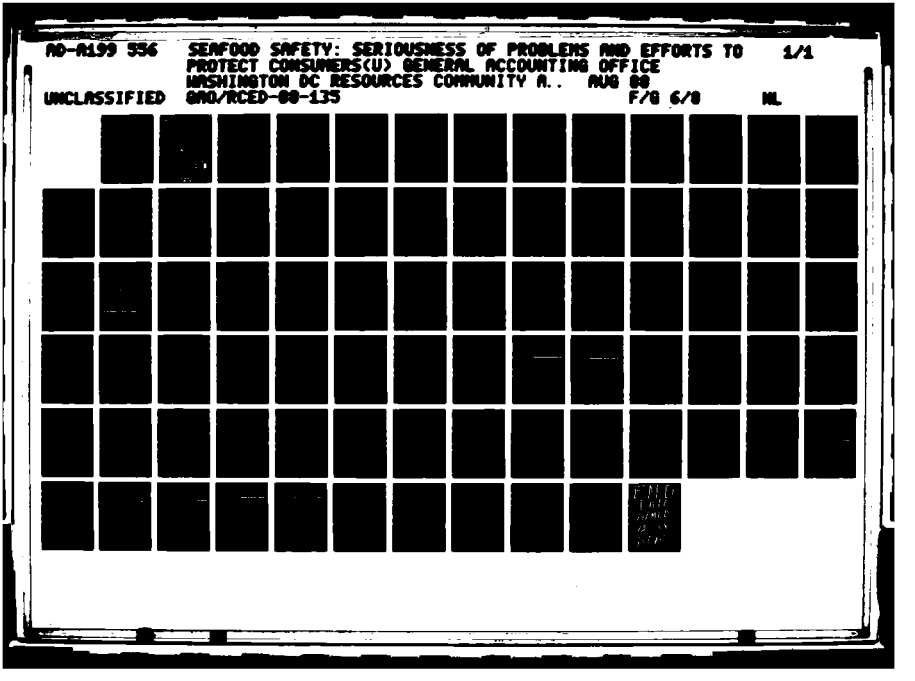
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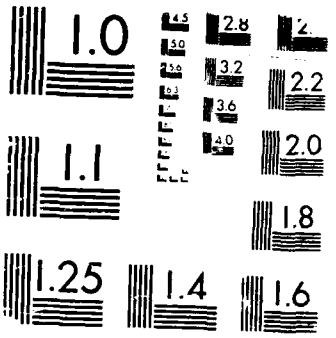
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United States General Accounting Office

GAO

Report to the Chairman, Subcommittee on Commerce, Consumer and Monetary Affairs, Committee on Government Operations, House of Representatives

August 1988

SEAFOOD SAFETY

Seriousness of Problems and Efforts to Protect Consumers

GAO/RCED-88-135

GAO

United States
General Accounting Office
Washington, D.C. 20548

Resources, Community, and
Economic Development Division

B-230836/001

August 10, 1988

The Honorable Doug Barnard, Jr.
Chairman, Subcommittee on Commerce,
Consumer and Monetary Affairs
Committee on Government Operations
House of Representatives

Dear Mr. Chairman:

As you requested, we have assembled information on the seriousness of consumer-related problems with seafood. We have emphasized seafood safety from the standpoint of human health and have also provided information on the misrepresentation issue involving the packaging of seafood.

As arranged with your office, unless you publicly release its contents earlier, we plan no further distribution of this report until 30 days after the date of this letter. At that time we will send copies to other appropriate congressional committees; the Secretary, Department of Health and Human Services; the Commissioner, U.S. Food and Drug Administration; the Director, the Centers for Disease Control; the Under Secretary for Oceans and Atmosphere, Department of Commerce; the Administrator, U.S. Environmental Protection Agency; the Assistant Secretary - Policy, Budget, and Administration, Department of the Interior; the Director, U.S. Fish and Wildlife Service; the Director, U.S. Geological Survey; the states contacted during the review; and the Director, Office of Management and Budget. We will also send copies to other interested parties upon request.

This report was prepared under the direction of John H. Luke, Associate Director. Other major contributors are listed in appendix VI.

Sincerely yours,

J. Dexter Peach

J. Dexter Peach
Assistant Comptroller General

Executive Summary

Purpose

Growing public awareness and concerns about seafood contamination have sparked a renewed interest in seafood safety. Concerns have been expressed that federal initiatives to protect consumers are not sufficient and a mandatory seafood inspection system should be implemented.

Because of these concerns and the attention given to seafood safety, the Chairman, Subcommittee on Commerce, Consumer and Monetary Affairs, House Committee on Government Operations, asked GAO among other things to gather information on the nature, extent, and seriousness of seafood safety problems; identify the governmental activities that address the issue; and obtain expert views on the need for changes, such as the need for a mandatory seafood inspection system or other changes in existing programs.

Background

Seafood can be exposed to a variety of biological and chemical contaminants that can cause acute or chronic illness in humans. Biological pathogens (including naturally occurring, water-borne and sewage-related bacteria and viruses) are among these contaminants. Naturally occurring, biologically produced toxins can also be present under certain conditions in some finfish and shellfish. Chemical contaminants such as heavy metals and pesticides are also present in our waters and trace levels in some seafood. Various federal and state activities exist to monitor and assess contaminants in seafood.

Results in Brief

GAO's findings on seafood safety were essentially threefold:

- Seafood illness data reported to the Centers for Disease Control from 1978 to 1984, while recognized as incomplete, represented about 5 percent of all food-borne illness cases. In addition, the U.S. Food and Drug Administration (FDA) in 1986 found adverse seafood samples—those in violation of regulations and requiring action—about 29 percent of the time, but the majority of these adverse findings would not be considered direct threats to human health. (Ch. 2.)
- Unlike the meat and poultry industry, the seafood industry is not subject to mandatory, 100-percent product inspection by the federal government. However, federal and state agencies perform safety-related inspections, data gathering, and research activities to help monitor the condition of the nation's seafood. (Ch. 3.)
- Many experts said that seafood safety problems do not reflect the need for major changes in federal programs. However, they identified specific

areas for improvement, such as better tests for microbiological pathogens and more research on chemical contamination and human illness. (Ch. 5.)

On the basis of this information, GAO believes that there does not appear to be a compelling case at this time for implementing a comprehensive, mandatory federal seafood inspection program similar to that used for meat and poultry.

GAO's Analysis

Extent and Nature of Seafood Safety Problems

Data on seafood safety from the Centers for Disease Control are acknowledged to be incomplete. However, they can provide at least an indication of the extent and nature of seafood safety problems. For the 1978-84 period, 100,166 food-borne illness cases were reported to the Centers. Seafood was associated with about 5 percent of these cases, and five deaths occurred. The data also showed that most of the seafood-borne illnesses were associated with three species groups. Two groups include finfish that can generate biological toxins—ciguatoxin or scombrotoxin—capable of causing acute illness. The third group, representing about 53 percent of seafood illness cases, was molluskan shellfish that can accumulate high levels of disease-causing agents, or "pathogens." When contaminated mollusks are eaten raw or undercooked, they may inflict humans with vibrio cholerae, hepatitis, or other serious illnesses, which in some cases may become chronic or fatal.

In fiscal year 1986, FDA's analysis of 6,528 samples identified 1,881 (29 percent) that were not in compliance with federal regulations for contaminants and proper labeling. To get an indication of the human health implication of these findings, GAO reviewed a portion of the noncompliant samples. GAO found that about 78 percent were not a direct threat to human health and that much of the remaining threat could be neutralized through proper cooking.

Seafood is exposed to an indeterminable number of chemicals, including heavy metals, polychlorinated biphenyls, and pesticides. Experts note that because of difficulties in developing direct relationships, much remains unknown regarding the levels of chemical exposure and human illness. Federal action levels have been established for 15 hazardous chemical substances that have been found in seafood, most of which are

suspected to be or are potentially carcinogenic or mutagenic. In fiscal year 1986, FDA tested 1,299 of the 6,528 samples for chemicals and found 118 adverse samples.

Federal and State Seafood Programs

While not subjected to the concept of 100-percent product inspection by the federal government, the seafood industry is subject to monitoring and assessment by federal and state agencies. FDA, the National Oceanic and Atmospheric Administration (NOAA), the Environmental Protection Agency (EPA), and several other federal agencies are involved with seafood safety and product misrepresentation. Their activities include inspection, product sample analysis, regulatory and enforcement activity, research, data gathering, and technical assistance to states and the industry. FDA estimates that it samples less than 1 percent of the domestic seafood and 3 percent of imported seafood products. FDA believes its efforts, while limited, are made more effective in that they are targeted to potential problem areas. NOAA estimates that it inspected about 10 percent of seafood consumed in fiscal year 1987 through its voluntary seafood inspection program.

In addition to other activities, FDA evaluates state shellfish safety programs. Notwithstanding state program improvements, 9 of the 24 states evaluated by FDA were found in fiscal year 1987 to have major problems in implementing programs, such as the assessment and classification of harvest areas, patrol and enforcement, and processing plant inspections. Limited resources were cited as a major reason why many states are having these problems.

Several federal initiatives of particular interest are currently underway. These include (1) two studies involving biological contamination of shellfish by NOAA and EPA, (2) the development of a risk information system for chemical contamination by EPA and (3) the development of a system by NOAA to reduce biologic hazards by focusing on critical control points in seafood harvesting and processing operations.

Expert Views on Seafood Safety

According to many government and private experts, problems with seafood safety are not major or widespread. However, many identified certain problem areas and opportunities for improvement. They expressed particular concern about (1) consumption of contaminated shellfish and (2) chemical contamination of seafood. Many experts suggested the need for greater resource commitment to these problems.

GAO Observations

On the basis of the information GAO gathered and the views of experts GAO interviewed, there does not appear to be a compelling case at this time for implementing a comprehensive, mandatory federal seafood inspection program similar to inspections used for meat and poultry. Among the factors leading GAO to this conclusion are that (1) available seafood-borne illness data, while recognized as incomplete, do not indicate widespread problems with the nation's seafood, (2) current federal and state monitoring and assessment activities, though recognized as limited, provide checks on seafood safety concerns and conditions, and (3) problem areas identified, such as incomplete knowledge on chemical contamination and the need to encourage proper cooking of seafood, are not generally the type that would be solved by a mandatory inspection program.

GAO believes that continuing attention and support are needed for a number of initiatives, including the development of the seafood surveillance model, research on chemical contaminants and tests of shellfish-growing waters, and increased public awareness of the known safety risks associated with eating raw shellfish. In addition to improving seafood safety, these activities could help provide a basis for designing a mandatory inspection program in the future, should one be deemed necessary.

Recommendations

GAO is making no recommendations.

Agency Comments

GAO discussed this report with the principal federal agencies and included their comments where appropriate. However, as requested, GAO did not obtain written agency comments or state and industry comments on a draft of this report.

Contents

Appendixes

Tables

Abbreviations

CDC	Centers for Disease Control
DDT	dichlorodiphenyl-trichloroethane
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
GAO	General Accounting Office
ISSC	Interstate Shellfish Sanitation Conference
MOU	memorandum of understanding
NMFS	National Marine Fisheries Service
NOAA	National Oceanic and Atmospheric Administration
NSSP	National Shellfish Sanitation Program
OTA	Office of Technology Assessment
PCB	polychlorinated biphenyls
PODS	Program Oriented Data System

Chapter 1

Introduction

The U.S. annual per capita consumption of seafood has increased over the past several years after a considerable period of relative stability. From 1910 to 1980, annual per capita consumption primarily remained between 10 and 12 pounds. In 1986 per capita consumption reached nearly 15 pounds, which, compared with 12.9 pounds in 1981, represents a 16-percent increase during the period. Medical research may have been responsible for some of the increase, having linked potential health benefits from higher seafood consumption with reduced intake of protein sources high in saturated fats.

Medical research and related scientific papers have drawn relationships between the consumption of fish and fish oils and lower mortality from coronary heart disease and strokes. Such work has indicated that seafood and/or fish oils can play a role in

- reducing levels of cholesterol and triglycerides, which have been linked to heart disease;
- favorably altering the balance of lipoproteins in the blood so as to reduce deposits on artery walls; and
- reducing cell clotting leading to heart attacks and strokes.

In addition, seafood has long been recognized as an easily digestible food and an excellent source of amino acids necessary for constructing body protein.

Aside from the health benefits of seafood, however, there are concerns about its safety in view of the various types of contamination it may be exposed to. Opportunity exists for both biological and chemical contamination, which can occur in seafood species in the natural environment, as well as during subsequent handling, processing, distribution, and final preparation for serving. Various aspects of seafood safety have been periodically assessed and discussed over many years. In fact, the consumption of raw molluskan shellfish[1] has been a topic of special concern for most of this century. Illness outbreaks and death from typhoid fever bacteria in shellfish during the first quarter of this century prompted action that led to the establishment of the National Shellfish Sanitation Program (NSSP) in 1925.

Concern over seafood safety during the last 20 years has resulted in several legislative proposals and information gathering, including the proposed Fishery Products Protection Act of 1967 and the proposed

[1] Molluskan shellfish are oysters, clams, and mussels.

Wholesome Fish and Fishery Products Act of 1969. In 1974 oversight hearings on fish processing and inspection were held, and later in 1979 the Congressional Research Service prepared a comprehensive informational report, Food Safety: Where Are We?, at congressional request, which presented facts on the state of seafood and related governmental programs and activities. GAO has also addressed elements of the seafood safety issue, as well as other topics that have a bearing on the issue Appendix III provides a list of these reports.

Recent Concerns About Seafood Safety

Recent initiatives and publicity have again focused attention on government seafood inspection and monitoring activities. These initiatives reflect a perception that seafood consumption may pose unacceptable health risks because seafood is not inspected in a fashion similar to that for meat and poultry under the direction of the U.S. Department of Agriculture. Some charge that major governmental reforms are necessary to reduce serious health threats posed by contaminated seafood that enters commerce because of limitations in existing inspection programs.

As a result of a congressional request, the Congressional Research Service assembled information on the concept of mandatory seafood inspection. Its report, Mandatory Federal Seafood Inspection: An Overview, issued in November 1983, provided highlights on the U.S. fishing industry and contrasted the current inspections of fishery products with the mandatory programs regulating meat and poultry. The report also posed some fundamental policy questions to be discussed by lawmakers considering whether governmental programs and responsibilities for seafood safety needed to be strengthened. These questions addressed costs and benefits, the nature of the seafood industry, domestic and imported seafood considerations, and what agency should have this responsibility. While this information did not provide a basis for making a decision on this issue, legislation was introduced in the 98th, 99th, and currently the 100th Congress calling for the establishment of a mandatory program of continuous seafood inspection similar to existing inspection programs for meat and poultry. No action has been taken by the Congress on the current bill, H.R. 1483, introduced on March 9, 1987.

In April 1983, a consumer advocacy group, Public Voice for Food and Health Policy, issued a report, A Market Basket of Food Hazards: Critical Gaps in Government Protection, which provided information on health problems possibly caused by contaminated food, including seafood. The report characterized governmental programs as inadequately designed to protect consumers from seafood contamination, claiming

these programs did not prevent seriously contaminated seafood from entering the marketplace. In 1986 Public Voice issued another report, The Great American Fish Scandal: Health Risks Unchecked, which presented information on health risks from contaminated seafood, food-borne illness data, and governmental programs addressing seafood inspection activities. The report concluded that the health risks, illness data, and a limited patchwork of government programs supported the need for mandatory seafood inspection.

On June 14, 1984, we issued our report, Problems In Protecting Consumers From Illegally Harvested Shellfish (Clams, Mussels, and Oysters), GAO/HRD-84-36, which presented information on problems facing federal and state authorities and the shellfish industry in ensuring that safe shellfish enter the marketplace. We cited problems with state shellfish programs concerning the survey and classification of growing waters, patrolling growing waters, limitations in fines and penalties to deter illegal harvesting, and related concerns affecting shellfish safety.

In 1987 the National Oceanic and Atmospheric Administration (NOAA), through the National Marine Fisheries Service (NMFS), started to develop a plan for a seafood surveillance system model for domestic and imported seafood, focusing primarily on safety control points on fishing vessels and in food processing operations. According to NMFS officials responsible for the project, a critical objective of the project is to address the facts about the nature and extent of the seafood safety problems and design a system targeted at particular problem areas. The National Academy of Sciences, as part of its work with NMFS on this project, will review the various types of biological contaminants that seafood could be exposed to and available seafood-borne illness data. NMFS officials believe this project can provide a surveillance system model that can effectively address biological contamination problem areas with seafood safety and have the support of the involved government agencies and major industry leaders.

On October 23, 1987, a bill (S. 1813) designed to reduce food-borne disease and improve the inspection of meat, poultry, and fish was introduced in the U.S. Senate. The bill provides authority for a testing program for microbiologic pathogens and chemicals in seafood. The bill was referred to the Senate Committee on Agriculture, Nutrition and Forestry, and currently remains with the Committee.

Objectives, Scope, and Methodology

In an August 26, 1986, letter and subsequent meetings, the Chairman, Subcommittee on Commerce, Consumer and Monetary Affairs, House Committee on Government Operations, asked GAO to provide information on the nature, extent, and seriousness of consumer-related problems with seafood from the standpoint of human health; identify government activities that address the issue; and obtain current views of government and private experts on seafood safety problem areas and the need for changes in government programs. We were also asked to gather information on the issue of seafood misrepresentation (i.e., product substitution, mislabeling, short-weighting). We did not conduct a review of the efficiency or effectiveness of the federal or selected state government programs and services identified in the assignment. However, we have issued other reports on related topics that have addressed the efficiency and effectiveness of federal and state programs. For example, some of the more recent reports have addressed the issues of water pollution and food inspection, including monitoring for pesticides and sampling procedures.

To obtain proper geographical coverage for these issues, we selected regional areas and states that had significant seafood harvesting and processing activity as well as federal activity addressing seafood safety concerns. In this regard, we selected several states along the Atlantic, Gulf, and Pacific Coasts of the United States (including Alaska), representing the majority of the marine and estuarine areas. We also selected several interior states that are essentially seafood receiver states, i.e., states having limited or no seafood processing or repacking activity.

With regard to federal programs and services, our work was performed at the offices of the U.S. Food and Drug Administration (FDA) headquarters, in Washington, D.C., and Rockville, Maryland, and several regional and district offices, and the Centers for Disease Control (CDC) in Atlanta, Georgia. In addition, we conducted our work at several organizational components of NOAA, in Washington, D.C., and Rockville, Maryland, including NMFS and several of its regional facilities; the National Ocean Service; and the Office of Oceanic and Atmospheric Research. We also conducted our work at the Environmental Protection Agency (EPA) in Washington, D.C., and at selected EPA regional offices. Some work was performed or information was obtained from several other federal agencies, including the U.S. Fish and Wildlife Service, the U.S. Geological Survey, and the National Institute of Environmental Health Sciences.

To obtain information on federal programs, we conducted interviews with federal agency officials and managers responsible for programs

directly addressing or contributing to data gathering on this issue. Interviews were conducted to obtain fundamental information on program objectives and findings and to obtain the views and perspectives of these representatives on problem areas and suggestions for changes in government activity. We also reviewed pertinent agency documents, reports, and data describing program activities. We did not independently verify these or other data provided by federal agencies.

To provide a basis for our review on the nature, extent, and seriousness of seafood safety problems, we obtained information on the various types of biological pathogens, toxins, and parasites that may contaminate seafood and cause illness in human beings. Information on these contaminants was obtained by reviewing various recognized reference materials, reports, and articles on seafood illness-causing agents and through interviews we held with government and private sector experts on this issue. We also obtained information on chemical contamination of seafood and the current state of knowledge of the relationships between levels of chemical contamination and human illness. We reviewed federal reports and special studies on this topic and obtained additional insight from interviews with federal officials and managers in FDA and EPA.

To provide some perspective on the types and the seriousness of contaminants in seafood, we obtained information on reported seafood-borne illness in the United States. Specifically, we reviewed reports and records maintained by CDC. This involved interviewing key program officials at CDC and reviewing published food-borne illness reports and unpublished data and files.

To obtain a perspective on the nature and extent of seafood problems found by FDA, we reviewed selected information on seafood sample analysis activity contained in the agency's Program Oriented Data System (PODS) and district office data systems. We focused our attention on samples taken in 1986 that were determined by FDA to be adverse, i.e., those requiring some type of regulatory action by FDA or voluntary corrective action by the responsible seafood establishment or importer.

We used PODS to select eight district offices whose seafood sample analysis workload represented about 80 percent of the total number of adverse samples found by FDA in 1986. Our selection of FDA district offices was also made to provide geographic coverage of the United states, including East Coast, Gulf of Mexico, and West Coast districts of FDA where the majority of seafood processing establishments are

located, as well as ports of entry for imported seafood products, such as New York City and Los Angeles. We also used PODS to identify selected information on agencywide seafood sample analysis activity. We used district office data systems and files at the eight district offices we selected for more detailed review of adverse seafood samples. We noted differences in PODS and district office data systems concerning the number of adverse samples identified. FDA officials advised us that they were aware of some data problems and were working to reconcile PODS and district office data systems. We did not attempt to reconcile data system differences.

Our review of FDA's adverse seafood samples provides a representation of FDA findings for fiscal year 1986. However, these data cannot be used to project the safety of seafood nationwide because of the targeted approach FDA uses in selecting samples. A detailed description of our review of FDA's adverse seafood sample findings is contained in appendix II.

Our work at state agencies included visits to agencies in 11 states and telephone contacts with agency representatives in 9 additional states. We conducted interviews with officials and program representatives of these state agencies and reviewed readily available state agency documents, reports, and data on their programs and activities. The purpose of this work was to (1) obtain basic information on seafood-borne illness in the state, state programs involved in seafood establishment inspection and sample analysis, and monitoring and enforcement of harvesting areas and (2) obtain state officials' views on the seafood safety issue and changes they believe are needed to better address the issue. We did not independently verify the data provided by state agencies.

We conducted interviews with several academicians, private sector experts, and association representatives. Our objective was to obtain their views on the nature and extent of problems with seafood safety and their suggestions for needed changes in government programs related to the seafood safety and misrepresentation issues.

In total, during our review we interviewed about 350 federal and state government representatives and private sector and academic experts. Because of the numerous topics covered during our review, and the varying knowledge and interests of the public and private sector experts we contacted, we focused our interviews on topics that the interviewees were familiar with and, therefore, did not ask the same questions of all persons interviewed.

Our review was primarily performed between September 1986 and September 1987, with additional information obtained through December 1987. We performed our work in accordance with generally accepted government auditing standards. As requested, we did not obtain official comments on a draft of this report. However, we sought the views of responsible federal and state officials during the course of our work and incorporated them in the report where appropriate.

Chapter 2

Biological and Chemical Contamination in Seafood

Seafood can be exposed to a wide variety of biological and chemical contaminants that, in turn, can cause illness in humans. Such contamination can occur in the natural environment as well as during subsequent handling, processing, and final preparation of seafood products. Seafood is not unique in this regard—all food products can be exposed to various types of contamination at any number of stages between the actual growing areas and the ultimate preparation for human consumption.

CDC statistics on food-borne illness, while generally recognized as incomplete, indicate that seafood-related illness represented about 5 percent of all reported food-borne illness cases during the period 1978 to 1984. Most of the reported seafood illnesses were associated with two finfish groups that can transmit biologically produced chemical toxins and with molluskan shellfish, which can transmit microbiological pathogens. Our review of FDA's adverse seafood samples for 1986 showed that about 78 percent of the adverse findings would not generally be considered as serious, direct threats to health. An additional 8 percent of the remaining adverse samples that would be categorized as serious sample findings were related to pathogens that would be effectively neutralized when the product is properly cooked. The majority of the other adverse findings considered serious were related to chemicals identified in the seafood samples.

Seafood can be exposed to an indeterminable number of chemicals, including heavy metals, pesticides, and polychlorinated biphenyls (PCB). FDA and EPA have established action levels for 15 hazardous chemicals that have been found in seafood. Because of the difficulties in establishing direct relationships, much remains unknown about the effects of varying levels of chemical contamination and human illness.

Seafood Can Transmit Pathogens, Natural Toxins, and Parasites

Seafood may be exposed to a variety of pathogens, biological toxins, and parasites that can cause acute illness in humans. Exposure to these contaminants can occur in finfish, crustaceans, or mollusks either in their natural environment or through subsequent handling. The majority of seafood-related illnesses reported to CDC were attributed to two species groups of finfish that can produce biological toxins (ciguatoxin and scombrotoxin) and raw or undercooked molluskan shellfish that transmit pathogens.

Seafood Pathogens

Disease-causing pathogens that can contaminate seafood include a variety of naturally occurring water-borne pathogens and other microbiological pathogens that either enter the water from domestic sewage or pass from humans or other warm-blooded animals to seafood during subsequent handling. Among the naturally occurring water-borne pathogens are the several vibrio species and other bacterial pathogens. The microbiological pathogens that may contaminate seafood include such contaminants as salmonellae, staphylococcus aureus, and hepatitis A. Overall, these pathogens have caused seafood-connected illness in the United States, but generally these illnesses are mild and of short duration. Some pathogens, however, can cause more serious illness and death, especially for persons with other underlying medical problems.

Several bacterial pathogens are of special concern with raw molluskan shellfish. These include the naturally occurring vibrios indigenous to shellfish-growing waters, such as vibrio parahaemolyticus, vibrio cholerae, and vibrio vulnificus. Vibrio vulnificus infection causes high fever, chills, and, in some cases, death. Most cases resulting in fatalities have involved persons with previously existing liver or iron metabolism problems who are at highest risk from this type of infection. According to FDA information, between October 24, 1986, and August 11, 1987, there were 37 vibrio cases involving oysters from Gulf of Mexico waters. Of these cases six fatalities were associated with the consumption of raw oysters contaminated with vibrio vulnificus.

Vibrio cholerae is another pathogen that may naturally occur in sufficient numbers in brackish water and seawater and appear in significant concentrations in shellfish. This bacterium is widespread along the Atlantic and Gulf Coasts of the United States, as well as in some Pacific Coast estuaries. According to the Director of the Institute for Food Science and Technology at the University of Washington, when cholera has occurred in the United States in recent years, it has been the milder form rather than the more severe form of years ago.

Viral pathogens are also of particular concern, especially with raw molluskan shellfish from sewage-polluted waters. According to an NMFS expert on viruses in shellfish, hepatitis is now the most serious viral pathogen in shellfish, but other viruses, such as the Norwalk virus, which causes viral gastroenteritis, have played a major role in recent years in illnesses related to the consumption of shellfish. Hepatitis causes malaise, appetite loss, nausea, vomiting, fever, and jaundice. Mild cases are often mistaken for flu; severe cases can cause liver damage and death. Viral gastroenteritis symptoms include vomiting, diarrhea,

abdominal cramps, low-grade fever, and malaise. The illness usually lasts 24 to 48 hours, and medical attention is often not required.

Toxins in Seafood

Two naturally occurring toxins in finfish—ciguatoxin and scombrotoxin—have been principal contributors to seafood-borne illness over the past several years. More infrequent illnesses have been attributed to paralytic shellfish poison and botulism, the latter having caused a high rate of fatalities.

Ciguatoxin poisoning results from eating predaceous subtropic or tropic finfish, such as grouper, red snapper, barracuda, sea bass, amberjack, and skipjack. These fish feed on smaller fish that have, in turn, fed on marine plankton carrying the toxin. Fish from certain waters may be free from the toxin at one time, but not at other times. According to a July 1980 Journal of the American Medical Association article, consumers buy most of these toxic fish from restaurants and fish markets. Symptoms of the disease include sensation of pain or heat and tingling or burning of the skin; diarrhea and vomiting often occur as well. While ciguatoxin can cause death in rare instances, the disease is generally of short duration. In recent years, ciguatoxin has accounted for about one-third of the finfish-related illnesses reported to CDC. Federal research conducted over the last decade, including work by NMFS, has helped develop rapid methods for testing these species for ciguatera toxicity.

According to a 1980 Journal of Food Protection article, scombrotoxin poisoning occurs after eating certain finfish that contain high concentrations of a naturally occurring chemical substance—histidine—in their flesh. Tuna, bonito, swordfish, and mackerel are included among these species. Without proper refrigeration, marine bacteria normally occurring in these fish multiply and produce histamine, which acts as a toxin. This illness is generally mild and involves such symptoms as nausea, abdominal cramping, vomiting, diarrhea, flushing, headache, and burning sensations that can last for several hours.

Botulism is the most serious type of bacterial food poisoning, with a fatality rate of about 25 percent. This toxin is produced by the bacterium clostridium botulinum, which may be present in water and mud. Botulism can cause human illness when seafood containing the bacterium is consumed after being subjected to inadequate heat processing, allowing the bacterial spores to grow and produce the toxin. According to a 1980 Journal of Food Protection article, despite the natural occurrence of this bacterium, most seafood illness cases involving botulism

have occurred from improper seafood processing, which permits the bacterium to grow and produce toxin in an anaerobic (oxygen-free) environment.

Various molluskan shellfish absorb certain marine organisms that accumulate and develop a toxic substance known as paralytic shellfish poison. Consumption of shellfish contaminated with this toxin can cause tingling, numbness, burning sensations, paralysis, gastrointestinal pain, and respiratory distress. Death may occur without prompt and appropriate treatment. Paralytic shellfish poison seldom involves commercially harvested shellfish. Rather, most cases have been connected with persons who have harvested shellfish for their own consumption from areas that were known to have high concentrations of the toxin-producing organisms.

A recent incident of apparent shellfish toxin poisoning occurred in late 1987 and was traced to Canadian waters off the Atlantic provinces and in the Gulf of St. Lawrence. By mid-December the unidentified toxin had affected 100 Canadians and killed 1. Canadian scientists ruled out the well-recognized paralytic shellfish poisoning and do not believe it is the result of heavy metals, pesticides, or other chemical contamination. They believe the toxin is a new strain of biologically produced chemical toxin, like paralytic shellfish poisoning.

Seafood Parasites

In addition to microbiological pathogens and toxins, finfish may also contain naturally occurring parasitic worms, such as anisakid nematode worms, tapeworms, and fluke. All of these parasitic worms are capable of causing illness in humans.

The nematode worm can cause severe gastric upset for as long as 10 days. In some cases vomiting and stomach pains may be so severe that the worms may have to be removed surgically. These worms can sometimes penetrate the stomach or intestinal wall and invade other organs. Tapeworms and fluke can also be present in fresh finfish. Tapeworms can live in the intestinal tract of humans for years and cause weakness, abdominal pain, loss of weight, and anemia. Fluke worms, found in salmon, can cause illness similar to that resulting from tapeworms.

According to the University of Oregon Extension Service, while processors preparing fresh fish fillets try to remove worms and worm larvae, it is generally recognized that this is only about 70-percent effective

under the best circumstances. However, all of these parasitic worms survive and cause illness in humans only if the host finfish is eaten raw or inadequately cooked.

Proper Handling and Cooking Are the Best Defense Against Most Biological Pathogens

According to experts and literature on this subject, properly handled and cooked seafood will eliminate many seafood-related causes of illness: pathogenic bacteria, viruses, and parasites. Proper handling prior and subsequent to cooking also minimizes or eliminates the potential for cross-contamination or recontamination of pathogens. Cooking may also reduce levels of some toxic chemicals. However, there are some toxins that cooking may not eliminate, such as ciguatoxin and scombrotoxin. Histamine in fish is quite heat-resistant and will remain to adversely affect persons who consume it. Paralytic shellfish poison is also heat-resistant and not destroyed by cooking.

Contamination of food in general, including seafood, often occurs after it reaches the stage of ultimate preparation for human consumption. Improper handling and preparation at home or in restaurants have been cited as a reason for many food-related illnesses. For example, according to a 1987 report on food-borne disease outbreaks by the New York Department of Health,[1] mishandling of food at food service establishments/restaurants or in the home was associated with 101 of the 140 food-borne disease outbreaks in the state in 1985. The most frequent confirmed mishandling factors included improper refrigeration, improper hot-holding, inadequate cooking, unclean equipment, and infected food handlers.

Chemical Contamination of Seafood

Additional contamination of seafood can take place through contact with heavy metals, pesticides, and other chemical contaminants, including PCBs. Fish and shellfish, particularly molluskan shellfish, are exposed to an indeterminable number of chemicals and tend to concentrate these contaminants in their bodies at levels many times the level existing in the surrounding marine environment. While the presence of various types and levels of chemical contaminants are recognized, it is difficult to develop direct relationships between levels of many chemical contaminants and human illness. Because of these uncertainties, the potential seriousness of this issue remains unclear.

[1] New York State Department of Health, Bureau of Community Sanitation and Food Protection, A Review of Foodborne Disease Outbreaks in New York State 1985, April 1987.

Numerous Chemical Contaminants Exist

According to an April 1987 report, Wastes in Marine Environments, by the Office of Technology Assessment (OTA), industry worldwide uses about 65,000 chemical compounds. The report also noted that about 1,000 new chemicals enter commerce each year, resulting in a highly complex mixture of chemicals in the environment.

According to a toxic chemicals specialist for the NMFS Northwest and Alaska Fisheries Center, the safety of seafood cannot really be determined until more work is accomplished to identify the different chemicals that exist in the aquatic environment and seafood species and to determine their health effects on humans. Even for most of the chemicals that scientists have classified as "associated" or "highly probably associated" with cancer in humans or for which sufficient evidence exists for their causing cancer in experimental animals, little data are available on concentrations in marine organisms.

Several carcinogenic chemicals or chemical compounds found in urban sewage or in industrial and agricultural pollution are affecting fish, crustaceans, and molluskan shellfish. High concentrations of these chemicals have been identified close to point sources of pollution in harbors, estuaries, rivers, and large inland waters, such as the Great Lakes. Over the last several years, studies by certain federal agencies, including NOAA and EPA, have identified high levels of chemical as well as other contaminants in various coastal and estuarine areas, including Commencement Bay, San Francisco Bay, Santa Monica Bay, Narragansett Bay, and Boston Harbor. Some of these area surveys and research work identified chemical levels in marine species higher than in species found in the open seas of the North Atlantic and North Pacific Oceans.

Federal and state efforts continue to survey marine, estuarine, and freshwater fishing areas to determine the presence of chemical and other substances. Work is directed at building data bases on the status and changing conditions in U.S. waters, seafood species, and other living resources and providing the basis for further research and studies. Chapter 3 on federal and state programs describes some of these activities.

Studies Addressing the Potential Threat of Chemical Contamination

Documentation indicates chemical contaminants may represent a threat to human health, although direct evidence of health effects is generally lacking. A 1987 OTA report stated that scientists do not know the human health risks from exposures to 90 percent or more of all chemicals in various wastes that get into the environment. Various studies have

attempted to identify the effects of chemical consumption on human health.

In 1987 a compendium of work on cancer risk in the Great Lakes was prepared by University of Wisconsin researchers, with federal and state funding, which related research on the potential cancer risks from the consumption of Great Lakes fish.[2] The report pointed out that despite the detection of chemical carcinogens in the Great Lakes since the 1960s, no chronic human health effects have been directly attributed to the consumption of Great Lakes fish. It also stated, however, that toxic substances still may affect human health, although the effects are difficult to measure. It further stated that the best sources of information linking human health effects with chemical exposure are epidemiological studies correlating known levels of chemical exposure to documented health effects in people. The report related two recent studies that correlated short-term health effects in infants with maternal consumption of Great Lakes fish, which, according to the report, offer the only evidence of human health effects from the consumption of Great Lakes fish. One epidemiological study pointed out that infants of mothers who consumed substantial amounts of Great Lakes fish showed lower birth weights, smaller head circumferences, and slower responsiveness than infants of mothers who did not consume Great Lakes fish. The other study involving Great Lakes fish indicated that concentrations of PCBs in mothers' blood serum during pregnancy correlated positively with the number and types of infectious illnesses their infants suffered during the first 4 months after birth. The study indicated, however, that there is no evidence that PCBs caused these effects or that there is any chronic problem developing.

The report also presented other research work that compared the carcinogenic risks of average consumption of contaminants in U.S. fish with the average consumption of Great Lakes fish by sports fishermen. It indicated that risks of cancer from average U.S. fish consumption are much less than those from Great Lakes sport fish consumption for two reasons. Ocean fish, which constitute a large share of the average consumer's diet, typically have lower levels of contaminants than Great Lakes sport fish. Further, sport fishermen eat more fish than the average consumer and therefore are at greater risk.

[2] Kenneth M. Bro, William C. Sonzogni, and Mark E. Hanson, Relative Cancer Risks of Chemical Contaminants in the Great Lakes

Information was also presented on estimates of carcinogenic risks from eating Great Lakes sport fish. The report stated that estimated cancer risks from Great Lakes fish ranged from less than 1 additional cancer death per 1,000 Great Lakes anglers to up to over 30 additional deaths per 1,000. According to the report the range of cancer deaths per 1,000 was related to fish species' differences and the high fat content of some species. It also stated that the principal contributors to the estimated risks were PCBs and dichlorodiphenyl-trichloromethane (DDT).

A 1983 Harvard School of Public Health study also emphasized the potential health threats of chemical contaminants.[1] The study found carcinogenic risks from consuming freshwater fish to be several times greater than for most marine fish. In general, freshwater and estuarine fish from industrialized regions present risks about 10 times greater than fish from less-developed estuaries and 50 to 100 times greater than fish from offshore fisheries. The study also found that most known carcinogenic risks come from PCB contamination, although DDT residues also contribute significantly.

According to 1986 EPA guidelines for carcinogen risk assessment, epidemiological studies are capable of detecting only comparatively large increases in the relative risk of cancer, and negative results from such studies cannot prove the absence of carcinogenic action. Further, a guidance manual prepared for EPA in 1986 on health risk assessment of chemically contaminated seafood states that although heavy consumption of contaminated seafood may pose a substantial human health risk, it is virtually impossible to directly measure the health risks of eating seafood.[2]

Federal Testing for Chemical Presence in Seafood

FDA, EPA, and other agencies have been studying the issue of chemical contamination and human health. In this regard, FDA, in conjunction with EPA for pesticides, has set actionable levels for 15 chemical substances that have been found in seafood, all of which (except for mercury) are suspected to be or are potentially carcinogenic or mutagenic. Among these are chlordane, DDT, and PCBs. Appendix IV lists the 15 chemical substances for which action levels have been established. An FDA headquarters official stated that while efforts continue to better

[1] Michael Stewart Connor, Comparison of the Carcinogenic Risks from Fish vs. Ground Water Contamination by Organic Compounds

[2] Tetra Tech, Inc., Puget Sound Estuary Program Guidance Manual for Health Risk Assessment of Chemically Contaminated Seafood, June 1986

understand the relationships between chemical contamination and human health, making decisions to set actionable levels for such substances is a difficult, time-consuming process.

As part of its responsibility to help ensure the safety of food in interstate commerce, FDA takes seafood samples and selectively tests for the presence of chemical contaminants. The samples taken and tests performed are based on FDA's experience and knowledge of the potential presence of selected chemicals noted above as well as others. According to PODS, in 1986 the agency took 963 domestic and 336 imported seafood samples for which chemical tests were performed. Because of the multiple-chemical testing capability of FDA, one or more chemicals can be tested for each sample taken. Chemical testing of the 963 domestic samples identified 35 adverse samples, or 3.6 percent at or above the established action levels. Most of these adverse samples contained PCBs. Chemical testing of the imported samples identified 83 adverse samples, or 25 percent at or above the established action levels. Most of the adverse imported samples were for methyl-mercury in swordfish or shark.

Chemical Contaminants in Seafood May Not Be as Great a Concern as Toxins in Other Foods

Concern over the health risks of chemical contaminants in seafood is not equally shared by some who have examined the issue. For example, EPA region X officials told us that their concerns about toxins in most fish and shellfish are not as great as their concerns about toxins in some other foods, such as pesticides on leafy vegetables, carcinogens in charcoaled meats, and toxins in chicken and milk.

Research by a cancer expert has further indicated that risks of cancer in humans from chemical pollutants pale next to risks from cancer-causing substances that occur naturally in food. Although previously mentioned studies cite PCBs and DDT as principal contributors to cancer risk in fish, according to this expert, even daily consumption of 100 times what is estimated to be the average intake of DDT or PCBs would produce a possible hazard that is small relative to such common exposures as conventional home air, peanut butter, or mushrooms.[1]

In addition, according to a 1981 OTA report, dietary components such as high-fat, low-fiber content and nutritional habits that affect hormonal

[1]Bruce N. Ames, "Ranking Possible Carcinogenic Hazards," Science, April 1987.

and metabolic balances are more important than food additives and contaminants."

Seafood-Related Illness Data From CDC

CDC, a part of the Public Health Service, is one of the federal agencies charged with helping to protect the public health. CDC is to provide leadership and direction in the prevention and control of diseases and other preventable conditions and in response to public health emergencies. As part of its responsibilities, CDC compiles and analyzes information on food-related illness outbreaks and cases. CDC compiles this information from reports submitted to it by state and local health departments, individual physicians, as well as federal agencies, such as FDA, the U.S. Department of Agriculture, and others.

CDC acknowledges that the information it receives may represent only a small portion of the food-related illnesses that are probably occurring in the United States. According to CDC's Report on Foodborne Disease Outbreaks Annual Summary for 1982, the amount of information CDC receives is dependent on the interest and motivation of state health authorities and physicians in reporting information to CDC. According to CDC, many states do not regularly provide reports on food-borne illness. It was also noted that while certain infectious diseases are required to be reported to CDC, such as hepatitis, noninfectious food-related illnesses are only voluntarily reported through the surveillance systems of the states. CDC's published reports pointed out that the serious illness situations would generally be expected to come to CDC's attention. While CDC data are incomplete, they offer some indication of the nature, extent, and seriousness of food-related illness in the United States.

CDC officials said that health risks associated with seafood are generally no greater than risks associated with other foods. They added that although the risks are greater with some seafood than with others, how seafood is prepared plays an important part in the level of risk. Molluskan shellfish was cited as a species group that, when consumed raw or undercooked, generally presents a greater health risk than other seafood.

According to the Director, Center for Infectious Diseases, CDC, seafood has the potential to become a major health problem. However, he believes, existing controls make seafood a fairly safe product. The

"OTA, Assessment of Technologies for Determining Cancer Risks from the Environment, June 1981

potential for seafood's becoming a health problem exists because many people eat seafood's raw or inadequately cooked.

Seafood-Related Illness as a Percentage of All Food-Related Illness

Our review of CDC data for the years 1978 through 1984 showed that seafood was a notable contributor to food-borne illness. During this period all seafood-related illness accounted for about 5 percent of the individual cases reported to CDC and about 10 percent of all the reported food-borne illness outbreaks (2 or more cases). During this period five seafood-related deaths were reported, which accounted for 3.6 percent of all the food-related deaths. This information is provided in table 2.1.

Table 2.1: Comparison of Reported Seafood Illness Outbreaks, Cases, and Deaths With All Food Illness for the Period 1978 Through 1984

Categories	Seafood-related illness	All food-related illness	Seafood-related illness as a percentage of all food-related illness
Outbreaks	368	3,770	9.76
Cases	5,080	100,166	5.07
Deaths	5	141	3.55

Source: Compiled by GAO from CDC published reports and unpublished data

Types of Seafood Causing Illness

To provide information on the types of seafood implicated in illness incidents, table 2.2 presents CDC data for the period 1979 through 1982 for three groups—molluskan shellfish, nonmolluskan shellfish, and finfish and other species. The nonmolluskan group includes crustacean shellfish, i.e., crab, shrimp, lobster, and crawfish. Mollusks and finfish accounted for the vast majority of seafood-related outbreaks and cases reported to CDC. Of the 3,621 seafood illness cases for the period, 1,906 were related to molluskan shellfish and 1,635 were related to finfish. Nonmolluskan shellfish were associated with 80 cases.

Table 2.2: Comparison of Seafood-Related Illness Outbreaks, Cases, and Deaths by Species Group for the Period 1979 Through 1982

	Outbreaks		Cases		Deaths	
Species	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
Molluskan shellfish	87	32	1906	53	1	25
Nonmolluskan shellfish	13	5	80	2	0	0
Finfish and other species	169	63	1635	45	3	75
Total	**269**	**100**	**3621**	**100**	**4**	**100**

Source: Compiled by GAO from CDC published reports and unpublished data

Disease Agents Causing Seafood-Related Illness

According to CDC, there are essentially four groups of disease-causing agents that may be present in seafood—chemicals, bacteria, viruses, and parasites. For the period 1978 through 1983, CDC was able to verify the agent in 50.6 percent, or 2,488 cases, of the 4,916 seafood cases for which it had information. Chemicals and bacteria were found to be the cause in 89.2 percent of these cases. The majority of chemical-caused illness involved biologically produced chemicals, such as ciguatoxin and scombrotoxin found in specific varieties of finfish and paralytic shellfish toxin found in molluskan shellfish. Table 2.3 provides information on the disease-causing agents identified by CDC in the 2,488 seafood-related illness cases.

Table 2.3: Identified Disease-Causing Agents in Seafood-Related Illness for the Period 1978 Through 1983

	Outbreaks		Cases		Deaths	
Agent	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
Chemical	189	75.3	1,074	43.2	4	80.0
Bacterial	47	18.7	1,145	46.0	1	20.0
Viral	12	4.8	226	9.1	0	0.0
Parasitic	3	1.2	43	1.7	0	0.0
Total	**251**	**100.0**	**2,488**	**100.0**	**5**	**100.0**

Source: Compiled by GAO from CDC published reports and unpublished data

During our review, NMFS, as part of its Model Seafood Surveillance Program, reviewed CDC's published food-borne illness data for the period 1978 through 1982 and found similar information on the nature, extent, and seriousness of seafood-related illness. Its analysis indicated that 87 percent of the seafood-related illnesses were related to ciguatoxin and scombrotoxin generated by two specific finfish groups or from illness commonly associated with raw molluskan shellfish. It also determined that 81 percent of all reported seafood illness for the period was in nine states or territories—California, Connecticut, Florida, New York, Washington, Hawaii, Guam, Puerto Rico, and the Virgin Islands. NMFS' review showed also that nearly half of all of the seafood-related illnesses were in four states and territories—Hawaii, Guam, Puerto Rico, and the Virgin Islands. According to the Program Director, NMFS' preliminary analysis of CDC's data tends to support the position that the majority of problems with seafood safety are narrowly focused on a few specific species with particular kinds of problems. He also said the National Academy of Sciences will conduct a more detailed examination of CDC seafood illness data, including its unpublished data through fiscal year

1987, as part of the work it will do on the Model Seafood Surveillance Program.

Seafood Illness Information From Selected States

In addition to the CDC seafood-related illness data and information we obtained from CDC officials, we visited or called health officials in 20 states. We obtained readily available statistics on seafood-related illnesses in each state for 1986. In addition, we obtained state health officials' views on the relative significance of seafood illness compared to other food-related illness. Many states did not have readily available statistics or summary data on seafood-related illness; however, some of the officials or representatives offered their views on the seafood safety issue.

Of the 20 states, representatives of 11 provided information on seafood-borne illness in their states for 1986. Six of the 11 states had between 0 and 15 individual seafood-related illness cases. Four states had from 78 to 126 seafood-related cases. One state did not have data on cases but had some seafood outbreak information. Six of these states provided information on the amount of seafood-borne illness to all food-borne illness. For these states, seafood represented between 0 and 13 percent of all food-borne illness cases. For example, in 1986 New York State had 13 seafood-borne outbreaks involving 126 persons. This represented about 8.8 percent of the food-borne illness reported in the state. Four of the outbreaks involving 37 people were associated with the consumption of raw or undercooked molluskan shellfish (raw clams). An official in the State Bureau of Community Sanitation and Food Protection noted that shellfish cases have decreased substantially (about 50 percent per year) since 1982, when over 1,000 cases were reported. The reason for this decline was not known.

Most of the state health representatives said that although seafood can and does cause illness, they generally do not look at seafood as a major cause of food-borne illness. Others, however, viewed seafood more critically, citing it as a significant contributor to food-borne illness. Some said there are special concerns with shellfish because they are frequently eaten raw or undercooked.

Adverse Seafood Samples Identified by FDA

FDA, also a part of the U.S. Public Health Service, has extensive responsibilities and pursues activities directed at protecting the public health against impure and unsafe foods, drugs and cosmetics, and other potential hazards. As part of its work to help assess the condition of foods, including seafood, it takes product samples and analyzes them to determine their compliance with established federal regulations concerning food contamination and proper labeling. Those that are not in compliance are referred to as adverse samples.

According to FDA, the level of seafood sample analysis is quite small, roughly estimated at representing less than 1 percent of domestic seafood and less than 3 percent of imported seafood.[7] FDA officials said they target much of their sampling to areas known or suspected of having the greatest potential for problems. However, because of FDA's targeted approach, adverse sample findings cannot be generalized to all seafood available for consumption. FDA records showed that in fiscal year 1986 it took 1,814 domestic seafood samples and determined that 218, or 12 percent, were adverse in some way, i.e., in violation of regulations and requiring regulatory action or voluntary action on the part of the processor. FDA took 4,714 imported seafood samples and determined that 1,663, or 35 percent, were adverse.

We reviewed information on the fiscal year 1986 adverse samples in 8 FDA districts representing 67 of the 218 adverse domestic seafood samples (31 percent) and 1,447 of the 1,663, adverse imported seafood samples (87 percent). FDA officials stated that they do not categorize adverse samples by level of seriousness. We used criteria presented in the National Research Council's 1985 report entitled An Evaluation of the Role of Microbiological Criteria for Foods and Food Ingredients to classify microbiological pathogens, natural toxins, and indicator organisms. We used the categories "direct," "indirect," and "no hazard" to convey the relative seriousness of the findings. We assigned FDA samples that involved levels of chemical contaminants or additives at or above FDA action levels and unlabeled sulfites as a direct hazard to health.

Our review of these adverse samples at selected FDA districts showed that about 78 percent, while in violation of federal regulations and requiring corrective action, would not be categorized as a direct safety

[7] An FDA official in the Office of Regional Operations advised us that FDA has not developed estimates of the percentage of domestic seafood represented by the domestic seafood samples taken for compliance purposes, although he acknowledged that less than 1 percent could be regarded as a judgmental estimate. FDA has, however, estimated that its imported seafood samples represent about 3 percent or less of imported seafood.

hazard. Of the remaining 22 percent of the adverse sample findings that would be considered serious, 38 percent were related to biological contamination problems such as salmonella or similar pathogens that would be neutralized when the product is properly cooked. The majority of the other adverse findings considered serious were related to chemicals and additives identified in the seafood samples. Appendix II provides additional information on FDA inspection and seafood sample analysis activity.

Table 2.4 shows our categorization of the adverse samples we reviewed.

Table 2.4: Adverse Domestic and Imported Seafood Samples Included in GAO's Review

	Domestic		Imported	
Categories	**Number**	**Percent**	**Number**	**Percent**
Direct[a]	14	21	317	22
Indirect[b]	28	42	115	8
No hazard[c]	14	21	508	35
Economic[d]	11	16	86	6
Undeterminable[e]	0	0	421	29
Total	**67**	**100**	**1,447**	**100**

[a]A direct hazard includes such contaminants as pathogens, food additives, toxins, and chemicals, at or above FDA action levels and unlabeled sulfites.

[b]An indirect hazard includes such contaminants as nonpathogenic Escherichia coli or fecal coliform, defective can seams, and decomposition.

[c]No hazard includes such contaminants as distasteful contaminants and rancid or odorous products and failure by importers to file with FDA the process under which the seafood was processed.

[d]Economics includes any form of misrepresentation, such as short weighting, product substitution, and mislabeling.

[e]A finding may be undeterminable for various reasons, but the principal reason is that the imports were automatically detained and an analysis was not performed to determine the results. A major reason for not performing an analysis is that the importer chose to recondition the product to correct the suspected problem.

Source: Compiled by GAO from FDA data management systems and records.

Federal and State Programs Addressing Seafood Safety

While the seafood industry is not subject to the concept of 100-percent government product inspection that characterizes the meat and poultry industries, a number of federal and state programs address various elements of the seafood safety issue. At the federal level, FDA, NOAA, and EPA are the principal agencies performing oversight activities addressing seafood safety. Other federal offices, such as CDC, the U.S. Fish and Wildlife Service, and the U.S. Geological Survey, gather data and assess factors affecting the issue. Interagency efforts, such as the National Toxicology Program, also help to coordinate several federal agencies' efforts addressing chemical contamination concerns.

In addition to federal activities, a variety of state programs address seafood safety. These activities include seafood inspections, sample analysis, water quality assessments, and enforcement of harvesting regulations. Many of these activities are also performed at the county level. Specialized programs include state shellfish sanitation programs.

Federal Programs: An Overview

Several federal agencies have programs and services that are directly or indirectly related to seafood safety. Collectively, these agencies provide a considerable oversight function to help protect consumers from illnesses caused by seafood contamination. A brief description of agency responsibilities and principal programs involving seafood safety follows.

U.S. Food and Drug Administration

In accordance with the Food, Drug and Cosmetic Act (21 U.S.C. 301), FDA is responsible for ensuring that all foods, including seafood, destined for interstate commerce are safe and protecting consumers against adulterated, decomposed, unsanitary, and misbranded food products.

To address its broad responsibilities, FDA has established a number of general and specifically targeted programs. These include the following:

- Seafood plant inspections and sample analyses under domestic and imported food programs to detect violative products and prevent their entry into interstate commerce. The majority of FDA inspections are focused on plant sanitation; others are targeted to address particular FDA compliance concerns. Sample analyses are generally taken during FDA inspections in accordance with FDA headquarters compliance programs and operational plans or because of concerns raised by individual inspectors. FDA has the authority to seize adulterated seafood and prosecute domestic and import violators. In addition, FDA has the authority to detain or temporarily hold food being imported into the United States

while it makes assurances that the product is not misbranded or adulterated. In 1986 FDA conducted 1,381 inspections of seafood establishments and took 1,814 domestic seafood samples and 4,714 imported seafood samples for regulatory analysis. Appendix II provides statistical information on FDA inspections and sample analyses conducted in fiscal years 1984, 1985, and 1986 as well as a review of sample findings at selected FDA districts in 1986.[1]

- The National Shellfish Sanitation Program, in which FDA, state governments, and private industry work together to help prevent human illness associated with eating oysters, clams, and mussels. FDA evaluates state activities to determine compliance with the program's guidelines. FDA's role was modified in 1984 with the establishment of the Interstate Shellfish Sanitation Conference but remains a focal point in determining state program compliance with long-established standards. FDA evaluations are discussed later in this chapter.
- Salmon program participation in which inspectors from FDA and the National Food Processors Association monitor U.S. salmon harvesting and processing on a voluntary basis. The Association samples each lot, and FDA spot checks the samples. FDA also inspects the actual canning process to ensure that sanitation standards are maintained.

In addition, FDA, as part of its overall responsibilities, publishes reports and articles advising the public of special concerns with foods, including seafood, and has issued articles over the years pointing out the special concerns with the consumption of raw seafood and shellfish in particular. The FDA Consumer, a magazine available to the public, has been one of FDA's principle vehicles for communicating this information.

According to FDA's current Action Plan, dated May 1987, FDA is in the process of taking actions to better address food safety issues and improve its coverage of imported products, including seafood. These actions are needed as a result of the substantial differences in food manufacturing that exist around the globe.

[1]GAO has issued reports on FDA's inspection and sample analysis activities pointing out that improvements are needed. Among these reports are Pesticides: Need to Enhance FDA's Ability to Protect the Public From Illegal Residues (GAO/RCED-87-7, Oct. 27, 1986); Food Inspections: FDA Should Rely More on State Agencies, (GAO/HRD-86-2, Feb. 18, 1986).

National Oceanic and Atmospheric Administration

NOAA is responsible for mapping and charting the estuarine and coastal waters of the United States and the Exclusive Economic Zone[1]; assisting the states in managing, using, and conserving resources in the coastal zone; managing and conserving the fishery resources of the Fisheries Conservation Zone; and describing, monitoring, and predicting conditions in the atmosphere and oceans. NOAA has three organizational components—NMFS, the National Ocean Service, and the Office of Oceanic and Atmospheric Research—that have programs and services that address the seafood safety issue.

National Marine Fisheries Service

NMFS has the primary federal responsibility for conserving, managing, developing, and protecting living marine resources that depend upon healthy and productive marine and estuarine habitats. Three NMFS programs involving seafood safety are described below.

- The Voluntary Seafood Inspection Program, under which NMFS conducts a voluntary, fee-based inspection and grading program for fish and shellfish products. This program, while considered primarily a marketing enhancement program, provides services that involve seafood safety. The current inspection program offers three services: (1) plant sanitation, product inspection, grading, and certification services; (2) lot inspection services on an as-needed basis; and (3) miscellaneous services, which include inspection for plant sanitation only, laboratory analyses services, consultive services, label and specification review, and lot inspection services. Participating companies contract with NMFS to obtain any of these services that they require. Some government and institutional buyers require suppliers to obtain selected NMFS program services prior to purchasing their products. According to the program manager, while industry participation in the program has increased, the amount of seafood inspected through the program has decreased. Program statistics show that the average number of plants participating in the program increased from 96 in 1981 to 141 in 1987. The amount of seafood inspected, however, declined from 19.2 percent of U.S. consumption in 1981 to 10.2 percent in 1987. According to the program manager, the increase in plants inspected was largely the result of participation by a number of small processors that were interested in inspections required for sales to federal agencies. The program manager also said that the drop in the percentage inspected was due largely to the decision of the tuna processing industry to close most of its U.S.

[1]The Exclusive Economic Zone, established by presidential decree in 1983, extends 200 miles beyond the baseline from which the U.S. territorial sea is measured.

plants in favor of contracting with foreign processors. Efforts are ongoing to expand program participation through a processing plant certification technique based on NMFS approval of the quality control systems and procedures at seafood plants.

- Enforcement activities under the Lacey Act of 1981 (16 U.S.C. 3371), which provides for the control of illegally taken fish and wildlife. NMFS is responsible for enforcing the law as it applies to molluskan shellfish. NMFS entered into a memorandum of understanding in July 1986 with FDA to improve cooperation in the enforcement of laws against the illegal harvest, transport, export, import, sale, and purchase of molluskan shellfish. In fiscal year 1986 NMFS conducted 123 investigations into alleged molluskan shellfish violations of the Lacey Act.
- Saltonstall/Kennedy Grants, which are awarded to fisheries' science researchers to conduct studies to improve the management, development, and use of fishery resources. A current project is to develop a comprehensive plan for a national study to address and help arrive at conclusions on the indications of disease risk in human consumers of shellfish. Among other recent grant projects addressing seafood safety issues are studies on parasite detections systems, canned salmon integrity, detection of ciguatoxin, requirements to inhibit botulism in vacuum-packaged smoked fish, procedures to reduce histamine problems in tuna, fish poisoning investigation, and alternatives to bisulfites in shrimp.

National Ocean Service

The National Ocean Service is responsible for publishing nautical charts, predicting tidal heights and times, collecting and maintaining oceanographic data, and conducting assessments to help determine marine-resources use strategies that will maximize benefits to the nation and minimize environmental damage or conflicts among uses. Three principal National Ocean Service programs involving seafood safety are the following:

- The National Marine Pollution Program, established within the National Ocean Service to serve as a federal focal point for planning marine pollution research and disseminating marine pollution data. The office carries out its responsibilities by (1) keeping agencies informed of marine pollution trends through a project catalog and program summaries and (2) identifying priority needs and problems and making recommendations through workshops, work groups, and preparation of 5-year plans addressing marine pollution problems.
- The National Status and Trends Program, intended to provide comprehensive, high quality, and continuing information about the status of

environmental quality in the coastal and estuarine areas of the United States. This program established an information base to quantify the current status and long-term, temporal, and spatial trends of key contaminant concentrations and biological indicators of effects in the coastal and estuarine environments of the United States. Since 1984, the program has conducted research on (1) toxic organics and trace metals in sediment, (2) toxic chemicals in bivalve mollusks and surface sediments, (3) a toxic sampling program involving 1,400 fish and sediments for 50 sites nationwide, and (4) an assessment of historical data on the concentration of PCBs and DDT in living marine resources.

- The National Estuarine Inventory Program, which assesses the use and health of the nation's estuaries. The inventory identifies 101 of the nations's most important estuaries and their fundamental physical, hydrologic, biological, and land use characteristics. Of the approximately 20 million acres of estuarine waters in the inventory, 15 million acres have been evaluated and classified for shellfishing (approved, conditionally approved, restricted, prohibited, and nonproductive). To aid states in conducting sanitary surveys of shellfish harvesting areas, the National Ocean Service is preparing a national data base of information on the shellfish growing waters.

Office of Oceanic and Atmospheric Research

The Office of Oceanic and Atmospheric Research conducts an integrated research and development program of laboratories and extramural research projects that address a wide range of oceanic and atmospheric topics and issues. Its Office of Sea Grant and Extramural Programs coordinates programs of research, education, and advisory services through grants, contracts, and cooperative agreements primarily with colleges and universities. This office, designed to accelerate national development and utilization of marine and Great Lakes resources, has addressed such topics as fisheries management, seafood technology, aquaculture, marine mining, coastal protection, energy, and ocean engineering, among others. Recent and current projects funded by the Office of Sea Grant and Extramural Programs have included

- projects to assess the potential for the commercial depuration of hard clams to reduce or eliminate viral pathogen contamination,
- the development of a new biological monitor for sewage-related bacteria in coastal waters,
- the development of a rapid detection method for the hepatitis A virus in shellfish and the estuarine environment, and

- the assembly of information on the nature and extent of about 200 health advisories and alerts regarding seafood consumption issued by states and municipalities.

Environmental Protection Agency

EPA has the overall responsibility for maintaining and restoring water quality to provide for the protection and propagation of fish, shellfish, and wildlife and allow for recreation in and on the water. Its primary water quality control focus has been on the reduction of pollutants in water. In carrying out its responsibilities, EPA works with the states to monitor environmental quality and is responsible for reporting to the Congress on the overall quality of the nation's waters. In addition, EPA and FDA are responsible for establishing safe levels of contaminants in foods, and they work together on chemical risk assessment and risk management activities.

EPA's work related to seafood safety issues has evolved in response to various laws that have given the agency wide-ranging responsibility for establishing and supervising numerous regulatory and management programs having direct and indirect effects on the quality of water. Two statutes are particularly important with regard to EPA's involvement in seafood safety issues:

- Under the Federal Water Pollution Control Act (33 U.S.C. 1251, et seq.), EPA has broad authority to develop comprehensive programs for preventing or reducing pollution in navigable waters. In developing such programs, EPA is to consider improvements necessary to conserve such waters for protection and propagation of fish, other aquatic life, and wildlife; recreational purposes; and withdrawal of such water for public water supply, agricultural, industrial, and other purposes.
- Under the Marine Protection Research and Sanctuaries Act of 1972 (33 U.S.C. 1401), EPA regulates the transportation and ultimate disposal of materials in ocean waters. The act's purpose is to prevent or strictly limit the disposal of materials that would unreasonably affect human health, public welfare, the marine environment, ecological systems, or economic potential.

EPA implements these acts through its Office of Water, whose activities include construction grants, National Pollutant Discharge Elimination System permitting, compliance and enforcement, water quality management grants, controls for combined sewage overflows, groundwater and surface water monitor controls, and ocean dumping permits.

Other EPA activities include geographically focused programs identifying chemical contamination in major bodies of water. They have included the Great Lakes Program, the Chesapeake Bay Program, and other estuary initiatives managed under the National Estuaries Program (Buzzard Bay, Puget Sound, Narragansett Bay, Long Island Sound, Albemarle-Pamlico Sound, and San Francisco Bay).

The agency is also developing its Integrated Risk Information System to assist states in risk assessment and risk management. It is a means for EPA to help assemble and communicate agreed-upon scientific information on the risks associated with particular chemicals. The system was designed to provide the nonscientist with information about the adverse health effects of exposure to a chemical and the rationale for regulatory activities. In December 1987 EPA completed for review and comment its draft report Guidance Manual for Assessing Human Health Risks From Chemically Contaminated Fish and Shellfish. This is to provide guidance for health risks assessment related to chemically contaminated fisheries and intended for use by state and local agencies responsible for assessing potential risks from local fish and shellfish consumption.

In addition, EPA's Health Effects Research Laboratory is presently involved in a human feeding program to determine the effectiveness of measures to protect the public from viral and bacterial risks associated with shellfish, specifically clams and oysters, that are often eaten raw.

Centers for Disease Control

As part of its broad responsibilities, CDC within the Public Health Service analyzes information on food-related illness outbreaks and cases, including those involving seafood contamination. CDC gathers this information from reports submitted by state/local health departments and physicians, as well as federal agencies, such as FDA. While its information may represent only a small portion of food-related illness cases, CDC is the only centrally compiled food-borne data system providing information on seafood-borne illness. CDC seafood illness statistics are presented in chapter 2.

U.S. Fish and Wildlife Service

The Fish and Wildlife Service is the federal agency charged with providing leadership, direction, and training in cooperation with international agencies, foreign governments, states, and the private sector to organize and carry out programs to maintain and manage fish health. In the seafood safety area, the Fish and Wildlife Service is responsible for the fish

and wildlife portion of the National Contaminant Biomonitoring Program. This program's primary objective is to ascertain the nationwide levels and trends of selected environmental contaminants in freshwater fish. Accordingly, the program helps to determine whether levels of pollutants in fish vary by geographic regions and changes that occur over time.

U.S. Geological Survey

Unlike most federal agencies, the U.S. Geological Survey possesses neither regulatory nor developmental authority. However, its Water Resources Division appraises the nation's water resources and provides hydrologic information that can serve as the basis for other agencies' studies related to seafood safety. One program of particular note within the Water Resources Division provides earth science data to improve waste water disposal practices and mitigate contamination of resources by toxic substances.

National Toxicology Program

In 1978, the Department of Health and Human Services established the National Toxicology Program to strengthen and coordinate federal research involving toxic chemicals. An extension of the Public Health Service's responsibility for safeguarding the public's health, the toxicology program can provide general assistance to federal agencies involved in seafood safety issues by (1) broadening the spectrum of toxicologic information obtained on chemicals selected, (2) increasing the number of chemicals tested, (3) developing tests and procedures responsive to regulatory needs, and (4) communicating plans and results to other governmental agencies, the medical and scientific communities, and the public. The program is composed of appropriate toxicology and related programs of the National Institutes of Health, CDC, and FDA. The Executive Committee for the program also includes the heads of the National Institutes of Health; National Cancer Institute; National Institute of Environmental Health Sciences; National Institute for Occupational Safety and Health; FDA; EPA; and Consumer Product Safety Commission; the Assistant Secretary for Health, Department of Health and Human Services; and the Assistant Secretary of Labor for Occupational Safety and Health Administration, Department of Labor.

Interagency and Cooperative Agreements on Seafood Safety Concerns

In addition to the various individual agency programs and activities, a number of interagency agreements, cooperative agreements, and memorandums of understanding (MOU) are related to seafood safety concerns. Such agreements exist between federal agencies, between federal agencies and state governments and organizations, and between the United States and foreign governments. These agreements are used to help improve communications and cooperation between groups for their mutual benefit and interests in performing their missions and responsibilities. Some agreements cover broad issues while others are more narrowly focused. Some of the topics covered by these agreements include seafood inspection activities and procedures, shellfish sanitation and water quality monitoring, research and study related to fisheries and seafood safety, and international agreements on seafood standards for quality and safety. Appendix V lists the agreements we identified.

To gain some perspective on the value of interagency and cooperative agreements, we contacted several agency representatives who were involved with seven of the agreements we identified. All of the representatives we contacted felt that such agreements are valuable tools federal agencies and others use to accomplish specific objectives that are of mutual interest and concern to the parties of the agreements. Several of the representatives pointed out that such agreements help to avoid duplication of effort and make better use of the limited resources of the involved parties. Views were also expressed that there should be greater use of these kinds of agreements and that their success can be related to the level of involvement and support by the top management of the agencies and parties to the agreements.

An example of an MOU is the agreement between NMFS and FDA on research activities for fisheries products. Its purpose is to improve and increase the cooperation and coordination of research efforts, avoid duplication, and make more efficient use of federal resources supporting research that is of interest to both parties. The areas of research covered include safety, quality, nutrition, and labeling requirements for fish and shellfish products. According to NMFS and FDA officials who participate at research meetings and are members of the MOU's groups, this MOU provides an effective mechanism for contributing to each agency's mission and benefits federal activities in these areas.

State Government Programs Addressing Seafood Safety

In addition to federal activities, state governments' counterpart agencies to the federal FDA, NMFS, EPA, and others also provide programs and services that address certain aspects of seafood safety in their respective states. State officials and representatives of state agencies from the 20 states we contacted discussed a range of activities addressing seafood concerns, including seafood establishment inspections, seafood sample analysis, water quality assessments, and patrol of harvesting areas. In some states, county governments also perform functions in coordination with or in addition to state programs and services. All of the states were involved in molluskan shellfish activity and were members of the Interstate Shellfish Sanitation Conference (ISSC). All of the states had shellfish sanitation programs except Colorado and Illinois because they are essentially shellfish receiver states.

Seafood Inspection and Sample Analysis

The states we contacted performed to varying degrees food establishment inspections involving processors, packers, repackers, wholesalers, retail outlets, and restaurants. Inspections of the facilities—like the federal FDA inspections—are essentially to evaluate the sanitary conditions of the facilities. Officials from several states informed us that their seafood inspection and sample analysis activities generally do not find serious health or safety problems. Some officials stated that basic plant sanitation problems are found, but they are generally considered minor problems.

According to some of the state officials, seafood samples are usually taken by exception rather than routinely. State officials said seafood samples are usually tested for fecal contamination or decomposition, which are indicators of other potential contamination. Testing for chemicals is generally the result of periodic monitoring associated with planned efforts or special projects when states believe they have reason to suspect a chemical presence.

Water Quality Monitoring

Most state representatives informed us that they assess environmental conditions in waterways and harvesting areas and take water and/or seafood species samples to test for contaminants that may be suspected or known to exist in certain bodies of water. Some state officials said they perform routine water and/or species analysis to monitor water conditions. Other state officials, however, said they do not perform routine sample testing but take samples when they suspect a problem.

State Patrol and Enforcement of Harvesting Areas

The extent and type of patrol and enforcement activities governing seafood harvesting areas vary among the states. According to several state patrol and enforcement officials, these activities provide some protection against commercial and recreational harvesting of seafood in restricted areas that contain unacceptable levels of pollutants. All shellfish harvesting states that are members of the ISSC carry out patrol and enforcement activities as part of their shellfish sanitation programs.

State Shellfish Sanitation Programs

Most states involved with shellfish harvesting, processing, and distribution in interstate commerce, as well as some states receiving interstate shipments of shellfish products, conduct shellfish sanitation programs based on the guidelines established under the NSSP. In 1982, ISSC was established to further the guidance of the NSSP and help create greater compliance and uniformity among state shellfish sanitation programs and industry practices.

Among the principal elements of state shellfish sanitation programs are (1) survey and classification of growing waters, (2) patrol and enforcement of controls and restrictions on growing areas, and (3) processing plant inspections and analyses. FDA's role has traditionally been to evaluate state programs to determine compliance with established standards and guidance.

FDA's Evaluations of State Shellfish Sanitation Programs

Since 1983, FDA has evaluated state shellfish sanitation control programs and reported its findings to ISSC. In conformity with a 1984 MOU between FDA and ISSC, FDA issued three reports to ISSC on state shellfish sanitation programs. The first report was issued for the 1983-85 period, the second for 1986 and the third for 1987. These reports covered the 23 member states of the ISSC and the District of Columbia.[3] The primary focus of FDA's evaluation of the states' shellfish sanitation programs is to identify deficiencies that have public health significance and threaten the integrity of ISSC certification assurances. FDA classifies its findings as either major or other.[4]

[3]The Shellfish Sanitation Program of Connecticut was not evaluated in 1986.

[4]A "major" nonconformity signifies a potential health hazard involving some urgency to correct. It is a substantial deviation from national guidelines representing a widespread problem rather than an isolated instance or a single instance that has remained uncorrected for some time. An "other" nonconformity is a lesser deviation from national guidelines.

FDA's first two reports discussed the same basic problems. They showed that most states do not conform to ISSC regulations regarding (1) growing area surveys and water classification, (2) patrol and enforcement, and (3) plant sanitation. Some states had major nonconformities in these areas. FDA's 1986 report indicated that states have shown little improvement in complying with ISSC regulations from 1985 to 1986. Less frequently found nonconformities were in program elements, including (1) legal authority and administrative procedures, (2) monitoring for paralytic shellfish poison, (3) laboratory capacity and procedures, and (4) depuration facilities. FDA found a few major nonconformities in the areas of administrative procedures and monitoring for paralytic shellfish poison.

According to the FDA report to ISSC on the status of states' programs for 1986, major problems continue with shellfish sanitation in the United States. It also stated that FDA's evaluation reports indicate that there was no decisive change in the level of shellfish sanitation safeguards in the United States in 1986 compared to the 1985 level. The 1986 report also stated that industry participation in the ISSC and commitment to the principles of the NSSP appear to have decreased.

Survey and Classification of Growing Areas

In 1985 and 1986, FDA found that 20 and 19, respectively, of the states evaluated, were not in conformity with ISSC regulations on growing area surveys and water classification. Several states had major nonconformities with this program element.

A basic problem some states have had with the survey of growing areas and water classification is the use of the fecal coliform standard to determine what constitutes a public health threat.[5] The fecal coliform standard is an indicator of the need to look further to determine if a problem exists. To resolve this issue, an interagency task force was established and has proposed a 6-year project to determine the most valid and reliable method of identifying the potential health risk in shellfish. FDA's 1986 report stated that

"A major cause of concern is that nationally there has been a dramatic reduction in the availability of safe shellfish resources for harvesting. Continuation of this decline will: (1) increase pressures on State programs to expand the number of growing area surveys in anticipation of increasing harvesting opportunities and (2)

[5]The fecal coliform standard is a microbiologic standard used to measure the level of fecal contamination in harvesting waters.

require increased patrol activities to control illegal harvesting (bootlegging) in contaminated waters."

The report further stated that "Many state programs are understaffed and insufficiently funded to perform the requested sanitary surveys and water quality analyses needed to assure proper growing water classification."

Patrol and Enforcement Activities

For patrol and enforcement activities, FDA reported that 19 and 13 states were in varying degrees of nonconformity with ISSC regulations during 1985 and 1986, respectively. Of these, 2 and 1 state(s) had major nonconformities during 1985 and 1986, respectively.

FDA reported that "the states often do not have sufficient funds to maintain their normal levels of patrol and apprehension, much less to increase this effort." FDA's report further stated that

"The problem of declining resources is of particular concern because as the supply declines, the value of remaining resources increases. This situation is ideal for an increase in illegal harvesting. The potential value of oyster resources in polluted waters is now great enough to offset risks and civil fines associated with apprehension. . . . In some cases illegal harvesters are brought before courts on second and third offenses, and are given low fines which are often regarded as a cost of doing business."

During ISSC's 1986 annual conference, state officials raised concerns about the degree of nonconformity of patrol functions. As a result, a patrol committee was established to develop guidance on the issue of inadequate shellfish patrol resources and to present possible solutions at the 1987 annual conference. A major task of the patrol committee was to develop a questionnaire to obtain information on member states' enforcement and patrol activities and resources. This information was to help develop some uniform criteria to better assess states' resource commitment and workload. According to the committee chairman, all states did not respond to the questionnaire, and many of the proper questions were not asked. He further stated that the committee does not have any plans to develop another questionnaire or continue its efforts on this matter.

In its 1986 report, FDA concluded that state programs face new challenges to meet industry and public health needs in areas of growing

water classification and patrol. It added that until significant improvements are made in the availability of safe shellfish resources for harvesting, efforts to improve patrol and enforcement capabilities will become increasingly important to ensure that only safe molluskan shellfish are getting to the marketplace.

Plant Inspections and Sanitation

FDA found that 18 and 17 states were in nonconformity with ISSC regulations on plant sanitation during the 1985 and 1986 reporting periods, respectively. Three states had major nonconformities during 1985 but eliminated them in 1986. The 1986 report, however, stated that additional sanitation control requirements in the revised NSSP Manual of Operations will likely make it more difficult for states to remain in program conformity.

States Views on FDA's Evaluation of Their Shellfish Programs

Most state shellfish program officials said FDA's evaluations of their shellfish programs were fair and adequate or had no complaints about the evaluations. Some state officials had concerns with FDA's evaluations regarding the lack of standardized evaluation criteria. They said FDA's evaluation guidelines are too general, allowing too much personal latitude for FDA shellfish inspectors in making program assessments. According to its 1986 report, FDA has made several modifications to evaluation procedures, including providing criteria for evaluating a representative number of units within each program element (e.g., growing areas and certified dealers) and the use of separate reports on individual program elements.

FDA 1987 Evaluation Report to ISSC

In April 1988, FDA issued its 1987 report to the ISSC on the status of state shellfish sanitation programs. The report stated that 15 of the 24 state programs were in substantial conformity, compared with 16 of 23 state programs evaluated in 1986. Nine states had major program deficiencies of public health significance and are not in conformity with the interstate certification requirements of the NSSP. Areas of nonconformity included misclassification of shellfish growing areas, inadequate patrol and enforcement, and shellfish dealers operating under unsanitary conditions. The report also noted improvements in one state with prior major nonconformities, but, for others, the improvements were not sufficient to move them from major nonconformity status. The report noted that, in part, the significant program accomplishments that had been

achieved were attributed to the development of state action plans to correct major nonconformities and FDA's technical assistance to several states.

The report also identified growing concern that achievements may be overshadowed by increasing problems with illegal harvesting and improper shellfish depuration in some areas. The report stated that these problems can have an immediate and profound impact on public health and consumer confidence. These problems, the report concluded, are the result of state funding's not keeping pace with program needs.

Seafood Misrepresentation Occurs but Is Not a High-Priority Concern

Many federal and state officials said that although seafood misrepresentation occurs, it is not considered a high-priority concern. Recognizing federal and state resource limitations, they place greater emphasis on health and safety problems.

Seafood misrepresentation takes several different forms, including short-weighting, substituting a lower value species for a higher value species, and improper labeling. The Federal Food, Drug and Cosmetic Act gives FDA responsibility to ensure the safety of food in interstate commerce, including seafood. Specifically, the act prohibits the introduction of adulterated or misbranded seafood into interstate commerce. FDA also administers the Fair Packaging and Labeling Act, which requires that label information be conspicuously displayed and comprehensible to the consumer under ordinary conditions of purchase and use. FDA has authority to seize seafood (i.e., take legal possession) that does not meet the requirements of these acts. In addition, FDA has authority to detain or temporarily hold food being imported into the United States while it makes assurances that the product is not misbranded or adulterated. FDA is responsible for seafood that enters interstate commerce, while the individual states are responsible for the condition of seafood within their boundaries.

FDA Gives Priority to Health and Safety Inspections

FDA normally gives priority to health and safety inspections over misrepresentation inspections. Under its Domestic Food Labeling and Economics Program, FDA conducts inspections of domestic food establishments and analyzes samples of food that inspectors collect when they suspect violations of FDA regulations. Under FDA's General Program for Imported Foods, FDA samples imported seafood products to determine if they comply with the requirements of the Food, Drug and Cosmetic Act and the regulations promulgated under this act, including those governing product misrepresentation.

An FDA Consumer Safety Officer, Center for Food Safety and Applied Nutrition, who is one of the agency's experts on economic problems with seafood, said she believes misrepresentation problems are more prevalent in fish and fish products than other types of food. She added that this is primarily because of the great variety of fish species and the wide range of prices. Notwithstanding this, she said, the Center devotes most of its resources and efforts to safety issues rather than misrepresentation problems.

Although misrepresentation inspections are conducted in conjunction with regularly scheduled inspections, most of the violations FDA identifies during its inspections and through sample analysis are safety-related. For example, in the 8 district offices we visited, FDA identified 1,514 adverse samples during 1986, of which 220 were misrepresentation findings (see table 4.1).[1]

Table 4.1: Domestic and Imported Seafood Samples FDA Found During Fiscal Year 1986 With Misrepresentation Violations at the District Offices GAO Visited

FDA district	Domestic	Imports	Total
Baltimore	0	2	2
Boston	0	9	9
Los Angeles	2	62	64
New Orleans	0	3	3
New York	1	11	12
Orlando	6	67	73
San Francisco	0	10	10
Seattle	2	45	47
Total	**11**	**209**	**220**

Source: Compiled by GAO from FDA data management systems and records

Another FDA Consumer Safety Officer in the Center for Food Safety and Applied Nutrition, an expert in food additives, stated that while food economics problems may not generally be viewed as having implications for health or safety issues, FDA recognizes the special health significance associated with proper labeling. For example, some additives, such as sulfites on shrimp, can cause allergic reactions in consumers who are sensitive to sulfites. Such reactions can be serious, even deadly. In addition, product substitution, such as surimi being sold as crab meat, may also result in allergic reactions. In this regard, food labeling requirements to identify sulfites or imitation products do play an important public health role.

FDA and the Department of Commerce initiated an Approved Market Names for Fish and Invertebrates project in 1985. Project activities include assembling common/usual names for some 1,300 fishery products in interstate commerce, which is nearly complete. The purpose of the project is to provide a convenient source, approved by regulatory agencies, which will establish market names for species in interstate commerce and establish a mechanism for naming new species as they

[1]FDA found some seafood samples with more than one adverse finding. Data presented in the following tables include all the misrepresentation findings in the samples we reviewed.

are identified. According to a NOAA representative, the project's objectives are being met and the results concerning commonly used fish names will be placed in the Federal Register for public comment in the summer of 1988.

Misrepresentation violations for imports deal with short-weight, product substitution, and improper labeling of the product, as shown in table 4.2.

Table 4.2: Types of Misrepresentation Violations for FDA Imported Seafood Samples Conducted During Fiscal Year 1986 by FDA District Offices GAO Visited

District	Short-weight	Substitution	Labeling[a]
Baltimore	1	0	1
Boston	0	3	6
Los Angeles	0	1	61
New Orleans	2	0	1
New York	0	4	7
Orlando	0	0	67
San Francisco	1	0	9
Seattle	15	3	27
Total	**19**	**11**	**179**

[a]This includes any sample with improper labeling. The two principal deficiencies were false or misleading labeling and mandatory labeling omitted.

Source: Compiled by GAO from FDA data management systems and records.

States Emphasize Seafood Safety Over Misrepresentation

States give higher priority to seafood safety than misrepresentation. Many cited limited resources to detect or identify misrepresentation violations as the reason for this priority. Only two of the states we visited had readily available statistics on seafood misrepresentation violations. Virginia had statistics showing it found 3 misrepresentation violations during 1986, and New York had statistics showing it found 78 violations. New York's findings were primarily excessive liquid in oyster containers, substitution of calico scallops for bay scallops, and insufficient shrimp in breaded shrimp.

Because of limited inspections and the lack of information, the extent of misrepresentation occurring in the states is uncertain. One state official said he believes a significant amount of product misrepresentation goes undetected because the priority of federal and state programs is health and safety concerns.

Few significant misrepresentation problems were found during state inspections. For example, a southern state official said that his state does not find many misrepresentation problems because the state has a

limited capability to detect such findings. His state only checks for the proper weights and visually inspects for substitution but does not have the capability to sample products and test for substitution. The type of misrepresentation violations states found included substituting one species of fish for another, not having all ingredients on ingredients lists, having no ingredients list, selling previously frozen fish as fresh fish, adding water to containers of seafood, overbreading seafood, not declaring or having excessive food additives, and mislabeling crab meat.

Some state officials said a misrepresentation violation is more likely to occur at the retail level. One state official said that at the retail and restaurant level, there is a great deal of misrepresentation. He said, however, that the local health departments are responsible for retail and restaurant inspections. According to another state official, it is difficult to verify the species at the retail level because all fish fillets tend to look alike.

Some state officials said that their inspections were limited to verifying the ingredients statements and other aspects of labeling, such as the existence of a proper label and product weight. County officials in a few states inspect in total or partially for misrepresentation at the retail and restaurant level.

Industry Representatives Said Misrepresentation Occurs, but Many Do Not View It as a Major Problem

Many industry representatives told us they knew of misrepresentation situations but did not view misrepresentation as a major industry problem or practice. However, results of a National Fishery Institute survey of its membership in 1985 showed that certain misrepresentation practices were viewed by the respondents as being widespread.

Many industry representatives, including officials from the Alaskan and Oregon seafood industry, the West Coast Fisheries Development Foundation, and the Pacific Fishery Management Council, told us that misrepresentation occurs, but they do not consider it a major problem. Many officials said they believe misrepresentation occurs mostly at the retail and restaurant level. An official explained that processors cannot deceive the wholesalers or corporate buyers, but the wholesaler may deceive retailers and restaurant personnel, and the consumer is the easiest to deceive. Several industry officials said retail labeling problems included product substitution and frozen and thawed fish being sold as fresh fish.

The current and former chairmen of the University of Alaska's Marine Advisory Program said they were not aware of any attempts by processors or retailers to deceive seafood customers in Alaska. They said there is a nomenclature problem with rockfish being sold as ocean perch or red snapper and other species of sole being sold as English sole. They said using such names is not deception but a way to simplify marketing.

According to a West Coast Fishery Development Foundation official, although local terminology may not be technically correct (for example, red snapper used for local rockfish), in his view, it is not an attempt to deceive the consumer. He said to keep a continuing market relationship, if there is a shortage of a specific fish, a processor may ship a similar fish instead. However, the owner of a seafood processing plant in Oregon said that some distributors will tell a retailer that the species is something other than what it is if this will help sell the product. A member of the Mid-Water Trawlers Cooperative pointed out that sometimes a fish picks up a product name that has to be changed for marketing purposes. For example, slime sole is marketed as Dover sole although it has no relationship to the European Dover sole. A West Coast Fisheries Development Foundation official said that selling prefrozen fish as fresh fish is occurring less frequently.

A Gulf of Mexico Fishery Management Council official said he has heard of substituting a lower value fish for a higher value species. As examples he cited black drum being sold as red drum and sheepshead being sold as other species. He was also aware of overbreading shrimp but did not know the extent of this industry practice. In addition, he said he believed it is a typical seafood industry practice to add water to oysters, but he said health standards require oysters to be washed and as a result they may obtain extra water during that process. According to the owner of one of the largest finfish processors in Louisiana, product substitution has occurred at the wholesale level but has decreased significantly in recent years. In his view, a national chain at the retail level probably would not substitute one product for another, but a chain below the nation level would be more likely to make such a substitution.

In 1986, the National Fishery Institute reported the results of membership surveys on seafood quality and inspection and the results of 10 regional forums they held as part of their annual meeting process in January 1985. The results showed that overglazing (adding water to increase weight) is a widespread practice. In addition, they expressed concern about overbreading, short-weighting, and improper product

substitution. About 56 percent of the questionnaire respondents rated FDA's efforts as adequate or better in enforcing labeling requirements.

Views on Changes Needed in Government Programs Addressing Seafood Safety

Federal and state officials, private sector experts, and academics identified changes that they believed may be necessary to better address the seafood safety issue. Articles and reports on safety-related problems by seafood experts also provide information on the nature and extent of problems and the types of changes that appear to be warranted.

Many experts stated that there are not major or widespread problems with seafood safety or with the governmental programs and activities to address seafood safety concerns. Many officials and experts, however, did acknowledge problem areas and opportunities where programs and services should be improved or where additional effort is needed. Some said the problem areas are well known by government authorities, industry, and academicians. Most of the suggestions for change would require greater resource commitment to this issue.

Views on Mandatory Seafood Inspection

Many public officials and private experts did not believe that seafood safety warranted major changes in the way the government is currently addressing the issue. Several of these officials and experts also said the various governmental inspection activities are adequate, in their view, to monitor seafood and seafood products. Some added that a mandatory inspection program would provide little or no additional protection to consumers and would probably be a high-cost program.

Some experts viewed a mandatory seafood inspection system as enhancing consumer confidence in seafood quality and benefiting the industry in general through increased sales. Others, while not necessarily supportive of a mandatory federal inspection program, offered suggestions for changes or improvements to federal programs that would require additional resources.

As previously mentioned, the 1986 Public Voice for Food and Health Policy report stated that the dangers presented by contaminated fish and shellfish warrant a mandatory federal inspection program. According to this group, the seafood industry could also benefit from a mandatory system through increased consumption, improved quality, and enhanced consumer confidence.

Following are some of the responses we received on the need for a mandatory federal seafood inspection program.

- A spokesman for the California Seafood Institute said the Institute was opposed to a large-scale mandatory seafood inspection program primarily because seafood was already safe for consumption.
- A spokesman for the Pacific Coast Federation of Fisherman's Association expressed concern about the merits of any large-scale federal inspection efforts. He emphasized the need for education of fisherman, processors, middlemen, and consumers on how to properly handle seafood.
- The Oregon State University Seafood Laboratory director said a massive seafood inspection system would be very costly, would probably generate some quality improvements, but would have no significant impact on seafood safety.
- A seafood processing plant owner in Oregon said an intensive inspection system would involve on-call inspectors ready to work long hours and at other times be idle. He added that the seafood industry is characterized by peaks and valleys of activity--workers often put in 12-hour days and weekends and on other occasions have no work at all.
- The Gulf of Mexico Fishery Management Council executive director favored a mandatory federal inspection system because he felt it would increase consumer confidence in seafood products and thus increase sales. He also believed that most seafood industry firms would want a mandatory, continuous federal inspection program.
- Florida's Bureau of Grades and Standards chief said he favored mandatory federal inspection because it would alleviate public concerns about unsafe seafood and would help eliminate the competitive advantage of firms that do not comply with seafood regulations. Florida's Division of Law Enforcement chief also favored federal inspection of seafood but expressed concern about the costs of the program.
- The New England Fisheries Foundation director said that large seafood firms would favor a mandatory federal inspection program. He added, however, that many small firms could have difficulty handling the additional costs that would be incurred to satisfy inspection requirements.
- The University of Massachusetts Marine Station director stated that mandatory federal inspection of finfish is not needed but said there is a need for an increased federal role to monitor shellfish. He said shellfish possess a greater potential for contamination because they are "filter-feeders." Massachusetts, he noted, has one depuration plant that needs a stricter state inspection program.
- The chief of Maryland's Division of Food Control said that a mandatory federal inspection of domestic seafood was not needed. However, she said that the federal government needs to expand its inspection of imported seafood.

Suggestions to Improve Government Programs and Services

Federal and state government officials and seafood experts provided suggestions for changes or improvements in existing governmental programs and services. While such suggestions covered a wide range of areas for potential improvement, many were associated with shellfish safety and the broader issue of chemical contamination. Most changes suggested would require an increase in resources.

Shellfish Safety

Officials and experts provided suggestions to improve seafood safety. The more frequently offered suggestions included

- conducting research to develop new indicator tests for bacterial and viral pathogens in shellfish growing waters,
- expanding public awareness efforts to communicate the potential health risks associated with eating raw or undercooked shellfish,
- intensifying state and federal law enforcement efforts to curtail illegal harvesting and distribution of shellfish from closed/contaminated harvesting areas, and
- increasing testing of shellfish for heavy metals and other chemical contamination.

Better Pathogen Indicator Tests

Several officials said governmental efforts should be intensified to develop better indicator tests to determine the presence of bacterial or viral pathogens in shellfish-growing waters. Current tests for the presence of fecal contamination were developed years ago. Studies conducted since these tests were established expressed concerns regarding limitations of the tests and stated that efforts to develop better tests should be given high priority.

Studies that support the need for an improved indicator to identify the relationship between viral contamination and health problems include the following:

- A Baylor College of Medicine and School of Public Health/University of Texas study showed that neither fecal nor total coliform acts as a good predictor of the concentration of viruses in oysters. The study concluded that bacterial standards do not reflect the occurrence of enteroviruses in marine waters. The study also found no correlation between the presence of viruses in water and the presence of viruses in oysters.
- A Brookhaven National Laboratory study in the late 1970s found little difference in virological quality between areas of Long Island, New York, and New Jersey designated as open or closed to shellfishing.

Viruses were discovered in samples yielding relatively low coliform counts, most of which were below the accepted standard. The study found also that viral isolations did not correlate with coliform counts and concluded that the use of bacterial standards as indexes of the overall sanitary quality of water and shellfish needed to be reevaluated.

The need for a better indicator of viral contamination in shellfish is widely recognized. According to an article by an NMFS official in the September 1985 issue of the Journal of Food Protection, microbiologists and virologists at state health departments believe that guidelines restricting the levels of enteric virus contamination in shellfish would reduce the incidence of shellfish-borne illness. A recent article in the British journal PHS Microbiology Digest also pointed out an urgent need to reassess all aspects of shellfish sanitation from a virological standpoint. An article in the January 1985 Journal of the Royal Society of Health, another British journal, declared that the use of coliform as an indicator of pathogenic viruses in shellfish is increasingly recognized as inadequate.

The fecal coliform test may not be an adequate indicator for some bacterial pathogens. Studies found no correlation between vibrio cholerae and fecal coliform in oysters. One study found that research has not established that fecal coliform standards adequately reflect the presence of potentially pathogenic bacteria of natural aquatic origin in shellfish. An April 1987 report by the Office of Technology Assessment also pointed out that current standards are based solely on water quality, while levels in sediments and shellfish are not regulated. Sediments, however, are probably an equal or more likely source of pathogens in shellfish.

In contrast, a microbiologist from FDA's Northeast Technical Services Unit pointed out that the present bacterial standard for shellfish seems to work well for disease prevention, with only a few isolated instances of disease occurring from shellfish taken from waters that meet the present standards. He also stated that claims of epidemics caused by shellfish taken from clean waters are suspect because there is no way to ensure that shellfish supposedly harvested from approved waters actually came from those waters.

Several of the public officials we contacted expressed concerns about the currently used indicator tests for microbiological contamination and the need to develop better indicator tests. Some of these comments follow:

- According to the Chief, Food Protection Section, Department of Health, State of New York, current indicator tests to determine the presence of bacterial contamination do not adequately protect the public because harvesting areas that may have low bacteria levels may be contaminated by viruses. He believed efforts need to be taken to develop methods to ensure bacterial, as well as viral, safety in shellfish-growing waters.
- A microbiologist at FDA's Northeast Technical Services Unit pointed out that studies of the Escherichia coli and fecal coliform indicator tests have concluded that these tests are not good predictors of the presence of pathogens that may cause gastrointestinal illness.
- A Maryland shellfish program official said that the state strongly believes the fecal coliform level may have no association with human health risk in the absence of significant pollution sources. The official pointed out that the fecal coliform standard was never intended to be the final determining factor in assessing human health risks and that the state of Maryland recognizes the need for valid tests for shellfish contamination.

Need for Public Awareness Initiative

The need for public awareness also was noted by many officials who pointed out such concerns as the potential health risks associated with eating raw or undercooked molluskan shellfish. Eating mollusks raw or undercooked presents potential risks of viral hepatitis, norwalk virus, and a number of other viral or bacterial pathogens that may contaminate shellfish before it is eaten. This concern is attributed in part to the limitations of the indicator tests used to gauge fecal contamination in growing waters.

Several government officials and seafood experts expressed concern also about eating raw seafood in general and believed that a trend in this direction could result in an increase in seafood-related illness. Following are some examples of the concerns expressed and information obtained through articles on this subject.

- FDA's Seafood Products Research Center director described shellfish as "dirty" filter-feeders. She said the public needs to be educated about the health risks and encouraged not to eat raw shellfish.
- The Director of the program in infectious diseases and clinical microbiology at the University of Texas Medical School has been quoted as recommending that anyone with underlying immunologic disease (cancer, diabetes, or chronic gastrointestinal disease) should probably never consume uncooked shellfish.

- A March 1986 article in The New England Journal of Medicine suggested that until effective control measures are developed, the public should be warned that consumption of raw clams and oysters poses a risk of illness.
- Louisiana officials told us that eating raw seafood increases health risks. Because of the high health risks associated with eating raw seafood, the Deputy Secretary of the Louisiana Department of Health and Human Resources said, the state has considered requiring restaurants serving raw seafood to post warnings of possible health hazards.
- The Massachusetts Division of Food and Drugs director said that consumption of raw shellfish is a major source of illness and believes it represents about 25 percent of seafood-borne illnesses in the United States.
- A University of California at Davis epidemiologist said that he was concerned about the trend of raw seafood consumption and thought that the trend would lead to an increased occurrence of infections. This official further stated that a general warning about the risks of eating raw seafood is needed.

Need to Curtail Illegal Harvesting

Several public officials also expressed concerns regarding the illegal harvesting and distribution of shellfish. The extent of illegal harvesting is not known by law enforcement groups, but many believe a substantial problem exists in some areas of the country. Limited law enforcement resources to address illegal harvesting and ineffective fines and penalties for offenders have made illegal harvesting profitable. The primary concern of officials, however, is that illegal trade involves harvesting areas that are prohibited or periodically closed for public health reasons. Some officials stated that illegally harvested shellfish may very well be the cause of many of the mollusk-associated illnesses that occur annually.

- The FDA Shellfish Sanitation Branch manager said illegal harvesting of contaminated molluskan shellfish may be the single greatest problem facing the shellfish industry and public health officials. He further stated that preventing illegal harvesting should be a high priority to better ensure the safe consumption of raw molluskan shellfish.
- Representatives from NMFS' Enforcement Division said illegal shellfish harvesting is a significant problem, especially in certain areas of the country. NMFS gives priority to this issue under its Lacey Act authority; however, it has more investigative leads on illegal shellfish activity than it can handle. NMFS works with state authorities; however, many states also have limited fisheries enforcement resources.

- In GAO's 1984 report, Problems in Protecting Consumers From Illegally Harvested Shellfish (Clams, Mussels, and Oysters) GAO/HRD-84-36, June 14, 1984, the issues associated with illegally harvested shellfish and factors affecting regulatory and enforcement authorities were discussed. We reported that law enforcement agencies had insufficient resources to prevent illegal harvesting of shellfish and court-assessed fines were inadequate to deter illegal harvesting.
- Massachusetts' Chief of Marine Bureau, Division of Law Enforcement, said that because of illegal shellfish harvesting in contaminated areas, the market has been flooded with contaminated shellfish, posing a threat to public health. He indicated that the main reason is inadequate patrol resources and the courts' view of these violations as relatively unimportant, which results in their rendering mild penalties that do not deter this illegal activity.
- New York's Chief of the Food Protection Section, Department of Health, believes illegal shellfish harvesting is occurring in the state and causing illness, but its impact is not evident because bootleggers mix contaminated and noncontaminated products.
- An editorial in The New England Journal of Medicine raised questions about consumption of raw shellfish and offered suggestions to address the issue.[1] A key position in the editorial was the need to strengthen enforcement activities to control illegal shellfish harvesting.

Chemical Contamination of Seafood

As discussed in chapter 2, chemical contamination of food is an issue of growing concern. Knowledge of toxic chemicals in many of the nation's fresh, estuarine, and marine waters has increased but, because research on the relationships between chemical contamination and human illness has not yet produced the direct evidence desired by the medical science community, the seriousness of this issue remains unclear.

Views and suggestions of certain officials on what needs to be done to better address this concern include the following:

- FDA's Boston District Consumer Safety Monitor said its sampling indicates measurable levels of chemical residues in certain species of fish and shellfish. Although the situation is approaching a public health concern, he believed that more contaminant monitoring and sampling assessments are needed to document this concern.

[1]Barbara A. Rockett, M.D., "Consumption of Raw Shellfish—Is the Risk Now Unacceptable?," The New England Journal of Medicine, March 13, 1986, Vol. 314, No. 11.

- New York's Director, Division of Environmental Health Assessment, suggested that the federal government needs to update its standards and develop more standards for toxic contaminants in finfish.
- In California, seafood experts recommended changes in FDA's enforcement efforts regarding chemical contaminants, including (1) testing for more contaminants; (2) establishing tolerances for more contaminants, especially for heavy metals and modern industrial chemicals and pesticides; (3) notifying the state more promptly of violative seafood findings; and (4) more routine monitoring of seafood from Southern California.
- A Colorado Water Quality Control Division researcher and Louisiana state seafood regulators said the federal government needs to determine tolerance levels for more contaminants.
- A Virginia Institute of Marine Science official said the biggest weakness in the existing seafood monitoring program is that there are certain chemicals determined to be unsafe and these are usually the only ones that are monitored. The number listed as unsafe is extremely small compared with the number of chemicals being added to the environment whose long-term effects are generally unknown. He stated that as a result of his studies, he found 340 chemicals compounds in the Chesapeake Bay, most of which have not been assessed for safety. As a result, he believes oysters that come from NSSP-approved growing areas are not necessarily safe to eat because of the long-term effects of accumulating toxic chemicals in humans.

Some other officials expressed the general view that the levels of chemical contamination in seafood should not be a major concern. For example, San Francisco and Los Angeles FDA District officials said they are not finding any significant problems from their surveillance of chemicals in seafood. The Laboratory Director of FDA's San Francisco Laboratory said, in general, chemical contamination of food is not the problem the public believes it is.

Additional Suggestions for Changes and Improvements in Seafood Safety

In addition to the above, other suggestions were offered by some of the public officials and private experts. The following reflect the principal areas for improvements that were identified:

- While not supportive of a mandatory inspection system, some officials and experts said that additional but selective inspection activities and seafood sample analysis would be an appropriate improvement. In this regard, several also believed more sampling of imported seafood products would be useful.

- More consumer education in general about seafood handling and preparation was also mentioned by several experts. Mishandling of seafood and improper cooking have been regarded as a major cause of seafood-borne illness.
- A few government officials suggested that FDA be given embargo authority and/or develop more effective procedures for seizing products in violation of federal standards. FDA has requested states having this authority to take such action. The current process to get court-ordered seizure authority is time-consuming and delays the ability of the federal government to seize products. GAO addressed this matter in an earlier report, Legislative Changes and Administrative Improvements Should Be Considered for FDA to Better Protect the Public From Adulterated Food Products, (GAO/HRD-84-61, Sept. 26, 1984).
- The need for education of and technical assistance to the seafood industry.
- A wide range of comments on the need for more and/or continued research on the issue of seafood quality control and safety. These ranged from harvesting quality control and handling to processing and distribution of seafood products.

Chapter 6

Summary and Observations

Federal legislators have discussed seafood safety for many years, focusing on the federal programs and activities addressing the issue. In recent years interest has again surfaced questions about seafood contamination and the adequacy of the government programs. Claims have been made by some that federal efforts to monitor seafood are inadequate and permit serious threats to the public health. Some also claim that some type of federal mandatory seafood inspection program is needed to adequately address these problems.

To help assess the nature, extent, and seriousness of seafood safety problems, we identified government activities addressing the issue and obtained the views of many government and private seafood experts on the changes that they view as necessary to help improve seafood safety.

Nature and Extent of Seafood Safety Problems

Seafood can be exposed to a wide variety of biological pathogens, toxins, and parasites that in turn can cause illness in humans. In addition, seafood can be exposed to an indeterminable number of chemicals, including heavy metals, pesticides, and other chemicals such as polychlorinated biphenyls. FDA and EPA have established action levels for 15 hazardous chemical substances that have been found in seafood, almost all of which are suspected to be or are potentially carcinogenic or mutagenic. Experts have noted that because of the difficulties in developing direct relationships, much is unknown regarding chemical contamination and human illness. Seafood is not unique in this regard—all food products can be exposed to various types of biological and chemical contamination at any number of stages between the growing areas, processing, distribution, and preparation for human consumption.

Complete statistics on the nature and extent of human illness caused by eating seafood do not exist. However, we obtained some perspective on the extent of the problem by examining data from CDC and FDA. Available seafood-borne illness data from CDC, while recognized as incomplete, do not indicate a widespread problem with the nation's seafood. The data showed that during the period 1978 through 1984, 5,080 seafood illness cases (representing about 5 percent of all food-borne illness cases) and 5 deaths were reported to CDC. In addition, other information showed that the majority of the seafood cases were associated with three species groups. One involved raw molluskan shellfish that were contaminated with microbiological pathogens. According to numerous sources, the risk associated with shellfish is reduced significantly if it is properly cooked. The other two species groups were particular finfish

species that transmitted naturally produced chemical toxins—ciguatoxin and scombrotoxin—that can be deadly if eaten.

Our review of FDA statistics does not indicate widespread, serious problems with seafood. In fiscal year 1986, FDA took about 6,500 samples and found about 1,900 to be adverse. Our review of a portion of these adverse seafood samples showed that about 78 percent would not be considered particularly serious problems or direct threats to health. For those samples where serious problems were detected, many were associated with biological pathogens that would be subsequently neutralized if the product was properly handled and cooked. The remainder of the cases, which would not be affected by cooking, were primarily chemical contaminants.

Federal and State Programs

The federal government has not followed the concept of 100-percent product inspection for seafood, as is currently used for meat and poultry. We found, however, that it conducts, through a number of agencies, programs to help monitor and assess current and changing conditions affecting the relative safety of the nation's seafood. These activities include inspections, product sample analysis, water quality assessments, research and data gathering, enforcement activities, and technical assistance to states and industry.

In addition, state governments also conduct, to varying degrees, similar activities that help to monitor the condition of seafood in their respective states. These activities include seafood establishment inspections, seafood sample analysis, water quality assessments, and patrol of harvesting areas. Also, most of the states with shellfish harvesting, processing, and shipping activities conduct shellfish sanitation programs and are participants in the Interstate Shellfish Sanitation Conference. The federal government, primarily through FDA, provides oversight of many of the state activities to help improve their effectiveness.

Admittedly, the level of federal and state inspection and product sample analysis activity is limited, relative to the volume of seafood and seafood products entering the marketplace. FDA officials said their sampling coverage represents less than 1 percent of domestic and 3 percent of imported seafood. FDA's efforts are, however, targeted to known or suspected problem areas, as opposed to broader based sampling, and in recent years have surfaced some type of adverse finding about 25 percent of the time. In addition, NOAA, through its voluntary inspection program, inspected about 10 percent of the seafood consumed in the United

States in fiscal year 1987. Information from selected states indicated that they also perform similar inspections and sample analysis activities but generally do not find serious health or safety problems.

Collectively, federal and state programs represent a considerable amount of activity that contributes to the monitoring and assessment of changing conditions associated with seafood safety. The effectiveness of such programs in correcting or preventing problems was, however, beyond the scope of our review.

Expert Views on the Seafood Safety Issue

Many government officials and private experts stated that they believed problems either with seafood safety or with the governmental programs and activities addressing seafood safety concerns are not major or widespread. Many officials and experts agree, however, that certain areas of concern warrant special attention. The principal areas of concern included

- the need to develop better tests to measure microbiological contamination in shellfish-growing waters and in shellfish stock,
- the need to create a greater public awareness of the potential health risks associated with consuming raw or undercooked molluskan shellfish,
- the need for more government attention to curtail the illegal harvesting of shellfish from closed/contaminated harvesting areas, and
- the need for more research to better understand chemical contamination in seafood and its human health implications.

These areas of concern are being addressed, to varying degrees, by federal programs, as illustrated by the following:

- NOAA and EPA are currently performing research directed at developing better microbiological indicator tests for shellfish-growing waters.
- Some public awareness and public advisory initiatives are being taken by federal and state authorities to communicate special concerns.
- NOAA is developing a plan for a seafood surveillance system model for domestic and imported seafood focusing on safety control points in harvesting and processing operations. The National Academy of Sciences is participating by reviewing the various types of contaminants that seafood could be exposed to and reviewing available seafood-borne illness data to help put the problems in some perspective.

- Action is being taken by a number of federal agencies to increase their knowledge of the implications of chemical contamination for human illness. Government and private authorities recognize that this work is a long-term effort and, in addition to seafood, affects many other foods.

GAO Observations

Growing public awareness of seafood safety, resulting from increased claims of serious seafood contamination problems, has led to proposals for a mandatory seafood inspection system similar to inspections used for meat and poultry. However, on the basis of the information we gathered and the views of experts we interviewed, there does not appear to be a compelling case at this time for implementing such a comprehensive federal mandatory seafood inspection system.

Essentially, three factors support this position. First, available seafood illness statistics, while incomplete, do not indicate widespread problems—seafood illnesses reported to CDC represented about 5 percent of all food-borne illness and were focused on a few species groups. Second, while not viewed as a comprehensive inspection effort, federal and state monitoring and assessment activities do provide checks on seafood safety and conditions. Third, concerns that the experts identified, such as the need for better microbiological tests, more public awareness, more attention to illegal harvesting, and additional research on chemicals, are generally not the type of problems that would be solved by a mandatory seafood inspection program.

Nevertheless, continuing attention and support are needed for a number of the initiatives currently underway. These include research on chemical contamination and microbiological tests for growing waters, NMFS development of a seafood surveillance system, and efforts to improve public awareness of risks associated with the consumption of raw or undercooked shellfish. The NMFS seafood surveillance study is designed to provide a basis for addressing microbiological seafood safety problem areas. In addition to improving seafood safety, activities such as these could also help to provide a basis for designing a mandatory inspection program, should one be deemed necessary in the future. We believe that strong oversight of these areas by appropriate federal and state agencies is needed to help ensure that the intended objectives are accomplished.

Appendix I

States GAO Contacted During the Review

Alabama[a]	Massachusetts
Alaska	Missouri[a]
California	New Jersey[a]
Colorado[a]	New York
Florida	Oregon
Georgia[a]	Pennsylvania[a]
Illinois[a]	South Carolina[a]
Louisiana	Texas[a]
Maine	Virginia
Maryland	Washington

[a]Contacted by telephone

Description and Statistical Information on FDA Seafood Establishment Inspections and Seafood Sample Analyses

FDA Inspections

According to its records, FDA conducted a total of 1,381 inspections of seafood establishments in fiscal year 1986.[1] According to FDA officials, about 4,000 seafood establishments that participate in interstate commerce are subject to its inspections. While the frequency of these inspections may vary among its district offices, FDA tries to conduct an inspection of these establishments at least once every 2 years. FDA visits some establishments more frequently than others when problems are found during inspections. To help increase its coverage, FDA also has contracts with state governments to make some inspections.

Table II.1 provides statistical information on the number of FDA seafood establishment inspections conducted in fiscal years 1984, 1985, and 1986. Most FDA inspections are focused on general plant sanitation (about 65 percent of the inspections conducted).

Table II.1: FDA Inspections of Seafood Establishments in Fiscal Years 1984, 1985, and 1986

	Number of inspections		
Focus of inspection	**1984**	**1985**	**1986**
Sanitation	891	545	957
Contaminants (pesticides/metals)	143	65	104
Additives (food additives and colors)	99	48	114
Economics	30	12	39
Shellfish	260	203	167
Total	**1,423**	**873**	**1,381**

Source: Compiled by GAO from FDA data management systems and records

FDA Sample Taking and Analysis

According to FDA headquarters officials, domestic seafood samples are taken primarily from seafood establishments during inspections. Inspectors take samples on the basis of FDA headquarters guidance or direction and can take samples of products they believe warrant further analysis. FDA officials told us that domestic product sample analysis represents less than 1 percent of the domestic seafood supply in a year. FDA records indicated that for fiscal year 1986, 1,814 domestic seafood samples were taken and analyzed for various potential problems. Of the samples analyzed, 218 (or 12 percent) were found to be adverse (those in violation of regulations and requiring action).

According to FDA officials, FDA uses seafood sample analysis more extensively to determine if imported products meet the federal standards. FDA

[1]Seafood establishments include processors, shippers, packers, repackers, labelers, relabelers, warehousers, and importers.

officials told us that imported seafood sample analysis represents coverage of less than 3 percent of imported seafood products entering the United States in a year. FDA uses various means to select imported seafood samples. As with domestic seafood, samples may be taken on the basis of FDA headquarters guidance or at the discretion of the FDA inspector. In addition, imported products may also be subjected to FDA's automatic detention procedure. Under this procedure, if FDA's experience or other information indicates potential problems with a particular product, importer, or country, the agency can put the importer or country on its automatic detention list. FDA districts then automatically detain such imports and may take samples for FDA laboratory analysis or require the importer to have an independent, FDA-approved laboratory conduct specific analyses to determine whether the products comply with FDA standards.

Table II.2 provides information on FDA domestic and imported seafood samples, the number found to be adverse, and the percentage of adverse findings for fiscal years 1984, 1985, and 1986. The number of adverse seafood samples is the total of the different types of adverse conditions FDA identified, including biologic contamination, chemical contamination, food additives, and economic violations. For the 3-year period, considering all domestic and imported seafood samples, FDA identified adverse conditions in about 35 percent of the samples taken.

Table II.2: FDA Domestic and Imported Seafood Samples Taken, Adverse Samples, and Percentage of Adverse Samples for Fiscal Years 1984, 1985, and 1986

Fiscal year	Total samples	Total adverse sample	Percent of total adverse to total sample
Domestic Seafood Samples			
1984	1,406	412	29.3
1985	2,253	378	16.8
1986	1,814	218	12.0
Imported Seafood Samples			
1984	3,879	1,892	48.8
1985	4,672	1,912	40.9
1986	4,714	1,663	35.3

Source: Compiled by GAO from FDA data management systems and records.

Table II.3 shows a distribution of the 218 adverse domestic and 1,663 adverse imported seafood samples for fiscal year 1986 by the type of finding. Because FDA found some seafood samples with more than one adverse finding, we classified such samples according to the most severe finding. Table II.4 shows the distribution of the 1986 domestic and

imported seafood samples taken by finding classification categories. As previously noted, 12 percent of the domestic and 35 percent of the imported samples were found to be adverse.

Table II.3: FDA Adverse Domestic and Imported Seafood Samples by Finding Categories for Fiscal Year 1986

	Number of adverse seafood samples	
Finding	**Domestic**	**Imported**
Biologic contamination	139	1,292
Chemical/pesticide contamination	50	93
Food additive	12	163
Economic/misrepresentation	17	115
Total	**218**	**1,663**

Source: Compiled by GAO from FDA data management systems and records

Table II.4: FDA Domestic and Imported Seafood Sample Findings for Fiscal Year 1986

FDA sample finding classification categories	1[a]	2[b]	3[c]	4[d]	5[e]	Total
Domestic	1,106	161	218	328	1	**1,814**
Imported	2,823	190	1,663	26	12	**4,714**
Total	**3,929**	**351**	**1,881**	**354**	**13**	**6,528**

[a]Sample complied with established standards for the analysis performed.

[b]Sample failed to comply with established standards for the analysis performed but is not appropriate for regulatory action because of the insignificance of the violation.

[c]*Adverse finding found.* Sample does not comply with established standards and the violation is significant to support regulatory action. Samples held without analysis for evidence in regulatory proceedings are also included in this classification.

[d]Sample is not the type requiring classification.

[e]The sample was collected for analysis, but FDA decided not to review, analyze, or hold for further action.

Source: Compiled by GAO from FDA data management systems and records.

Review of FDA Adverse Seafood Sample Findings in Fiscal Year 1986

To obtain a more detailed perspective on the significance of FDA's adverse seafood sample findings, we selected 8 FDA District Offices whose 67 adverse sample findings collectively represented 30 percent of the adverse domestic seafood samples and the 1,447 adverse seafood sample findings representing 87 percent of the adverse import samples (see table II.5) for fiscal year 1986. These eight districts also provided geographic and regional coverage of the country, representing East Coast, Gulf of Mexico, and West Coast districts of FDA. We reviewed information that would provide basic information on these adverse seafood samples to determine their nature, extent, and seriousness.

Table II.5 shows the number of fiscal year 1986 adverse seafood samples at the eight FDA District Offices we visited.

Table II.5: Number of Fiscal Year 1986 Adverse Domestic and Import Seafood Samples GAO Reviewed by FDA District

	Adverse samples	
District	**Domestic**	**Imports**
Baltimore	7	9
Boston	3	129
Los Angeles	5	773
New Orleans	4	8
New York	2	141
Orlando	11	156
San Francisco	4	116
Seattle	31	115
Total	**67**	**1,447**

Source: Compiled by GAO from data management systems and records from the eight FDA district offices included in GAO's review

To assess the potential health impact of the adverse seafood samples, we reviewed the districts' sample records to determine the reason for the adverse classification. According to FDA officials, FDA does not classify its adverse seafood sample findings regarding their seriousness. We used criteria presented in the National Research Council's 1985 report entitled An Evaluation of the Role of Microbiological Criteria for Foods and Food Ingredients to classify microbiological pathogens, natural toxins, and indicator organisms. We used the categories direct, indirect, and no hazard to public health to relate the seriousness of safety-related findings.

Twenty-one percent of the domestic adverse seafood samples and 22 percent of the imported adverse seafood samples were characterized as having a direct impact on public health. The significance of the findings for seafood samples is shown in table II.6.

Table II.6: Significance of Findings for Domestic and Imported Seafood Samples Included in GAO's Review

	Domestic		Imported		Total	
	Number	Percent	Number	Percent	Number	Percent
Direct[a]	14	21	17	22	331	22
Indirect[b]	28	42	115	8	143	9
No Hazard[c]	14	21	508	35	522	34
Economic[d]	11	16	86	6	97	6
Undeterminable[e]	0	0	421	29	421	28
Total	**67**	**100**	**1,447**	**100**	**1,514**	**100[f]**

[a]A direct hazard includes such contaminants as pathogens, food additives, toxins, and chemicals at or above FDA action levels and unlabelled sulfites.

[b]An indirect hazard includes such contaminants as nonpathogenic Escherichia coli or fecal coliform. We also included decomposition as an indirect hazard because of the possibility of high histamine or scombroid toxin and defective can seams because of the possibility of disease-causing bacteria.

[c]No hazard includes such contaminants as distasteful contaminants and rancid products and failure by the importer to file with FDA the process under which the seafood was processed.

[d]Economics includes any form of misrepresentation such as short-weighting, product substitution, and mislabeling.

[e]Undeterminable includes imports automatically detained and then reconditioned by the importer, which resolved the reason for the detention without an analysis being performed.

[f]Does not add due to rounding.

Source: Compiled by GAO from data management systems and records from the eight FDA district offices included in GAO's review.

The final status of the sampled seafood included in GAO's review is shown in table II.7. A sample analysis is not always conducted before a determination is made on how to resolve the problem. For example, a product may be destroyed, relabeled, exported, reconditioned, or not allowed to be imported without conducting a laboratory analysis.

Table II.7: Final Status of Domestic and Imported Seafood Samples Included in GAO's Review

Status	Domestic	Imported	Total
Distributed[a]	18	335	353
Destroyed[b]	25	156	181
Relabeled[c]	3	89	92
Refused entrance/exported[d]	0	445	445
Reconditioned[e]	0	332	332
Other[f]	21	90	111
Total	**67**	**1,447**	**1,514**

[a]Seafood distributed to U S consumers

[b]Seafood destroyed under federal supervision

[c]Seafood relabeled to comply with FDA regulations

[d]Seafood refused entrance into the United States or exported from the United States

[e]Seafood reconditioned (cooked or treated to bring into compliance with FDA standards) to kill the bacteria in the product

[f]Samples were included as "other" for various reasons, including 64 samples for which the final status was not known (61 imports and 3 domestic), 25 with combinations of the above categories (24 imports and 1 domestic), and 5 domestic cases still in process

Source: Compiled by GAO from data management systems and records from the eight district offices included in GAO's review

Related GAO Reports

Water Quality: Pollution of San Francisco Bay and the Sacramento-San Joaquin Delta (GAO/RCED-87-156FS, June 18, 1987).

Water Pollution: Application of National Cleanup Standards to the Pulp and Paper Industry (GAO/RCED-87-52, Mar. 18, 1987).

Seafood Marketing: Opportunities to Improve the U.S. Position (GAO/RCED-87-11BR, Oct. 22, 1986).

Pesticides: Need to Enhance FDA's Ability to Protect the Public From Illegal Residues (GAO/RCED-87-7, Oct. 27, 1986).

Pesticides: Better Sampling and Enforcement Needed on Imported Food (GAO/RCED-86-219, Sept. 26, 1986).

Food and Drug Administration: Laboratory Analysis of Product Samples Needs to Be More Timely (GAO/HRD-86-102, Sept. 30, 1986).

Pesticides: EPA's Formidable Task to Assess and Regulate Their Risks (GAO/RCED-86-125, Apr. 18, 1986).

Food Inspections: FDA Should Rely More on State Agencies (GAO/HRD-86-2, Feb. 18, 1986).

Uses of Saltonstall/Kennedy Fisheries Development Funds (GAO/RCED-85-145, Aug. 30, 1985).

Legislative Changes and Administrative Improvements Should Be Considered for FDA to Better Protect the Public From Adulterated Food Products (GAO/HRD-84-61, Sept. 26, 1984).

FDA's Oversight of the 1982 Canned Salmon Recalls (GAO/HRD-84-77, Sept. 12, 1984).

Evaluation of Selected Aspects of FDA's Food Manufacturing Sanitation Inspection Efforts (GAO/HRD-84-65, Aug. 30, 1984).

Problems in Protecting Consumers From Illegally Harvested Shellfish (Clams, Mussels, and Oysters) (GAO/HRD-84-36, June 14, 1984).

Need to Strengthen Coordination of Ocean Pollution Research (GAO/CED-82-108, July 14, 1982).

Foreign Investment in U. S. Seafood Processing Industry Difficult to Assess (CED-81-65, Mar. 30, 1981).

Followup on the National Marine Fisheries Service's Efforts to Assess the Quality of U.S.-Produced Seafood (CED-81-125, June 22, 1981).

Need to Assess the Quality of U.S.-Produced Seafood for Domestic and Foreign Consumption (CED-81-20, Oct. 15, 1980).

Developing Markets for Fish Not Traditionally Harvested by the United States: The Problems and the Federal Role (CED-80-73, May 7, 1980).

Food and Drug Administration's Program for Regulating Imported Products Needs Improving (HRD-77-72, July 5, 1977).

Federal Support for Restaurant Sanitation Found Largely Ineffective (MWD-76-42, Dec. 8, 1975).

Protecting the Consumer From Potentially Harmful Shellfish (Clams, Mussels, and Oysters) (B-164031(2), Mar. 29, 1973).

Current Regulatory Action Levels Established by FDA for Poisonous or Deleterious Substances in Seafood

Chemical substance[a]	Seafood group	Action level (parts per million)
Aldrin and dieldrin	Fish	.3
Benzine hexachloride	Frog legs	.3
Chlordane	Fish	.3
DDT, DDE, and TDE[b]	Fish	5.0
Endrin	Fish and shellfish	.3
Heptachlor and heptachlor epoxide	Fish and shellfish	.3
Kepone (chlordecone)	Crabmeat	.4
	Fish and shellfish	.3
Mercury (methyl mercury)	Fish, shellfish and crustaceans, and other aquatic animals	1.0
Mirex	Fish and shellfish	.1
PCBs[c]	Fish	2.0
Toxaphene	Fish	5.0

[a]Paralytic shellfish toxin was intentionally excluded from this appendix because it is a biologically produced chemical toxin.

[b]When the amounts of DDT, DDE, and TDE are added, any of the three found below .2 parts per million for fish is not counted for compliance purpose.

[c]PCBs found at 2 parts per million in fish are the only poisonous or deleterious substance for which FDA has established a tolerance level that is promulgated through FDA's official rulemaking process.

Source: FDA Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Food.

Interagency and Cooperative Agreements and Memorandums of Understanding Related to Seafood Safety Identified by GAO

Type of agreement	Parties	Purpose
Memorandum of understanding	U.S. Department of Agriculture and Department of Commerce	To make effective use of federal resources by the cross-utilization of inspection personnel for fishery, fruit, and vegetable inspection and certification services.
Cooperative agreement	Department of Commerce and State of Alaska	To establish working arrangements for the effective discharge of fishery products inspection responsibilities of each party. (Similar agreements have been established with 10 other states.)
Interagency agreement	FDA and U.S. Army	To provide for a collaborative effort to develop new assay procedures and the development of rapid analytical methods to detect, quantify, and confirm seafood toxins.
Interagency agreement	EPA and FDA	To establish a cooperative effort to study bacteriological problems in the Narragansett Bay.
Interagency agreement	FDA and NMFS	To establish arrangements for the study of PCBs in bluefish along the Atlantic Coast of the United States.
International agreements	United States and Republic of Korea	To establish agreements on exchange of fisheries research, promotion of sanitary conditions of shellfish, and other related purposes.
International agreement	United States and Canada	To provide for cooperative efforts toward the sanitary control of the shellfish exported to the United States. (Similar agreements have been established with other foreign governments.)
Memorandum of understanding	NMFS and FDA	To establish improved cooperation and coordination on fisheries research efforts for more efficient use of federal resources.
Memorandum of understanding	FDA and ISSC	To foster and improve the sanitation and quality of shellfish in the United States.
Memorandum of understanding	FDA, NOAA, EPA, and Fish and Wildlife Service	To improve cooperation and coordination of monitoring efforts and avoid duplication of work on shellfish-growing waters to maximize the federal resources devoted to monitoring estuarine coastal and other waters, especially shellfish-growing waters.
Memorandum of understanding	FDA and NMFS	To increase and improve efforts in the enforcement of laws against the illegal harvesting, transportation, export, import, sale, and purchase of molluskan shellfish.
Memorandum of agreement	U.S. Department of Agriculture and Department of Commerce	To establish working agreements for developing federal standards for federal procurement of food items, including fish and fishery products.
Memorandum of understanding	FDA and NMFS	To set forth working relationships for each agency to effectively discharge its responsibilities related to the inspection and standardization activities for fishery products.

Major Contributors to This Report

Resources, Community, and Economic Development Division, Washington, D.C.	John H. Luke, Associate Director,(202) 275-6111 Frank V. Subalusky, Group Director Glen Trochelman, Assignment Manager Richard E. Iager, Evaluator-in-Charge John A. Thomson, Evaluator Gregory D. Knight, Writer/Editor Benjamin F. Grassi, Typist
Atlanta Regional Office, Atlanta, Georgia	Charles R. Chappell, Regional Assignment Manager Richard J. Wade, Site Senior Linda S. Lootens, Evaluator Lori M. Webster, Evaluator
Boston Regional Office, Boston, Massachusetts	Thomas J. McGrane, Regional Assignment Manager Bruce Skud, Site Senior Elmer L. Johnson, Evaluator
Seattle Regional Office, Seattle, Washington	Charles D. Mosher, Regional Assignment Manager Walter R. Eichner, Site Senior Barbara A. Billinghurst, Evaluator Virginia B. Proano, Evaluator

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