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Sanitation Agreements:
Their Effectiveness in
Protecting Public Health**

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Number 23
Spring 1986

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\$1.00

Voluntary Interstate Shellfish Sanitation Agreements: Their Effectiveness in Protecting Public Health A Perspective From New York State

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ABSTRACT

Shellfish contaminated with bacteria and/or viruses can cause a variety of human illnesses which range in severity from the unpleasantness of gastroenteritis to more serious diseases such as hepatitis. There is no readily available and reliable technical test for these agents on which to base regulatory protections. Consequently, individuals who eat shellfish are at risk of becoming ill.

The National Shellfish Sanitation Program (NSSP) of the federal government, a voluntary interstate agreement, has not been effective in preventing disease outbreaks. Pressure to find alternative methods of assuring safe shellfish has led to the formation of a new voluntary program, The Interstate Shellfish Sanitation Conference.

Despite the best efforts of government officials, shellfish-related disease outbreaks continue to occur. The large number of cases in recent years may suggest that current regulatory guidelines do not effectively protect the public health and that reform of those guidelines is warranted.

Without a reliable and cost effective technical standard by which shellfish can be judged, other non-technical solutions must be considered. Possible regulatory alternatives include an increased federal role, regional alliances among states, various unilateral actions by individual states, or structural and/or financial alterations of the Interstate Shellfish Sanitation Conference (ISSC).

INTRODUCTION

Since the early 1900s, governments have searched for ways to prevent citizens from contracting illnesses associated with the consumption of raw or partially cooked shellfish. In the United States the roles of federal and state governments have changed over time and reflect changes in the evolving programs used to protect consumers from contaminated shellfish. Despite the best efforts of government officials,

however, outbreaks of shellfish-related disease continue to occur.

On February 25, 1985 as many as 50 people got sick from clams served at a \$250 per plate political dinner in Albany, New York.¹ Following an investigation by the State Department of Health it appears the implicated clams had been harvested from unpolluted Rhode Island waters and were properly stored prior to being served. This example of illness caused by shellfish which appear to have met all existing health standards is indicative of how troublesome effective control of shellfish-related disease can be.

The New York Sea Grant Institute of State University of New York and Cornell University has been concerned with the issue of shellfish-caused human disease and its prevention, and has sponsored research programs in shellfish management and shellfish pathology. In keeping with this interest, the authors set out to analyze the current regulatory environment and explore new policy options.

THE PROBLEM

Shellfish are filter-feeding organisms which circulate seawater and particulate matter through their gills and digestive systems, where needed nutrients and oxygen are removed. Potentially harmful bacteria and viruses in the water are caught on the gills of shellfish and then passed through the digestive system of the animal. They may concentrate in the animal's body tissues in amounts dangerous to humans who consume them. The greatest hazard to humans is when shellfish are eaten raw or steamed and neither bacteria nor viruses are immobilized. It is then that bacterial agents such as *Vibrio cholera* and salmonella are active, potentially causing diseases such as cholera and "food poisoning" or Salmonosis. Viruses associated with shellfish disease are less well understood than bacteria, but are widely considered to be a source for major concern. Viral Hepatitis and Gastroenteritis may have shellfish vectors.

There are no readily available and cost effective tests to determine whether a shellfish is contaminated with these agents. This is primarily due to an absence of scientific data about the actions of bacteria and viruses. The research needs in this area are extensive, and conclusive results cannot be expected for many years.² In the meantime, in the words of one county health official after the outbreak in Albany, "There is no test, no way to tell whether clams are good or not, the only way you can tell is if they make you sick."³

Shellfish are typically exposed to pathogenic bacteria and viruses when living in waters contaminated with human sewage. Because of this, officials have devised a system wherein growing waters are tested for pollutants. Actions to close polluted waters are taken by state officials on an individual basis for each locality, based on site surveys and water quality testing. Fecal coliform bacterial levels are used as indicators of potentially harmful contaminants.

Enforcement of bans on taking shellfish from closed waters is difficult, and poaching is common. Individual diggers see the potential reward of a high market price for shellfish and realize the penalty for illegal harvest is minimal. Fines levied against violators are often small and have, in some cases, come to be thought of as a cost of doing business.

As shellfish disease outbreaks continue to occur, new questions about the safety of shellfish consumption are being asked by federal, state and local officials. Pollution of our waters continues, often with chemical substances whose human health effects are not well understood. In addition, during transportation of shellfish to market, bacteria and viruses may multiply to reach unsafe levels despite their being harvested from waters which had met all standards. As long distance transportation of the product becomes commonplace, a once local problem becomes national, even international in scope.

Traditionally, the federal government has been responsible for regulating matters of interstate and international trade. In the case of shellfish this has not been the case. All regulation of interstate shipments of shellfish in the United States has been through voluntary agreements between states, with the federal government acting in a supervisory role. Memoranda of Understanding between the federal government and foreign countries control importation of shellfish. Because of these negotiated agreements in both interstate and

international shellfish trade, the federal government has been reluctant to act decisively.

Federal and state officials are responsible for assuring that foods reaching the market are safe. In the case of shellfish this is complicated by the fact that these animals go through no purification process, such as the pasteurization of milk, and show no outward signs of contamination. Efforts to regulate the shellfish industry in the interest of protecting public health are the subject of this analysis.

REGULATORY FRAMEWORK

***The Federal Government**

The role of the federal government in shellfish sanitation has been to oversee and supervise individual state programs, and to "impose" standards on some foreign suppliers. To do this the federal government has set up suggested guidelines for growing, harvesting, and shipping of shellfish. Annual appraisals of state shellfish sanitation regulation and enforcement programs are conducted by federal officials to check for state compliance with suggested NSSP guidelines. However, federal involvement does not have the force of law and consequently the quality of programs varies from state to state. Primary responsibility for the specifics of program control remains within state agencies. Although the specific authorities granted to departments are not consistent among states, New York State is illustrative of the delineation of agency responsibility.

***New York State Department of Health**

The Department of Health (DOH) is responsible for protecting the health of state residents through disease control, supervision of the sanitary conditions of public eating and drinking establishments, control and supervision of nuisances affecting or likely to affect the public health, and promotion of education in disease prevention and control.⁴

The Department receives reports from local health officers and county health departments of all cases of food-borne illness. These cases are used as presumptive evidence of a violation of Public Health Law.⁵ DOH can take action to prevent the sale of shellfish in restaurants, where the overwhelming majority of shellfish are consumed. Additionally, DOH takes the lead in identifying and tracking shellfish-related disease outbreaks through the work of its Food-borne Disease Surveillance Program.⁶

***New York State Department of Environmental Conservation**

Under the Fish and Wildlife Law of New York the Department of Environmental Conservation (DEC) is given authority to manage and regulate shellfish resources of the state.⁷ The department has regulatory and enforcement powers over all aspects of shellfish harvesting, processing, and shipping. Specific activities of the department include: permitting of shellfish harvesters, shippers and re-shippers, setting of water quality standards for harvestable waters, and enforcement of closed waters provisions.⁸

The department has rules and regulations which cover tagging of shellfish to enable DEC officials to trace the product through the marketplace.⁹ At harvest, shellfish are placed in bags marked with information directly linking the product to its point of origin. Record keeping requirement assure that these tags are kept on file by shippers or retailers so that shellfish can be traced should they be implicated in a disease outbreak.

It is by way of resource management, enforcement of water quality standards, and product identification procedures that DEC exerts its authority to assure sanitary control over shellfish grown and sold within New York State.

***The New York State Department of Agriculture and Markets**

The Department of Agriculture and Markets has the responsibility of assuring that food products sold in New York are both pure and wholesome.¹⁰ Specific activities of the department include inspection of all markets and retail food establishments to assure proper handling and storage of shellfish.

In addition, the Agriculture and Markets law specifically prohibits sale of any food products which are adulterated or misbranded. Under this law a "misbranded" product is one that is incorrectly or misleadingly labeled. An "adulterated" food is one that contains a substance harmful to human health.¹¹ If it is determined that shellfish at a retail establishment are in any way adulterated, the department may seize, quarantine, or destroy those found to be impure or unwholesome.¹² By monitoring shellfish at the retail level, inspecting shipments, and embargoing contaminated products, the Department of Agriculture and Markets does its part to protect New Yorkers from contaminated shellfish.

***The Shellfish Industry**

In New York, hard clams, oysters, scallops, and mussels are the primary shellfish harvested from inshore waters. The majority of the landings are of hard clams harvested from the Great South Bay of Long Island. Clams are most often dug by individuals called baymen, who work independently. Harvesting is restricted to hand methods and requires a minimal investment in equipment.¹³ Because of this, individuals can enter and exit the industry quite easily.

Baymen sell their day's harvest to shippers at the dock for cash. The shippers may then sell to re-shippers or to wholesalers.¹⁴ Shippers often buy from many different baymen and co-mingle the shellfish to obtain the count and size combinations desired by customers. If co-mingling occurs, the shipper must keep a record of tags on the opened bags as required by DEC. The shippers sell their purchases to restaurants or retail establishments, where they finally reach the consumer.

Baymen are involved in shellfish sanitation by harvesting from approved areas only, according to the conditions of their permit from DEC. It is common for poaching to occur, however, as much of the enforcement is left to an honor system and the economic incentive to harvest from illegal areas is great.¹⁵ Additionally, baymen often discount assertions that there is a relationship between public health risks and shellfish.¹⁶

Some Long Island baymen have attempted to address the problem of inferior shellfish by launching a program of their own. The New York Green Seal Program is an attempt to assure consumers of a safe product by establishing accountability on the part of the harvester. To date, no disease outbreak has been associated with Green Seal clams.

INTERSTATE REGULATION

***History: The National Shellfish Sanitation Program**

The first attempt at a comprehensive solution to the problems of shellfish sanitation occurred 60 years ago. In 1925, the United States Public Health Service (PHS) sponsored a conference on shellfish and human health to deal with the widespread outbreaks of shellfish-related illnesses that were taking place. In particular, the preceding year had seen an alarming outbreak of typhoid that resulted in at least 150 known deaths.¹⁷ As a direct result of this conference, the National Shellfish

Sanitation Program was born. A hybrid federal-state cooperative program, the NSSP was designed as a voluntary agreement between the Public Health Service and state agencies which assigned the federal and state governments specific responsibilities in assuring proper sanitation of shellfish. The newly formed NSSP included industry involvement as well.

Individual states were to adopt laws and regulations governing the sanitary control of the shellfish industry. States were then responsible for sanitary and bacteriological surveys of growing waters and shoreline, inspection of shippers, and issuing permits to shippers and diggers.

The federal component of the program involved annual appraisals by the PHS of the states' shellfish sanitation programs. This generally included inspecting a percentage of the growing waters and processing plants to see that they were properly certified, as well as reviewing enforcement efforts of the states to control poaching from closed beds. Industry played a hand by obtaining the proper permits and abiding by the established standards.

As the program evolved, the PHS further refined its role by developing the NSSP Manual of Operation. This manual was issued in three parts: part one deals with standards for the sanitation of shellfish growing areas; part two establishes guidelines for sanitation of harvesting and processing of shellfish; and part three consists of standards by which the PHS evaluates the state shellfish sanitation programs. These three manuals provided a foundation upon which the national program was based. The NSSP thus represents the first attempt by the federal government to standardize widely varying state programs on a voluntary basis. Shortcomings or inconsistencies in state programs are brought to light during annual evaluations in accordance with part three of the Manual of Operations.

The 1925 conference was followed by periodic national workshops, in which the program was refined and updated. A change in the federal component of the NSSP occurred in 1968 when the Public Health Service was reorganized under the Department of Health, Education and Welfare (now Health and Human Services) and the Food and Drug Administration (FDA) was given responsibility for the NSSP.¹⁸ In the opinion of some state officials, the cooperative philosophy that had existed between the states and the PHS became more enforcement-oriented under the FDA.¹⁹

One federal responsibility under NSSP was the periodic publication, for the purposes of interstate commerce, of a list of certified shippers. The Interstate Certified Shellfish Shippers List (ICSSL) was designed to provide assurances to receiving states that shellfish products consumed within their borders were harvested, processed and shipped in accordance with accepted procedures.

In the absence of major recurring disease outbreaks, the NSSP was judged to be fairly effective in promoting standards for the industry. However, the voluntary and decentralized structure of the NSSP made it ineffective in responding to those disease outbreaks that periodically occurred and unable to effectively coordinate response measures among the different states. This is the central shortcoming of the program that has been in effect for the last 60 years: outbreaks of shellfish-related diseases have to be dealt with by individual states, regardless of the source of the causative agent or the shellfish vectors. There is no formal mechanism by which one state may deal with unfit shellfish originating from another state or country. Under NSSP there is little New York can do to correct such a situation, providing that the shipper selling the product is on the certified list. In addition, no formal procedures for a receiving state to penalize either the shipper or the originating state exists.

A major turning point for the NSSP took place in 1973 with the publication by the General Accounting Office (GAO) of a highly critical report.²⁰ This report reviewed the activities of four shellfish-producing states, including New York, and determined that they were not fulfilling their obligations under the terms of the NSSP. In particular, water quality measurements and shellfish plant inspections by states were found to be inadequate. The 1973 GAO report was also highly critical of the FDA's role in monitoring the state's programs, noting that the FDA was putting its stamp of approval on state programs based on very limited inspection and oversight.

In an attempt to address these flaws in the National Shellfish Sanitation Program, the Food and Drug Administration proposed regulations in 1975 that would have established a National Shellfish Safety Program. This proposed program reflected the FDA's concern with assuring shellfish sanitation in the stream of interstate commerce. The proposal would have formalized the FDA's role and established federal regulations to govern the program.²¹

By assuming such formal regulatory authority, the FDA could require states to have comprehensive and standardized shellfish sanitation programs. Interstate shipment would have been better controlled by giving the FDA the authority to embargo shipments. Uniformity of standards could have been imposed nationwide. Foreign countries would have been required to sign Memoranda of Understanding with the FDA stating their agreement to and compliance with federal standards before being allowed to ship shellfish into the United States.

This proposed National Shellfish Safety Program was a major shift in emphasis for the FDA. It was a recognition that the previous mechanisms for protecting consumers had not been wholly effective. In addition, the National Shellfish Safety Program sought to overcome the Achilles heel of the NSSP: the lack of any sanctioning power over the states short of totally decertifying a state program. The FDA wanted to be able to "provisionally certify" a state program, a less severe sanction than total decertification. The FDA had previously been reluctant to decertify state programs because this would undercut the cooperative nature of the NSSP.

The reaction to these proposed regulations by the individual states was sharply critical. Opposition centered on the argument that federal control would impose economic penalties on the industry and unnecessarily burden states with increased regulatory costs. As a result of this response, the FDA was directed by Congress to undertake an economic analysis of the cost of the proposed regulation.²²

This analysis determined that it would cost the industry a maximum of \$24 million and the states a maximum of \$6.2 million annually to comply with the proposed shellfish safety program.²³ The increased cost to industry would result primarily from stricter enforcement of handling, storage, and transportation provisions. Similarly, increased costs to regulators would result from more frequent water quality surveys and tighter enforcement of regulations. It was estimated that this worst-case scenario would increase the cost to the industry by 5.5%. The study further concluded that the proposed National Shellfish Safety Program would "NOT adversely affect employment and productivity, competition, or the use of energy" [emphasis added].²⁴

Despite this study, the FDA backed down from its attempt to impose federal regulation. In fact, these worst-case assumptions of costs

were used as one of the justifications for withdrawing the proposed rules. The proposal for the National Shellfish Safety Program was formally withdrawn on February 26, 1985.²⁵

In addition to the economic analysis, a further GAO report²⁶ issued in 1984 in response to a severe outbreak of shellfish-related viral gastroenteritis was used by the FDA as another justification for scrapping the proposed rules. The 1984 GAO report was critical of the FDA, stating it had acted arbitrarily and without enough input from the states.

It is clear that the FDA did a major about-face between 1975 and 1985 in its philosophy toward shellfish sanitation. Pressure from states undoubtedly contributed to this, but other underlying causes are less clear. After the withdrawal of the proposed National Shellfish Safety Program, the FDA gave its endorsement to a new organization, one that would hopefully alleviate the shortcomings of the NSSP without requiring the FDA to take formal control of the program: the Interstate Shellfish Sanitation Conference.

***Change: The Interstate Shellfish Sanitation Conference (ISSC)**

Without a central authority to assure compliance, state programs diverged substantially from the standards set by NSSP. By the mid 1970s, the publication of the 1973 GAO report had made it increasingly apparent to those involved that the shellfish industry and its regulators faced a problem of major proportions. Specifically, disease outbreaks continued, and stocks of harvestable animals had declined considerably in some areas. The very survival of the shellfish industry was uncertain. In October of 1979, representatives of fifteen shellfish producing states met in Ocean City, Maryland to discuss alternative methods of regulating themselves on a national scale. Also attending were FDA officials and representatives of industry.

A committee to investigate options was set up and deliberated for two years,²⁷ producing a final draft proposal which was mailed to state shellfish control officials along with an announcement of a national meeting to be held in Maryland. At this meeting in September of 1982, the ISSC was formally created. The stated purpose of the organization was, "fostering and improving the sanitation of shellfish through interstate cooperation and through uniformity of state shellfish programs."²⁸

The ISSC was organized to closely parallel in structure the National Conference of Inter-

state Milk Shippers (IMS). Ironically, the IMS itself was initially patterned after the old NSSP.²⁹ Founding members of ISSC believed that the cooperative program that served the milk industry so well could solve the problems faced by the shellfish industry.

Critics held that the success of the IMS could not easily be duplicated by the ISSC. The primary argument of the critics of this comparison was that shellfish do not go through a purification similar to pasteurization of milk. The industries and products these regulatory organizations are set up to control are simply different. The goals of the organizations, however, remained similar: reciprocity between states, uniformity of procedure, and reduction of duplicated effort to ensure a sanitary product.

To accomplish these goals the IMS includes federal, state, and industry participation in three councils where the substantive issues faced by the milk industry are dealt with. Industry representation provides for greater cooperation with final regulations, but this sector of the IMS has no voting power. Industry's ability to control outcomes is limited to its ability to shape debate prior to a vote. Compliance with the IMS recommendations remains voluntary on the part of states. At this writing it appears this voluntary cooperative system has served the milk industry well. Historical problems of interruptions in interstate trade due to inconsistent policies of different states have been eliminated. Problems of unsanitary milk have all but disappeared.

The ISSC is structurally similar to the IMS. It is under the control of federal agencies, state agencies, and members of industry who have established themselves as members of the conference.³⁰ There are sixteen (16) voting members on the Executive Board, as well as six (6) non-voting members. Those on the board are selected from representatives of the three components of the ISSC (industry, the federal government, and state government). The board manages the administrative affairs of the ISSC but does not make policy decisions.³¹

Three standing task forces "provide for continuity of action in carrying out the objectives of the Conference."³² The consideration of important issues takes place in these task forces. Members of task forces are appointed by the Board chairperson and are approved by the Board. Task Force I deals primarily with "Growing Area" concerns, Task Force II considers "Processing and Distribution" issues, and Task Force III is responsible for "Administrative

Matters" such as MOU's, etc. Each task force has subcommittees to which regulatory proposals are forwarded.

At the outset of the ISSC, NSSP regulations were adopted as a starting point. From this base the organization set out to reform existing regulations to better fit the shellfish industry. One of the first needs addressed by the conference was an update of the FDA standard as contained in the NSSP. The process of rewriting the NSSP Manuals of Operation has taken time, but a revised version of Part I was completed by the ISSC meeting in August of 1985. A revision of Part II is in draft form and is expected to be adopted in August 1986. Once these revisions are finalized it is envisioned that they will be used as model ordinances upon which member states will base their shellfish sanitation programs.³³ In this manner the ISSC expects to meet its goals of increased cooperation and elimination of duplicated effort.

According to the current chairman of the Board, Richard Thompson, the ISSC functions like a grand jury. There are only three actions which the ISSC can take on any issue: a determination that the problem is not within its scope of activity and refusal to consider action upon it; a decision that not enough information is available and that further study by committee is warranted; or, resolution of the issue is arrived at and a recommendation made to conference participants. In short, the ISSC is a formal organization which takes issues and studies them until a compromise plan for resolving the problem is arrived at.

Examples of matters considered by the ISSC and reviewed at the August, 1985 meeting are: fecal coliform indicators for classification of growing areas, consideration of bacterial market standard (fecal coliform vs. *E. coli*), uniform standards for depuration (the controlled purification of contaminated shellfish), regulations for transportation and distribution of shellfish, development of comprehensive identification and packaging systems, as well as others. Another important issue for discussion is corrective actions toward a state which fails to conform to ISSC guidelines.

The most significant result of the ISSC's first three years of deliberations is a willingness for concerned members of the shellfish industry, regulators, and receiver states to meet and search together for solutions to their common problems. The very existence of the ISSC is an acknowledgment that the problems faced by the

shellfish industry are in need of direct and timely solutions.

Critics of the ISSC point out that the organization has been in existence for three years and the problems that plague the industry are at least as serious now as they were in 1979, when alternative methods of regulating the shellfish industry were first discussed. While the committee-type organization of the ISSC operates smoothly when the issues are non-controversial, strict measures that have an economic impact on individual states are easily blocked. Regional differences can pit different areas of the country against each other and solutions which benefit one region may be to the serious detriment of another. Opponents of the ISSC also point to its lineage as a source of problems. An organization that begins life with all of the accumulated baggage of a 60-year-old program is bound to inherit the problems and personalities that existed under the old program.

The central argument against the ISSC, however, is that it suffers from the same crippling shortcoming as its NSSP predecessor did--lack of a mechanism for enforcement. Without specific regulatory authority to enforce compliance among the states, any guidelines agreed upon are implemented at the discretion and convenience of individual regulatory agencies. The attempt by the FDA to formalize its control over the industry in 1975 was an attempt to put some "teeth" in the program. This shortcoming is particularly worrisome to New York policymakers in that the ISSC has by all measures failed to protect the citizens of New York from unwholesome shellfish originating from out of state sources.

ALTERNATIVES

Given the perceived shortcomings of the present structure, it may be wise for New York policymakers to consider a spectrum of alternatives to assure sanitary shellfish from inter- and intra-state sources. The authors will detail policy options for working within the present ISSC structure, as well as outline several alternatives in lieu of the Interstate Shellfish Sanitation Conference.

***ALTERNATIVE #1: FEDERAL CONTROL OF SHELLFISH SANITATION PROGRAM**

By having the federal government assume nationwide control over the program by promulgating federal regulations, several benefits

would be realized. Most importantly, a degree of uniformity in standards and enforcement would necessarily follow. FDA inspectors could provide an effective deterrent to the interstate shipment of unhealthy shellfish. Unlike the situation of the states, there would be no question of the legality of the FDA undertaking such a move, providing that national regulations had been promulgated. National regulations could provide specific punitive measures for noncompliance.

A final point to consider is that the FDA already has inspectors in the field who are familiar with the problems and shortcomings of the present system. They are a valuable resource in terms of knowing what has to be improved and where the faults in the present system lie.

Federal control of a unified shellfish program also has its drawbacks. The Bauman Amendment of the Coastal Zone Management Act, which requires the FDA to consult states and conduct economic analysis of proposed regulations, might hinder the process of federalizing the program.³⁴ Federal regulation would also increase direct costs to both the industry and the taxpayers. Some states harbor lingering resentment because they feel that the FDA was heavy-handed in its past attempts to assume control.

The present federal political climate is antithetical to increased federal regulation of industry, especially when states are also not enthusiastic about such a proposal. Support for an increased federal role would quickly dissipate at the first mention of the "state's rights" argument that would be sure to arise. Finally, at a time of decreasing federal agency budgets, manpower and funding required for the FDA to carry out an expanded role would be difficult to obtain.

***ALTERNATIVE #2: REGIONAL ALLIANCES AMONG THE STATES**

Regional alliances among the states could be effected by a series of Memoranda of Understanding between states. These agreements could detail the requirements for shellfish to be shipped between signatory states. To a large extent, informal contacts already exist between neighboring states, and drawing up Memoranda of Understanding between them would be easier than trying to achieve an agreement on a national scale. The smaller size of regional alliances might make the adoption of uniform standards easier because consensus will have to be reached by fewer participants. Neighboring

states also tend to have similar industries and markets, providing common ground for solving problems as they arise. Regional groups might be able to react faster to a problem than a national organization because of the smaller area they represent.

Unfortunately, there are also problems that arise as a result of regional alliances. First, it is likely that regional alliances run the risk of legal challenge. The Commerce Clause of the U.S. Constitution prohibits barriers to interstate trade, and it is likely that regional alliances may be seen as such.

Another fault in this approach is that it does not recognize the nationwide scope of the problem. Cross-country shipments of shellfish products are common, and regional alliances would be unable to effectively regulate them. In addition, some of the problems plaguing the industry are technical in nature and nationwide in scope: the lack of viral standards, disagreement over testing standards, and other technical hurdles.

Regional alliances might be seen as a last resort, an admission that a more permanent solution could not be found. In some respects regional alliances would incorporate the worst features of both national and state programs. A regional alliance would not address the problems associated with trade between regions, and would not have any stronger legal basis than the current cooperative program.

***ALTERNATIVE #3: UNILATERAL ACTION BY NEW YORK STATE**

There are a number of actions that New York can take in addition to, or in spite of, developments on national or regional levels. The state has the authority to embargo shellfish from sources that it feels are not meeting the standards held for internal harvesters. Aquaculture, the controlled growth of clams and oysters, can be encouraged or even be chosen as the only method of shellfish production permitted in New York. Regulators could demand that all shellfish go through depuration, a process whereby shellfish are placed in clean water and over time are able to purify themselves of many contaminants. In short, there are numerous avenues which may be followed within the state to prevent contaminated animals from reaching the market.

This kind of action may be a good way for regulators to see direct results in a short period of time. There is no need for compromise or cooperation with other states or organizations. In

fact, independent action on the part of New York officials may be the only way to protect its industry and its interest.

Of course, problems with these approaches can be anticipated. Depuration is a process which has been hailed as the "solution" to shellfish related disease, but serious scientific doubts of its efficacy remain. However, mechanical purification may be so expensive that it raises the price of clams and oysters beyond what the market will bear. Aquaculture has similar drawbacks. In many instances culturists utilize the same water supply as the wild harvest, subjecting cultured shellfish to the same problems.

Any action New York considers outside the scope of the ISSC will not be met with a favorable response from other states or the FDA. Because the success of the ISSC is so dependent upon mutual respect and cooperation, efforts to work around the organization will leave the state open to accusations of scuttling the ISSC. Unilateral action could cause working relationships that agencies have with neighboring states to deteriorate. Finally the legality of strong action may be challenged in court if the result is to restrict interstate trade.

***ALTERNATIVE #4: IMPROVE THE ISSC**

Another alternative would be to work within the present ISSC organization. By instituting permanent funding, the organization would be strengthened considerably. The continuity of the ISSC would be enhanced if a full or part-time staff could be hired. Travel expenses for the members of the committees could be provided on a regular basis. At the present time one of the weaknesses of the ISSC is that the committees meet too infrequently to accomplish much. By securing a steady source of funding, the ISSC would have a day-to-day presence, and an ongoing organization. Funding might be secured by a variety of means: contributions from member states on a formula basis or a tax on interstate shellfish shipments are two possibilities.

Working within present structure of the ISSC many seem wise in light of the experience of the Interstate Milk Shippers. Despite product and industry differences IMS is highly successful in its work. If the experience of the Milk Shippers is any guide, the ISSC may become more effective as the organization matures.

There are drawbacks to working within the ISSC structure and establishing it on a more permanent basis. Funding a cooperative

program like this is difficult under the best of circumstances. State agencies would have to make a commitment to allocate money and staff resources to support the ISSC. More importantly, states must be willing to be flexible about what they perceive to be their interests. The cooperative nature of the ISSC assures that there is no final arbiter of conflicts--the states must collectively agree on what is in the best interests of all. Finally, it may be difficult to secure cooperation from those already opposed to the ISSC.

CONCLUSIONS

The problems of shellfish related disease are complex and not easily rectified. The multiple layers of government involved in the pro-

cess are an indication of the convoluted nature of the problem. The ISSC as a mechanism to reform shellfish sanitation is a positive step that has brought together interested parties and begun discussion of alternatives. The organization has also been successful in bringing up to date the old NSSP manuals of operation.

The major problems faced by this organization are those actions it has yet to take. Because ISSC is based on cooperative effort it is unlikely that the group will take strong action that may be damaging to its constituencies.

Unless alternative methods of regulating the harvest, processing, sale and transportation of shellfish are seriously considered by public officials, the difficulties of shellfish-related disease will continue.

Endnotes

- ¹*Times Union*, Albany, New York. March 6, 1985, p. A-1.
- ²Rita R. Colwell, ed. *Natural Toxins and Human Pathogens in the Marine Environment: Problems and Research Needs*, Maryland Sea Grant, 1982.
- ³*Times Union*, Albany, New York. March 6, 1985, p. A-1.
- ⁴*New York State Public Health Law*, Sections 201.1, 1350-1354.
- ⁵*New York State Public Health Law*, Sections 324.1, 2101.1, 2103 and 10.2.
- ⁶William F. Leavy, *New York State Department of Health Internal Memorandum*. (Field Memorandum Series 80-71) November 20, 1980.
- ⁷*New York State Environmental Conservation Law*, Articles 11 and 13.
- ⁸*New York State Environmental Conservation Law*. Section 13-301 to 13-0371.
- ⁹*New York State Environmental Conservation Law*, Section 13-0317, subject to regulation under 13-0319. See also 6 NYCRR 42, Sanitary Control Over Shellfish, Section 42.8.
- ¹⁰*New York State Agriculture and Markets Law*, Sections 3 and 16.
- ¹¹*New York State Agriculture and Markets Law*, Sections 200 and 201.
- ¹²*New York State Agriculture and Markets Law*, Section 202.
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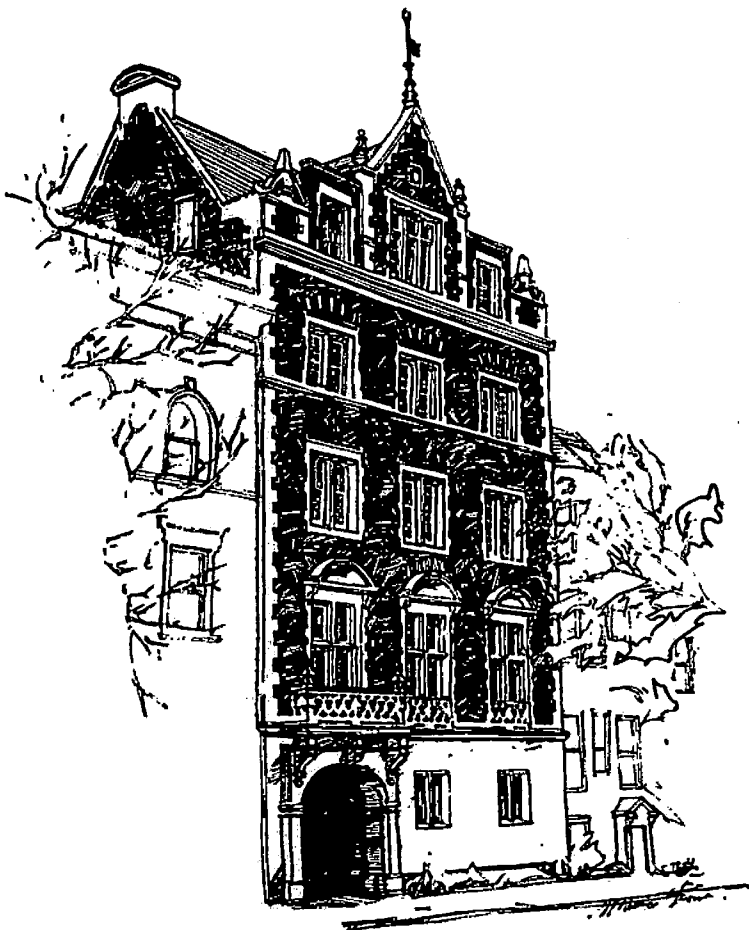
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