minimum water bath 188F, time 120 minutes in bath. This cook achieves F=31, ref. 185F, z=16	Water-bath temperature and time of pasteurization	Recording thermometer	Each batch	Quality-control person	Recook, reject product or hold for evaluation.	Thermal process record	• Daily record review • Periodic process validation (minimum annually). • Calibration of temperature re-corder to MIG thermometer daily and annual calibration of MIG thermometer
Refrigerated Storage	Bacterial pathogen, growth in packed product	50 F maximum for cooler	Temperature of cooler	Recording thermometer and visual check	Continuous checks every four hours during operation	Quality-control person	• Hold and evaluate based on time and temperature of exposure • Adjust cooler	• Recorder charts • Cooler temperature record	• Daily record review • Calibration of temperature recorder with MIG thermometer weekly

Firm Name: *ABC Crab Co.*

Firm Address: *Anywhere, USA*

Product Description: *Pasteurized crabmeat in hermetically sealed steel cans*

Method of Storage and Distribution: *Refrigerated*

Signature:

Date:

Intended Use and Consumer: *Ready to eat without further processing*

**Models may not be fully consistent with guidance contained in FDA's Fish and Fishery Products Hazards and Control Guide.*

Pickled Fish: Description of Process Flow

Notes:

Example: For Illustrative Purposes Only
(Models may not ***be*** *fully consistent with guidance contained in FDA's Fish and Fishery Products Hazards and Control Guide.)*

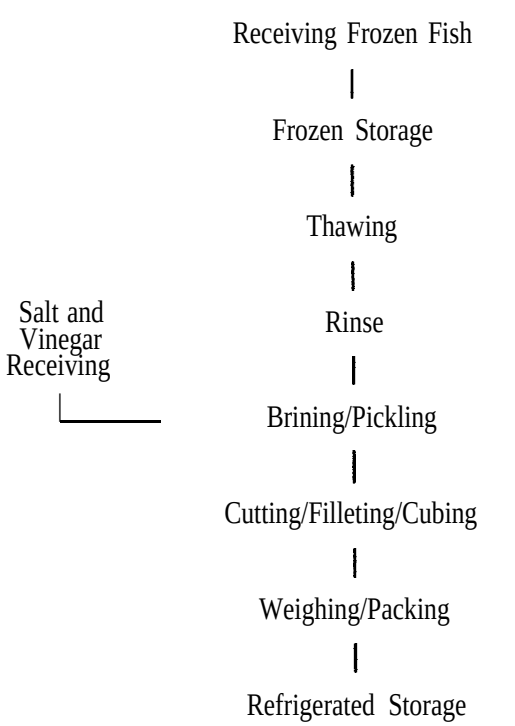
Frozen, headed and gutted river herring *(Alosa.* spp) is received by truck and placed in frozen storage. Fish are thawed under refrigeration.

This fish are rinsed with recirculated water at 40 F or less. After rinsing, the fish are placed in the brining/pickling tank. The brine concentration is maintained at 80 percent salinity with a vinegar concentration of 2.5 percent using 120-grain distilled vinegar. The process time is five days at refrigeration temperatures.

After the brining/pickling process is complete, the fish are sent to the cutting/filleting/cubing area where processes are performed by hand.

The processed product is packaged and stored under refrigeration.

Pickled Fish Processing Flow Chart

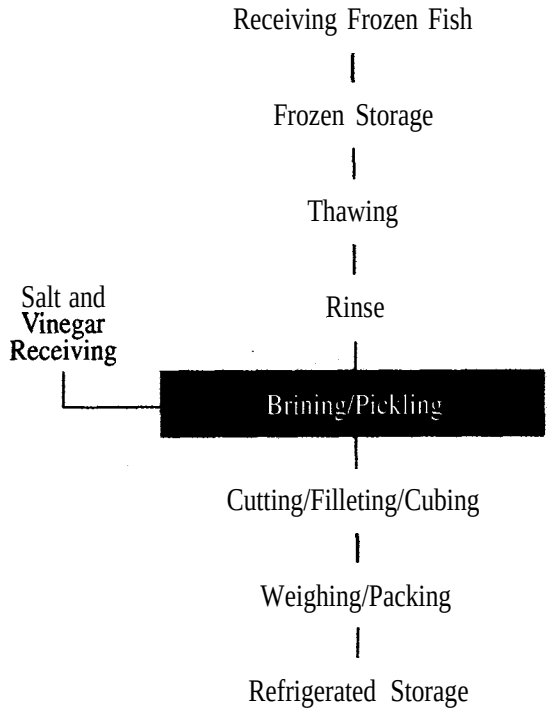


Continued

Notes:

Pickled Fish Processing Flow Chart

Shaded step is Critical Conhvl Point



*Example: For Illustrative Purposes Only**

Hazard-Analysis Worksheet

(1) Ingredient/processing step	(2) Identify potential hazards introduced, controlled or enhanced at this step.	(3) Are any potential food-safety hazards significant? (Yes/No)	(4) Justify your decision for coumn 3.	(5) What preventative measure(s) can be applied to prevent the significant hazards?	(6) Is this step a critical control point? (Yes/No)
Receiving Frozen Fish	BIOLOGICAL • Pathogens • Parasites CHEMICAL Environmental contaminants PHYSICAL None	Yes No No	Raw product is reservoir of pathogens. Parasites do not survive in frozen fish. No historical evidence for harvest areas used.	Risk minimized by salting/pickling.	No
Frozen Storage	BIOLOGICAL Pathogens CHEMICAL None PHYSICAL None	No	Microbial growth is unlikely in frozen storage.		
Thawing	BIOLOGICAL Pathogens CHEMICAL None PHYSICAL None	Yes	Elevated temperatures would permit growth of pathogens.	Risk minimized by salting/pickling.	No
Rinsing	BIOLOGICAL None CHEMICAL None PHYSICAL None				

Firm Name: ABC Fish Co. Product Description: Pickled river herring in glass jars

Fii Address Anywhere, USA

Method of Storage and Distribution: *Refrigeration*

Signature: Intended Use and Consumer: *Ready to ear without further processing*

Date:

**Models* may *not be fully consistent with guidance contained in FDA'S Fish and Fishery Products Hazards and Control Guide.*

*Example: For Illustrative Purposes Only**

Hazard-Analysis Worksheet

(1) Ingredient/processing step	(2) Identify potential hazards introduced, controlled or enhanced at this step.	(3) Are any potential food-safety hazards significant? (Yes/No)	(4) Justify your decision for column 3.	(5) What preventative measure(s) can be applied to prevent the significant hazards?	(6) Is this step a critical control point? (Yes/No)
Salt and Vinegar Receiving	BIOLOGICAL None CHEMICAL None PHYSICAL None				
Brining/Pickling	BIOLOGICAL Pathogens CHEMICAL None PHYSICAL None	Yes	Pathogens will grow if salt and vinegar concentrations are not properly controlled.	Proper brining	Yes
Cutting/Filleting/Cubing	BIOLOGICAL Pathogen contamination CHEMICAL None PHYSICAL None	No	SSOP		
Weighing/Packing	BIOLOGICAL Pathogen contamination CHEMICAL None PHYSICAL None	No	SSOP		
Refrigeration	BIOLOGIAL Pathogens CHEMICAL None PHYSICAL None	No	Pathogens do not grow at salinity and pH range of the product.		

**Models* may *not be fully consistent with guidance contained in FDA's Fish and Fishery Products Hazards and Control Guide.*

*Example: For Illustrative Purposes Only** – HACCP Plan Form

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measures	(4) Monitoring				(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
Brining/ Pickling	Pathogen growth	For five days, maintain a minimum salt concentration of 80 percent and vinegar concentration of 2.5 percent, 120-grain strength	Monitor salt and vinegar concentration	Monitor salt content with salinometer and vinegar content by tritration	Daily	Quality-control person	• Adjust salt and vinegar concentrations • Rework product	• Process log • Ingredient log	• Daily record review • Quarterly check of final product to assure process pH is less than 4.6

Firm Name: *ABC Fish Co.*

Firm Address: *Anywhere, USA*

Product Description: *Pickled river herring in glass jars*

Method of Storage and Distribution: *Refrigeration*

Intended Use and Consumer: *Ready to eat without further processing*

Models may not be fully consistent with guidance contained in FDA's Fish and Fishery Products Hazards and Control Guide.

Vacuum Packed Hot Smoked Salmon, Cooked Ready-to-Eat Product: Description of Process Flow

Example: For Illustrative Purposes Only
(Models may not be fully consistent with guidance contained in FDA's Fish and Fishery Products Hazards and Control Guide.)

Salmon are caught in set nets, which are positioned near the shoreline. The fish are held on ice in the round (whole, uneviscerated) until delivery to the processing plant, usually within a few hours of harvest. At the processing facility, the raw material is placed into totes, iced and placed in a cooler until needed for processing.

The totes are brought from the cooler into the processing area where they are placed onto a tote dumper that lifts the tote and dumps the product into a hopper. As needed, the hopper door is opened, and the fish flow onto a table. An employee aligns the fish toward an automatic header and eviscerator. After heading and eviscerating, the fish are transported via a conveyer belt to a table where employees fillet the fish. Employees at the end of the fillet line check for bones and inadequate evisceration, sort by size and place the fillets into a brine solution. This fish are brined for 24 hours under refrigeration to achieve the desired water-phase salt content.

After brining, the brine tanks are drained. The fillets are rinsed and placed onto racks for surface drying prior to smoking. Drying takes approximately four hours and is performed under refrigeration. After drying, the racks are rolled into the smoking/cooling unit. The fish are hot smoked for approximately six hours.

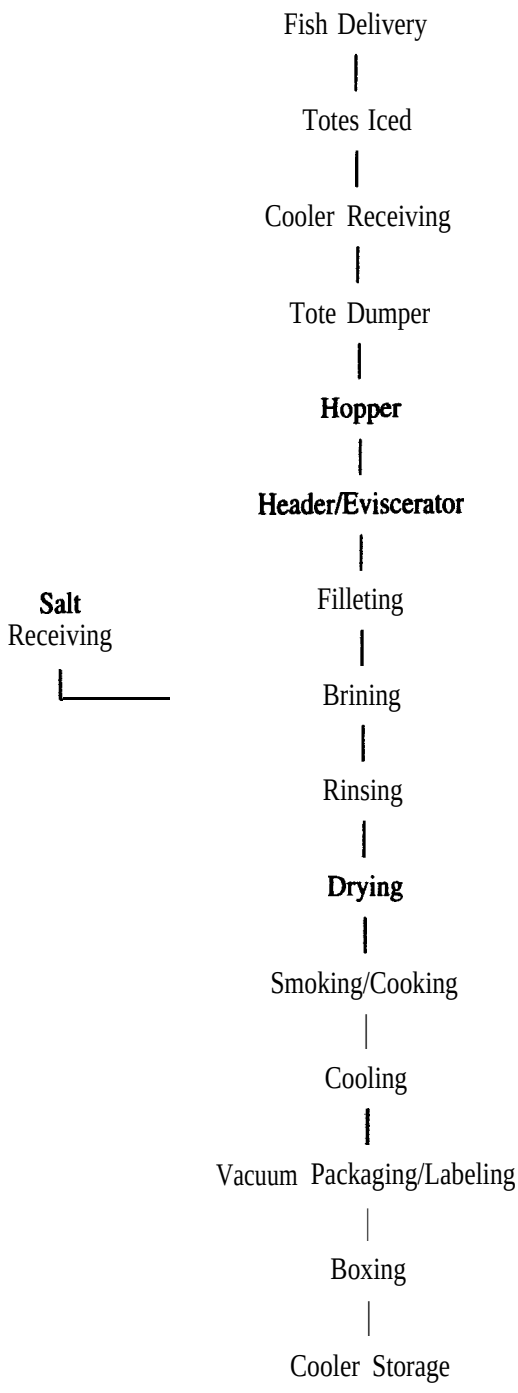
After smoking, the racks are removed from the unit and rolled into the cooler. Employees remove the smoked salmon from the racks and place them into relabeled packages. The packages are vacuum sealed and then placed into 25-pound boxes. The boxes are palletized and stored in a cooler until distributed.

Continued

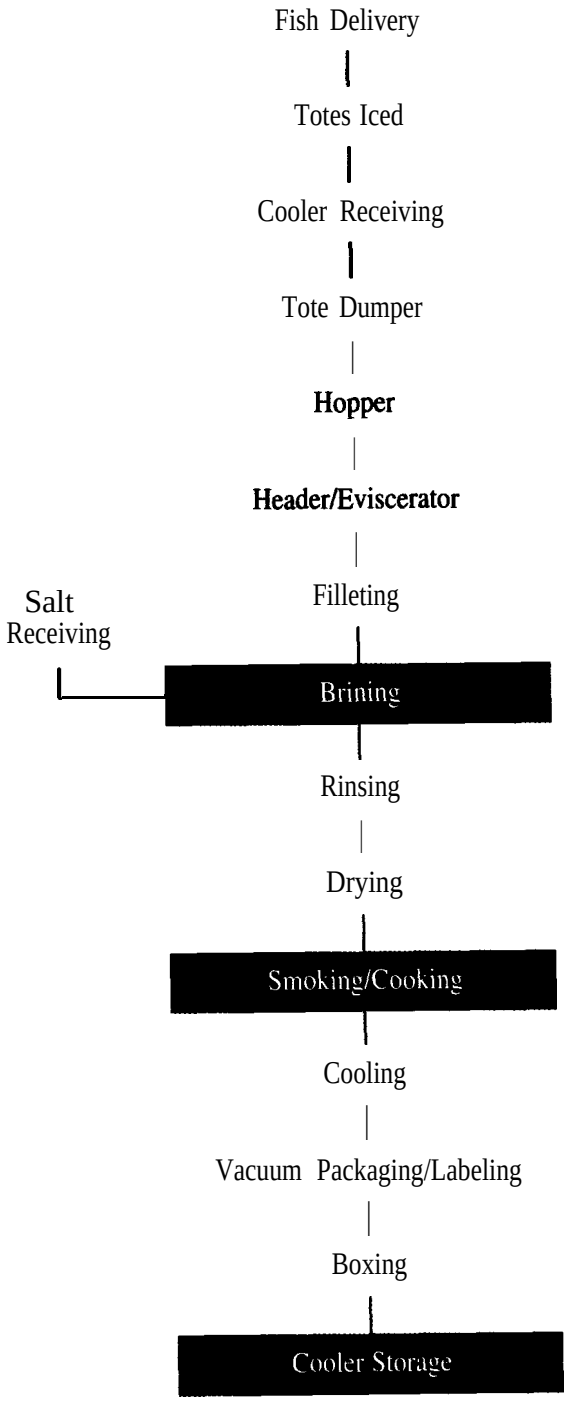
Notes:

Notes:

Vacuum Packaged Hot Smoked Salmon
Processing Flow Chart



Vacuum Packaged Hot Smoked Salmon
Processing Flow Chart
Shaded *step is Critical* ***Control*** *Point*



Notes:

*Example: For Illustrative Purposes Only**

Hazard-Analysis Worksheet

(1) Ingredient/processing step	(2) Identify potential hazards introduced, controlled or enhanced at this step.	(3) Are any potential food-safety hazards significant? (Yes/No)	(4) Justify your decision for column 3.	(5) What preventative measure(s) can be applied to prevent the significant hazards?	(6) Is this step a critical control point? (Yes/No)
Fish Delivery	BIOLOGICAL • Bacterial pathogens	Yes	Raw seafood can be natural sources for pathogens.	Hazard is controlled at the smoking/cooking step.	No
	• Parasites	Yes	Parasites occur in wild-caught fish	Hazard is controlled at the brining and smoking/cooking step.	No
	CHEMICAL None				
	PHYSICAL None				
Totes Iced	BIOLOGICAL Bacterial pathogens	No	Period of time at this location is short.		
	CHEMICAL None				
	PHYSICAL None				
Cooler Receiving	BIOLOGICAL Bacterial pathogens	Yes	Temperature abuse can allow the growth of pathogenic microorganisms.	Hazard is controlled at the brining and smoking/cooking step.	No
	CHEMICAL None				
	PHYSICAL None				
Tote Dumper	BIOLOGICAL Bacterial pathogens	No	Period of time at this location is short.		
	CHEMICAL None				
	PHYSICAL None				

Firm Name: *ABC Smoked Salmon Co.* Product Description: *Smoked salmon*

Fii Address: *Anywhere, USA*

Method of Storage and Distribution: *Refrigeration*

Signature: Intended Use and Consumer: Ready *to* eat *without further* processing

Date:

*Models may not *be fully consistent withguidance contained in FDA's Fish and FisherProducts Hazards and Control Guide.*

Example: For Illustrative Purposes Only*

Hazard-Analysis Worksheet

(1) Ingredient/processing step	(2) Identify potential hazards introduced, controlled or enhanced at this step.	(3) Are any potential food-safety hazards significant? (Yes/No)	(4) Justify your decision for column 3.	(5) What preventative measure(s) can be applied to prevent the significant hazard?	(6) Is this step a critical control point ? (Yes/No)
Hopper	BIOLOGICAL Bacterial pathogens CHEMICAL None PHYSICAL None	No	Period of time at this location is short.		
Header/Eviscerator	BIOLOGICAL Bacterial pathogens including C. *botulinum* CHEMICAL None PHYSICAL Metal Fragments	Yes No	Raw seafood can be a natural source of pathogens. Subsequently brining and rinsing will remove any metal fragments; little opportunity for any metal to become embedded into the flesh of fish.	Hazard is controlled at the brining and cooking step, which is based on a high initial load of *C. botulinum.*	No
Filleting	BIOLOGICAL Bacterial pathogens CHEMICAL None PHYSICAL None	Yes	Pathogens can be introduced from knives and handling.	Hazard is controlled at the smoking/cooking step.	No
Salt Receiving	BIOLOGICAL None CHEMICAL None PHYSICAL None				
Brining	BIOLOGICAL • *C. botulinum* growth and toxin production in finished product • Other bacterial pathogens CHEMICAL None PHYSICAL None	Yes Yes	Salt content in the flesh in combination with the smoke and heat treatment is necessary to control growth. Salt content in the flesh is insufficient to inhibit growth.	Proper brining Hazard is controlled at the smoking/cooking step.	Yes No

*Models may *not be* fully *consistent with guidance contained in FDA's Fish and Fishery Products Hazards and Control Guide.*

*Example: For Illustrative Purposes Only**

Hazard-Analysis Worksheet

(1) Ingredient/processing step	(2) Identify potential hazards introduced, controlled or enhanced at this step.	(3) Are any potential food-safety hazards significant? (Yes/No)	(4) Justify your decision for column 3.	(5) What preventative measure(s) can be applied to prevent the significant hazards?	(6) Is this step a critical control point? (Yes/No)
Rinsing	BIOLOGICAL Bacterial pathogens CHEMICAL None PHYSICAL None	No	Period of time at this location is short.		
Drying	BIOLOGICAL Bacterial pathogens CHEMICAL None PHYSICAL None	Yes No	Salt content in the flesh is insufficient to inhibit growth.	Hazard is controlled at tbe brining and smoking/cooking step.	No
Smoking/cooking	BIOLOGICAL Bacterial pathogen survival CHEMICAL None PHYSICAL None	Yes	Adequate cook is necessary to inactivate the bacterial pathogens in the raw materials and introduced during processing.	Proper smoking, cooking and brining	Yes
Cooling	BIOLOGICAL Pathogen recontamination CHEMICAL None PHYSICAL None	No	Controlled by SSOPs		
Vacuum Packaging/Labeling	BIOLOGICAL Bacterial pathogens introduced during packaging/labeling CHEMICAL None PHYSICAL None	No	Controlled by SSOPs		

*Models may not *be fully consistent with guidance contained in FDA's Fish and Fishery Products Hazards and Control Guide.*

*Example: For Illustrative Purposes Only**

Hazard-Analysis Worksheet

(1) Ingredient/processing step	(2) Identify potential hazards introduced, controlled or enhanced at **this** step.	(3) Are any potential food-safety hazards significant **(Yes/No)**	(4) **Justify your decision for column 3.**	(5) What preventative **measure(s)** can be applied to prevent tbe **significant** hazards?	(6) **Is this step** a critical **control** point? **(Yes/No)**
Boxing	BIOLOGICAL Bacterial pathogens CHEMICAL None PHYSICAL None	No	Period of time at this location is short		
Cooler Storage	BIOLOGICAL *C. botulinum growth* CHEMICAL None PHYSICAL None	Yes	*C. botulinum can* grow if not refrigerated	Proper refrigeration	Yes

***Models may not be fully consistent with guidance contained in FDA's Fish and Fishery Products Hazards and Control** Guide.

*Example: For Illustrative Purposes Only** – HACCP Plan Form

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measures	(4) Monitoring				(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
Smoking/Cooking	Bacterial pathogen survival	Minimum internal temperature of fish of 145 F for 30 minutes	Fish internal temperature and time	Thermocouple probes in the three thickest fish in the coldest part of oven	Continuous with visual check at the end of each batch	Smoker operator	Recook, destroy, or hold product and evaluate	Thermocouple recording chart	• Daily record review • Study identifying cold spot in the smoker • Calibration of the recording device at the beginning and end of each day • Quarterly testing of water phase salt content
Cooler storage	*C.botulinum* Type E toxin production during storage	Maximum cooler temperature of 40 F.	Cooler temperature	Recorder thermometer	Record continuously check chart every 12 hours.	Quality-control person	• Readjust cooler thermostat • Hold and evaluate based on time and temperature of exposure	Cooler temperature chart	• Daily record review • Weekly calibration of recording thermometer

*Models may not be fully consistent with guidance contained in FDA's Fish and Fishery Products Hazards and Control Guide.

Frozen Breaded Fish Sticks: Description of Process Flow

Notes:

Example: For Illustrative Purposes Only
(Models may not be fully consistent with guidance contained in FDA's Fish and Fishery Products Hazards and Control Guide.)

The fish sticks are not fully cooked. They are packed in a PET tray with a heat-sealed plastic film lid. There is no atmosphere modification. Each package is labeled with a "use by" date, cooking instructions and the phrase, "keep frozen." The product is intended for the general public.

Imported frozen minced fish (either pollock or haddock) is received in frozen blocks via freezer truck. The blocks are transferred to frozen storage (-10 F).

Dry ingredients (batter, breading) and packaging materials are delivered to the plant by truck. Dry goods are placed in dry, cold storage.

To be processed, the fish blocks are removed from the freezer, one pallet at a time. Cases are opened and blocks unwrapped. Blocks are cut into preformed fish sticks. As sticks proceed on a conveyor belt, they are culled for uniformity and then battered and breaded, twice each. Recirculated batter is chilled to 45 F.

From the last breading application, the portions pass through a fryer containing soy bean oil for less than one minute at 400 F. This fryer sets the batter/breading but does not cook the fish.

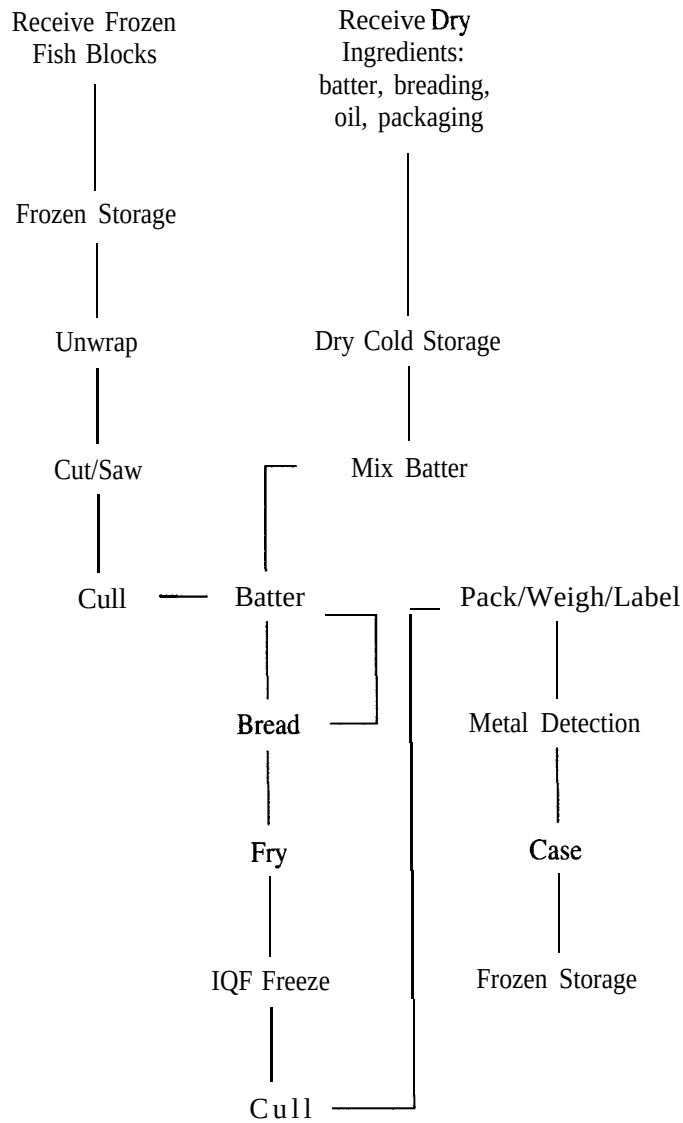
The fish sticks exit the fryer and enter a nitrogen tunnel for individual quick freezing. The nitrogen tunnel freezer is set at -120 F; the exposure time is 6 to 10 minutes.

As the fish sticks exit the freezer, they are culled for breading uniformity, and packaged into either consumer packages (8 oz. or 22 oz.) or large food-service cartons (10 pounds). Then they are labeled and passed through a metal detector. Packages are cased, palletized and stored in the freezer at -10 F. Product is shipped on freezer trucks to retail or food service distribution centers.

Continued

Notes:

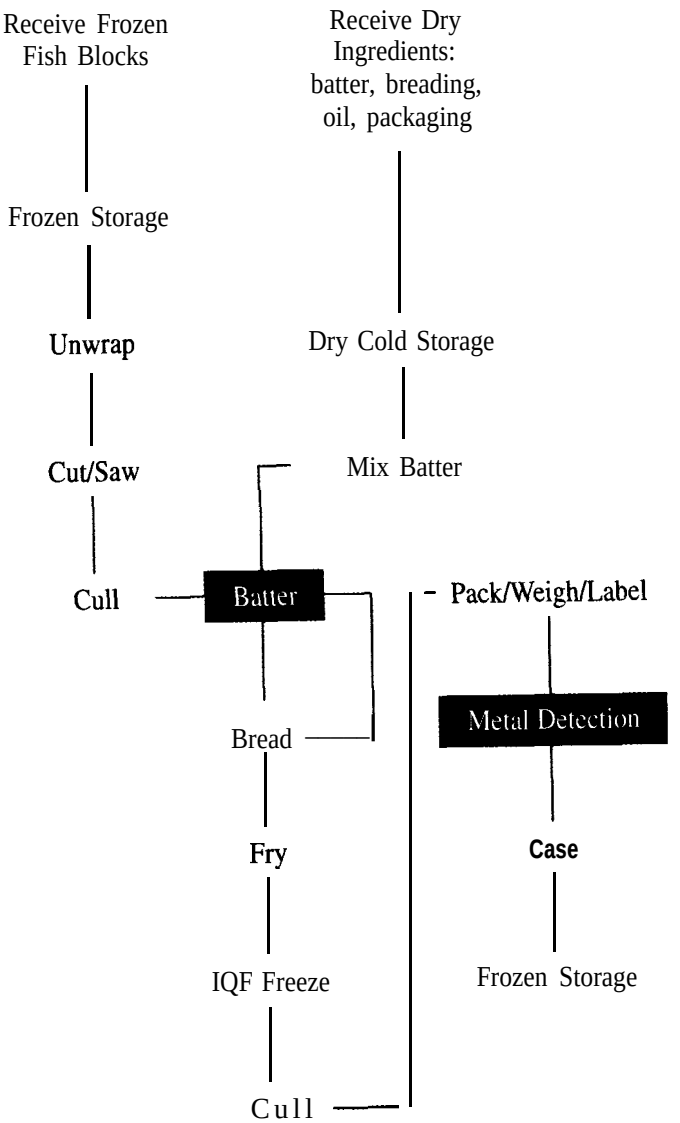
Breaded Fish Sticks Process Flow Chart



Notes:

Breaded Fish Sticks Process Flow Chart

Shaded step is Critical Control Point



Continued

*Example: For Illustrative Purposes Only**

Hazard-Analysis Worksheet

(1) Ingredient/processing step	(2) Identify potential hazards introduced, controlled or enhanced at this step.	(3) Are any potential food-safety hazards significant? (Yes/No)	(4) Justify your decision for column 3.	(5) What preventative measure(s) can be applied to prevent the significant hazards?	(6) Is this step a critical control point? (Yes/No)
Receiving Frozen Fish Blocks	BIOLOGICAL • Pathogens	No	Instructions for proper cooking by consumers on label		
	• Parasites	No	Unlikely to be present		
	CHEMICAL None				
	PHYSICAL Bones	No	Hazard analysis indicates that this inherent defect is not "reasonably likely" to result in the food being unsafe for consumption.		
Frozen Storage	BIOLOGICAL Pathogens	No	Product is frozen so opportunity for pathogen growth or contamination is low.		
	CHEMICAL None				
	PHYSICAL None				
Unwrap	BIOLOGICAL Pathogens	No	• Period of time at this step is short. • Product is frozen.		
	CHEMICAL None				
	PHYSICAL None				

Firm Name: *ABC Breaded Fish Stick Co.* Product Description: Partially *cooked, battered and breaded fish sticks*

Fii Address: *Anywhere, USA*

Method of Storage and Distribution: Frozen

Signature: Intended Use and Consumer: Cook *and* serve

Date:

Models* may ***not be fully consistent with guidance contained in* *FDA's Fish and Fishery* ***Products Hazards and Control Guide.***

*Example: For Illustrative Purposes Only**

Hazard-Analysis Worksheet

(1) Ingredient/processing step	(2) Identify potential hazards introduced, controlled or enhanced at **this** step>	(3) Are any **potential** food-safety hazards significant? **(Yes/No)**	(4) **Justify** your decision for **column** 3.	(5) What preventative measure(s) can be applied to **prevent the** significant **harzards?**	(6) **Is this ste a critical** control point? **(Yes/No)**
Cut/Saw	BIOLOGICAL Pathogens	No	• Period of time at this step is short. • Product is frozen.		
	CHEMICAL None				
	PHYSICAL Metal fragments	Yes	Risk of contaminating the product with broken saw blades	Metal detector at later step	No
Cull	BIOLOGICAL Pathogens	No	• Period of time at this step is short. • Product is frozen.		
	CHEMICAL None				
	PHYSICAL None				
Receive Dry Ingredients	BIOLOGICAL Pathogens	No	Possibility of pathogen contamination is remote as documented by past experience.		
	CHEMICAL None				
	PHYSICAL None				
Dry Cold Storage	BIOLOGICAL None				
	CHEMICAL None				
	PHYSICAL None				
Mix Batter	BIOLOGICAL Pathogens	No	• Risk is low due to short mixing time. • Potable water is used.		
	CHEMICAL None				
	PHYSICAL None				

**Models may not be* furry *consistent with guidance contained* in *FDA'S Fish and Fishery Products Hazards and Control Guide.*

*Example: **For Illustrative** Purposes **Only****

Hazard-Analysis Worksheet

(1) Ingredient/processing step	(2) Identify potential hazards introduced, controlled or enhanced at this step.	(3) Are any potential food-safely hazards significant? (Yes/No)	(4) Justify your decision for column 3.	(5) What preventative measure(s) can be applied to prevent the significant hazards?	(6) Is this step a critical control point? (Yes/No)
Batter	BIOLOGICAL Pathogens	Yes	Pathogen growth (staph toxin) if batter held too long at elevated temperature	Keep temperature low.	Yes
	CHEMICAL None				
	PHYSICAL Metal fragments	Yes	Metal fragments from wire-mesh conveyers	Metal detector at later step	No
Breading Operation	BIOLOGICAL Pathogens	No	Application of dry breading does not promote pathogen growth.		
	CHEMICAL None				
	PHYSICAL Metal fragments	Yes	Metal fragments from wire-mesh conveyor	Metal detector at later step	No
Fryer	BIOLOGICAL None				
	CHEMICAL Rancid cooking oil	No	Potential for toxic compounds from cooking oil is remote.		
	PHYSICAL None				
IQF Freeze	BIOLOGICAL Pathogens	No	Product is frozen within minutes of frying, making pathogen growth remote.		
	CHEMICAL None				
	PHYSICAL None				
Cull	BIOLOGICAL Pathogens	No	• Period of time at this step is short. • Product remains frozen.		
	CHEMICAL None				
	PHYSICAL None				

Models may not be fully consistent* with ***guidance contained in FDA's Fish and Fishery Products Hazards and Control* Guide.

*Example: For Illustrative Purposes Only**

Hazard-Analysis Worksheet

(1) **Ingredient/processing** step	(2) Identify potential hazards **introduced, controlled or enhanced at this step.**	(3) Are any potential **food-safety hazards significant? (Yes/No)**	(4) **Justify your decision for column 3.**	(5) **What preventative measure(s) can be applied to prevent the significant hazards?**	(6) **Is this step a critical *control* point? (Yes/No)**
Pack/Weigh/Label	BIOLOGICAL None CHEMICAL None PHYSICAL None				
Metal Detection	BIOLOGICAL None CHEMICAL None PHYSICAL Metal fragments	Yes	Metal fragments from saw and conveyer belts	Operable metal detector/ reject mechanism	Yes
Case	BIOLOGICAL Pathogens CHEMICAL None PHYSICAL None	No	• Tie at this step is short so pathogens unlikely to grow. • Product remains frozen.		
Frozen Storage	BIOLOGICAL Pathogens CHEMICAL None PHYSICAL None	No	Product is frozen so pathogen growth unlikely.		

**Models may not be fully consistent with guidance contained in FDA's Fish and Fishery Products Hazards and Control Guide.*

*Example: For Illustrative Purposes Only**– HACCP Plan Form

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measures	(4) Monitoring				(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
Batter	Bacterial pathogens	Batter temperature less than or equal to 50 F	Temperature of batter	Check temperature in hold tank	Every hour	Quality-control person	• Cool if temperature reaches 50 F. • If batter temperature is over 50 F for more than four hours, dump batter and reclean hold tank.	Quality-control log	• Check records daily. • Calibrate thermometer weekly.
Metal Detection	Metal	Max. 2 mm ferrous, 2.5 mm nonferrous	Ferrous and nonferrous	Metal detector	Continuous	Labeling operator checks hourly to ensure detector is on.	If detector is not on or fails sensitivity check, all product since last acceptable check is held and rechecked for metal.	• Operator's log	• Run test material with metal of appropriate size to check sensitivity daily. • Supervisor reviews operator logs daily.

Firm **Name:** *ABC Breaded Fish Stick Co.*

Product Description: *Partially cooked, battered and breaded fish sticks*

Firm Address: *Anywhere, USA*

Method of Storage and Distribution: *Frozen*

Signature:

Intended Use and Consumer: *Cook and Serve*

Date:

Models may not be fully consistent with guidance contained in FDA's Fish and Fishery Products Hazards and Control Guide.