

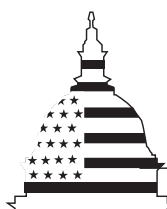
GAO

Report to the Committee on Agriculture,
Nutrition, and Forestry, U.S. Senate

January 2001

FOOD SAFETY

Federal Oversight of Seafood Does Not Sufficiently Protect Consumers



G A O

Accountability * Integrity * Reliability

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Abbreviations

CDC	Centers for Disease Control and Prevention
CCP	critical control point
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
GAO	General Accounting Office
HAACP	Hazard Analysis and Critical Control Point (system)
QMP	Quality Management Program
USDA	U.S. Department of Agriculture



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

January 31, 2001

The Honorable Richard G. Lugar
Chairman
The Honorable Tom Harkin
Ranking Member
Committee on Agriculture, Nutrition, and Forestry
United States Senate

Contaminated food products cause an estimated 76 million foodborne illnesses annually in the United States, according to the Centers for Disease Control and Prevention (CDC). Seafood (finfish and crustaceans) represented about 15 percent of the documented foodborne illness outbreaks in the United States,¹ according to CDC's data for 1997, the latest year for which such data are available. Seafood-related illnesses could result in a variety of problems, ranging from mild gastrointestinal discomfort to neurological damage or death.

Recognizing the potential for foodborne illness posed by seafood, the Food and Drug Administration (FDA) implemented a new science-based seafood safety program in 1997—the Hazard Analysis and Critical Control Point (HACCP) system. The U.S. Department of Agriculture (USDA) also adopted a HACCP system for meat and poultry products.² HACCP systems are designed to improve the safety of food by having industry identify and control known microbiological, physical, and chemical hazards in products before they enter the market. FDA's HACCP regulations require that domestic seafood-processing firms conduct an analysis to identify hazards that are reasonably likely to occur and to develop and implement a plan to control them.³ In addition, the HACCP regulations require seafood-processing firms to implement a written sanitation-operating procedure to, among other things, avoid spreading contamination from one work surface to another, control employee health conditions, and control pests. FDA

¹Molluscan shellfish—oysters, clams, mussels, and whole or roe-on scallops—are discussed in a separate report. CDC derives estimates of foodborne illness from, among other things, reported occurrences of two or more cases of a similar illness resulting from the ingestion of a common food, which is referred to as an *outbreak*.

²USDA is responsible for the safety of meat, poultry, and some egg products while FDA is responsible for the safety of all other foods.

³21 C.F.R. part 123. Processing firms subject to HACCP requirements include those that handle, store, prepare, head, eviscerate, and freeze seafood products.

inspects seafood-processing firms to verify their compliance with these HACCP requirements. Some state regulatory authorities also conduct HACCP verification inspections under contract or in partnership with FDA.

Imported seafood—which constitutes more than one-half of all the seafood consumed in the United States—must meet these requirements as well. That is, U.S. importers are required to demonstrate that seafood products from foreign countries are produced in accordance with HACCP regulations for U.S. seafood. The easiest way for importers to meet HACCP responsibilities and requirements is to obtain seafood from foreign firms in countries having an agreement with FDA that documents the equivalent seafood safety systems. Currently, FDA has not completed any agreements for seafood; therefore, importers are required to take affirmative steps to demonstrate that seafood products from foreign countries are produced in accordance with regulations for U.S. seafood. Such affirmative steps include, for example, maintaining a copy of the foreign firms' HACCP plan on file or obtaining a certificate from a foreign government's appropriate inspection authority. FDA also inspects some foreign seafood firms as well as U.S. importers to determine their compliance with FDA's HACCP regulations and some imported seafood products at the U.S. port of entry to verify their safety.

In response to your request, we evaluated the effectiveness of FDA's system to control the risk of foodborne illness resulting from unsafe domestic and imported seafood. To conduct this review, we visited the three FDA districts in which the largest volumes of seafood are produced—Seattle, New England, and Florida—to analyze the results of FDA's inspections, to conduct a probability sample of FDA's inspection reports,⁴ and to interview FDA and industry personnel. We also reviewed selected aspects of the seafood programs of Chile and Canada because these countries are large exporters of seafood products to the United States and they have implemented HACCP systems. In addition, we reviewed the status of pending seafood equivalence agreements, FDA's inspection reports of foreign seafood firms, the results of FDA's seafood inspections of U.S. importers, and seafood examinations at ports of entry. Appendix I provides additional details on our scope and methodology.

⁴See appendix 1 for a description of the sample and the sampling errors associated with the estimates based on this sample.

Results in Brief

FDA has made some progress in ensuring the safety of seafood consumed by the public. In 1997, the agency implemented the HACCP system and inspected all seafood-processing firms in its inventory at least once to verify that firms were, in fact, implementing the HACCP requirements. According to FDA's December 2000 report on the HACCP system for seafood,⁵ the percentage of seafood firms with a HACCP plan that included all of the required components increased from 31 percent in 1998 to 44 percent in 1999. However, FDA recognizes that there are still gaps in HACCP's implementation and that certain segments of the industry are lagging behind. Our evaluation of FDA's seafood safety program identified a number of weaknesses in FDA's domestic and imported seafood programs. With regard to domestic seafood, we found that four program weaknesses limit FDA's ability to prevent unsafe seafood from reaching consumers. First, although FDA's HACCP regulations apply to all seafood-processing firms, for a variety of reasons, a significant number of seafood products are not being processed under HACCP systems, including those processed on board fishing vessels. For example, FDA's inventory of seafood-processing firms includes only 250 vessels that are subject to HACCP requirements. The actual number of fishing vessels that should be under HACCP requirements is not known because neither FDA nor any other organization we contacted currently collects such data. However, an official in one FDA district office noted that from 400 to 800 fishing vessels in his district may perform some type of processing on board. Second, even when seafood products have been processed under a HACCP system, there are serious weaknesses. For example, we estimate that in the three districts we studied, about 48 percent of the seafood products subject to HACCP requirements and selected for examination were not being processed at the time of FDA's inspections. As a result, the inspections for these products were limited to a paperwork review, and as a general rule, inspectors did not return to inspect the product as required by FDA's compliance manual. Furthermore, over half of the inspections identified serious violations, such as the failure to identify likely hazards. Third, even when inspectors identified significant violations, FDA did not issue warning letters—one of the agency's principal means of notifying regulated firms of serious violations—in a timely manner. In calendar year 2000, 94 percent of the warning letters exceeded the 15-day review and approval time frame recommended in FDA's Regulatory Procedures Manual. The warning letters

⁵*Evaluation of FDA's Hazard Analysis Critical Control Point (HACCP) Program for Seafood for Calendar Years 1998 and 1999* (Dec. 8, 2000).

took an average of 73 days to approve. Fourth, while USDA has objective, quantifiable data to assess the effectiveness of its HACCP system for meat and poultry, FDA does not for seafood. FDA acknowledges some of these problems. However, while Congress increased FDA's funding by \$32 million from fiscal year 1999 through fiscal 2000 for its food programs, FDA believes it needs additional resources to resolve these problems.

FDA's regulation of imported seafood also provides insufficient assurance that the products are safe. FDA's system for ensuring the safety of imported seafood is based on four basic strategies—equivalence or compliance agreements, reviews of importers' records, inspections of selected foreign firms, and port of entry product examinations. We identified difficulties in the implementation of each of these strategies. First, according to FDA officials, the easiest way to ensure that imported seafood is processed under an acceptable HACCP system is for importers to purchase products from countries with which FDA has an equivalence or compliance agreement. However, FDA has so far been unable to complete seafood equivalence or compliance agreements with any country. Second, in the absence of such agreements, U.S. importers must have records from their foreign customers showing that the products offered for entry into the United States have been processed under HACCP requirements. However, we found that less than one-third of the importers that FDA inspected had the required documentation to demonstrate compliance with the HACCP requirements. Third, FDA's inspections of selected foreign seafood firms often identified serious problems, such as the absence of HACCP plans, but FDA has not followed-up with an automatic examination of these firms' products at U.S. ports of entry. Fourth, FDA's last strategy for ensuring the safety of imported seafood—port of entry examinations and product testing—has been widely discredited as an effective approach to ensuring the safety of imported products, and as we previously reported,⁶ such inspections are labor-intensive. In addition, FDA is unable to keep pace with the growing levels of imported foods. For example, in 1999, FDA tested less than 1 percent of all seafood imported into the United States. FDA acknowledges some of the limitations of its imported seafood safety system but states that reaching equivalence or compliance agreements with other countries takes considerable time and resources.

⁶See *Food Safety: Federal Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable* (GAO/RCED-98-103, Apr. 30, 1998).

We are providing the Congress with two matters for consideration and making several recommendations to the Commissioner of FDA aimed at (1) achieving stronger implementation of the HACCP system for seafood and (2) providing greater assurances to the public that both domestic and imported seafood products are safe. In commenting on a draft of this report, FDA essentially concurred with six of our recommendations to the agency and disagreed with two. FDA disagreed with our recommendation that all seafood-processing firms, including vessels, operate under HACCP requirements and that FDA develop goals and time frames for establishing equivalence agreements. We continue to believe that these two recommendations have merit.

Background

CDC estimates that contaminated food causes 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths in the United States each year. On the basis of the number of confirmed outbreaks of foodborne disease in 1997, the latest year for which CDC's data are available, seafood is one of the leading causes of foodborne illness outbreaks in the United States.⁷ For example, seafood products represented about 15 percent, or 26, of the 169 foodborne illness outbreaks with a confirmed source—a level greater than that associated with meat and poultry products, which are consumed at, respectively, 8 and 6 times the rate of seafood. However, CDC officials said that foodborne illness outbreaks are generally underreported and that it is easier to identify the source of some diagnosable illnesses, such as scombroid poisoning from seafood, than illnesses resulting from some nonspecific gastrointestinal symptoms caused by other foods. FDA also noted that some seafood-related illnesses may be caused by fish caught recreationally. The actual number of individual cases of illness resulting from traced outbreaks were higher for meat and poultry (619 and 353 cases, respectively) compared with 108 cases for seafood. Seafood outbreaks may have involved fewer individual cases of illness because seafood has much lower consumption rates than meat and poultry.

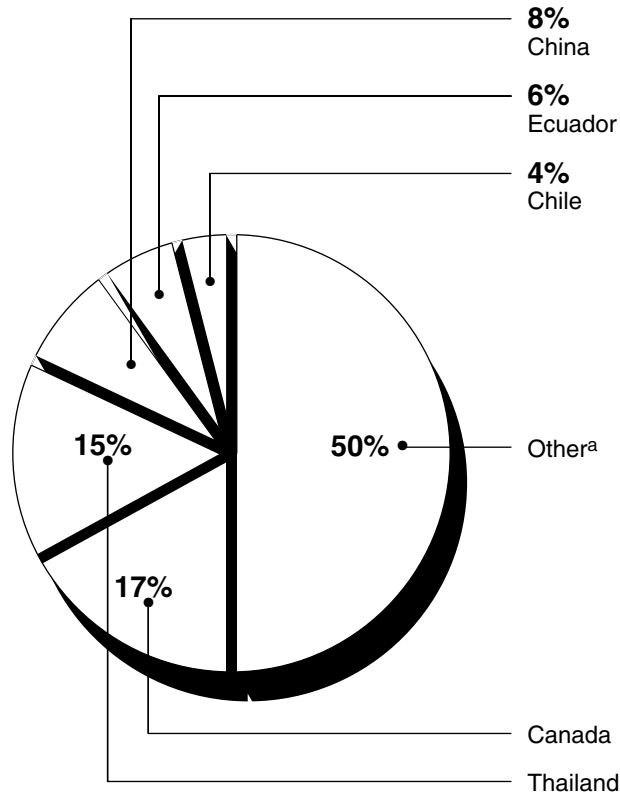
⁷According to CDC, only a fraction of foodborne illnesses are routinely reported, and since most foodborne illnesses are sporadic, only a small number are identified as being part of an outbreak.

Biological, chemical, and physical hazards can cause seafood-related illnesses. Biological hazards include clostridium botulinum, listeria monocytogenes, salmonella, and pathogenic staphylococcus. Chemical hazards include compounds such as methylmercury, which can cause illness from long-term exposure. Physical hazards include foreign objects in food that can cause harm when eaten, such as glass or metal fragments. According to FDA officials, two naturally occurring marine toxins with potentially serious health effects—scombrototoxin and ciguatoxin⁸—cause most reported seafood-related illnesses, including gastrointestinal and neurological problems. These naturally occurring toxins are biological in origin but are categorized as chemical hazards, are heat resistant, and cannot be inactivated by cooking. Appendix II provides additional information on seafood-related illnesses and their symptoms.

Since 1980, seafood consumption in the United States has risen about 22 percent, from 12.5 pounds per person in 1980 to 15.3 pounds per person in 1999. According to data from the National Marine Fisheries Service, the United States imported about 3.9 billion pounds of fishery products during 1999 from about 160 countries. The top five seafood-exporting countries—Canada, Thailand, China, Ecuador, and Chile—accounted for 50 percent of the volume of imported seafood. Imported products include fresh and frozen tuna and salmon as well as crustaceans, such as shrimp and lobsters. Figure 1 shows the proportion of U.S. seafood imports from five leading exporting countries.

⁸FDA noted that a number of illnesses from ciguatoxin are from recreational versus commercial fishing but did not provide any specific data.

Figure 1: Percentage of 1999 U.S. Seafood Imports from Major Exporting Countries
By volume



^aComprises imported seafood from about 160 countries.

Source: National Marine Fisheries Service, National Oceanic and Atmospheric Administration.

FDA is responsible for ensuring the safety of both domestic and imported seafood under the Federal Food, Drug, and Cosmetic Act (FFDCA). In 1997, following recommendations by the National Academy of Sciences and others, FDA adopted a program of preventive controls designed to identify hazards early in the seafood-production process and minimize the risk of contamination. The HACCP regulations made seafood-processing firms responsible for identifying harmful microbiological, chemical, and physical hazards that are reasonably likely to occur and for establishing critical control points to prevent or reduce contamination. The HACCP system is based on seven principles that each seafood firm must address.

-
- *Conduct a hazard analysis.* Identify hazards that are reasonably likely to occur.
 - *Identify the critical control points (CCPs).* Identify a point, step, or procedure in the production process where controls can be applied to prevent, eliminate, or reduce a food safety hazard that is reasonably likely to occur to an acceptable level.
 - *Establish critical limits for each CCP.* Set the maximum or minimum value at which a hazard must be controlled at each CCP to prevent, eliminate, or reduce the hazard to an acceptable level.
 - *Monitor each CCP.* Establish monitoring activities that will ensure that the process is under control at each CCP.
 - *Establish corrective actions.* Define actions to be taken when monitoring discloses a deviation from established critical limits.
 - *Establish verification procedures.* Establish verification procedures to ensure that HACCP plans accomplish their intended goal—ensuring the production of safe products.
 - *Establish record-keeping and documentation procedures.* Maintain documentation, including the HACCP plan, CCP monitoring, critical limits, and verification activities.

Under the HACCP rule, seafood-processing firms are responsible for conducting a hazard analysis and for developing and implementing HACCP plans for hazards determined to be reasonably likely to occur: natural toxins, microbiological contamination, chemical contamination, pesticides, drug residues, decomposition in certain species, parasites, unapproved use of food or color additives, and physical hazards. For each hazard identified, the firms must establish critical control points to prevent or reduce contamination. Firms must also establish and monitor sanitation procedures to ensure, among other things, the (1) general cleanliness of food contact surfaces, including utensils, gloves, and outer garments, and (2) control of employee health conditions.

To assist industry with HACCP compliance, FDA published the *Fish and Fisheries Products Hazards and Controls Guide*, which discusses, among other things, how to perform a hazard analysis, develop a HACCP plan, and identify critical control points. The guide provides species-specific and process-related examples of hazards reasonably likely to occur, but as its name suggests, this document is only guidance; seafood firms are not required to follow it. The guide, according to FDA, has been translated into other languages, is used by regulatory authorities in other countries, and has served as a catalyst for discussions between the seafood industry, other

interested stakeholders, and FDA about the scientific merits of hazards and controls.

According to the National Fisheries Institute,⁹ seafood firms generally support the HACCP system because it has, among other things, caused the industry to look at how best to manage hazards and how to look at food safety from a science-based perspective—for example, what hazards are likely to cause illness, how frequently people are becoming ill, and how serious those illnesses are. Also, according to FDA, two surveys of the industry taken by the New York Sea Grant Extension program and others report that in response to HACCP, the industry is engaging in upgrades to facilities, equipment, and daily plant operations to ensure safety.

To help implement and oversee HACCP systems, for industry personnel and FDA inspectors, FDA developed a training and certification program that is intended to ensure that they have the necessary expertise to evaluate HACCP systems. The training program is offered by the National Seafood HACCP Alliance—an academic, government, and industry consortium. The Alliance’s course is the standardized curriculum by which FDA evaluates other HACCP courses; it contains the information necessary to meet the HACCP-training requirements. Course participants receive a certificate. The seafood HACCP regulations require that industry personnel responsible for developing HACCP plans, reassessing and modifying the plan, and performing record reviews successfully complete training in the application of HACCP principles for fish and fishery products at least equivalent to those received under the FDA-approved course. However, the regulations also state that job experience will qualify an individual to perform these functions if he or she has provided knowledge at least equivalent to that provided through the standardized curriculum.

FDA periodically inspects seafood firms to check on their sanitary conditions and to verify compliance with the HACCP requirements. To determine whether seafood firms identify all safety hazards and whether they are consistently controlling those hazards, FDA inspectors survey the plant and then review the HACCP records. From 1998 through 1999, FDA inspected all seafood firms in its inventory at least once to verify compliance with the new HACCP-based system. In the budget for fiscal year 2000, Congress provided \$267 million for FDA’s food programs—a \$32

⁹The National Fisheries Institute advocates the interests of the seafood industry in Congress and before regulatory agencies.

million increase over FDA's budget for fiscal year 1999. Some of this increase was to enhance the coverage of both domestic and imported foods, including the increased inspection of high-risk food and continued implementation of the HACCP requirement for seafood. While FDA believes that additional funds are needed to ensure the safety of the food supply, it now inspects seafood firms annually. Prior to these annual inspections, FDA inspected seafood firms once every 4 years on average, according to FDA officials.

Generally, FDA personnel inspect one or two seafood products at each firm inspected. The number of seafood products handled by each firm varies. According to FDA, seafood-processing firms collectively handle over 350 species of fish. For example, the seafood firms that we visited in Norfolk and Philadelphia processed a wide range of products, including fresh and frozen fish, such as salmon, tuna, bluefish, mahi-mahi, mackerel, and grouper; crustaceans, such as lobster and crabs; and shellfish, such as oysters and clams. FDA's policy was to give priority to inspecting products considered to be high-risk, including

- vacuumed-packaged seafood (these products are subject to the growth of *Clostridium botulinum*, a toxin producing bacteria);
- ready-to-eat seafood, such as cooked shrimp and crabmeat and hot or cold smoked fish (these products are subject to the growth of pathogens from post-process contamination);
- histamine-forming species, including mahi-mahi, tuna, and bluefish (these products are subject to histamine formation—a toxic substance); and
- stuffed seafood products (processing and handling may allow toxins to develop in these products).

FDA can take several regulatory actions when firms are cited for HACCP violations. For example, if in the agency's judgment the violation cited is of regulatory significance, it may issue the firm a warning letter. FDA issues warning letters in cases where violations raise safety concerns that may lead to enforcement action, such as product seizure or injunction (a court order to refrain from distributing a product), and/or prosecution if not promptly and adequately corrected. In the case of importers, a warning letter could advise them of a forthcoming detention. Firms that receive warning letters are asked to respond to FDA in writing within 15 working days to indicate what actions will be taken to correct the problems identified. If the firm does not correct the violation promptly and

adequately, FDA can pursue enforcement actions, such as product seizure or injunction through the courts.

In 1996, USDA issued HACCP regulations for meat and poultry firms. However, before implementing HACCP, USDA established the prevalence, or baseline, levels for a number of microbial organisms in meat and poultry, including salmonella, E-coli, listeria, and campylobacter. These baseline data provided USDA with a starting point for evaluating the effectiveness of HACCP in terms of lowering the bacterial levels in the product. For example, USDA regularly collects and tests samples of meat and poultry products for the presence of salmonella and then compares the results with pre-HACCP baseline data.

Domestic Seafood Safety System Does Not Effectively Protect Consumers From Unsafe Seafood

FDA has made some progress in ensuring the safety of domestic seafood consumed by the public. According to FDA's December 2000 report on the evaluation of the HACCP system for seafood, the percentage of seafood firms with a HACCP plan that included all of the required components increased from 31 percent in 1998 to 44 percent in 1999. However, FDA recognizes that gaps still exist in HACCP's implementation and that certain segments of the industry are lagging behind. Our evaluation shows that several flaws in FDA's system for ensuring the safety of domestic seafood may allow unsafe seafood products to reach consumers. First, a significant number of seafood firms and/or products are not operating under the HACCP regulations. Second, even when seafood-processing firms are subject to HACCP requirements, FDA inspections do not fully evaluate the firms' operations because such inspections were frequently limited to a paperwork review rather than actual observation of product processing. Furthermore, at both these inspections and those where FDA observed the processing of products subject to HACCP requirements, the agency found that over half of the HACCP plans had serious violations. Third, when violations of regulatory significance were identified, FDA did not take timely action to issue warning letters notifying seafood firms that they must correct the violations promptly and adequately to avoid further enforcement action, such as seizure or injunction. Finally, FDA lacks, and has no immediate plans to obtain, the basic information needed to assess the effectiveness of its HACCP requirements to ensure the safety of seafood.

Many Seafood Firms Are Excluded From HACCP Requirements

HACCP regulations apply to all seafood-processing firms, but a significant number do not operate HACCP systems. As a result, the benefits of HACCP—identifying and controlling food safety hazards—are not being fully obtained, thus placing consumers at risk of consuming unsafe seafood.

While FDA is responsible for overseeing all seafood-processing firms operating in interstate commerce, it does not have an effective system to identify such entities because it does not have a registration requirement for seafood firms. Although the exact number of seafood firms under FDA's jurisdiction is unknown, industry and government officials believe it is larger than the approximately 3,600 or so seafood firms in FDA's official inventory. FDA officials stated that the agency has the authority to register some seafood-processing firms under its authority to impose emergency permit control regulations. However, the agency does not require registration of any seafood-processing firm except those that process low-acid or acidified canned food.¹⁰ FDA uses a variety of ways to identify seafood firms under its jurisdiction, including checks of the telephone book yellow pages, newspapers, magazines, trade periodicals, state inventory records, and consumer complaints. However, we reported in the past that such identification efforts are time-consuming, costly, and ineffective and pointed out to FDA that a simple registration system based on a requirement that processors operating in interstate commerce notify FDA when they begin operations would cost little.¹¹

Furthermore, while all land-based seafood-processing firms are subject to HACCP requirements, thousands of commercial fishing vessels are exempt, even though they may present hazards and risks similar to those posed by land-based seafood-processing firms. FDA's HACCP regulations exempt vessels that (1) harvest and transport fish without any further processing

¹⁰FDA's authority to require firms to register is based on 21 U.S.C. 344. Section 344 allows FDA to impose emergency permit control regulations on manufacturers, processors, or packers whose food operations may be contaminated with microorganisms that are (1) injurious to health and (2) cannot be adequately determined after being released into interstate commerce. So far, FDA has used this authority only to regulate acidified foods and the thermal processing of low-acid foods packaged in hermetically sealed containers. 21 C.F.R. 108.25(c)(1) and 108.35(c)(1).

¹¹See *Food Safety and Quality: Uniform, Risk-Based Inspection System Needed to Ensure Safe Food Supply* (GAO/RCED-92-152, June 26, 1992) and *Food Safety and Quality: Limitations of FDA's Bottled Water Survey and Options for Better Oversight* (GAO/RCED-92-87, Feb. 10, 1992).

and (2) head, eviscerate, or freeze fish on board solely to prepare them for holding. Fishing vessels that process fish beyond these provisions, (e.g., factory ships that fillet or pack their catch), are subject to HACCP requirements. Currently, FDA's inventory shows that 250 vessels are subject to HACCP requirements. However, the number of vessels that should be subject to HACCP requirements and inspections is not known because neither FDA nor any other organization we contacted has information on vessels that process fish on board. An official for the state of Alaska noted that the number of vessels that process fish on board and are thus subject to state inspections is almost twice as large as the number of vessels in FDA's inventory. Also, an official in one of FDA's district offices noted that from 400 to 800 fishing vessels in his district may perform some type of processing.

FDA officials said they decided to exempt most vessels from the regulatory definition of "processors" and thus exempt them from HACCP regulations because of practical considerations. Namely, the fishing fleet is so large that FDA believes that inspecting the fleet would overwhelm the inspection system. FDA also believes that if it requires the fleet to comply with HACCP requirements, some fishing vessels may decide to avoid heading and gutting fish on board. FDA officials said that this would pose a greater risk for product safety and quality. While these observations have merit, the HACCP regulations are intended to cover the heading, eviscerating, or freezing of seafood products so that hazards reasonably likely to occur during these processing steps may be controlled.

Finally, about one-third of the seafood products FDA inspected are not required to have a HACCP plan, including many products at warehouses and repacking firms. Under the seafood HACCP regulations, seafood-processing firms are required to identify the food safety hazards that are reasonably likely to occur and implement measures to control these hazards; then FDA inspectors independently make a similar assessment during their inspections. If the seafood firm determines and the FDA inspector agrees that no hazards are reasonably likely to occur, the seafood firm is not required to have a HACCP plan for the products inspected. FDA inspectors may determine that a firm does not need a HACCP plan because, in their view, the product is of low risk.

According to FDA's statistics for inspections in 1999, HACCP plans were not required for 30 percent, or 1,055, of the 3,525 products inspected because the inspector determined that no hazards were reasonably likely to occur. For example, on the basis of the seafood hazards guide, FDA inspectors concluded that there were no risks associated with 516 products because storage at warehouses and repacking firms did not present a significant hazard. Therefore, HACCP plans were not needed for seafood products at these locations. FDA officials said that most warehouses do not handle high-risk products, such as scombroid species. However, temperature controls for refrigerated products are very important to prevent certain hazards, such as botulism in smoked vacuum-packed products or scombroid poisoning in certain fish species. FDA officials said that final product storage, especially for nonfrozen product, is a weakness at some seafood firms because refrigeration problems, such as equipment breakdowns or uncalibrated thermometers, may prevent these firms from keeping seafood products at appropriate temperatures.¹² Our review of a sample of FDA inspection reports from three districts verified that some firms experience problems ensuring that temperatures are maintained. For example, we estimate that in about 30 percent of these reports, FDA inspectors found that instruments such as freezer and cooler thermometers were not properly calibrated. Without a HACCP plan with critical controls and monitoring procedures, such problems may go undetected for prolonged periods of time and jeopardize product safety.

In contrast, USDA's regulations for meat and poultry products require that every plant in its inventory of approximately 5,700 plants, identify at least one critical control point for each identified hazard. Agency officials said they are not aware of any meat and poultry operations that can be deemed, categorically, to pose no likely hazards.¹³ Some USDA officials involved with meat and poultry regulation, including the Assistant Deputy Administrator for District Enforcement Operations, stated that it is difficult to understand how no hazards are likely to occur in seafood firms.

¹²In its comments on a draft of our report, FDA said that frozen products are most likely to remain that way even if electrical outages occur because modern day freezers are able to retain cold.

¹³*Fed. Reg.* 4561 (Jan. 30, 1998).

FDA Is Not Effectively Ensuring HACCP Implementation

FDA uses on-site unannounced inspections to assess a firm's compliance with HACCP requirements. As part of this process FDA inspects the general sanitary conditions of the firm and equipment. Critical components of the inspection also include an evaluation of HACCP plans, review of HACCP records, and in-plant observations of the product selected for inspection. However, we found that FDA inspectors frequently could not conduct in-plant observations of the selected product. We estimate that in almost half (48 percent) of the seafood inspections at three FDA districts in fiscal year 1999, the selected product was not being processed on the day of the inspection. In other words, FDA inspectors did not make an in-plant observation of the product but instead conducted a paperwork review. FDA officials said that because inspections are unannounced, there were instances where the product selected was not being processed and FDA inspectors were limited to a review of plant records to verify compliance. FDA's compliance manual recommends that inspectors return to physically inspect the product if at the time of their plant visit, the product was not being processed. However, FDA inspectors generally did not return to the firm to inspect the products originally selected for inspection. Officials in the three districts we visited said that, as a general rule, insufficient inspection resources prevent them from returning to observe the selected product. FDA inspection records did not show such follow-up inspections, and FDA inspectors told us they did not conduct them. In an October 1999 memorandum to FDA District Directors, FDA acknowledged the need to observe the selected product during processing by stating that HACCP inspections emphasized the need for more in-plant observations of the selected products. An FDA official explained that inspectors should spend most of their inspection time observing the selected product in the processing environment, especially those that are considered high-risk.

In addition, almost 3 years after HACCP was implemented, FDA's data on industry compliance shows that many seafood firms have yet to meet the basic requirements for a HACCP plan. That is, 22 percent (542 of 2,470) of the products inspected by FDA in 1999 that required a HACCP plan did not have one.¹⁴ Of those that did have a HACCP plan as required, FDA's data show that more than half (1,080 of 1,928) contained serious deficiencies, according to FDA inspectors. The plans were judged to have serious deficiencies because, according to FDA's compliance manuals, they (1) did not identify hazards that FDA considers serious, such as pathogens and toxins; (2) did not identify an appropriate critical control point where the hazard could be controlled; (3) did not identify an appropriate critical limit, or operating parameter for the critical control point; (4) did not identify appropriate monitoring procedures; (5) did not identify appropriate record-keeping procedures; and (6) did not identify adequate corrective action procedures.¹⁵

According to FDA officials, the grading system used for this evaluation required that HACCP plans have all five of the most significant components adequately addressed and, therefore, was a rigorous evaluation of the industry's compliance.¹⁶ FDA said that it was not easy for seafood firms to score 100 percent on all elements, even though they succeeded in many of the individual elements. In general, FDA believes that it will take time for all of the seafood firms subject to HACCP regulations to fully comply with the requirements. In its December 2000 HACCP evaluation report for seafood, FDA said it would intensify its inspection efforts to focus on improving compliance.

Our analysis of a probability sample of inspections' records from three FDA districts yielded similar results. We estimate that in about 55 percent of the FDA inspections of products with HACCP plans, the inspector found one or

¹⁴FDA reviews only one or two product types during an inspection, although some firms produce more than two types.

¹⁵Detailed information on seafood-processing firms' compliance with HACCP requirements comes from FDA's National Seafood HACCP Inspection Database, initiated in 1998. The database provides details of seafood processors' preventive controls, which, according to FDA officials, allows FDA to focus inspections on problem areas and evaluate the state of the industry in-depth.

¹⁶The five basic components include the identification and description of hazards, critical control points, critical limits, monitoring procedures, and record-keeping procedures for all of the hazards that apply to that firm.

more serious violations. Table 1 summarizes the type and estimated frequency of the violations identified by FDA inspectors.

Table 1: Estimated Percentage of Occurrences of Nine Types of Serious HACCP Violations in Fiscal Year 1999 Inspection Records for Three FDA Districts

Type of violation	Estimated percentage of occurrences ^a
Inadequate identification of hazards	16
Inadequate identification of critical control points	21
Inadequate identification of critical limits	23
Inadequate written monitoring procedures	16
Inadequate implementation of monitoring procedures	21
Inadequate identification of corrective action procedures	21
Inadequate corrective actions	12
Inadequate monitoring records	31
Inadequate corrective actions records	9

^aSee appendix 1 for sampling errors for these estimates. These estimates are based only on cases for which the product had a HACCP plan. The only exception was the estimates of the inadequate identification of critical control points, which is based on cases for which the product had a HACCP plan and for which the 1999 version of Form 3501 (Domestic Seafood HACCP Report) was used to record the inspection results. Each case could be subject to more than one type of violation.

The potential health risks associated with these violations are significant because they can involve the failure to establish critical limits for high-risk products, such as cooked ready-to-eat seafood. The failure to establish cooking critical limits for cooked ready-to-eat products can allow pathogens such as listeria monocytogenes to survive, and possibly cause listeriosis—a serious and often fatal condition to humans. FDA’s compliance data for fiscal year 1999 show that 40 percent of the HACCP plans covering cooked ready-to-eat products did not establish adequate time and temperature critical limits to prevent, reduce, or eliminate these types of hazards.

Even if the plans were complete, according to FDA requirements, they would still omit a serious hazard because methylmercury, a highly toxic substance, is not identified or covered in FDA’s seafood guide as a hazard reasonably likely to occur. According to a July 2000 National Research Council report, contaminated fish is the major source of human exposure

to methylmercury in the United States and can cause, among other things, serious neurological problems, such as mental retardation in young children. The risk to public health posed by methylmercury is based on how much of the contaminant is in fish and how much fish people eat.

FDA's guidance to industry does not discuss the identification and control of methylmercury even though FDA's tests for methylmercury in shark and swordfish found that 9 of 18 samples analyzed in 1998 and 1999 met or exceeded FDA's 1.0-part-per-million action level.¹⁷ These test results pertained to imported products.

FDA officials said that most commercial seafood species have very low levels of methylmercury. They also said that the species that contain the highest average amounts of methylmercury—shark and swordfish—are expensive and, therefore, consumed infrequently. Thus, FDA considers that, in most species, methylmercury is not a hazard that is reasonably likely to occur and that HACCP controls are not needed. Furthermore, FDA's position is that if there were an industrial incident or similar event that could raise the levels of mercury in commercial seafood, they would examine whether HACCP controls are warranted and issue new guidance as necessary.

FDA has been evaluating new data on the health effects of methylmercury from the consumption of fish. However, the agency has not established a timeline for completing its evaluation. Moreover, FDA officials stated that the agency is unlikely to include any guidance to industry in the next edition of its Fish and Fisheries guide to be issued in calendar year 2001. In the meantime, FDA advises industry and inspectors not to identify methylmercury as a hazard reasonably likely to occur. However, before HACCP's implementation, FDA's draft Fish and Fisheries Guide identified methylmercury as a potential hazard in certain seafood species consumed by humans, including swordfish and tuna. Furthermore, in 1995, FDA updated its consumer advisory warning pregnant women and women of childbearing age to limit their consumption of shark and swordfish because of potential methylmercury contamination. In January 2000, FDA revised its methylmercury advisory and now recommends that women who are pregnant, or who are of childbearing age and may become pregnant, avoid

¹⁷“Action levels” are agency guidelines that, when exceeded, may pose a threat to public health.

eating the four species of fish known to have the highest levels of methylmercury: shark, swordfish, king mackerel, and tilefish.

Even when FDA identifies serious violations at a seafood-processing firm, it does not take timely regulatory action to ensure compliance. When interactions between inspection personnel and plant personnel fail to obtain compliance, warning letters are the principal means of notifying the plants of serious violations and achieving prompt corrective action before proceeding to more stringent enforcement actions. Warning letters are to be issued for violations of regulatory significance—i.e., violations that affect product safety and may lead to enforcement action, such as product seizure or injunction, if not promptly and adequately corrected. To ensure the prompt and adequate correction of serious violations, FDA's regulatory procedures manuals state that warning letters should be approved within 15 working days of the receipt of the district office's recommendation.

According to FDA's analysis of 52 warning letters processed in calendar year 2000, 94 percent, or 49, exceeded recommended issuance time frames thus significantly delaying notification to industry of observed problems that needed correction. On average, 73 days elapsed between the receipt of the district offices' recommendation and the approval of the warning letters.

Our analysis of 162 warning letters issued to domestic firms nationwide after inspections conducted in fiscal year 1999 parallels these findings—that is, three-quarters of the letters exceeded the issuance time frames by 30 days or more. More significantly, we found that 67 percent of these letters were associated with high-risk products, including scombrototoxin-susceptible seafood, which, if not properly handled, could cause serious health problems requiring hospitalization, particularly in the case of elderly individuals.

FDA headquarters officials explained that issuance time frames are exceeded primarily because of the need to ensure that recommendations in district offices' warning letters are consistent with agency policy. They explained that changes in agency policy are sometimes necessitated by changes in the science associated with HACCP systems and that, in some cases, a significant amount of time is needed to review new or updated policy to ensure that it is interpreted correctly. Also, a significant number of the recommendations in the domestic warning letters submitted by the districts require changes because the letters did not correctly cite serious or critical deficiencies. FDA district officials cited an increase in the

number of warning letters issued and the lack of adequate resources as reasons for not meeting the issuance time frames for warning letters. In this regard, an October 1999 FDA memorandum states that an analysis of recommendations in warning letters showed that only 5 percent of the district offices' draft warning letters were approved as written. On the basis of its review, FDA headquarters provided a summary of the problems identified to field personnel and boilerplate language to be used in warning letters to help correctly communicate the problems identified during inspections.

FDA Lacks Information to Assess the Effectiveness of HACCP Requirements for Seafood

FDA lacks objective, measurable data to determine whether its HACCP program for seafood is effectively reducing hazards. Currently, neither FDA nor the industry is required to collect such data, and FDA officials said that they have no plans to require data collection in the future because seafood products are subject to many different hazards, making it difficult to select one or more to measure.

A guiding principal of the Government Performance and Results Act is the development and use of objective and measurable performance measures to demonstrate results on how well an organization is achieving its goal. In this regard, prior to the implementation of its HACCP program, USDA determined the prevalence of salmonella—a microbial organism—in meat and poultry so that it could evaluate whether HACCP requirements were effective in lowering salmonella levels. USDA set targets for reducing the incidence of salmonella contamination in meat and poultry products by establishing performance standards. Recent USDA reports show that, under this program, the levels of salmonella contamination in meat and poultry are declining.

FDA has no baseline data or requirement to systematically measure any changes in the level of seafood contaminants, although the agency did test a limited number of seafood samples for surveillance and compliance purposes. In 1999, FDA analyzed a total of 769 domestic seafood samples (of which 473 were analyzed for the presence of biological hazards) and found that 94, or 20 percent, contained hazards such as salmonella, listeria, and scombrototoxin.¹⁸ FDA officials said that, unlike meat and poultry,

¹⁸FDA officials said that the samples collected were collected on a “for-cause” basis. That is, the samples represent products that FDA suspected were going to be violative and, therefore, are not representative of the food supply.

seafood is affected by a variety of microbiological and chemical pathogens and that there is no single widespread bacterial hazard, such as salmonella, in meat and poultry.

While all seafood may not be affected by a single widespread hazard, such as salmonella, some species of seafood are often affected by specific hazards. For example, tuna, mahi-mahi, and bluefish are likely to produce histamines when not kept at the proper temperature. The resulting illness—scombroid poisoning—causes nausea, diarrhea, sweating, and headaches. Similarly, subtropical and tropical fish, including grouper and snapper, accumulate a naturally occurring toxin, called “ciguatera.” Ciguatera poisoning involves a combination of gastrointestinal neurological and cardiovascular disorders. Scombrototoxin and ciguatera, which cannot be eliminated by cooking, contributed to over 88 percent of all confirmed food illness outbreaks for seafood reported by CDC in 1997.

While FDA does not have a performance-based method for measuring reductions in seafood-related hazards, it does collect data on seafood firms’ compliance with regulatory requirements and uses those data to evaluate progress. For example, in 1992, FDA compiled descriptive compliance data from seafood firms that handled high-risk products. The data describe the processes in place, such as the types of monitoring systems, and some of the problems identified in 1992, such as the extent of sanitation violations. Although FDA compared HACCP compliance data from 1998 and 1999 with the 1992 data, the results do not objectively measure whether seafood produced under the HACCP system has experienced measurable reduction in contamination.

FDA’s Approaches to Ensuring the Safety of Imported Seafood Are Not Effective

As with domestic products, FDA’s approaches for ensuring the safety of imported seafood provide only limited protection against unsafe seafood reaching consumers. First, FDA has been unable to develop equivalence or compliance agreements that document foreign countries’ equivalence or compliance with the U.S. seafood safety system. Second, FDA’s reviews of importers’ documentation have shown that many do not have records of foreign seafood firms’ compliance with U.S. requirements for HACCP programs as is required in the absence of equivalence agreements. When documentation has been available, it often did not adequately demonstrate such compliance. Third, although FDA inspects some foreign firms and often finds serious deficiencies, it does not take follow-up actions, such as automatically detaining products from these firms at U.S. ports. Fourth, FDA’s traditional strategy of visually examining and/or testing imported

seafood at U.S. ports has been widely discredited as an effective method for ensuring the safety of imported foods. Moreover, FDA's port of entry examinations and testing are unable to keep pace with the growing level of imports.

FDA Lacks Country-to-Country Equivalence Agreements

FDA has authority to enter into voluntary agreements with individual countries recognizing the equivalence or compliance of their seafood safety systems. Moreover, under the provisions of the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), the agency is obligated to at least take equivalence requests from other countries under consideration.¹⁹ FDA defines equivalence agreements as those in which FDA finds one or more of an exporting country's requirements equivalent to our own.

Currently, however, FDA has no equivalence or compliance agreements with countries that export seafood to the United States, although the agency has compliance agreements for molluscan shellfish (fresh and frozen oysters, clams, mussels, and whole or roe-on scallops).²⁰ FDA officials said that they have received requests for equivalence determinations from approximately 30 countries that export seafood to the United States. After an initial review, FDA concluded that 8 of the 30 interested countries were viable candidates and is now discussing equivalence agreements with Australia, Canada, and New Zealand and a compliance agreement with Japan. However, FDA has not developed a timetable for completing these agreements. Furthermore, according to FDA officials, the agency is considering how seafood safety processes or procedures might change, should it complete an equivalence agreement, but has not made any decisions yet. Specifically, the agency is considering (1) adjusting the rate at which the agency examines imports at ports of entry in order to focus more attention on imports from countries not yet found to be equivalent, (2) having a standing arrangement for immediate inspection by the regulatory authority in the exporting country whenever a problem is found with a product being offered for entry into the United

¹⁹See article 4, Agreement on the Application of Sanitary and Phytosanitary Measures, World Trade Organization Agreement, 1994.

²⁰Compliance agreements are those in which each side pledges compliance by its producers with the requirements of the other importing country. FDA has memorandums of understanding regarding molluscan shellfish with Canada, Chile, Korea, Mexico, and New Zealand.

States, and (3) the frequency of on-site audits in countries with which the agency develops equivalence agreements.

FDA officials acknowledge that equivalence agreements would help ensure that adequate safety and sanitation standards exist for imported seafood. FDA officials said that the United States and Canada have had discussions and have engaged in activities aimed at determining the equivalence of the two systems. These discussions began in the summer of 1997. FDA and Canadian officials would not discuss in detail the ongoing deliberations regarding each other's system. They said that the time required to determine equivalence is partly due to Canada's changes to its seafood safety system in 1997 that required a reevaluation by FDA. However, Canadian concerns with the U.S. system also contributed to the long discussions. Officials of the Canadian Food Safety Inspection Agency said that during their on-site visit of U.S. seafood plants, they identified a number of areas of concern with the U.S. system, such as FDA's not verifying the adequacy of HACCP plans before seafood firms implemented them. In Canada, seafood firms must submit their HACCP plans to the food inspection agency for review before they are implemented. Appendix III provides further information on selected aspects of the U.S., Canadian, and Chilean seafood safety inspection systems.

Unlike USDA, FDA is not legally required to certify that countries that export food products to the United States have safety, sanitation, and inspection programs that provide an equivalent level of safety to that of the U.S. system. Under the meat and poultry inspection acts, USDA's Secretary of Agriculture must certify that exporters of meat and poultry products have equivalent food safety systems before their products can be exported to the United States. As of January 1, 1998, the Secretary had certified that 37 countries had equivalent systems. In our 1998 report on imported food safety, we concluded that the lack of equivalence requirements for FDA-regulated imported foods adversely affects the agency's ability to keep unsafe foods out of U.S. commerce.²¹ We recommended that Congress strengthen FDA's ability to ensure the safety of imported foods by requiring that all food eligible for importation to the United States—not just meat and poultry—be produced under equivalent food safety systems. Because equivalence agreements with major exporters of seafood to the United States are lacking, FDA relies on a review of paperwork at importers' offices to attempt to determine whether importers have met their

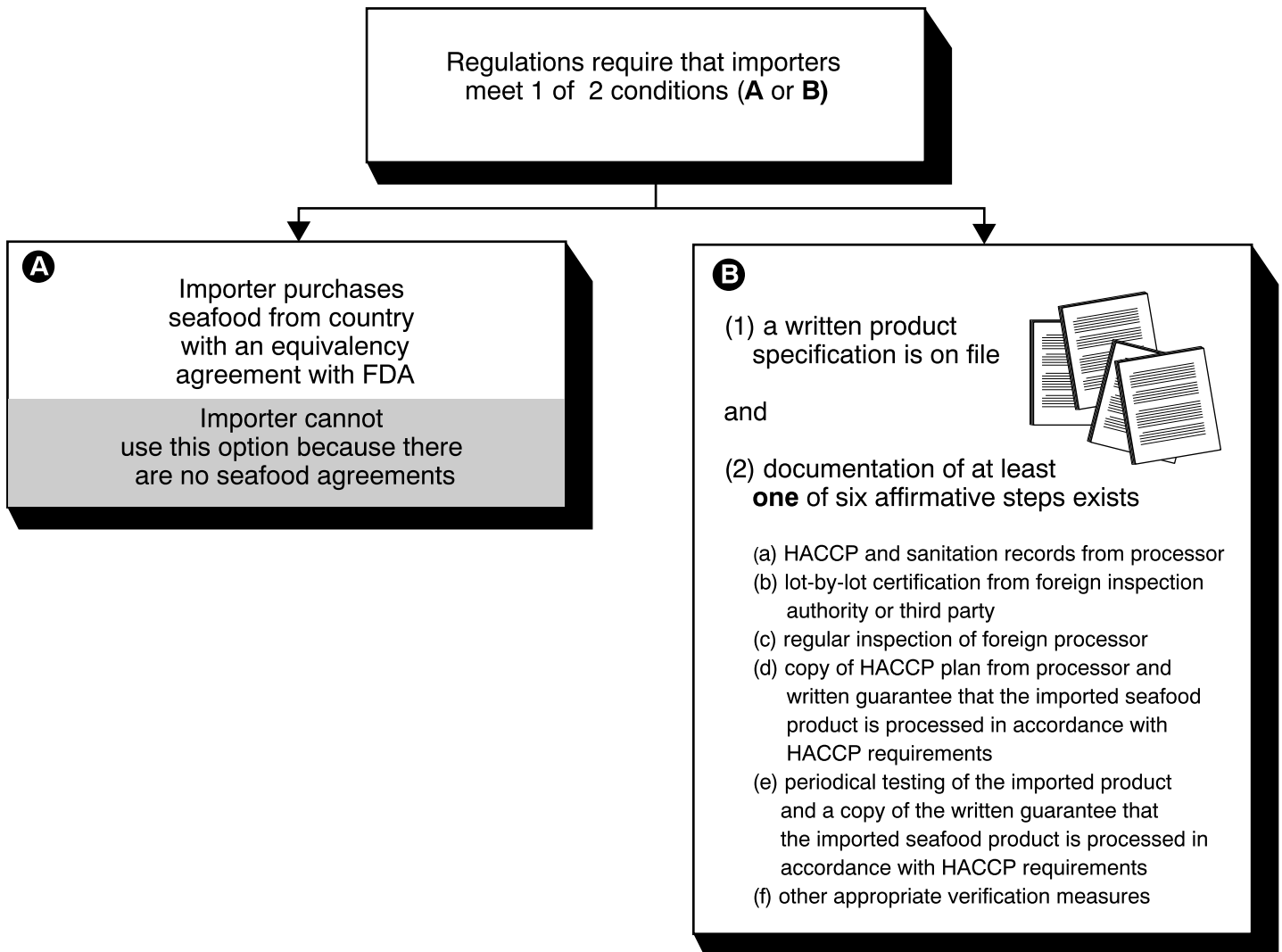
²¹See GAO/RCED-98-103.

responsibilities and requirements under the seafood HACCP regulations. While legislation was introduced in 1999, Congress has not yet acted to strengthen FDA's ability to ensure that imported foods, including seafood, be produced under equivalent safety systems.

Most Importers Lack Required Documentation to Demonstrate Compliance With HACCP Requirements

In the absence of any seafood equivalence agreements between the U.S. and foreign countries, federal regulations hold importers responsible for demonstrating that the seafood they bring into the United States is produced under systems that are equivalent to or compliant with HACCP requirements for domestic seafood. The HACCP regulations for seafood require importers to obtain products from a country with which FDA has an equivalence agreement or to take affirmative steps to document foreign firms' efforts to comply with the U.S. requirements. Figure 2 shows regulatory requirements for importers and the documentation they can use to demonstrate compliance. However, less than a third of the importers that FDA inspected met these requirements, according to our analysis of FDA's inspection records of importers for fiscal year 1999.

Figure 2: Importers' Regulatory and Compliance Requirements



We found that importers had the required product documentation for less than one-third of the products inspected.²² That is, only 27 percent (116 of 432 seafood products) listed in the FDA inspection forms showed that the importer had (1) a written product specification document²³ and (2) documentation for at least one of the six possible affirmative steps required by the regulations. Of those that had the required documentation on file, 57 percent (66 of 116) had a copy of the foreign firms' HACCP plan and written guarantee, and 50 percent (58 of 116) had a copy of a lot-by-lot certificate from the foreign government's inspection authority. Few importers (16 percent, or 18 of 116), chose regular inspections of the foreign processor's facilities as a method for demonstrating compliance.

Furthermore, the FDA inspection forms showed that, in many cases, the 66 HACCP plans that the importers obtained did not identify hazards that, according to FDA's seafood guide, are reasonably likely to occur, although exceptions may occur in each specific case, as shown in the following examples:²⁴

- Thirteen of the HACCP plans were for scombroid species (tuna, mahi-mahi, and bluefish), but only 6 identified scombrototoxin as a hazard reasonably likely to occur. FDA's seafood guide states that it is reasonable to assume that, without proper controls, these species of fish will contain unsafe levels of histamine, resulting in the formation of scombrototoxin.
- Twelve of the HACCP plans were for shrimp, which may contain sulfites—a chemical hazard, but only 3 identified any chemical hazards as being reasonably likely to occur.

²²To record importer inspection findings, FDA inspectors fill out a standardized form after each importer is inspected. The forms indicate whether importers have the required documentation, and if so, whether it documents the foreign firm's compliance with U.S. HACCP requirements. We obtained and analyzed all of FDA's inspection forms for fiscal year 1999 that were completed at 350 importer firms (covering 432 seafood products).

²³Written product specifications are designed to ensure that the product is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.

²⁴The guide gives information on determining which hazards are "reasonably likely to occur" under ordinary circumstances and, thus, provides information that would likely result in a HACCP plan that is acceptable to FDA.

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- Fifteen of the HACCP plans described processing steps, such as filleting and mixing, that can present physical hazards, such as metal fragments. But only two of those HACCP plans identified such hazards.²⁵
 - Eight of the HACCP plans involved such species as grouper, mackerel, and snapper, which can carry ciguatoxin, but none of them identified ciguatoxin as a hazard that was reasonably likely to occur. Ciguatoxin is one of the leading causes of seafood-related illnesses, according to CDC's data.

FDA issued warning letters to 33 importers for serious deviations from the HACCP regulations. Forty-eight percent (15 of 33) of the warning letters noted repeat violations from the previous inspection, such as the failure to adequately perform one of six affirmative steps and the failure to have written product specifications.

To further ensure the safety of imported seafood, FDA issued an import alert in January 1998 that is to be used to detain seafood products destined to importers that did not verify foreign seafood firms' compliance with U.S. HACCP requirements. The import alert is to be adjusted to include importers that do not meet HACCP requirements. However, despite the number of violations identified by inspectors and noted in warning letters to seafood importers, FDA had listed only two of these importers on the alert. FDA's recently released report on its seafood program acknowledges that importers have experienced problems with major provisions of the importer requirements, but FDA officials said that educating importers on their responsibilities is important.²⁶ FDA's strategy is to provide importers with additional information about HACCP requirements, coupled with FDA enforcement.

²⁵The guide states that under ordinary circumstances, it would not be reasonably likely to expect that metal fragments could enter the food from manual cutting. The inspection forms that we reviewed did not specify whether the cutting was manual or mechanical.

²⁶"FDA's Hazard Analysis Critical Control Point (HACCP) Program for Seafood for Calendar Years 1998 and 1999" (Dec. 9, 2000).

FDA Does Not Take Enforcement Actions on Deficiencies Identified in Its Overseas Inspections

FDA conducts limited inspections of selected foreign seafood firms to determine the firms' compliance with the agency's seafood regulations.²⁷ FDA personnel visited four foreign countries in fiscal year 1999—Ecuador, Vietnam, Taiwan, and the Philippines—to inspect 37 seafood firms and to provide education on the U.S. HACCP requirements. None of these foreign visits were conducted for equivalence determination purposes. During those inspections, FDA found numerous HACCP-related problems, and issued 24 warning letters to foreign firms. However, only about half of them responded to FDA's letters. To date, FDA has not taken further enforcement actions against the nonresponding firms. Table 2 provides examples of the types of problems that FDA found during these inspections.

Table 2: Problems Found During Inspections in Four Exporting Countries, Fiscal Year 1999

Countries Visited	Number of firms inspected	Number of FDA warning letters and foreign firm responses ^a	Examples of problems found
Ecuador	10	Six warning letters issued—three responses received	<p>No HACCP plan.</p> <p>HACCP system and sanitation monitoring inadequate for tuna.</p> <p>Hazards not listed in HACCP plan.</p> <p>HACCP plan did not identify hazards, such as aquaculture drugs and environmental chemical contaminants for farm-raised fish and shrimp.</p> <p>Clostridium botulinum hazard was not adequately controlled.</p> <p>HACCP plan did not identify a potential hazard—staphylococcus aureus—and did not control its formation in hydrated batter mixes.</p>
Taiwan	9	One warning letter issued—one response received	<p>HACCP plan did not identify potential histamine hazards in scombroid species.</p> <p>HACCP plan did not address aquaculture drugs or environmental chemical hazards.</p>

²⁷FDA's criteria for selecting foreign firms includes previous compliance problems and the volume of seafood exported to the United States.

(Continued From Previous Page)

Countries Visited	Number of firms inspected	Number of FDA warning letters and foreign firm responses ^a	Examples of problems found
Philippines	9	Nine warning letters issued—three responses received	HACCP plan did not list hazards, critical limits, and monitoring procedures. Monitoring controls for critical control points were nonexistent or inconsistent, and corrective actions were inappropriate.
Vietnam	8	Eight warning letters issued—six responses received	Processor did not have records to indicate that scombroid species were histamine-free. HACCP plan did not identify aquaculture drugs and environmental chemical hazards.

^aAs of April 28, 2000.

When FDA notes deficiencies during foreign visits and they are not corrected, FDA can place the foreign product under import alert and detain it at the U.S. port of entry for further examination and testing. In 1998, FDA issued a generic import alert to cover all foreign firms that do not comply with HACCP requirements. An official in FDA's imports office said that he is unaware of any instances where deficiencies identified by the Office of Seafood and the Office of Regulatory Affairs during foreign country visits were communicated to the imports office. If the deficiencies had been communicated, the import alert could be updated to ensure that products from foreign firms where problems were identified could be subjected to increased scrutiny at the port of entry. After we discussed this matter with senior FDA officials, FDA added nine firms to the import alert and is in the process of adding another firm. Nonetheless, FDA believes that the foreign seafood firms they visited are making progress in learning and complying with the new HACCP requirements.

Port of Entry Inspections Are Widely Discredited

FDA may detain individual shipments at U.S. ports of entry so it can conduct visual examinations and/or collect and test product samples while it determines if the product is misbranded or adulterated. However, port of entry inspections for imported food have been widely discredited as an effective means for ensuring product safety. Furthermore, FDA's port of entry examinations have been unable to keep pace with the growing volume of seafood product imported into the United States.

According to the U.N. Food and Agriculture Organization, testing products at the port of entry involves a concentration of inspection resources on the imported product itself and is an attempt to compensate for a lack of knowledge about the producer's processing, hygiene, and sanitation practices. Recognizing the limitations of this method, FDA's draft guidance on equivalence criteria states that, by itself, the end-product inspection and testing at the port of entry cannot be relied upon to provide adequate protection. In our 1998 report on imports, we also reported that reliance on end-product testing is an ineffective, resource-intensive, and statistically invalid approach to ensuring the safety of imported food. We made a number of recommendations to improve the effectiveness of FDA's port of entry-inspection system, such as providing inspectors with more consistent and accurate data for selecting imported products for inspection but emphasized that FDA's reliance on port of entry inspections was an ineffective means for ensuring the safety of imported food. Therefore, to strengthen FDA's ability to ensure the safety of imported food, we recommended that Congress require all food eligible for importation to the United States—not just meat and poultry—be produced under equivalent food safety systems.²⁸

Furthermore, FDA's port of entry inspections are unable to keep pace with the growing volume of imported seafood products. For example, from 1998 through 1999, imported seafood products increased by 7 percent (from 3.6 billion to 3.9 billion pounds), while the proportion of foreign seafood entries detained for visual and/or laboratory examination decreased from 5 to 3 percent. In 1999, less than 1 percent of imported seafood entries were subjected to the laboratory portion of the examination. According to FDA officials, insufficient resources and an increased volume of imported seafood products resulted in the reduced rate of FDA port of entry inspections and tests of imported seafood products. While increased resources would be helpful, as we have previously reported, the most effective method to ensure the safety of imported seafood is to certify that imported products are produced under equivalent food safety systems.

Conclusions

Since FDA first issued the HACCP regulations for seafood, seafood-processing firms have made some progress in implementing the new system. However, several important weaknesses compromise the overall

²⁸See GAO/RCED-98-103, and *Food Safety: Changes Needed to Minimize Unsafe Chemicals in Food* (GAO/RCED-94-192, Sept. 26, 1994).

effectiveness of the federal seafood safety system. If left uncorrected, they will continue to undermine the goal of HACCP systems—that is, controlling hazards in the production process before the product reaches the market. More importantly, U.S. consumers may continue to be placed at risk of contracting foodborne illness from contaminated domestic and imported seafood products.

Without requiring registration of all domestic seafood firms, FDA cannot effectively ensure that all seafood products are processed under the HACCP regulations. Similarly, FDA cannot ensure that all seafood products are operating under HACCP systems if it continues to exclude vessels that meet its criteria for land-based seafood firms. Unless FDA verifies that industry identifies and controls all hazards reasonably likely to occur, it cannot ensure that industry is implementing an effective HACCP system. And without the actual observation of the seafood products selected for inspection, FDA inspectors cannot ensure full compliance with HACCP requirements. Also, without prompt completion of its ongoing evaluation of methylmercury, FDA is unable to give direction to the industry on whether it should establish HACCP controls for this hazard, thus potentially placing consumers at risk of exposure to unsafe levels of methylmercury. Furthermore, without FDA's timely notification to industry when deficiencies are observed, serious problems are not corrected promptly. Finally, without baseline data, such as that provided by regular microbial testing, FDA is unable to measure the HACCP program's effectiveness and is unable to identify when and where corrective actions are needed.

Concerning imports, FDA does not have seafood equivalence or compliance agreements with any foreign country, which is one of the most effective methods for ensuring the safety of imports. Lacking such agreements, FDA must rely, in part, on a review of importers' records to ascertain that imported products are processed under an acceptable HACCP system. However, most importers have not had the required documentation to demonstrate that the product offered for entry has been processed under HACCP controls. In addition, by not communicating the results of foreign firms' inspections to U.S. port of entry personnel, the likelihood that unsafe products from these firms are not inspected prior to their release into the U.S. market is increased. Finally, port of entry inspections are insufficient to ensure the safety of imported seafood, are an inefficient use of resources, and have been unable to keep pace with increasing import shipments.

Matters for Congressional Consideration

To strengthen FDA's ability to ensure that all domestic seafood products are processed under HACCP requirements, the Congress should provide FDA with comprehensive authority to require the registration of all seafood-processing firms.

To strengthen FDA's ability to ensure the safety of imported seafood, the Congress should amend the Federal Food Drug and Cosmetic Act to require FDA to certify that seafood eligible for importation into the United States is produced under equivalent food safety systems.

Recommendations for Executive Action

To better ensure the safety of domestic and imported seafood consumed in the United States, we recommend that the Commissioner of FDA

- require that all seafood-processing firms, including vessels that meet FDA's HACCP criteria for land-based seafood firms, operate under HACCP requirements;
- conduct in-depth audits of seafood firms that operate HACCP systems to verify that they identify and control all hazards reasonably likely to occur;
- emphasize to inspectors the need to revisit firms to observe the processing of seafood product(s) selected for inspection as required by FDA's compliance manual and establish a system to monitor inspections to ensure that such revisits occur;
- develop milestones for completing the agency's ongoing evaluation of methylmercury and determine whether it is a seafood hazard reasonably likely to occur;
- issue warning letters within FDA's required time frames;
- develop baseline information, such as regular microbial test results, and use it to assess the effectiveness of HACCP systems over time;
- develop specific goals and time frames for establishing equivalence agreements while Congress considers whether to mandate FDA's certification of other countries' equivalence before their seafood products are allowed entry into the United States; and

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- communicate HACCP system deficiencies identified during FDA's importer inspections and foreign country inspections to port of entry personnel so that potentially contaminated imported seafood is examined before being allowed to the United States.

Agency Comments and Our Evaluation

We provided FDA with a draft of this report for review and comment. FDA stated that it had made significant improvements in the regulation of the seafood industry through the establishment of the HACCP system, but recognized that areas need to be strengthened. FDA said it plans to or has begun actions to address these areas. Regarding the eight specific recommendations we made to FDA, the agency generally concurred with six and disagreed with two. FDA also raised some concerns about inferences that could be drawn from the report. For example, FDA said that our draft report implied that seafood was, on the whole, riskier than other commercial sources of animal protein because of the way we presented foodborne illness outbreak data for seafood in comparison to data for meat and poultry. FDA said that, according to CDC, outbreak data should not be used to determine whether seafood is more or less dangerous than other foods. We modified our report to include the actual number of cases associated with seafood and meat and poultry outbreaks. We also added CDC's observation that diagnosable illnesses, such as scombroid poisoning from seafood, are more easily recognized than illnesses from nonspecific gastrointestinal symptoms caused by other foods. (See app. IV for FDA's written comments and our response. FDA also provided technical comments, which we incorporated into the report as appropriate.)

FDA generally concurred that it should (1) verify that HACCP systems identify and control all hazards reasonably likely to occur; (2) emphasize to inspectors the need to revisit firms to observe actual product processing and establish a system to ensure that those visits occur; (3) develop milestones for completing its ongoing evaluation of methylmercury and determining whether it is a hazard reasonably likely to occur; (4) issue warning letters in a more timely manner; (5) develop baseline data, such as testing for a specific hazard, to measure the effectiveness of its seafood safety program; and (6) communicate HACCP system deficiencies identified during FDA importer inspections and foreign country inspections to port of entry personnel.

FDA did not concur with our recommendation to require that all seafood-processing firms, including vessels, operate under HACCP requirements. FDA said that the vast majority of vessels currently exempt from the

HACCP requirements conduct limited processing on board, making it unlikely that they would introduce significant food safety hazards that need to be controlled. While FDA's comments provide additional information on the agency's position on this issue, we continue to believe that our recommended action is warranted. Numerous fishing vessels handle high-risk products, such as tuna, which if not kept at appropriate temperatures, can result in foodborne illness. Absent a comprehensive inventory of all seafood-processing operations, including those on board vessels, FDA is unable to ensure that the HACCP system for identifying and controlling hazards is uniformly and consistently applied. If upon reviewing a vessel's operation, FDA determines that food safety hazards are not reasonably likely to occur, FDA may decide that a HACCP plan is not required for that vessel. Furthermore, seafood processors and vessels that are not exempted from HACCP requirements are required to establish and implement a written sanitation standard operating procedure. Therefore, bringing vessels under the HACCP regulatory requirements would require them to have written sanitation operating procedures, even if FDA determined they do not need a HACCP plan.

FDA also did not concur with our recommendation that the agency develop specific goals and time frames for establishing equivalence agreements while Congress considers mandating the certification of other countries' equivalence before their seafood products are allowed entry into the United States. In commenting on this recommendation, FDA noted that foreign equivalencies is one of its priorities for fiscal year 2001, but said that a considerable exchange of data among the countries involved must take place before equivalency determinations can be made. We continue to believe, however, that this recommendation has merit for a variety of reasons. First, without goals and time frames, there is little or no incentive to complete equivalence agreements. For example, FDA and the Canadian Food Inspection Agency have had discussions and have engaged in activities aimed at determining equivalence of the two countries' systems for over 3-1/2 years, since Canada first requested such action in 1997. Second, importers are responsible for ensuring that imported seafood meets HACCP requirements either by importing from countries with an equivalence agreement or by providing documentary support. However, because FDA has no equivalence agreements, seafood importers must use the more difficult and costly alternative of providing documentary support. Finally, it is generally recognized that establishing equivalence agreements with countries that have comparable safety and sanitation systems is the most effective way to ensure the safety of imported food. Equivalence agreements will help FDA reduce its reliance on importer and port of entry

inspections and enable it to leverage its staff resources by sharing the responsibility for seafood safety with the exporting countries. Establishing goals and time frames will help FDA measure its progress toward obtaining such agreements and assist Congress in determining when to mandate that FDA certify an exporting countries equivalence, if Congress decides to do so.

We conducted our review from February through December 2000 in accordance with generally accepted government auditing standards.

As agreed with your offices, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from the date of this letter. At that time, we will send copies to congressional committees with jurisdiction over food safety issues; the Embassies of Canada and Chile; the Secretary of Agriculture; the Secretary of Health and Human Services; the Director, Office of Management and Budget; and other interested parties. We will make copies available to others on request.

If you have any questions about this report, please contact me at (202) 512-3841. Major contributors to this report are listed in appendix V.



Lawrence J. Dyckman
Director, Natural Resources
and Environment

Scope and Methodology

As you requested, we evaluated the Food and Drug Administration's (FDA) system to better control the risk of foodborne illness resulting from unsafe domestic and imported seafood. As agreed with your office, we excluded molluscan shellfish (mussels, clams, oysters, and roe-on scallops) from this review because those products are regulated under a different regulatory structure. A separate GAO report will address federal efforts to ensure the safety of those products.

To obtain FDA's views on its program for domestic and imported seafood, we interviewed cognizant government and industry officials. Specifically, we interviewed officials and/or reviewed documents from FDA's Center for Food Safety and Applied Nutrition, Office of Seafood; Office of Regulatory Affairs; Office of Enforcement, Division of Compliance Policy; and Division of Import Operations and Policy. To obtain industry's views on the Hazard Analysis and Critical Control Point (HACCP) system for seafood and FDA's oversight of seafood firms, we also met with the National Fisheries Institute—a seafood trade association whose membership includes domestic and international firms. To learn about other HACCP regulatory systems, we interviewed U.S. Department of Agriculture (USDA) officials to discuss their implementation of a HACCP system for meat and poultry and the performance data requirements associated with that program.

To assess FDA's system for ensuring the safety of domestic seafood, we visited three of the FDA districts where large volumes of seafood are processed—Florida, New England, and Seattle—and met with officials to discuss relevant regulations, policies, and procedures. We also visited seafood firms to observe FDA's seafood inspections first-hand and met with seafood industry personnel in the three districts, including officials and members of the National Food Processors Association. We also participated in the HACCP training course on seafood offered by the Seafood HACCP Alliance.

We analyzed 97 FDA inspections of domestic seafood products as recorded on FDA's Form 3501 for fiscal year 1999. They were randomly selected from all 3501 forms in the three districts for fiscal year 1999. Table 3 shows our sampling plan for the three districts. We also analyzed 227 seafood warning letters issued nationwide during calendar years 1998 and 1999 and through the first 4 months of calendar year 2000 to assess the time frames for issuing warning letters and other pertinent information. Of these 227 warning letters, 162 were issued to domestic processors after inspections conducted in fiscal year 1999. In recognition of FDA's time frames that allow 30 working days for FDA to process a warning letter, we did not

consider any warning letter that was issued within 45 calendar days after the date of the inspection to have exceeded the issuance time frames.

Table 3: Sampling Plan for Three FDA Districts, Fiscal Year 1999

District's name	Number of inspections	Number of inspections sampled
Florida	404	29
Seattle	633	36
New England	374	32
Total	1,411	97

Since we used a sample (called a “probability sample”) of 97 inspection forms to develop our estimates of inspections in the three districts we visited, each estimate has a measurable precision, or sampling error, that may be expressed as a plus/minus figure. A sampling error indicates how closely we can reproduce from a sample the results that we could obtain if we were to take a complete count of the universe by using the same measurement methods. By adding the sampling error to and subtracting it from the estimate, we can develop upper and lower bounds for each estimate. This range is called a “confidence interval.” Sampling errors and confidence intervals are stated at a certain confidence level—in this case, 95 percent. For example, a confidence interval at the 95-percent confidence level means that in 95 out of 100 instances, the sampling procedure we used would produce a confidence interval containing the universe value that we are estimating.

Table 4 shows sampling errors for selected estimates used in this report. Because we report subsets of the 97 inspections, such as only the products with HACCP plans, sampling errors are larger than they would be if we reported estimates based on the entire 97 inspection reports. Sampling errors range from 7 to 14 percent at the 95-percent confidence level.

**Appendix I
Scope and Methodology**

Table 4: Sampling Errors for Selected Estimates for Three District Offices, Fiscal Year 1999

Products	Estimated percentage	Sampling error
All products		
Products that did not need HACCP plans	32	±9 percent
Products inspected on 1999 version of Form 3501		
Products not being processed on the day of inspection	48	±14 percent
Products with a HACCP plan		
Products with at least one violation found	55	±13 percent
Products not identifying hazards that were reasonably likely to occur	16	±8 percent
Products with a HACCP plan and inspected on 1999 version of Form 3501		
Products with inadequate identification of critical control points	21	±5 percent
Products with a HACCP plan		
Products with inadequate identification of critical limits	23	±11 percent
Products with inadequate written monitoring procedures	16	±9 percent
Products with inadequate implementation of monitoring	21	±10 percent
Products with inadequate identification of corrective actions	21	±11 percent
Products with inadequate corrective actions	12	±8 percent
Products with inadequate monitoring records	31	±11 percent
Products with inadequate corrective action records	9	±7 percent
Products with a HACCP plan that had a valid answer to question on instrument calibration		
Products that did not calibrate instruments properly	30	±12 percent

Table 5 shows sampling errors for four subgroups used in table 4.

Table 5: Sampling Errors for Selected Subgroups for Three District Offices, Fiscal Year 1999

Products	Estimated percentage	Sampling error
Products inspected on 1999 version of Form 3501	51	±10 percent
Products with a HACCP plan	60	±10 percent
Products with a HACCP plan and inspected on 1999 version of Form 3501	28	±9 percent
Products with a HACCP plan that had a valid answer to question on instrument calibration	54	±10 percent

We also visited two of the leading seafood exporters to the United States—Canada and Chile—to (1) obtain an understanding of their rules and

regulations, (2) compare those countries' seafood safety programs with the U.S. program, and (3) observe how those countries implement their safety rules and regulations for seafood.

To assess FDA's system for imported seafood, we (1) examined the status of FDA's equivalence determinations with leading exporters of seafood to the United States and (2) reviewed and compared USDA and FDA authorities regarding equivalence determinations. We also analyzed FDA's foreign country seafood inspection reports for fiscal year 1999 for the four countries visited—Ecuador, Vietnam, Taiwan, and the Philippines. We compared FDA's findings during those foreign inspections with FDA's actions at U.S. ports of entry. We also obtained and analyzed all of FDA's records of importers' inspections for fiscal year 1999 (3502 forms) and verified with FDA officials that FDA inspectors were adequately trained and did not encounter difficulties when completing these forms. Finally, we compared and contrasted selected aspects of FDA's HACCP system for seafood with those of Canada and Chile.

We conducted our review from February through December 2000 in accordance with generally accepted government auditing standards.

Seafood-Related Illnesses

Seafood-related microbiological, chemical, and physical hazards can cause illnesses. According to the Centers for Disease Control and Prevention's (CDC) data, in 1997, the leading causes of seafood-related outbreaks were two natural toxins—ciguatera (42 percent of all outbreaks) and scombrototoxin (46 percent of all outbreaks). Table 6 summarizes some seafood-related hazards and the illnesses they cause.

Table 6: Selected Illnesses Caused by Seafood and Seafood Products

Agent	Illness	Symptoms	Primary products
<i>Clostridium botulinum</i>	Foodborne botulism	Gastroenteritis, weakness, vertigo, and blurred vision. Can lead to respiratory failure and airway obstruction. Death among untreated patients up to 70 percent of cases.	Semipreserved fish products, including smoked, salted, and fermented fish.
<i>Listeria monocytogenes</i>	Listeriosis	Can cause meningitis, septicemia, and perinatal disease. Fatality rate can be as high as 70 percent.	Ready-to-eat products, such as crabmeat and smoked fish.
<i>Salmonella</i>	Salmonellosis	Nausea, vomiting, cramps, diarrhea, fever, and headache. Death is possible in people with weakened immune systems.	Any fish products.
Ciguatera toxin	Ciguatera poisoning	Gastrointestinal symptoms, such as diarrhea, nausea, vomiting, and abdominal pain and neurological symptoms, dizziness, and blurred vision.	Any fish caught in tropical reef and island waters, but most common in amberjack, barracuda, snapper, grouper, and reef fish.
Scombroid toxin	Scombroid poisoning	Itching, redness, allergic symptoms, headache, diarrhea, and peppery taste.	Most common in mahi-mahi, tuna, bluefish, mackerel, and skipjack.
Methylmercury	Methylmercury poisoning	Most dangerous for fetuses and infants: symptoms include mental retardation, cerebral palsy, deafness, and blindness. Adult symptoms may include numbness, tunnel vision, impaired hearing, muscle weakness, headache, irritability, and inability to concentrate.	Nearly all fish products. Highest concentrations are found in large fish, such as swordfish, shark, and tuna.

Seafood Safety Programs in the United States, Canada, and Chile

The United States, Canada, and Chile have adopted HACCP-based seafood inspection programs to ensure the safety of their seafood products. As summarized in table 7, the programs differ in several ways.

Table 7: Characteristics of the Seafood Safety Program in the United States, Canada, and Chile

Program features	United States	Canada	Chile ^a
Industry required to register with oversight agency	No	Yes	Yes ^b
Written hazard analysis required	No	Yes	Yes
Written HACCP plan required	Yes	Yes	Yes
Preimplementation review of HACCP plans	No	Yes	Yes
Required HACCP training for industry	Yes	No	Yes
Sanitation requirements	Yes	Yes	Yes
Frequency of federal inspections	At least once per year	Quarterly	Every 2 to 3 months

^aHACCP applies to exporters only.

^bExporters only.

The following sections discuss the inspection programs of Canada and Chile only.

Canada's Seafood Safety Program

To ensure the safety of its domestic seafood, Canadian officials said that in 1992, Canada adopted a HACCP-based system that encompasses safety and quality. In 1996, the Canadian Food Inspection Agency and industry formed a task force to further study and improve the system. The resulting Quality Management Program (QMP) requires that all seafood companies develop, maintain, and implement comprehensive quality and safety plans. Seafood companies are required to register with the inspection agency, and each processor's QMP plan must include the following:

- Management roles and responsibilities, which may include a written description of each manager's accountability or a written statement of commitment signed by all management staff.
- Product and process information that includes product descriptions and processing steps.

- A prerequisite plan that addresses facilities design; construction; maintenance; and all potential sources of contamination, including employee hygiene; and company recall procedures.
- A regulatory action point plan that describes controls designed to ensure that the products meet fish inspection regulations addressing tainted, decomposed or unwholesome products, packaging materials and ingredients, and labeling requirements.
- A HACCP plan identifying and addressing any health and safety hazards related to the product or process by applying the seven HACCP principles.
- Steps for verifying and maintaining the QMP plan.

The inspection agency reviews the QMP plans, including HACCP plans, before they are put into effect by seafood firms. A written hazard analysis is part of the required documentation. Once the plan is implemented, the inspection agency conducts in-depth audits of the QMP's implementation.

For imported seafood products, Canada adopted a two-tier regulatory system. Importers that have a regular license can import seafood products from any country but must notify the inspection agency within 48 hours of the product's entry. Depending on the product's history, the inspection agency decides whether to detain the product for visual examination and/or testing. Inspection agency officials stated that, on average, they test about 15 percent of all imported seafood in this category. Alternatively, importers may voluntarily participate in the QMP for Importers. The program allows seafood importers to develop their own system for monitoring and evaluating products that they import while the inspection agency conducts quarterly audits of participating companies to ensure compliance with seafood safety standards. Importers must perform or have performed product testing at a minimum frequency of 15 percent or as otherwise established in Canadian agreements with other countries. The inspection agency has also provided an incentive for importers to obtain products from foreign companies that have a good history of compliance. Under this arrangement, foreign seafood firms with a good compliance record are considered for reduced inspection frequencies at an importer's request. If approved, they are incorporated in the "A" list. To be part of this list, a foreign seafood firm must, at a minimum, have 10 acceptable inspections from at least 30 imported lots of seafood. Firms on the "A" list are subjected to unannounced inspections at predetermined frequencies.

Chile's Seafood Safety Program

In 1994, Chile implemented a HACCP-based inspection program for seafood to improve the effectiveness of its seafood exporters' certification program and to respond to future requirements of Chile's major export markets—the European Union (Directive 91/493/CEE) and the United States. The Chilean National Seafood Service (Servicio Nacional de Pesca, Sernapesca) administers Chile's seafood safety program. Chilean officials said that the HACCP system in Chile is modeled after the U.S. National Marine Fisheries Service System and Canadian systems. Therefore, it incorporates sanitation, safety, and quality features. Seafood exporters, including factory vessels, must be registered and authorized to export through the certification program. It is illegal to operate without registering with Sernapesca. In order to receive an export certification, exporters must implement the HACCP requirements.

Sernapesca issued procedures manuals, technical norms, and inspection instructions. Together, these documents instruct industry and inspectors on how to review and validate HACCP plans, how to collect official samples, and how to conduct objective inspections. Sernapesca must review and approve HACCP plans. Seafood exporters are required to maintain a written hazard analysis plan and to have it available for inspection. Officials think it is important to know the reasoning for inclusion or exclusion (in the HACCP plans) of hazards reasonably likely to occur.

Sernapesca conducts monthly sanitation inspections of seafood exporters. If the exporter fails the sanitation inspection, it is removed from Sernapesca's approved exporter list and thus can no longer receive export certification. Vessels are inspected when they come into port—every 3 months on average. Seafood firms are instructed to conduct biweekly verifications of their HACCP systems, and Sernapesca inspects firms once every 2 to 3 months, depending on the product. After inspection, firms are classified I through IV, depending on the number of deficiencies observed by inspectors. These categories determine whether firms will continue to be certified.

Comments From the Food and Drug Administration

Note: GAO's comments supplementing those in the report text appear at the end of this appendix.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JAN 17 2001

Mr. Lawrence J. Dyckman
Director, Resources, Community,
and Economic Development Division
Food and Agriculture Issues
U.S. General Accounting Office
441 G Street, Northwest, Room 2T23
Washington, D.C. 20548

Dear Mr. Dyckman:

Enclosed are the Food and Drug Administration's comments on the draft report entitled, "FOOD SAFETY: Federal Oversight of Seafood Does Not Sufficiently Protect Consumers," GAO/01-204.

Sincerely,

Melinda K. Plaisier
Associate Commissioner
for Legislation

Enclosure

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FOOD AND DRUG ADMINISTRATION COMMENTS ON THE GENERAL
ACCOUNTING OFFICE DRAFT REPORT ENTITLED, FOOD SAFETY: Federal
Oversight of Seafood Does Not Sufficiently Protect Consumers GAO/01-204

The Food and Drug Administration (FDA) welcomes this report and appreciates the opportunity to review the General Accounting Office's (GAO) draft report, and provide comments. In addition to FDA's responses to the recommendations, we have a number of more general comments regarding the draft report.

While FDA believes that significant improvements for regulating the seafood industry have been made through establishment of the FDA's Hazard Analysis and Critical Control Point (HACCP) program, we also recognize that there are areas in the program that need to be strengthened. As described in the general comments below, FDA has already completed or plans to initiate steps to address these areas.

GENERAL COMMENTS

FDA has made substantial progress in ensuring the safety of seafood consumed by the public. FDA's 1997 science-based HACCP regulations initiated a landmark program aimed to further ensure the safety of seafood. The HACCP system focuses on identifying and preventing hazards that could cause foodborne illnesses rather than relying on spot-checks of manufacturing processes of finished seafood products to ensure safety. The FDA HACCP program was designed to increase the margin of safety that U.S. consumers already enjoyed and to reduce seafood related illnesses to the lowest possible levels.

As the draft report acknowledges, FDA has made progress in ensuring the safety of seafood consumed by the public since implementation of the seafood HACCP program in 1997. As noted in a December 8, 2000 Dear Colleague letter to the industry, the seafood industry has made substantial progress toward implementing the full range of preventive controls that became mandatory in December, 1997. Recently, FDA conducted an evaluation of the 1998-1999 HACCP Program which documented that the HACCP program had been implemented by about 3600 U.S. seafood processors, most of which are small businesses, that collectively process over 350 species of fish. FDA's evaluation reflected steady progress between 1998 and 1999 and revealed that a significant majority of processors are doing well on most of the individual elements of the program. Over half have succeeded in all elements – a difficult standard to achieve. Furthermore, two surveys of the seafood industry, one taken by the New York Sea Grant Extension Program and several by a consortium of academic, Federal, state, and industry entities known as the Seafood HACCP Alliance, report that, as a result of the FDA program, the industry is acquiring a better understanding of food safety hazards and how to control them. As a result, the industry is engaging in significant upgrades in facilities, equipment, and daily plant operations to ensure safety. Thus far, implementation of these state-of-the-art preventive controls by the seafood processing industry contributes to a significant increase in the margin of safety for consumers of these products.

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The Seafood HACCP program has also dramatically increased the frequency of government inspections. Before the seafood HACCP program, FDA averaged seafood processor inspections only once every four years. After the implementation of the 1997 seafood HACCP program, the frequency of inspections increased to annual, and will be even more frequent this fiscal year for the highest risk processors that continue to have compliance problems.

FDA's evaluation of the 1998-1999 program also shows there are some gaps and that certain segments of the industry were clearly lagging behind. Accordingly, FDA will intensify its inspection efforts to focus particularly on those seafood processors that: a) need to control for pathogens; b) need to control for histamines (which can cause allergic-type reactions); and c) still have not completed their HACCP plan.

FDA believes that seafood processed by these three categories of firms present the highest risk to consumers, and so the Agency is redoubling its efforts toward these. This will mean more frequent inspections of noncompliant firms; more extensive laboratory testing for pathogens and histamines; and, ultimately, enforcement action where appropriate.

In addition, the following actions have already been taken, or are in process, to strengthen the HACCP Program for seafood:

- Improved guidance and training to the industry and regulators on control of pathogens and histamine;
- Development of an inspector certification program that emphasizes knowledge of controls for pathogens and histamine;
- Development of guidance for fishing vessel operators to address proper handling of fish that can form histamine;
- Development of guidance for aquaculture operators to prevent pathogen contamination of aquaculture sites;
- Increased emphasis on compliance by foreign processors and increased surveillance of imports;
- Creation of a National Seafood HACCP Inspection Database that collects information on the details of seafood processors' preventive controls for safety.

Because some of the actions described above were already phased in during calendar year 2000, FDA expects to see additional progress in ensuring the safety of seafood consumed by the public. FDA may also make future refinements once data from the inspections in 2000 are available.

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In addition to the above, we have the following comments to clarify misconceptions in the draft report.

See comment 1.

1. There is no reason to conclude that commercial seafood is, on the whole, riskier than other commercial sources of animal protein. The draft report implies that seafood is more likely to cause foodborne illness than other foods, notably meat and poultry, because more outbreaks (i.e., two or more illnesses from a single source) are reported to the Centers for Disease Control and Prevention (CDC) from seafood than from other foods. However, as CDC has explained¹, CDC data cannot be used to determine whether seafood is more or less dangerous than other foods. Outbreaks are generally underreported to CDC, and those that are reported tend to be for easily diagnosable illnesses, such as scombroid poisoning from seafood, rather than illnesses resulting from nonspecific gastrointestinal symptoms caused by other foods. Other factors include the varying numbers of illnesses that occur within outbreaks and the fact that most foodborne illnesses occur as sporadic cases rather than as part of an outbreak.

The draft report's reference to FDA sampling conducted in 1999 implies that seafood is unsafe because 20 percent of those samples contained contaminants. However, these samples were primarily taken "for cause;" in other words, they were targeted toward suspected problems and are not representative of the seafood supply. This should be made clear in the report.

Finally, the report fails to acknowledge that some foodborne illnesses are associated with seafood that are no longer, or never were, in interstate commerce. Examples are catch from recreational and subsistence fishing over which the Federal government has little or no control.

See comment 2.

2. The draft report raises undue concerns about potential risks from two categories: domestic fishing vessels and domestic firms found not to need HACCP plans. First, the draft report states that FDA's inventory includes only about 250 of several thousand domestic fishing vessels that, in addition to fishing, engage in processing activities that would be covered under the HACCP requirements if the activities occurred on land. The report should recognize that FDA regulations exempt from HACCP requirements heading, evisceration and freezing on harvest vessels if done to prepare a fish for holding on the trip back to shore because it generally does not introduce a safety hazard and because it may promote quality. These activities account for the majority of "processing" done aboard ships, and are low risk, whether performed by a shore-based processor or by a fishing vessel. In fact, most land-based processors that perform only minimal handling such as that performed on fishing vessels would not need a HACCP plan for those activities.

¹ CDC explained this to GAO in a January 11, 2001 e-mail to GAO and in a May 2, 1990 letter from former CDC Director Roper to Rep. John Dingell.

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See comment 2.

Second, the draft report suggests that consumers are at risk because FDA has incorrectly identified as many as 30% of inspected firms as presenting no hazards and thus not needing HACCP plans. The draft report notes that many of these firms are warehouses or those that minimally process nonscombroid finfish. These operations are most likely to have no hazards associated with them that are reasonably likely to occur and therefore are appropriately exempted from the HACCP requirements.

The draft report asserts that HACCP controls are essential for refrigerated warehouses in order to maintain adequate storage temperature. We agree that such controls are needed in warehouses that hold the product refrigerated but not frozen because frequently there are hazards associated with the refrigerated storage of microbiologically sensitive fishery products (e.g., cooked, ready to eat fishery products) and scombroid species that warrant HACCP systems. However, there usually are no hazards associated with the frozen storage of the same products because the abuse needed to cause thawing and spoilage is not reasonably likely to occur. Warehouses have lost electrical power for days as a result of hurricanes, but their products have remained frozen due to the ability of modern freezers to retain cold.

With respect to nonscombroid finfish, the report should further state that most nonscombroid finfish are wild-caught in open ocean waters and are not subject to hazards such as animal drug residues and environmental contaminants. Additionally, many processors of these species only perform icing, heading, gutting, and freezing, activities that generally do not introduce hazards to the product, since the product is still raw, minimally handled, not dramatically transformed, and not packaged.

See comment 3.

3. The draft report statement that FDA's port-of-entry inspections have been widely discredited does not account for recent actions to strengthen that program. The report should state that FDA's port-of-entry inspections and sample collections are a critical component of its import operation because the foreign industry is not readily available for inspection. FDA's ability to examine and collect samples, when used strategically, enhances enforcement of HACCP requirements by providing analytical evidence that the products are or are not in compliance with FDA requirements. Product testing is also very useful in import operations to 1.) verify that corrective actions promised by the foreign producers following violative inspections have occurred; and 2.) determine illegal activities, such as product substitution, while products are still in import status.

GAO was highly critical of FDA's import program in a report issued in April, 1998. However, since that time, FDA has taken additional action to strengthen the import program and further protect consumers from unsafe imported food. In a radio address on July 3, 1999, President Clinton specifically directed the FDA and the U.S. Customs Service to take all actions available to 1.) prevent distribution of imported unsafe food by means such as requiring food to be held until reviewed by FDA; 2.) destroy imported food that poses a serious public health threat; 3.) prohibit the re-importation of food that had been previously refused admission for safety reasons; 4.) set standards for private laboratories for the collection and analysis of samples of imported food for the purpose of gaining entry into the United States; 5.) increase the amount of the bond posted for

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imported foods when necessary to deter premature and illegal entry in the United States; and 6.) enhance enforcement against violations of U.S. laws related to the importation of foods, including through the imposition of civil monetary penalties.

The President also asked the Secretary of Health and Human Services and the Secretary of Treasury to report on the steps they will take in each area identified in his directive to protect consumers from unsafe imported foods. On December 11, 1999, this report was issued. The report outlined the progress made in each of the six areas and a timeframe for fully implementing the planned activity for each of them. Indeed, in its' 2001 Program Priorities, FDA has targeted certain of the activities required to implement the FDA and U.S. Customs Service joint Action Plan for completion in fiscal year 2001.

FDA has also augmented its border surveillance activities with a significant increase for foreign establishment inspections as well as improved educational programs for foreign governments and processors.

4. The draft report gives insufficient credence to information FDA now has to assess the effectiveness of seafood HACCP requirements. The draft report notes that FDA collects data on seafood firms' compliance with its HACCP requirements and uses that data to evaluate progress. The draft report suggests, however, that FDA cannot adequately evaluate the effectiveness of its program because these data do not objectively measure whether the regulatory requirements are causing a reduction in contamination.

The cornerstone of the seafood HACCP program is prevention through the application of controls that are scientifically known to work. For example, where it is known through scientific analysis that a cooking step at a certain temperature and duration during commercial processing will kill all pathogens, a valid indicator of public health prevention is whether the processor's cook step achieved that temperature and duration. FDA's evaluation up to this point has focused on indicators of this nature. FDA has data about the application of preventive controls before initiation of the HACCP program, and has used that data as a baseline for measuring progress.

The draft report notes that USDA established a performance standard for the reduction of salmonella in order to evaluate the effectiveness of its HACCP program for meat and poultry. It should also note that regulation of seafood is not directly analogous with regulation of meat and poultry. Seafood is fundamentally different from meat and poultry in that it is subject to many potential hazards but suffers from no single pressing problem. Selecting a single numerical measure under such circumstances would be of limited value because, for example, monitoring fishery products for the presence of a pathogen would provide no indication of how histamine is being controlled. Additionally, the frequency and occurrence of pathogens such as salmonella, tends to be low, partly because fish are cold-blooded. This was confirmed in a baseline study FDA conducted on salmonella in seafood. Setting performance standards for contaminants that are already at low levels can be impractical and not necessarily relevant to significant public health end points.

See comment 4.

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Moreover, FDA has more objective criteria than acknowledged in the draft report. For example, numerical limits (e.g., tolerances, action levels) and processing control standards to help determine whether a product is adulterated. These standards have been integrated into the HACCP program as critical limits and targets of control strategies.

Finally, FDA is in the process of substantially upgrading its own program of finished product sampling and analysis and intends to use that data as part of its annual evaluation effort.

5. The draft report places undue emphasis on "equivalence agreements" in assuring safety of imports. The draft report implies that a lack of "equivalence" agreements with foreign countries is significantly impairing the Agency's ability to assure the safety of imported seafood.

Under an equivalence agreement, the government of an importing country would recognize the regulatory system in an exporting country as being equivalent to that of the importing country, (e.g., it provides the same "appropriate level of protection" as exists in the importing country, even if it employed different measures to do so.) Nations that are realistic candidates for equivalence determinations are those with highly advanced regulatory structures, i.e., countries that are the most likely to be shipping safe seafood to the U.S. already.

It is true that FDA is considering whether it could shift some regulatory scrutiny away from products from an "equivalent" country and therefore focus more on problem areas. FDA already triages its border testing based on experience with commercial sources, and so there is little room for notable reduction. Accordingly, to assure the safety of seafood imports in the short term, FDA will place a higher priority on the problem areas, through increased foreign inspections, technical assistance, education, and border surveillance.

GAO RECOMMENDATION

To better ensure the safety of domestic and imported seafood consumed in the United States, we recommend that the Commissioner of FDA

require that all seafood-processing firms, including vessels that meet FDA's HACCP criteria for land-based seafood firms, operate under HACCP requirements,

FDA COMMENT

We do not concur. As was previously discussed, the very limited nature of the processing conducted by the vast majority of harvesting vessels that are presently exempt from HACCP coverage makes it unlikely that they would introduce significant food safety hazards that need to be controlled. As such, these vessels would be classified as among the lowest risk firms in FDA's inventory. It is highly unlikely that land-based processors that perform the same functions in the same manner would need HACCP plans either. To

See comment 5.

See comment 2.

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the contrary, in order to speed up implementation of the seafood HACCP program where it is most needed, FDA is, instead, focusing its resources toward more frequent inspections higher-risk processors that are noncompliant.

GAO RECOMMENDATION

conduct in-depth audits of seafood firms that operate HACCP systems to verify that they identify and control all hazards reasonably likely to occur,

FDA COMMENT

We understand that the intent of this recommendation is that FDA establish a timetable for reviewing and bringing into compliance all the seafood HACCP plans of all the domestic processors.

FDA agrees with GAO about the importance of correct HACCP plans, which conforms with the Agency's own priorities for the program and the changes in focus that we intend to make. For the near future, FDA intends to focus its inspection efforts on three categories of processors whose compliance lagged during the first two years of inspections: (1) processors of products for which pathogens are a hazard that need to be controlled; (2) processors of products involving "scombroid species" that can form a toxin (scombrototoxin) if time-temperature abused; and (3) all processors that need a HACCP plan but have yet to develop one. This is a risk-based approach that addresses the areas of greatest need from a public health standpoint. FDA also agrees that all inspections of such processors should examine all HACCP plans, not just those for products being produced at the moment of the inspection. FDA will implement further changes as resources are available.

GAO RECOMMENDATION

emphasize to inspectors the need to revisit firms to observe the processing of seafood product(s) selected for inspection as required by FDA's compliance manual, and establish a system to monitor inspections to ensure such visits occur,

FDA COMMENT

FDA generally agrees with this recommendation, but with certain caveats. The recommendation is based on GAO's findings in three districts that in 48% of inspections, the product targeted for inspection was not being processed on the day of the inspection, so the inspector instead focused his/her attention on an analysis of HACCP plans and records. In cases where the inspector could not observe the target product because it was not being processed that day, the inspector sometimes observed other, lower risk products being processed in addition to conducting a review of records and HACCP plans for the target product.

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For many seafood processors, operations are both seasonal and sporadic, in that production may start and stop depending upon the availability of fish. Even before HACCP, FDA inspection strategy had to accommodate the fact that a processor might not be operating when the inspector arrived. Moreover, many processors are located in remote locations so that it could be highly impractical to return immediately for a follow-up inspection. HACCP ameliorates this problem to a great extent by enabling the inspector to review the plan and records portion of the processor's preventive control system even when fish are not available for processing. These records are a critical part of the inspection and are a major underpinning of the entire HACCP system. As such, these records can be highly revealing, as the draft report acknowledges in the second recommendation above.

FDA is committed to reviewing its operations to see if inspections may be planned in a way that would reduce the percentage of firms not processing the target product on the day of inspections. At the same time, the agency is committed to a focused, risk-based approach that frees resources for more return visits to firms that process higher risk products and were not processing during the initial inspection.

GAO RECOMMENDATION

develop milestones for completing the agency's ongoing evaluation of methylmercury and whether it is a seafood hazard reasonably likely to occur,

FDA COMMENT

We concur. One of the Agency's priorities for fiscal year 2001 is to review its overall public health strategy for methylmercury in commercial seafood and make any modifications that are found necessary in light of new data that have become available in recent years. The first step in this review has been a re-assessment of the agency's longstanding consumption advice that focused on species with the highest average levels of methylmercury. FDA issued a revised consumer advisory on January 12, 2001 based upon this review. That Consumer Advisory recommended that women who are pregnant, or who are of childbearing age and may become pregnant, avoid eating the four species of fish known to have the highest levels of methylmercury: shark, swordfish, king mackerel, and tilefish.

GAO RECOMMENDATION

issue warning letters within FDA's required timeframes,

FDA COMMENT

FDA essentially agrees with this recommendation. FDA will be reassessing the appropriateness of the 15-day requirement as well as the factors that have contributed to the lengthy review times before issuance of Warning Letters with the intent of making appropriate changes to facilitate their timeliness. As an interim measure, the agency is

**Appendix IV
Comments From the Food and Drug
Administration**

committing to reducing during the current fiscal year the review time to an average of 30 days from the current average of over 70 days. As part of reduction effort, FDA will consider whether additional "direct reference" should be extended to field staff so that more warning letters may be issued directly by the field without the need for prior review in headquarters.

GAO RECOMMENDATION

develop baseline information, such as regular microbial testing, and use it to assess the effectiveness of HACCP systems over time,

FDA COMMENT

FDA essentially agrees with this recommendation. The agency's general comments on this report describe the limitations associated with using pathogen monitoring to assess the effectiveness of the HACCP system. Nonetheless, the agency is in the process of substantially upgrading its own program of finished product sampling and analysis and intends to use that data as part of its evaluation effort. This sampling will include microbiological and histamine analysis of appropriate products. It should be noted that FDA has already done this for salmonella by conducting a nation-wide survey of salmonella levels in a wide variety of commercial seafood products, both domestic and imported. The survey confirmed that the levels for these pathogens in fish are generally very low, although they did show some higher levels in certain aquaculture products. The agency is using this information to begin developing good aquaculture practices guidelines that will be integrated into the HACCP program.

GAO RECOMMENDATION

develop specific goals and timeframes for establishing equivalence agreements while Congress considers whether to mandate FDA's certification of other countries' equivalence before their seafood products are allowed entry into the United States,

FDA COMMENT

FDA does not concur. While we consider equivalence determinations to be an ongoing activity, the development of meaningful timetables has not proven possible, primarily because other countries are involved in the considerable amount of data on regulatory systems that must be exchanged in order to permit a determination. For FY 2001, FDA plans to continue to make progress toward accomplishing foreign equivalence assessments and has listed it as one of its priorities.

See comment 5.

See comment 6.

GAO RECOMMENDATION

communicate HACCP system deficiencies identified during FDA importer inspections and foreign country inspections to port-of-entry personnel so that potentially contaminated imported seafood are examined before being allowed in the United States.

FDA COMMENT

FDA agrees with this recommendation. As of now, nine firms have been placed on "Detention Without Physical Examination" (DWPE) and one additional firm is in the process of being placed in that status. These products may no longer be entered into the United States without the importer first demonstrating that they were produced in compliance with the HACCP regulation. The responses to the warning letters made by eight additional firms were satisfactory, with no need for further agency action. Correspondence continues with the remaining seven firms. Additional firms will be placed on DWPE as conditions warrant.

The following are GAO's comments on the Food and Drug Administration's letter dated January 17, 2001.

GAO's Comments

1. We modified our report to include the actual number of cases associated with seafood and with meat and poultry outbreaks. We also added CDC's observation that reported illness outbreaks tend to be for illnesses more likely to be recognized. According to CDC, diagnosable illnesses, such as scombroid poisoning from seafood, are more easily recognized than illnesses from nonspecific gastrointestinal symptoms caused by other foods.

2. We believe that until FDA develops an inventory that identifies and assesses each vessel's on-board activities, FDA's view that vessels not performing functions beyond preparing the catch for holding pose little or no risks lacks credibility. Numerous fishing vessels handle high-risk products, such as tuna, which if not properly handled or held—kept at the appropriate temperature—may result in foodborne illness. Furthermore, although the number of vessels processing seafood on-board is unknown, federal and state officials' estimates lead us to conclude that a significant number could be conducting on-board processing similar to that conducted by land-based seafood firms. Land-based seafood firms that head, eviscerate, and freeze products are required to comply with the HACCP regulations. Exempting vessels from the HACCP regulations also eliminates the requirement for a written standard operating procedure for sanitation aimed at ensuring basic sanitation procedures and practices. We modified the report to clarify the HACCP regulatory requirements for vessels.

With respect to FDA's comments on domestic firms found not to need HACCP plans, we did not mean to suggest that all 1,055 of FDA's determinations exempting products from needing HACCP plans were incorrect. We do question, however, whether FDA inspectors were justified in exempting as many as 516 of these products on the grounds that storage and repacking firms do not handle products presenting significant hazards. In our view, many of these firms handle products with significant hazards and should have HACCP plans. We did modify the report to include FDA's view that frozen products do not present significant food safety risks.

3. We agree that since the publication of our 1998 report, FDA has initiated actions to improve controls over imported foods aimed at preventing unscrupulous importers from bypassing or subverting port-of-entry

activities. However, the fact remains that without equivalence agreements, FDA has to rely on labor-intensive inspections of products at the port of entry as its primary line of defense against the entry of unsafe foods. We continue to believe that port-of-entry inspections alone do not effectively ensure the safety of imported seafood. Using port-of-entry inspections to augment a program certifying that imported products are produced under equivalent food safety systems is a much more efficient and effective way to ensure the safety of imported foods. Providing FDA with authority similar to that provided for the Food Safety and Inspection Service would allow FDA to leverage its resources and provide greater assurance that imported seafood is safe. Accordingly, we did not modify the report.

4. We agree with FDA's comment that its efforts to gather and analyze seafood firms' compliance with HACCP requirements have merit but continue to believe that compliance information alone is not a good indicator of the seafood program's impact on reducing contamination that could cause foodborne illness. A performance-based measurement, such as that used by USDA, would improve FDA's evaluation of the effectiveness of its programs for ensuring seafood safety. While there may not be any single widespread hazard in seafood, scombrototoxin and ciguatoxin caused 46 and 42 percent of seafood illness outbreaks, respectively. Therefore, we continue to believe that FDA should identify the hazards of most concern (e.g., scombrototoxin), develop baseline information on such hazard(s), and use that information to assess the effectiveness of its programs in reducing the prevalence of such hazards. We modified the report to provide additional information regarding FDA's compliance-based data.

5. We continue to believe that an emphasis on equivalence agreements by establishing goals and time frames is appropriate because equivalency is generally a more effective way to ensure the safety of imported food. Equivalence agreements will help FDA reduce its reliance on importer and port-of-entry inspections and enable it to leverage its staff resources by sharing the responsibility for seafood safety with the exporting countries. Goals and time frames are standard management tools used to monitor the progress of important initiatives, such as equivalence agreements. Without them, there is less incentive to complete the initiatives. In this regard, FDA and the Canadian Food Inspection Agency have had discussions and engaged in activities aimed at determining the equivalence of the two countries' systems since Canada first requested such action in 1997. Furthermore, without any equivalence agreements for seafood, importers must use the more difficult and costly alternative of providing documentary support that the exporting seafood processor has a HACCP system that

meets U.S. requirements. We also recommend that Congress consider mandating that FDA certify other countries' equivalence before their seafood products are allowed entry into the United States. If Congress decides to act in this regard, we would envision that Congress would provide FDA a number of years to complete such determinations. By establishing goals and time frames for equivalence agreements, FDA would assist Congress in this effort. FDA could establish alternative provisions for countries that export seafood to the United States and have systems that are not equivalent, such as requiring them to provide laboratory tests or other assurances that the seafood meets U.S. standards.

See comment 2.

See comment 5.

6. We commend FDA for taking action to add foreign firms to its import alert list after we brought this issue to its attention. We modified the report to include this information.

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Acknowledgments

In addition to those named above, Maria Cristina Gobin, Randolph D. Jones, Leo Acosta, Roberto Pinero, Alicia Antonetti, Fran Featherston, Carol Herrnstadt Shulman, and Oliver Easterwood made key contributions to this report.

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Appendix V
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