REPORT TO THE CONGRESS

Protecting The Consumer From Potentially Harmful Shellfish (Clams, Mussels, And Oysters) B-164031(2)

Food and Drug Administration
Department of Health, Education,
and Welfare

BY THE COMPTROLLER GENERAL OF THE UNITED STATES

MARCH 29, 1973

COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON D C 20548

B-164031(2)

To the President of the Senate and the
Speaker of the House of Representatives

This is our report on protecting the consumer from potentially harmful shellfish (clams, mussels, and oysters). The Food and Drug Administration, Department of Health, Education, and Welfare, is responsible for administering activities discussed in this report.

We made our review pursuant to the Budget and Accounting Act, 1921 (31 U.S.C. 53), and the Accounting and Auditing Act of 1950 (31 U.S.C. 67).

We are sending copies of this report to the Director, Office of Management and Budget, and to the Secretary of Health, Education, and Welfare.

Elmer B. Staats

Comptroller General
of the United States

Contents

ABBREVIATIONS

CDC	Center for Disease Control
FDA	Food and Drug Administration
FD&C Act	Food, Drug, and Cosmetic Act
GAO	General Accounting Office
HLW	Department of Health, Education, and Welfare
NSSP	National Shellfish Sanitation Program
PHS	Public Health Service

COMPTROLLER GENERAL'S REPORT TO THE CONGRESS

PROTECTING THE CONSUMER FROM POTENTIALLY HARMFUL SHELLFISH (CLAMS, MUSSELS, AND OYSTERS) Food and Drug Administration Department of Health, Education, and Welfare B-164031(2)

D I G E S T

WHY THE REVIEW WAS MADE

The General Accounting Office (GAO) wanted to know whether the National Shellfish Sanitation Program (NSSP)--a voluntary, tripartite cooperative program of Federal, State, and shellfish industry representatives--is effectively insuring that potentially harmful shellfish are not reaching the American consumer and that imported shellfish are meeting U S domestic standards

Background

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 Shellfish, as defined under NSSP, include all edible species of oysters, clams, and mussels, either shucked or in the shell, fresh or frozen Processed shellfish, whether domestic or imported, are monitored by FDA under the FD&C Act

For fresh and frozen shellfish shipped interstate, FDA seldom uses the regulatory powers of the FD&C Act but relies, instead, on its participation in NSSP

FDA administers this tripartite program for the Federal Government FDA annually reviews each State's compliance with NSSP requirements and endorses, or withholds endorsement of, a State's program If FDA withdraws its endorsement of a State's program, other member States must refuse shellfish shipments from that State

There are 20 shellfish-producing States During 1971 about 136 million pounds of shellfish were harvested by these States and another 16 million pounds were imported

About 2 million acres of the national shellfish-harvesting acreage, or about 20 percent, have been closed to domestic harvesting because of contaminated waters. About 1,620 shellfish plants are certified under the program to ship their products in interstate commerce

GAO reviewed selected activities of four shellfish-producing States--Maryland, Massachusetts, New York, and Washington--to assess the effectiveness of the four FDA district offices responsible for monitoring the activities of these States These shellfish-producing States accounted for about 53 percent of the dollar value of the national shellfish production in 1971

GAO asked FDA to analyze water samples collected from 10 approved

growing areas in these States and accompanied FDA on its inspection of 30 shellfish plants selected by GAO These plants represent about 5 percent of the certified plants in the four States and account for about 11 percent of the shellfish sales by these States

Shellfish meat samples were collected during the plant inspections, and, at GAO's request, FDA analyzed them for bacteria counts and for the presence of toxic metals--mercury, lead, and cadmium--and pesticides

GAO also used water and shellfish meat sample results previously collected and analyzed by the States to evaluate the timeliness of State actions and the effectiveness of FDA monitorship under the program

FINDINGS AND CONCLUSIONS

Overall findings

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

2 FDA is not adequately monitoring the States to insure that shellfish reaching the consumer are pure, safe, and wholesome

3 The States included in GAO's review are not fulfilling their responsibilities for insuring that shellfish are harvested from only safe waters and are processed under sanitary plant conditions

Potentially harmful shellfish reaching the consumer

There is a potential health hazard associated with eating contaminated shellfish because they can carry infectious viral hepatitis, typhoid, salmonellosis, certain forms of gastroenteritis, and polio.

FDA has not established Federal standards for bacteria or toxic metals, except mercury, in shellfish and has not requested the Environmental Protection Agency--which regulates pesticides--to establish pesticide standards. Instead, FDA relies upon the States to enforce the NSSP bacteriological and pesticide standards Toxic metal guidelines which NSSP has had under consideration for several years have not yet been made a part of the program

Analyses of shellfish meat samples furnished to FDA by 14 States in 1970 showed that 24 percent of the samples exceeded allowable limits under the NSSP bacteriological standards Of the samples analyzed during 1971 by the four States included in GAO's review, 31 percent exceeded the allowable limits. (See pp 14 and 15.)

An FDA analysis of shellfish meat collected during the joint FDA-GAO plant inspections showed that 17 percent of the samples exceeded 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 (See p 15.)

The shellfish meat samples also contained other contaminants (See p 16)

The States are not required to sample shellfish FDA is not required under NSSP to evaluate States' sampling programs that do exist and does not generally collect shellfish samples during its own plant inspections

Of the four States reviewed, one had a State-wide market-sampling program, two had limited programs, and one had no meaningful program Neither FDA nor the four States routinely trace violative shellfish to their source to determine whether the waters are misclassified and unsafe for harvesting (See p 17)

Need for improved monitoring of shellfish-growing waters

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 States have not always adequately posted or patroled closed growing areas to deter illegal harvesting (See p 23)

Plant sanitation conditions

Of the 30 shellfish plants[1] inspected by FDA at GAO's request, 12, or 40 percent, had insanitary conditions, of which 8, or about 27 percent, were considered to be significant

FDA is not aware of industrywide sanitation conditions because of the limited number of inspections and methods of selecting plants to be inspected FDA plant evaluation procedures do not give adequate consideration to the effectiveness of States' actions to obtain correction of prior insanitary conditions or to the significance of current plant deficiencies FDA does not notify violators officially of sanitation standards violated or monitor cases to promote corrective action (See p 35)

Control over imported shellfish

About 15 8 million pounds of fresh, frozen, and processed (cooked, smoked, etc) shellfish were imported into this country in 1971, of which 12 4 million pounds were harvested from waters uncertified under NSSP standards Since the quality of the shellfish harvested and the conditions under which they were processed were unknown, the domestic safeguards to insure the marketing of safe and sanitary shellfish were not always available Further, an apparent inequity exists in that foreign shellfishermen are not required to harvest from only certified waters (See p 48)

RECOMMENDATIONS

With respect to NSSP, GAO recommends that the Secretary, HEW, direct the Commissioner, FDA, to

--Notify States to close growing areas rated below standard unless the States justify, in writing,

[1]The names of the plants are included in appendix XII

that there is no health hazard (See p 33)

--Develop with the States a systematic survey plan for monitoring all growing areas, including a minimum number of sampling stations and frequency of sampling (See p 33.)

--Develop an effective patrol program with each State specifying frequency of patrols and posting criteria for closed areas (See p 33)

--Withdraw endorsement of a State's program if the State does not take aggressive and timely action to correct program deficiencies relating to control over approved and closed growing areas (See p 33)

--Annually assess the overall sanitation conditions of a representative number of shellfish plants (See p 46)

GAO has also recommended a number of changes for incorporation into NSSP The changes, if enacted by the tripartite, will strengthen the existing program by requiring the States to have an effective market-sampling program and to consider the significance of conditions found and the adequacy of followup actions when evaluating plant inspection activities (See pp 20, 33, and 47)

Additionally, to carry out its responsibilities under the FD&C Act, GAO recommends that the Secretary, HEW, direct the Commissioner, FDA, to

--Use the regulatory powers under the FD&C Act in those instances where NSSP is not effective in correcting insanitary conditions. (See p 47)

--Establish Federal bacteriological standards of quality for shellfish and enforce them if satisfactory compliance cannot be obtained under NSSP (See p 20)

--Establish Federal standards for toxic metals in shellfish and request the Environmental Protection Agency to establish standards for pesticides in shellfish. (See p 21)

--Collect and analyze market samples of shellfish meat taken during inspections of shellfish plants (See p. 21)

--Issue written notices in all cases where FDA finds insanitary conditions in shellfish plants and request written responses on action taken or planned to correct the violations and to insure continued compliance (See p 47)

--Obtain and monitor the results of all State inspections of shellfish plants and the followup actions taken when insanitary conditions are found (See p 47)

AGENCY ACTIONS AND UNRESOLVED ISSUES

GAO submitted drafts of this report to the Secretary, HEW, the State agencies responsible for shellfish activities in the four States included in GAO's review, and a representative of the shellfish industry, for comments

The recipients agreed generally with the findings discussed in the report HEW concurred in GAO's recommendations and advised that a

number of corrective actions had been, or would be, taken (See pp 21, 34, and 47)

HEW stated that one of the principal reasons FDA had not played a more active role during the last several years was due to the fact that FDA's limited manpower resources have been directed toward attempting to cope with what appeared to be even more critical problems, such as microbiological contamination and drug hazards

Need for additional substantive increases in FDA staffing for inspection activities has been recognized by the President, HEW, and FDA, according to HEW, and a substantial increase for such activities was included in the Department's most recent (fiscal year 1973) budget request

Comments of State agencies and shellfish industry representatives are discussed on pages 54 through 59

MATTERS FOR CONSIDERATION BY THE CONGRESS

The Congress should consider enacting legislation which permits importing fresh, frozen, and processed shellfish from only those countries that harvest and process shellfish under conditions which are at least equal to domestic standards to insure that only safe and wholesome shellfish are imported

Under the Federal Meat Inspection Act, a similar requirement exists to insure that imported meat has been slaughtered and processed under conditions at least equal to domestic standards (See p. 52)

CHAPTER 1

INTRODUCTION

The programs of the Food and Drug Administration (FDA), Department of Health, Education, and Welfare (HEW), are directed at a single overall objective--consumer protection. Among other things FDA's mission is to insure that food (including shellfish) is safe, pure, and wholesome, that drugs and therapeutic devices are safe, effective, and properly labeled, and that certain consumer products are presented honestly to the public.

One of FDA's responsibilities under the Food, Drug, and Cosmetic Act, (FD&C Act), as amended (21 U.S.C. 301), is to insure that food (including shellfish) shipped or received in interstate commerce is processed under sanitary conditions. If FDA finds adulterated products or insanitary plant conditions that may cause adulteration, it can initiate one or more of the following legal actions through the Department of Justice.

--Prosecution of an individual who violates provisions of the FD&C Act.

--Enjoinder of a plant or individual to perform or not perform some action.

--Seizure of any food that is adulterated or misbranded when introduced into, or while in, interstate commerce.

In practice, FDA seldom uses the regulatory powers of the FD&C Act to assure itself that fresh and frozen shellfish are safe and sanitary but, rather, relies on its participation in the National Shellfish Sanitation Program (NSSP) to achieve this purpose. Processed shellfish, whether domestic or imported, are monitored by FDA under the FD&C Act.

The purpose of NSSP is to prevent shellfish-borne illness by controlling the shellfish-growing areas and sanitary conditions at plants which handle fresh or frozen shellfish. It is a voluntary, tripartite, cooperative program of Federal, State, and shellfish industry representatives established in 1925 at the request of State and local health authorities and industry representatives, following

a major outbreak of typhoid fever in the United States attributed to sewage-polluted oysters. In establishing or modifying program requirements, each group in the program has an equal number of votes and a two-thirds majority vote is required to effect a program change. FDA is responsible for insuring that proposed changes do not conflict with Federal laws and regulations.

At the Federal level, NSSP was initially administered 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, FDA assumed responsibility for administering the program.

FDA is administered by a Commissioner under the direction of the HEW Assistant Secretary for Health. Policies and procedures are established at FDA's headquarters, Rockville, Maryland, and operations are carried out by 19 district offices in the United States and Puerto Rico. Six FDA districts monitor the activities of the 20 shellfish-producing States, all of which are members of NSSP. (See app. I.) FDA also encourages inland States to monitor the quality of shellfish received from producer States.

FDA's appropriation for fiscal year 1972 was about $110 million, of which about $1.1 million was for NSSP and related research activities. According to FDA, NSSP member States spend about $6 million annually for shellfish activities.

Shellfish, as defined in the NSSP Operations Manual, are all edible species of oysters, clams, and mussels, either shucked or in the shell, fresh or frozen. (See photograph on p. 9.) The 1971 commercial shellfish harvest in the United States was about 136 million pounds worth about $149 million. An additional 16 million pounds were imported. The shellfish harvested in the four States included in our review accounted for about 53 percent of the value of the 1971 national production.

The quality of shellfish is directly related to the waters in which they grow and feed. Most shellfish live in coastal zones--called growing areas--where sea water and fresh water mix. Because they feed by pumping water through their bodies, they accumulate micro-organisms, chemicals, and toxic metals from their marine environment. Since

people frequently eat partially cooked or raw shellfish, a health hazard may be present if the shellfish were harvested from contaminated waters.

The types of shellfish covered by NSSP Clockwise from extreme left sea clam, mussel, hard shell clam, soft shell clam, and oyster

NSSP consists of eight program elements on which FDA rates member States. The NSSP member States are required to adopt adequate laws and regulations to insure control of sanitation in the shellfish industry and, among other things, must

--Survey shellfish-growing areas to identify pollution sources that could adversely affect the waters and test the waters for bacteriological quality.

--Post growing areas that are unsafe for shellfish harvesting and patrol such areas to deter illegal harvesting.

--Inspect shellfish plants for compliance with NSSP sanitation standards.

--Provide evidence to FDA that the above and other program elements have been met. (See app. II.)

NSSP also has set bacteriological standards for shellfish at the wholesale market level. Shellfish harvested from approved growing areas and handled in accordance with NSSP criteria are considered safe for consumption if they meet these standards. (See photographs on p. 11.)

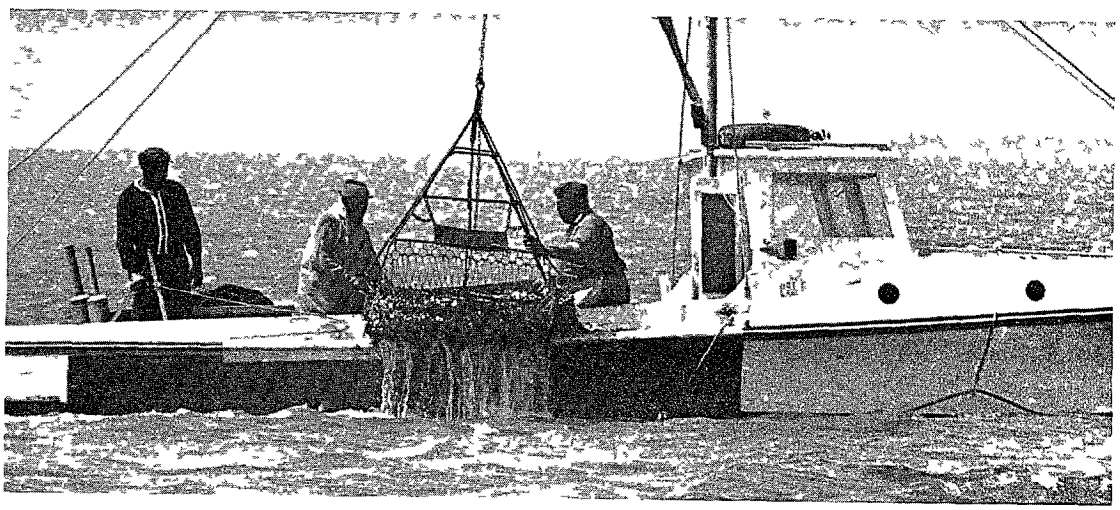
FDA reviews annually each State's compliance with NSSP requirements and endorses or withholds endorsement of a State's program. To qualify, a State must receive a rating of at least 70 percent for each of the eight program elements. A State is given 90 days to correct elements rated below 70 percent. FDA's endorsement signifies to third parties that the State has met the NSSP requirements. If FDA withdraws its endorsement of a State's program, the names of the shellfish plants in that State are no longer listed in FDA's semimonthly publication of interstate shellfish shippers. According to FDA, NSSP member States must refuse shellfish shipments from States which lose endorsement.

Industry's role under NSSP is to obtain shellfish from safe sources, maintain plants which meet program sanitation standards, and keep records of the origin and disposition of shellfish.

The General Accounting Office (GAO) reviewed NSSP's effectiveness of insuring that shellfish are harvested from waters which meet program bacteriological standards, that potentially harmful shellfish are not reaching the consumer, and that imported shellfish meet our domestic standards.

Furnished by the Food and Drug Administration

Shellfishermen tonging oysters



Furnished by the Food and Drug Administration

Vessel dredging for sea clams

CHAPTER 2

POTENTIALLY HARMFUL SHELLFISH REACHING THE CONSUMER

There is a potential health hazard associated with eating contaminated shellfish, because they can carry infectious viral hepatitis, typhoid, salmonellosis, certain forms of gastroenteritis, and polio.

FDA is responsible under the FD&C Act for insuring that shellfish shipped or received in interstate commerce are pure, safe, and wholesome. Rather than independently establish criteria applicable to domestic shellfish, FDA relies on its participation in NSSP to fulfill this responsibility. Bacteriological and some pesticide standards have been established under NSSP to determine the quality of shellfish at, among other places, the wholesale market level. Shellfish meeting these standards are considered safe for human consumption.

Sample analyses showed that enough shellfish not meeting NSSP bacteriological standards are reaching the consumer for us to question NSSP's effectiveness. Further, shellfish market-sampling programs in three of the four States included in our review were inadequate and prompt or effective followup action was not always taken when samples exceeded the bacteriological limits provided by the standards.

SHELLFISH EXCEEDING BACTERIOLOGICAL LIMITS

Shellfish having a fecal coliform[1] count of 230 or less and a total plate count[2] of 500,000 or less are satisfactory and presumed safe for consumption according to NSSP.

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[1]Fecal coliform--a health hazard indicator--is bacteria which indicate the presence of fecal pollution and other harmful bacteria.

[2]Plate count is the total bacteria present and indicates whether shellfish have been handled properly, e.g., held under proper temperature, processed under sanitary conditions--improper handling indicator.

Guidelines for interpreting sample results state that shellfish with a high fecal coliform count and a low plate count were probably harvested from an improperly classified growing area and are potentially hazardous. Shellfish with high fecal coliform and plate counts are also considered potentially hazardous and may have been harvested from waters not meeting approved growing area criteria. NSSP requires the States, in these situations, to take investigative or corrective actions. In either case, the possibility also exists that such shellfish could have been illegally harvested from closed growing areas. (See ch. 3.)

In April 1969 an FDA shellfish laboratory official concluded that bacteria counts in shellfish were excessive beyond reasonable expectations and were an extreme public health hazard. Data supporting this statement included the results of 33 samples from 3 States which showed that 17 samples, or about 51 percent, exceeded the fecal coliform limit of 230 and that 12 samples, or about 36 percent, had fecal coliform counts of over 1,600.

In discussing the potential health hazard associated with the consumption of shellfish that exceed NSSP bacteriological limits, FDA and State shellfish officials advised us that shellfish with fecal coliform counts in excess of about 900 to 1,000 would be cause for alarm. According to FDA officials, the potential health hazard increases as the fecal coliform counts increase.

One State included in our review which allows shellfish to be harvested from restricted waters[1] will immediately close such growing areas if fecal coliform counts exceed 1,600. According to FDA, there is a greater hazard associated with fecal coliform counts in the range of 1,600 at

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[1]Under certain conditions, NSSP permits the harvesting of shellfish from growing waters of marginal quality. Shellfish obtained from such sources must be purified at plants with approved purification procedures. Only one such plant was in operation at the time of our review. Conditions at this plant are discussed on p. 43.

time of harvest than with fecal coliform counts of 1,600 at the wholesale market. FDA explained that, because this health hazard indicator organism may multiply when shellfish are removed from the water, a high fecal coliform count at or near the time of harvest is more indicative that the shellfish and growing areas may be contaminated with fecal pollution and other harmful bacteria.

In November 1970 FDA became increasingly concerned with the bacteriological quality of market shellfish and viewed the situation as a serious public health threat. At that time FDA surveyed shellfish-producing States to determine the number, source, and results of shellfish samples that had been analyzed by shellfish-producing States. Although FDA planned to use this data to determine whether shellfish were meeting the bacteriological standards, we were told that due to resource limitations the data was never fully evaluated.

Our review of the results of 2,700 shellfish samples obtained by FDA from 14 States during the survey showed that the bacteriological standards were not met in 638, or about 24 percent, of the samples. The fecal coliform limit--the health hazard indicator--was exceeded in 548, or about 20 percent, of the samples. The plate count limit--the improper handling indicator--was exceeded in 166, or about 6 percent, of the samples. Of the 638 samples, 76, or about 3 percent, exceeded the allowable limits for both fecal coliform and plate counts. The following schedule summarizes the results of samples exceeding allowable limits.

	High fecal coliform count (note a)	High fecal coliform (note a) and high plate count (note b)	High plate count (note b)	Samples exceeding limits
Fecal coliform counts				
231 to 900	214	16	-	230
901 to 1,600	55	10	-	65
Over 1,600	203	50	-	253
High plate count only	-	-	90	90
Total	472	76	90	638
Percent of 2,700 samples	17 5	2 8	3 3	23 6

[a]Samples with fecal coliform count over 230

[b]Samples with plate count over 500,000

According to FDA, the data analyzed might not be representative of the true bacteriological quality of shellfish meats reaching retail markets and the consumer.

The four States included in our review collected and analyzed shellfish meat samples during calendar year 1971. Analysis results available to us at the time of our review showed that 333, or 31 percent, of 1,085 samples exceeded the allowable limits, as shown below.

State	Samples	High fecal coliform counts: 231 to 900	901 to 1,600	Over 1,600	High plate counts	Samples exceeding limits: Number	Percent
A	191	31	12	59	9	111	58
B	226	49	6	37	1	93	41
C	631	42	18	63	4	127	16
D	37	2	-	-	-	2	5
Total	1,085	124	36	159	14	[a]333	31

[a]Includes 26 samples of shellfish shipped to State A from one other State, 70 samples shipped to State B from 7 States, and 53 samples shipped to State C from 8 States.

It should be noted that 319 samples, or 29 percent, exceeded the fecal coliform limit of 230 and that almost one-half of these were in excess of 1,600, about 7 times the limit.

ANALYSIS OF SHELLFISH SAMPLES COLLECTED DURING FDA-GAO PLANT INSPECTIONS

To find out if potentially hazardous shellfish were still reaching the wholesale market and thus the consumer, we had FDA collect shellfish samples at the plants we visited to inspect sanitation conditions. (See ch. 4.)

Of 92 samples collected, 17 percent exceeded allowable limits. Shellfish at 11 plants in 4 States exceeded the fecal coliform limit of 230 and at 2 plants in 2 States exceeded the plate count limit of 500,000. The results of the violative samples are shown below.

	High fecal coliform count	High fecal coliform and high plate count	High plate count	Total
Fecal coliform counts				
231 to 900	6	-	-	6
901 to 1,600	2	-	-	2
Over 1,600	6	1	-	7
High plate count only	-	-	1	1
Total	14	1	1	16
Percent of 92 samples	15	1	1	17

Because it takes 1 to 2 weeks until sample analysis results are known, shellfish from the lots sampled probably reached the consumer.

Analysis for other contaminants

The shellfish samples taken at our request were also analyzed for mercury, lead, cadmium, and various pesticides, and several samples were found with significant amounts of these contaminants. (See app. XI.) Although some pesticide tolerance guidelines have been established under NSSP, none have been established for toxic metals in shellfish and those proposed by FDA were rejected by the program participants.

FDA officials said they had proposed certain guideline levels for toxic metals in shellfish to the State and industry representatives in October 1971 at the annual NSSP conference. These levels were based on data collected from four major shellfish-harvesting areas in the United States. Due to the lack of adequate toxicity data, FDA decided to use these levels as an indicator of metals pollution in shellfish-growing areas. These levels, according to FDA, would have provided State health authorities with a method of detecting any increase in metals contamination in growing areas and thereby permit the States to take action in locating new sources of pollution before the metals in shellfish reached a dangerous level.

FDA further stated that, due to the opposition of the shellfish industry because it feared bad publicity and due to the wide span of data reported caused by variation in the laboratory procedures used by analysts, both industry and State NSSP representatives felt that further work was needed particularly in the area of toxicology before any guideline levels could be set for metals in shellfish.

According to FDA, it would have to establish a research component if it were to maintain current and valid scientific standards. FDA stated that a research component would enable it to study and establish microbiological standards of quality, to determine the need for setting metal tolerances in shellfish, and to investigate pesticide contamination of shellfish. FDA explained that NSSP lost two shellfish laboratories and related scientific research personnel when PHS was reorganized in 1968 and NSSP was transferred to FDA. This viewpoint is shared by others participating in NSSP. (See p 57.)

Toxic metals

We found that 4, or 12 percent, of the 34 shellfish samples analyzed for toxic metals contained cadmium in excess of FDA's proposed alert levels. Sample results for mercury and lead did not exceed proposed alert levels

FDA said it would establish enforcement standards for metals for marine foods as toxicity data is developed and that it would take action when excessive levels of metals constituting a health hazard are found.

Pesticides

Two samples exceeded the NSSP limits provided by the guidelines for the pesticide chlordane. FDA advised us that these guidelines were established in 1968 before any wholesale survey was made of pesticides in shellfish and that it was collecting additional data on pesticides in shellfish

LIMITED MARKET-SAMPLING PROGRAMS

Although NSSP has bacteriological market standards, the States are not required, but are encouraged by FDA, to have market-sampling programs Consequently, FDA is not required

by NSSP to evaluate the States' market-sampling activities. FDA generally does not collect shellfish samples during its plant inspections.

Of the four States reviewed, only one had a State-wide market-sampling program. The programs of two States were limited to monitoring specific market areas. The fourth State analyzed only 28 samples a year and had no meaningful market-sampling program.

INADEQUATE FOLLOWUP ACTION WHEN SHELLFISH SAMPLES EXCEED LIMITS

Although the NSSP guidelines state that high fecal coliform counts indicate that the shellfish may have been harvested from polluted waters, we found little evidence that either FDA or the States were reappraising the growing areas for compliance with the NSSP water quality criteria when samples exceeding allowable limits were found.

Officials in the three States which have market-sampling programs advised us that, when sample results exceeded allowable limits, they generally obtained followup samples at the plants involved but did not routinely reappraise the areas from which the samples had been obtained. None of the growing areas from which 16 violative samples were collected by FDA at our request had been reappraised by either FDA or the States.

Further, sample results which exceed limits were not being used to identify harvesters for followup action.

Also State records showed that in one instance, where sample results from three different plants identified a single growing area as the source of the problem, the State had not closed the area even though water samples indicated that certain sections of the area should have been closed. After we brought this to FDA's attention, FDA said that a recommendation would be made to the State to immediately close most of the area because the water did not meet NSSP criteria FDA advised us in June 1972, 6 months after the problem growing area was identified, that the State was reappraising the area.

FDA also did not collect market samples in the four States reviewed and did not effectively use State and city[1] sample data. For example, in one case where a city had a more extensive sampling program than the State, FDA did not know what use was made of the sample data. The results could be used for identifying problem areas. In another State, although FDA maintained a log of State sample results exceeding allowable limits, apparently the data was not used.

CONCLUSIONS

FDA has not developed Federal shellfish bacteriological standards that are enforceable under the FD&C Act. Rather, it encourages participating States to enforce the NSSP standards.

Quantities of shellfish at the wholesale market level do not meet the NSSP bacteriological standards, and a high percentage of these shellfish have high fecal coliform counts which the program defines as being potentially hazardous. Although program criteria state that high fecal coliform counts indicate that the shellfish came from improperly classified areas, neither FDA nor the States included in our review routinely trace shellfish with high counts to the growing areas to determine whether the waters were misclassified. Even after an area was identified as the source of shellfish with high fecal coliform, FDA and the State did not act effectively to determine the quality of the water.

Three of the four States did not have comprehensive market-sampling programs. Market and in-plant sampling of shellfish is a means of objectively assessing whether shellfish going to the consumer have been harvested from approved growing areas and handled in a sanitary manner Market sampling should be made a program requirement and FDA should monitor it.

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[1] Although not NSSP participants, some large cities monitor the quality of shellfish at the market level with local public health programs.

FDA, although responsible under the FD&C Act for insuring that shellfish introduced into interstate commerce are pure, safe, and wholesome, has not established criteria to act against plants or States whose shellfish do not meet these requirements, i.e , Federal tolerance levels have not been established for bacteria or for toxic metals except for mercury. Further, FDA has not requested the Environmental Protection Agency--which regulates pesticides--to establish pesticide tolerance for shellfish. The research capabilities of FDA have not been reviewed, and therefore we have no comment about the adequacy of such capability.

RECOMMENDATIONS TO THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE

We recommend that the Secretary, HEW, direct the Commissioner, FDA, to

--Propose to the States and industry the following changes for incorporation into NSSP

1. A requirement that States have a market-sampling program to insure coverage of all interstate shellfish shippers. FDA should evaluate this program annually.

2. A requirement that States take followup actions when meat samples in excess of limits are found indicating a problem attributable to the growing waters. These actions should include recording violations by harvester and growing area, formally notifying the harvester, analyzing shellfish and water samples from the growing area, and closing growing areas from which shellfish with bacteria counts in excess of limits have been harvested.

Additionally, to carry out its responsibilities under the FD&C Act, we recommend that the Secretary, HEW, direct the Commissioner, FDA, to

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

--Establish Federal standards for toxic metals in shellfish and request the Environmental Protection Agency to establish standards for pesticides in shellfish.

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

HEW concurred in our recommendation for a proposed change to NSSP to require States to have a market-sampling program and stated that FDA also planned to conduct microbiological studies and to review available data to establish microbiological standards of quality for market shellfish enforceable by FDA.

On our recommendation for a proposed change to NSSP that States take followup actions when meat samples in excess of limits are found indicating a problem attributable to the growing waters, HEW stated that the same objectives could be accomplished by establishing Federal microbiological regulatory limits which, if exceeded, would unequivocally implicate shellfish harvested from polluted waters. Until such a limit is set, FDA will try to get States to close growing areas where data is suggestive of producing potentially hazardous shellfish.

We concur with HEW's alternative proposal as long as needed followup actions, if any, will be accomplished in accordance with the establishment of Federal microbiological regulatory limits.

According to HEW, it has established an enforcement guideline for mercury in marine foods including shellfish and will (1) develop standards of quality for shellfish as supportive scientific evidence permits, (2) establish enforcement guidelines for metals for marine foods as toxicity data is developed, and (3) discuss the possibility of setting tolerances for pesticides with the Environmental Protection Agency.

HEW has advised us that FDA will collect "in-line" and finished product samples during shellfish plant inspections when there is reason to believe that the plants may be operating under insanitary conditions whereby the products may be contaminated with filth. We believe, however, that FDA

should not limit shellfish sample collections to only those plants that have insanitary conditions, but rather should collect samples during all plant inspections to identify shellfish which may have become contaminated before entering the plants.

CHAPTER 3

MONITORING OF SHELLFISH-GROWING WATERS SHOULD BE IMPROVED

FDA has not effectively monitored States' efforts to control both approved and closed growing areas to insure that shellfish are harvested only from safe waters and has endorsed States' programs even though NSSP requirements were not met Also, some States are not insuring that open growing areas are safe and in some instances have not reappraised areas despite indications that the waters are questionable, if not polluted. Further, States have not always adequately posted or patrolled closed growing areas to deter illegal harvesting

To insure that only safe shellfish are harvested, the State must survey open growing areas to check water conditions for pollution and post and patrol closed areas to prevent the harvesting of unsafe shellfish The underlying assumption of NSSP is that shellfish harvested from waters meeting its growing-areas criteria are safe for human consumption. For an area to be classified approved (open) under NSSP, not more than 50 percent of the water samples can exceed the coliform (bacteria) water standard of 70 and not more than 10 percent of the samples can exceed a coliform count of 230[1] unless it can be shown that the coliform organisms are not of direct fecal origin Additionally, the area cannot be so contaminated with industrial wastes or other pollutants that consumption of shellfish might be hazardous

As a part of FDA's evaluation of State programs, a numerical rating is given for the quality of the States' work to control shellfish-growing areas This rating is reduced if the water quality data is not current

[1]One State we reviewed has a limit of 330 because of the NSSP-approved laboratory method used.

LOW-RATED GROWING AREAS NOT CLOSED

States must comprehensively survey each shellfish-growing area before approving it for harvesting. The survey, required every 10 years, includes bacteriological analyses of the waters, observation of shoreline conditions to identify actual or potential sources of pollution, and an evaluation of hydrographic (wind, currents, etc.) factors. States are also required to reappraise each open area biennially to identify changes affecting classification.

FDA reviews annually the quality and timeliness of the State's work in evaluating open areas. A numerical rating is given for the quality of the work, and appropriate reductions are made if reappraisal is over 2 years old The average rating for these areas must be at least 70 percent for program endorsement Areas rated less than 70 percent will ordinarily be closed.

Two of the four States included in our review had not closed low-rated areas. Because FDA did not rate the third State during the 2-year period ended June 30, 1970, we could not determine the total number of areas that would have been rated low. However, in 1971 FDA gave 24 of the 47 areas in this State low ratings and data showed that at least four areas would have been rated low in 1970. The fourth State did not have a low-rated area.

In its 1971 evaluation of one of the two States that did not close low-rated areas, FDA rated 116 of the State's 126 open areas below 70 percent and gave an average rating for all areas of only 22 percent In December 1970, after noting that many low-rated areas were open, we questioned FDA's endorsement of this State's program FDA advised the State in February 1971 that 24 open low-rated areas needed reappraisals to justify the approved status. In April 1972, at the conclusion of its 1971 evaluation, FDA again advised the State that reappraisals were still needed for 21 of these areas and for 95 others. In addition, FDA recommended immediately closing 20 of these areas because of contamination, including 10 referred to the State in February 1971. State officials advised us in May 1972 that, although 19 of the 20 areas identified for immediate closure were still open, actions had been initiated to close them. They also stated that work had not been done to justify the open status

of the additional 96 low-rated areas and that it would take a year or more to accomplish it with current resources.

In its most recent (1970) evaluation of the second State which did not close low-rated areas, FDA gave low ratings to 17 of the 38 areas and an average rating of 55 percent for all growing areas. According to FDA, the State did not analyze the growing area data or prepare written justification supporting the approved classification--a requirement of NSSP. In March 1972, 9 months after being notified of the low ratings, the State had completed comprehensive resurveys and written appraisals on only 38 percent of the areas. FDA previously rated one of the areas low and later closed part of the area as a result of the survey. FDA advised us in June 1972 that the State had still not reevaluated seven of the areas.

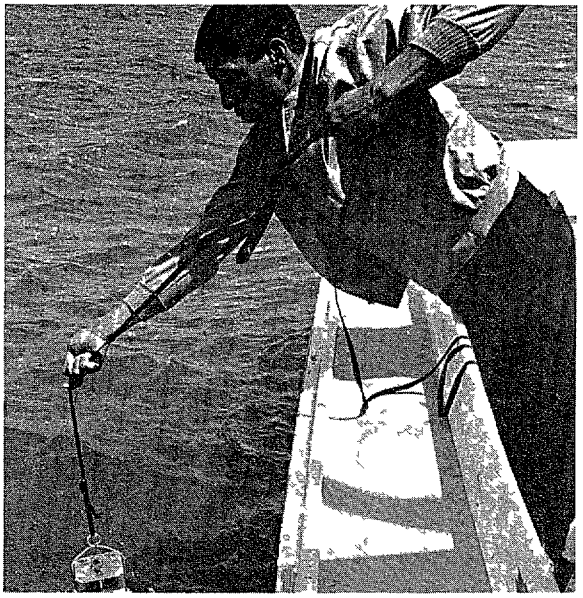
We believe the lack of current and valid water quality data to be the most significant of the several factors contributing to the low ratings FDA concluded in its most recent evaluation of growing areas in the four States that insufficient bacteriological data precluded an adequate assessment of the water quality in some areas. In two States FDA noted that the water-sampling stations in some areas were incorrectly located, in three States water samples were not taken during the most unfavorable hydrographic conditions, contrary to NSSP requirements, and some areas had insufficient numbers of sampling stations, and in all four States the water samples collected and analyzed were inadequate to permit assessing the water quality of some growing areas. A systematic sanitary survey plan mutually acceptable to FDA and the States is needed for each approved area. (See photographs on p. 26 of water samples being collected for bacteriological analyses.)

UNTIMELY ACTION TO CLOSE QUESTIONABLE GROWING AREAS

Three States did not act quickly to close growing areas which did not meet NSSP water quality criteria.

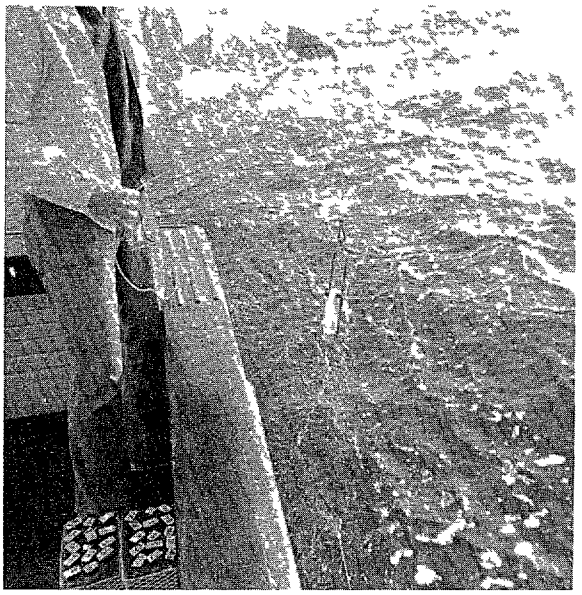
One State's records indicated that four areas should have been closed at least a year earlier. For example, one area did not meet NSSP criteria in September 1970 but was open through November 1971--a period of 14 months. In a

fifth area, harvested shellfish meat had been repeatedly found to contain bacteria counts in excess of limits allowable under NSSP market standards. (See ch. 2.) This area was still open at the conclusion of our fieldwork in



Furnished by the Food and Drug Administration

Sanitarian obtaining water sample from the bottom of an oysterbed for bacteriological analysis



Collection of water samples from shellfish growing area

May 1972, 4-1/2 months after the State knew of the problem. According to State officials who were resurveying the area, decisions to reclassify waters take much thought and analysis because of political and economic implications.

Another State's analyses of 10 of 14 water samples obtained from one area during July and August 1968 showed bacteria significantly in excess of the NSSP limits, but the State had not closed the area or obtained additional water samples. In view of the sample results, we asked FDA to evaluate this area during its 1971 review. FDA, using the same 1968 data, recommended that the State close it.

The third State's 1970 data indicated that water samples taken at certain testing stations in a growing area had high coliform counts and that 9 of the 10 tests between January and May 1971 showed coliform counts exceeding the NSSP limits. Moreover, a March 1971 analysis of 12 shellfish meat samples from the area showed that the fecal coliform limit of 230 for shellfish meat at the wholesale market level was exceeded, as follows

Sample	Fecal coliform count	Sample	Fecal coliform count
1	9,180	7	2,400
2	16,090	8	5,420
3	3,480	9	9,180
4	3,480	10	9,180
5	2,400	11	16,090
6	3,480	12	3,480

Although a neighboring State prohibited harvesting in the area by its shellfishermen in May 1971, the State included in our review and responsible for classification of the area did not prohibit harvesting At our request FDA and the State analyzed water and shellfish meat from this area in October 1971 and found that both significantly exceeded NSSP limits. The sample results were given to the State, and closure action was taken in November 1971. Three other areas were not closed until March 1972, although available data clearly indicated they should have been closed at least 15 months earlier.

To assess water quality conditions in selected open growing areas, we asked FDA to collect and analyze 131 water samples from 10 shellfish-growing areas in four States. These samples were collected from October through December 1971 We selected the areas on the basis of our review of State records which indicated questionable classifications of growing areas. Analyses of 102 water samples taken from 7 areas showed that 65 exceeded the NSSP growing area coliform limit of 70 indicating the waters could be unsafe for shellfish harvesting The coliform counts that exceeded the limit ranged from 75 to 1,700.

On the basis of these sample results and other State data, FDA recommended that one State close one area, a second State close part of an area, and a third State close two areas and immediately reappraise a third. For the two remaining areas, FDA felt that the samples were not representative of the condition of the waters when other known data was considered and did not recommend any action.

At the conclusion of our fieldwork in May 1972, the States had closed part of one area and were in the process of closing three areas completely and part of another.

FDA acknowledged that in some cases the time taken by some States to close questionable areas had been unduly long. FDA said that it had attempted to have the States act more expeditiously through establishing corrective timetables FDA advised us that, because of widespread deteriorating coastal water quality, the job of classifying shellfish water is considerably greater for States in several respects than it was some years ago It stated that in former days a single State agency would classify shellfish waters more on the basis of remoteness from pollution sources than on other factors.

According to FDA, classification of shellfish waters is a major national issue today and involves a multiplicity of complex technical and administrative issues. FDA told us that the impact of closing shellfish waters had taken on much greater ramifications than just regulating the shellfish industry as it now involves controversial conservation policies, environmental impacts, pollution control strategies, socioeconomic effects and political considerations.

According to FDA, States need to streamline their procedures to close questionable shellfish areas One improvement that should be made, according to FDA, is that shellfish control agencies make their sanitation surveys public documents. FDA officials told us that an almost universal deficiency in State programs was the lack of a central, systematic file of sanitation survey data, investigational reports, and engineering and public health analyses. Because States often lack these files, FDA believes that its job of evaluating State programs was made much more difficult.

INADEQUATE CONTROL OVER CLOSED GROWING AREAS

Patroling of closed growing areas in three States was inadequate to deter illegal harvesting, closed areas were not adequately posted in two States, and FDA and the States had no current formal patrol policy in three States.

The States' responsibilities for policing closed areas are satisfied when they post warning signs, delineate boundaries and notify harvesters of closed areas, and patrol closed areas to prevent illegal harvesting. FDA and the States are to agree on the specifics in a formal patrol policy document. (See chart on p. 30 of closed area.)

Three of the four States' patrol programs were deficient because of limited weekend patrol activities. For example, in one State, only 7 of 33 closed areas were patrolled on Sundays in 1 month during the harvesting season.

FDA was reviewing this State's program and advised us that this deficiency would be brought to the State's attention. FDA had previously given unqualified approval to the patrol activities in this State even though we found no evidence that FDA had independently verified the State's patrol data, including the inspection of closed areas, as NSSP requires.

FDA criticized another State's patrol program because (1) patrol coverage between the hours of 10 p.m. and 5 a.m. was inadequate, (2) weekend coverage was reduced 24 percent, and (3) the State's pursuit boat was incapable of catching illegal harvesters. (FDA estimated that only about 50 percent

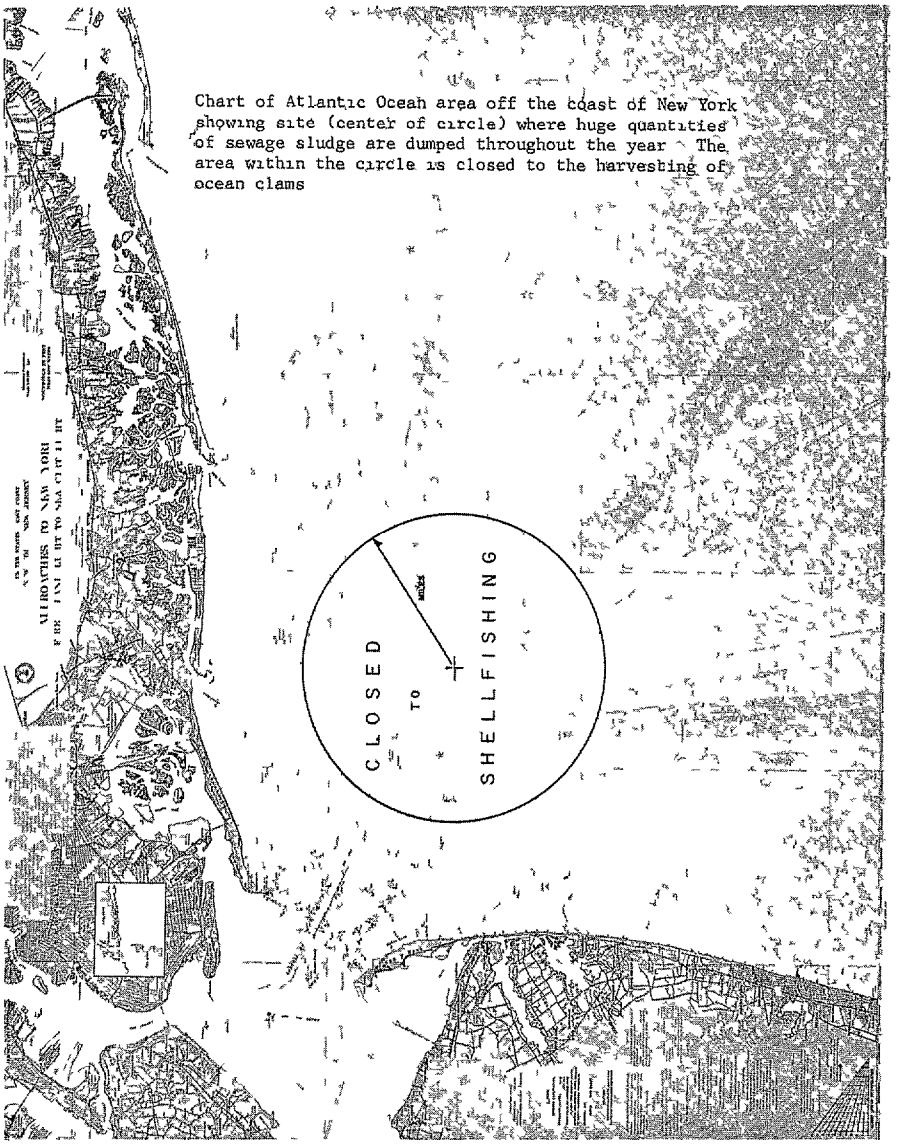


Chart of Atlantic Ocean area off the coast of New York showing site (center of circle) where huge quantities of sewage sludge are dumped throughout the year. The area within the circle is closed to the harvesting of ocean clams

of the violators sighted were actually arrested.) FDA made the following observations in its March 1972 report for this State.

> Certain areas had poor and some very poor patrol coverage, both in terms of manpower and equipment. A number of positions were vacant and it was unknown whether or not these would be filled. Additional equipment, including larger motors and better communication gear is needed. Depletion or relaying projects are very much needed for certain areas. Existing penalties for illegal harvesting are inadequate and should be strengthened. The monthly patrol activity reports are not being forwarded to the FDA Regional Office as agreed upon in the Manual of Operations. Increased night patrol appears necessary for certain areas. Greater efforts are needed to alert the judges hearing illegal harvesting cases as to the public health threat involved.

During a joint State-GAO field trip to collect water samples in this State, we saw a harvesting boat in a closed area. The shellfisherman removed his clamming equipment from the water and left the area at the request of the State official.

In the third State, FDA also cited inadequate patrol equipment, in frequency of patrols, and lack of night patrols as deficiencies. FDA concluded in its 1971 evaluation of this State's patrol program that illegal recreational and commercial shellfishing was occurring in polluted areas.

Two of the four States had not posted enough warning signs and/or replaced weathered or missing signs. In one State, we visited five closed areas and could not find any warning signs or markers. FDA advised us that posting of prohibited areas in this State was generally poor and that the areas we visited were particularly dificient. In another State, we visited 8 closed areas and found that over half of the approximately 200 required postings were either illegible or missing.

NSSP requires that FDA and the States jointly determine and document each State's patrol needs and annually review the document and revise it as necessary. The documentation should identify closed areas and the frequency and type of patrol required.

Of the four States reviewed, one had no documentation and two had outdated documentation that had not been revised for 6 and 7 years, respectively.

FDA threatened to withdraw endorsement of eight State programs during fiscal years 1970 and 1971 According to FDA, most of the States responded by making appropriate corrections, such as closing growing areas and/or by obtaining additional resources for NSSP activities.

FDA told us that the only real sanction it has in NSSP is to withdraw endorsement of a State's program. FDA believes, however, that there is a need for it to have intermediate sanctions available. According to FDA, intermediate sanctions have been proposed but were voted down by State and industry representatives in October 1971 at the annual NSSP conference. FDA told us that it would attempt to incorporate other sanctions in NSSP for consideration of the participating States and the shellfish industry.

For example, FDA plans to propose procedures for provisional endorsement of State programs when any of the eight program elements fall below the required minimum of 70 percent or when other significant deficiencies exist. The proposed procedure would require a State to submit a plan for timely corrective action acceptable to FDA. The plan would list necessary corrective measures in order of priority or significance and a specific timetable for completion. Failure to provide progressive improvement would be grounds for complete withdrawal of endorsement by FDA.

CONCLUSIONS

FDA has not effectively carried out its monitoring role under NSSP and has continued to endorse States' programs even though it knew States were not fulfilling NSSP requirements. FDA has not enforced the NSSP provision that individual growing areas rated below 70 percent be closed and has continued to endorse one State's program without making the required annual appraisals.

The four shellfish-producing States included in our review were not fulfilling their responsibilities to insure that areas approved for shellfish harvesting were safe and in some instances had allowed growing areas to remain open for harvesting despite indications that the quality of the waters was questionable, if not polluted. States' patrol programs to deter illegal harvesting of shellfish from closed areas were also deficient in three of the four States reviewed.

As of June 1972 the shellfish programs of all four States were still endorsed by FDA even though program deficiencies had not been corrected. Consumers are not being adequately protected against shellfish harvested from unsafe waters. (See ch 2 for discussion of shellfish with questionable bacteriological content reaching the consumer.)

RECOMMENDATIONS TO SECRETARY OF HEALTH, EDUCATION, AND WELFARE

With respect to NSSP, we recommend that the Secretary, HEW, direct the Commissioner, FDA, to

--Notify States to close growing areas rated below standard unless the States justify, in writing, that there is no health hazard

--Develop with the States a systematic survey plan for monitoring all growing areas, including a minimum number of sampling stations and frequency of sampling.

--Develop an effective patrol program with each State specifying frequency of patrols and posting criteria for closed areas.

--Withdraw endorsement of a State's program if the State does not take aggressive and timely action to correct program deficiencies relating to control over approved and closed areas.

--Propose to the States and industry the following changes for incorporation into NSSP

A requirement that States obtain shellfish samples from questionable growing waters and close those areas where meat samples

are found which exceed the bacteriological limits.

HEW concurred in our recommendations and stated that instructions would be issued to its field offices for use in notifying States of substandard areas and for developing timetables for corrective actions. The instructions are to include the criteria necessary to assess the acceptability of written justifications submitted by the States

HEW advised us that it would propose changes to NSSP making it mandatory for the States to develop (1) a systematic survey plan for monitoring all growing areas and (2) an effective patrol program.

HEW advised us that there was a need for FDA to have intermediate sanctions available as an alternative to withdrawing endorsement of a State's program and that it had endorsed FDA's plans to propose procedures at the annual NSSP conference for provisional endorsement (See p. 32.)

On our recommendation for a proposed change to NSSP that States be required to obtain shellfish samples from questionable growing waters and close those areas where meat samples are found which exceed the bacteriological limits, HEW stated, that the same objectives could be accomplished by establishing Federal microbiological regulatory limits which, if exceeded, would unequivocally implicate shellfish harvested from polluted waters. We concur with HEW's alternative proposal as long as needed followup actions are in accordance with established Federal microbiological regulatory limits. (See p. 21)

CHAPTER 4

PLANT SANITATION CONDITIONS

FDA, although responsible for enforcing good sanitation practices in shellfish plants, is not aware of industrywide sanitation conditions. FDA inspectors, accompanied by GAO personnel, found at 30 plants in four States that 12, or 40 percent, had insanitary conditions, of which 8, or about 27 percent, had significant insanitary conditions. FDA and the States do not always take effective followup action to insure that insanitary conditions are promptly corrected

REGULATORY AND NSSP PROGRAM RESPONSIBILITY

FDA is responsible under the FD&C Act for insuring that food (including shellfish) shipped in interstate commerce is safe, pure, and wholesome and is processed under sanitary conditions. FDA considers food adulterated and therefore prohibited from interstate commerce if it is

--Composed in whole or in part of any filthy, putrid, or decomposed substance or if it is otherwise unfit for food.

--Prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth or rendered injurious to health.

When adulterated products or insanitary plant conditions are found, FDA can initiate one or more of the following legal actions through the Department of Justice.

--Prosecution of an individual who violates provisions of the FD&C Act.

--Enjoinder of a plant or individual to perform or not perform some act.

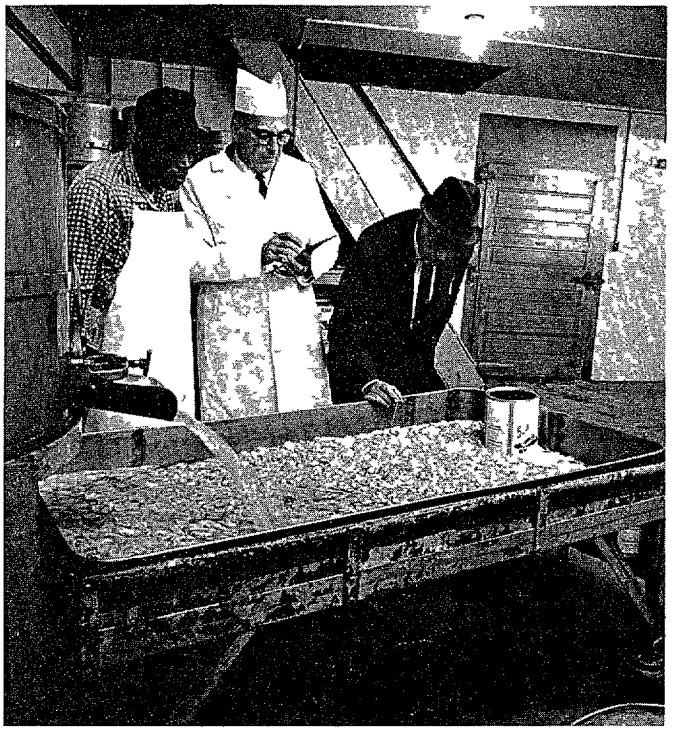
--Seizure of any food that is adulterated or misbranded when introduced into, or while in, interstate commerce

Also, it is FDA policy to issue letters on adverse findings to top management of firms when significant insanitary conditions are found. The letter includes a request for a

written response within 10 days on the action taken, or to be instituted, to correct the violations. The policy also requires an FDA followup inspection to be made within 30 days. Neither of these actions preclude the use of other legal remedies.

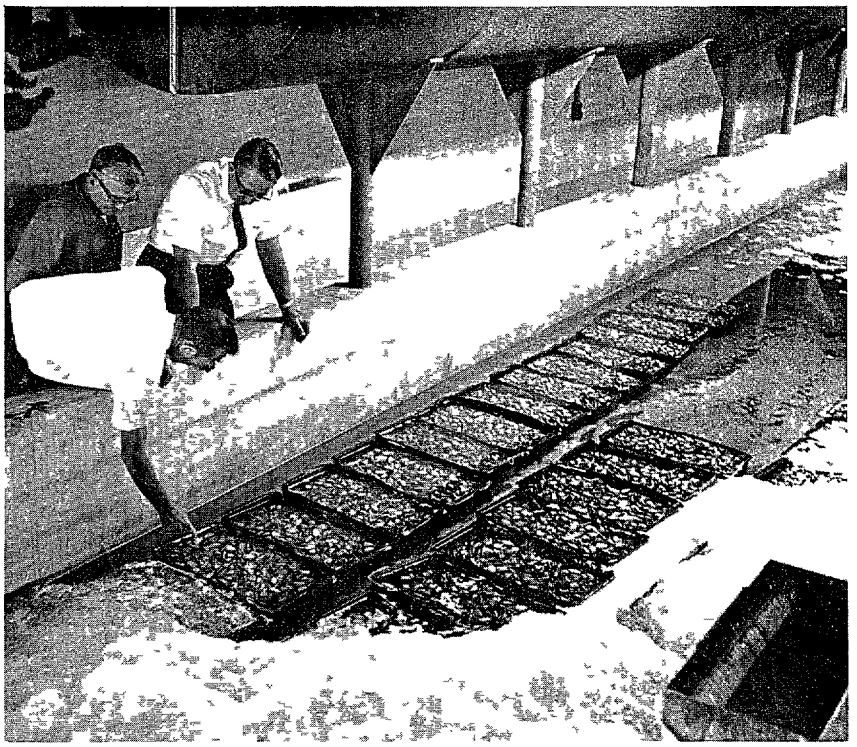
Generally FDA does not use its regulatory powers under the FD&C Act to inspect shellfish plants that ship products interstate or to enforce sanitary standards, but rather relies on its role under NSSP to insure that participating States are adequately policing the sanitation conditions in the shellfish industry.

Under the NSSP program the States are required to inspect and rate shellfish plants to insure compliance with sanitation standards. Plants that comply with the standards are certified by the State to ship shellfish in interstate commerce, and FDA periodically publishes a listing of the certified plants. If a plant's sanitation rating drops below prescribed limits or if any individual sanitation item is repeatedly violated, the States are required to suspend or revoke the plant's certification. (See photographs below, depicting in-plant operations.)



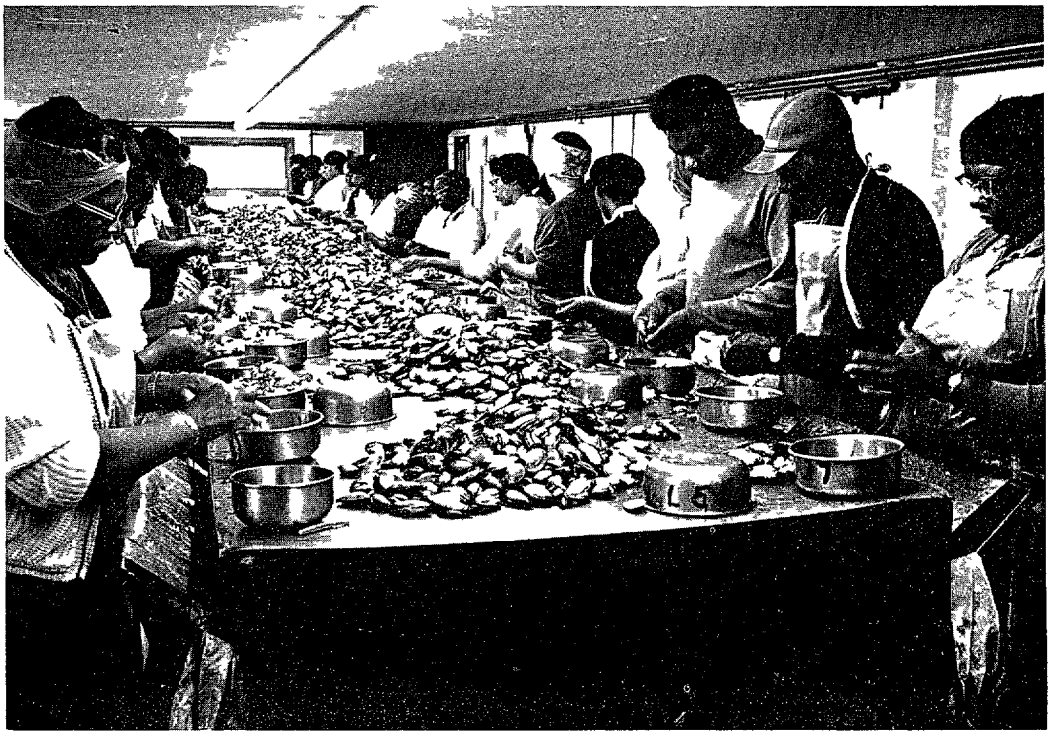
Furnished by the Food and Drug Administration

Shucked oysters being washed with ice water in a blow tank to remove impurities



Furnished by the Food and Drug Administration

Live whole clams being desanded in salt water which has been treated with chlorine and ultraviolet light to kill bacteria



Furnished by the Food and Drug Administration

Workers shucking clams

INDICATION OF SERIOUS INSANITARY CONDITIONS IN THE SHELLFISH INDUSTRY

We selected 30 shellfish plants--21 randomly and 9 on the basis that they were operating and available for inspection at the time of our fieldwork--located in the four States included in our review and asked FDA to inspect these plants while accompanied by GAO personnel. The plants inspected represent about 5 percent of the 644 plants listed on the Interstate Shellfish Shippers List for the four States and account for about $9 million, or about 11 percent, of shellfish sales by these States. Nationally, these plants represent about 6 percent of total industry sales. Inspection results were classified by FDA, at our request, on the basis of the following criteria.

Significant insanitary conditions--These are conditions or employee practices which can be expected to cause, or have caused, adulteration of the product with gross filth or bacteria.

Insanitary conditions--These conditions pose a less serious potential for product adulteration.

Minor insanitary conditions--These conditions would not reasonably be considered as having a potential for adulterating the product.

In compliance--This term is self-explanatory.

The results of the inspections follow

	Number	Percent
Significant insanitary conditions	8	26.7
Insanitary conditions	4	13.3
Minor insanitary conditions	6	20.0
In compliance	12	40.0
Total	30[a]	100.0

[a]The names of the plants are included in appendix XII.

Some of the insanitary conditions observed during the inspections were

--Active rodent infestation.
--Flies in processing and packing areas.
--Use of insanitary equipment.
--Insanitary employee practices.
--Improper washing of shellfish.
--Inadequate refrigeration of shellfish.

Examples of insanitary conditions

The types and extent of insanitary conditions varied among the plants inspected. The determination of whether a plant should be classified as having significant insanitary conditions was a matter of FDA's judgment under the criteria shown previously. A description of the significant insanitary conditions found at two plants follows.

PLANT A has annual sales of about $150,000 and ships about 50 percent of its product interstate.

Findings of joint FDA-GAO inspection

The more significant insanitary conditions found were

1. Mud mixed into shucked shellfish during shucking operations.

2. A sewage condition causing plant wastes to surface on ground 30 feet from plant.

3. Double doors to shucking room open and ducks at entrance and around plant.

4. Flies in processing and packing rooms.

5. Dirty shellfish containers and decomposed material in the storage area.

6. Workbenches not sanitized.

7. Unsanitized cans in contact with shellfish before packing.

Corrective action planned or taken

1. The insanitary conditions were discussed with plant management which promised corrective action.

2. Two days after the inspection, the State sent a letter to the plant citing the insanitary conditions and requesting corrective action within 2 weeks and notifying the plant that its interstate shipping certification might be suspended or revoked.

3. A State reinspection made 41 days after the joint FDA-GAO inspection found the above conditions corrected.

PLANT B has annual sales of about $710,000 and ships about 10 percent of its products interstate. Shellfish account for about $695,000 of the annual sales.

Findings of joint FDA-GAO inspection

Some of the more significant insanitary conditions were

1. Active rodent infestation.
2. Breading material adulterated by rodent activity.
3. Inadequate employee hand-washing facilities.
4 Faulty shellfish-washing equipment.
5. Improperly stored pesticide.

Corrective action planned or taken

1. The insanitary conditions were discussed with plant management which promised corrective action.

2. About 4,650 pounds of rodent-contaminated breading material were destroyed.

3. The plant was scheduled for reinspection by FDA.

APPRAISAL OF INSPECTION PROGRAM

FDA does not have meaningful data to use in evaluating a State's shellfish plant inspection program or assessing industrywide sanitation conditions. Less than half the required inspections are being made by FDA, plants inspected are not randomly selected, and the system of rating plant sanitary conditions needs improvement.

Inspectional requirements

Although the States are responsible primarily for plant inspections under NSSP, FDA must annually inspect a representative number of shellfish-processing plants as a part of its evaluation of a State's program. The number of plants to be randomly selected and inspected is in the NSSP Manual of Operations.

There are 11 FDA employees--called shellfish consultants--who are responsible for monitoring all program elements of NSSP, including inspecting a representative number of the 1,620 certified shellfish plants in the country. Seven of these consultants in six FDA districts are responsible for monitoring program activities in the four States included in our review and in eight other NSSP member States.

FDA is not inspecting the prescribed number of shellfish plants required to assess the effectiveness of each State's program to insure industry compliance with program sanitation standards. In the four States, less than half the required plant inspections were made as shown below.

State	Fiscal year	Required number of plant inspections	Number inspected
A	1970	85	37
B	1971[a]	73	19
C	1971	74	43
D	1970	59	31[b]
Total		291	130
Percent		100	45

[a]Calendar year.

[b]The 31 inspections were made on a cursory basis during a single 5-day period. FDA did not inspect any plants during the next 17 months.

Because FDA did not randomly select the plants to be inspected, the results cannot be considered representative of the sanitation conditions of the shellfish plants in a State nor can they be used to assess industrywide conditions.

In addition, FDA appraises the States' shellfish plant inspection program using only the average of FDA's ratings Little, if any, consideration is given to the effectiveness of States' actions to obtain correction of prior insanitary conditions or to the significance of current plant deficiencies.

To rate plants FDA uses a checklist showing prescribed deductions for varying insanitary conditions. To pass, a plant needs a score of 80 and the average for all plants must be at least 70. For over 60 of the ratable items, including such conditions as the presence of flies, rodent infestation, and muddy shellfish, a deduction of only 2 points or less is provided.

Of the 30 shellfish plants inspected jointly by FDA-GAO, 12 had either insanitary or significant insanitary conditions But only 2 of the 12 plants received a failing rating (74.5 and 79.5) under the NSSP criteria, indicating that insanitary conditions were not being adequately considered in the numerical rating

FOLLOWUP ACTION BY FDA AND THE STATES

FDA should improve its followup action to insure correction of insanitary conditions in shellfish plants. Generally FDA does not reinspect shellfish plants or otherwise follow up on insanitary conditions and does not notify shellfish plant management, in writing, of inspection results as is done when insanitary conditions are found during other food plant inspections. Rather, FDA refers these plants to State officials for followup action. Further, State inspections were not always effective, and FDA did not routinely receive copies of shellfish plant inspection reports from three of the four States reviewed.

The extent of insanitary conditions found during joint FDA-GAO inspections and the repetitive conditions noted on many State inspection reports indicate that followup action is not always effective. Although NSSP requires frequent State inspections of shellfish plants and correction of insanitary conditions, we found many instances of repeated violations of sanitary standards.

The inspectional histories of 80 plants in four States for the period January 1970 through May 1972 showed that

39 plants had repetitive insanitary conditions. Examples of insanitary conditions found four or more times at individual plants are shown below.

Insanitary condition	Number of repeat violations
Dirty walls and ceilings	10
Plants not protected from rodents and insects	10
Dog allowed inside plant	7
Dirty shellfish-holding coolers	6
Inadequate floor drainage in processing area	5
Inadequate fly control	4
Use of insanitary containers	4
Ice not protected from potential contamination	4

The above is distressing because a basic NSSP requirement for a plant to be listed in the FDA published Interstate Shellfish Shippers List is that the same sanitation condition cannot be repeatedly violated. This is not being enforced.

Shellfish purification plant

One State included in our review owns and operates a shellfish purification plant.[1] NSSP provides that shellfish harvested from restricted growing areas may be marketed after being purified at plants approved for this purpose. The plant's operating and quality control procedures must be acceptable to FDA, and the purification system must demonstrate that it is consistently effective.

FDA's records show that sanitation conditions at this plant have been unacceptable for some time. Inspection records for 1967 noted several unacceptable conditions, such as a cross-connection between the depuration tank, catch basin, and floor drain, incoming water depuration suction pipe located near a cesspool, and treated water being inadequately distributed in depuration tanks. The inspection records also showed that the plant was closed for a short time until certain improvements were made.

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[1]Purification plants are rated separately as a program element under NSSP. (See p. 62.)

Pertinent comments from subsequent inspection records follow.

Date	Comments
July 1969	General good plant sanitation practices where food products are being handled are far from acceptable. This could probably close the plant right now. * * * Possible solutions include. a. Build a new plant * * * , b. Close the plant until good sanitary practices are achieved , c Prepare and be able to enforce a timetable for completion of the necessary sanitary requirements and the noted deficiencies which now exist. * * * If funds are not forthcoming to improve sanitary conditions, the plant should be closed.
August 1969	* * * I feel that additional push or threats to get them to complete plant renovations * * * will not get the job done * * * I believe we should bring these deficiencies to the attention of the state again, but present no specific timetable for correction. Why should we be the scapegoat for the state if they have to close the plant?
June 1971	Plant design and sanitation deficiencies regarding this plant have been reported by the Public Health Service for several years * * * The following are * * * deficiencies that still remain. (1) There is an insufficient number of epoxy coated depuration tanks * * * (2) There is an insufficient number of ultraviolet water treatment boxes. * * * (3) * * * the water intake pump is not adequate to change the depuration water in the tanks.

(4) * * * There is no partition between the storage area and the food processing portion of the plant.

* * * * *

(9) There is no internal fly control at the depuration plant.

April 1972 * * * [The depuration plant] does not meet minimum NSSP requirements * * *.

June 1972 * * * the depuration plant is not being operated in accordance with the provisions we had agreed upon at our April meeting.

Subsequent followup by FDA showed that the conditions noted in the July and August 1969 and the June 1971 inspections were satisfactorily resolved

In April 1972 the FDA district director formally advised the State and FDA headquarters that the depuration program was rated "zero." Under NSSP, a State is allowed 90 days to correct program elements rated under 70 percent. On June 28, 1972, the district director again advised FDA headquarters of the plant's unsatisfactory history and stated that the State's depuration plant was not consistently producing shellfish safe for human consumption. Further, this official stated that decisive action should be taken to correct this potential health hazard which has been debated and talked about since at least 1968. The district director recommended that FDA withdraw endorsement of the State's program if revised plant operating procedures were not implemented by July 12, 1972. The State approved new operating procedures for the plant on July 25, 1972.

On August 15, 1972, the Commissioner, FDA, advised the State that new plant operating procedures must be fully implemented at the earliest possible date. He stated that unless this was done shellfish processed for interstate shipment could not be considered safe.

FDA district officials advised us that, based upon a review of the plant's records in September 1972, there were indications that shellfish were being purified satisfactorily. To insure continued effectiveness of the procedures to

control quality of shellfish, however, FDA believes there is a need to conduct an independent onsite evaluation of the entire purification operation.

CONCLUSIONS

Serious insanitary conditions may exist in the shellfish industry warranting FDA's periodic assessment and attention. FDA should officially notify violators of the sanitation standards violated, request a prompt reply, and monitor the case to insure prompt corrective action. As a means of keeping FDA continously aware of industry conditions, FDA should obtain feedback on the results of all States' shellfish plant inspections and of the followup action taken when insanitary conditions are found.

The insanitary conditions found during the joint FDA-GAO inspections, as well as the repetitiveness of many of the conditions, suggest that FDA's evaluation of the States' performance is not disclosing insanitary conditions; therefore FDA lists plants in the interstate shippers list that do not meet basic NSSP requirements. If FDA is to continue relying on the States to enforce the sanitation practices in the shellfish industry, FDA's evaluation procedures should be modified to emphasize monitoring the thoroughness of State inspections and the adequacy of corrective action. When NSSP is ineffective in obtaining correction of insanitary plant conditions, FDA should unilaterally enforce the sanitation requirements of the FD&C Act.

FDA should independently evaluate plants that purify shellfish from restricted waters to insure that they are following the revised procedures and that these procedures effectively control shellfish quality.

RECOMMENDATIONS TO SECRETARY OF HEALTH, EDUCATION, AND WELFARE

With respect to NSSP, we recommend that the Secretary, HEW, direct the Commissioner, FDA, to

--Annually assess overall sanitation in a representative number of shellfish plants.

--Conduct an independent onsite evaluation of the purification plant operated by one State included in our review to assess the effectiveness of plant operating procedures to insure the quality of shellfish.

--Propose to the States and industry the following change to NSSP.

A revision to the method of evaluating States' plant inspection activities to recognize the significance of conditions found and the adequacy of followup action taken.

Additionally, to carry out its responsibilities under the FD&C Act, we recommend that the Secretary, HEW, direct the Commissioner, FDA, to.

--Use the regulatory powers under the FD&C Act when NSSP is not effective in correcting insanitary conditions.

--Issue written notices when FDA finds insanitary conditions in shellfish plants and request written responses on actions taken or planned to correct the violations and to insure continued compliance.

--Obtain and monitor the results of all State inspections of shellfish plants and the followup actions taken when insanitary conditions are found.

HEW concurred in our recommendations and stated that appropriate guidelines and instructions would be issued to the field to implement the applicable recommendations.

HEW advised us that it had scheduled an inspection of the purification plant, including sample collection and analysis.

On our recommendation that FDA use the regulatory powers under the FD&C Act when NSSP is not effective in correcting insanitary conditions, HEW advised us that FDA had initiated a regulatory compliance program in fiscal year 1973 for inspecting certified State shellfish plants that should help to improve conditions and stimulate States to taking corrective action. HEW stated also that FDA would propose in the Federal Register as soon as possible that no State certified interstate shellfish shipper will appear on FDA's list if the plant is found to be producing and shipping shellfish in violation of the FD&C Act.

CHAPTER 5

CONTROL OVER IMPORTED SHELLFISH

About 15.8 million pounds of fresh, frozen, and processed (cooked, smoked, etc.) shellfish were imported into this country in 1971, of which 12.4 million pounds were harvested from waters uncertified under NSSP standards. Since the quality of the shellfish harvested and the conditions under which they were processed were unknown, the domestic safeguards to insure the marketing of safe and sanitary shellfish were not always available.

A primary function in the prevention of shellfish-borne illness under NSSP is the control of shellfish-growing areas. The program's basic assumption is, and has been, that only shellfish harvested from areas meeting approved growing water criteria are safe for human consumption. The program does not allow domestic shellfish to be harvested from unapproved areas In addition, standards have been established under NSSP, which if effectively implemented, would control the sanitary handling of shellfish from time of harvest through the processing operations and through the wholesale market level.

FDA does not have legal authority to enforce domestic NSSP water quality and plant sanitation standards in foreign countries that harvest, process, and export shellfish to the United States. Two foreign countries are NSSP members, and for one of these, only one large growing area has been certified for harvesting under the program. Therefore FDA cannot apply the same standards to imported shellfish as it applies to domestic shellfish.

FRESH AND FROZEN SHELLFISH

To prevent shellfish from being imported from uncertified countries before July 1971, FDA (1) relied on States to take appropriate action under their laws to prohibit importing shellfish from non-NSSP member countries and (2) analyzed samples of the imported shellfish denying entry of the product if bacteriological limits for fresh and frozen shellfish were exceeded. Although the latter appears to be a solution, testing considerations including lack of

resources mitigate against this approach. For example, a recent court ruling on imported shellfish stated, in part, that·

> There are tests which can be performed to determine whether shellfish, including clams, are carriers of salmonellosis and possibly typhoid, but these tests do not provide a feasible approach to protection in that they are costly, incomplete and/or destroy the marketability of the product.

In July 1971 FDA ruled that certain imported fresh and frozen shellfish harvested from uncertified waters might have become contaminated with filth or rendered injurious to health and thereby violated the FD&C Act. In April 1972 the District Court of the United States for the Southern District of California upheld FDA's position. The court ruled, in part, that FDA's barring of live clams from the uncertified waters of that country was not an arbitrary or capricious act, because such clams may be injurious to health and because this method provides the best protection for the public Department of Commerce records indicate that 378,000 pounds and 843,000 pounds of shellfish were imported from this country in 1970 and 1971, respectively. Although the court ruled in FDA's favor in this case, it did not resolve whether FDA has the authority to bar shellfish from other non-NSSP member countries solely because the condition of foreign growing waters are unknown.

The receiving State in this case refused to prohibit shellfish from uncertified foreign waters, claiming that the control of such shellfish is solely within Federal jurisdiction. Therefore any country could ship shellfish to this State and FDA might have to prove that the growing waters--country-by-country--were unsafe. For example, Commerce records indicate that 103,000 pounds and 90,000 pounds of fresh, frozen, and preserved shellfish were imported in 1970 and 1971, respectively, from 13 and 10 non-NSSP member countries. Commerce records do not show the quantities that were fresh or frozen as opposed to processed which are not subject to NSSP.

PROCESSED SHELLFISH

Processed shellfish taken from waters not certified under NSSP--unknown waters--are allowed into the country. About 11.5 million pounds of such processed shellfish came into the country in 1971. Importing shellfish harvested from uncertified waters is inconsistent with the NSSP standards prohibiting our domestic shellfishermen from harvesting about 2 million acres (see footnote, p. 13), or 20 percent of the national harvesting acreage, because the waters do not meet NSSP standards.

Although proper processing (cooking) should kill all harmful bacteria, FDA considers all shellfish taken from uncertified waters adulterated per se and does not allow the domestic shellfishing industry to process shellfish from uncertified areas. FDA's rationale for not permitting this practice follows.

> Under the provisions of the Federal Food, Drug, and Cosmetic Act, a food is deemed to be adulterated if, among other reasons, it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. We consider shellfish taken from polluted waters to have been held under insanitary conditions, and thus to be adulterated under the provisions of the Act. This is true even though the shellfish may have been canned or otherwise processed to destroy the microorganisms contributed by growth of the shellstock in polluted waters or by insanitary handling. Although such processing may eliminate the health hazard arising from the consumption of raw or lightly cooked shellfish from polluted waters, and destroy the microorganisms which are the recognized objective measures of sanitary quality, it does not remove or eliminate filth acquired from polluted waters, and thus does not legalize the acticle.

Even if shellfish are adequately processed, harmful bacteria can still be introduced if the product is not properly canned or packaged. Also the processing may not

eliminate any chemical health hazards. In commenting on the use of domestic clams harvested from unapproved areas for commercially processed chowder, an FDA official stated that

> * * * Although the health hazard potential from bacteria and viruses would be eliminated by heat processing, heat treatment would have little or no effect on most chemical contaminants.

Since most imported processed shellfish are harvested from unknown and possibly polluted foreign waters and processed in foreign plants not subject to FDA inspection, the public has no assurance that such shellfish are safe.

Because foreign shellfishermen, unlike domestic shellfishermen, are allowed to harvest from noncertified areas--an apparent inequity--we solicited the views of major domestic shellfish associations and producers. The 13 respondents said nearly unanimously that importing shellfish harvested from noncertified waters was inequitable to domestic shellfishermen. Pertinent comments from three respondents follow.

1. We have done our utmost, with the help of state and federal health departments to assure that we produce the highest quality products possible for our customers. We do not want them subjected to "dirty" bacterized products even though they are sterilized. * * * Obviously we are unalterably opposed to importation of competitors' products that do not meet the standards our products meet. * * *

* * * * *

2. It is contradictory that the United States should import shellfish from questionable areas throughout the world and yet its' own shellfishermen can only harvest from clean areas. * * * Because of our high standards there is an estimated 450,000 acres [in one State] of potential shellfish producing bottom of which 156,892 acres or approximately 34% of the total is classified as uncertified.

Because of these restrictions we cannot harvest from large areas which limits our supply, making the price of shellfish in the world markets high.

* * * * *

3. The domestic shellfishermen are not allowed to fish in restricted areas but if an imported product may be processed from any area, then this puts our fishermen at an unfair disadvantage as to the volume of raw material available for his work. Also, why should the importer be allowed to heat treat and kill all bacteria when this is not permitted in this country.

CONCLUSIONS

Because no Federal law prohibits the entry of foreign shellfish harvested from unknown growing waters, there is no assurance that about 12.4 million pounds of shellfish imported in 1971 came from waters meeting domestic standards. Although in July 1971 FDA initiated a new policy under the FD&C Act to bar the importing of fresh and frozen shellfish harvested from unknown waters, the courts have not resolved FDA's authority to proceed in this manner.

Our domestic shellfishermen, unlike their foreign competitors, are only allowed to harvest from NSSP-approved areas, and about 20 percent of the domestic harvesting acreage is closed to them. They may be competing against imports from waters of a poorer quality. Closing this loophole would require foreign countries to have the same standards for harvesting as we apply to domestic shellfisherman and processors.

MATTERS FOR CONSIDERATION BY THE CONGRESS

The Congress should consider enacting legislation which permits importing fresh, frozen, and processed shellfish from only those countries that harvest and process shellfish under conditions which are at least equal to domestic standards. Such legislation would help insure that only safe, pure, and wholesome shellfish are imported and would eliminate the apparent inequity to our domestic shellfishermen.

Under the Federal Meat Inspection Act, as amended (21 U.S.C. 601), which is administered by the Department of Agriculture, a similar requirement exists to insure that imported meat has been slaughtered and processed under conditions at least equal to domestic standards.

CHAPTER 6

FEDERAL, STATE, AND INDUSTRY COMMENTS

We submitted drafts of this report to the Secretary, HEW, the State agencies responsible for shellfish activities in the four States included in our review, and the Shellfish Institute of North America, for comments. The recipients agreed generally with our findings.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

HEW generally agreed with our conclusions and recommendations. (See pp. 21, 34, and 47.) HEW stated that the report established that NSSP had not been truly effective and that the State shellfish regulatory agencies had not taken timely action on matters of plant sanitation and closing questionable shellfish-growing areas. HEW acknowledged that FDA had not been forceful enough in seeking corrective measures with responsible State shellfish control agencies by using the sanctions available under NSSP.

HEW stated that one of the principal reasons FDA had not played a more active role during the last several years was due to the fact that FDA's limited manpower resources had been directed toward attempting to cope with what appeared to be even more critical problems, such as microbiological contamination and drug hazards. According to HEW, the need for additional substantive increases in FDA staffing for inspection activities has been recognized by the President, HEW, and FDA and a substantial increase for such activities was included in the Department's most recent (fiscal year 1973) budget request.

STATES AND SHELLFISH INSTITUTE

Overall, all parties were of the opinion that NSSP is an effective program which should be continued. The Shellfish Institute stated that the report has in realistic terms pointed out weaknesses of a working program and should be used to correct those areas of weakness. The four States and the Shellfish Institute did not comment on all matters discussed in the report or on each report segment.

Potentially harmful shellfish

The States and the Shellfish Institute pointed out that, even though bacteriological limits have been exceeded, the record of outbreaks of disease attributable to shellfish under NSSP has been good.

The disease normally associated with shellfish is hepatitis and because the symptoms of this disease are normally not recognized for a period of 10 to 50 days, it is extremely difficult to establish a causal relationship between hepatitis and contaminated shellfish. This was illustrated in a recent report by HEW's Center for Disease Control (CDC)

> On July 30-31, 1971, 12 persons attended a family reunion in * * *. Five persons subsequently became ill with hepatitis between August 9 and September 5.
>
> * * * * *
>
> All patients denied a history of exposure to hepatitis, blood transfusions, parenteral drug use, and recent foreign travel. At the reunion, however, the patients had shared one meal together at which only steamed clams were served. Six persons ate the clams, and five subsequently became ill. The person who ate clams but did not become ill received [treatment] soon after the first cases were recognized The six persons who did not eat clams remained well.
>
> * * * * *
>
> The original source of the clams could not be determined, since the merchant purchases his clams from many sources.
>
> * * * * *
>
> The occurrence of five cases of hepatitis within a 4-week period, the high attack rate (five of six) for those eating the steamed clams, and the

> zero attack rate for those who did not, suggest a common source outbreak of shellfish-associated hepatitis. Since the large shellfish-associated hepatitis outbreaks of the early and mid 1960's, only small sporadic outbreaks, such as this one, have been reported to CDC * * *.
>
> * * * * *
>
> When clams are steamed only until the shells open, the internal temperature is not high enough to inactivate the infectious agent of hepatitis * * *.

According to FDA, even if it were possible to analyze the shellfish served at the reunion, current laboratory procedures could not detect the presence of the hepatitis virus.

CDC, which has responsibility for collecting communicable disease statistics, has had difficulty in establishing a reliable reporting system for shellfish-borne illnesses. CDC estimates that only about 10 percent of communicable disease cases are reported. CDC records for fiscal year 1971 showed that 1,600 cases of hepatitis were reported to them, in which the individual stated that shellfish had been eaten within 60 days before onset of the disease. CDC cautioned that the 1,600 individuals may also have experienced other factors that could have caused the hepatitis and that these figures should not be interpreted as being definite hepatitis cases due to shellfish ingestion.

Although major outbreaks of disease may not have been attributed to shellfish in recent years, FDA (see p. 28) acknowledges the widespread deterioration of coastal water quality. NSSP, as a preventative program, is designed to preclude outbreaks of diseases caused by contaminated shellfish, to accomplish this the shellfish meat and water quality standards must be closely monitored.

We believe that until such time as reliable data on outbreaks becomes available, and the deterioration of coastal waters is reversed, the need for establishing and enforcing program standards by NSSP participants must be emphasized.

Market samples

The Shellfish Institute agreed with our recommendations that NSSP should be revised to require States to have a market-sampling program to insure coverage of all interstate shellfish shippers and that FDA should evaluate this program annually. The Shellfish Institute believes that the program could be made uniform since certain States have had experience in market-sampling techniques, with effective tracing of product to the processor, harvester, and growing areas so that appropriate action could be taken where necessary.

One State said that its market-sampling program insured coverage of all shellfish plants. An official of this State subsequently said that (1) not all plants in one area were inspected annually and that the sampling program could be improved through a more comprehensive plant inspection program and (2) only a limited number of samples were analyzed for plants in another area of the State which were inspected twice yearly.

Bacteriological standards

One State advised us that the bacteriological standards governing the shellfish industry should be critically reviewed and the Shellfish Institute emphasized the need for additional biological and bacteriological data. The Shellfish Institute and another State also stated that we misinterpreted the use of the bacteriological standards. Our interpretation of the results of laboratory analysis of shellfish market standards was based on the NSSP guidelines established for this purpose. (See p. 13.) Results of laboratory tests of water samples were referred to FDA for interpretation and action. (See p. 28.)

Research

According to the Shellfish Institute and two States, FDA should restore research capability within FDA to maintain a strong shellfish program and to provide FDA with the means of doing needed research on shellfish and program standards. The loss of these laboratories and related scientific personnel is discussed on page 17.

Water quality

One State, although concurring in our recommendations dealing with shellfish-growing waters, stated that several of the recommendations might be difficult to achieve because of unforeseen problems.

Another State acknowledged the deficiencies relating to its water quality program but advised us that water conditions had changed since our review. This State advised us that its shellfish water control program had been fragmented before July 1971 but that, after that date, the program had been centralized within one State agency. This State also advised us of several steps which had been taken to strengthen its water quality program. Priority is also being given to the development of methods for shellfish refrigeration and protection as the State believes the unsatisfactory bacteriological quality of the shellfish meat attributed in the report to poor quality of growing waters may be due to improper handling of shellfish after harvesting.

Patrol

According to one State, steps had been taken to strengthen its patrol program, although it was too early to fully evaluate the effectiveness of the action. Another State agreed that FDA and the States need to establish an effective patrol program that specifies the frequency of patrols and posting criteria for closed areas. This State believed, however, that its Sunday patrol program was adequate and advised us that it dispatched patrol boats when notified that boats were heard and seen on Sunday in a suspicious circumstance.

Plant sanitation

The Shellfish Institute agreed that good plant sanitation conditions and proper handling procedures must be adhered to. One State advised us that it had accelerated its control over plant sanitation, and another State acknowledged the need to revise plant inspection rating forms.

Shellfish purification plant

The State which operates the purification plant said that the plant had established new operating rules, regulations, and a sampling program and was operating satisfactorily under the regulations. This State said also that, although the management and operation of the plant had greatly improved over the past 2 years, much more still had to be done at the plant.

Imported shellfish

The Shellfish Institute and one State concurred that fresh, frozen, and processed shellfish should be imported from only those countries that harvest and process shellfish under conditions which are at least equal to domestic standards. The other three States did not comment on this matter.

CHAPTER 7

SCOPE OF REVIEW

We assessed NSSP's effectiveness at four FDA district offices--Baltimore, Boston, New York, and Seattle--for insuring that shellfish for human consumption are harvested from only safe growing areas and are processed in a sanitary manner.

Selected aspects of four States' programs monitored by these district offices were reviewed. These districts monitor 12 shellfish-producing States having about $129 million, or about 87 percent, of the value of domestic shellfish production at the wholesale level. The four States reviewed account for about $79 million, or about 53 percent, of the value of domestic production.

We interviewed State officials responsible for shellfish activities in the above States and corresponded with industry representatives and trade associations.

We examined pertinent laws, regulations, practices, and procedures for the interstate shipment of foods, program requirements of NSSP, and pertinent records of both FDA and the States. We also interviewed FDA headquarters, district office, and laboratory officials.

We accompanied FDA shellfish consultants and FDA and State food inspectors on sanitation inspections of 30 shellfish plants in the four States. Shellfish meat samples collected during these inspections were analyzed in Federal and State laboratories to determine conformance with program bacteriological market standards and to determine the levels of toxic metals--mercury, lead, and cadmium--and pesticides FDA collected water samples from open growing areas and, at our request, analyzed them to determine conformance to NSSP bacteriological standards.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON D C 20201

NOV 28 1972

Mr. Morton A. Myers
Assistant Director
Manpower and Welfare Division
General Accounting Office
Washington, D.C. 20548

Dear Mr. Myers·

The Secretary has asked that I respond to your letter of October 6 in which you asked for our comments on a GAO draft audit report to the Congress entitled, "Protecting the Consumer from Potentially Harmful Shellfish." Our comments are enclosed.

We appreciate the opportunity afforded us to review this report in draft form.

Sincerely yours,

James B. Cardwell
Assistant Secretary, Comptroller

Enclosure

Department of Health, Education, and Welfare Comments on a Draft of a Report by the Comptroller General to the Congress entitled, "Protecting the Consumer from Potentially Harmful Shellfish"

The Department generally agrees with the conclusions in this report, with certain exceptions noted later These relate principally to the way that the identified problems can be resolved. The report establishes that the National Shellfish Sanitation Program (NSSP) has not been truly effective, also that there has not been timely action by State shellfish regulatory agencies on matters of plant sanitation and closing questionable shellfish growing areas We acknowledge, also, that the Food and Drug Administration has not been forceful enough in seeking corrective measures with responsible State shellfish control agencies by using the sanctions available under NSSP In this connection, however, and to put this matter into a better balanced perspective, we would like to point out the principal reasons why FDA has not played a more active role in this area During the last several years, FDA's limited manpower resources have been directed towards attempting to cope with what appeared to be even more critical problems such as microbiological contamination and drug hazards. The need for additional substantive increases in FDA staffing for inspection activities has been recognized by the President, HEW and FDA, however, and a substantial increase for such activities was included in the most recent budget request.

GAO Recommendation

With respect to the NSSP, the Secretary HEW should direct the Commissioner FDA to

--Notify States to close growing areas rated below standard unless the States justify in writing that there is no health hazard.

Department Comment

We concur Instructions will be issued to the regional offices containing guides to (i) the manner that States should be notified of substandard areas, and (ii) developing timetables for corrective actions. These instructions will also include the criteria necessary to assess the acceptability of written justifications submitted by the States

--Develop with the States a systematic survey plan for monitoring all growing areas including a minimum number of sampling stations and frequency of sampling.

Department Comment

We concur and will propose this as a mandatory requirement in the NSSP Manual of Operations.

--Develop an effective patrol program with each State specifying frequency of patrols and posting criteria for closed areas.

Department Comment

We concur and will propose this as a mandatory requirement in the NSSP While this subject is covered in Part III of the NSSP Manual of Operations, it is suggested, rather than clearly stated as a requirement

--Withdraw endorsement of a State's program if the State does not take aggressive and timely action to correct program deficiencies relating to control over approved and closed growing areas.

Department Comment

We concur, but believe that the Commissioner of FDA needs other, lesser intermediate sanctions -- which we plan to propose for adoption at the next National Workshop of the NSSP, namely "Provisional Endorsement " Where State program deficiencies have been found, FDA will establish with the State officials a definite timetable for corrective action to be taken.

--Annually assess the overall sanitation conditions of a representative number of shellfish plants

Department Comment

We concur and will prepare suitable guidelines for our field staff They will provide for inspection of a statistically valid number of shellfish plants annually to assess compliance with the FD&C Act

--Conduct an independent on-site evaluation of the purification plant operated by one State (included in the GAO review) to assess the effectiveness of plant operating procedures to ensure the quality of shellfish

Department Comment

We concur, and have assigned an inspection of this plant including sample collection and analysis. An on-site comprehensive study has been scheduled to investigate critical processing parameters along with laboratory analyses of physical, bacteriological, and chemical plant processes.

--Propose to the State and industry the following changes for incorporation into the NSSP

(a) A requirement that States have a market sampling program to assure coverage of all interstate shellfish shippers FDA should evaluate this program annually

Department Comment

We concur in this recommendation However, we plan to carry it a step further Our initial procedures will be to conduct microbiological studies and review available data for the purposes of establishing microbiological standards of quality for market shellfish enforceable by FDA These standards will be proposed in the Federal Register as soon as possible, they can be applied to market shellfish by FDA independently of State actions.

(b) A requirement that States take follow-up actions when meat samples in excess of limits are found indicating a problem attributable to the growing waters These actions should include recording violations by harvester and growing area, formally notifying the harvester, analyzing shellfish and water from the growing area and closing growing areas from which shellfish with bacteria counts in excess of limits have been harvested

(c) A requirement that States obtain shellfish samples from questionable growing waters and close those areas where meat samples are found which exceed the bacteriological limits.

Department Comment

FDA believes that the same objectives can be accomplished by the establishment of Federal microbiological regulatory limits which, if exceeded, would unequivocally implicate shellfish harvested from polluted growing waters No such microbiological guidelines, or limits, have been established FDA will examine existing information with a view toward proposing a microbiological limit that FDA can enforce on shell stock received by interstate shellfish shippers Until such a limit is set, FDA will make every effort to get States to close growing areas where available data is suggestive of producing potentially hazardous shellfish.

(d) A revision to the method of evaluating States' plant inspection activities to recognize the significance of conditions found and the adequacy of follow-up actions.

Department Comment

We concur The present numerical sanitation rating system has given control officials and the shellfish industry a false sense of compliance FDA will eliminate the numerical rating system from the field inspection form and make a more concerted effort to even more precisely evaluate State inspection programs and follow-up effectiveness.

GAO Recommendation

Additionally, to carry out its responsibilities under the FD&C Act, GAO recommends that the Secretary, HEW, direct the Commissioner, FDA, to

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

Department Comment

FDA initiated a regulatory compliance program in FY 1973 for inspection of certified State shellfish plants that should assist in causing improvements and stimulate States to taking corrective action. Further, FDA will make a proposal in Federal Register as soon as possible that no State certified Interstate Shellfish Shipper will appear on FDA's list if the plant is found to be producing and shipping shellfish in violation of the FD&C Act

--Establish Federal bacteriological standards of quality for shellfish and enforce them if satisfactory compliance cannot be obtained under the NSSP

Department Comment

We concur and will develop standards of quality for shellfish as supportative scientific evidence permits

--Establish Federal standards for toxic metals and request the Environmental Protection Agency to establish standards for pesticides in shellfish

Department Comment

We have established an enforcement guideline for mercury in marine foods including shellfish and other enforcement guidelines for metals will be established by FDA for marine foods as toxicity data are developed. When excessive levels of metals constituting a health hazard are found in these foods, FDA action will be taken Enforcement guidelines have already been established for several pesticides in marine foods. Other pesticide guidelines will be developed for marine foods as the need for such action is supported by market sampling and toxicological data. We will also discuss the possibility of setting tolerances for pesticides with EPA

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

Department Comment

During plant inspections, a FDA inspector will collect in-line and finished product samples if there is reason to believe that a plant may be operating under insanitary conditions, whereby, the product may be contaminated with filth FDA will intensify its inspection of shellfish plants as field manpower becomes available and trained for this new activity

--Issue written notices in all cases where FDA finds insanitary conditions in shellfish plants and request written responses on action taken or planned to correct the violations and to ensure continued compliance

Department Comment

We concur and appropriate instructions will be issued to the regional offices to affect the recommended action

--Obtain and monitor results of all State inspections of shellfish plants and the follow-up actions taken when insanitary conditions are found

Department Comment

We concur and appropriate instructions will be issued to the regional offices to affect the recommended action.

In addition to these comments certain statements in the body of the report should be revised for accuracy as follows

[See GAO note.]

GAO note: The deleted comments relate to matters in the draft report but omitted from the final report.

SHELLFISH INSTITUTE OF NORTH AMERICA

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November 13, 1972

Mr. Morton A. Myers
Assistant Director
United States General Accounting Office
Manpower and Welfare Division
Washington, D. C. 20548

Dear Mr. Myers Re B-164031 (2)

We appreciate your sending a copy of your draft report on protecting the consumer from potentially harmful shellfish, for our review and comments.

The comments we wish to offer are as follows

Even though the GAO has pointed out the weakness of the program to pressure from political levels, it has been long understood by industry and members that this particular program has often been cited as a model in the exclusive involvment of all levels of the business ranging from producer to regulatory personnel. The need to continue this cooperative program is more than obvious when one looks to some of the weaknesses pointed out by GAO

The GAO report has in realistic terms pointed out weaknesses of a working program and should be used to correct those areas of weakness It should not be used to draw conclusions of removal of a program that is so vitally linked to the management and health of the country's estuaries.

The report points out the need for adequate funding of both the FDA and the states in their enforcement work It is recommended that in the final report to Congress that it should be pointed out that the NSSP has been in existence for 47 years and that during that entire period there has been no major outbreak of disease attributed to commercially harvested shellfish that were produced under the standards set in the NSSP A truly remarkable record

We in the industry are fully in accord with the protection of public health and the necessity for producing at all times a clean and wholesome product. Good plant sanitation must be adhered to along with proper handling procedure at all points.

The GAO has misinterpreted the use of the bacteriological guidelines in the NSSP. These guidelines have been set up as a monitoring device to insure a good quality product Even though these bacteriological guidelines are exceeded, there has been no major outbreak of disease attributed to commercially harvested shellfish that were produced under the standards set in the NSSP. Reference in the GAO report that an adulterated product has been shipped is incorrect. Bacteria is a natural part of all foods and no definite bacteriological limits have been set for oysters and clams above which they would be considered unacceptable for human consumption.

We cannot emphasize too strongly the necessity for technical knowledge, biological as well as bacteriological needed in carrying out a successful NSSP. Our experience is that we have been working with a dedicated group of enforcement people together with research marine biologists that have made the success of the program possible. The GAO draft report points out some areas that need strengthening. This can be brought about by adequate funding both at the federal and the state level and the continued cooperation of industry

We, therefore, recommend that sufficient funds be provided to the FDA to give them the facilities and staffing to correct any weaknesses which the GAO has pointed out and to improve the NSSP on an on-going basis.

We strongly urge the NSSP continue to be administered as now structured and that any weaknesses be corrected through adequate funding for staffing and facilities. As a matter of fact we had such facilities at one time Congress, the States and Industry worked very hard in procuring these facilities and then through administrative re-organization NSSP lost the laboratories The GAO report indicates the need for these facilities to be within the framework of the NSSP. These laboratories which are strategically located in highly productive areas can not only insure the high quality of food products for the consumer's protection but would also insure high water quality thus supporting and increasing the environmental integrity of our resources. At the same time the ability of doing research on aquatic animals which the FDA needs would be provided.

The laboratories we are referring to are located at Dauphin Island, Alabama, Narragansett, Rhode Island, and Purdy, Washington. It is understood that these laboratories might be available and might be able to be returned to the FDA's Shellfish Program. The FDA has just recently proven its ability to rise to crises which have arisen, and we believe that if

recommendations we have made are followed, they will be in a better position to give leadership on any unforeseen crises which might arise

We concur that there should be included in the NSSP a requirement that all states have a market sampling program to assure coverage of all interstate shellfish shippers. FDA would then evaluate this program annually. This could be made uniform since certain states have had experience in market-sampling techniques, with effective tracing of product to the processor, harvester, and growing area so as to take appropriate action, where necessary. The NSSP is a sufficiently workable, and viable program to permit this uniform approach.

There is an economic disadvantage to our domestic shellfisherman - on the matter of the manner in which imports may come in from uncertified waters or polluted waters. Our own shellfisherman must harvest from waters approved by the NSSP cooperative arrangement.

All shellfish sold in this country should come from approved harvest areas, regardless of country of origin. Otherwise, this has and continues to place an imbalance and an unfair competitive position in the lap of our domestic shellfishermen. Shellfishermen are aware of this unfairness and think it should be corrected.

We, therefore, concur with the findings and recommendations on the importation of fresh, frozen, and processed shellfish from only those countries that harvest and process shellfish under conditions which are at least equal to our domestic standards.

We support the NSSP and work closely with industry, state and federal people to resolve problems and changes in procedures as they come up. Currently we are working on problems, and quality of the product going to the consumer is kept uppermost in mind at all times

If we can be of any further service in connection with this study, please advise.

Sincerely,

EVERETT A. TOLLEY
Executive Director

EAT ir

STATE OF NEW YORK
DEPARTMENT OF
ENVIRONMENTAL CONSERVATION
ALBANY

HENRY L DIAMOND
COMMISSIONER

November 6, 1972

Dear Mr. Myers

As Commissioner of the New York State Department of Environmental Conservation, responsible for the New York State Shellfish Sanitation Program, I would like to thank you for the opportunity to review and submit this Department's comments regarding the report entitled, "PROTECTING THE CONSUMER FROM POTENTIALLY HARMFUL SHELLFISH", B-164031 (2).

The report essentially describes four specific areas within the shellfish sanitation program dealing with bacteriological and related criteria of market shellfish, monitoring of shellfish-growing waters, plant sanitation conditions and control over imported shellfish

The section of the report dealing with bacteriological and related criteria of market shellfish recommends that all states have a market sampling program to assure coverage of all interstate shellfish shippers Speaking for the State of New York, I feel that our State shellfish program does assure adequate coverage for all shellfish harvested and marketed within the State of New York by our licensed dealers. It is noted that all licensed dealers in the upstate regions are inspected twice yearly by personnel of our State shellfish program as well as local health department authorities in the area. In addition, upstate dealers are checked regularly by our conservation officers on their handling of shellfish, including sanitation. Dealers in the Long Island-Metropolitan area are inspected on a monthly basis.

The second part of the report deals with monitoring shellfish-growing waters. This section of the report recommends that the states develop systematic survey plans for all growing areas, discusses effective patrol programs and recommends withdrawal of endorsement of a state program

if the state does not take aggressive and timely action to correct program deficiencies relating to control over approved and closed growing areas. In general, we have no quarrel with these recommendations. However, it appears that some of these recommendations have been made on the basis of dealing with absolutes, and in certain areas represent ideals to strive for but which, in reality, are difficult to achieve. Experience with the State program has indicated that in any given year problems arise which, due to their nature, require deviation from the planned program. As a result, our program has been set up to review systematically a number of key shellfish growing areas per year while gathering limited information on the remaining areas. This system does result in a staggered system for reporting all water quality in New York's shellfish waters. It has resulted in detailed sanitary surveys of each area every 5 years with interim checks every 2 years. Environmental changes, except in special situations, are usually gradual rather than drastic. Past experience indicates that this system works satisfactorily While a considerable effort has been expended in our shellfish patrol program, we have recently initiated a number of steps to strengthen this element of our program, which cannot be fully evaluated until actual operating experience has been gained.

The section dealing with plant sanitation conditions makes certain recommendations after implying that poor sanitary conditions are found in many shellfish plants. As indicated above, the New York State shellfish program does carry out a thorough plant inspection program. While some deficiencies have been noted in New York shellfish plants, they have been discussed with our FDA Regional Shellfish Consultant and our program works continually to correct the situations. It is felt that most deficiencies noted on our inspection reports do not present serious health hazards to the consumer. This statement implies that changes may be required in the National Shellfish Sanitation Program's Manual of Operations, involving a review of all elements rated on the plant inspection forms and an assessment of their relative weights under current industry practices.

The last element of the review deals with control over imported shellfish and in reviewing this section, I can only

Mr. Morton A. Myers November 6, 1972

add that the State of New York would fully endorse the recommendations presented in this section of the report

In conclusion, this program does present a critical review of certain elements of the National Shellfish Sanitation Program and also of several state shellfish programs. I feel strongly that the concept and philosophy of the National Shellfish Sanitation Program is sound although certain changes within the program should be considered and reviewed. Of major importance in this category would be the bacteriological standards governing the shellfish industry. This report indicates that violations of the bacteriological water and shellfish standards do occur and yet records indicate that there have been no major outbreaks of illness attributed to shellfish within the past few years.

Analysis of this type of information confirms the need for a critical review of these standards and I can only stress that this be given top priority by the national program. It is also noted that the national program, at one time, had three research laboratories assigned to carry out investigations in this area and other areas of critical importance to the shellfish program. During recent reorganizations within certain federal agencies, these laboratories have been reassigned. We object strongly to this action and stress that the input from these laboratories is extremely critical in order to maintain a strong shellfish sanitation program

In closing, I would again offer my thanks on behalf of the State of New York for the opportunity to review and comment on this report

Sincerely,

Commissioner

Mr. Morton A. Myers
Assistant Director
U. S. General Accounting Office
Manpower & Welfare Division
Washington, D. C. 20548

State of Maryland

OFFICE OF THE SECRETARY
DEPARTMENT OF HEALTH AND MENTAL HYGIENE
301 WEST PRESTON STREET BALTIMORE, MARYLAND 21201 Area Code 301 383 3010

Neil Solomon, M D, Ph D Secretary

November 10, 1972

Mr. Morton A. Myers
Assistant Director
United States General Accounting Office
Washington, D. C. 20548

B-164031(2)

Dear Mr. Myers:

Thank you for your recent letter concerning the General Accounting Office report on shellfish and the opportunity to review this report prior to its final draft.

This Department recognizes many of the shortcomings noted in the report and agrees that constant surveillance of shellfish producing waters is imperative for the protection of the consuming public. We have difficulty, however, in accepting the conclusions reached primarily due to the age of the data contained in the discussion and what appears to be discrepancies in the standards used to evaluate shellfish waters.

[See GAO note.]

It would appear that conclusions to the effect that areas of Maryland waters now used for shellfish production are unsafe are drawn from sampling data collected in 1970-1971. Such conclusions are not currently valid.

Prior to July 1, 1971, the shellfish water control program in Maryland was fragmented, with much of the work dependent upon local Health Departments. Since that date, this program has been centralized with all personnel employed directly by the State Department of Health and Mental Hygiene. The following points of this program are submitted for your information:

1. All open shellfish waters are sampled once each month, with problem areas

sampled more frequently as need is determined. All closed areas are sampled twice each month as required by Maryland law.

2. Shellfish samples are collected from each open section each month during the harvesting season and examined for bacteriological quality, pesticides, and heavy metals.

3. All laboratory results are logged for each individual sampling point to allow for continuous evaluation of water quality.

4. Shoreline survey capabilities have been expanded to provide a complete survey of all shoreline areas each three years. Areas under survey have been expanded to include inland evaluation of tributary streams.

5. Surveys are designed on the basis of total drainage basins, and include running accounts of all known points of discharge including sewage treatment plants, commercial discharges, and agricultural operations.

6. All water sampling results have been recently computerized to provide monthly median reports based on the twelve preceding months sampling for coliform and fecal coliform from each shellfish water sampling point.

7. Every effort is made to locate sampling stations in the most indicative areas. As previously indicated, sampling is conducted throughout the year, and not restricted seasonally as the report indicates. Samples are collected using a bottom sampling technique which has the approval of the Food and Drug Administration, and samples are collected under all weather and tidal conditions, with prescheduled trips cancelled only when storm conditions interfere with the safety of personnel.

The control of shellfish following harvesting has also been accelerated since the evaluation which resulted in the report. In the past, packers were often notified by local Health Departments of violations found during inspections. All such letters now originate from the State Department of Health and Mental Hygiene. Local Health Department records were not evaluated when this report was prepared.

[See GAO note.]

Maryland law forbids the sale of shellfish from uncertified sources. This coverage includes all products which originate outside the United States, and excludes the sale of many which are allowed by Federal authorities to be sold interstate. At present, the only known shellfish entering Maryland from uncertified sources are sea clams from waters beyond the three mile limit. Although those waters are Federal responsibility, they have not been certified.

Priority has been given to the development of methods of shellstock refrigeration and protection, and there is reason to believe that unsatisfactory bacteriological quality of Maryland shellfish which has been attributed by the report to the poor quality of growing waters is in fact due to improper handling of shellstock following harvest.

As previously indicated, the Maryland Department of Health and Mental Hygiene is in agreement with the objective of the National Shellfish Sanitation Program, and has, in fact, assigned these activities highest priority. This program has greatly improved since the dates covered by the General Accounting Office report, and I sincerely believe the report in its present form presents an inaccurate description of conditions in Maryland.

Sincerely yours,

Neil Solomon, M.D., Ph.D.
Secretary of Health and Mental Hygiene

GAO note Deleted comments refer to material contained in draft report which has been revised or which has not been included in the final report.

JAMES B COULTER
SECRETARY

STATE OF MARYLAND
DEPARTMENT OF NATURAL RESOURCES
STATE OFFICE BUILDING
ANNAPOLIS 21401

JOSEPH H MANNING
DEPUTY SECRETARY

November 10, 1972

Mr Morton A Myers
Assistant Director
Manpower and Welfare Division
U S General Accounting Office
Washington, D C 20546

Dear Mr Myers

Your letter of October 12th to Secretary Coulter has been referred to me for reply I find it difficult to reply to many of the sections of the draft report attached to your letter as it is quite general and does not specifically apply to Maryland However, I would like to say initially that we consider our shellfish sanitation program as good as, or better than, any other in this country We have not had a case of communicable disease traced to Maryland shellfish since 1926 This, I think, in itself is noteworthy and shows that we are doing an adequate job of protecting the consumer from the possibility of having contaminated shellfish become available on the market We have consistently received scores above 90, mostly approaching the 100% levels, in the ratings by the Public Health Service and lately by the FDA on our control program I think these items should be brought to your attention We have confidence in the National Shellfish Sanitation Program and are conscientiously living up to the agreements and provisions of this program

[See GAO note]

Mr M A Myers November 10, 1972

[See GAO note]

On Pages 35 and 36, we note again that you feel patrol activities are not adequate We disagree completely with you as far as Maryland is concerned We believe that our patrol activities are adequate and the proof is the lack of violations and the good record which I mentioned earlier in this letter Furthermore, you spoke of lack of night patrol and Sunday patrol Harvesting in Maryland is illegal at night or on Sunday The general public and the licensed watermen are well aware of this, and we are frequently notified that boats are heard, perhaps at night, and seen on Sunday, in a suspicious circumstance We immediately dispatch patrol boats to the area in question

[See GAO note]

Concerning your comment on Page 40, we agree that the Secretary of Health, Education and Welfare should develop with the States, taking into consideration the location of closed areas, such as harbors, towns, and other populated areas, a policy which would

Mr M A Myers November 10, 1972

be acceptable to both parties We do not believe this should be a unilateral action

In conclusion, I would like to reiterate that we do not consider our present program inadequate but are always agreeable to suggestions for improvement which we could accomplish using our present budgetary allowance and equipment perhaps to better advantage We would be glad to discuss this with you at any time and with an open mind

Thank you for the opportunity to comment on this draft proposal, and if we can be of any further assistance in elaborating on our comments, we would be more than glad to discuss them with you

Sincerely,

Fred W Sieling
Commercial Fisheries
Coordinator

FWS c

cc James B Coulter
Joseph H Manning
Paul W McKee
Roy Rafter
James Clise

GAO Note Comments pertaining to draft report material not pertinent to the final report have been omitted.

STATE OF WASHINGTON
DEPARTMENT OF SOCIAL AND HEALTH SERVICES
DANIEL J EVANS
GOVERNOR
HEALTH SERVICES DIVISION
P O BOX 1788 OLYMPIA WASHINGTON 98504
WALLACE LANE M D M PH
ASSISTANT SECRETARY

November 10, 1972

Morton A Myers, Assistant Director
Manpower and Welfare Division
United States General Accounting Office
Washington, D C 20548

Dear Mr Myers

This is in reply to your letter forwarding to us a copy of the draft report on protecting the consumer from potentially harmful shellfish We appreciate the responsibilities and role of the General Accounting Office and the difficulties inherent in the evaluation of the shellfish program This state has participated in the National Shellfish Program for an extended period and we believe the program is effective in providing safe shellfish in commerce We do not believe the report properly reflects the benefits We are aware of our program deficiencies The program has evolved consistent with environmental changes Obviously there are budget limitations

We believe the report is in error in indicating that member states must refuse shellfish shipments from states with programs not endorsed by FDA We endorse such action but do not believe that it is mandatory

We believe the report indicates misunderstanding or misinterpretation of the significance of levels of indicator organisms used in the evaluation of both shellfish growing waters and market shellfish In addition, interpretation of results of shellfish samples and growing water samples accomplished by the audit team, are not valid in the absence of field investigations

The federal government is responsible for accomplishing the necessary basic research on shellfish sanitation We do not believe the research is being accomplished, therefore, suggest the report indicating federal monies are spent on this activity is in error Certainly there are several unmet research needs essential to safer shellfish control

[See GAO note]

In closing I would like to reaffirm our belief that only safe shellfish should be introduced into commerce. We believe the National Shellfish Program properly funded and operated will provide the required protection.

Sincerely,

Wallace Lane M D

Wallace Lane, M.D.
Assistant Secretary

WL vm

GAO note Comments pertaining to the draft report material not pertinent to the final report have been omitted

FRANCIS W SARGENT
GOVERNOR

ARTHUR W BROWNELL
COMMISSIONER

The Commonwealth of Massachusetts
Department of Natural Resources
Leverett Saltonstall Building
100 Cambridge Street, Boston 02202

November 28, 1972

Morton A. Myers, Assistant Director
United States General Accounting Office
Washington, D. C. 20548

Dear Mr. Myers:

This Department has reviewed your orgainzations revised draft report on protecting the consumer from potentially harmful shellfish.

The report, from this Department's point of view, is, essentially, a review of comments previously made to us by the Federal Food and Drug Administration. I agree with many of your comments, but not all. I personally feel that many times the FDA over-reacts particularly in the field of enforcement. The recent "Red Tide" situation in Massachusetts is a clear indication of the capabilities of the Commonwealth of Massachusetts to act when needed.

On page 52c your revised report has taken into consideration the improvements made to this Department's Shellfish Depuration Plant at Newburyport since 1971. Although much more still must be done at the plant, we believe that the management and operation of the plant has improved greatly over the past two years.

Sincerely,

Arthur W. Brownell
Commissioner

DIVISION OF
ENVIRONMENTAL HEALTH
TEL (617) 727 2690

The Commonwealth of Massachusetts
Department of Public Health
600 Washington Street Room 320
Boston 02111

December 8, 1972

Mr. Martin A. Myers
Assistant Director
United States General
Accounting Office
Washington, D.C. 20548

RE: Draft Report on "Protecting The Consumer From Potentially Harmful Shellfish," prepared by General Accounting Office

Dear Sir.

The draft of your report, "Protecting The Consumer From Potentially Harmful Shellfish," has been referred to me for comment.

The report is very negative but factual, however the following points should be commented upon.

Although the report states many deficiencies in the program under the guidelines of the National Shellfish Sanitation Program Manual of Operations, the infrequency of shellfish related diseases is consistent with the inception of the N.S.S.P.

The report also alludes to the fact that the so-called alert levels for toxic elements in sediments and shellfish are standards. In fact, as stated in the Toxic Element Survey Report, prepared by the Massachusetts Water Resources Commission, the alert level concept was developed to be used as a guide or indicator of metal pollution in shellfish growing waters and was not intended to reflect the toxicity of metals contained in shellfish."

The report also discusses a history of sanitation problems related to the Newburyport Shellfish Treatment Plant over a period of approximately seven years. At the present time the Plant has new Rules and Regulations for its operation and a sampling program and is presently operating satisfactory under the Regulations.

Very truly yours,

Gerald W. McCall

Gerald W. McCall
Associate Engineer

cc Ken Croke, G.A.O.
1903 J. F. K. Building
Boston, Mass.
C/Egmc

SHELLFISH HARVESTING DATA BY STATE AND FDA REGIONAL OFFICE LOCATION - 1971

State	Shellfish production in pounds
Alabama	246,000
California	959,000
Connecticut	407,000
Delaware	8,039,000
Florida	3,621,000
Georgia	138,000
Louisiana	9,937,000
Maine	5,271,508
Maryland	29,498,000
Massachusetts	2,640,000
Mississippi	1,165,000
New Jersey	31,957,000
New York	13,430,730
North Carolina	254,000
Oregon	321,000
Rhode Island	1,345,000
South Carolina	1,608,000
Texas	4,759,000
Virginia	14,836,000
Washington	5,975,000
Total	136,407,238

FDA regional office locations	
Boston, Massachusetts	9,663,508
New York, New York	45,387,730
Philadelphia, Pennsylvania	52,373,000
Atlanta, Georgia	7,032,000
Dallas, Texas	14,696,000
Seattle, Washington (including California)	7,255,000
Total	136,407,238

APPENDIX X

NATIONAL SHELLFISH SANITATION PROGRAM ELEMENTS

An evaluation is made by FDA for each of the following eight program elements

GENERAL ADMINISTRATIVE PROCEDURES - The adequacy of States legal authority to enforce the provisions of the NSSP and the adequacy of records maintained for monitoring purposes

LABORATORY PROCEDURES - The State laboratory practices and procedures for assuring that the laboratories are using currently accepted methods in making bacteriological, toxiological, chemical and physical analyses.

SANITARY SURVEY - A review of States efforts to assure that the shellfish growing waters are not polluted and are safe for shellfish harvesting. The factors influencing the sanitary quality of an area should be reappraised at least biennially. A comprehensive survey of each growing area in an approved category should be made at least once every ten years This includes an evaluation of all sources of actual or potential pollution, and the distance of such pollution from the growing areas; effectiveness and reliability of sewage treatment works, the presence of industrial wastes, pesticides, etc., which would cause a public-health hazard to the consumer of shellfish, and the effect of wind, stream flow, and tidal currents in distributing polluting materials over the growing areas.

RELAYING AND DEPLETION - The State's program for removing shellfish from an unsafe area for harvesting and transferring them to a safe area prior to harvesting.

CONTROLLED PURIFICATION - The effectiveness of the purification process at plants employing this method to cleanse shellfish of polluted material.

PATROL - The State's effectiveness to patrol and post restricted shellfish areas to prevent unauthorized harvesting

HARVESTING (Refers to boats and trucks only) - The sanitary condition of harvesting boats and trucks used to transport bulk shellfish

SHUCKING-PACKING - The conditions under which shellfish are shucked and packed including sanitation and storage conditions from point of harvest to wholesale market level A shucking plant is where shellfish meat is removed from the shell

APPENDIX XI

TOXIC METAL AND PESTICIDE ANALYSES

OF SHELLSTOCK COLLECTED AS PART OF FDA-GAO

INSPECTIONS OF INTERSTATE SHELLFISH SHIPPERS

State	Sample	Toxic Metals			Pesticides
		Cadmium	Mercury	Lead	
A	1	1.9*	-	-	Traces
	2	1.3	-	-	"
	3	1 1	-	-	"
	4	1 57*	01	-	"
	5	.89	.01	-	"
	6	1.6*	.01	-	"
	7	.51	.01	-	"
	8	.45	.01	-	"
	9	-	-	-	"
	10	.48	.01	-	"
	11	-	-	-	"
	12	.51	.06	-	"
B	13	.2	.05	4	None
	14	.3	04	1.0	"
	15	.2	.05	1 2	"
	16	2	09	1.3	"
	17	.2	05	6	Traces
	18	1.9*	01	.7	"
	19	1.7	07	-	"
	20	.36	06	-	"
	21	2	.02	.4	"
	22	.1	.01	.2	None
C	23	-	-	-	12 chlordane**
	24	.43	04	-	Traces
	25	-	-	-	.35 chlordane** and 03 DDT
	26	-	-	-	Traces
	27	-	-	-	"
	28	.31	.04	11	"
	29	N/A	N/A	N/A	"
D	30	.9	.04	.4	None
	31	1 0	.014	04	"
	32	1.1	02	.35	"
	33	1 15	.01	.6	"
	34	3	Traces	.5	"

Legend

N/A - Not analyzed

* - Above FDA's October 1971 proposed alert level for cadmium The alert levels varied by geographical area and species of shellfish.

** - Above the NSSP interim guidelines for pesticides in shellfish of 03 p p m for chlordane

LISTING OF SHELLFISH PLANTS

INSPECTED DURING GAO REVIEW

Condition	Name	Location	Date of Inspection
Significant insanitary	Chesapeake Shellfish Co	Sherwood, Maryland	Nov 2, 1971
	D&C Oyster Farms	Sequim, Washington	Oct 5, 1971
	Harold Bozman	Upper Fairmont, Maryland	Nov 2, 1971
	Leonard E Copsey	Mechanicsville, Maryland	Oct 28, 1971
	McNasby Oyster Co	Annapolis, Maryland	Oct 26, 1971
	Newburyport Shellfish Co	Newburyport, Massachusetts	Nov 18, 1971
	Northwest Oyster Farms, Inc	Nahcotta, Washington	Sept 14, 1971
	Soffron Bros Clam Co	Ipswich, Massachusetts	Aug 30, 1971
Insanitary	Ellison Brothers Oyster Co	Olympia, Washington	Sept 28, 1971
	L I Sea Clam Corp	Point Lookout, L I , New York	Sept 2, 1971
	Quality Sea Foods, Inc	Worcester, Massachusetts	Nov. 17, 1971
	Whitecap Seafood Co	Ipswich, Massachusetts	Oct 27, 1971
Minor insanitary	Coast Oyster Co	South Bend, Washington	Oct 27, 1971
	Frank M Flower&Sons, Inc	Bayville, New York	Oct 12, 1971
	Ipswich Shellfish Co , Inc	Ipswich, Massachusetts	Oct 27, 1971
	Long Island Oyster Farm, Inc	Greenport, L I , New York	Sept 20, 1971
	Minterbrook Oyster Co	Gig Harbor, Washington	Sept 1, 1971
	Pacific Fish Co	Seattle, Washington	Sept 29, 1971
In compliance	Brill's Crescent Seafood Co , Inc	Baltimore, Maryland	Oct 27, 1971
	Essex Farms	Royal Oak, Maryland	Nov 16, 1971
	H D Dukes&Son	Girdletree, Maryland	Nov 1, 1971
	Howard L Mallowes&Son, Inc	Marion, Massachusetts	Nov 19, 1971
	Johnson&Gunstone	Port Townsend, Washington	Oct 4, 1971
	Neptune Seafood, Inc	Patchogue, L I , New York	Oct 12, 1971
	S Pisacano Fish Market	Yonkers, New York	Sept 22, 1971
	Sanborn, J A , Co , Inc	Boston, Massachusetts	Sept 28, 1971
	Schermerhorn Fish Market, Inc	Springfield, Massachusetts	Oct 1, 1971
	Shellfish, Inc	West Sayville, L. I , New York	Nov 1, 1971
	Sunrise Fish Co , Inc	Islip, L I , New York	Nov 1, 1971
	Winant&Co , Inc	L I City, New York	Nov 1, 1971

APPENDIX XIII

PRINCIPAL OFFICIALS OF THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE RESPONSIBLE FOR ADMINISTRATION OF ACTIVITIES DISCUSSED IN THIS REPORT

	Tenure of office	
	From	To
SECRETARY OF HEALTH, EDUCATION, AND WELFARE		
Caspar W Weinberger	Feb. 1973	Present
Frank C. Carlucci (acting)	Jan 1973	Feb. 1973
Elliot L. Richardson	June 1970	Jan. 1973
Robert H. Finch	Jan. 1969	June 1970
Wilbur J. Cohen	Mar 1968	Jan 1969
John W. Gardner	Aug 1965	Mar. 1968
ASSISTANT SECRETARY (HEALTH) (note a)		
Richard L Seggel (acting)	Dec. 1972	Present
Merlin K. DuVal, Jr.	July 1971	Dec. 1972
Roger O. Egeberg	July 1969	July 1971
Philip R. Lee	Nov. 1965	Feb. 1969
COMMISSIONER, FOOD AND DRUG ADMINISTRATION		
Charles C. Edwards	Feb. 1970	Present
Herbert L. Ley, Jr.	July 1968	Dec. 1969
James L. Goddard	Jan. 1966	June 1968

[a]Before November 1972 this position was designated as Assistant Secretary for Health and Scientific Affairs. In March 1968 the Assistant Secretary was given direct authority over the Public Health Service and the Food and Drug Administration and the functions of the two organizations were realigned.