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FOOD SAFETY

Federal Oversight of Shellfish Safety Needs Improvement

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Contents

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Accountability * Integrity * Reliability

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Chairman
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Ranking Minority Member
Committee on Agriculture, Nutrition, and Forestry
United States Senate

Molluscan shellfish—oysters, clams, mussels, and scallops—cause over 100,000 illnesses annually, according to the most recent available estimates from the Food and Drug Administration (FDA).[1] Unlike meat and most other seafood products, which are normally cooked before consumption, molluscan shellfish (hereafter, shellfish) are frequently eaten raw, heightening the risk of illness from a variety of pathogens that may be present. The severity of the illnesses that occur from contaminated shellfish varies. On one end of the spectrum, Norwalk and Norwalk-like viruses, which cause the vast majority of illnesses, result in mild gastrointestinal discomfort. On the other end, *Vibrio vulnificus* (hereafter *V. vulnificus*) bacteria cause severe illnesses and, frequently, death, generally in persons with weakened immune systems because of adverse health conditions, such as liver disease. *V. vulnificus* bacteria in shellfish, primarily raw oysters, have been the cause of 275 reported illnesses resulting in 143 deaths since 1989, according to FDA.

FDA is the federal agency responsible for ensuring the safety of shellfish. In 1982, FDA, state regulators, and shellfish industry representatives formed the Interstate Shellfish Sanitation Conference (ISSC) to promote uniform shellfish safety policies. The ISSC develops policies for the safe harvesting, processing, and distribution of fresh and frozen shellfish. FDA must concur with the ISSC's proposed policy changes before they are incorporated into the National Shellfish Sanitation Program's (NSSP) catalogue of safety procedures, referred to as the model ordinance. When

[1] FDA defines molluscan shellfish as all edible species of oysters, clams, mussels, and whole or roe-on scallops; either shucked or in the shell, fresh or frozen, whole or in part. Scallops are excluded from the definition when the final product is the shucked abductor muscle only, the most commonly eaten part of the scallop. FDA issued its estimate of shellfish-related illnesses in its December 1995 final rule on the procedures for the safe and sanitary processing and importing of fish and fishery products. Neither FDA nor the Centers for Disease Control and Prevention have current estimates of the number of shellfish-related illnesses that occur annually.

new policies are adopted into the model ordinance, the participating states and foreign countries incorporate them into their own program requirements and are responsible for enforcing them. All 30 of the states that harvest and/or process shellfish commercially participate in the ISSC. In addition, four foreign countries—Canada, Chile, South Korea, and New Zealand—have memorandums of understanding with FDA in which they agree to abide by NSSP's shellfish safety policies. Raw shellfish from countries that have not signed such memorandums are not permitted to enter U.S. commerce. The ISSC member states and foreign countries are responsible for inspecting their shellfish processing plants, classifying shellfish growing areas to limit harvesting to areas that meet water quality standards, and patrolling shellfish growing areas to prevent illegal harvesting. FDA oversees ISSC member states' and foreign countries' shellfish safety programs primarily by (1) conducting evaluations to ensure they comply with NSSP policy and applicable federal regulations and (2) providing technical assistance, such as helping conduct water quality studies or helping implement new shellfish safety policies.

A significant change to shellfish safety policy occurred in December 1997, when FDA required processors of seafood, including shellfish, to implement Hazard Analysis Critical Control Point (HACCP) systems. Under the HACCP regulations, which were also incorporated into the NSSP, processors of raw molluscan shellfish are required to identify safety hazards that are reasonably likely to occur and to establish controls to prevent or reduce contamination to acceptable levels. FDA and ISSC do not require shellfish processors to treat *V. vulnificus* as a hazard that must be controlled under their HACCP plans because the bacteria occurs naturally in oysters, the general population is not susceptible to illness from it, and the amount of *V. vulnificus* needed to cause illness in susceptible individuals is unknown. According to the ISSC, these characteristics distinguish *V. vulnificus* from other known hazards associated with shellfish and pose challenges in determining the appropriate public health intervention strategies. As such, the ISSC has adopted various strategies, such as educating at-risk consumers, and continues to propose new strategies aimed at reducing *V. vulnificus*-related illnesses.

Concerned about shellfish safety, you requested that we evaluate (1) FDA's approach to oversight of state and foreign shellfish safety programs and (2) the ISSC's strategy for reducing the illnesses and deaths associated

with *V. vulnificus* bacteria.[2] To conduct this review we visited six states—Florida, Louisiana, New Jersey, New York, Texas, and Washington—to gather information on state implementation of shellfish safety requirements. During 1999, these six states collectively produced about 65 percent of the nation's shellfish, and shellfish from Florida, Texas, and Louisiana was the source of almost all reported shellfish-related illnesses caused by *V. vulnificus* bacteria that could be traced to a particular state. Appendix I provides additional details on our scope and methodology.

Results in Brief

Several weaknesses exist in FDA's approach to overseeing domestic and foreign shellfish safety programs. First, FDA does not use existing information, including shellfish production and illness data, to make risk-based decisions about which programs should receive the most oversight. For example, in 2000, FDA devoted essentially the same amount of staff time to annual evaluation activities in Louisiana, a very large oyster producer and one of the major sources of reported *V. vulnificus*-related illnesses, as it did in Delaware which produces relatively few oysters and has not been the source of any reported *V. vulnificus*-related illnesses. As a result, FDA's resources are not being used efficiently to achieve the greatest level of shellfish safety. FDA officials said that they have not yet moved to a risk-based approach to overseeing shellfish safety programs in part because the states wanted to receive uniform FDA oversight. Second, FDA's ability to fully assess relative risk and allocate its limited oversight resources is limited by weaknesses in the compliance and effectiveness information it gathers on states' and foreign countries' shellfish safety programs. Currently, FDA does not have sufficient information, such as the results of all plant inspections in the 30 states and the four exporting countries, to assess the extent of compliance with some safety requirements. FDA also does not have objective, measurable data on the effectiveness of HACCP requirements and other efforts by states and foreign countries to reduce the amount of bacteria in shellfish and associated illnesses. FDA officials acknowledged the desirability of having better data on compliance and effectiveness. However, they believe it is not currently possible to directly assess the effectiveness of shellfish safety efforts because of problems in accurately measuring reductions in shellfish-related pathogens and illnesses.

[2] The safety of all other seafood, excluding molluscan shellfish, is discussed in our report, *Food Safety: Federal Oversight of Seafood Does Not Sufficiently Protect Consumers* (GAO-01-204, Jan. 31, 2001).

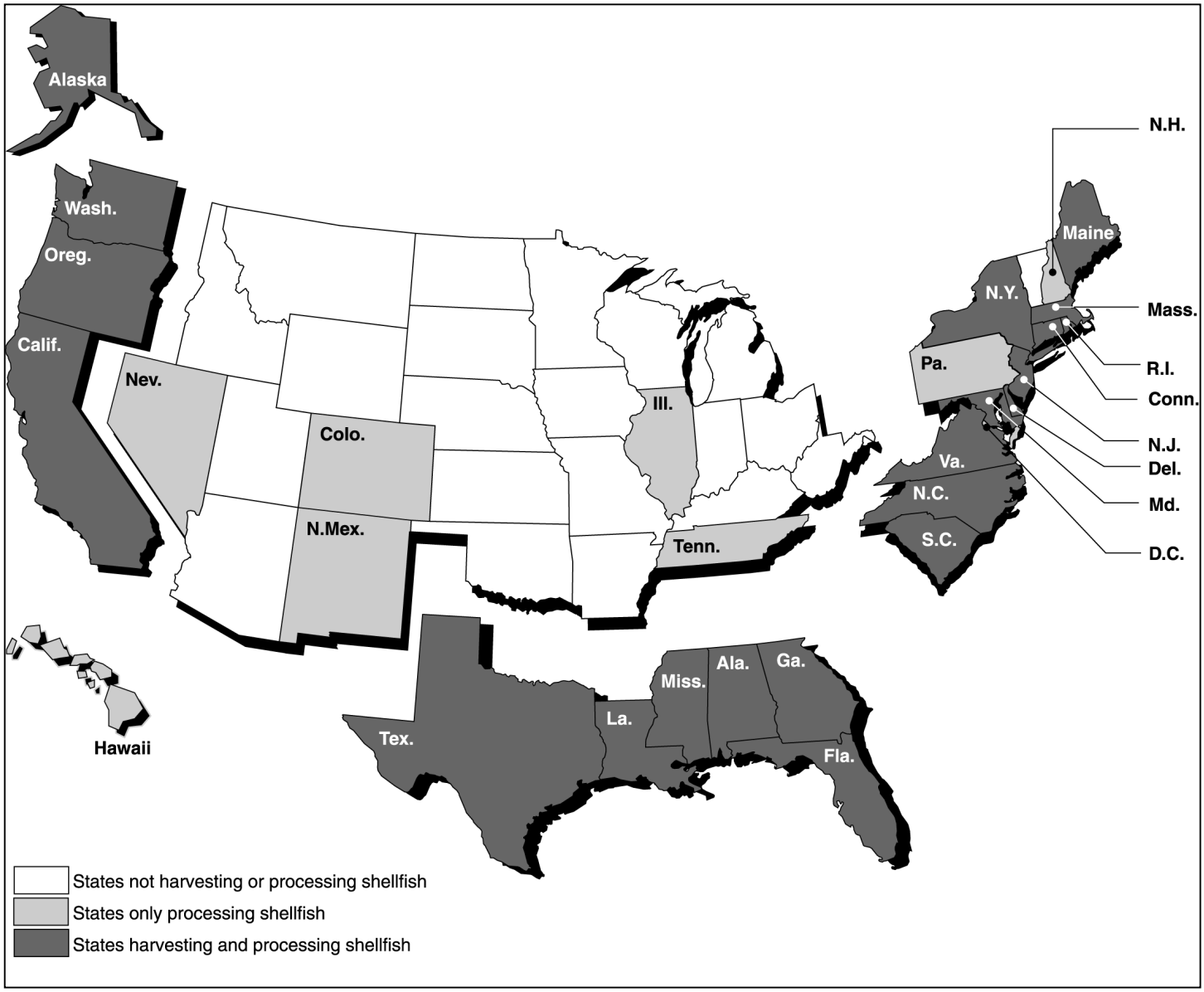
The ISSC's efforts to reduce *V. vulnificus*-related illnesses and deaths have not been effective. Despite various actions by the ISSC, the annual number of reported illnesses and deaths associated with *V. vulnificus* has remained relatively constant since 1994. The ISSC is now developing a strategy that, if adopted, would rely primarily on educating at-risk consumers, to reach the goal of reducing the rate of *V. vulnificus* related illnesses and deaths by 60 percent by 2008. If the states do not meet this goal, one of several potential controls designed to achieve the desired outcome, such as post-harvest treatment to kill bacteria, will be implemented. However, if the states rely on education alone, it is questionable whether significant illness reductions will be achieved prior to 2008 because the ISSC's past education efforts have not demonstrated that education is likely to have this effect. Two strategies—mandating refrigeration of oysters shortly after harvest and requiring immediate phase-in of post-harvest treatment—may reduce *V. vulnificus*-related illnesses and deaths more quickly than the proposed ISSC strategy. However, these options have disadvantages as well, such as the potential for negative economic impacts on some segments of the shellfish industry.

We are making several recommendations to the Commissioner of the Food and Drug Administration aimed at improving federal oversight of the shellfish safety program and at providing consumers with increased protections against illnesses resulting from *V. vulnificus*. In commenting on a draft of this report, FDA and the ISSC generally concurred with our recommendations. However, in response to our recommendation that FDA gather data, such as microbial test results, to measure program effectiveness, FDA and the ISSC said that while they recognize the importance of effectiveness data, they are uncertain what the most appropriate measures would be. Nonetheless, the agencies said they will work together to investigate the development of program effectiveness measures.

Background

Molluscan shellfish—oysters, clams, mussels, and scallops—have been a part of the American diet for several centuries. Today, domestic shellfish are commercially harvested from the waters of the Atlantic, Pacific, and Gulf of Mexico and shipped to consumers throughout the United States. Twenty-two coastal states harvest shellfish from their waters and 8 other states process shellfish that were harvested elsewhere, as shown in figure 1.

Figure 1: Map of Shellfish Harvesting and Processing States

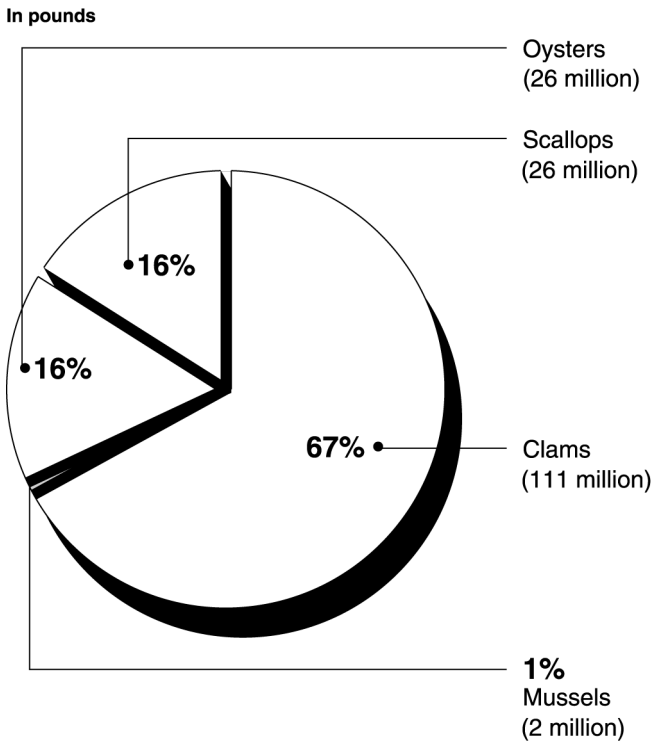


Source: Interstate Shellfish Sanitation Conference.

During 1999, the United States commercially harvested and processed about 165 million pounds of clams, oysters, scallops, and mussels. Figure 2 shows the amount and percentage of each type of shellfish harvested. Production varied by state—New Jersey and Massachusetts fishermen

harvested most of the nation's clams, whereas Washington, Louisiana, and Texas were the main oyster-harvesting states. Massachusetts and Virginia were the two top scallop-harvesting states, and mussels were harvested primarily in Maine.

Figure 2: U.S. Shellfish Production by Type of Shellfish, 1999



Source: National Marine Fisheries Service.

In addition, some foreign countries export molluscan shellfish to the United States. While any foreign country may export cooked shellfish to the United States, only certified shippers from countries that have memorandums of understanding with FDA and have agreed to abide by the shellfish safety policies incorporated into the NSSP are permitted to export fresh or frozen uncooked shellfish into the country. Four countries—Canada, Chile, Korea, and New Zealand—have such agreements. The amount of fresh and frozen uncooked shellfish that these countries export to the United States is not known. The National Marine Fisheries Service tracks total shellfish imports but does not have data on the percent of shellfish imports that are uncooked and destined to be sold for raw consumption.

Unlike meat, and most other seafood products, which are normally cooked before consumption, shellfish, particularly oysters, are frequently eaten raw, thus potentially exposing consumers to a variety of pathogens. In 1995, FDA estimated that shellfish caused over 100,000 illnesses and cost the nation about $201.9 million annually. Many of these illnesses are not reported because the symptoms are mild and the individuals affected do not seek medical attention. However, the ISSC believes FDA's estimate significantly overstates the actual number of annual illnesses related to shellfish.

As shown in table 1, FDA estimated that the greatest number of shellfish-related illnesses are attributable to the Norwalk virus, which occurs primarily in feces-contaminated growing waters.[3] The virus can cause nausea, vomiting, diarrhea, abdominal cramps, and occasionally fever in humans, but the symptoms usually persist for less than 48 hours.

Table 1: Principal Pathogens and FDA's Estimates of Associated Cases of Shellfish-Related Illnesses, 1995

Pathogens	Cases of illness
Norwalk virus	100,000
Hepatitis A virus	1,000
Vibrio vulnificus	60
Other marine toxins	20
Paralytic shellfish poisoning	10
Other	Unknown[a]
Total	**101,090**

[a]Additional pathogens, such as Campylobacter jejuni, Giardia, and other Vibrios affect fish as well as shellfish. FDA did not estimate the number of illnesses from these pathogens linked to shellfish alone.

Source: FDA.

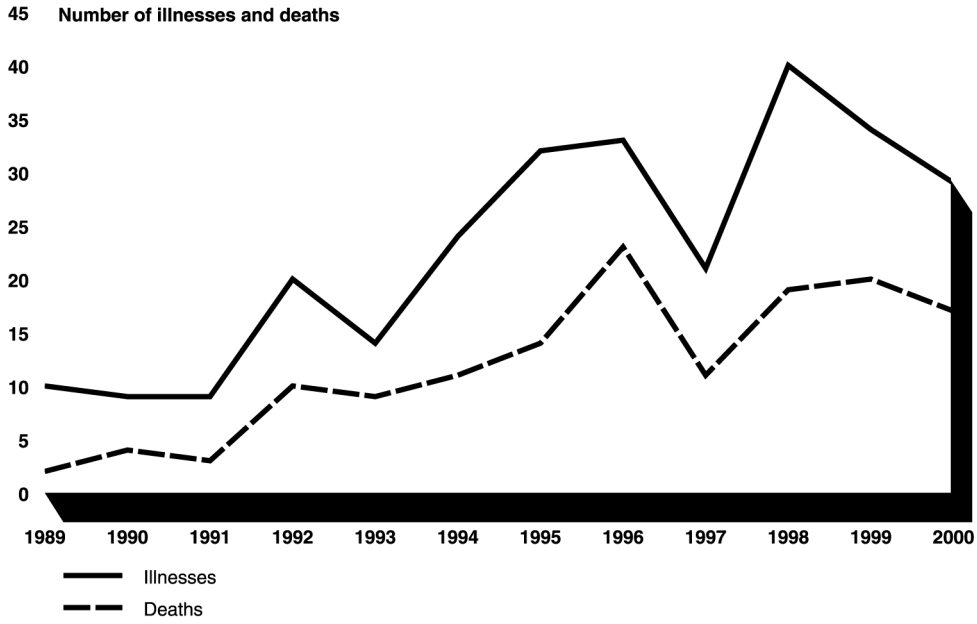
FDA also estimated that about 60 percent of the cost of shellfish-related illnesses, or about $120.5 million annually, is the result of *V. vulnificus* bacteria. Although the number of *V. vulnificus*-related illnesses is small, the costs of the disease are high because of the high mortality rate—about 52 percent of those who become ill eventually die. *V. vulnificus* is a naturally occurring bacterium found in all coastal waters and is more abundant in oysters and clams during the warm-weather months of April

[3] Because individuals suffering from this illness generally do not seek medical help, the Centers for Disease Control and Prevention has no data on the number of reported cases of shellfish-related Norwalk illness.

through October. Most healthy people do not become ill from *V. vulnificus*, but certain medical conditions put some people at risk of developing a potentially fatal infection known as septicemia. These conditions include, alcohol-related liver disease, hemachromatosis, cancer, chronic kidney disease, and HIV/AIDS, among other conditions. FDA has estimated that between 12 million and 30 million Americans have conditions that put them at increased risk for *V. vulnificus*-related illness.

According to FDA data, from 1989 through 2000, 275 reported illnesses resulting in 143 deaths were linked to shellfish containing *V. vulnificus*. The annual number of reported illnesses and deaths is somewhat higher at the end of this time period than at the beginning, as shown in figure 3. It is not known whether this increase is due to better reporting, greater shellfish consumption, or an actual increase in the rate of shellfish-related illnesses.

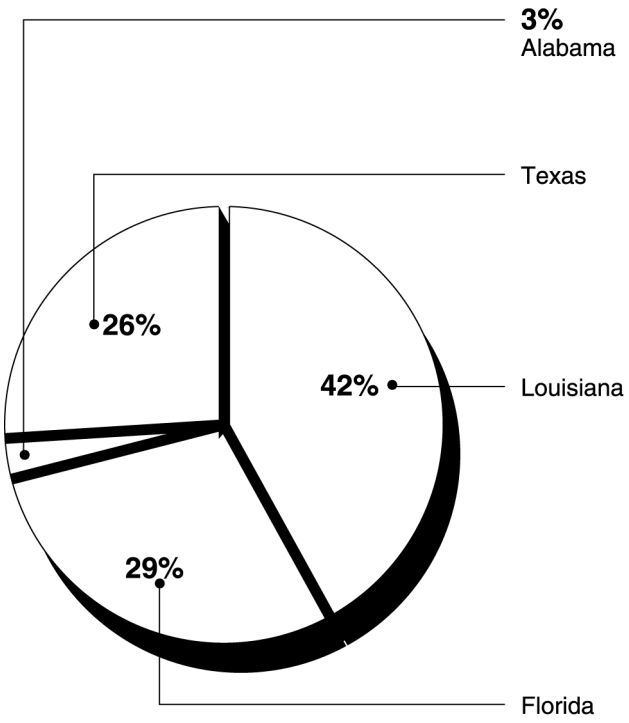
Figure 3: *V. vulnificus*-related Illnesses and Deaths From Shellfish Reported to FDA, 1989-2000



Source: FDA

Almost all of the *V. vulnificus*-related illnesses that could be traced to a particular state between 1989 and 2000 were associated with eating raw oysters harvested in Louisiana, Texas, and Florida, as shown in figure 4.

Figure 4: Known Sources of *V. vulnificus*-related Illnesses From Shellfish Reported to FDA, 1989-2000



Source: FDA.

The shellfish safety program is one of four FDA-state cooperative programs where FDA's role is primarily oversight of state programs rather than direct enforcement of safety requirements.[4] FDA has delegated to the ISSC the primary responsibility for developing shellfish safety policy. FDA, each of the 30 states that produces and/or processes shellfish, the four countries that have active shellfish agreements with the United States, and representatives of the shellfish industry are members of the ISSC. The ISSC has met annually to discuss and adopt new shellfish safety policies, which are then compiled in the NSSP model ordinance.[5] Only the state representatives may vote on changes to shellfish safety policy. Federal agencies, including FDA, industry, and foreign country representatives do

[4] The other three FDA-state programs are radiological health, retail food protection, and milk safety.

[5] Beginning in 2001, the ISSC will meet biennially instead of annually.

not vote, but FDA must concur with new policies before they are formally adopted.

Once new shellfish safety policies have been incorporated into the NSSP, member states and foreign countries are responsible for adopting them into law and taking necessary enforcement actions. States and foreign countries manage shellfish safety by taking the following required actions:

- **Classify growing areas**. States and foreign countries divide their coastal shellfish growing waters into distinct geographic regions. For each area, states and foreign countries must identify potential sources of pollution and test the water regularly for bacteriological or other contamination. Pathogens may naturally occur in the growing water or result from human activities, such as discharges of human sewage and chemicals. States and foreign countries use these tests to determine limitations on shellfish harvesting for each growing area. Each area is classified as approved, conditionally approved, restricted, conditionally restricted, or prohibited. Growing areas are then designated as either open or closed. Prohibited areas are never open and restricted areas are only open for special harvesting. The other classified areas are normally open, subject to the limitations of their classifications. All harvest areas, regardless of classification, are subject to closure in emergency situation that have the potential to make the water unsafe.
- **Patrol shellfish growing areas**. States and foreign countries conduct patrols of growing areas to prevent harvest of shellfish from closed areas and to check that boats are not dumping their waste overboard into shellfish growing areas. Harvesting from closed areas and overboard discharge of waste into shellfish growing areas have been identified as sources of shellfish-related illnesses in the past.
- **Inspect shellfish processing plants**. States and foreign countries conduct regular, comprehensive, on-site, inspections of shellfish processing plants and issue annual certifications that permit processors to sell their shellfish products in interstate commerce. The regular inspections and annual certification provide notice to consumers and health officials in other states that the shellfish products purchased from the processor have been grown, harvested, processed, and shipped in accordance with NSSP safety requirements. These requirements include implementing general sanitation procedures commonly used throughout the food industry, such as ensuring the safety of the water and ice that come into contact with food or food contact surfaces, preventing cross-contamination from unsanitary objects, and excluding pests from the processing plant. Since December 1997, processors have also been required to implement HACCP systems under which they must identify

safety hazards that are reasonably likely to occur and establish control procedures to prevent or reduce contamination from such hazards to acceptable levels.

- **Operate laboratories**. States and foreign countries operate laboratories to test growing waters and shellfish meats for the presence of pathogens, among other purposes.

FDA oversees states' and foreign countries' shellfish safety programs to ensure that they comply with all shellfish safety requirements. FDA carries out this responsibility primarily by (1) evaluating states' and foreign countries' programs and (2) providing technical assistance, such as helping conduct water quality studies or helping implement new shellfish safety policies. In fiscal year 2001, FDA expects to use about 8 staff years to conduct evaluations of states' and foreign countries' programs and 6 staff years to provide technical assistance and training to states' and foreign countries' staff.[6] In evaluating these programs FDA, among other things, assesses whether the state or foreign country is properly classifying and patrolling shellfish growing areas and inspecting processing plants to identify those that are not fully meeting the applicable safety requirements.

Weaknesses Exist in FDA's Oversight of Domestic and Foreign Shellfish Programs

Several weaknesses exist in the way FDA oversees states' and foreign countries' efforts to ensure shellfish safety. First, FDA has not adopted a risk-based approach to overseeing states' and foreign countries' shellfish programs. Although risk-based approaches are generally recognized as the most effective method for targeting limited resources, FDA's oversight approach is based on essentially equal treatment of all participants in the shellfish safety program. Second, FDA lacks sufficient information on states' and foreign countries' compliance with some NSSP safety requirements and has no data on the effectiveness of states' and foreign countries' shellfish safety programs. Both of these weaknesses limit FDA's ability to allocate its oversight resources to most effectively reduce the risk of consumers becoming ill from eating unsafe shellfish.

[6] Overall, in fiscal year 2000, FDA used 54.3 staff years to administer the molluscan shellfish program. This number includes program evaluation, research laboratory, policy, and administrative personnel.

FDA's Oversight of States' and Foreign Countries' Shellfish Programs Is Not Risk-Based

The level of food safety risk in a state's or foreign country's shellfish program principally depends on the size and type of the shellfish industry, the public's rate of consumption of shellfish, and the state's or foreign country's compliance with safety requirements, such as properly classifying growing waters. For example, the risk of shellfish-related illnesses is likely greater for a state or foreign country that contains a larger number of firms selling raw oysters, and that does not fully comply with NSSP safety requirements, than it would be for one that sells significantly fewer raw oysters and fully complies with the requirements. (Raw oyster consumption has been associated with the most serious shellfish-related illnesses.) Changes in the organization of a state's or foreign country's shellfish safety program, the officials implementing the program, or its funding, can also affect a program's compliance with NSSP requirements and, consequently, the level of food safety risk. Although much of this information is currently available, FDA does not use the information to target its program oversight and thus does not make the most effective use of its limited resources.

FDA seeks to provide essentially equal oversight to each shellfish safety program, regardless of differences among the programs that could affect their relative food safety risks, such as the amount and type of shellfish produced and the shellfish-related illnesses that have occurred. To illustrate, from fiscal years 1998 through 2000,

- FDA devoted approximately the same level of resources to evaluate the Delaware program as it did to evaluate the Louisiana program, although Delaware produces substantially less shellfish and has experienced far fewer reported cases of shellfish-related illnesses than Louisiana; and
- FDA used slightly fewer resources to assess growing areas, processing plants, and other aspects of New Zealand's shellfish program than it used to assess Chile's program, although New Zealand exports tons of oysters to the United States each year and has reported cases of shellfish-related illnesses from local toxins, while Chile exports about one-seventh as many oysters to the United States and has reported fewer shellfish-related illnesses.

Similarly, FDA does not use the results of its previous state program evaluations to help allocate its shellfish oversight resources. In a summary of its fiscal year 1999 evaluations, FDA identified several states that had significant deficiencies in aspects of their shellfish safety programs. For example, FDA reported that seven states did not have the legal authority to enforce HACCP requirements, four states had failed to collect and/or analyze the required number of growing area water samples, and one state

had not developed an education program to limit illegal harvesting of shellfish in closed growing areas. Several states were deficient in multiple areas. However, the following year (fiscal year 2000), FDA devoted essentially the same level of oversight resources to evaluate each state's program, regardless of the degree of problems the state had previously had in implementing the shellfish safety requirements.

We and other organizations, such as the National Academy of Sciences, have previously reported that including risk as one of several decisionmaking factors can help an agency more efficiently target its oversight resources to activities that have the greatest potential for enhancing food safety.[7] FDA officials said the agency plans to adopt a more risk-based approach to its oversight of states' and foreign countries' shellfish programs. In this regard, they said that near the end of fiscal year 2001, they would begin discussing alternatives for redesigning the program to more effectively target oversight resources. However, at this time, FDA has neither developed a plan nor budgeted resources to study alternative program designs.

FDA Lacks Electronic Access to Information on State Compliance With Some Safety Requirements and Has No Data on the Effectiveness of State Programs

The states currently maintain paper records of shellfish processing plant inspections that show the extent to which processors comply with sanitation and HACCP requirements. However, most states do not enter such information into an electronic database. The lack of electronic data on the results of states' inspections of processing plant limits the states' and FDA's ability to identify statewide and/or national trends in compliance. In the absence of electronic compliance data, FDA relies on its own limited number of plant visits to estimate statewide and national trends in compliance with safety requirements. Despite large differences in the number of processing plants in each state, with some states having more than 150 processing plants, FDA estimated compliance with sanitation and HACCP requirements based on, on average, eight processing plants in each state.[8] According to an FDA official, the agency assessed approximately the same limited number of processing plant inspections in each state because (1) the agency does not have sufficient

[7]See *Food Safety: U.S. Needs a Single Agency to Administer a Unified, Risk-Based Inspection System* (GAO/T-RCED-99-256, Aug. 4, 1999) and *Ensuring Safe Food from Production to Consumption* (National Academy Press, 1998).

[8] The actual number of plants visits in any one state ranged from 3 to 14. FDA evaluated fewer than eight plants only in those states that had fewer than eight commercial plants.

resources to evaluate more and (2) the states requested that FDA use a uniform system of evaluation. FDA has developed electronic systems for recording inspection results in another FDA-state cooperative program and agrees that a similar system for shellfish processors would be beneficial. According to an FDA official, the agency has developed and is currently testing electronic templates and storage capability so that, in the retail foods program, state inspectors using laptop computers can complete inspection reports electronically. The results of individual plant inspections can then easily be compiled electronically into a summary database. FDA plans to wait until this program is fully implemented in the retail foods program before considering adapting it for use in shellfish plant inspections.

Some states also lack sufficient tracking systems for patrols of growing waters. As a result, FDA does not have the data it needs to verify states' compliance with patrol requirements. At its 1999 annual meeting, the ISSC adopted new minimum frequency requirements for patrols that are based on the risk of illegal harvesting from each growing area. In fiscal year 2000, FDA assessed states' compliance with the patrol requirements and found that 14 of the 22 shellfish-harvesting states—including 9 of the top 10 oyster-harvesting states—did not have adequate tracking systems in place to document the frequency of growing water patrols. FDA believes that most states met or exceeded the required patrol frequencies, but without an adequate tracking system in each state, FDA does not have the data needed to verify this belief. Furthermore, without a tracking system, a state's noncompliance will likely remain undetected if it reduces its patrol frequency to a level below the minimum requirement for any reason, such as budget constraints.

In addition to limited access to information on state compliance with shellfish safety requirements, FDA does not collect any data to measure the overall effectiveness of states' and foreign countries' programs in reducing bacteria or illness levels. For example, FDA has no direct measure of whether (1) the growing water classification or processing plant sanitation requirements actually result in safer shellfish or (2) taken as a whole, some states' or foreign countries' programs are more effective in producing safe shellfish than others. Furthermore, although FDA justified HACCP implementation in shellfish processing plants by citing expected reductions in shellfish-related illnesses, the agency has not evaluated HACCP effectiveness either in terms of illness or pathogen reduction.

In our January 2001 report on seafood safety, we reached a similar conclusion—that FDA lacked objective, measurable data to determine whether its HACCP program for seafood is effectively reducing hazards.[9] In that report, we noted that a guiding principal of the Government Performance and Results Act is the use of objective, measurable data to assess how well an organization is achieving its goals. For example, prior to implementing its HACCP program, the U.S. Department of Agriculture determined the prevalence of salmonella bacteria, among others, in meat and poultry so that it could evaluate whether HACCP requirements were effective in lowering bacterial levels and thus lowering risks to consumers.

According to FDA officials, the agency has not attempted to directly measure effectiveness because it has not found reliable and meaningful ways to measure either reductions in bacteria or illness for shellfish. FDA officials said the agency relies on its compliance assessments to determine whether states' and foreign countries' shellfish safety programs are effective in protecting consumers' health. However, compliance data show only what actions were taken by shellfish processors, not whether these actions had the desired impact—safer shellfish. Despite the difficulties associated with measuring reductions in bacteria or illnesses, we continue to believe that such measurements can and should be made. In response to a recommendation in our report on seafood safety, FDA noted that it had tested seafood for salmonella, and plans to test for the presence of other pathogens. In addition, the ISSC plans to measure reductions in illness to determine the effectiveness of its *V. vulnificus* control strategy for raw oysters.

[9] *Food Safety: Federal Oversight of Seafood Does Not Sufficiently Protect Consumers* (GAO-01-204, Jan. 31, 2001).

The ISSC's Efforts to Reduce *V. Vulnificus*-Related Illnesses and Deaths Have Not Been Effective, and the Success of Its Proposed Strategy in the Near Term Is Questionable

V. vulnificus-related illnesses and deaths have continued throughout the past decade despite the ISSC's efforts to reduce them. The ISSC is now developing a strategy that, if adopted, would principally rely on consumer education to meet an illness reduction goal of 60 percent by 2008. If the goal is not met, controls such as subjecting harvested oysters to treatments that will reduce bacteria to nondetectable levels will be implemented. However, past education efforts have not shown any demonstrable reductions in *V. vulnificus*-related illnesses. As a result, it is unlikely that education alone will significantly reduce illnesses by 2008. Options exist that may reduce *V. vulnificus*-related illnesses and deaths more quickly than the proposed ISSC strategy, but each option has advantages and disadvantages.

Initiatives to Reduce *Vibrio vulnificus*-Related Illnesses Have Been Ineffective

During the past 6 years, the ISSC has employed two main strategies to reduce illnesses and deaths associated with *V. vulnificus*. The ISSC has required that oysters be refrigerated within certain time frames after harvest and has implemented programs to educate those at-risk of *V. vulnificus* illness on the dangers of eating raw shellfish. The biggest health concern about *V. vulnificus* is with oysters because they are the type of shellfish that are most often eaten raw and have been associated with most of the reported illnesses and deaths.

Regarding refrigeration, in August 1995 FDA informed the ISSC that additional controls were urgently needed to reduce the risk of illness from *V. vulnificus* in Gulf Coast oysters. Because the level of *V. vulnificus* can increase 10-fold in 3-½ hours and can reach its maximum 100-fold growth in 14 hours at summer temperatures, FDA concluded refrigeration following harvesting is likely to be effective in controlling illnesses if they result from bacterial growth after harvest. Although the amount of *V. vulnificus* bacteria needed to cause illness is unknown, limiting its growth is considered desirable because it may lower the risk of illness. As FDA has demonstrated, immediate refrigeration maintains "at harvest" levels of *V. vulnificus* in oysters. According to FDA, "while immediate refrigeration is probably not practical for many small harvesting vessels, a maximum time at uncontrolled temperatures of 2 hours would allow small harvesting vessels to move their catch to larger vessels with onboard refrigeration."

Shortly after FDA's notification, the ISSC amended the NSSP to include an interim control plan that required oysters to be under refrigeration at 45 degrees Fahrenheit within certain time frames, depending on the water temperature, if the oysters were harvested from a state that was the source of two or more confirmed cases of *V. vulnificus* illness. The

refrigeration time frames, as shown in table 2, ranged from 36 hours when the water temperature was at its lowest—below 65 degrees Fahrenheit—to 6 hours when the water temperature was at its highest—-84 degrees Fahrenheit or greater.

Table 2: 1995 NSSP Post-harvest Refrigeration Requirements for States Subject to Shellfish Temperature Controls

Action level	Water temperature	Maximum hours from harvest to temperature control
Level 1	Less than 65 degrees Fahrenheit	36
Level 2	65 to 74 degrees	14
Level 3	Greater than 74 to 84 degrees	12
Level 4	Greater than 84 degrees	6

Source: National Shellfish Sanitation Program Model Ordinance.

A 1996 ISSC-commissioned evaluation of the refrigeration requirements found that the action level 4, 6-hour requirement reduced bacteria levels in shellfish subjected to it, but refrigeration occurring 12 or more hours after harvest (i.e. levels 1, 2, and 3) did not lower the bacterial levels in shellfish subject to these requirements.

Nonetheless, in 1997, the ISSC modified the temperature control requirement for action level four. The change increased the time from harvest to refrigeration from 6 hours to 10 hours when the water temperature is greater than 84 degrees Fahrenheit. All of the other requirements remained the same. According to the ISSC Executive Director, the modification was made to accommodate concerns from the shellfish industry about difficulties in implementing the 6-hour requirement and because no evidence existed that a 6-hour requirement would be any more effective in reducing illnesses than a 10-hour one. Because the amount of *V. vulnificus* bacteria needed to cause illness is unknown, according to the ISSC, there is no conclusive evidence that the refrigeration controls had any impact on reducing the number of *V. vulnificus*-related illnesses.

According to a September 2000 survey by the Gulf Oyster Industry Council of the five Gulf states—Alabama, Florida, Louisiana, Mississippi, and Texas—all the states have implemented the NSSP's refrigeration controls or have more stringent requirements. For example, Florida limits the time from harvest to refrigeration to 6 hours in June, July, August, and September. However, only Louisiana responded that harvesters were

taking the additional step of voluntarily icing shellfish on harvest boats. Louisiana estimated that 5 percent of its harvesters take this step. Four of the five states said they had no plans to work with harvesters to obtain voluntary icing or refrigeration of shellfish on harvest boats or to offer incentives to add refrigeration capacity to boats.[10]

In addition to refrigeration requirements, the ISSC initiated education programs aimed at reducing *V. vulnificus*-related illnesses and deaths. Beginning in 1996, the ISSC developed and distributed education materials designed to increase the number of high-risk consumers who (1) receive and understand the health message regarding the dangers of eating uncooked shellfish (comprehension) and (2) say they would not eat raw oysters (behavior change). The information was distributed to physicians who were to provide the educational materials to their at-risk patients and counsel them on the potential impacts of eating raw shellfish.

In 1999, the ISSC evaluated the effectiveness of the *V. vulnificus* education campaign.[11] To evaluate the educational materials, the ISSC sent questionnaires to both medical providers and patients. The ISSC received a total of 880 responses—641 from medical providers and 239 from patients. The response rate was 5 percent from providers and less than 1 percent for patients. The report concluded that "if these respondents are representative of persons with liver disease who enjoy eating raw shellfish, then these educational materials, presented by physicians, were effective in persuading those at high-risk to change their behavior." However, because of the very low response rate, statistically valid conclusions cannot be drawn about the effectiveness of the education effort. That is, the survey results cannot be interpreted as providing evidence that the educational materials were an effective way to change high-risk behavior and by so doing reduce the number of illnesses associated with *V. vulnificus*. Furthermore, the ISSC discontinued its efforts to use physicians as the primary means for disseminating educational materials because (1) the process was difficult for states to administer and (2) it was impossible to determine how often the educational material actually reached patients.

[10] Mississippi said it is investigating this issue.

[11] *Vibrio Vulnificus Model Education Campaign: ISSC Final Report*, Interstate Shellfish Sanitation Conference, April 1999.

Between March 1999 and September 2000, the ISSC tried several different approaches to educating high-risk individuals on the dangers of eating raw shellfish. The ISSC (1) printed and disseminated educational materials to at-risk individuals and health care providers, (2) conducted a pilot educational conference on *V. vulnificus* for state and national agencies, and (3) produced and broadcast a 30-second television message on the dangers of eating raw oysters, which reached an audience estimated at 5 million people in Florida, Louisiana, and Texas. The ISSC distributed educational materials to individuals through partnerships with various organizations linked to those at-risk, such as the American Liver Foundation. (Certain diseases, such as liver disease, are very common among those affected by *V. vulnificus*.) For example, the Foundation's Gulf Coast Chapter, located in Florida, distributed over 12,400 brochures through patient support groups, liver transplant centers, and health fairs. However, the ISSC did not measure whether these education activities improved the awareness of the at-risk target population or whether the education efforts led to any behavioral changes.

A September 2000 study by the Gulf Oyster Industry Council also examined the status of some of the *V. vulnificus* public education programs in the five Gulf Coast states. The Council found that all five states required warnings about the risks of eating raw oysters to be posted in restaurants, bars, and similar establishments and that in three states the warning must be on the menu. However, none of the states have studied whether these warnings have had any impact on changing the behavior of at-risk consumers. Despite requiring the consumer warning for the past 2 years, according to FDA data, Texas experienced more reported *V. vulnificus*-related illnesses in 2000 than it had in the past several years.

Even with the NSSP's refrigeration requirements and the ISSC's education efforts, *V. vulnificus*-related illnesses and deaths remain a problem. Between 1994 and 2000, 30 illnesses and 16 *V. vulnificus*-related deaths were reported annually, on average, to FDA. Although fluctuations in reported illnesses and deaths occurred from one year to the next, they have remained relatively constant overall during this period, as shown in table 3. Nearly all of these illnesses and deaths were associated with eating raw oysters.

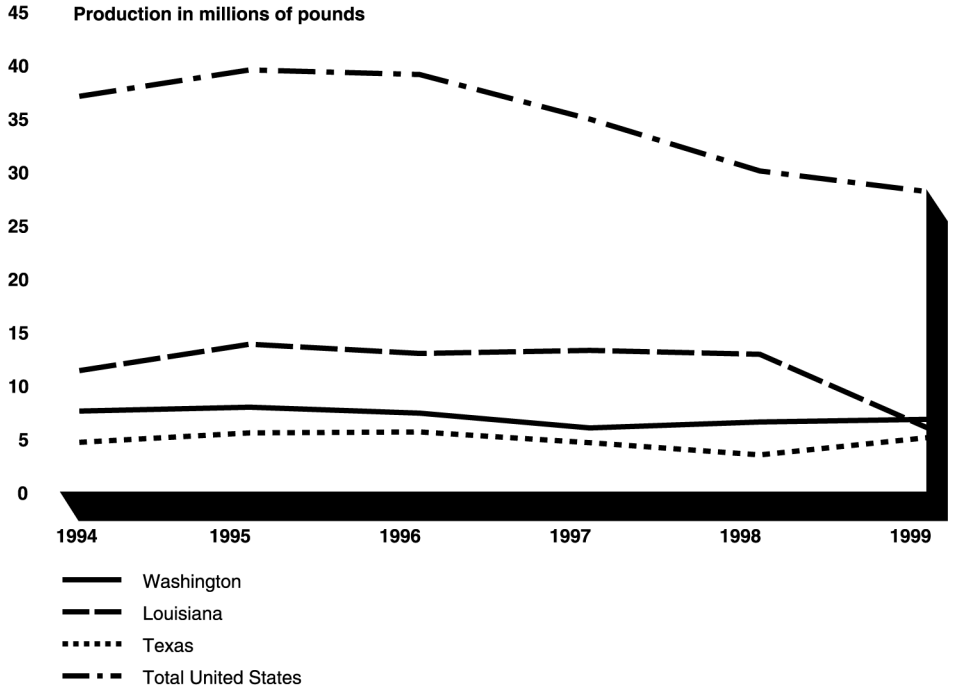
Table 3: *V. vulnificus*-related Illnesses and Deaths From Shellfish Reported to FDA, 1994-2000

Year	Illnesses	Deaths
1994	24	11
1995	32	14
1996	33	23
1997	21	11
1998	40	19
1999	34	20
2000	29	17

Source: FDA.

If the number of illnesses remained relatively constant, but the production and consumption of raw oysters increased, then the rate of illness per pound of oysters would be declining. However, while the level of raw oyster consumption during this time is unknown, between 1994 and 1999 the annual production of oysters remained about the same or declined slightly, as shown in figure 5. Therefore, the available data do not show a reduction in the number or the rate of *V. vulnificus*-related illnesses from 1994 to 1999.

Figure 5: Annual U. S. Oyster Production, 1994-99



Source: National Marine Fisheries Service.

The ISSC's Proposed Strategy Is Unlikely to Reduce *V. vulnificus*-Related Illnesses and Deaths in the Near Term

Recognizing that its efforts have not significantly affected *V. vulnificus*-related illnesses, the ISSC began developing a *V. vulnificus* control plan in 1999. The plan required that states develop a risk management plan for oysters if they have had two or more confirmed *V. vulnificus*-related illnesses since 1995, traced to the consumption of commercially harvested raw or undercooked oysters originating from their waters. The goal of the plan was to reduce the rate of *V. vulnificus*-related illnesses, as measured in certain states (Florida, Texas, California, Louisiana, Georgia, South Carolina, and Alabama), by 40 percent collectively by the end of 2005 and 60 percent collectively by the end of 2007. A consumer education program to convince at-risk individuals to reduce or stop their consumption of raw oysters was the only required activity aimed at achieving the illness reduction goals. The plan also included a number of other elements, such as suggested activities to provide incentives for the shellfish industry to increase its capacity to treat oysters after harvest to reduce *V. vulnificus* bacteria levels.

If the states collectively failed to meet the 60-percent goal by the end of 2007, one of several potential controls, or equivalent measures, considered necessary to achieve the illness reduction goal would have to be implemented. These potential controls include, among others, requiring that during the months of May through September, when *V. vulnificus* levels are known to be highest, (1) all oysters be subjected to post-harvest treatment to reduce *V. vulnificus* bacteria to a nondetectable level, (2) all oysters be labeled "for shucking by a certified dealer," or (3) shellfish growing areas be closed for the purpose of harvesting oysters intended for the raw market.

FDA supported the plan, but on a very close vote, the plan was not adopted by the ISSC at its 2000 annual meeting. Instead, the plan was returned to the ISSC's *V. vulnificus* subcommittee to revise and present it for reconsideration at the July 2001 ISSC annual meeting. The revised plan changed the states in which progress in meeting the illness reduction goal will be measured to California, Florida, Louisiana, and Texas. In addition, the revised plan states that if inadequate progress is being made toward meeting the illness reduction goal, the ISSC's *Vibrio* Management Committee will propose policy alternatives to be considered at the 2005 meeting, such as a reduction in time from harvest to refrigeration and phased-in post-harvest treatment requirements. However, like last year's version, the proposed 2001 control plan contains only one activity the states are required to implement—educate at-risk consumers to reduce or stop their consumption of raw oysters. The plan also allows the states to take whatever other actions they believe are needed to meet the illness reduction goal.

Even if the revised control plan is approved in 2001, it is questionable whether education initiatives alone will result in significant illness reduction because the ISSC has not demonstrated that education has been or will be effective. FDA is also concerned about the ISSC's relying on education alone to achieve its illness reduction goals. According to a letter from FDA to the Chairman of the ISSC, "while we believe that education of consumers and health care professionals should be part of such a strategy, we do not believe that the illness reduction goal (60% reduction by the end of 2007) is likely to be achieved through education efforts alone."

The effectiveness of educating at-risk individuals is also questionable because some individuals may not be aware they are at increased risk. For example, FDA noted that individuals may be at increased risk from eating raw oysters if they have liver disease, which may have no symptoms. Furthermore, according to the Center for Science in the Public Interest, a

consumer advocacy group, alcoholics with liver damage, a significant portion of the at-risk population, are frequently in denial about their condition and therefore unresponsive to consumer education efforts.

Under the ISSC's revised *V. vulnificus* control plan, the date that the states must meet the 60-percent goal for reducing illnesses has been changed from 2007 to 2008.[12] If the plan is approved in 2001, and the states do not meet the goal by 2008, they will be required to implement post-harvest treatment, or equivalent controls, for oysters. As such, the plan includes the goal of providing industry with incentives to help develop post-harvest treatment capacity. The plan calls for developing the capacity by the end of the third year of plan implementation to treat 20 percent of the oysters from certain Gulf Coast states that are harvested between May and September and are intended to be eaten raw. However, the plan does not provide any details on which post-harvest treatment technologies have been shown to be capable of reducing the levels of *V. vulnificus* bacteria to nondetectable levels, what type of incentives, if any, are needed to develop adequate post-harvest capacity, and what actions will be taken should the 20-percent goal not be achieved. Without a detailed plan for developing adequate post-harvest treatment capacity that addresses these issues, among others, the ISSC runs the risk that, come 2008, adequate post-harvest treatment capacity may not exist to meet the illness reduction goal. As such, the states would be required to implement one of the other alternative controls, closing growing areas or diverting oysters to be shucked rather than sold for raw consumption. While these controls would achieve the illness reduction goal, they would have a greater negative economic impact on the oyster industry than post-harvest treatment.

According to an ISSC official, the ISSC plans to create a separate, detailed plan for how states can develop adequate post-harvest treatment capacity after the passage of the proposed *V. vulnificus* control plan. Furthermore, according to an FDA official, the prospect of closing states' shellfish growing waters or requiring shellfish to be shucked instead of sold for raw consumption if the illness reduction goals are not met by 2008 should provide a significant incentive for states to promote, and industry to voluntarily adopt, post-harvest treatment technology well before the deadline.

[12] The date was changed because the ISSC had agreed to a 7 year timeframe for meeting its final illness reduction goal from the year of plan approval. To leave the date as originally proposed in 2000 would have meant reducing the amount of time for meeting the plan's goals.

Options for Reducing Illnesses and Deaths Related to *V. vulnificus* in Shellfish

Two primary options offer the potential for reducing illnesses and deaths more quickly than the proposed ISSC strategy while still maintaining a market for raw oysters—more stringent refrigeration requirements and phasing in mandated post-harvest treatment. Both of these options have a number of advantages and disadvantages.

As mentioned previously, FDA has demonstrated that immediate refrigeration maintains "at harvest" levels of *V. vulnificus* in oysters. Even though a control strategy, such as immediate refrigeration, may prevent the growth of *V. vulnificus* in an oyster, FDA cannot determine whether this will be sufficient to reduce the illness rate because it has no information on the infectious dose of *V. vulnificus*—that is the risk of illness in relation to different levels of exposure to *V. vulnificus*. It is possible that the amount of bacteria present at the time of harvest will be sufficient to cause illness. However, if illnesses are due to the growth of bacteria after harvest, limiting or reducing bacteria growth at that point would clearly reduce illnesses.

While the impact of immediate refrigeration on *V. vulnificus*-related illnesses is not known, a recent FDA study concluded more rapid refrigeration would reduce illnesses associated with a different species of *Vibrio* bacteria. According to FDA's December 2000 draft assessment of the risks posed by *Vibrio parahaemolyticus* in raw shellfish,[13] the most important factor related to the risk of illness caused by *V. parahaemolyticus* is the level of the bacteria found in oysters at the time of harvest.[14] The second most important risk factor— for the Gulf Coast states only—is the amount of time oysters are left unrefrigerated after harvest. FDA's analysis indicated a significant reduction in the probability of illness when oysters are cooled immediately after harvest and kept refrigerated. For the Gulf Coast states, FDA estimated that if oysters were iced or refrigerated aboard ship while harvesting operations continued, the probable number of annual illnesses from *V. parahaemolyticus* would decrease from 3,000 to about 240.

[13] *Draft Risk Assessment on the Public Health Impact of Vibrio Parahaemolyticus in Raw Molluscan Shellfish*, Center for Food Safety and Applied Nutrition, FDA, December, 2000.

[14] Unlike potential victims of *V. vulnificus*, those at risk of illness from *V. parahaemolyticus* are not limited to persons with underlying health conditions. *V. parahaemolyticus* can cause diarrhea, vomiting, or abdominal cramps, but the symptoms usually end without treatment and are of moderate severity and short duration.

The disadvantages of requiring more rapid refrigeration include (1) no guarantee that illnesses from *V. vulnificus* in shellfish would be reduced, (2) logistical challenges associated with equipping oyster-harvesting boats with manual or mechanical refrigeration, and (3) costs to the oyster industry to comply with the requirements.

Regarding post-harvest treatment, three different processes designed to reduce *V. vulnificus* bacteria to nondetectable levels are currently in limited, voluntary, commercial use in the Gulf region: (1) hydrostatic pressure, (2) a mild heat treatment known as cool pasteurization, and (3) cryogenic individual quick freezing. Mandating post-harvest treatment of all oysters destined for the raw market may result in a quicker reduction in *V. vulnificus*-related illnesses than would be achieved under the ISSC's proposed plan.[15] Such a plan could be phased in and include incentives to build up treatment capacity over time. Furthermore, according to a March 2000 report by the Research Triangle Institute on the economic impacts of requiring post-harvest treatment of oysters, oyster processors would benefit from such treatment because "revenues are estimated to rise more than the increase in costs associated with the treatment technologies."[16] The report estimated that the cost of treatment of raw half-shell oysters would range from 3.3 cents to 17.7 cents per oyster, and the cost for treatment of shucked oysters would range from a decrease of 2.9 cents to an increase of 0.2 cents per oyster, depending on the technology used and the region of the country. Net revenues are estimated to increase because (1) two of the treatment processes, hydrostatic pressure and cool pasteurization, actually reduce the costs of producing shucked oysters and (2) companies that use post-harvest treatment reported obtaining between 1 and 2 cents more for treated shucked oysters and between 3 and 7 cents more for treated, raw, half-shell oysters.

This approach's disadvantages include, according to the March 2000 Research Triangle Institute report, (1) a potential decrease in demand for treated oysters by some types of consumers, which could have a negative economic impact on the industry, and (2) the potential shutdown of some processing plants because they lack the resources to install and maintain

[15] Post-harvest treatment requirements could be applied only to those states that have had *V. vulnificus*-related illnesses linked to their shellfish and/or to certain times of the year when *V. vulnificus* levels are known to be highest.

[16] *Economic Impacts of Requiring Post-Harvest Treatment of Oysters: Final Report*, Research Triangle Institute, March 2000.

post-harvest treatment equipment or because revenues are not sufficient to cover production and treatment costs. In addition, some industry groups are concerned that mandating post-harvest treatment would eliminate the option for consumers to purchase raw, untreated oysters. While the production of untreated oysters would not be eliminated throughout the United States if post-harvest treatment was required only in certain states during certain months of the year, consumers in those states required to treat oysters may find it more difficult or expensive to purchase untreated, raw oysters.

Conclusions

By providing uniform and equal oversight of the 30 states and four countries that produce shellfish for the U.S. market, FDA is not using its limited resources wisely. States' and foreign countries' shellfish programs pose different levels of risk for consumers, requiring more intensive oversight for some states and countries than for others. However, FDA has not made use of available data on compliance with safety requirements by states and foreign countries and has not developed data on the effectiveness of states' and foreign countries' programs in reducing bacteria levels in shellfish or related illnesses. Such information would enable FDA to target its resources on those areas presenting the highest level of risk.

V. vulnificus—the most deadly of shellfish-related illnesses—continues to pose a significant risk for some individuals. The ISSC's proposed strategy, yet to be formally adopted, may not significantly reduce *V. vulnificus*-related illnesses until after 2008, when proven control measures will be required. However, even then, capacity to implement one such control, post-harvest treatment, may not be available, and the ISSC does not yet have detailed plans for ensuring such capacity. Without adequate capacity, alternate control measures, such as eliminating the sale of raw oysters during certain months, would be required. The fact that such alternatives would have a greater negative economic impact on the oyster industry could create pressure to postpone their implementation.

Recommendations for Executive Action

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

- adopt a risk-based approach to overseeing states' and foreign countries' shellfish safety programs that includes

- a standardized, automated system to capture the results of states' and foreign countries' inspections of processing plant and patrols of growing water; and
- baseline data, such as the results of regular shellfish microbial tests, to assess over time the effectiveness of states' and foreign countries' shellfish safety programs, including HACCP.

- work with the ISSC to prepare and implement a detailed plan for developing adequate post-harvest treatment capacity to help achieve the ISSC's goals for reducing illnesses

Agency Comments and Our Evaluation

We provided FDA and the ISSC a draft of this report for their review and comment. Both FDA and the ISSC generally concurred with the draft report's recommendations. However, the ISSC raised concerns about the draft report's characterization of some information. FDA's and the ISSC's written comments and our responses are contained in appendixes II and III, respectively. FDA and the ISSC also provided technical comments, which we incorporated into the report as appropriate.

FDA generally concurred with our recommendations, although it said that in some cases additional study and/or consultation with the ISSC would be necessary to determine the feasibility of implementing them. Specifically, FDA concurred with our recommendation that the agency adopt a risk-based approach to overseeing states' and foreign countries' shellfish safety programs. FDA also acknowledged the merits of our recommendation that it develop and implement an automated system for capturing the results of states' shellfish plant inspections and growing water patrols. FDA said it will assess the costs and benefits of such a system for the shellfish program when information about similar projects it already has under way for other programs has been evaluated. Regarding our recommendation that it gather data to assess the effectiveness of state and foreign country shellfish safety programs, such as the results of microbial tests, FDA responded that additional testing for Norwalk-like viruses, the most common sources of illnesses from molluscan shellfish, is not feasible at this time, although the agency is working on new testing procedures. Nonetheless, FDA said it will review, in consultation with the ISSC, whether testing (1) of shellfish growing waters for other pathogens, such as salmonella, and (2) of shellfish meats, as the Europeans now do, should be added to the program. Finally, FDA agreed with our recommendation that it work with the ISSC to prepare and implement a detailed plan for developing enough post-harvest treatment capacity to help achieve the ISSC's illness reduction goals.

The ISSC concurred with the draft report's recommendation that FDA (1) adopt a risk-based approach to overseeing states' and foreign countries' shellfish safety programs, (2) develop and implement an automated system for capturing the results of states' shellfish plant inspections and growing water patrols, and (3) work with the ISSC to prepare and implement a detailed plan for developing adequate post-harvest treatment capacity to help achieve the ISSC's goals for reducing illnesses. In response to our recommendation that FDA gather data, such as microbial test results, to measure program effectiveness, the ISSC said that while it welcomes meaningful effectiveness measures, it questions the practicality of using bacterial levels in shellfish to measure effectiveness. Nonetheless, the ISSC said it will investigate with FDA the development of program effectiveness measures. We recognize the difficulties inherent in obtaining effectiveness data but believe it is critical to identifying program shortcomings and strengths and making required changes over time. Effectiveness measures may be the results of microbial tests or other indicators that the ISSC and FDA believe are appropriate.

The ISSC did not agree with some information or characterizations of issues made in the draft report. For example, the ISSC did not agree with the draft report's citation of FDA's estimate that shellfish cause over 100,000 illnesses each year. The draft report clearly states that FDA's shellfish-related illness figure is an estimate made in 1995. Norwalk viruses associated with shellfish consumption make up the vast majority of FDA's estimate and are frequently not reported. CDC has no data on the level of such nonreporting and thus has not made any estimate of such illnesses. Nonetheless, we modified the report to note that the ISSC believes FDA's estimate significantly overstates the annual number of shellfish-related illnesses.

The ISSC was also concerned about, among other issues, the draft report's characterization of its proposed strategy as relying primarily on education to reach its V*. vulnificus* illness reduction goal by 2008. The ISSC said education is only one of the components of its strategy and that the plan includes intermediate goals and assessments prior to 2008. However, it acknowledged that education is the only mandatory component of its plan. Our draft report states that the proposed plan establishes an interim illness reduction goal and allows the states to adopt additional controls beyond education. Nonetheless, because education is the only required activity contained in the proposed plan, we continue to believe that at this time the plan relies primarily on education to meet the illness reduction

goals. Whether any additional actions are taken by the states or the ISSC in the future remains to be seen.

We conducted out review from August 2000 through June 2001 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 Secretary of Health and Human Services; the Director, Office of Management and Budget; and other interested parties. We will also 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 IV.

Lawrence J. Dyckman
Director, Natural Resources
and Environment

Appendix I: Scope and Methodology

To evaluate the Food and Drug Administration's (FDA) approach to oversight of state and foreign country shellfish safety programs, we reviewed the existing shellfish safety policies contained in the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish, and the Hazard Analysis and Critical Control Point regulations that apply to shellfish processing plants, among other relevant shellfish safety policy and guidance documents. We visited six states—Florida, Louisiana, New Jersey, New York, Texas, and Washington—to gather information on the state's implementation of shellfish safety requirements and FDA's approach to oversight of the states. During 1999, these six states collectively produced about 65 percent of the nation's shellfish. In each of these states we interviewed state officials responsible for shellfish safety, gathered documentation regarding program implementation, and visited shellfish processing plants. We reviewed FDA's evaluation reports of states' and foreign countries' shellfish safety programs for fiscal years 1998, 1999, and 2000 and discussed the findings with state and FDA officials. We interviewed officials in FDA's Center for Food Safety and Applied Nutrition, Office of Seafood and Office of Field Programs. In addition, we interviewed officials in FDA's Office of Regulatory Affairs, Division of Federal-State Relations, including FDA staff who conduct the evaluations of the state and foreign country shellfish safety programs. We also interviewed officials and reviewed documents from the Interstate Shellfish Sanitation Conference (ISSC) and the shellfish industry.

To evaluate the ISSC's strategy for reducing illnesses and deaths associated with *V. vulnificus* bacteria, we reviewed scientific information regarding the bacteria's prevalence and impact on human health. We reviewed documentation of the ISSC's efforts to educate those at risk from *V. vulnificus* to avoid eating raw shellfish as well as policies regarding temperature control of harvested shellfish to reduce bacterial growth. We visited the three states—Florida, Texas, and Louisiana—that have been the source of nearly all of the reported *V. vulnificus*-related illnesses from shellfish that could be traced to a particular state. In each of these states we met with state officials responsible for shellfish safety as well as shellfish industry officials, including some who have begun to treat oysters post-harvest to kill bacteria. We also interviewed ISSC and FDA officials regarding the history of the policy initiatives designed to reduce *V. vulnificus*-related illnesses.

Appendix II: Comments From the Food and Drug Administration

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUN 22 2001

Mr. Lawrence J. Dyckman
Director
Natural Resources and Environment
United States General Accounting Office
441 G Street, NW
Washington, DC 20548

Dear Mr. Dyckman:

Please find the enclosed comments from the Food and Drug Administration on the General Accounting Office (GAO) draft report entitled, Food Safety: Federal Oversight of Shellfish Safety Needs Improvement (GAO 01-702).

If we can be of further assistance, please call Ms. Cathy Songster at (301) 827-5262.

Sincerely yours,

Theresa M. Mullin, Ph.D.
Acting Associate Commissioner
for Planning

Enclosure

FOOD AND DRUG ADMINISTRATION COMMENTS ON THE GENERAL ACCOUNTING OFFICE DRAFT REPORT ENTITLED, FOOD SAFETY: FEDERAL OVERSIGHT OF SHELLFISH SAFETY NEEDS IMPROVEMENT (GAO-01-702)

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

GENERAL COMMENTS

The National Shellfish Sanitation Program (NSSP) is a cooperative program among the FDA, State and foreign shellfish regulatory authorities, and the molluscan shellfish industry. It was established in the 1920's, principally in response to large outbreaks of typhoid fever and other bacterial diseases related to the consumption of sewage-contaminated molluscan shellfish.

By far the most important component of the program is surveillance of the shellfish growing waters for contaminants that would warrant closure of the waters until the abatement of the contaminant. Because the literally thousands of miles of growing waters are State resources, the States have historically assumed responsibility for the day-to-day operation of the program, with FDA assuming the role of auditor of the State programs. FDA has never vested the States or the ISSC to act on its behalf; nonetheless, FDA has elected to work cooperatively with the States on shellfish safety and therefore generally tries to work within the ISSC framework when developing or implementing shellfish safety policy.

In the decades since its establishment, the program has proven to be effective in preventing the reoccurrence of this type of illness, primarily through the opening, closing, and patrol of shellfish harvesting waters. Similarly it has essentially eliminated the occurrence of illness from the natural toxins, such as "red tide," that at times affect molluscan shellfish. In this regard, the NSSP provides a public health benefit from a relatively small Federal commitment. The total budgets for all of the State programs have been estimated to be around $100 million, while the Federal expenditure is under $10 million.

Nevertheless, FDA agrees with the GAO that this program can and should be improved, and that FDA's efforts ought to be "risk-based." New public health concerns have provided considerable challenges to the original, conventional strategies of the program. For example, sewage-based viral pathogens such as Norwalk-like virus are extremely difficult to detect directly with today's technology; and whether these viruses are likely to be present in the water – and thus in the shellfish – must be inferred from "indicators" that are less than perfect. We continue to look for better ways of knowing whether pathogenic viruses are present. Another major challenge is how to control pathogens that are unrelated to sewage, such as *Vibrio vulnificus*, for which potential growing water

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monitoring strategies are still not well understood. FDA will continue to work with the ISSC to develop and implement solutions to these and other public health challenges.

We also agree with GAO that *Vibrio vulnificus*, in particular, represents an important public health issue that needs to be effectively addressed. GAO correctly quotes the FDA that we have communicated to the ISSC that education alone is not likely to fix this problem.

GAO RECOMMENDATIONS

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

Adopt a risk-based approach to overseeing state and foreign country shellfish safety programs that includes

- A standardized, automated system to capture the results of states' and foreign countries' inspections of processing plant and patrols of growing water; and
- Baseline data, such as the results of regular shellfish microbial tests, to assess over time the effectiveness of states' and foreign countries' shellfish safety programs, including HACCP.

FDA COMMENT

FDA concurs in part. The Agency's comments will address each aspect of the proposal individually:

Risk-based approach generally. FDA agrees in principle with the idea of a "risk-based" approach as the GAO uses the term, i.e., an approach that focuses more resources on problem areas and areas of higher risk than on non-problem areas and areas of lower risk. As the GAO points out, FDA audits tend to involve roughly the same expenditure of resources for all states, regardless of size of shellfish program or compliance history. Similarly, all foreign audits involve roughly the same expenditure of resources. The concern is that, by allocating resources in this manner, FDA might not be devoting enough resources to potential problem areas.

FDA's traditional approach relies in part on the fact that, through decades of experience, FDA shellfish specialists have in-depth knowledge of the states and countries that they audit; thus, one principal function of an audit is to look for changes, either pro or con, from the previous audit. FDA's specialists are able to do this quite efficiently. Consequently, the Agency is confident that its audit approach can and does detect problems in a timely manner.

See comment 1.

The same principle holds true for audits of foreign programs. The GAO draft appears to conclude that FDA has inadequate information on the status of the New Zealand program; however, in the past four evaluations, conducted over the course of eight years,

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FDA has evaluated/inspected nearly every growing area and processing plant in that country's program. FDA's knowledge of New Zealand's program is extensive.

Nonetheless, the Agency has been considering for some time how and whether it can expand and contract its audits to take various risk and compliance factors into account and thus build additional efficiencies into the system. Also, it is possible that the prospect of a reduced audit the next year, or a greater time interval between audits, as a result of good performance on this year's audit, would serve as an additional incentive for States and Foreign countries to operate excellent programs. The Agency is in the process of reviewing the compliance program for the molluscan shellfish program and will consider modifications to address this issue. A likely early step will be to more closely link the numbers of operations performed (e.g. number of processing plant inspections) to the size of the industry and/or resource. FDA will initiate discussions with the ISSC on the topic of transition to a risk-based system at the Conference in July 2001, and will take interim steps to pilot such a system before that time.

A standardized, automated system: FDA acknowledges the benefits of electronic systems for capturing these kinds of data and is in the process of investigating, piloting, and implementing a number of similar systems. In FDA's Seafood HACCP Program for fish and fishery products other than molluscan shellfish, FDA Investigators, as well as State sanitarians operating under partnership agreements or contracts with FDA, complete standardized forms containing detailed information on the results of HACCP inspections. The completed forms are faxed to FDA's Office of Seafood, where they are electronically entered into a national database. A pilot is about to begin that will test the feasibility of transmitting data directly from a PC in a field office to the central database. If the pilot is successful, FDA plans to expand this arrangement to all FDA District Offices and cooperating State regulatory agencies.

Each of these projects has involved considerable work to resolve: logistical difficulties (e.g. differences in operating systems); security and privacy issues; resource concerns (e.g. funds to provide sufficient computers to FDA District Offices and some State regulatory agencies and time for data entry); and concerns by some State regulatory agencies (e.g. to either share their data with FDA or to take the time necessary to enter the data). Any program to develop an electronic program for molluscan shellfish processing plant inspection and growing area patrol data would face similar challenges. FDA will assess the costs and benefits of undertaking such a project when information about the similar projects already underway has been evaluated.

It must be remembered that neither States nor sovereign foreign nations can realistically be mandated to adopt automated data systems of FDA's choosing. Fortunately, the reliance on paper has not, up to this point, prevented the Agency from drawing reasonable conclusions about the status of the programs it audits. For example, while GAO is correct that a number of States do not have tracking systems in place that are designed to document the frequency of patrol in individual shellfish growing areas, FDA's shellfish specialists have been able to determine that patrol frequencies were

See comment 2.

adequate by examining documents maintained for other purposes, such as patrol officer log sheets.

Baseline data, involving testing, to evaluate the program: It is important to recognize that the molluscan shellfish program already relies on extensive testing as a prerequisite to marketing. Because of the critical connection between water quality and product safety, water testing occurs on a regular basis as a principal means of determining whether harvesting may or may not occur. The issue that GAO is raising is whether additional, direct testing of product should be added.

GAO's recommendation raises a number of issues. For example, water closure based on indicator bacteria, coupled with findings from shoreline surveys that inventory potential pollution sources, is the only practical way to protect consumers of raw molluscan shellfish from Norwalk-like viruses. Currently, viruses are not practically detectable in shellfish. (While it is possible to detect viruses using state-of-the-art molecular technology, this process is very new, difficult, and expensive and few laboratories have the expertise to do it.) Consequently, for the most common source of illness from molluscan shellfish, additional testing is not feasible at this time. However, we are working on testing procedures.

Unlike viruses, a range of pathogenic bacteria, such as salmonella, could be tested for, although at some expense. Their presence in growing water tend to be more variable than the presence of the indicator bacteria; consequently, it is more likely that testing will detect the indicator even when the pathogenic bacteria are not present than vice versa. For that reason, closing water when certain levels of indicator bacteria are detected is regarded as a conservative public health approach. Because the testing is for a single indicator bacteria and not for a range of pathogens, it can be performed repeatedly throughout the year at a manageable cost.

The Agency will review, in consultation with the ISSC, whether direct testing should be added to the program. In all likelihood, this testing would have to be financed through State revenues as part of their programs.

Another possibility would be to add testing of the shellfish meats, in addition to the water, for the indicator bacteria, as the Europeans now do. FDA's Dauphin Island laboratory is conducting an evaluation of the relative merits of water testing vs. meat testing in order to better understand the strengths and weaknesses of the European system versus the North American system of water testing. This study is still ongoing.

GAO RECOMMENDATION

Work with the ISSC to prepare and implement a detailed plan for developing adequate post-harvest treatment capacity to help achieve the ISSC's goals for reducing illness.

FDA COMMENT

FDA agrees with this recommendation. The ISSC continues to work on the development of a package of incentives for voluntary post-harvest treatment (PHT) of Gulf Coast oysters in order to achieve the *Vibrio vulnificus* illness reduction goals contained in the proposal to be deliberated at this year's conference. As GAO notes, the proposal includes a target of 20% PHT of Gulf Coast oysters intended for raw consumption during the key illness months in 3 years.

Over the course of the past year, a committee of the ISSC and its Executive Board have expended considerable effort to refine the Conference's plan for ensuring that there is sufficient PHT capacity to meet the proposed goals. To date, the ISSC has taken the following actions in this regard:

- Agreed to fund a project that will bring together PHT processors and prospective wholesale buyers of the product in order to establish markets for PHT oysters;
- Developed a proposal that will be considered for adoption by the ISSC this year that would establish acceptable labeling for PHT product. Labeling that would explain to the consumer the difference between a PHT oyster and a non-treated oyster is regarded as a fundamental marketing incentive for the industry to produce PHT product.
- Developed an FDA-supported proposal that will be considered for adoption by the ISSC this year that would: (1) bring consistency to the way in which PHT processes are validated for special labeling; (2) ensure that processors would not face different validation standards in the states in which their product is sold; and (3) make clear what scientific standard a processor should follow in order to validate the process.
- Agreed to fund an independent taste-test of PHT and non-PHT product that can be used for marketing purposes. This would provide oyster processors with better information about how consumers like the PHT oysters in comparison to the traditional non-treated ones.

As part of this effort, FDA has:

- Agreed to expedite the review of the petition to permit irradiation as a PHT;
- Initiated research to measure the effectiveness of hydrostatic pressure processing as a PHT to reduce Vibrio vulnificus levels in oysters.

TECHNICAL COMMENTS

1. Page 2, 3rd line, delete "laws" and replace with "own program requirements." Changes to the Model Ordinance tend to be technical and detailed, and only infrequently necessitate changes in State statute.

5

2. Page 6, the map of shellfish harvesting and processing states: Virginia should be characterized as one of the "states harvesting and processing shellfish."

GAO's Comments

1. Our draft report does not conclude that FDA has inadequate information on the status of the New Zealand program. We mention the New Zealand program only as an example of a foreign program that receives essentially the same level of FDA oversight as other foreign programs, despite the fact that it is a much bigger oyster exporter to the United States and has reported more shellfish-related illnesses than, for example, Chile.

2. While it may be possible for FDA to assess compliance with patrol frequency requirements through a manual review of documents maintained for other purpose, we continue to believe that an automated system for tracking patrol frequencies would provide more accurate, timely information that would be more easily accessible to FDA's shellfish specialists.

Appendix III: Comments From the Interstate Shellfish Sanitation Conference

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

Interstate Shellfish Sanitation Conference
209-2 Dawson Road, Columbia, SC 29223
Phone (803) 788-7559 Fax (803) 788-7576
Email: ISSC@ISSC.org

June 26, 2001

Lawrence J. Dyckman, Director
Natural Resource and Environment
United States General Accounting Office
441 G Street, NW
Washington, DC 20548

Dear Mr. Dyckman:

Thank you for providing the Interstate Shellfish Sanitation Conference (ISSC) an opportunity to review and comment on your draft report entitled, "Food Safety: Federal Oversight of Shellfish Safety Needs Improvement (GAO-01-702)".

The Executive Board of the ISSC has reviewed the report and their comments have been incorporated into the attached document. FDA has a representative on the Executive Board, however the agency did not participate in this ISSC review. The report focuses on two major areas, FDA oversight of Domestic and Foreign Shellfish Programs and ISSC efforts to reduce *Vibrio vulnificus* related illnesses and deaths. The comments are formatted consistent with the draft report.

The ISSC is in general agreement with your recommendations regarding the two major topics of your report. However, in several instances the Conference disagrees with your explanation of FDA, State, and ISSC involvement in the National Shellfish Sanitation Program. We also do not agree with many of your characterizations related to FDA oversight and the *V. vulnificus* issue. Regardless, we will continue to work with FDA to find effective risk-based methods for evaluating the appropriateness of the guidelines and implementation of the NSSP. We are also committed to reducing illness associated with *V. vulnificus* and will continue our efforts to explore appropriate measures which can be implemented to address illnesses associated with this organism.

The ISSC Executive Board and membership appreciates your efforts in preparation and communication in the development of this report. Your efforts were thorough and the depth of knowledge obtained by your staff is to be commended. Should you have any questions on comments regarding this response, please contact Ken B. Moore, ISSC Executive Director or me at 508-563-1779 Ext. 122.

Sincerely,

J. Michael Hickey, Chairman
ISSC Executive Board

JMH:ch

cc: ISSC Executive Board
Ken B. Moore, Executive Director
Vibrio Management Committee

INTERSTATE SHELLFISH SANITATION CONFERENCE COMMENTS ON THE
GENERAL ACCOUNTING OFFICE DRAFT REPORT
"FEDERAL OVERSIGHT OF SHELLFISH SAFETY NEEDS IMPROVEMENT"
GAO/01-702

The Interstate Shellfish Sanitation Conference (ISSC) welcomes and appreciates the opportunity to review and comment on the General Accounting Office's (GAO) draft report. The ISSC is in general agreement with your recommendations regarding the two major topics of your report. However, in several instances the Conference disagrees with your explanation of FDA, State, and ISSC involvement in the National Shellfish Sanitation Program. In addition to specific responses to the report, we have included a number of general comments.

GENERAL COMMENTS

The National Shellfish Sanitation Program (NSSP) was developed in 1925 when the U. S. Public Health Service responded to a request for assistance from local and state public health officials in controlling typhoid fever and other bacterial diseases associated with the consumption of raw molluscan shellfish (oysters, clams, and mussels.)

The public health control procedures established by the Public Health Service were dependent on the cooperative and voluntary efforts of State regulatory agencies. These efforts were augmented by the assistance and advice of the Public Health Service (now the Food and Drug Administration) and the voluntary participation of the shellfish industry. These three parties combined to form a tripartite cooperative program. The guidelines of the program have evolved into the NSSP Handbook which is managed and updated by the ISSC. The cooperative nature of the NSSP allows FDA to administer a domestic and international program with a relatively small federal commitment.

In the many years since its establishment, the program has proven to be effective in minimizing the reoccurrence of illness associated with bacterial pathogens originating from human waste. The NSSP has also responded and essentially eliminated the occurrence of illness from natural toxins associated with Harmful Algae Blooms. The ISSC, NSSP and FDA continue to face new challenges in assuring that molluscan shellfish are safe for human consumption. Naturally occurring pathogens, particularly *Vibrio parahaemolyticus* and *Vibrio vulnificus* are one of those challenges we must address. Our commitment has not changed since 1925. The ISSC Vibrio Management Committee is aggressively pursuing effective and appropriate strategies that will address this food safety concern.

(1) Letter to the Honorable Richard G. Lugar:

Page 1. Molluscan shellfish—oysters, clams, mussels, and scallops—cause over 100,000 illnesses annually, according to the most recent available estimates from the Food and Drug Administration (FDA).

- The ISSC is very aware of the potential risk of eating raw shellfish and recognizes that raw molluscan shellfish are among the most hazardous of all potentially hazardous foods. The Conference does not concur with the projection that molluscan shellfish cause over 100,000 illnesses each year. In this case, perhaps the best way to reality test this estimate is to consider the likelihood that 275 people are getting sick every day from raw molluscan shellfish (100,000 divided by 365 days). In most cases, shellfish related illness occurs in outbreaks. If over 100,000 illnesses were occurring, we would be observing an ongoing repetition of national outbreaks. However, no such outbreak have been detected. The ISSC continues to be concerned by the use of these purported but not confirmed projections based on extrapolations rather than simply reporting the actual numbers of illnesses or rates of illness per unit population or some other

See comment 1.

customary index. State illness surveillance systems traditionally have been used to assess significant changes in illness patterns for the purpose of allocating resources. Significant changes in illness outbreak patterns provide more important information than does total numbers of illnesses. The ISSC encourages others to recognize this premise.

(2) Results in Brief

(a) Page 3. FDA officials said that they have not yet moved to a risk-based approach to overseeing shellfish safety programs in part because the states wanted to receive uniform FDA oversight.

- Your statement infers that the states want to receive uniform intensity in FDA oversight is somewhat misleading. The states do not want the same level of intensity of FDA oversight. Rather, uniformity to states means consistency by FDA in evaluating individual state program findings. States are not opposed to a risk-based approach in any food safety program.

See comment 2.

(b) Page 3. Currently, FDA does not have sufficient information, such as results of all plant inspections in the 30 states and for the four exporting countries, to assess the extent of compliance with some safety requirements.

- The ISSC believes FDA has access to sufficient information to assess the extent of compliance, however, we acknowledge the Agency may not use a sufficient amount of the information to conduct statistically valid analysis. We suggest you replace the word "have" with "use".

See comment 3.

(c) Page 3. The ISSC is now developing a strategy that, if adopted, would rely primarily on educating at-risk consumers, to reach the goal of reducing the number of *V. vulnificus* related illnesses and deaths by 60 percent by 2008.

Now on p. 4.

- The ISSC strongly disagrees with this statement. Education is but one component of a strategy to reduce illnesses and deaths caused by *V. vulnificus*. The ISSC does not have one view on the effectiveness of education. While education is clearly part of the strategy, the reason why it is the only mandatory component at this point is because it is already ongoing and can be implemented by states within existing state statutory authorities. Other controls that could be phased in may require new regulations or laws, and states will need time to make these mandatory.

See comment 4.

- The ISSC and GAO seem to agree that a broad series of controls and strategies are needed to control the *V. vulnificus* problem. It must be emphasized that active attempts to bring about other control measures (PHT, icing, targeted closures) are all progressing simultaneously with the educational consumer awareness initiative. The Conference's primary disagreement with GAO on the *V. vulnificus* issue appears to be on the appropriate method and timeframe for implementation.

- The present plan includes intermediate goals and assessments, which will occur sooner than 2008.

(d) Page 4. However, if the states rely on education alone, it is questionable whether significant illness reductions will be achieved prior to 2008 because the ISSC's past education efforts have not demonstrated that education is likely to have this effect.

2

Two strategies—mandating refrigeration of oysters shortly after harvest and requiring immediate phase-in of post harvest treatment—may reduce *V. vulnificus*-related illnesses and deaths more quickly than the proposed ISSC strategy.

- These strategies are a part of the ISSC proposal. The ISSC and GAO disagreement is relative to the determination of the appropriate strategy and timeframe for implementation. The ISSC appreciates GAO's comments and suggestions. Issue 00-201 will be discussed at the ISSC meeting in July and your suggestions could possibly be incorporated.

(3) Background

Now on p. 7.

(a) Page 8. In 1995, FDA estimated that shellfish caused over 100,000 illnesses and cost the nation about $201.9 million annually.

See comment 1.

- Refer to comment (1) (a). It is difficult to attempt to estimate these numbers when such little scientific supporting information exists to support the estimates.

Now on p. 7.

(b) Page 8. Table 1: Principal Pathogens and FDA's Estimates of Associated Cases of Shellfish-Related Illnesses, 1995

See comment 1.

- Same comment as 1(a).

Now on p. 8.

(c) Page 9. The annual number of reported illnesses and deaths is somewhat higher at the end of this time period than at the beginning as shown in Figure 3, page 9 of the report. It is not known whether this increase is due to better reporting, greater shellfish consumption, or an actual increase in the rate of shellfish-related illnesses.

See comment 5.

- This statement is phrased in a way which might suggest the rate of shellfish-related illnesses has increased. The ISSC disagrees. We projected that the number of reported cases would increase as a result of attention the issue has received from ISSC, FDA, consumer groups, physicians, the media and others. The rate of increase has been much below what we anticipated.

(4) Weaknesses Exist in FDA's Oversight of Domestic and Foreign Shellfish Programs

Now on p. 11.

(a) Page 12. Several weaknesses exist in the way FDA oversees states' and foreign countries' efforts to ensure shellfish safety. First, FDA has not adopted a risk-based approach to overseeing state and foreign country shellfish programs. Although risk-based approaches are generally recognized as the most effective method for targeting limited resources, FDA's oversight approach is based on essentially equal treatment of all participants in the shellfish safety program. Second, FDA lacks sufficient information on states' and foreign countries' compliance with some NSSP safety requirements and has no data on the effectiveness of state/foreign country shellfish safety programs. Both of these weaknesses limit FDA's ability to allocate its oversight resources to most effectively reduce the risk of consumers becoming ill from eating unsafe shellfish.

See comment 6.

- The Conference agrees that FDA has not adopted a risk-based approach. We disagree, as in 2(b), that FDA lacks sufficient information on state and foreign compliance and has no data on the effectiveness of state/foreign country shellfish safety programs. It may be that we do not agree on the appropriate measures for effectiveness. We also disagree that these two

findings should be considered weaknesses. We agree they represent areas which need improvement.

Now on p. 13.

(b) Page 14. FDA relies on its own limited number of plant visits to estimate statewide and national trends in compliance with safety requirements.

See comment 7.

- FDA routinely conducts file audits of state inspections. This information is also used by the Agency in its evaluation of compliance.

Now on p. 13.

(c) Page 14. According to an FDA official, the agency assessed approximately the same limited number of processing plant inspections in each state because (1) the agency does not have sufficient resources to evaluate more, and (2) the states requested that FDA use a uniform system of evaluation.

See comment 8.

- While we agree FDA assessed approximately the same number of processing plants in each state, we think the number is sufficient to evaluate a state program. Different plants are evaluated in different years. The purpose of the FDA visit is not to regulate the plants but to assess the ability of the state program to implement the requirements of the NSSP. The number of plants chosen in conjunction with historical information should provide an adequate amount of information for a state program evaluation. We agree trend analysis could be a helpful tool for the FDA. The ISSC will support FDA efforts to improve this area of their audit effort.

Now on p. 14.

(d) Page 15. Although FDA believes that most states met or exceeded the required patrol frequencies, without adequate tracking systems in each state, FDA does not have the data needed to verify this belief. Furthermore, without a tracking system, states' noncompliance will likely remain undetected if a state reduces its patrol frequency to a level below the minimum requirements for any reason, such as budget constraints.

- As you indicated the ISSC has developed a risk-based system for determining frequency of patrols. We are continuing to improve this element of the program and will discuss development of an effective tracking system. We appreciate your comments.

(e) In addition to limited access to information on state compliance with shellfish safety requirements, FDA does not collect any data to measure the overall effectiveness of state and foreign country programs in reducing bacteria or illness levels. For example, FDA has no direct measure of whether (1) the growing area water classification or processing plant sanitation requirements actually result in safer shellfish or (2) taken as a whole, some states' or foreign countries' programs are more effective in producing safe shellfish than others.

See comment 9.

- While the Conference would welcome a meaningful measure of effectiveness, we question the practicality of using bacterial levels in products consumed raw or illness as a measure of effectiveness (Particularly when the rate of illnesses per unit population is so small.) The Conference and FDA will discuss and investigate the development of performance measures.

Now on p. 15.

(f) Page 16. According to FDA officials, the Agency has not attempted to directly measure the effectiveness because they have not found reliable and meaningful ways to measure either reductions in bacteria or illnesses for shellfish. FDA officials said the Agency relies on its compliance assessments to determine whether state or foreign safety programs are effective in protecting consumers' health. However,

compliance data show only what actions were taken by shellfish processors, not whether these actions had the desired impact – safer shellfish. Despite the difficulties associated with measuring reductions in bacteria or illnesses, we continue to believe that such measurements can and should be made.

See comments 6 and 9.

- The Conference disagrees for the reasons stated in 4(e).

(5) ISSC's Efforts to Reduce *V. vulnificus* Related Illnesses and Deaths Have Not Been Effective and the Success of its Proposed Strategy in the Near Term is Questionable

Now on p. 16.

(a) Page 17. According to FDA, "while immediate refrigeration is probably not practical for many small harvesting vessels, a maximum time at uncontrolled temperatures of 2 hours would allow small harvesting vessels to move their catch to larger vessels with onboard refrigeration."

- The use of refrigeration to address *Vv* levels is included in the ISSC *V. vulnificus* proposal. The Conference appreciates your suggestions.

Now on p. 18.

(b) Page 19. In 1999, the ISSC evaluated the effectiveness of the V. *vulnificus* education campaign. To evaluate the educational materials, the ISSC sent questionnaires to both medical providers and patients. The ISSC received a total of 880 responses – 641 from medical providers and 239 from patients. The response rate was 5 percent from providers and less than 1 percent for patients. The report concluded that "if these respondents are representative of persons with liver disease who enjoy eating raw shellfish, then these educational materials, presented by physicians were effective in persuading those at high-risk to change their behavior." However, because of the very low response rate, statistically valid conclusions cannot be drawn about the effectiveness of the education effort. That is, the survey results cannot be interpreted as providing evidence that the educational materials were an effective way to change high-risk behavior and by doing reduce the number of illnesses associate with *V. vulnificus*.

See comment 10.

- The response rate, although low, was not unusual for this type of survey. Your statement regarding the statistical validity is a very unfair characterization.

Now on p. 19

(c) Page 20. However, the ISSC did not measure whether these education activities improved the awareness of the at-risk target population or whether the education efforts lead to any behavior changes.

- We are presently negotiating with a contractor to measure the effectiveness of our educational activities. Evaluation has been a component of our educational efforts.

Now on p. 22.

(d) Page 23. However, like last year's version, the proposed 2001 control plan contains only one activity the states are required to implement—educate at-risk consumers to reduce or stop eating raw oysters. The plan also allows the states to take whatever other actions they believe are needed to meet the illness reduction goal.

See comment 4.

- As in 2(c) and (d), it appears GAO disagrees with the ISSC strategy and timeframe for implementation. Our strategy reflects our recognition of the public health and legal significance in 1(b).

Now on p. 22.

(e) Page 23. Even if the revised control plan is approved in 2001, it is questionable whether education initiatives alone will result in significant illness reduction because the ISSC has not demonstrated that education has been or will be effective.

See comment 11.

The Conference disagrees with your statement that the ISSC has not demonstrated that education has been or will be effective. Demonstrating effectiveness in a program designed to reach 30 immunocompromised individuals, many of whom are non-English speaking, in a population of 300 million is not a simple task. The ISSC evaluation objective is to find people who modified their behavior and abstained from eating raw molluscan shellfish as a result of the ISSC Education Program. The ISSC proposal includes evaluation components and clearly recognizes the time necessary to achieve statistical reliability in measuring success.

Now on p. 22.

(f) Page 23. The effectiveness of educating at-risk individuals is also questionable because some individuals may not be aware they are at increased risk. For example, FDA noted that individuals may be at increased risk from eating raw oysters if they drink two or three alcoholic drinks a day because this can cause liver disease, which may have no symptoms.

See comment 12.

- The vast majority of these people are aware that they are at increased risk. If we educate the vast majority and encourage the appropriate behavior change, we will see statistically significant reductions in illnesses. Your statement, attributed to FDA, regarding the risk of eating raw oysters for individuals consuming two or three alcoholic drinks is not consistent with the ISSC understanding of the FDA's most recent position of this issue. The FDA's present position is that chronic alcoholism increases risk rather than two or three drinks a day.

(6) Conclusions

(a) However, FDA has not made use of available data on compliance with safety requirements by states and foreign countries and has not developed data on the effectiveness of state and foreign country programs in reducing bacteria levels in shellfish or related illnesses.

See comments 6 and 9.

- The Conference disagrees as stated in 4(e).

(7) General Comments on Conclusions

- With regard to FDA oversight, your suggestion that FDA is not using its limited resources wisely seems harsh. We would agree that FDA could use resources more effectively. We agree improvements can and should be made.

- With regard to *V. vulnificus,* we disagree with your opinion that illness may not be significantly reduced until 2008. We agree that ISSC does not have a detailed plan to ensure post-harvest treatment capability, but this is a matter which will be given a very high priority when Issue 00-201 is adopted. You suggest in your last sentence that pressure may be applied to postpone implementation. With regard to the *V. vulnificus* issue, it is our opinion that the pressure at some time in the future will probably not be greater than the pressure at the present time.

See comment 13.

(8) Recommendations for Executive Action

6

See comment 9.

As stated earlier, the ISSC agrees with your recommendations with the exception of the example used for baseline data. The Conference does not agree that regular shellfish microbiological testing would be an appropriate measure of effectiveness; however, your comments will be discussed with FDA to determine the merits of investigating this approach. The ISSC and FDA will discuss and investigate performance measures, which could be used for evaluation.

(9) Agency Comments on Our Evaluation

- NA

7

GAO Comments

1. Our draft report acknowledges that FDA's figure for shellfish-related illnesses is an estimate made in 1995 and that neither FDA nor the CDC have current estimates. Given the fact that many shellfish-related illnesses from Norwalk viruses are not reported, the FDA estimate is the best available data on this issue. However, we revised the draft report to note that the ISSC believes FDA's estimate significantly overstates the actual number of annual illnesses related to shellfish.

2. According to FDA, one of the reasons for its current oversight approach was that the states wanted uniform FDA oversight. The ISSC does not agree that this is the case. Nevertheless, both FDA and the ISSC agree that in the future FDA should adopt a risk–based approach to overseeing states' and foreign countries' programs.

3. While FDA could review the paper records from all state plant inspections if it chose to, the fact remains that it has not done so. As a result, we continue to believe that FDA does not have sufficient information to assess the extent of statewide and national compliance with some safety requirements and that automated systems for recording the results of state activities would help alleviate this problem.

4. The draft report states that the ISSC's proposed plan establishes an interim illness reduction goal and allows the states to adopt additional controls beyond education. However, as the ISSC acknowledges, education is the only required activity contained in the proposed plan. While additional actions may be taken by the states or the ISSC in the future, at present such actions remain to be seen.

5. We disagree. The draft report clearly states that the number of reported illnesses has increased but the reason for the increase is not known.

6. See comment 3 for our response regarding whether FDA has sufficient information on compliance. FDA told us that it assesses states, and foreign countries' compliance with shellfish safety requirements but had not attempted to directly measure the effectiveness of these program requirements in lowering bacterial levels or reducing illnesses and deaths. While compliance data are helpful in determining whether safety requirements have been implemented, they do not provide any measure of whether those requirements effectively reduce illnesses associated with shellfish consumption. The ISSC appears to believe

that data on program compliance is an appropriate measure of effectiveness. We do not agree.

7. We agree that FDA reviews some states' processing plant inspection files as a part of its evaluation process. However, the limited number of plant visits and file reviews conducted by FDA only allows the agency to draw conclusions on the plants it visited or reviewed, not to project statewide or national trends in compliance.

8. The concern we raised in the draft report was not whether FDA could assess the states' ability to implement the requirements of the NSSP. Rather our concern was that FDA relied on a limited number of plant visits to estimate statewide and national trends in compliance with safety requirements. See comment 7.

9. We recognize the difficulties inherent in developing meaningful measures of the effectiveness of states' and foreign countries' shellfish safety activities. Nonetheless, as our recommendation suggests, we believe it is critical to identify measures of program effectiveness and to gather data on these measures over time. These measures may be the results of microbial tests or other indicators that the ISSC and FDA believe are appropriate.

10. While the response rate may not be unusual for this type of survey, the low response rate still precludes any assumptions from being made about the at-risk population as a whole. As such, the survey results do not provide statistically sound evidence for the conclusion that this education effort was effective in changing the behavior of at-risk individuals.

11. We recognize that demonstrating the effectiveness of consumer education in reducing shellfish-related illnesses and deaths is not a simple task. However, the ISSC has evaluated only one of its education initiatives. Because of the low response rate to the evaluation survey, no conclusions can be drawn regarding the at-risk population as a whole, as we discussed in comment 10. As such, we do not believe the ISSC has demonstrated that education has been or will be effective.

12. We revised the report to reflect FDA's current position on this issue.

13. The likely impact of education on reducing *V. vulnificus*-related illnesses and deaths is uncertain, other possible controls are voluntary, a detailed plan to ensure adequate post-harvest treatment capacity

does not exist, and proven controls will not be required until after 2008. As such, we believe our conclusion that *V. vulnificus*-related illnesses and deaths may not be significantly reduced until after 2008 is fair and reasonable. In addition, while the shellfish industry may be under considerable pressure at this time to develop controls to reduce *V. vulnificus*-related illnesses, if the ISSC's illness reduction goals are not reached by 2008 and post-harvest treatment capacity is not available, industry members may press for additional time to obtain such capacity.

Appendix IV: GAO Contacts and Staff Acknowledgements

GAO Contacts

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Acknowledgments

In addition to those named above, Stephen D. Secrist, Katherine B. Mannen, Robert P. Lilly, and Fran A. Featherston made key contributions to this report.

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