BY THE U.S. GENERAL ACCOUNTING OFFICE

Report To The Honorable Thomas J. Downey House Of Representatives

Problems In Protecting Consumers From Illegally Harvested Shellfish (Clams, Mussels, And Oysters)

Protecting the public from oysters, clams, or mussels that are illegally harvested from polluted waters and unfit to eat has been a long-standing problem facing the Congress, shellfish-producing states, and the Food and Drug Administration (FDA). Most shellfish are from approved growing areas and safe to eat, but some are illegally harvested.

Shellfish regulation comes from the voluntary cooperative National Shellfish Sanitation Program, initiated by state and local health officials in 1925. The states identify pollution sources, test water for bacteriological quality, and patrol growing areas.

FDA reviews state programs and suggests improvements but under the current program has no enforcement authority to ensure adherence to the program's guidelines. Current problems include.

- --Not enough law enforcement staff to patrol closed harvesting areas.
- --Low court-assessed fines with little deterrent effect.
- --Inadequately inspected growing areas and surrounding properties
- --Difficulty in tracing contaminated shellfish to growing areas or persons harvesting them

This report discusses three alternatives for shellfish regulation.

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UNITED STATES GENERAL ACCOUNTING OFFICE
WASHINGTON, D.C. 20548

HUMAN RESOURCES
DIVISION

B-215245

The Honorable Thomas J. Downey
House of Representatives

Dear Mr. Downey:

At your request, we have reviewed the manner in which the Food and Drug Administration (FDA) has carried out its responsibility in administering the National Shellfish Sanitation Program. As you requested, we focused our review on whether (1) FDA has adequate legal authority to enforce federal standards designed to ensure the safety and quality of shellfish, (2) FDA is effective in regulating the interstate shellfish industry, and (3) a stronger or different federal role is needed to regulate shellfish.

As discussed with your office, we obtained comments on this report from the Department of Health and Human Services and the four states visited during our review: Maryland, New Jersey, New York, and Virginia. We received written comments from everyone except New Jersey, and these were considered in finalizing the report.

As arranged with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from its cover date. At that time we will send copies to interested parties and make copies available to others upon request.

Sincerely yours,

Richard L. Fogel
Director

GENERAL ACCOUNTING OFFICE
REPORT TO THE HONORABLE
THOMAS J. DOWNEY
HOUSE OF REPRESENTATIVES

PROBLEMS IN PROTECTING CONSUMERS FROM ILLEGALLY HARVESTED SHELLFISH (CLAMS, MUSSELS, AND OYSTERS)

D I G E S T

In 1982, over 162 million pounds of clams and oysters valued at about $173 million were harvested in 24 states. Similar data were not available for mussels. The vast majority of the shellfish are taken from clean waters and are safe to eat. Some, however, are taken from posted or polluted areas and may be contaminated and unfit for human consumption, especially if eaten raw. Illnesses which have been associated with the consumption of contaminated oysters, clams, and mussels include typhoid fever, viral hepatitis, cholera, acute diarrheal disease, and paralytic and neurotoxic shellfish poisoning. Medical consequences include fever, constipation, nausea, abdominal discomfort, jaundice, dehydration, respiratory failure, and death. (See p. 1.)

Following an incident in 1983, when 750 New Yorkers became ill after consuming raw clams, Congressman Thomas J. Downey requested GAO to examine the Food and Drug Administration's (FDA's) role in regulating the interstate shellfish industry. He expressed particular interest in determining whether a stronger or more appropriate federal role needed to be defined in the interests of both the consumer and industries of the various shellfish-producing states. (See p. 3.)

REGULATION OF THE SHELLFISH INDUSTRY

In 1925, the federal government, shellfish-producing states, and the shellfish industry formed the National Shellfish Sanitation Program, a voluntary cooperative program for protecting the consumer from shellfish-borne illness. Under program guidelines each party assumed specific duties and responsibilities for controlling shellfish-growing areas and maintaining sanitary conditions in shellfish-processing plants. The states, for example, identify pollution sources, test water for bacteriological quality, and patrol growing areas. FDA reviews state programs

and suggests improvements. Industry agreed to harvest and process shellfish under sanitary conditions. (See pp. 1 and 6.)

In 1968, the Secretary of Health and Human Services (HHS) designated FDA as the principal federal agency responsible for shellfish regulation. In 1975, FDA attempted to formalize its authority by promulgating regulations to govern the program. Congressional action, prompted by shellfish-producing states that opposed federal regulation, initially blocked FDA's attempt to promulgate regulations. Subsequently FDA undertook an economic analysis of cost data received in response to the proposed regulations and determined that there would be insufficient additional public health benefits to justify the additional cost of the proposed regulations. As of April 1984, FDA planned to withdraw its regulations. (See p. 2.)

PROBLEMS IN REGULATING SHELLFISH

FDA, state enforcement authorities, and the shellfish industry have been working to improve the sanitary quality of shellfish shipped in interstate commerce, but problems still need to be overcome because:

--The National Shellfish Sanitation Program is voluntary, and FDA cannot assure that members are adhering to program requirements. These requirements include identifying pollution sources that could affect shellfish-growing waters, testing waters for bacteriological quality, patrolling growing areas to deter illegal harvesting, and inspecting processing plants for compliance with sanitation standards. Each state in the program is responsible for enacting legislation and regulations to assure compliance with its program. FDA functions in an advisory capacity under this program. (See pp. 5 and 6.)

--Law enforcement agencies, according to state officials, do not have sufficient staff or equipment to adequately enforce shellfish program requirements and patrol areas closed to shellfish harvesting. In New York, for example, about 36 percent of the approximately

190,000 acres closed to shellfish harvesting are located in Nassau and Suffolk counties which have only 12 environmental conservation officers to patrol these areas on a 24-hour basis and perform various other functions, including the enforcement of clean air, water, toxic waste, and pesticide laws. (See p. 9.)

--Fines assessed by the courts for illegal harvesting have generally been so low as to have little impact as a deterrent. In New Jersey, for example, fines for illegally harvesting shellfish were seldom more than $25, which is far less than the value of 1 day's illegal harvest. Moreover, while New Jersey law allows the confiscation and forfeiture of vessels and equipment used in illegal harvesting activities, the state seldom resorts to this action because it does not have proper facilities and staff for maintaining confiscated property. (See p. 11.)

--In New York, some growing areas and surrounding properties (as potential sources of shellfish pollution) have not been adequately inspected. Staff responsible for examining over 1 million acres of shellfish lands has been reduced from four to one, and the number of sanitary surveys completed annually to determine possible sources of pollution has dropped from the state required 30 to 23. In addition, shoreline inspections, which are a major component of the sanitary surveys, have generally not been made. (See p. 12.)

--Contaminated shellfish often cannot be traced back to the growing areas from which they were harvested and the persons who harvested them. Following the 1983 outbreak of shellfish-related illness in New York, state officials found that identification tags required to be affixed to each container of shellfish were missing, mutilated, or illegible; did not identify the original shipper or date of shipment; or had been changed to show the shellfish were harvested from an approved area. (See p. 10.)

ALTERNATIVES FOR REGULATING THE SHELLFISH INDUSTRY

There are different alternatives for regulating the shellfish industry. Three are discussed below. Each alternative has advantages and disadvantages, and none may address all of the problems associated with the regulation of shellfish, particularly the lack of sufficient state resources.

1. Leave regulatory authority with the states and allow FDA to continue to function in an advisory capacity. (See p. 13.)

Advantages

--States are most familiar with their own programs.

--States can set their own goals and priorities.

--FDA would not need an increase in resources.

Disadvantages

--Lack of central authority.

--No legal basis for program guidelines.

--Lack of uniformity among state programs.

--No central forum for handling interstate disputes.

2. Grant specific regulatory authority to FDA to administer the shellfish program. This would alleviate some of the problems FDA has encountered in its attempt to formalize the National Shellfish Sanitation Program. (See p. 16.)

Advantages

--Program guidelines would become legally enforceable.

--FDA would assume a central position of authority.

Disadvantages

--Creation of an adversary relationship between FDA and states.

--Adverse effect on state programs.

--FDA would need a significant increase in resources.

3. Form a cooperative relationship among the states, FDA, and the shellfish industry in which each party has a voice in the direction and regulation of shellfish and specific duties and responsibilities. Under this option compliance with program requirements would be achieved through the states exerting pressure on each other to comply with the guidelines. When a state choose not to comply, others will not accept its products. (See p. 17.)

Advantages

--Formal organization to effect change.

--Creation of an open environment to discuss problems and settle interstate disputes.

--States can put pressure on each other for compliance.

--Self-imposed requirements may be more effective than federal regulation.

Disadvantages

--"Committee" process of regulation may be time consuming.

--No legal basis for state actions.

--Industry may be in a position to influence public health matters.

AGENCY COMMENTS

HHS stated that the report presented an accurate description and balanced evaluation of FDA's involvement in administering the National Shellfish Sanitation Program. HHS stated that the three regulatory alternatives presented in the report coincided with FDA's actual experience based on its involvement in administering the program. In addition, HHS stated that it

favors a cooperative relationship among the states, FDA, and the shellfish industry for regulating the shellfish program activities. FDA has been developing such an approach for the past 2 years and has supported the formation of the Interstate Shellfish Sanitation Conference.

GAO received comments from HHS, Maryland, New York, and Virginia. New Jersey advised GAO that it could not provide comments at this time. New York generally agreed with the report, but offered technical suggestions which have been considered and where appropriate included in the final report.

In commenting on the report, Maryland and Virginia, although geographically similar, in the same FDA district, reviewed by the same FDA inspector, and each with much of their harvesting taken from the Chesapeake Bay, had widely different viewpoints on what the report presented. Maryland generally agreed with the report and provided some minor technical changes for consideration.

The Director of Virginia's Bureau of Shellfish Sanitation was critical that the report presented a series of options that might be pursued in regulating the harvesting of shellfish, rather than taking a position on whether FDA was adequately administering the National Shellfish Sanitation Program. GAO believes that the problems discussed in chapter 2 of the report, as well as the number of reported incidences of shellfish-related illnesses which occurred over the past 3 years demonstrate weaknesses in FDA's present regulatory approach. However, GAO also recognizes the inherent complexity of regulating this industry and that there are different approaches that can be taken, each of which have advantages and disadvantages. For the shellfish program to function properly, the principal parties involved--FDA, the states, and the Congress--need to fully explore and discuss all possible approaches and reach an agreement on the one which will be most workable and provide the greatest degree of protection to the consumer at a reasonable cost. (See pp. 19 to 21.)

Contents

ABBREVIATIONS

FDA	Food and Drug Administration
FD&C	Federal Food, Drug and Cosmetic Act
GAO	General Accounting Office
HHS	Department of Health and Human Services
ISSC	Interstate Shellfish Sanitation Conference
NMFS	National Marine Fisheries Service
NSSP	National Shellfish Sanitation Program
PHS	Public Health Service

CHAPTER 1

INTRODUCTION

Illness associated with the consumption of raw or partially cooked shellfish was a problem long before the recording of early American history. However, it was not until the early 20th century that the eating of shellfish from contaminated waters became a public health concern in the United States. Before that time the greatest concern about shellfish centered on their availability, and a number of states passed laws to prevent the depletion of this natural resource.

In 1924, a major outbreak of typhoid fever occurred in the United States. The outbreak resulted from the consumption of oysters harvested from sewage-contaminated water. There were about 1,500 reported cases of typhoid fever and 150 deaths in New York, Washington, D.C., and Chicago alone. Evidence gathered at the time indicated that the shellfish, which pump vast quantities of water through their bodies, had accumulated micro-organisms, chemicals, and heavy metals from the marine environment.

Since people frequently eat shellfish raw or partially cooked, there is a chance that they will become ill if the shellfish were harvested from contaminated waters. (See app. II for shellfish-related diseases.) Even in some cases where shellfish are fully cooked, the presence of marine biotoxins can result in shellfish poisonings. As a result of the 1924 typhoid outbreak, the National Shellfish Sanitation Program (NSSP), a voluntary cooperative program of federal, state, and shellfish industry representatives, was established. Its purpose is to prevent shellfish-borne illness by controlling the shellfish-growing areas and sanitary conditions at plants which handle fresh or frozen shellfish.

There are about 15,000 species of shellfish classified into approximately 70 families. In this report, shellfish are defined as all edible species of clams, mussels, and oysters. In 1982, over 162.6 million pounds of oysters and clams valued at about $173.7 million were harvested in the United States. The National Marine Fisheries Service (NMFS) does not keep statistics on mussels. Shellfish harvesting is conducted in all states on the east, west, and gulf coasts and in Alaska and Hawaii. At present, membership in NSSP is as follows: all 24 of the shellfish-producing states in the United States; 4 states which do not harvest but do purchase shellfish; the District of Columbia; Springfield, Missouri; Chicago, Illinois; and 7 foreign countries.

FEDERAL INVOLVEMENT IN REGULATING THE SHELLFISH INDUSTRY

At the federal level, the interstate shipment of shellfish was initially regulated by the Public Health Service (PHS) under authority of title III of the Public Health Service Act, as amended (42 U.S.C. 241). When PHS was reorganized in 1968, the Food and Drug Administration (FDA) was designated the principal federal agency with jurisdiction over the regulation of the interstate shipment of shellfish.

FDA has enforcement authority under the Federal Food, Drug and Cosmetic Act (FD&C Act) to prevent the introduction of adulterated and misbranded food into interstate commerce. Pursuant to this authority, FDA could promulgate regulations concerning sanitation of shellfish entering interstate commerce. In 1975, proposed regulations which would have formalized NSSP were published but they were never implemented for reasons discussed on pages 6 to 8.

FDA is responsible under NSSP for evaluating the effectiveness of state shellfish sanitation control programs. If FDA finds deficiencies in state programs during these evaluations, it is responsible for working with state officials to seek timely corrections. However, when state officials are unable, or unwilling, to make the necessary corrections, the only sanction available to FDA is to withdraw its endorsement of the state's shellfish control program. When this occurs, FDA removes all firms in that state from its Certified Shellfish Shipper's List and notifies all other states of its action. The list is FDA's monthly publication of the names and locations of firms that are certified by state officials to have complied with NSSP guidelines. The removal of a firm from the list would alert those who receive the list that the firm may not be in compliance with NSSP. Even though FDA has this authority, according to the Director, Shellfish Sanitation Program, it has seldom used it. Under the present program, NSSP may withdraw endorsement only from an entire state. There is no provision for FDA to decertify part of a state or a particular processor within a state.

FDA is administered by a Commissioner under the direction of the Department of Health and Human Services (HHS) Assistant Secretary for Health. Policies and procedures are established at FDA's headquarters, Rockville, Maryland, and operations are carried out by 22 district offices in the United States and Puerto Rico. Six FDA regions monitor the activities of the 24 shellfish-producing states. FDA also encourages inland states to monitor the quality of shellfish coming into their states.

FDA relies primarily on the FD&C Act (21 U.S.C. 301) as its principal enforcement tool. However, problems as they relate to shellfish are not always subject to remedies under the act. For example, even if FDA promulgated regulations on the sanitation of shellfish found in interstate commerce, the agency would govern only the interstate shipment of shellfish. FDA can seize or enjoin shellfish that are either adulterated or misbranded once they have entered interstate commerce and prosecute those responsible for delivering such products into interstate commerce. However, FDA's authority does not extend to regulations of the growing area where shellfish are harvested. Such regulatory authority remains under the jurisdiction of the individual states.

FDA can also initiate action under other federal laws to ensure that food (including shellfish) is safe, pure, and wholesome. For example, the Congress enacted the Lacey Act Amendments of 1981 (16 U.S.C. 3371) to provide for the control of illegally taken fish and wildlife. The Congress recognized that the illegal movement of fish, including shellfish, across state lines had become a problem. The Senate Committee on Agriculture, Nutrition and Forestry had pointed out in earlier hearings that hundreds, and perhaps thousands, of tons of fish harvested illegally from polluted or posted areas (designated by signs as unfit for harvesting) were being moved across state lines and fines and penalties were not sufficient to deter violators from these acts.

As of April 1984, FDA was developing a Memorandum of Understanding with the Department of Commerce relative to the provisions of the Lacey Act. This Memorandum of Understanding would encourage NMFS, a component of the Department of Commerce, to give higher priority to shellfish enforcement patrolling by providing a mechanism by which FDA and state officials could refer cases of illegally harvested shellfish to NMFS for enforcement.

OBJECTIVES, SCOPE, AND METHODOLOGY

We performed this review at the request of Congressman Thomas J. Downey who, because of a 1983 outbreak of illness associated with the consumption of raw or partially cooked shellfish in New York, asked that we determine whether (1) FDA has adequate legal authority to enforce federal standards designed to ensure the safety and quality of shellfish, (2) FDA is effective in regulating the interstate shellfish industry, and (3) a stronger or different federal role is needed to regulate shellfish.

To accomplish our objectives we (1) obtained information on the 24 shellfish-producing state programs to determine whether they were functioning within the general framework of NSSP, (2) determined the major differences between the states' and FDA's roles as carried out under the program, (3) evaluated proposed suggestions for improving NSSP, and (4) analyzed FDA's evaluations of state programs to determine how successful FDA had been in getting identified deficiencies corrected. We visited 4 of the 24 shellfish-producing states--New York, New Jersey, Maryland, and Virginia. In these states we interviewed state officials and reviewed selected records provided by those officials. We chose these states because they account for more than 50 percent of the shellfish harvested in the United States. We further contacted state officials in New Hampshire, Pennsylvania, and Kentucky to determine how they monitored shellfish shipped into their states.

We reviewed all of FDA's evaluations of state shellfish programs for fiscal years 1981 and 1982 to determine whether (1) each state was performing in accordance with NSSP requirements and (2) FDA was accomplishing its stated responsibility under the program of getting states to take needed regulatory action under the FD&C Act.

We also reviewed FDA policies and procedures concerning shellfish sanitation control and appropriate state laws and interviewed FDA officials at FDA headquarters in Rockville, Maryland, and Washington, D.C., and at the FDA regional office in Brooklyn, New York, and the district office in Baltimore, Maryland.

Our fieldwork was done from April through August 1983 and was performed in accordance with generally accepted auditing standards.

CHAPTER 2

PROBLEMS ENCOUNTERED IN REGULATING SHELLFISH

With the enactment of various state laws designed to curtail the illegal harvesting of shellfish, the states have made some progress in preventing the sale of shellfish that have been illegally harvested. The shellfish-producing states we visited allow part of the fees collected for shellfish permits to be returned directly to shellfish programs. These funds can be used to purchase new equipment and vehicles and to employ additional personnel to assist in managing the shellfish programs. Despite steps taken by the states to prevent illegal harvesting, shellfish taken from nonapproved waters continue to reach the consumer through normal distribution channels. FDA and state enforcement authorities and the shellfish industry have been working to improve the sanitary quality of shellfish shipped in interstate commerce, but more needs to be done because:

--NSSP is a voluntary program, and no regulations have been promulgated to address problems of noncompliance with the program.

--Law enforcement agencies have insufficient resources to prevent the illegal harvesting of shellfish.

--Contaminated shellfish cannot be traced back to the growing areas from which they were harvested and to the persons who harvested them. In commenting on our draft report, New York stated that people who harvest shellfish from uncertified waters will neither admit that such shellfish were illegally harvested nor place a tag on illegally harvested shellfish which correctly identifies the harvester and the harvest location.

--Court-assessed fines have been inadequate to deter illegal harvesting.

--Growing areas and surrounding properties (as potential sources of shellfish pollution) in one state have not been adequately inspected.

REPORTED INCIDENTS OF SHELLFISH-RELATED ILLNESS

Shellfish have been implicated in numerous studies performed by academia, PHS, and FDA as potential disease carriers which must be regulated. In early fiscal year 1983, there were about 2,000 reported cases of shellfish-related illnesses, about a 6-percent increase over the number of incidences reported in

fiscal year 1982. While most of the cases reported in these 2 years were in New York (1,611), other cases were reported in Florida (38) and in Texas and Louisiana (472). (See app. II for a detailed account of the number of reported shellfish-related illnesses in the United States and Canada since 1900.)

A report prepared by FDA's Northeast Technical Service Unit, Davisville, Rhode Island, in July 1983 showed that between 1900 and 1983, there were about 12,000 reported incidences of illnesses in the United States and Canada caused by the consumption of clams, oysters, and mussels.

NSSP HAS LAUDABLE OBJECTIVE BUT CANNOT ENFORCE COMPLIANCE

Currently, shellfish, as a source of food, are regulated under NSSP whose purpose is to oversee the activities and operations of each participating state and to determine the degree of compliance with the requirements defined in FDA's manual of operations. Although the manual serves as a guide to be followed by states wishing to participate in NSSP, there are no legal sanctions for noncompliance.

Under NSSP, the states, FDA, and industry agreed to accept specific duties and responsibilities. NSSP member states agreed to adopt laws and regulations to ensure control of sanitation in the shellfish industry. For example, the states agreed to identify pollution sources that could adversely affect growing waters, test waters for bacteriological quality, patrol growing areas to deter illegal harvesting, inspect shellfish-processing plants for compliance with sanitation standards, and provide evidence to FDA to show they are carrying out their responsibilities under the program. FDA reviews annually each state's compliance with NSSP guidelines and offers suggestions for improvements in the state programs. Industry's role is to obtain shellfish from safe sources, maintain plants which meet program sanitation standards, and keep records of the origin and disposition of shellfish harvested for sale.

In a 1972 memorandum to FDA, the Department of Health and Human Services' Office of General Counsel expressed its concern about the legal status of NSSP. The memorandum was a result, in part, of an effort by Virginia to seek relief in the courts for an unsatisfactory shellfish program rating, given by FDA, which would have caused the state to be dropped from FDA's Certified Shellfish Shippers List. The memorandum concluded that since NSSP is a voluntary program without legal sanctions to deal with instances of noncompliance, it is questionable whether any attempts by FDA to impose FD&C Act sanctions for shipping shellfish in interstate commerce after a state's program has been decertified would have been upheld by the courts.

In 1975, FDA proposed regulations to control the interstate shipment of shellfish. These regulations were designed to strengthen the voluntary NSSP by formalizing the procedures under which the existing program had been operating. The regulations would further define the scope, requirements, and responsibilities of the states and federal agencies involved in administering the shellfish program. FDA believed that the proposed regulations would serve as an incentive to shellfish-producing states to improve their enforcement programs and would improve the relationship between FDA and the state agencies.

According to FDA the proposed regulations created misunderstandings, confusion, and distrust toward the agency by state officials. This caused a deterioration in federal-state relationships and a breakdown in communication that was necessary to maintain NSSP. The Congress, because of the states' rights issues raised by the shellfish-producing states, amended the Coastal Zone Management Act of 1976 (commonly referred to as the Bauman Amendments, P.L. 94-370), which directed the Secretary of Health, Education, and Welfare (and, by delegation, FDA) not to promulgate final regulations concerning the National Shellfish Sanitation Program until 1977. Because of these difficulties FDA sought other approaches to strengthen NSSP and improve shellfish quality. FDA has been developing this approach for the past 2 years and has supported the formation of the Interstate Shellfish Sanitation Conference (ISSC) (see ch. 3). In commenting on the report Virginia stated that FDA could modify its proposed regulations with state and industry input and promulgate them under the Federal Administrative Procedures Act. Virginia further stated that FDA has not attempted to do this, nor has it attempted to comply with the requirements imposed by the Bauman Amendments. Virginia stated that these are not insurmountable objectives and could be accomplished if FDA so desired.

According to FDA's Director, Shellfish Sanitation Program, FDA undertook an economic analysis of cost data received in response to its proposed regulations and determined that there would be insufficient additional public health benefits to justify the additional cost to the industry and shellfish-producing states. FDA stated that there are alternative non-regulatory means of assuring the safety and sanitary quality of shellfish including working with the newly formed ISSC, and updating and revising the NSSP Manual of Operations. FDA advised us that it plans to formally withdraw the proposed regulations because of the adverse effect in federal/state relations. However, as of April 1984, it had not done so.

The lack of action by FDA in promulgating the regulations has been viewed differently by the various shellfish-producing states we visited. The Director of Virginia's Bureau of Shellfish Sanitation stated that it would be a tragedy if FDA withdrew its proposed regulations. He maintains that through the efforts of the states and industry, the proposed regulations were blocked by the states but, in retrospect, he felt the states' opposition to FDA's regulation was a mistake because he believes that stronger federal regulation is the only way the industry will survive. He advised us that in his opinion there is a need for stronger regulatory action by FDA. Maryland health officials, however, opposed additional federal intervention. New York environmental officials and New Jersey health officials expressed support for a more active role by FDA in shellfish sanitation.

In commenting on our draft report, New York stated that

--There is no confidence among states that the annual appraisals performed by FDA are consistent from state to state or within a state over time. The procedure for reviewing state programs needs to be standardized, and states must become confident that an FDA Regional Shellfish Specialist performing a review of a given state in a given region would come to a similar evaluation of a different state in a different region. One shortcoming of the existing NSSP is FDA's inability to timely amend NSSP or to comprehensively revise it over time.

--One of the strengths of FDA's program historically has been providing technical assistance, both to individual states and to shellfish sanitation programs in general. Demands for such assistance from various states have significantly weakened this aspect of NSSP. More staff and resources for such technical services are greatly needed.

--There is growing concern regarding the effectiveness of NSSP in controlling the sanitary quality of shellfish imported from foreign countries. For example, depurated hard clams[1] from Great Britain were implicated in New York/New Jersey illness outbreaks in 1983. FDA may not be applying the same standards or degree of scrutiny to foreign-harvested shellfish as to those harvested within the United States.

[1]Clams which have been placed in clean water to be cleansed of any harmful bacteria.

--Investigations of the causes of shellfish-related illnesses should be conducted by FDA. Although the state strongly suspects that most recent illnesses were caused by consumption of virally contaminated shellfish, either from uncertified waters or depuration plants in Great Britain, these sources can be confirmed in very few cases.Additional federal assistance in determining the cause(s) of viral contamination should be available.

INSUFFICIENT STAFF AND FQUIPMENT TO CONTROL ILLEGAL HARVESTING

Enforcement officials at the four states visited told us that they did not have sufficient staff or equipment to adequately enforce the shellfish program requirements. For example, in New York there are about 1.1 million acres of shellfish-growing waters, of which about 190,000 (17 percent) are closed to shellfish harvesting. About 36 percent (69,000 acres) of the growing areas closed to shellfish harvesting are located in Nassau and Suffolk counties. These two counties, according to state records, have 12 environmental conservation officers who, in addition to performing other administrative duties, are also responsible for enforcing fish and game laws and other environmental laws, including those laws dealing with clean air, clean water, toxic waste, chemicals, and pesticides. We were told by the Director of New York's Division of Law Enforcement, Region I, Department of Environmental Conservation, that because of the shortage of staff, closed areas were either not patrolled at all or not patrolled around the clock. New York Environmental Conservation officials estimated that the additional resources needed for effective enforcement could cost as much as $3 million more each year.

In New Jersey, state police officials told us that they had insufficient staff to prevent or control illegal shellfish-harvesting activities. These officials advised us that illegal harvesting activities can only get worse because the marine police have been given more responsibilities without an increase in staff. In August 1983, there were 68 marine officers located at four marine substations along the New Jersey coast and in the headquarters office. They are responsible for enforcing laws pertaining to shellfish and finfish, boating safety, illegal clamming, search and rescue, and drug enforcement. In addition, these officers must patrol, on a routine basis, about 170,000 acres of closed shellfish waters to prevent illegal harvesting. These officials told us that they would need twice their current staff, which would cost an estimated $2 million per year, to adequately patrol these areas. Total patrol hours by the marine police in New Jersey were down about 54 percent from 1982 with night patrol hours reduced by 77 percent. Although FDA had

recommended that surveillance of condemned and restricted waters be increased, particularly during nondaylight hours, routine patrols had been almost eliminated. According to one New Jersey official, the illegal harvesting of shellfish in that state is a way of life.

The Chief of Enforcement, Virginia Marine Fisheries Commission, told us that because of budgetary constraints, his staff has been reduced over the past 3 years. Presently, the staff is 9 persons under its 87 maximum strength. This official told us that although he cannot guarantee complete coverage of the 83,300 acres of growing areas closed to harvesting, he believes his staff is doing a good job since, in his opinion, the illegal harvesting of shellfish is not a major problem in Virginia.

In Maryland, we were told that of 1.5 million acres of shellfish waters, only 2 percent are closed to harvesting and those that are have very little if any shellfish. According to one official, illegal harvesting from closed areas is not a problem in Maryland.

INABILITY TO IDENTIFY SOURCE AND ORIGINAL HARVESTER OF SHELLFISH

The source of shellfish distributed in normal business channels is traced by means of information on tags required to be fixed to each container of shellfish. This information should identify the original in-state or out-of-state shipper. We were told by state officials responsible for regulating the program in the four states visited that shellfish which have been identified, or suspected to have caused an illness, can be traced to the shipper, but it is impossible to trace shellfish to the specific harvester or body of water from which they were harvested because people who harvest shellfish from uncertified waters, as a general rule, will not correctly identify the harvest location.

In instances where shellfish are suspected of causing an illness, local health officials determine where the shellfish were consumed, or where they had been purchased, and check the shellfish container for tags bearing information on the name and certification number of shipper, date of shipment, original shipper's number, date of original shipment, and the body of water from which the shellfish were harvested.

One outbreak of illness caused by the consumption of shellfish occurred in New York in 1982 and affected over 400 persons. Initial reports of illness were received by local health officials from persons who became ill. In this instance, state

officials found that tags were missing, mutilated, or illegible, and information on the tags relating to original shipper or date of shipment was missing. One official told us that even if information on the tagged containers had been completed, he would not have been able to identify the original harvester or the body of water from which the shellfish were harvested since shellfish stocks are usually commingled by dealers. Officials from New York, New Jersey, and Maryland told us that the current system for tagging is inadequate. One New York official told us that state control is lacking, and some dealers purchase tags which contain preprinted information, such as the dealers' name, permit number, and location of harvest. He told us that most of the shellfish harvested are tagged "Great South Bay," a prime harvesting area, regardless of where the shellfish were actually harvested.

FINES ARE INADEQUATE TO DETER ILLEGAL HARVESTING

Officials in the states we visited told us that the penalties and fines imposed for illegal taking of shellfish from nonapproved waters are not sufficient to deter illegal harvesting. One official said that the number of incidences of illegal harvesting would decrease considerably if the courts would impose stiffer fines and penalties. For example, in New Jersey, the maximum fine and penalty for illegal harvesting from polluted water is $500 and/or 6 months in jail for first offenders, and $1,000 and/or 12 months in jail for second offenders. The law also allows for the confiscation and forfeiture of vessels, vehicles, and equipment that are used in violations. In 1981 and 1982, there were 180 violators apprehended for illegally harvesting shellfish from nonapproved waters in New Jersey. We were told that violators were usually fined no more than $100 and in most cases, they were fined only $25. One official told us that an illegal harvester can gain more from part of 1 day's illegal catch than the average penalty imposed. This official said that an illegal harvester's vessel or equipment is seldom confiscated because the state does not have the proper facilities or sufficient staff for maintaining the vessel.

In New York, the fine for illegal harvesting may run up to $1,000 and/or 12 months in jail with escalating penalties for repeat offenders. In addition, New York's law further provides for forfeiture of vessel for a third conviction. In 1981 and 1982, there were 647 violators apprehended for illegally harvesting shellfish from nonapproved waters. We were told by state law enforcement officials that violators usually receive a fine of about $50 and are seldom incarcerated. In Maryland and Virginia where there have been few reported incidences of illegal harvesting, we were told by enforcement officials that

in instances when violators have been apprehended for harvesting from nonapproved areas, the courts have been lenient in imposing fines and penalties. For example, in Maryland, of 14 violators apprehended during 1981 and 1982, the courts imposed these fines or penalties: 3 cases dismissed without fines, 4 had fines of $100, 4 had fines of $50, 2 had fines of $25, and in 1 of these cases the violator was placed on 6 months' probation. In Virginia 2 of 10 violators apprehended during 1981 and 1982 had fines of $100, 4 had fines of $50, 2 had fines of $25, and 2 cases were dismissed without fines.

GROWING AND SURROUNDING AREAS ARE NOT BEING ADEQUATELY INSPECTED

To determine whether a growing area is suitable for shellfish harvesting, a sanitary survey of the area must be conducted. During a sanitary survey all prospective shellfish-growing waters are surveyed to determine sources of possible pollution. Surveys are made on an average of every 5 or 6 years in Maryland, Virginia, and New Jersey, with more frequent partial surveys as necessary.

The program for certification of growing areas in the above three states appeared to be operating smoothly. New York, however, has experienced some problems in the last few years. According to one New York official, the program had operated in the past with four sanitary engineers who inspected the shoreline for possible pollution sources, and received data and made recommendations regarding the certification of shellfish lands. Presently one person performs all of these functions. This individual advised us that he could not possibly examine over 1 million acres of shellfish lands for which he had responsibility in a timely manner. In 1983, New York completed 23 surveys instead of the 30 which were required, and in most cases, these have not included the shoreline survey which is a major component of the sanitary surveys.

CHAPTER 3

ALTERNATIVES FOR ADDRESSING PROBLEMS IN REGULATING THE SHELLFISH INDUSTRY

Our discussions with state and FDA officials, our review of recent FDA evaluations of state shellfish programs, and recent actions taken by ISSC identified three alternatives for regulating the harvesting of shellfish. These alternatives are: (1) leave regulatory authority with the states, (2) grant specific regulatory authority to FDA, and (3) form a cooperative tripartite relationship among the states, FDA, and the shellfish industry, in which all three parties have a voice in the direction and regulation of the shellfish program.

In 1982 FDA, the industry, and 22 shellfish-producing states formed ISSC, in an attempt to bring about improved regulation. FDA and state officials believe this organization, given time, shows some promise for achieving this objective. This alternative, as well as the others, has advantages and disadvantages and none may address all of the problems discussed in chapter 2, particularly the problem of the resources needed by the states to adequately enforce shellfish sanitation policies.

Officials in the states we visited and officials in inland states with whom we spoke had varying opinions on the future direction of the shellfish program. One state official believed that a strong central authority is needed if the consumer is to be protected; however, another state official believed the status quo was sufficient to regulate the industry. Officials in four states told us that they believed FDA should take a more active role in such areas as research, standards development, and information flow, but no additional regulatory authority was necessary. Officials in three states believed a cooperative effort among the states, FDA, and the shellfish industry was the best future direction of the shellfish program.

LEAVE AUTHORITY WITH THE STATES

One alternative for regulating the shellfish program would be to maintain the status quo by leaving authority over the program with the states. FDA would continue to function in an advisory capacity. The advantages and disadvantages of this alternative are discussed below.

Advantages

--States are most familiar with their own programs.

--States can set their own goals and priorities.

--FDA would not need an increase in resources.

We believe the primary advantage to this approach is that each state is most familiar with its own program and its particular problems. Having operated under the NSSP guidelines for over 50 years, each state knows how best to apply the guidelines to its own particular set of circumstances. In addition, each state has established its regulations, functions, and organization around its administration of the shellfish program. We believe changes in program administration could force some states to revise their program's structure.

Under the present system, each state can set its own priorities and goals. For example, although shellfish sanitation is a health issue, it is approached somewhat differently by each of the states we visited. In Virginia, program direction comes from the State Department of Health. The Commissioner, according to a Virginia health official, has significant authority over public health matters. Maryland, however, while emphasizing public health and safety, approaches shellfish sanitation more from a water management point of view. According to one Maryland official, the state's priority is to keep the Chesapeake Bay clean enough to permit the harvesting of shellfish, and if the water is clean enough for this purpose, it will be clean enough for all other uses.

If the authority is left with the states, FDA would not have to increase its resources. FDA currently dedicates about 60 staff years to the shellfish program. Officials in FDA's Bureau of Foods told us that if FDA remained in an advisory capacity, it would not need an increase in staff and resources.

Disadvantages

--Lack of central authority.

--No legal basis of NSSP guidelines.

--Lack of uniformity among state programs.

--No central forum for handling interstate disputes.

The primary disadvantage of leaving the authority with the individual states is the lack of a central authority and the fact that the NSSP guidelines have no basis in law or regulation. For example, one east coast state, according to FDA's fiscal year 1982 evaluation, did not meet the NSSP guidelines. FDA advised the state of this situation, but because of a lack of authority and because the NSSP guidelines are voluntary and have no legal basis, FDA took no further action against that state. Because the NSSP guidelines have no legal basis in federal law, it is questionable as to whether noncompliance actions would have resulted in favorable judgments in the courts to prevent the introduction of adulterated food in interstate commerce. The other actions available to FDA would have been to use its enforcement authority under the FD&C Act or to suggest that the other states embargo shipments of shellfish originating in the noncomplying state.

In commenting on our draft report, Maryland pointed out that many states have incorporated federal guidelines into state law or regulation. Both Maryland and Virginia commented, however, that state guidelines are not uniform. Virginia pointed out that each state is influenced by local politics and regional differences, and the consumer receives increasingly less protection as each state deviates from NSSP mandates.

An FDA Bureau of Foods official told us that operating under the NSSP guidelines has been a frustrating experience for both FDA and the states. He said the states look to FDA for leadership and all it can do is advise. He indicated that FDA wants states to comply with the guidelines, but because the program is voluntary, FDA cannot mandate that program improvements be made.

Retaining the status quo has a number of other disadvantages. NSSP guidelines allow some flexibility which has led to a lack of program uniformity among the shellfish-producing states, including the classification of growing areas and the biological standards used to certify growing waters.

In addition, under NSSP there is no central forum for handling interstate disputes. States also have difficulty in taking actions against other states or out-of-state shippers who ship adulterated products or harvest illegally. For example, one New York official told us that the state has been unable to collect a sizable fine from an out-of-state firm that was harvesting illegally in New York waters. The official told us that New York State environmental conservation officers boarded a 93-foot vessel harvesting illegally in New York waters. The officers confiscated nearly 300 bushels of clams, and the harvester was assessed a $5,000 fine. Although the state has

the authority to confiscate the boat and equipment of harvesters who take shellfish illegally, the official told us his department did not have the facilities to dock a vessel of that size so it could not detain the ship. The harvester subsequently left New York waters and returned to his home port. Since that time the state has been unable to collect the fine.

GIVE FDA SPECIFIC AUTHORITY TO ADMINISTER THE PROGRAM

A second alternative for regulating the industry would be for the Congress to grant specific authority to FDA to administer the shellfish program. This would alleviate some of the problems FDA has encountered in its attempt to formalize NSSP through promulgating regulations under authority of the FD&C Act.

Advantages

--NSSP guidelines would become legally enforceable.

--FDA would assume a central position of authority.

We believe the primary advantage to this alternative would be to give FDA specific legal and regulatory authority to enforce the NSSP guidelines. With specific authority from the Congress, FDA would be in a position to take regulatory action against states or shellfish dealers who do not comply with program requirements. Legally defensible regulations on water classification, biological levels in raw shellfish, and processing plant standards could be promulgated and enforced in compliance programs similar to those for other food products and drug products.

In a central position of authority, FDA could better focus its efforts for research into shellfish-related disease and standards development. FDA could also act as a conduit for information flow and new developments in the shellfish program. FDA would also be in a better position to settle disputes between and among the states and the shellfish industry.

Disadvantages

--Creation of an adversary relationship between FDA and states.

--Adverse effect on state programs.

--FDA would need a significant increase in resources.

We believe granting central authority to FDA would do nothing to eliminate the adversary relationship which exists between FDA and the states. Three of the states in our review did not favor this approach. FDA's failure to promulgate regulations in 1975 was due primarily to state reactions to its proposal.

Currently FDA does not have the staff and resources to fully administer the program under this alternative. A Bureau of Foods official told us that FDA would need a significant increase in resources to administer the program under this alternative. But even with a great increase, he believed the program would probably be unmanageable from a public health standpoint. Even with enforceable standards, it would be a monumental task to assure that all growing waters are properly classified and difficult to prevent illegal harvesting. There would also be no practical way for FDA to assure that the states patrol growing areas.

FORM A COOPERATIVE FEDERAL/ STATE/INDUSTRY PROGRAM

A third alternative for regulating the shellfish industry would be to formulate a joint federal/state/industry program possibly similar to the National Conference on Interstate Milk Shipments.[1] In this program, all parties have a specific responsibility and have a voice in program direction. Compliance with program requirements is achieved through the states exerting pressure on each other to comply with the guidelines. When a state chooses not to comply, others will not accept its products.

Advantages

--Formal organization to effect change.

--Creation of an open environment to discuss problems and settle interstate disputes.

--States can put pressure on each other for compliance.

--Self-imposed requirements may be more effective than federal regulation.

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[1]The National Conference on Interstate Milk Shipments, formed in 1950, is a voluntary organization composed of representatives from state and local regulatory agencies, the dairy industry, and FDA. This conference deliberates on the problems that affect sanitation requirements in the processing and distribution of milk and milk products in interstate commerce.

In September 1982, regulatory officials from 22 states, FDA and other federal agencies, and the shellfish industry began a movement in this direction and formed ISSC. The purpose of ISSC, which is a voluntary organization, is to provide a formal structure wherein state regulatory authorities can establish updated guidelines and procedures for the sanitary control of the shellfish industry. In a program of this nature, each party--FDA, the states working individually and collectively, and the shellfish industry--has specific duties and responsibilities. Each also has a voice in which direction the program will go.

In contrast to the adversary relationship of strong central control, this alternative could offer a more open environment to discuss problems and should be more conducive to improvements in regulation and standards. Officials in three of the four states we visited believed that given time, ISSC may be able to bring improvements in the shellfish program. One New Jersey official believed ISSC would provide the program uniformity which in turn should help minimize future interstate problems. Another official told us that ISSC is an organization that can make decisions on program direction. Under the old NSSP no one had decision-making authority.

A Bureau of Foods official told us that through ISSC or a similar organization, FDA is hoping that a mechanism will be developed to promote better compliance with the program. FDA believes that states will put considerable pressure on each other to follow the procedures and guidelines they adopted, and this will put a greater burden on the states to comply. In addition, with an established organization, representing all the states with which FDA can interact, the official believes there will be a mechanism that can deal with changes needed to improve the program.

Finally, while this alternative gives the industry a voice in the administration of the program, it also sets out its duties and responsibilities. Since these are self-imposed requirements, they may be more effective than requirements placed on the industry by another organization.

Disadvantages

--"Committee" process of regulation may be time consuming.

--No legal basis for state actions.

--Industry may be in a position to influence public health matters.

We believe one disadvantage of this alternative is that the committee process of regulation tends to be more time consuming. Under NSSP some issues were carried over for years without being brought to a conclusion.

Although the states can put outside pressure on noncomplying states or shippers, there will be no legal basis for these actions. The intention is that states participating in ISSC will adopt into state law or regulation the conference guidelines. Under this alternative each state would enforce its own program and there would likely be differences in program direction and enforcement.

One state official with whom we spoke is very much opposed to other states telling him how to run his program. He told us that directives from FDA would be much more acceptable.

Finally, officials in one state, while firmly believing that industry should have a voice in matters that directly concern them, feared that the industry may also be in a position to influence areas outside of their expertise, particularly matters of public health.

New York commented that the industry is presently in a position to lobby and potentially influence matters related to shellfish sanitation and questioned whether the degree of influence might change under ISSC. Maryland, on the other hand, expressed the opinion that ISSC recognizes both the positive and negative factors associated with industry participation. Maryland commented that

> ". . . the ISSC elicits industry expertise and participation in the Task Forces which deliberate the recommended solutions to problems brought before the Conference. The Task Force is carefully constructed to provide equal voting weight with three members from industry and three members from the State regulatory officials. On the conference floor, however, where the actual vote is taken to adopt or reject the recommendation as a Conference guideline, only the state regulatory officials can vote. The final decision is made by the state officials."

HHS AND STATE COMMENTS AND OUR EVALUATION

We requested comments from HHS and the four states visited during the review. We received comments from HHS, Maryland, New York, and Virginia. New Jersey advised us that due to other priority work, it could not provide comments at this time.

In summary, HHS indicated it was pleased with the thorough treatment of the subject matter and agreed with the analyses of the three regulatory alternatives that could apply to the shellfish program. HHS stated that the advantages and disadvantages of each approach, as we discussed, coincide with FDA's actual experience based on its involvement in administering the shellfish program. In addition, HHS stated that it favors a cooperative relationship among the states, FDA, and the shellfish program activities. FDA has been developing such an approach for the past 2 years and has supported the formation of ISSC. HHS commented that it believes the ISSC procedure provides a proper balance to assure the protection of the public interests.

Maryland and New York, in commenting on this report, suggested changes to some of the issues under discussion. We have considered these suggestions and where appropriate have made changes in this report.

The Director of Virginia's Bureau of Shellfish Sanitation expressed the opinion that the Shellfish Sanitation Control Program in the United States is near collapse, and that it is becoming increasingly difficult to assure that shellfish offered to the consumer are safe and wholesome. The Director was critical that our report presented a series of options that might be pursued in regulating the harvesting of shellfish, rather than taking a position on whether FDA was adequately administering NSSP.

As discussed in chapter 3 of this report, there are different approaches that can be taken to regulate shellfishing, and each has advantages and disadvantages. We believe the principal parties involved--FDA, the states which harvest shellfish, NMFS, and the Congress--should fully explore and discuss various approaches to regulation and agree on the one that will be most workable and provide the greatest degree of protection to the consumer at a reasonable cost.

The Director was also critical of FDA's enforcement-oriented posture and commented that this was quite different from prior PHS cooperative efforts to deal with the states. When PHS was reorganized in 1968, FDA was designated as the principal federal agency with jurisdiction over the regulation of the interstate shipment of shellfish. According to the Director, in 1975 FDA proposed the adoption of a set of regulations for the sanitary control of shellfish in the United States which would have legalized NSSP and given FDA the authority to administer the program under federal mandates. The Director

stated that FDA did not consult with the states before publishing the proposed regulations and while, in most instances, the states and industry believed standardized national regulations were needed, they objected to FDA's unilateral attempt to adopt such regulations without state participation in their formation.

The Director stated further that the 9th National Shellfish Sanitation Workshop held in Charleston, South Carolina, in 1975 adopted resolutions recommending (1) FDA be given the authority to properly administer the shellfish program, (2) a National Shellfish Advisory Commission be established to advise FDA on the formation, revision, and implementation of shellfish regulations, and (3) FDA standardize shellfish sanitation control procedures throughout the country. According to the Director, FDA rejected these recommendations which led to the amendment of the Federal Coastal Zone Management Act in 1976 prohibiting FDA from adopting its proposed regulations until it determined the degree of additional protection it would provide the consumer and the effects and cost of the regulations on the states and industry. Since that time, the Director stated that FDA has assumed a noncommittal, advisory-only approach to NSSP.

The Director concluded by stating that the only acceptable alternative for assuring that shellfish shipped in interstate commerce are safe and wholesome for human consumption is

> ". . . for the Congress to direct FDA to get back in the game and carry out its responsibilities to the American people . . . [through] . . . Memoranda of Understanding with the states backed by adequate rules and regulations . . . [or alternatively by taking] . . . strict enforcement action under the present provisions of the federal Food, Drug and Cosmetics Act or the Public Health Service Act. . . ."

We would agree that this is one alternative, but in the past FDA has attempted to formalize NSSP and the states strongly objected to the proposed regulations. In addition, the Congress amended the Costal Zone Management Act which prevented FDA from issuing final regulations until the completion of the environmental impact study. Because FDA has determined that no additional health benefits would result, and because of continuing state objection, the alternative for FDA to promulgate regulations to formalize NSSP without specific congressional guidance may not be practical.

APPENDIX I

THOMAS J. DOWNEY
2nd District, New York

1111 Longworth House Office Building
Telephone: (202) 225-3826

District Office
4 Udall Road
West Islip, New York 11795
Telephone: (516) 661-6777

Congress of the United States
House of Representatives
Washington, D.C. 20515

COMMITTEE ON WAYS AND MEANS
SUBCOMMITTEES:
TRADE
PUBLIC ASSISTANCE AND UNEMPLOYMENT COMPENSATION
SELECT COMMITTEE ON AGING

March 9, 1983

Hon. Charles Bowsher
Comptroller General
U.S. General Accounting Office
441 G. Street N.W.
Washington, D.C. 20548

Dear Mr. Bowsher:

I am writing to request a GAO "White Paper" study of the federal role in regulating the shellfish industry.

As you are probably already aware, the shellfish industry (and more specifically, the clamming industry) is a major industry in many coastal states. The Long Island area, of which my district is a part, credits clamming as its third largest industry, bringing in approximately $100 million per year to the Island's economy. More than 6,000 baymen and 1,100 shippers work in this local industry.

Over the past few months, 750 New Yorkers became ill after consuming raw clams. As a result, the entire industry is in a crisis and very few clams are being sold. New York's share of the national clam market has gone from more than 50% in the early 1970's to less than 30% as of the end of 1982. The crisis may reduce that percentage further in 1983.

While weak enforcement of state laws against poaching is largely at fault for New York's current crisis, many, including officials at the New York Department of Health, feel that the federal Food and Drug Administration should also absorb some of the blame. New York's clam industry cannot support the New York consumer demand for clams and importation from other clam-producing states is therefore common. What many see as a problem is the unclear authority of the FDA, under the National Shellfish Sanitation Program, to enforce even minimum standards for shellfish sanitation among all clamming states.

It is my understanding, from discussions with FDA officials, that the FDA has been given no actual legal authority to enforce federal standards in the clamming industry. The result appears to be that federal agencies offer no effective health standards for this interstate food industry. The consumer faces a threat to his or her well-being by any continued consumption of this product.

Regulation of the clamming industry may, in the final analysis, be more appropriately handled at state and local levels. However, the unclear nature of the federal role in this interstate food industry demands clarification. I am therefore requesting an investigation into the effectiveness of the present FDA role in the

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interstate clamming industry. I am interested in determining whether a stronger or more appropriate federal role can be defined in the interests of both the consumer and industries of the various clam-producing states.

I understand that the information outlined in this letter must certainly be augmented for the purposes of a full investigation. I therefore hope you will contact Jon Donner of my staff, who has an extensive file on this issue.

Your assistance in this regard is greatly appreciated. I look forward to working with your office.

Sincerely,

THOMAS J. DOWNEY
Member of Congress

TJD:jd

APPENDIX II

REPORTED SHELLFISH ILLNESSES IN THE UNITED STATES AND CANADA

Year	Health problem	Reported cases	Source	State
1900	Typhoid	4	Mussels	Maine
	Typhoid	10	Raw soft clams	Massachusetts
1902	Typhoid	80	Oysters & clams	New Jersey
	Typhoid	62	Oysters	Massachusetts
	Typhoid	25	Unknown	Maine
1904	Typhoid	21	Oysters	New York
1908	Typhoid	5	Mussels & clams	Connecticut
	Typhoid	110	Mussels	Connecticut
1909-10	Typhoid	45	Clams	New Jersey
1911	Typhoid	14	Oysters	New York
	Typhoid	83	Oysters	New York
1915	Typhoid	38	Oysters	New York
1916	Typhoid	30	Oysters	Illinois
1917	Typhoid	33	Unknown	California
1919	Typhoid	10	Oysters	New Jersey
1921	Typhoid	30	Oysters	Florida
	Typhoid	5	Unknown	New York
1922	Typhoid	6	Unknown	New York
1923	Typhoid	32	Oysters	Illinois
	Typhoid	8	Unknown	New York
1924	Typhoid	1,500	Oysters	New York
	Typhoid	10	Clams	Connecticut
1925	Typhoid	244	Unknown	New York
1926	Typhoid	8	Clams	Connecticut
	Typhoid	95	Clams	New Jersey
	Typhoid	67	Unknown	New York

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Year	Health problem	Reported cases	Source	State
1927	Typhoid	50	Unknown	New York
	Unknown	28	Mussels	California
	Unknown	3	Oysters	Unknown
1928	Typhoid	27	Unknown	New York
1929	Typhoid	45	Unknown	Maine
	Typhoid	3	Clams	Connecticut
1930	Typhoid	26	Unknown	New York
	Typhoid	3	Clams	Connecitcut
1931	Typhoid	27	Unknown	New York
	Typhoid	4	Clams	Connecticut
1932	Typhoid	14	Unknown	New York
	Typhoid	5	Clams	Connecticut
1933	Typhoid	2	Clams	Connecticut
	Typhoid	7	Oysters	New York
	Typhoid	4	Mussels	New York
	Typhoid	83	Clams	New York
1934	Gastroenteritis	11	Clams	New York
	Typhoid	3	Oysters	New York
	Typhoid	1	Mussels	New York
	Typhoid	23	Clams	New York
1935	Typhoid	5	Oysters	New York
	Typhoid	2	Mussels	New York
	Typhoid	52	Clams	New York
	Gastroenteritis	33	Clams	New York
1936	Gastroenteritis	1	Clams	New York
	Typhoid	10	Oysters	New York
	Typhoid	3	Mussels	New York
	Typhoid	23	Clams	New York
	Typhoid	26	Oysters	Maryland
1937	Typhoid	5	Oysters	New York
	Typhoid	3	Mussels	New York
	Typhoid	29	Clams	New York
	Gastroenteritis	2	Clams	New York

Year	Health problem	Reported cases	Source	State
1938	Gastroenteritis	1	Clams	New York
	Typhoid	4	Oysters	New York
	Typhoid	7	Mussels	New York
	Typhoid	27	Clams	New York
1939	Typhoid	12	Clams	New York
	Gastroenteritis	22	Oysters	New York
	Typhoid	87	Oysters	Louisiana
1940	Food poisoning	30	Clams	New York
	Food poisoning	15	Oysters	New York
	Food poisoning	60	Clams	New York
	Food poisoning	8	Clams	New York
	Gastroenteritis	20	Clams	New York
	Typhoid	5	Oysters	New York
	Typhoid	1	Mussels	New York
	Typhoid	24	Clams	New York
1941	Food poisoning	73	Oysters	New York
	Typhoid	4	Oysters	Florida
	Typhoid	11	Oysters	Florida
	Typhoid	2	Oysters	North Carolina
	Typhoid	1	Oysters	New York
	Typhoid	12	Oysters	New York
	Typhoid	300	Clams	New York
1942	Food poisoning	38	Oysters	California
	Typhoid	66	Oysters	Florida
	Gastroenteritis	3	Clams	New York
	Typhoid	2	Oysters	New York
	Typhoid	8	Clams	New York
1943	Typhoid	5	Clams	New York
	Food poisoning	16	Oysters	New York
	Typhoid	2	Mussels	New York
	Typhoid	3	Oysters	New York
1944	Food poisoning	17	Oysters	New York
	Gastroenteritis	400	Clams	Massachusetts
	Typhoid	7	Clams	New York
	Typhoid	1	Mussels	New York
	Typhoid	2	Clams	New York

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Year	Health problem	Reported cases	Source	State
1945	Typhoid	23	Clams	New York
	Gastroenteritis	2	Oysters	Massachusetts
	Typhoid	14	Clams	Connecticut
	Typhoid	8	Clams	New York
	Typhoid	1	Oysters	Washington
	Typhoid	1	Oysters	New York
1946	Diarrhea	300	Oysters	Texas
	Typhoid	3	Clams	California
	Typhoid	1	Clams	New York
1947	Food poisoning	118	Oysters	Alabama
	Food poisoning	100	Oysters	Florida
	Food poisoning	100	Oysters	North Carolina
	Typhoid	5	Oysters	Florida
	Typhoid	3	Clams	New York
1948	Food Poisoning	2	Clams	Kentucky
	Gastroenteritis	13	Clams	Washington
	Typhoid	1	Clams	Connecticut
	Typhoid	5	Clams	New York
	Typhoid	1	Oysters	New York
1949	Typhoid	1	Clams	New York
	Typhoid	1	Oysters	New York
	Gastroenteritis	1	Clams	New York
1951	Unknown	12	Clams	Unknown
	Typhoid	2	Clams	New York
1952	Gastroenteritis	66	Clams	New York
	Typhoid	1	Clams	New Jersey
1953	Gastroenteritis	16	Oysters	California
1954	Food poisoning	6	Oysters	Florida
	Typhoid	1	Clams	New York
1961	Infectious hepatitis	84	Oysters	Mississippi and Alabama
	Infectious hepatitis	459	Clams	New Jersey and New York
	Infectious hepatitis	15	Clams	Connecticut
	Infectious hepatitis	31	Oysters	Alabama
	Food poisoning	3	Mussels	Unknown

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Year	Health problem	Reported cases	Source	State
1962	Food poisoning	4	Oysters	Florida
	Infectious hepatitis	3	Clams	New York
1964	Infectious hepatitis	249	Clams	Pennsylvania
	Infectious hepatitis	123	Clams	Connecticut
	Infectious hepatitis	3	Oysters	North Carolina
	Infectious hepatitis	43	Clams	New York
	Infectious hepatitis	2	Oysters	British Columbia
	Infectious hepatitis	3	Clams	Washington, D.C.
1966	Infectious hepatitis	4	Clams	New Jersey
	Infectious hepatitis	3	Clams	Massachusetts
	Gastroenteritis	5	Oysters	Illinois
	Gastroenteritis	3	Clams	Rhode Island
	Gastroenteritis	66	Clams	Massachusetts
	Gastroenteritis	100	Clams	Connecticut
	Gastroenteritis	33	Clams	New Jersey
	Infectious hepatitis	4	Clams	New Jersey
	Gastroenteritis	2	Clams	Virginia
1967	Infectious hepatitis	3	Oysters & Clams	Unknown
	Gastroenteritis, Salmonella	22	Oysters	New York
1968	Gastroenteritis	17	Clams	Connecticut
	Infectious hepatitis	3	Clams	New York
1969	E. coli	2	Oysters	Washington
	Virbrio	71	Oysters & Clams	Washington
	Infectious hepatitis	6	Clams	New York
	Bacillus cereus	4	Oysters	Indiana
	Infectious hepatitis	13	Oysters	Florida
1970	Staphylococcus	4	Clams	New York
	Unknown	7	Oysters	Washington
	Unknown	3	Clams	Colorado
1971	Infectious hepatitis	5	Clams	Massachusetts
	Infectious hepatitis	3	Clams	Rhode Island
1972	Infectious hepatitis	1	Clams	Florida
	Infectious hepatitis	1	Clams	Massachusetts

APPENDIX II

Year	Health problem	Reported cases	Source	State
1973	Infectious hepatitis	268	Oysters	Texas
	Infectious hepatitis	15	Oysters	Georgia
	Infectious hepatitis	10	Oysters	New Mexico
	Infectious hepatitis	1	Clams	Minnesota
1975	Unknown	50	Clams	Connecticut
	Unknown	2	Clams	New York
1976	Unknown	36	Oysters	Hawaii
	Unknown	9	Oysters	Hawaii
	Unknown	3	Clams	New York
1977	Shigella flexneri	9	Clams	Massachusetts
	Staphylococcus aureus	5	Shellfish	Nevada
	Vibrio cholera	2	Shellfish	Guam
	Vibrio para haemolyticus	20	Shellfish	Guam
	Unknown	3	Shellfish	California
	Unknown	50	Shellfish	Connecticut
	Unknown	23	Shellfish	Connecticut
	Unknown	3	Shellfish	Delaware
	Unknown	47	Clams	Rhode Island
	Unknown	3	Shellfish	Washington
	Unknown	5	Shellfish	Guam
	Infectious hepatitis	17	Shellfish	Washington
1978	Unknown	2	Clams	California
	Unknown	23	Clams	Connecticut
	Unknown	4	Clams	Connecticut
	Unknown	10	Clams	Connecticut
	Unknown	6	Clams	Connecticut
	Unknown	2	Clams	Connecticut
	Unknown	26	Clams	New Jersey
	Unknown	10	Shellfish	Guam
1979	Shigella flexneri	26	Shellfish	Arizona
	Shigella sonnei	11	Shellfish	California
	Vibrio para-haemolyticus	3	Shellfish	Guam
	Infectious hepatitis	8	Shellfish	Unknown
	Infectious hepatitis	10	Oysters	Alabama and Georgia
	Cholera	10	Oysters	Florida

APPENDIX II

Year	Health problem	Reported cases	Source	State
1980	Norwalk virus	6	Oysters	Florida
	Gastroenteritis	46	Oysters	Florida
	Vibrio para-haemolyticus	4	Oysters	Florida
	Gastroenteritis	8	Clams	New Jersey
	Gastroenteritis	17	Clams	New Jersey
	Cholera	3	Oysters	Florida
	Gastroenteritis	90	Oysters	North Carolina
	Gastroenteritis	10	Oysters	North Carolina
	Gastroenteritis	6	Clams	New Jersey
	Infectious hepatitis	1	Clams	New Jersey
1981	Gastroenteritis	210	Clams	New York
	Cholera	1	Clams	Rhode Island
1982	Gastroenteritis	443	Clams	New York
	Gastroenteritis	659	Clams	New York
	Gastroenteritis	230	Oysters	New York
	Cholera	1	Oysters	South Carolina
	Gastroenteritis	472	Oysters	Louisiana and Texas
	Gastroenteritis	15	Oysters	Alabama
	Gastroenteritis	9	Oysters	Florida
1983	Pliesmonas shigelloides	18	Oysters	Florida
	Vibrio para-haemolyticus			
	Edwardsiella tarda			
	Salmonella			
	Pliesmonas shigelloides	2	Oysters	Florida
	Pliesmonas shigelloides	9	Oysters	Florida
	Gastroenteritis	3	Clams	New York
	Gastroenteritis	5	Clams	New York
	Gastroenteritis	63	Clams	New York
	Gastroenteritis	7	Clams	New Jersey
	Gastroenteritis	4	Clams	New York
	Gastroenteritis	16	Clams	New York
	Gastroenteritis	2	Clams	New York
	Gastroenteritis	5	Clams	New York
	Gastroenteritis	24	Clams	New York
	Gastroenteritis	4	Clams	New York
	Gastroenteritis	2	Clams	New York
	Gastroenteritis	10	Clams	New Jersey

APPENDIX II

Year	Health problem	Reported cases	Source	State
1983	Gastroenteritis	5	Clams	Hawaii
	Gastroenteritis	135	Clams	New Jersey
	Gastroenteritis	20	Clams	New Jersey
	Gastroenteritis	4	Clams	New York
	Gastroenteritis	24	Clams	New York
	Gastroenteritis	14	Clams	New York
	Gastroenteritis	33	Clams	New York
	Gastroenteritis	11	Clams	New York
	Gastroenteritis	36	Clams	New York
	Gastroenteritis	15	Clams	New York
	Gastroenteritis	400	Clams	New Jersey
	Gastroenteritis	14	Clams	New York
	Gastroenteritis	1,100	Clams	New Jersey

APPENDIX III

NSSP PARTICIPANTS

States

Alabama
Alaska
California
Connecticut
Delaware
Florida
Georgia
Hawaii
Louisiana
Maine
Maryland
Massachusetts
Mississippi
New Hampshire
New Jersey
New York
North Carolina
Oregon
Pennsylvania
Rhode Island
South Carolina
Texas
Virginia
Washington

Cities

Washington, D.C.

FDA Contract Receiver States

Arizona
Colorado
Ohio
Oklahoma
Wisconsin

Receiver/Shipper States

Vermont
Kentucky

Independent Receiver States and Cities

Indiana	Chicago, Illinois
	Springfield, Missouri

APPENDIX IV

DEPARTMENT OF HEALTH & HUMAN SERVICES — Office of Inspector General

MAR 22 1984

Mr. Richard L. Fogel
Director, Human Resources
Division
United States General
Accounting Office
Washington, D.C. 20548

Dear Mr. Fogel:

The Secretary asked that I respond to your request for our comments on your draft of a proposed report "Problems in Protecting Consumers from Illegally Harvested Shellfish (Clams, Mussels, and Oysters)." The enclosed comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

We appreciate the opportunity to comment on this draft report before its publication.

Sincerely yours,

Richard P. Kusserow
Inspector General

Enclosure

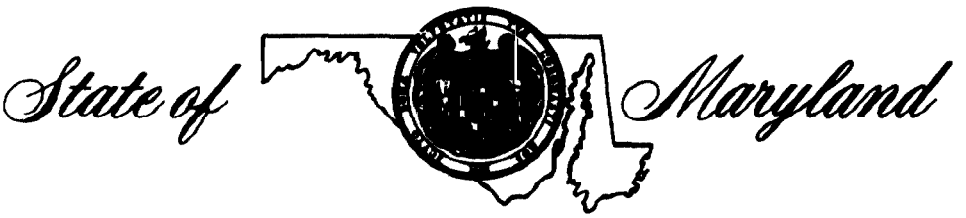
APPENDIX IV

COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES ON THE GENERAL ACCOUNTING OFFICE'S DRAFT OF A PROPOSED REPORT, "PROBLEMS IN PROTECTING CONSUMERS FROM ILLEGALLY HARVESTED SHELLFISH (CLAMS, MUSSELS, AND OYSTERS)" REPORT NO. HRD-84-36, DATED FEBRUARY 22, 1984

General Comments

We have reviewed the General Accounting Office's (GAO's) draft of the proposed report. The report presents an accurate description and balanced evaluation of the Food and Drug Administration's (FDA's) involvement in administering the voluntary National Shellfish Sanitation Program. Overall, we are pleased with the thorough treatment of the subject matter and agree with the analysis of the three regulatory alternatives that could apply to this program. The advantages and disadvantages of each of these approaches, as discussed by GAO, coincide with FDA's actual experience with them.

Although the report does not include recommendations, we favor a cooperative relationship among the states, FDA, and the shellfish industry. FDA has been developing this approach for the past two years and has supported the formation of the Interstate Shellfish Sanitation Conference (ISSC). One concern shared by FDA and GAO is the possibility that industry might be in a position to unduly influence decisions concerning public health matters. To prevent this, ISSC procedures exclude industry representatives from participating in the final ISSC decision-making process. At this time, we believe the ISSC procedures provide a proper balance to assure the protection of public interests.



OFFICE OF ENVIRONMENTAL PROGRAMS
DEPARTMENT OF HEALTH AND MENTAL HYGIENE
201 WEST PRESTON STREET • BALTIMORE, MARYLAND 21201 • AREA CODE 301 • 383-
TTY FOR DEAF: Balto. Area 383-7555
D.C. Metro 565-0451
Adele Wilzack, R.N., M.S., Secretary
William M. Eichbaum, Assistant Secretary

March 23, 1984

Mr. Seth Patters
United States General
Accounting Office
Washington, DC 20548

Dear Seth:

Thank you for the opportunity to review the draft report concerning the National Shellfish Sanitation Program. In general, the report is very good. However, I would like to offer some comments for your consideration.

A. page 15 "NSSP guidelines have no basis in law or regulations".

It is true that the NSSP guidelines have no basis in federal law. Many states, however, have incorporated the guidelines into state law or regulation, thereby, giving them the force of law. There is some discrepancy in uniformity in state adoption of guidelines, but most of the basic tenets can be found in all participating state's law or regulation.

While it is true that FDA actions are limited, it is also true that FDA fails to make known program discrepancy information to the states participating in the program. This lack of information prevents states from taking effective action which would reinforce the FDA findings.

-age 15 "no central forum for handling disputes"

The Interstate Shellfish Sanitation Conference was founded to provide this central forum. Our recent experience at our first annual meeting in Louisiana leads us to believe the ISSC provides a viable alternative.

Additional FDA authority would not resolve the problem cited in the New York example. FDA cannot force a state to increase its personnel and I strongly doubt FDA would have pursued the matter with any greater success than the State. The matter could have been better handled if the state involved had invoked the Lacy Act.

GAO note: Page references in appendixes V through VII have been changed to correspond to the final report.

APPENDIX V

page 16 "Legally defensible regulations on water classification, biological levels in raw shellfish and processing plant standards could be promulgated and enforced in compliance programs ..."

There is nothing preventing FDA from accomplishing these objectives under the voluntary program. Many states are already applying the general good manufacturing practices for food processing to shellfish processors.

page 17 "the program would be unmanageable from a public health standpoint"

I heartily agree. The federal government is too far removed from the minute details involved in protecting growing waters to be effective. Because of federal resource limitations, thousands of acres of productive bottom would probably end up restricted because the necessary intensive monitoring could not be carried out. Both the public and the industry would be unjustly denied resource use.

page 19 "We believe one disadvantage of this alternative is that the Committee process of regulation tends to be more time consuming. Under the NSSP, some issues were carried over for years without being brought to conclusion."

Although this statement is true, it is misleading as it stands. The new ISSC does not permit this type of carryover without resolution. Each issue brought before the Conference must be resolved in one of three ways at the annual meeting:
1) adopted by the Conference;
2) rejected by the Conference;
3) referred to a Task Force for study.

The Task Force must come to the next annual Conference with a recommendation to adopt or reject the issue and its recommended solution.

This provision is designed to counteract the inability to resolve issues which existed in the NSSP.

The Committee process of regulation is no more time consuming than the federal administrative procedures adoption process. For example, consider the establishment of tolerance for PCB contamination in fish and shellfish by FDA.

1973 - FDA adopted a PCB standard of 5 ppm
1977 - FDA considered revising standard to 2 ppm
1981 - FDA holds evidentiary hearings on new proposed standard
1981 - Federal judge rules in favor of FDA; FDA Commissioner is sent the legal decision and all associated information for review before Commissioner issues final ruling
1984 - final ruling remains unissued

APPENDIX V

A similar process in the ISSC would be: 1981 - proposed guideline of 2 ppm introduced to Conference Task Force; 1981 - Task Force recommended adoption or rejection - either way issued resolved!

or

Task Force recommends study with recommendation to be presented to 1982 Conference. 1982 - Task Force recommends Conference adopt or reject proposed guideline - either way issued resolved! (It is conceivable that the Task Force if some new information became available could recommend another year of study, but it is not likely.)

page 19 "there will be no legal basis for these actions"

There will be no federal legal basis for these actions. The intention, however, is that states participating in the ISSC will adopt into state law or regulation the Conference guidelines, thereby giving them the effect of state law or regulation. This has been the practice in the Interstate Milk Shipment Conference for the past 30 years and has been an effective regulatory tool.

page 19 "industry may be in a position to influence ... matters of public health"

Industry influences public health matters are the time, whether through the legislative process, the regulatory process or economics. One only has to look at the compromises involved on the national level with cigarettes and auto seat belts. The ISSC recognizes both the positive and negative factors associated with industry participation. To balance these factors, the ISSC elicits industry expertise and participation in the Task Forces which deliberate the recommended solutions to problems brought before the Conference. The Task Force is carefully constructed to provide equal voting weight with three members from industry and three members from the State regulatory officials. On the conference floor, however, where the actual vote is taken to adopt or reject the recommendation as a Conference guideline, only the state regulatory officials can vote. The final decision is made by the state officials.

I hope these comments are of some use to you. Please send me five copies of the final report. Thanks again for the opportunity to review the draft.

Sincerely,

Mary Jo Garrens, Head
Standards, Regulations and
Certification Section
Division of Technical Analysis

MJG:nem

APPENDIX VI

New York State Department of Environmental Conservation
Building #40 - State University of New York
Stony Brook, New York 11794

Henry G. Williams
Commissioner

April 3, 1984

Mr. Richard L. Fogel
Director
U. S. General Accounting Office
Washington, D. C. 20548

Dear Mr. Fogel:

Thank you for the opportunity to review and comment on the Draft GAO Report, regarding the Food and Drug Administration's National Shellfish Sanitation Program. The comments of the Department of Environmental Conservation follow:

1. Page 2, first full paragraph - This paragraph discusses FDA policy of removal of shellfish shipping firms from the Interstate Shippers' list. It would be useful to provide a further, more detailed review of the history and status of FDA actions pursuant to the Food, Drug and Cosmetic Act. A thorough review should reveal the legal strengths and weaknesses of this program.

2. Page 5, last statement at bottom of page - It would be useful to point out the reason for this statement which is as follows: Persons who harvest shellfish from uncertified waters are criminals. Such persons will not admit that such shellfish were illegally harvested and will not place a tag on illegally harvested shellfish that correctly identifies the harvester and the harvest location.

3. Page 6, first paragraph - Here again, the paragraph whets one's appetite for a full explanation of legal authorities and available sanctions of the Food and Drug Administration. Such a complete review would be a great help to the report.

4. Page 7, last sentence of paragraph concluding at the top of the page - We hope that when the report is finalized, the precise status of the expected withdrawal of the proposed regulations can be included. We would also hope that the current status of the FDA-ISSC Memorandum of Understanding will be mentioned.

5. There are additional problems with the existing FDA programs which are not thoroughly aired in this section. Some of these include:

   a) There is no confidence among states that the annual appraisals performed by the FDA are consistent from state to state or within a state over time. The procedure for reviewing state

APPENDIX VI

programs needs to be standardized, and states must become confident that an FDA Regional Shellfish Specialist performing a review of a given state in a given region would come to a similar evaluation of a different state in a different region.

b) The procedures for developing and amending the Manual of Operations for the NSSP should be discussed. One shortcoming of the existing program is the inability of FDA to timely amend the NSSP or to comprehensively revise it over time.

c) One of the strengths of the FDA's program historically has been the provision of technical assistance, both to individual states and to shellfish sanitation programs in general. In the 1960's, FDA's three research laboratories performed pioneering work in virology, trace metal contamination of shellfish, and depuration. Erosion of their capability over time, as well as increasing demands for such assistance from various states, have significantly weakened this aspect of the NSSP. More staff and resources for such technical services, as well as appropriate vehicles to incorporate the findings of such research into the Manual of Operations, are greatly needed.

d) There is growing concern regarding the effectiveness of the NSSP in controlling the sanitary quality of shellfish imported from foreign countries. For example, depurated hard clams from Great Britain were implicated in New York/New Jersey illness outbreaks in 1983. FDA may not be applying the same standards or degree of scrutiny to foreign-harvested shellfish as to those harvested within the U. S.

e) As noted in (c) above, the NSSP is not only a regulatory program. Research, development, and investigations are an important part of the program, particularly at the Federal level. Investigations of the causes of shellfish related illnesses should be conducted by FDA. Although we strongly suspect that most of our recent illnesses were caused by consumption of virally contaminated shellfish, either from uncertified waters or depuration plants in Great Britain, these sources can be confirmed in very few cases. Additional Federal assistance in determining the cause(s) of viral contamination should be available.

5. Page 9, first paragraph - We recommend revising the figures in this paragraph to incorporate statements which specify the entire acreage of growing waters and the entire acreage of uncertified areas. Similar such statements should be provided for all states in the report for comparative purposes. In New York, there are 1.1 million acres of shellfish growing waters in the Marine District. Of these, 190,000 acres, or 17.27%, are presently uncertified.

7. Page 9, first paragraph, last sentence - Between the words "needed for" and "enforcement," the words "completely effective" should be inserted to make the statement accurate.

8. Page 10, first paragraph - It might be noteworthy to point out that Maryland only considers 2% of their growing waters uncertified compared to over 17% for New York. This strongly suggests that the process of deciding whether growing waters should be uncertified may not be the same in both states, regardless of their conformity to the National Shellfish Sanitation Program. In any event, it would probably be worthwhile to explore an explanation for the apparent discrepancy.

9. Page 10, second and third paragraphs - At the end of paragraph 2, it is indicated that it is impossible to trace shellfish to a specific body of water. In paragraph 3, it is correctly noted that shipping tags must indicate the body of water from which the shellfish were harvested. This apparent inconsistency should be explained.

10. Page 11, last paragraph - In 1983, New York's law was amended to change the penalties for harvest in uncertified waters. A copy of our new law is appended hereto.

11. Page 12 - In 1983, New York conducted water quality studies in 23 growing areas. Changes in status as certified or uncertified were made in 13 areas as a result of these studies.

12. Page 16, second full paragraph - The report does not make it clear what kind of shellfish sanitation program the FDA would operate with central authority. Clearly, the full conduct of a shellfish sanitation program by the Federal Government would result in a staggering Federal cost. All aspects of the program from research and development, through growing water enforcement and inspection of shellfish in wholesale and retail commerce,also could probably not be administered effectively through Federal authority. Presumably, the recommendation here is to consider Federal regulation of the nature previously proposed via Federal regulations and sanctions against states which do not comply therewith. This should be made clear. There should also be some discussion of the existing level of Federal fiscal and other support to the State's programs, as well as a discussion of the prospects of enhancement of such support.

13. Page 15, first paragraph - The paragraph references seizure authority under the Food and Drug Cosmetic Act. Here again, the reader is puzzled as to what authority the FDA really has.

14. Page 16, second paragraph - It is unclear to us why central authority would allow FDA to improve its research focus.

15. Page 17, last paragraph - While we agree that granting central authority to the FDA would place it in an adversary role with the states, it should be noted that, to a degree, such an adversary relationship already exists.

16. Page 17, footnote - Many participants in the ISSC have also been involved in the Interstate Milk Shipments Conference and characterize

it as largely successful. A review of the history and evaluation of the milk program would be an important contribution to this evaluation of the ISSC as a shellfish sanitation program.

17. Page 18, second complete paragraph - It would be worthwhile to point out that while the industry and Federal participants in the ISSC advise, it is the State delegates who decide on modifications to the program.

18. Page 19, fourth paragraph - While we agree with the statement expressed in this paragraph, you should be aware that the industry is presently in a position to lobby and potentially influence matters related to shellfish sanitation. It is really questionable whether the degree of influence might change under the ISSC.

We very much appreciate the objectivity, cooperation and thoroughness with which the G.A.O. staff has pursued the preparation of this report. Thank you once again for providing us with this opportunity to comment.

Sincerely,

Gordon C. Colvin
Director of Marine Resources

GCC/bd
Attach.
cc: H. Doig
G. Firth
P. VanVolkenburgh
L. Hetling
L. Crowell
D. Squires

APPENDIX VII

COMMONWEALTH of VIRGINIA
Department of Health
Richmond, Va. 23219

JAMES B. KENLEY, M.D.
COMMISSIONER

March 21, 1984

Mr. Richard L. Fogel, Director
Human Resources Division
United States General Accounting Office
441 G Street, Room 6864
Washington, D.C. 20548

Dear Mr. Fogel:

The following is in response to your February 22, 1984 request for comments on the draft report to Congressman Downey on the General Accounting Office (GAO) review of the manner in which the Food and Drug Administration (FDA) has carried out its responsibility in administering the National Shellfish Sanitation Program (NSSP).

Unfortunately, the issue of how FDA is carrying out its responsibilities under the NSSP is insufficiently addressed in the draft report which is entitled "Problems In Protecting Consumers From Illegally Harvested Shellfish (Clams, Mussels, and Oysters)". It seems implicit from Congressman Downey's March 9, 1983 letter to the Comptroller General that he was "requesting an investigation into the effectiveness of the present FDA role in the interstate clamming industry". Conceivably, this request would apply to all shellfish in interstate commerce, not just clams. It was also the understanding of this office that the report would deal with the issue of whether or not FDA is adequately administering the NSSP, and if not, where the inadequacies are and what should be done to correct them.

Needless to say, it was very disappointing to see that there were no GAO CONCLUSIONS or RECOMMENDATIONS in the draft report, only a series of options that might be pursued with possible "pros" and "cons" for each. It is not believed this adequately satisfies the Congressman's request and certainly falls for short of the expectations of this office. In reading the report, one cannot help but feel that FDA has stated the same rationale for its inactivity in the NSSP that it has given to the states for the last nine years and in effect, the GAO has endorsed this position without actually saying so.

VDH
Virginia Department of Health

APPENDIX VII

It is the feeling of this agency that all the facts governing this situation should be set forth very straight forwardly and FDA's administration of the NSSP examined in detail. It is further believed a set of CONCLUSIONS should be developed from these facts and a course of action charted in the form of RECOMMENDATIONS and timetables. It is essential this be accomplished with due haste since the Shellfish Sanitation Control Program in the United States is near collapse, and it is becoming increasingly difficult to assure that shellfish offered the consumer are safe and wholesome. In fact, recent FDA program evaluations indicate that currently, shellfish produced in several states are potentially hazardous.

In order to determine the effectiveness of FDA's management of the NSSP, there are a number of issues that should be addressed. As you are aware, the change of administration of the NSSP in 1968 from the U.S. Public Health Service (PHS) to FDA brought with it a drastic change in philosophy. FDA's enforcement oriented posture was quite different from PHS cooperative efforts, and it took the states a long time to adjust to the new regime. In fact, things previously acceptable to PHS regarding the operation of the NSSP suddenly become no longer acceptable to FDA. Consequently, FDA became the federal "hammer" in order to carry out its shellfish control philosophies, which in turn sparked a States Rights response. Apparently, FDA surmised it had to assume dominant authority if it was to carry out its supposed mandates under the NSSP, and the only way it could do this was to contest the position of one of the major shellfish producing states (Virginia) and establish FDA's authority in managing the Shellfish Sanitation Control Program. FDA's strategy was to threaten withdrawal of endorsement of Virginia's shellfish program unless the state acquiesced to the FDA concepts of the NSSP. However, Virginia mounted a legal counterattack that resulted in FDA's conclusion that it had no authority to decertify a state since the NSSP had never been formerly adopted under the Federal Administrative Process Act. Accordingly, in 1975, FDA proposed the adoption of a set of regulations for the sanitary control of shellfish within the United States. These regulations would have legalized the NSSP and given FDA the authority to administer the program under federal mandates.

Unfortunately, FDA did not consult with the states prior to publishing the proposed regulations, and the states and shellfish industry united to oppose FDA's efforts. In most instances, the states and the industry believed standardized regulations at the national level were essential to the survival of the shellfish industry and the protection of public health, but they objected to FDA's unilateral attempt to adopt such regulations without state participation in their formation. In fact, the proposed regulations were generally acceptable with the exception of several sticky points that could have been worked out with proper state/industry participation. Supportive of this position are the compromise efforts made by the states and shellfish industry at the 9th National Shellfish Sanitation Workshop held in Charleston, S.C. in 1975. The workshop adopted resolutions recommending (1) FDA be given the legal authority necessary to properly administer the shellfish program. (2) A National Shellfish Advisory Commission be established for the purpose of advising FDA on the formation, revision and implementation of regulations governing the shellfish industry in the United States. (3) FDA standardize shellfish sanitation control procedures throughout the country through worksharing and cooperative training. FDA rejected these recommendations, which led to the successful admendment to the Federal Coastal Zone Management Act which prohibited FDA from

APPENDIX VII

adopting its proposed regulations until it determined the degree of additional protection they would provide the consumer and the effects of the additional cost of the regulations on the states and industry. Upon conclusion of the study, a report was to have been presented to the Department of Commerce. To the best of my knowledge, the study or report was never undertaken by FDA.

Instead, FDA began to assume a noncommittal advisory-only approach to the NSSP. State requests to FDA for action or direction were of no avail with the explanation that FDA was powerless to intervene. The refusal of FDA to become involved in matters concerning the interstate shipment of questionable or suspect shellfish caused state control agencies to become alarmed. Several futile attempts were made to get FDA to assume a stronger leadership role in NSSP, but FDA stood its ground. Accordingly, efforts to establish the Interstate Shellfish Sanitation Conference were spawned as a result of the concern over FDA's noneffectiveness in the NSSP.

While it is realized FDA's attempts to formally regulate the shellfish industry were countered by the states and industry, it is difficult to understand FDA's subsequent philosophies of inactivity in the NSSP. The 1973 GAO report entitled " Protecting The Consumer From Potentially Harmful Shellfish (Clams, Mussels, and Oysters)" clearly stated:

1. "Under the Food, Drug and Cosmetic Act (FD&C Act), the Food and Drug Administration (FDA) is responsible for insuring that food, including shellfish...shipped in interstate commerce is safe, pure, wholesome, and processed under sanitary conditions".

2. "Shellfish not meeting NSSP bacteriological standards are reaching the consumer in quantities sufficient for GAO to question NSSP's effectiveness".

3. "FDA is not adequately monitoring the states to insure that shellfish reaching the consumer are pure, safe and wholesome".

4. "The states are not fulfilling their responsibilities for insuring that shellfish are harvested from safe waters and are processed under sanitary plant conditions".

5. "FDA has not established federal standards for bacteria or toxic metals, except mercury, in shellfish".

6. "A high percentage of shellfish samples exceed allowable bacteriological limits. The sample results indicated that the shellfish had fecal contamination - a potential health hazard - and probably had been harvested from improperly classified or closed growing areas. The shellfish meats also contained other contaminants such as pesticides and heavy metals".

7. "Neither approved nor closed shellfish-growing areas were monitored effectively by FDA to insure that shellfish harvested were safe to eat. Timely action was not taken to close areas that had poor water quality and low rated areas were not closed contrary to NSSP requirements".

APPENDIX VII

8. Millions of pounds of shellfish are imported into the United States that have been harvested from waters that are not certified under NSSP standards. An inequity exists in that foreign shellfishermen are not always required to harvest from certified waters only as are domestic fishermen.

The report further recommended that in order to carry out its responsibilities under the FD&C Act, FDA be directed to:

1. Use the regulatory powers under the FD&C Act in those instances where NSSP is not effective in correcting insanitary conditions.

2. Establish federal bacteriological standards of quality for shellfish and enforce them if satisfactory compliance cannot be obtained under NSSP.

3. Establish standards for toxic metals in shellfish.

4. Collect and analyze market samples of shellfish taken during inspections of shellfish plants.

To date, most of the program deficiencies cited by the 1973 GAO report still exist, and in many instances have become more critical. In addition, only a few of the recommendations outlined in the report have been undertaken. FDA has not used its authority under the FD&C Act to control the interstate shipments of potentially hazardous shellfish, even upon requests from the states.

FDA's contention that one of the reasons it has not played a more active role during the past 10 years is due to the fact that FDA's limited manpower resources have been directed towards other more critical problems. However, this is difficult to comprehend in view of the fact FDA maintains some 10 regional offices and 22 district offices manned by a staff of about 2,850, of whom approximately 700 are field investigators. Since shellfish have been involved in more than 12,000 cases of disease outbreak since 1900, it seems that the proper control of shellfish sanitation practices should be a priority of the highest order for FDA instead of the hands off, strictly advisory role it has demonstrated since 1975.

As previously stated, the ISSC was inaugurated by the states and shellfish industry as a result of FDA's inactivity in the NSSP. The primary purpose of the ISSC is to undertake shellfish sanitation controls that FDA is either unwilling or unable to enforce. Originally, ISSC was envisioned as a forum for advising FDA. However, as the United States Shellfish Sanitation Control Program continued to deteriorate in the early 1980's, efforts were directed towards replacing the NSSP with an ISSC oriented program under state control instead of the tripartite endeavor previously in effect. Under such an arrangement, the states would assume responsibility for many control functions FDA is currently unable or unwilling to perform. It is believed this is a mistake since each partner (state, federal and industry) have certain responsibilities only they can perform in order to make the program work.

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Rather than attempting to structure a totally new program under ISSC based on untried principles, it would seem more prudent to seek means of requiring FDA to fully exercise its responsibilities in the NSSP and thereby standardize state participation. The 1975 state-industry resolutions, if properly implemented, would revitalize the NSSP and accomplish in a more dependable manner the functions envisioned for the ISSC. I am convinced the NSSP can be revitalized and, with proper support, continue to provide vital public health protection to the consumer.

One of the major difficulties with the ISSC is that it has no enforcement power. A state or group of states cannot take sanctions against another state since it would undoubtedly be contrary to the commerce clause of the United States Constitution. In addition, the ISSC is not able to react quickly in an emergency and, consequently, is noneffective in solving the day-to-day problems that occur in our efforts to insure the safety of shellfish. As an example, a large number of problems needing immediate attention were presented to the annual ISSC conference held in August, 1983. The vast majority of these problems could not be remedied by the conference and accordingly were assigned to committees for further study and reports in 1984. As of this date, over seven months later, the committees have not even been established and no work started on the problems. This, unfortunately, is a prime example of the difficulties associated with attempting to solve problems through the conference approach. A much better method of dealing with such problems would be to establish enforcement capabilities at the federal level with swift response at the state and industry level. There is no way uniform state enforcement will ever be achieved cooperatively by a conference of states. There must be strong federal participation.

In accordance with a January 11, 1982 letter from Joseph P. Hile, Associate Commissioner for Regulatory Affairs, U.S. Food and Drug Administration (copy attached), "FDA does not believe that the restrictions on the agencies' authority prevent the NSSP from reasserting itself and regaining any authority it may have lost in recent years". Further, "FDA believes that it can continue to provide necessary support to the NSSP without any additional legislative authority. The agency also believes that should the states in the NSSP fail to adequately assure that the nation's shellfish are safe and wholesome, FDA has adequate legislative authority to fill the void. Because the agencies' budget for food safety makes shellfish a high priority, the agency can make adequate funds available to assume additional responsibilities if it became necessary to do so".

As stipulated in the 1973 GAO report, the NSSP drastically needed strengthening at that time. There was an abundance of evidence many states were not carrying out their responsibilities under the NSSP in 1973 and unsafe shellfish were reaching the consumer. No improvements have been made in the program since 1973 and shellfish sanitation controls have become more lax as demonstrated by the 4,678 reported cases of associated disease outbreaks in the United States and Canada since that time. In addition, FDA has not moved to carry out the many recommendations of the 1973 GAO report, but instead has elected to take an inactive role in the NSSP while the dangers to public health through the interstate

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shipment of improperly harvested or processed shellfish become more imminent with each passing day. Perhaps FDA is only waiting for a congressional mandate to carry out its responsibilities in the NSSP since, according to Mr. Hile, it is not a question of additional authority or resources.

It is believed that the only acceptable alternatives for assuring that shellfish shipped in interstate commerce are safe and wholesome for human consumption are for the Congress to direct FDA to get back in the game and carry out its responsibilities to the American people. This can be accomplished through Memoranda of Understanding with the states backed by adequate rules and regulations, or, alternatively, take strict enforcement action under the present provisions of the federal Food, Drug, and Cosmetic Act or the Public Health Service Act. To do less will eventually result in the complete loss of public confidence in the quality of shellfish and the demise of the shellfish industry.

We disagree with GAO's assumption that by FDA's assuring a central position of authority, an adversary relationship would be created between FDA and the states, and there would also be an adverse effect on state programs. This did not happen when EPA was given the authority for the Safe Drinking Water Act, and it is not believed it would happen in this instance. In fact, it strengthened state programs by giving them stature.

We are well aware of the consequences of these recommendations and stand ready to support them as necessary. We do not believe the alternatives presented in the report are the only ones that should be considered. We are further convinced that a strong federal leadership and enforcement role is essential in the shellfish control program. It is hoped GAO will recognize this concept as the best viable alternative and so recommend to the Congress of the United States.

In further reference to the 1984 GAO draft report, it is believed the following specific comments are germane:

Page ii: "The National Shellfish Sanitation Program is voluntary and FDA cannot promulgate regulations to ensure that members are adequately adhering to program requirements."

Response: FDA presently has a set of regulations that could be modified with state/industry input and promulgated under the Federal Administrative Process Act. FDA has not attempted to do this nor has it attempted to comply with the requirements imposed by the Bauman Amendment to the Coastal Zone Management Act. These are not insurmountable objectives and could be accomplished if FDA so desired. In fact, the additional 4,678 cases of shellfish associated disease outbreaks that have occurred since 1973 are justification enough to substantiate such action.

Page ii: "Law enforcement agencies, according to state officials, do not have sufficient staff or equipment to adequately enforce shellfish program requirements and patrol areas closed to shellfish harvesting."

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Response: States without adequate resources to enforce program requirements should not be permitted to ship shellfish interstate.

Page iii: "Fines assessed by the courts have generally been so low as to have little impact as a deterrent to illegal harvesting."

Response: The courts must be educated as to the importance of establishing adequate fines and penalties as a deterrent in order to protect the public health and assure the continued viability of the industry.

Page iii: "In New York, some growing areas and surrounding properties (as potential sources of shellfish pollution) have not been adequately inspected."

Response: Shellfish harvesting should be prohibited from any area that lacks a current shoreline sanitary survey supported by regular bacteriological seawater examinations. This should be enforced by FDA.

As a matter of interest, when Virginia inquired of FDA in 1983 whether or not it was safe to accept shellfish from the State of New York in light of the difficulties being experienced in that area, FDA sent a collection of reports and newspaper articles on the situation with the comment that "it was hoped the attached information would enable Virginia to determine whether or not it should receive shellfish from New York."

Page 2: "FDA is responsible under NSSP for evaluating the effectiveness of state shellfish sanitation control programs."

Response: In addition, FDA is also responsible to assure that unsafe shellfish are not shipped interstate and all states on the approved shippers list fully comply with NSSP requirements.

Page 7: "According to FDA, the proposed regulations created misunderstanding, confusion and distrust toward the agency by state officials. This caused a deterioration in federal-state relations and a breakdown in communication that was necessary to maintain the NSSP."

Response: The situation described above was primarily caused by FDA's failure to communicate with the states concerning its proposed regulations prior to attempting to promulgate them. The states were not consulted about the content of the regulations beforehand. The states were not opposed to the need for regulations, but rather the unilateral approach assumed by FDA.

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Page 8: "He maintains that because of his efforts, the proposed regulations were blocked by the states..."

Response: This is an incorrect statement. It should read, He maintains through the efforts of the states and industry, the proposed regulations were blocked...

Page 10: "Shellfish ...suspected to have caused an illness, can be traced to a shipper, but it is impossible to trace shellfish to the specific harvester or body of water from which they were harvested."

Response: While it would be helpful to be able to trace shellfish back to the specific harvester and growing area, this capability assumes limited significance provided all other facets of the shellfish control program are operating efficiently. If a state is adequately monitoring the shoreline adjacent to shellfish areas and the water overlying such areas and utilizes the information to properly classify its growing areas, and further provided there is adequate posting and patrol of condemned areas, the ability to pinpoint harvesters and growing areas becomes less significant. In other words, effort should be made to assure total growing area control rather than partial or fragmented efforts. This type of control provides the best overall protection, but is costly. The real difficulty rests with the fact that most states are not committing sufficient resources to the classification of growing areas and the patrol of condemned areas.

Page 13: "One state official believed that a strong central authority is needed if the industry is to survive."

Response: This statement should read, One state official believed that a strong central authority is needed if the consumer is to be protected.

Page 13: Alternative I - Leave authority with the states.

Response: One of the prime difficulties presently associated with the NSSP and FDA's lack of leadership is the fact that states are setting their own goals and priorities. There is a complete lack of uniformity among the states relative to carrying out the requirements of the NSSP. Each state is influenced by local politics and regional differences. Consequently, the consumer is receiving increasingly less protection as each state deviates from the NSSP mandates.

Page 16: "Alternative II - Give FDA additional authority to administer the program."

Response: This alternative is the only feasible one for assuring adequate consumer protection. Congress should be petitioned to grant specific authority to FDA to administer the shellfish program. The NSSP guidelines would become legally enforceable, and FDA would assume a central position of authority. FDA could take regulatory action against states or shellfish dealers who do not comply with program requirements.

This position could be assumed by FDA without additional resources according to Mr. Hile and, if properly coordinated with the states and industry, would not create an adversary relationship between FDA and the states.

It is recognized that even with a strong central posture, FDA cannot guarantee the states will always carry out program requirements. However, if individual Memoranda of Understanding (MOU) are executed with each state and the state is required to submit a state plan for controlling its shellfish industry, FDA would be in a much better position to evaluate and enforce compliance. This could probably best be accomplished through the chief executive of each state. The submittal of a state plan and execution of an MOU should be prerequisites to FDA endorsement of state shellfish programs.

Page 17: Alternative III - Formation of a Cooperative Federal/State/Industry Program.

Response: We had such a program under NSSP prior to FDA's inactivity. For the reasons enumerated above, a program such as the ISSC will not work. The ISSC can serve as a valuable forum for discussing problems and making recommendations to FDA, but it cannot carry out the necessary enforcement procedures.

Page 27: "In the recent meeting of ISSC, a potentially serious disagreement among a number of states concerning the reasons for a high level of bacteria in harvested shellfish was aired, debated and brought to a conclusion which has apparently satisfied the states involved. FDA, in an advisory capacity, played an important role in the compromise and final solution." [See GAO note below.]

Response: FDA's primary role in this problem was to conduct a limited study concerning specific growing areas in Louisiana and the bacteriological quality of shellfish harvested therefrom. FDA took very little part in the deliberations concerning changing the bacteriological standard from fecal coliform

GAO note: Paragraph deleted from the final report.

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to E. coli. In fact, FDA stated publicly after the ISSC agreement that it did not support the change, and advised those receiver states under contract to FDA to continue to utilize the fecal coliform standard in its surveillance activities. If FDA did not agree with the ISSC decisions, it should have taken a strong stand when they were considered.

The disadvantages of alternative III such as the inability of committees to function in a timely manner, the lack of a legal basis for enforcement action and the possibility that industry may be in a position to influence public health matters far outweighs the insignificant advantages of this alternative.

These comments are presented only as a constructive attempt to find a solution to a very complex and critical problem with serious potential health concerns. The comments are in no way intended to be critical of any person, state or agency.

It is hoped GAO will reconsider its draft report on the basis of these observations and will initiate the effort necessary to revitalize the National Shellfish Sanitation Program and provide better assurance to the consumer that shellfish offered in the market are indeed safe and wholesome.

Thank you for the opportunity to comment on this draft document.

Sincerely,

Cloyde W. Wiley

Cloyde W. Wiley, Director
Bureau of Shellfish Sanitation

Enclosures

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