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FOOD SAFETY

FDA Needs to Reassess Its Approach to Reducing an Illness Caused by Eating Raw Oysters

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ACCOUNTABILITY ★ INTEGRITY ★ RELIABILITY

Highlights of [GAO-11-607](#), a report to the Honorable Rosa L. DeLauro, House of Representatives

Why GAO Did This Study

Vibrio vulnificus (*V. vulnificus*) is a bacterium that occurs naturally in the Gulf of Mexico. On average, since 2000, about 32 individuals a year in the United States have become ill from eating raw or undercooked oysters containing *V. vulnificus*, and about half have died. The Food and Drug Administration (FDA) is responsible for ensuring oyster safety and works with the Interstate Shellfish Sanitation Conference (ISSC), which includes representatives from FDA, states, and the shellfish industry to establish guidelines for sanitary control of the shellfish industry. GAO was asked to determine the extent to which FDA and the ISSC agree on the *V. vulnificus* illness reduction goal, use a credible approach to measure progress toward the illness rate reduction goal, have evaluated the effectiveness of their actions in reducing *V. vulnificus* illnesses, and whether the Gulf Coast oyster industry has adequate capacity to postharvest process oysters harvested April through October. GAO reviewed data and documents and interviewed officials in FDA, the ISSC, Florida, Louisiana, and Texas.

What GAO Recommends

GAO recommends that FDA work with the ISSC to agree on an illness reduction goal, improve its approach to measuring progress in reducing *V. vulnificus* illnesses, regularly evaluate its illness reduction strategies, and address the limitations in the FDA-commissioned report. FDA and the ISSC generally agreed with our recommendations.

View [GAO-11-607](#) or key components. For more information, contact Lisa Shames at (202) 512-3841 or shamesl@gao.gov.

FOOD SAFETY

FDA Needs to Reassess Its Approach to Reducing an Illness Caused by Eating Raw Oysters

What GAO Found

FDA and the ISSC do not agree on a common *V. vulnificus* illness reduction goal. In October 2009, FDA announced its intention to change its approach to *V. vulnificus* illnesses from reducing them to largely eliminating them. To do so, FDA would require states to use postharvest processing methods, which include a mild heat treatment known as low temperature pasteurization. FDA's announced approach was a change from the 60 percent illness rate reduction goal established by the ISSC in 2001, with FDA concurrence. In a November 2009 letter to FDA, the ISSC expressed disappointment that FDA had not followed a 1984 memorandum of understanding that calls for FDA and the ISSC to consult on such matters. If FDA and the ISSC are not in agreement on the illness reduction goal and strategies to achieve it, it will be difficult for the Gulf Coast states to move forward to significantly reduce the number of consumption-related *V. vulnificus* illnesses.

The approach FDA and the ISSC have been using to measure progress toward the previously agreed upon *V. vulnificus* illness rate reduction goal established in 2001 has limitations that undermine its credibility. For example, the ISSC continues to include California's results in its illness rate reduction calculation along with Florida, Louisiana, and Texas. Doing so overstates the effectiveness of consumer education and time and temperature controls—FDA's and the ISSC's primary strategies for reducing *V. vulnificus* illnesses—because California, unlike these other states, requires that all raw Gulf Coast oysters harvested during the summer and sold in the state be processed to reduce *V. vulnificus* to nondetectable levels, which has reduced *V. vulnificus* illnesses to nearly zero.

FDA and the ISSC have taken few steps to evaluate the effectiveness of their consumer education efforts since 2004. Likewise, they have not directly evaluated the effectiveness of the time and temperature controls implemented in 2010, which call for harvesters to ensure that oysters are cooled to specific temperatures within certain times to reduce *V. vulnificus* growth. Although data are not available, our discussions with state and oyster industry officials suggest 100 percent compliance with the controls is highly unlikely. Moreover, our analysis shows—even assuming 80 percent compliance in the summer months—it is unlikely that these controls will lead to the level of illness reduction estimated by a model developed by FDA.

The Gulf Coast oyster industry does not have sufficient capacity to process all of its oysters intended for raw consumption that are harvested from April through October to reduce *V. vulnificus* to nondetectable levels, according to an FDA-commissioned report. The report concluded that it will take a minimum of 2 to 3 years to develop the infrastructure needed to process these oysters. However, the report has some limitations that call into question the completeness of its cost and timeline estimates. For example, the report's cost estimates did not include some construction costs and costs associated with purchasing land needed to expand existing processing facilities or build new ones. Without this information, the full cost of developing sufficient processing capacity will not be known.

Contents

Letter		1
	Background	5
	FDA and the ISSC Do Not Currently Agree on a <i>V. Vulnificus</i> Illness Reduction Goal	11
	The Approach FDA and the ISSC Use for Measuring Progress toward Their Illness Rate Reduction Goal Has Limitations That Undermine Its Credibility	13
	FDA and the ISSC Have Taken Few Steps to Evaluate the Effectiveness of Consumer Education and Time and Temperature Controls	15
	Extent of Industry Compliance with Time and Temperature Controls Is Unknown	19
	Extent of Illness Reduction from Time and Temperature Controls Depends on Compliance Levels	23
	Adequate Capacity Does Not Exist to Use Postharvest Processing on Gulf Coast Oysters, and Questions Exist about the Feasibility of Developing Such Capacity	25
	Conclusions	31
	Recommendations for Executive Action	32
	Agency Comments and Our Evaluation	33
Appendix I	Estimating the Impact of Time and Temperature Controls on the Number of Illnesses from <i>V. Vulnificus</i>	36
Appendix II	Comments from the Department of Health and Human Services	50
Appendix III	Comments from the Interstate Shellfish Sanitation Conference	56
Appendix IV	GAO Contact and Staff Acknowledgments	60
Tables		
	Table 1: Time and Temperature Controls Implemented by Florida, Louisiana, and Texas Beginning May 1, 2010	10

Table 2: Comparison of Estimates between WHO/FAO Risk Simulation Model and GAO Replication of the Model for July, August, and September	40
Table 3: Time and Temperature Controls for 2010, by State and Month	41
Table 4: Comparison of FDA's Risk Calculator and GAO's Modification of WHO/FAO Risk Simulation Model Concerning Estimated Number of <i>V. Vulnificus</i> Illnesses per 100,000 Servings of Oysters at Baseline	45
Table 5: Estimated Percentage Reduction in the Number of <i>V. Vulnificus</i> Illnesses as a Result of Time and Temperature Controls, by State and Month	46
Table 6: Probability That the Time and Temperature Controls Will Reduce <i>V. Vulnificus</i> Illnesses to the Number Estimated by FDA's Risk Calculator or Lower, by Estimated Compliance Rate	48

Figures

Figure 1: Gulf Coast States and Oyster Harvest Areas	5
Figure 2: Amount and Value of Oysters Harvested by Gulf Coast States in 2009	6
Figure 3: Total Number of <i>V. Vulnificus</i> Oyster Consumption-Related Illnesses Reported Nationally, by month, from 2000-2010	7
Figure 4: Number of <i>V. Vulnificus</i> Oyster Consumption-Related Illnesses Reported Nationally, by Year, from 2000-2010	8
Figure 5: Sample Log Sheet	20
Figure 6: Sample Oyster Labels	22
Figure 7: Estimated Reduction in the Number of <i>V. Vulnificus</i> Illnesses as a Result of Time and Temperature Controls for Louisiana in August	24
Figure 8: Key Components of WHO/FAO Risk Simulation Model and GAO Modifications	38

Abbreviations

CDC	Centers for Disease Control and Prevention
FDA	Food and Drug Administration
ISSC	Interstate Shellfish Sanitation Conference
NOAA	National Oceanic and Atmospheric Administration
RTI	Research Triangle Institute International
<i>V. vulnificus</i>	<i>Vibrio vulnificus</i>
WHO/FAO	World Health Organization and the Food and Agriculture Organization

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G A O

Accountability * Integrity * Reliability

United States Government Accountability Office
Washington, DC 20548

September 8, 2011

The Honorable Rosa L. DeLauro
House of Representatives

Dear Ms. DeLauro:

Illnesses due to *Vibrio vulnificus* (*V. vulnificus*), a naturally occurring bacterium that is commonly found in oysters harvested from the Gulf of Mexico and that grows quickly—especially during warmer months (April through November)—are the most common cause of death from seafood consumption in the United States. Individuals with compromised immune systems can develop a severe and potentially fatal infection from eating raw or undercooked oysters contaminated with *V. vulnificus*. According to data provided by the Interstate Shellfish Sanitation Conference (ISSC)—a voluntary organization formed in 1982 by state officials from 22 states to promote uniform national shellfish safety policies—the number of *V. vulnificus* illnesses associated with raw oyster consumption has averaged about 32 a year nationwide since 2000. *V. vulnificus* illnesses are fatal about 50 percent of the time, according to the Centers for Disease Control and Prevention (CDC).

Under ISSC procedures, FDA, the federal agency responsible for ensuring the safety of oysters and other shellfish, must concur with the ISSC's proposed shellfish safety policies before they can be incorporated into the National Shellfish Sanitation Program's shellfish safety guidelines.¹ In 2001, the ISSC approved, with FDA concurrence, a change in the shellfish safety guidelines providing that individual states are to develop *V. vulnificus* risk management plans if two or more confirmed *V. vulnificus* illnesses since 1995 could be traced to the consumption of commercially harvested raw or undercooked oysters that originated from the state's waters. Initially, four states—Alabama, Florida, Louisiana, and Texas—exceeded that threshold and therefore, in

¹The National Shellfish Sanitation Program is a federal/state cooperative program recognized by FDA and the ISSC for the sanitary control of shellfish (i.e., oysters, clams, mussels, and scallops) produced and sold for human consumption. States agree to have adequate laws and regulations to provide a legal basis within the state for sanitary control of interstate phases of the shellfish industry and certify that shippers of shellfish meet National Shellfish Sanitation Program standards.

accordance with the shellfish safety guidelines, were expected to develop such plans.² The states' risk management plans relied primarily on consumer education aimed at high-risk (i.e., immune-compromised) individuals to reduce the rate of *V. vulnificus* illness and time and temperature controls to cool oysters to a specific temperature within a certain period after harvesting to reduce the growth of *V. vulnificus*.

The shellfish safety guidelines also included goals for reducing the rate of illness for four reporting states³—California, Florida, Louisiana, and Texas; for those states, the guidelines specified illness rate reduction goals of 40 percent by the end of 2006 and 60 percent by the end of 2008.⁴ If the 60 percent goal was not achieved, the Gulf Coast states (Alabama, Florida, Louisiana, Mississippi, and Texas) were to implement one or more illness reduction strategies identified in the guidelines—postharvest processing methods (such as a mild heat treatment known as low temperature pasteurization) to reduce *V. vulnificus* to nondetectable levels, closing oyster harvest areas, or removing oysters from their shells (i.e., shucking) for cooking prior to consumption—or “equivalent” strategies. According to FDA and the ISSC, however, by the end of 2008, the four reporting states achieved about a 35 percent *V. vulnificus* illness rate reduction and therefore missed the 60 percent goal by about 25 percent. Instead of imposing the illness reduction strategies specified in the guidelines if the illness rate reduction goals were not met, in May 2009, the ISSC approved, with FDA concurrence, new more stringent time and temperature controls. These controls were intended to help

²Mississippi submitted its *V. vulnificus* risk management plan in 2009 after it was determined that two or more confirmed cases of *V. vulnificus* consumption-related illnesses could be traced to the state's waters.

³According to a senior ISSC official, the ISSC selected the four states to report *V. vulnificus* illness data because of the quality of their reporting systems—each had been consistently reporting *V. vulnificus* illnesses for the longest time period—and because most other states were not reporting *V. vulnificus* illnesses.

⁴The ISSC calculates illness rate reduction as the change in the number of *V. vulnificus* illnesses per unit of population from baseline years 1995 through 1999. In those years, in the four states, there were 19.6 *V. vulnificus* illnesses and a population of 70,637,188, on average, resulting in an illness rate of 0.28 *V. vulnificus* illnesses per million people, according to ISSC data. In 2009 and 2010, there was a population of 85,419,577, on average, in the four states. Therefore, for example, to achieve the 60 percent illness rate reduction from the baseline years, the number of illnesses in the four states in 2009 and 2010 could not exceed 9.4 illnesses, on average.

achieve the approximately 25 percent illness rate reduction needed to meet the 60 percent goal by the end of 2010.

By October 2009, FDA announced its intent to change its approach to *V. vulnificus* illnesses from reducing them to largely eliminating them. Specifically, FDA said that, in spite of the ISSC's efforts, the number of *V. vulnificus* illnesses had not significantly declined and strategies that fall well short of eliminating *V. vulnificus* were no longer sufficient. FDA has also raised concerns with the current approach for measuring *V. vulnificus* illness reductions. Furthermore, in an October 2009 letter to the ISSC, FDA went on to say that academia, the oyster industry, and government, with the support of the ISSC, had developed postharvest processing technologies that could largely eliminate *V. vulnificus* illnesses and that the Gulf Coast oyster industry has the capacity to use postharvest processing on 100 percent of Gulf Coast oysters intended for raw consumption.

In your role during the 111th Congress as the Chairwoman of the House Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, you asked us to review efforts of FDA and the ISSC to reduce illnesses caused by oysters contaminated with *V. vulnificus* bacteria. Accordingly, this report examines the extent to which (1) FDA and the ISSC are currently in agreement on a *V. vulnificus* illness reduction goal, (2) FDA and the ISSC use a credible approach to measure progress toward their *V. vulnificus* illness rate reduction goal, (3) FDA and the ISSC have evaluated the effectiveness of consumer education programs and time and temperature controls in reducing *V. vulnificus* consumption-related illnesses, and (4) the Gulf Coast oyster industry has adequate capacity to use postharvest processing on oysters harvested during warmer months and intended for raw consumption.

To determine the extent to which FDA and the ISSC are in agreement on a *V. vulnificus* illness reduction goal, we reviewed the ISSC's meeting minutes and FDA's responses to ISSC proposals regarding illness reduction goals. To determine the extent to which FDA and the ISSC have used a credible approach to measure progress toward their *V. vulnificus* illness rate reduction goals, we analyzed the number of states used in determining *V. vulnificus* illness rate reduction, the effectiveness of primary *V. vulnificus* illness rate reduction strategies, and the effect of such factors as natural and manmade disasters on *V. vulnificus* illness rate reduction. To determine the extent to which FDA and the ISSC have evaluated the effectiveness of consumer education programs in reducing

V. vulnificus consumption-related illnesses, we reviewed relevant ISSC-commissioned surveys and studies and the *V. vulnificus* consumer education activities of Florida, Louisiana, and Texas. We also interviewed officials from these states' health agencies and members of the ISSC's *Vibrio* education committee. To determine the extent to which FDA and the ISSC have evaluated the effectiveness of time and temperature controls in reducing *V. vulnificus* consumption-related illnesses, we reviewed scientific literature and reports. We also analyzed the data in the model that was the basis for a tool that FDA developed for Florida, Louisiana, and Texas to use in determining their time and temperature controls. We also replicated the model to determine its validity and then modified it to simulate the impact of the time and temperature controls implemented by Florida, Louisiana, and Texas in May 2010 (see app. I). In addition, we interviewed a nonprobability sample of 11 leading *Vibrio* researchers about the scientific underpinnings of time and temperature controls⁵ and law enforcement officials from agencies in Florida, Louisiana, and Texas regarding their time and temperature enforcement activities. To determine the extent to which there is adequate capacity to use postharvest processing on Gulf Coast oysters harvested during warmer months and intended for raw consumption, we analyzed the 2011 FDA-commissioned Research Triangle Institute International (RTI) report that addressed the feasibility and economic impacts of requiring postharvest processing.⁶ We also interviewed the lead author of the RTI report. To address all four objectives, we interviewed knowledgeable officials from FDA, the ISSC, and state regulatory agencies in Florida, Louisiana, and Texas, as well as representatives from the Gulf Coast oyster industry. We also conducted site visits to Florida, Louisiana, and Texas and attended key ISSC meetings in Alabama and Florida.

We conducted this performance audit from May 2010 to September 2011 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that

⁵We selected interviewees from attendees at a November 2010 conference convening leading *Vibrio* researchers who had submitted research abstracts regarding the effect of temperature on *V. vulnificus* in Gulf Coast oysters and from referrals by FDA and state officials.

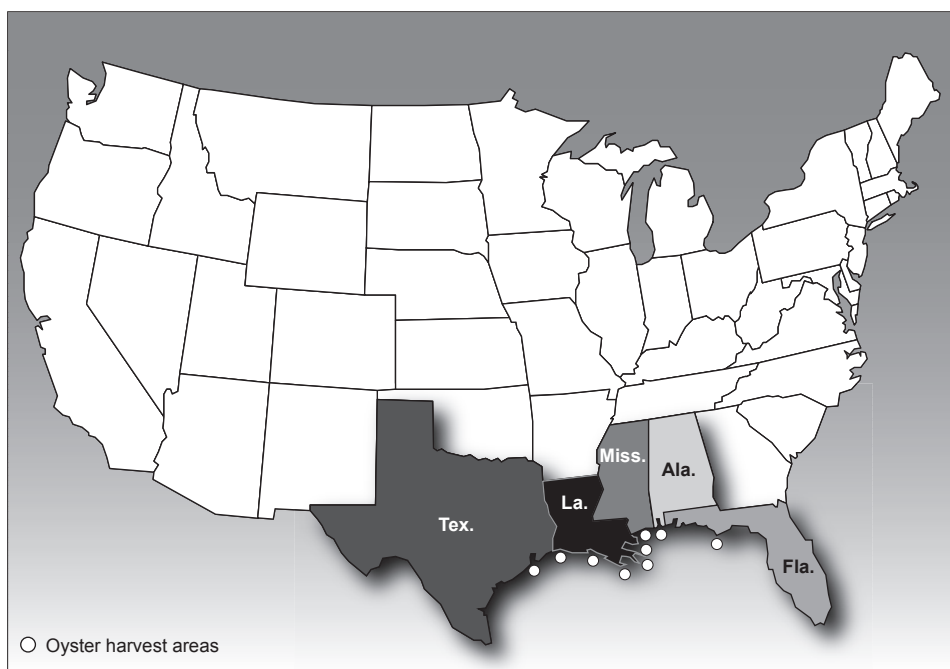
⁶RTI is a leading research institute whose largest single field of study is health research.

the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

Gulf Coast oysters are commercially harvested from the waters of the Gulf of Mexico adjacent to Alabama, Florida, Louisiana, Mississippi, and Texas and shipped throughout the United States. Figure 1 shows the Gulf Coast states and the location of the primary oyster harvest areas in the Gulf of Mexico.

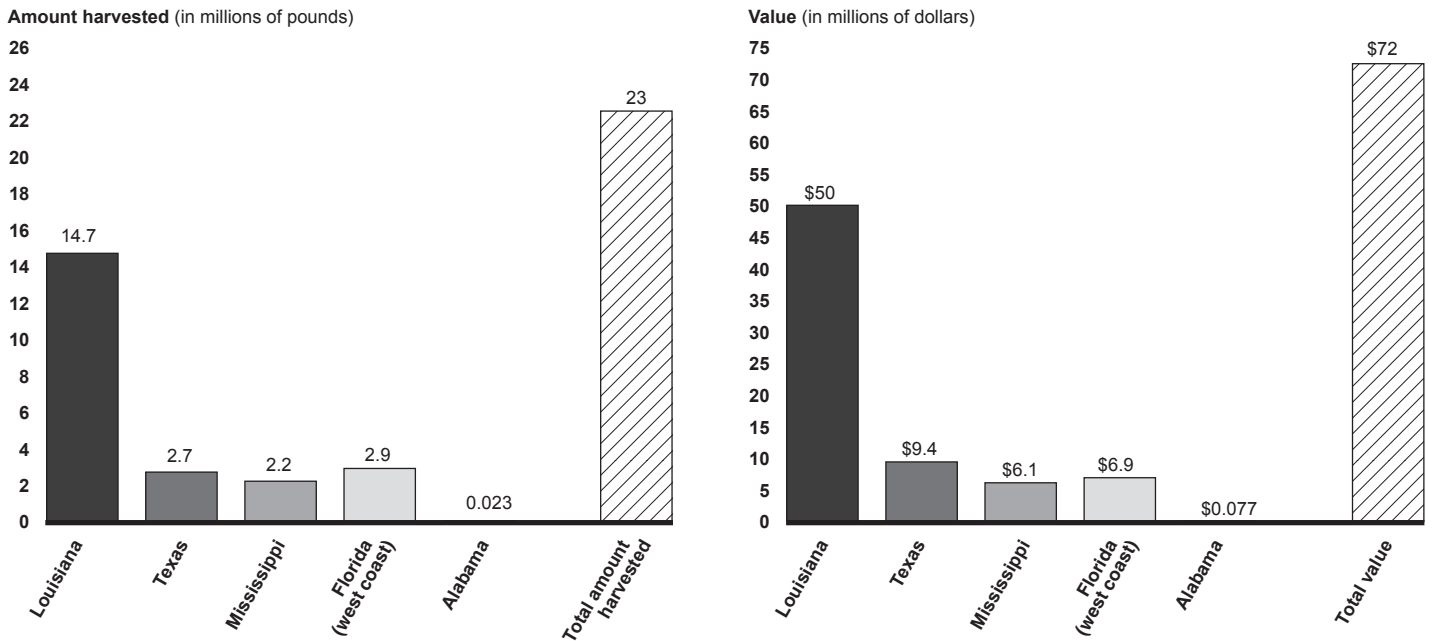
Figure 1: Gulf Coast States and Oyster Harvest Areas



Source: RTI.

According to statistics from the Department of Commerce's National Oceanic and Atmospheric Administration (NOAA), in 2009, the Gulf Coast region produced about 23 million pounds of oysters, approximately 63 percent of the nation's total domestic production, valued at about \$72 million. Figure 2 shows the amount and value of oysters harvested by Gulf Coast states in 2009, the most recent year for which these data are available.

Figure 2: Amount and Value of Oysters Harvested by Gulf Coast States in 2009



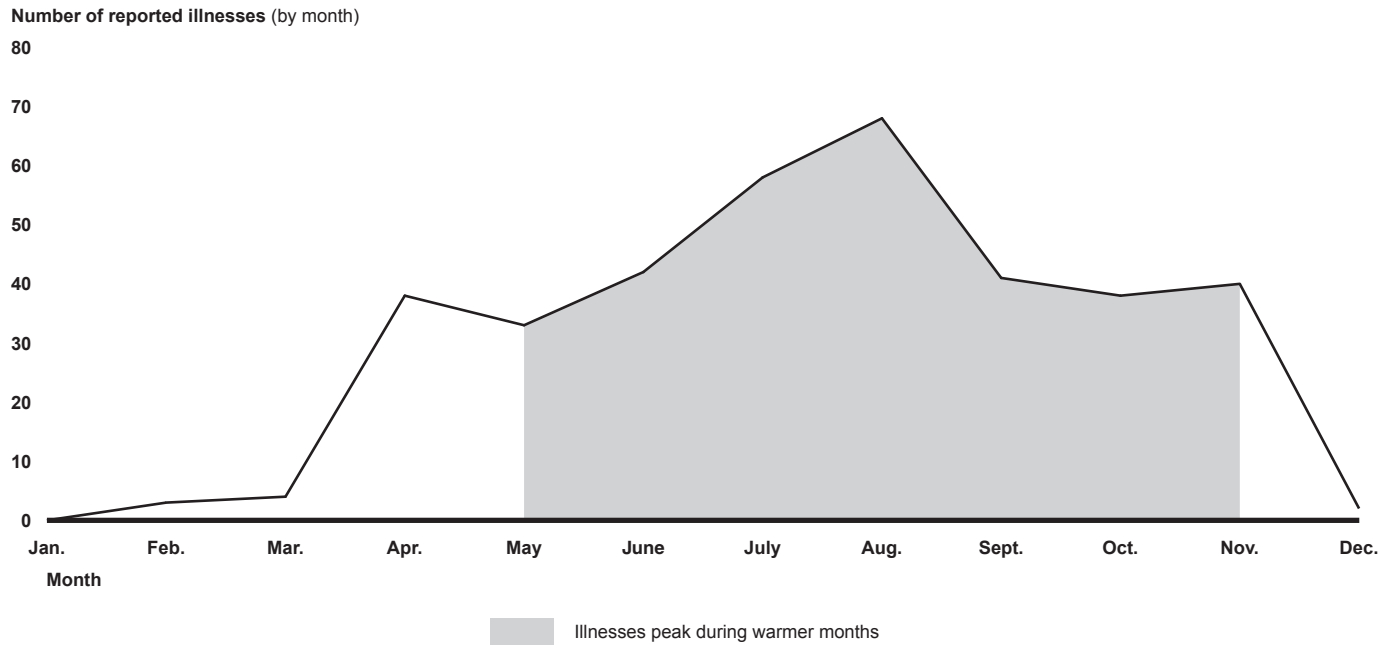
Source: NOAA.

Note: The amounts and value of oysters harvested are rounded.

Because *V. vulnificus* is more abundant in oysters harvested during the warmer-weather months (April through November), consumers who eat raw oysters harvested during this period are likely to be exposed to greater amounts of *V. vulnificus*. Although most healthy people do not become ill from *V. vulnificus*, people with certain medical conditions—such as chronic liver disease, hemochromatosis,⁷ cancer, kidney disease, diabetes, and human immunodeficiency virus/acquired immune deficiency syndrome—are at risk of developing a potentially fatal bloodstream infection known as septicemia, which is characterized by fever and chills, life-threatening low blood pressure, and blistering skin lesions. Figure 3 shows that *V. vulnificus* consumption-related illnesses peak during April through November and remain quite low from December through March.

⁷Hemochromatosis causes the body to absorb too much iron from food. The excess iron is stored in organs, especially the liver, heart and pancreas, leading to life-threatening conditions such as cancer, heart problems, and liver disease.

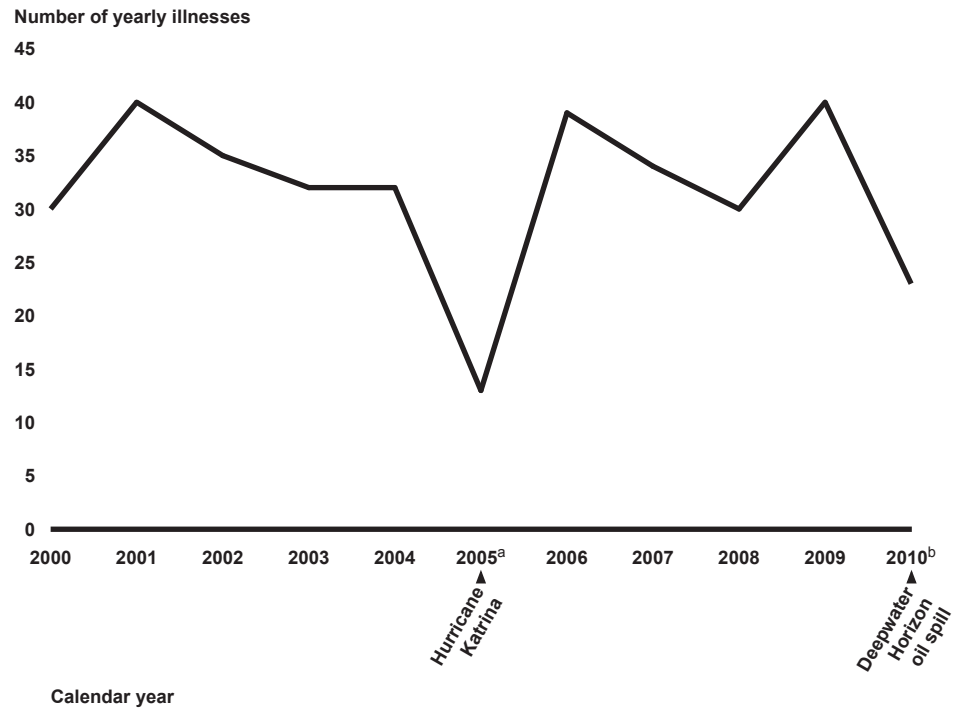
Figure 3: Total Number of *V. Vulnificus* Oyster Consumption-Related Illnesses Reported Nationally, by month, from 2000-2010



Source: GAO analysis, including preliminary 2010 ISSC data.

According to the ISSC’s data, since 2000, 348 *V. vulnificus* consumption-related illnesses have been reported nationally. As figure 4 shows, the number of *V. vulnificus* consumption-related illnesses reported nationally from 2000 to 2010 have been relatively consistent annually—with the exception of 2005 and 2010, when Hurricane Katrina and the Deepwater Horizon oil spill, respectively, severely reduced the oyster harvest.

Figure 4: Number of *V. Vulnificus* Oyster Consumption-Related Illnesses Reported Nationally, by Year, from 2000-2010



Source: GAO analysis, including preliminary 2010 ISSC data.

^aHurricane Katrina struck the Gulf Coast region in August 2005, causing significant damage to the oyster industry. Oyster beds and vessels along the Gulf Coast were extensively damaged, if not destroyed, by siltation and contamination related to Hurricane Katrina.

^bThe Deepwater Horizon oil spill in the Gulf of Mexico occurred in April 2010, causing significant damage to the oyster industry. The oil spill resulted in numerous harvest area closures and significant death of oysters from freshwater diversions that were used to prevent oil from reaching shorelines.

Although the number of *V. vulnificus* consumption-related illnesses is small, the costs of the disease are high because of the high mortality rate—about 50 percent, according to CDC—costing the nation about \$124 million annually, according to FDA. However, a senior ISSC official said FDA’s estimate overstates the annual costs related to *V. vulnificus* consumption-related illnesses because it does not factor in the age and pre-existing health condition of the victims.

As the federal agency responsible for ensuring the safety of shellfish, including oysters, in March 1984, FDA entered into a memorandum of understanding with the ISSC recognizing it as the primary voluntary national organization of state shellfish regulatory officials that provides guidance and counsel on matters related to the sanitary control of

shellfish. The ISSC provides a formal structure for state regulatory authorities to establish guidelines, and procedures for applying those guidelines, for the sanitary control of the oyster industry. These guidelines must be reviewed by FDA for consistency with existing laws, regulations, and policies before they can be adopted. In addition to FDA and state regulatory officials, the ISSC also includes members from the shellfish industry and other federal agencies.

Postharvest processing, closing oyster harvest areas, and shucking can all be expected to either substantially reduce or essentially eliminate exposure to *V. vulnificus* bacteria by consumers of raw oysters.⁸

However, when the 60 percent illness rate reduction goal was not met by the end of 2008, instead of implementing these strategies, FDA and the ISSC relied on estimates generated by FDA's *V. vulnificus* risk calculator in adopting time and temperature controls that they considered to be an equivalent strategy.⁹ Senior FDA and ISSC officials told us that although time and temperature controls are not equivalent to the other strategies in the guidelines in terms of the total amount of illness reduction each can achieve, they considered the new time and temperature controls to be equivalent in that, according to the risk calculator's estimations, they would equivalently help the states to achieve the approximately 25 percent illness rate reduction needed to meet the 60 percent goal by the end of 2010. Table 1 shows the time and temperature controls implemented in Florida, Louisiana, and Texas on May 1, 2010.

⁸Postharvest processing significantly reduces exposure to *V. vulnificus* bacteria by reducing it to nondetectable levels, which, as currently defined in the shellfish safety guidelines, would result in a reduction from the current average of 32 cases per year to approximately 1.2 cases per year, according to a 2005 report by the World Health Organization and Food and Agriculture Organization of the United Nations. Oyster harvest area closures essentially eliminate exposure to *V. vulnificus* bacteria because raw oysters could not be legally harvested from the closed areas. Shucking essentially eliminates exposure to *V. vulnificus* bacteria because shucked oysters are to be cooked before consumption, which destroys the *V. vulnificus* bacteria.

⁹The *V. vulnificus* risk calculator is a tool that was designed by FDA for the states to use to predict the level of *V. vulnificus* illness rate reduction they could achieve as a result of different combinations of time and temperature controls.

Table 1: Time and Temperature Controls Implemented by Florida, Louisiana, and Texas Beginning May 1, 2010

State	Period controls were in effect	Maximum time from harvest to refrigeration (hours)	Maximum time from refrigeration to internal oyster meat temperature of 55°F (hours)
Florida	May through October	6 ^a	2 ^a
Louisiana	May through October	1	6
Texas	May and October	4	6
	June and September	3	6
	July and August	1	6

Source: GAO analysis of Florida, Louisiana, and Texas 2010 *V. vulnificus* risk management plans.

^aThis is the rapid cooling control option, one of four time and temperature control options authorized in Florida's *V. vulnificus* risk management plan and the only option used during the summer of 2010 by the Florida oyster industry, according to a senior Florida regulatory official.

Although FDA had concurred with the use of new time and temperature controls earlier in 2009, in October of that year, a senior FDA official stated that the agency would require postharvest processing to reduce *V. vulnificus* to nondetectable levels. There are currently four methods for processing oysters after they have been harvested to reduce *V. vulnificus* to nondetectable levels: (1) high-pressure processing, (2) a mild heat treatment known as cool pasteurization, (3) cryogenic quick freezing, and (4) irradiation. Each of these processes—except irradiation—is currently in limited, voluntary commercial use in the Gulf Coast region. The senior FDA official indicated that the postharvest processing requirement would apply to all Gulf Coast oysters harvested during the warmer months of the year beginning with the 2011 harvest season. However, in response to concerns expressed by some members of Congress and the ISSC, among others, FDA suspended its plan to require postharvest processing until a study was done to determine how postharvest processing can be implemented in the fastest, safest, and most economical way. In 2010, FDA contracted with RTI to study the feasibility and economic impacts of requiring postharvest processing of Gulf state (Alabama, Florida

Louisiana, Mississippi, and Texas) oysters harvested from April through October and intended for raw consumption.¹⁰

FDA and the ISSC Do Not Currently Agree on a *V. Vulnificus* Illness Reduction Goal

In October 2009, a senior FDA official announced in a speech before the ISSC that, under FDA's Hazard Analysis and Critical Control Point rules, beginning in May 2011, FDA intended to require postharvest processing of all Gulf Coast oysters harvested during warmer months, when higher levels of *V. vulnificus* are more likely to be present, to reduce *V. vulnificus* to nondetectable levels.¹¹

According to FDA officials, the agency took this action for two primary reasons. First, consumer education activities and time and temperature controls, which had been in use by Louisiana, Florida, and Texas since 2001, had not achieved the 60 percent goal by the 2008 deadline.¹²

Second, validated methods of postharvest processing technology had become available. FDA noted that in California, since the state began requiring postharvest processing of Gulf Coast oysters in 2003, there had been zero consumption-related *V. vulnificus* illnesses. A senior FDA official said FDA now believes that postharvest processing of oysters is the control measure that best meets the intent of its Hazard Analysis and Critical Control Point seafood safety requirement to prevent, eliminate, or reduce to an acceptable level the occurrence of pathogens such as *V. vulnificus*.

In a November 2009 letter to FDA, the ISSC expressed disappointment that FDA had unilaterally decided to announce its intent to change its policy and had not followed the 1984 memorandum of understanding that calls for FDA and the ISSC to exchange information concerning the

¹⁰RTI International, *Analysis of How Post-harvest Processing Technologies for Controlling Vibrio vulnificus Can Be Implemented* (Research Triangle Park, North Carolina: March 2011).

¹¹FDA's Hazard Analysis Critical Control Point system focuses on identifying and preventing hazards that could cause food-borne illnesses rather than relying on spot checks of manufacturing processes of finished seafood products to ensure safety. Processors are required to determine whether there are food safety hazards that are likely to occur and identify the preventive measures that can control those hazards by preventing, eliminating, or reducing them to an acceptable level.

¹²According to the shellfish safety guidelines, the number of *V. vulnificus* illnesses in what the ISSC considers the four core reporting states— California, Florida, Louisiana, and Texas—is used to calculate illness rate reduction to determine if the 60 percent goal has been achieved.

shellfish safety program and resolve problems of interpretation and policy. According to the letter, the ISSC was concerned that FDA was now proposing to abandon the *V. vulnificus* risk management plans adopted in 2001 by the ISSC with FDA concurrence. Furthermore, the ISSC, with FDA's concurrence, had already agreed to implement new time and temperature controls to address *V. vulnificus* beginning in May 2010. The ISSC letter also stated that if FDA continued its effort without ISSC support, it was likely that many Gulf Coast states would choose not to exercise their enforcement responsibilities under the shellfish safety program with regard to postharvest processing, and instead might implement intrastate programs that could allow consumption of raw oysters produced within their state without the controls necessary to substantially reduce *V. vulnificus* illnesses. In its April 2010 response to the ISSC, FDA acknowledged the ISSC's concerns and agreed to work collaboratively with it to identify the steps needed before implementing a postharvest processing requirement for Gulf Coast oysters harvested during the warmer months. Specifically, FDA agreed to fund an independent study, which RTI later conducted, to assess how postharvest processing and equivalent controls could be implemented in the fastest, safest, and most economical way.

Nevertheless, FDA and the ISSC have not yet agreed on a new illness reduction goal and the strategies for achieving that goal. As we noted in our October 2005 report on practices that can help agencies enhance and sustain collaboration, agencies need to define and articulate the common outcome they are seeking to achieve that is consistent with their respective agency goals and missions.¹³ Also, to achieve the common outcome, collaborating agencies need to establish strategies that work in concert with those of their partners or are joint in nature. Furthermore, trust is a necessary element for a collaborative relationship and it is critical to involve all key stakeholders in decision-making. In summary, our October 2005 report indicates that absent effective collaboration, it is unlikely that agencies can develop and implement joint agreements. If FDA and the ISSC cannot agree on the *V. vulnificus* illness reduction goal and strategies to achieve the goal, it is unlikely that the states' efforts to significantly reduce the number of consumption-related *V. vulnificus* illnesses will be effective.

¹³GAO, *Results-Oriented Government: Practices That Can Help Enhance and Sustain Collaboration among Federal Agencies*, GAO-06-15 (Washington, D.C.: Oct. 21, 2005).

The Approach FDA and the ISSC Use for Measuring Progress toward Their Illness Rate Reduction Goal Has Limitations That Undermine Its Credibility

The approach FDA and the ISSC have been using to measure progress toward their 60 percent illness rate reduction goal established in 2001 has three main limitations that undermine its credibility: the limited number of states used in determining *V. vulnificus* illness reduction, overstatement of the effectiveness of the primary *V. vulnificus* illness reduction strategies, and not controlling for the effect of such factors as natural and man-made disasters.

Limited number of states used in determining V. vulnificus illness rate reduction. First, the approach FDA and the ISSC use for measuring progress toward their illness rate reduction goal is based on the inclusion of *V. vulnificus* illness data from four states: California, Florida, Texas, and Louisiana. *V. vulnificus* illnesses related to raw oyster consumption occur in other states, but the FDA and ISSC measurement approach does not capture either the scope of such illnesses from oysters harvested from the entire Gulf Coast region or the national scope of *V. vulnificus* illnesses. According to a senior ISSC official, the ISSC selected the four states because of the quality of their illness reporting systems since each had been consistently reporting *V. vulnificus* illnesses for the longest time period and because most other states were not reporting *V. vulnificus* illnesses. Since 2007, annually, about 20 states have reported *V. vulnificus* illnesses to CDC. Senior FDA officials told us they advised the ISSC to begin including more states in the *V. vulnificus* illness calculation to better reflect the occurrence of *V. vulnificus* illnesses nationally. According to FDA officials, the ISSC has not responded to their recommendation. A senior ISSC official acknowledged to us that analyzing national data would provide a more representative measure of progress toward the illness rate reduction goal than the current approach. The official told us that the ISSC is meeting in October 2011 to discuss, among other things, developing an alternative approach to measuring progress toward the illness rate reduction goal.

Overstatement of the effectiveness of primary V. vulnificus illness rate reduction strategies. In addition to not reflecting the national scope of *V. vulnificus* illnesses, the FDA and ISSC approach overstates the effectiveness of their primary *V. vulnificus* illness rate reduction strategies—consumer education and time and temperature controls—by including *V. vulnificus* illness data from California. Since 2003, California has required postharvest processing of all raw Gulf Coast oysters harvested from April through October and sold in the state and has reported two consumption-related *V. vulnificus* illnesses since the requirement took effect. A senior ISSC official acknowledged that California's postharvest processing requirement has reduced the number

of *V. vulnificus* illnesses in that state. This official also acknowledged that including California's results contributed significantly to achieving the interim 2006 40 percent illness rate reduction goal. For this reason, both California and FDA officials have requested that the ISSC no longer include California data in its illness rate reduction calculation. According to a senior ISSC official, however, California data should be included because reporting states should not be excluded based on the states' chosen *V. vulnificus* illness rate reduction strategies.

Lack of control for the effect of such factors as natural and man-made disasters. The FDA and ISSC measurement approach does not control for the effect of such factors as natural and manmade disasters. FDA, ISSC, and state officials we spoke with agree that the level of *V. vulnificus* illnesses is associated with the level of oyster production and consumption. When oyster production decreases as a result of factors such as natural or man-made disasters like Hurricane Katrina in 2005 and the Deepwater Horizon oil spill in 2010, the level of oyster consumption also decreases and, with it, the rate of *V. vulnificus* illnesses. Not controlling for the effect of factors external to the *V. vulnificus* illness rate reduction strategies chosen by FDA and the ISSC gives a misleading indication of the success of those strategies. In 2000, the ISSC considered a proposal to calculate illness rate as the number of illnesses divided by oyster production. According to a senior ISSC official, the ISSC did not approve the proposal because oyster production data were not readily available, which is no longer the case. After rejecting the 2000 proposal to account for production, in 2001 the ISSC adopted a proposal to calculate the illness rate as the number of illnesses per unit of population. A senior FDA official told us that FDA initially agreed with this proposal because illnesses per unit of population is a standard measure used by CDC for tracking the prevalence of many illnesses. In retrospect, however, FDA and ISSC officials told us that population should not be part of the calculation. A senior FDA official explained that tracking illnesses per unit of population is meaningful for certain types of illnesses but is not meaningful for others. For example, he told us that tracking illnesses per unit of population makes sense for illnesses that are passed from person-to-person or for food-borne illnesses associated with foods that are widely consumed but that it does not make sense for illnesses associated with foods like oysters, which are a specialty food and not widely consumed throughout the population.

In 2009, the ISSC adopted a proposal to change its measure of effectiveness from illness rate reduction to risk reduction, which would be based on the risk per serving of raw or undercooked oysters. Under the

proposal, the revised goal would be to reduce the risk per serving to a level equivalent to the current 60 percent illness rate reduction goal. FDA initially opposed the proposal but later concurred, stating that the change would eliminate the problems associated with the current approach for measuring *V. vulnificus* illness rate reduction. In March 2010, the ISSC appointed a workgroup to explore implementation of the proposal. According to a senior ISSC official, as of March 2011, the work group had held one conference call but had not yet determined how the concept of risk per serving would be applied and measured in the *V. vulnificus* illness context. According to the ISSC official, the proposal is scheduled to be implemented in January 2012.

FDA and the ISSC Have Taken Few Steps to Evaluate the Effectiveness of Consumer Education and Time and Temperature Controls

FDA and the ISSC have performed either very limited or no evaluations of the effectiveness of their key *V. vulnificus* illness reduction strategies. Specifically, the ISSC has not evaluated the effectiveness of consumer education efforts in reducing *V. vulnificus* illnesses since 2004, and FDA has not conducted any evaluations of its own. In addition, although the *V. vulnificus* risk calculator developed by FDA estimates that time and temperature controls can reduce *V. vulnificus* illnesses, FDA and the ISSC have not directly evaluated the effectiveness of the May 2010 time and temperature controls that the ISSC approved, with FDA concurrence, for the states to use in reducing consumption-related *V. vulnificus* illnesses.

The ISSC Has Not Evaluated the Effectiveness of Consumer Education Efforts Since 2004, and FDA Has Not Conducted Its Own Evaluations

The ISSC conducted consumer surveys in 2002 and 2004 that were intended to measure the extent to which (1) *V. vulnificus* education programs increased consumer awareness of the risks of eating raw oysters and (2) high-risk consumers refrained from eating raw oysters for health reasons. The 2002 survey of raw oyster consumers established baseline information on consumers' beliefs about raw oysters, consumption patterns, and knowledge of risks associated with eating Gulf Coast raw oysters. The 2004 follow-up survey measured whether raw oyster consumers changed their raw oyster consumption patterns during the previous 2 years as a result of the ISSC's and states' (Florida, Louisiana, and Texas) *V. vulnificus* consumer education efforts. The 2004 survey found no significant increase in overall consumer knowledge about the risk of eating raw oysters or the proportion of high-risk consumers who stopped eating them.

A senior FDA official said that the agency has not conducted its own evaluation of the effectiveness of *V. vulnificus* consumer education

efforts; instead it relied on the ISSC's surveys to determine the impacts of consumer education efforts. FDA officials told us that their review of consumer education efforts is limited to checking the *V. vulnificus* risk management plans implemented by Florida, Louisiana, and Texas to ensure the plans include a consumer education component. According to FDA and state officials, the states' *V. vulnificus* education efforts have included a variety of activities such as online *V. vulnificus* education courses for physicians, nurses, and dieticians; public service announcements for broadcast on television and radio; advisories included with the drug prescriptions of high-risk consumers; and brochures targeting high-risk consumers that contained information about the risk of eating raw oysters. FDA and ISSC officials stated that although they have not directly evaluated the states' education efforts since 2004, their indirect measure of the effectiveness of consumer education was whether they achieved their 2008 60 percent illness rate reduction goal. They acknowledged, however, that the goal was not achieved, and, therefore, presumably consumer education alone would not achieve the goal.

Some state officials told us that it is very difficult to measure and evaluate the direct impact that consumer education has on a relatively rare event, such as *V. vulnificus* illness. One state official said that his state did not have the expertise and financial resources to conduct an evaluation of the effectiveness of its consumer education programs. The same official added that it would be difficult to prove that a specific case of *V. vulnificus* was prevented because of consumer education efforts.

An ISSC official said that some members of the ISSC have concluded that consumer education is not going to result in a significant reduction in *V. vulnificus* illnesses. For example, one state official said that the effectiveness of education is hampered by the fact that some of those who are most vulnerable to *V. vulnificus* illness, such as alcoholics with liver disease, are risk takers who refuse to change their raw oyster consumption habits.

In our September 2005 report on managing for results, we noted that federal agencies should regularly measure the effectiveness of their programs to determine whether progress is being made toward performance goals.¹⁴ Specifically, agencies should compare their

¹⁴GAO, *Managing For Results: Enhancing Agency Use of Performance Information for Management Decision Making*, [GAO-05-927](#) (Washington, D.C.: Sept. 9, 2005).

programs' results against their goals and determine where to target program resources to improve performance. We recognize that it is difficult to assess the effectiveness of consumer education programs. Nonetheless, the absence of information on the effectiveness of *V. vulnificus* consumer education programs limits the ability of the ISSC and the states to identify and increase the use of consumer education approaches that are working well and discontinue those that have not been effective. Furthermore, without regular evaluations of the effectiveness of consumer education, ISSC and state officials cannot ensure that their resources are targeted strategically and are not wasted on efforts that are ineffective.

FDA and the ISSC Have Not Directly Evaluated the Effectiveness of Time and Temperature Controls in Reducing *V. Vulnificus* Consumption-Related Illnesses

Neither FDA nor the ISSC has directly evaluated the effectiveness of the new time and temperature controls in reducing *V. vulnificus* illnesses since they were implemented in May 2010. Instead, FDA and the ISSC have relied on illness rate reduction as the overall measure of effectiveness of all *V. vulnificus* illness reduction strategies combined. Both FDA and ISSC officials acknowledge, however, that doing so does not distinguish the effect of time and temperature controls from that of other factors. Consequently, illness rate reduction does not provide a direct indication of the effectiveness of the time and temperature controls, implemented and enforced by the states, in contributing to *V. vulnificus* illness reduction.

Senior FDA and ISSC officials told us that one way to more directly evaluate the effectiveness of time and temperature controls is to conduct studies to determine the level of *V. vulnificus* bacteria in oysters prior to and following implementation of the controls.¹⁵ FDA officials told us that such studies were conducted in 1998-1999 and 2007, prior to the

¹⁵In our July 2001 report on shellfish safety, we recommended that FDA gather baseline data—such as the results of regular shellfish microbial tests—to facilitate evaluations of the effectiveness of shellfish safety programs. In response, FDA said it would review, in consultation with the ISSC, whether testing of shellfish meats should be added to the program. FDA decided not to implement the recommendation because it did not believe that its program could be improved by testing shellfish meats for contaminants. See GAO, *Food Safety: Federal Oversight of Shellfish Safety Needs Improvement*, [GAO-01-702](#) (Washington, D.C.: July 9, 2001).

implementation of the new time and temperature controls.¹⁶ Those studies surveyed the level of *V. vulnificus* bacteria and other pathogens in oysters collected from both retail and wholesale establishments.¹⁷ The level of *V. vulnificus* bacteria found in 2007 was similar to that found in 1998-1999. According to the 2007 study, the similarity was not surprising given that time and temperature controls had not changed since the 1998-1999 study and that the ISSC's efforts to reduce *V. vulnificus* illnesses had focused on educating high-risk consumers. FDA officials told us that data from those studies could be compared against future study data to measure the effectiveness of new controls, including time and temperature controls, aimed at reducing exposure to *V. vulnificus* bacteria by consumers of raw oysters. A senior ISSC official told us that he intends to promote the use of such studies to evaluate time and temperature control effectiveness. FDA officials told us that, although they would like to repeat the 1998-1999 and 2007 studies, FDA has no plans to do so given the expense of the studies, competing priorities, and resource constraints.

To estimate the level of *V. vulnificus* illness rate reduction states might expect to achieve from time and temperature controls, FDA and the ISSC have relied on FDA's *V. vulnificus* risk calculator. Estimates generated by the risk calculator indicated that the new time and temperature controls implemented in May 2010 would help the states to achieve the 60 percent illness rate reduction goal by the end of 2010. To achieve the calculator's estimated illness rate reduction, oyster industry members would have to fully comply with the time and temperature controls. Our discussions with FDA, state officials, and oyster industry representatives, however, suggest that while data regarding compliance levels are unavailable, full

¹⁶See Cook et al., *Vibrio vulnificus and Vibrio parahaemolyticus in U.S. Retail Shell Oysters: A National Survey from June 1998 to July 1999*, J. Food Prot. 65:79-87 (2002); and DePaola et al., *Bacterial and Viral Pathogens in Live Oysters: 2007 United States Market Survey*, Appl. Environ. Microbiol. 76:2754-2768 (2010).

¹⁷The studies grouped the establishments into three types: (1) restaurants and "raw bars" where shellfish are opened on site for raw consumption; (2) seafood markets, including grocery stores, that offer oysters in the shell for retail sale; and (3) wholesale dealers selling oysters in the shell to the above establishments. The 2007 study noted that these data near the point of consumption provide considerable insight on the level of protection provided by the current U.S. system of shellfish safety controls. It cautioned, however, that such data do not identify which aspects of the system (e.g., harvest, transportation, and retail) account for bacterial growth or die-off.

compliance is highly unlikely. In January 2011 FDA and the ISSC determined the goal still had not been met.

To assess the precision of the risk calculator's estimates, we replicated and modified a risk simulation model—developed by the World Health Organization and the Food and Agriculture Organization (WHO/FAO) of the United Nations in partnership with FDA—that FDA used as a basis for developing the risk calculator. Our analysis indicates that even with 100 percent compliance, the risk of *V. vulnificus* illness under time and temperature controls may differ from the number estimated by the risk calculator. For example, in Texas in the month of August, FDA's risk calculator estimates that time and temperature controls will lead to 2.84 illnesses per 100,000 raw oyster servings. While this is accurate on average, the number of illnesses per 100,000 servings could be as low as 2.44 or as high as 3.63 (for a 90 percent uncertainty interval), according to our analysis. We find a similar range of uncertainty in the estimated number of *V. vulnificus* illnesses for Florida and Louisiana. See appendix I for more details about our analysis. While uncertainty is an inherent part of estimates produced by all quantitative models, the risk calculator does not report the amount of uncertainty associated with its estimates.

Extent of Industry Compliance with Time and Temperature Controls Is Unknown

Although under the shellfish safety guidelines, states are responsible for enforcing oyster industry compliance with time and temperature controls, senior officials in Florida, Louisiana, and Texas told us they do not track compliance rates. A senior ISSC official confirmed that these states do not systematically collect, analyze, and report compliance information. Enforcement consists largely of periodic state inspections of oyster-processing plants and on-the-water harvester activities. The latter includes checking log sheets on which harvesters record whether they are harvesting oysters for raw consumption and, if so, whether they are complying with various elements of the time and temperature controls. Enforcement personnel in Louisiana, Florida, and Texas told us they do not inspect all harvesting vessels and do not verify the accuracy of all of the information recorded by the harvesters whose vessels they do inspect. For example, a Louisiana official told us that Louisiana enforcement personnel are to check the log sheet to ensure the harvester has recorded the time harvesting began but has no way of verifying whether the information is accurate. Figure 5 shows a sample log sheet used in Louisiana.

Figure 5: Sample Log Sheet

HARVESTER-DEALER TIME/TEMPERATURE
LOG SHEET

Harvester Information:
BOAT NAME/NUMBER: _____
HARVESTER NAME/ LICENSE NUMBER: _____
HARVESTER SIGNATURE: _____ DATE: _____

Molluscan Shellfish Harvested for Other Than Raw (Half Shell) Consumption:
HARVESTING AREA/LEASE NO.: _____
PRODUCT INTENDED FOR OTHER THAN RAW CONSUMPTION:
CIRCLE ONE:
BEDDING SHUCKING RELAYING OTHER
(EXPLAIN) _____
TIME HARVESTING BEGINS: _____
TIME HARVESTING ENDS: _____
NUMBER OF SACKS OF OYSTERS HARVESTED: _____

Molluscan Shellfish Harvested for Raw (Half Shell) Consumption:
HARVESTING AREA/LEASE NO.: _____
TIME HARVESTING BEGINS: _____
NUMBER OF SACKS OF OYSTERS HARVESTED: _____

Certified Dealer Information:
TEMPERATURE OF COOLER WHEN UNLOADING
OYSTERS BEGINS _____
TIME WHEN LAST OYSTER FROM BOAT ARE PLACED IN
COOLER: _____
TEMPERATURE OF COOLER WHEN LAST OYSTERS
FROM THE BOAT ARE PLACED IN COOLER: _____
ORIGINAL CERTIFIED DEALER SIGNATURE _____
(OR AUTHORIZED REPRESENTATIVE)
DATE _____

Source: Louisiana Administrative Code, Title 51, Part IX, Chapter 3, Section 345.

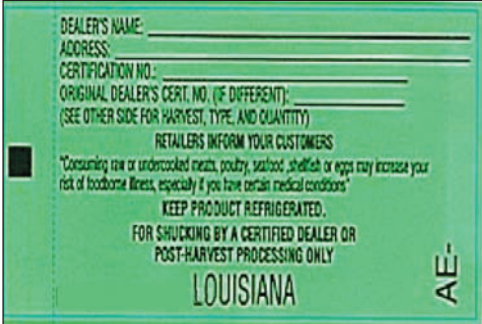
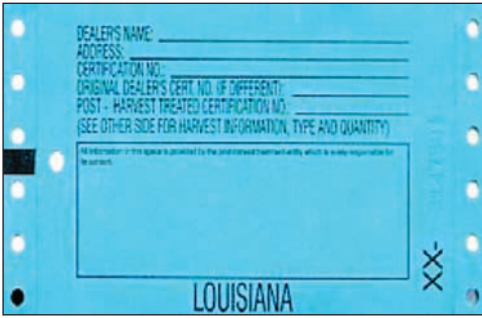

FDA is responsible for evaluating states' enforcement of time and temperature controls. However, FDA officials told us that FDA's evaluations do not include assessments of the degree to which states are ensuring industry compliance. Instead, FDA officials told us their evaluations consist of checking states' *V. vulnificus* risk management plans to ensure the plans include the time and temperature controls outlined in the shellfish safety guidelines, accompanying state officials on selected oyster-processing-plant inspections and on-the-water patrols, and reviewing selected shellfish safety plans and records.

A senior ISSC official told us the ISSC planned to evaluate the effectiveness of the new time and temperature controls, in part, based on the rate of oyster industry compliance and the level of states' enforcement. However, because FDA, the ISSC, and states did not collect any industry compliance or state enforcement data, when it came time to conduct the evaluation in January 2011, the ISSC had to rely on testimonial evidence from state officials regarding the extent of industry compliance and state enforcement.

Although data are unavailable regarding oyster industry compliance with time and temperature controls, our discussions with state officials and oyster industry members suggest full compliance is highly unlikely. During several discussions with state officials and oyster industry members, we were told of instances of intentional mislabeling, a form of seafood fraud.¹⁸ For example, harvesters initially labeled oysters harvested without meeting the new time and temperature controls for shucking or postharvest processing only but later mislabeled them for raw consumption. Figure 6 shows sample labels for oysters to be consumed raw and for oysters to be shucked or postharvest processed.

¹⁸As noted in our 2009 seafood fraud report, seafood fraud can include a variety of illegal activities undertaken for economic gain. Such fraud typically involves mislabeling the seafood product by, for example, providing incorrect information about it. See GAO, *Seafood Fraud: FDA Program Changes and Better Collaboration among Key Federal Agencies Could Improve Detection and Prevention*, [GAO-09-258](#) (Washington, D.C.: Feb. 19, 2009).

Figure 6: Sample Oyster Labels

Oyster label	Description
 <p>DEALER'S NAME: _____ ADDRESS: _____ CERTIFICATION NO.: _____ ORIGINAL DEALER'S CERT. NO. (IF DIFFERENT): _____ (SEE OTHER SIDE FOR HARVEST, TYPE, AND QUANTITY) RETAILERS INFORM YOUR CUSTOMERS *Consuming raw or undercooked meats, poultry, seafood, shellfish or eggs may increase your risk of foodborne illness, especially if you have certain medical conditions* KEEP PRODUCT REFRIGERATED. FOR SHUCKING BY A CERTIFIED DEALER OR POST-HARVEST PROCESSING ONLY LOUISIANA AE-</p>	<p>Green labels are to be attached to sacks of oysters that have been harvested without meeting time and temperature controls and that should not, therefore, be consumed raw and instead must be shucked or postharvest processed.</p>
 <p>DEALER'S NAME: _____ ADDRESS: _____ CERTIFICATION NO.: _____ ORIGINAL DEALER'S CERT. NO. (IF DIFFERENT): _____ POST - HARVEST TREATED CERTIFICATION NO.: _____ (SEE OTHER SIDE FOR HARVEST INFORMATION, TYPE AND QUANTITY) All information in this space is essential for the consumer to make a safe choice which is why responsible for the market. LOUISIANA XX</p>	<p>Blue labels are to be attached to sacks of oysters that have been harvested without meeting time and temperature controls but have been postharvest processed to reduce <i>V. vulnificus</i> bacteria to nondetectable levels.</p>
 <p>DEALER'S NAME: _____ ADDRESS: _____ CERTIFICATION NO.: _____ ORIGINAL DEALER'S CERT. NO. (IF DIFFERENT): _____ (SEE OTHER SIDE FOR HARVEST, TYPE AND QUANTITY) RETAILERS INFORM YOUR CUSTOMERS *Thoroughly cooking foods of animal origin such as beef, eggs, fish, lamb, pork, poultry, or shellfish reduces the risk of foodborne illness. Individuals with certain health conditions may be at higher risk if these foods are consumed raw or undercooked. Consult your physician or public health official for further information.* KEEP PRODUCT REFRIGERATED LOUISIANA XX</p>	<p>White labels are to be attached to sacks of oysters that have been harvested in compliance with time and temperature controls and may be consumed raw.</p>

Source: Louisiana Department of Wildlife and Fisheries.

According to two large oyster processors we spoke with operating in both Louisiana and Texas, mislabeling is widespread and is driven by a considerable financial incentive to avoid the costs of complying with the time and temperature controls and obtain the higher price accorded raw oysters. A senior Florida regulatory official told us that mislabeling was identified during a recent routine inspection of a local oyster-processing

plant and that he was aware of several occasions where oysters were served raw that should have been shucked or postharvest processed because they had not been harvested in compliance with the time and temperature controls. In July 2010, the ISSC sent a letter to member states informing them of deaths traced to raw consumption of oysters that should have been shucked or postharvest processed and requesting immediate action to ensure accurate labeling. According to a senior Louisiana law enforcement official, however, mislabeling is an easy practice to engage in and is very difficult for regulatory and law enforcement personnel to detect. During a January 2011 ISSC meeting, ISSC members acknowledged that compliance with the time and temperature controls was not as good as it should be. According to the meeting minutes, there have been numerous complaints from oyster processors regarding instances of noncompliance in Florida. At the January 2011 meeting, the ISSC passed a motion encouraging increased enforcement of the time and temperature controls by the Gulf Coast states. As of March 2011, however, the ISSC was unable to tell us what specifically they meant by increased enforcement or how the states planned to implement the motion. A senior FDA official told us that this motion is unlikely to be implemented in any meaningful way given limited state enforcement capacity.

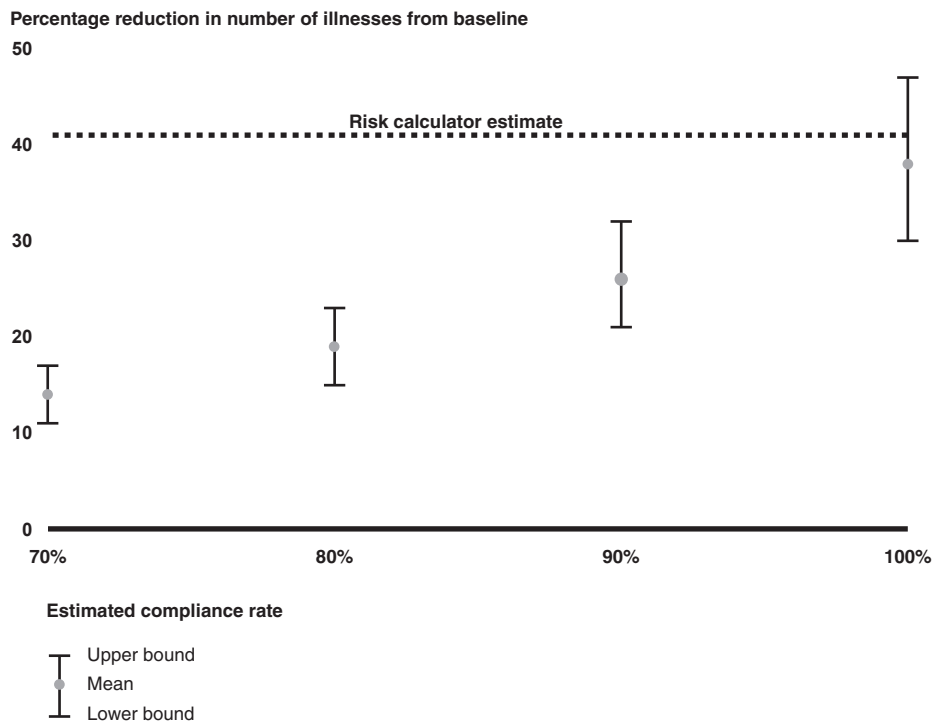
Extent of Illness Reduction from Time and Temperature Controls Depends on Compliance Levels

Given that compliance data are unavailable and that compliance rates are likely to be less than 100 percent, according to FDA, state officials, and oyster industry representatives, we used our modification of the WHO/FAO risk simulation model to estimate the effect of the compliance rate on the effectiveness of time and temperature controls in reducing *V. vulnificus* illness. Specifically, we estimated the number of illnesses during the summer months under the baseline scenario—in which the new more stringent 2010 time and temperature controls were not in effect—and under scenarios that assumed various levels of compliance with the new time and temperature controls. Our estimates show that the extent to which the new time and temperature controls would reduce *V. vulnificus* illnesses varies considerably with the level of compliance. For example, during a typical August month in Louisiana, assuming that 100 percent of oysters are harvested in compliance with time and temperature controls, the risk calculator estimates the controls will reduce illnesses by 41 percent on average, and our analysis estimates that illness reduction could range from 30 percent to 47 percent.¹⁹ As shown in figure 7, at lower levels of

¹⁹This is for a 90 percent uncertainty interval.

compliance, the illness reduction would be considerably smaller. If 80 percent of the oysters are harvested in compliance with these controls—meaning that 20 percent would be harvested out of compliance—we estimate that time and temperature controls would reduce illnesses by 15 percent to 23 percent. As a result, even assuming 80 percent compliance in the summer months, it is unlikely that these controls will lead to the level of illness reduction estimated by the risk calculator. We found that noncompliance would have a similar effect in the other summer months and in the other states. See appendix I for details.

Figure 7: Estimated Reduction in the Number of *V. Vulnificus* Illnesses as a Result of Time and Temperature Controls for Louisiana in August



Source: GAO.

Adequate Capacity Does Not Exist to Use Postharvest Processing on Gulf Coast Oysters, and Questions Exist about the Feasibility of Developing Such Capacity

According to a March 2011 FDA-commissioned report by RTI, the Gulf Coast oyster industry does not currently have adequate capacity to use postharvest processing on all Gulf Coast oysters intended for raw consumption that are harvested during warmer months.²⁰ The report found that two key issues need to be addressed to develop adequate capacity, including the construction of several central postharvest processing facilities. The report concluded that it would take at a minimum 2 to 3 years to develop the necessary capacity.²¹ However, we identified six issues of concern regarding the RTI report's economic analysis that call into question the completeness of its cost and timeline estimates.

RTI Report Finds Adequate Capacity Does Not Exist for Postharvest Processing without Additional or Expanded Facilities

In October 2009, FDA announced its intent to begin requiring postharvest processing, in part, because it believed that adequate capacity existed. RTI's March 2011 FDA-commissioned report, however, found that adequate capacity does not exist and identified two key issues that must be addressed to ensure such capacity. First, about five or six central postharvest processing facilities would be needed to accommodate smaller Gulf Coast oyster processors that may be unable to conduct postharvest processing at their current facilities due to various limitations. For example, these smaller facilities generally lack sufficient floor space for installing postharvest processing equipment without undergoing costly plant expansion, and their owners may lack the financial resources to expand their plants and purchase postharvest processing equipment. In addition, the report described several necessary steps in developing the central facilities, including: (1) determining the legal and operating structure of the facilities, (2) identifying the property where the newly constructed facilities are to be located or existing buildings are to be modified, and (3) securing the financing for developing the facilities. While central facilities may allow some smaller oyster processors access to postharvest processing facilities during the warmer months, other

²⁰In its report, RTI identified April through October as the warmer months.

²¹According to the RTI report, it will take a minimum of 2 years to increase postharvest processing capacity at existing processing facilities and 3 years to develop centralized postharvest processing facilities for use by smaller oyster processors.

challenges remain, such as the additional costs to transport oysters—refrigerated—to and from the central facilities.

Second, technical and financial assistance to several processing facilities would be needed to expand or alter their existing facilities, and purchase and install additional postharvest processing equipment. Again, the report describes several steps that must occur before initiating the expansion of existing facilities, such as developing plans for expanding the plant or altering the plant layout, and securing financing for purchasing additional equipment and constructing the expanded facility. Overall, the RTI report concluded that it will take a minimum of 2 to 3 years and, depending on the postharvest processing method used, about \$6 million to \$32 million in initial investment costs (excluding land purchase and construction costs for new centralized facilities) to develop the infrastructure required to ensure the Gulf Coast oyster industry has adequate capacity to use postharvest processing on all Gulf Coast oysters intended for raw consumption that are harvested during warmer months.

In our July 2001 report on shellfish safety, we raised the concern that if the 60 percent *V. vulnificus* illness rate reduction goal was not achieved by 2008, postharvest processing capacity may not be available because the ISSC did not have a detailed plan for ensuring such capacity.²² Consequently, we recommended that FDA work with the ISSC to prepare and implement a detailed plan for developing adequate postharvest processing capacity to help achieve the ISSC's *V. vulnificus* illness rate reduction goals. In its response, FDA agreed with our recommendation, and the ISSC agreed that it did not have a detailed plan to ensure postharvest processing capacity. At that time, ISSC officials said that the matter was a high priority and would be addressed at its upcoming July 2001 meeting. At the July 2001 meeting, the ISSC proposed that the *V. vulnificus* risk management plans include a process for implementing a required postharvest treatment capacity for 50 percent of all oysters intended for the raw consumption market—during the months of May through September—should the 40 percent illness reduction goal not be achieved by December 31, 2006.

In 2003, the ISSC surveyed oyster dealers with postharvest processing capabilities in Florida, Louisiana, and Texas and found that there was

²²[GAO-01-702](#).

sufficient capacity to use postharvest processing on 100 percent of the oysters harvested from May through September that were intended for raw consumption. According to FDA officials, until January 2011, when RTI presented its preliminary results, they believed there was sufficient capacity to use postharvest processing on all Gulf Coast oysters harvested from May through September. However, according to an ISSC official, the 2003 survey had major limitations such as quick freezing as a postharvest processing option, not considering the location of existing postharvest processing facilities, and not addressing whether existing facilities would treat their competitors' oysters. The RTI report indicated that quick freezing is not appropriate for oysters harvested in warmer months because this option substantially reduces their quality. The ISSC official said that in hindsight, FDA and the ISSC did not adequately define capacity in 2001 when they began to discuss postharvest processing capacity goals.

Six Issues of Concern Raise Questions about the Feasibility of Developing Adequate Postharvest Processing Capacity

FDA stated in October 2009 that postharvest processing should be required beginning in May 2011, in part, because it believed that adequate capacity existed. When the ISSC raised concerns, FDA tasked RTI with analyzing the feasibility and economic impacts of such a requirement. Although we believe that the overall method RTI used for its analysis is credible, its conclusion—that postharvest processing capacity to treat all Gulf Coast oysters intended for raw consumption that are harvested from April through October can be developed in a minimum of 2 to 3 years—is questionable due to six issues of concern we identified in RTI's economic analysis. We recognize that some of the issues we identified are the result of constraints faced by RTI, such as not being within the scope of the FDA-approved RTI report work plan, a lack of data, and the associated contractual report due dates (i.e., FDA needed the report completed before the 2011 summer oyster harvest season to help inform policy decisions). The six issues of concern are as follows.

- *Baseline data may not be representative of the industry.* The RTI report relied on 2008 data—such as oyster harvest volumes, oyster prices, and the number of Gulf Coast oyster processors—as a representative baseline to estimate economic impacts of a postharvest processing requirement. We believe the 2008 data are not necessarily representative of the current state of the Gulf Coast oyster industry due to the events that occurred in 2010—the Deepwater Horizon oil spill and the implementation, on May 1, 2010, of the new, more stringent time and temperature controls. The lead author of the RTI report explained that using the 2008 data as a

baseline was appropriate because 2008 was the most recent and complete year of data. Furthermore, the lead author said that it could take several years for the oyster industry to adjust to the 2010 events and that waiting for this adjustment to occur would not necessarily change the overall report's conclusions regarding the economic impacts of postharvest processing. However, the lead author acknowledged that using 2008 data was a limitation of the study and that using a baseline after the 2010 events would allow for more refined estimates. We believe the estimates in the report may be of limited use for determining how the market would respond to a postharvest processing requirement because the estimates are premised on the oyster industry's structure prior to the 2010 oil spill and implementation of the new time and temperature controls, which may not reflect the Gulf Coast oyster industry of the future. For example, oyster production was severely curtailed in 2010 compared with the baseline production in 2008. According to the Louisiana Department of Wildlife and Fisheries, the Louisiana oyster harvest was down by 50 percent in 2010. Given the baseline used, the results of the economic impact analysis may not provide a valid basis for the oyster-processing industry to make investment decisions if a postharvest processing requirement is implemented.

- *Key costs are excluded.* Certain key costs are excluded from the report's economic analysis. For example, the report does not include information on costs associated with purchasing land needed to expand existing postharvest processing facilities or construct new centralized facilities. The lead author of the RTI report said that land costs vary significantly by location. According to the lead author, a detailed analysis of such costs was not within the scope of the FDA-approved RTI report work plan. Although we agree that such costs are highly variable across regions, we believe that including a mean or median land cost would be better than omitting land costs altogether, as such costs may account for a large portion of the total costs to expand existing or construct new facilities. In addition, other significant costs are excluded from the economic analysis, such as construction costs for the new centralized facilities, insurance coverage for additional processing plant space and postharvest processing equipment, and costs for transporting oysters to and from the central postharvest processing facilities. The report acknowledges that insurance coverage may be a significant expense, especially in areas prone to severe weather and flooding. Furthermore, according to the report, processors will incur transportation costs if they are unable to install processing equipment at their facilities and instead have to rely on centralized facilities. Transportation costs would

include either paying for trucking services or purchasing and operating a refrigerated truck. According to the lead author, these costs were not included because a detailed analysis of such costs was not within the scope of the FDA-approved report work plan. If key costs are not analyzed and included in the cost estimates, the full scope of the financial resources needed to ensure the Gulf Coast oyster industry has sufficient capacity to use postharvest processing on oysters harvested during the warmer months will not be known.

- *Who would pay to expand processing capacity is not clear.* The RTI report does not clearly address who would pay for postharvest processing, which includes purchasing and installing the equipment, as well as transporting harvested oysters to and from postharvest processing facilities. The lead author of the RTI report said inquiring about possible financial sources available for subsidizing the expansion of postharvest processing capacity was beyond the scope of the report. However, she suggested that expansion could be subsidized by an entity within state government or by an oyster industry cooperative that was established to develop a financing mechanism. In addition, she said the ISSC could take the lead in coordinating the development of the financing mechanisms needed to expand postharvest processing facilities. We believe that identifying financial support is a major issue in assessing the feasibility of requiring postharvest processing, particularly considering state government budget constraints and the financial losses the oyster industry incurred as a result of the 2010 Deepwater Horizon oil spill and the ongoing effects of the recent economic recession. Difficulties in obtaining financing could impact the time frame for postharvest processing to become operational, and therefore the minimum 2 to 3 year estimate for increasing capacity might not be reliable.
- *Limited support exists for estimated time frame for increasing postharvest processing capacity.* According to the RTI report, existing processors would need a minimum of 2 years to increase their postharvest processing capacity; however, the report does not describe in detail the basis for the 2-year estimate. In addition, according to the report, it will take at least 3 years to develop the centralized postharvest processing facilities. The lead author of the report said that the estimates were based, in part, on information obtained from surveying Gulf Coast processors. However, the lead author acknowledged that few processors contributed cost information associated with purchasing, installing, and operating postharvest processing equipment because this type of information is proprietary. We recognize the proprietary nature of the cost data, but we believe

the basis for RTI's time frame estimates could be more transparent. For example, the report could provide specific time frames associated with the steps the report says are required to increase postharvest processing capacity. Absent such transparency, it is difficult to know whether the estimate is well supported and likely to be accurate.

- *Assumptions about postharvest processing for oysters shipped within state borders are likely inaccurate.* The RTI report's economic impact analysis assumes that three Gulf Coast states—Florida, Texas, and Louisiana—would require postharvest processing for oysters harvested in the warmer months that are intended for raw consumption and sold within the state's borders. However, statutes passed in 2011 in both Louisiana and Texas state that federal regulations that prohibit the interstate sale of oysters without postharvest processing do not apply to oysters harvested and sold within the state.²³ By not incurring the added cost of postharvest processing, these oysters would affect overall oyster prices. The lead author of the RTI report agreed that the availability of cheaper nonpostharvest processed raw oysters might significantly constrain the ability of retailers and restaurateurs, for example, to sell the higher-priced postharvest processed oysters. Although the RTI report's analysis includes a range of assumptions on the likely proportion of oysters sold within or outside of a state's borders, these assumptions are not incorporated in the economic impact model. Incorporating them is important because they provide oyster processors with important information on whether they should make investments in postharvest processing equipment. For instance, if some state regulations allow the sale, within state borders, of oysters intended for raw consumption without postharvest processing, certain processors may decide not to sell oysters outside their state to avoid the cost of postharvest processing equipment, which would place competitive pressure on all oyster prices. We believe that without including a range of assumptions about the proportion of oysters likely to be sold both within and outside of a state's borders, the overall economic impacts, including the likelihood of oyster processors investing in postharvest processing capacity, will not be fully known.
- *Postharvest processing costs may not be able to be passed on to consumers.* The RTI report also assumes that oyster processors can

²³La. Rev. Stat. § 56:437; Tex. Parks & Wild. Code. § 76.303.

pass on some of their postharvest processing costs to consumers. The studies cited in the report indicate there is no clear consensus on whether any of the postharvest processing costs could be passed on to consumers or, if the costs could be passed on, what the amount would be. These studies generally found that consumers preferred raw unprocessed oysters to postharvest processed oysters, and although some were willing to accept postharvest processed oysters, they were not necessarily willing to pay a higher price for them. The lead author of the RTI report agreed that the report's assumption that oyster processors can pass on some of their postharvest processing costs to consumers is uncertain. Without the ability to pass on their higher costs to consumers, many of the current oyster-processing establishments could face closure because, with the addition of postharvest processing costs, their total costs may exceed their returns. Also, oyster harvesters who depend on these processors may have to stop harvesting during the warmer months or quit harvesting altogether. Without an analysis that provides a range of estimates for the price increase that could be passed on to consumers, the Gulf Coast oyster industry will not have sufficient information to help determine whether postharvest processing is economically feasible.

Conclusions

It has been nearly 2 years since FDA informed the ISSC that the current *V. vulnificus* illness rate reduction goal does not sufficiently protect public health. However, since then, FDA and the ISSC have not come to agreement on what an appropriate *V. vulnificus* illness reduction goal should be or on the best strategy to achieve such a goal. In the absence of such agreement, it will be very difficult for FDA and the ISSC to make progress in reducing the number of *V. vulnificus* illnesses. In addition, the approach FDA and the ISSC use to measure progress in reducing *V. vulnificus* illnesses has three main limitations that undermine its credibility. For example, the approach is based on data from only four states, including California, which has had nearly zero consumption-related *V. vulnificus* illnesses since it began requiring postharvest processing of Gulf Coast oysters in 2003. Consequently, the FDA and ISSC measurement approach does not provide a credible representation of the Gulf Coast or national impact of *V. vulnificus* illnesses or the real status of their efforts to reduce them. Since 2001, FDA, the ISSC, and the Gulf Coast states have relied on consumer education and time and temperature controls to reduce *V. vulnificus* illnesses, but neither FDA nor the ISSC has routinely evaluated whether these strategies have been effective in reducing *V. vulnificus* illness. Our analysis shows that the extent to which the new time and temperature controls will reduce *V.*

vulnificus illnesses varies considerably with the level of compliance. Without regular evaluations of these illness reduction strategies, FDA, the ISSC, and state officials and policymakers have no way of knowing whether either strategy has been successful and should be continued or is ineffective and should be stopped, which can result in wasted resources and a failure to reach policy goals. Finally, FDA has concluded that because consumer education and time and temperature controls have not resulted in achievement of the 60 percent illness rate reduction goal, Gulf Coast oysters harvested during the warmer months and intended for raw consumption should be postharvest processed to reduce *V. vulnificus* to nondetectable levels. However, the 2011 FDA-commissioned RTI report found that adequate capacity to use postharvest processing on all Gulf Coast oysters harvested from April through October that are intended for raw consumption does not currently exist and is at best 2 to 3 years away. Furthermore, our review of the report's economic analysis found several issues that the report did not thoroughly address, which could significantly impact the feasibility of developing adequate postharvest processing capacity specified in the FDA-commissioned report.

Recommendations for Executive Action

To better ensure the safety of oysters from the Gulf of Mexico that are sold for raw consumption, we recommend that the Secretary of Health and Human Services (HHS) direct the Commissioner of FDA to work with the ISSC to take the following four actions:

- Agree on a nationwide goal for reducing the number of *V. vulnificus* illnesses caused by the consumption of Gulf Coast raw oysters and develop strategies to achieve that goal, recognizing that consumer education and time and temperature controls have not resulted in achievement of the 60 percent *V. vulnificus* illness rate reduction goal and that the capacity to use postharvest processing on Gulf Coast oysters harvested from April through October that are intended for raw consumption does not currently exist.
- Correct the limitations in the current approach to measuring progress toward the 60 percent *V. vulnificus* illness rate reduction goal or design and implement a new approach without these limitations.
- Regularly evaluate the effectiveness of *V. vulnificus* illness reduction strategies, such as consumer education and time and temperature controls, to determine whether they are successful and should be continued or are ineffective and should be stopped.

-
- Conduct further study of the six issues of concern we identified regarding the RTI report's economic analysis to ensure a more accurate assessment of the feasibility of developing adequate capacity and before FDA and the ISSC move forward with revising the National Shellfish Sanitation Program's shellfish safety guidelines to provide postharvest processing for oysters harvested from Gulf Coast waters during warmer months and intended for raw consumption.

Agency Comments and Our Evaluation

We provided a draft of this report to HHS and the ISSC for review and comment. In written comments, which are included in appendix II, HHS provided FDA responses, which generally agreed with the report's four recommendations. Specifically, FDA agreed with our first and second recommendations. Regarding our third recommendation, FDA agreed that the approach used to evaluate the effectiveness of illness reduction strategies has limitations that undermine its credibility. FDA also said that assessing the effectiveness of existing controls on illness reduction is extremely difficult. In an effort to better monitor compliance with time and temperature controls, FDA intends to take a number of steps, including conducting annual on-site checks at oyster landing sites and processing plants to examine compliance with *V. vulnificus* Hazard Analysis and Critical Control Point controls, harvester records, time and temperature logs, and actual product temperature. We recognize that assessing the effectiveness of *V. vulnificus* illness reduction strategies is difficult, but continue to believe it would be useful for FDA and the ISSC to attempt to do so, because without such evaluations it is difficult to determine whether the strategies are successful and should be continued or are ineffective and should be stopped.

Concerning our fourth recommendation, which identified six issues of concern in the FDA-commissioned report on postharvest processing capacity, FDA agreed to conduct further study or take other actions to address our concerns on four issues—key costs are excluded; who would pay to expand processing capacity is unclear; support for estimated time frame for increasing postharvest processing capacity is limited; and assumptions about postharvest processing for oysters shipped within state borders are likely inaccurate—but disagreed with one issue and neither agreed nor disagreed with the other issue. FDA disagreed with our assessment that the 2008 baseline data used in the study may not be representative of the Gulf Coast oyster industry. Furthermore, FDA said that use of 2010 data would not have represented a typical harvest year because the Deepwater Horizon oil spill resulted in closures of many Gulf Coast oyster harvest areas, thereby reducing oyster harvest levels.

However, we did not suggest that 2010 data be used for the baseline; instead we believe it is preferable to use a baseline from either an average of several years or a sensitivity analysis of alternative baselines, including one that incorporates data for 2010, the year of the Deepwater Horizon oil spill and the implementation of the new, more stringent time and temperature controls. FDA did not agree or disagree with our assessment that postharvest processing costs may not be able to be passed on to consumers. Instead, FDA stated that there are many uncertainties regarding whether the cost of postharvest processed oysters can be passed on to consumers. We believe the FDA-commissioned report's analysis could be improved by providing a range of postharvest processing cost estimates that can be passed on to consumers, which would help the oyster industry determine the extent to which postharvest processing is economically feasible. FDA also provided technical comments, which we incorporated as appropriate.

The ISSC stated in its written comments—which are included in appendix III—that it generally agreed with the recommendations in the report. The ISSC also provided additional information on the FDA and ISSC efforts to address *V. vulnificus* illnesses and the circumstances that led to the implementation of the current *V. vulnificus* illness reduction strategies. Also, the ISSC commented that the goal of the *V. vulnificus* risk management plans was to reduce *V. vulnificus* illnesses nationally and that four states—California, Florida, Louisiana, and Texas—were used to measure effectiveness. However, even though the ISSC states that the 60 percent illness rate reduction goal is a national goal, it determined achievement toward a national goal by calculating the rate of illness for those four states.

As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the appropriate congressional committees, the Secretary of Health and Human Services, the Executive Director of the Interstate Shellfish Sanitation Conference, and other interested parties. In addition, the report will be available at no charge on the GAO Web site at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-3841 or shamesl@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. Key contributors to this report are listed in appendix IV.

Sincerely yours,

A handwritten signature in black ink that reads "Lisa Shames". The signature is written in a cursive style with a horizontal line at the end.

Lisa Shames
Director, Natural Resources and Environment

Appendix I: Estimating the Impact of Time and Temperature Controls on the Number of Illnesses from *V. Vulnificus*

To estimate the impact of time and temperature controls on the number of illnesses from *Vibrio vulnificus* (*V. vulnificus*), we took several steps. We replicated a model developed by the World Health Organization and the Food and Agriculture Organization (WHO/FAO) that simulates the risk of illness from *V. vulnificus* based on several factors, such as water temperature and the number of hours that harvested oysters are left unrefrigerated.¹ We then modified the model to simulate the impact of the time and temperature controls implemented in Florida, Louisiana, and Texas in May 2010. Specifically, we examined the amount of uncertainty in the model's estimates of the risk of illness and the impacts of various levels of compliance with time and temperature controls on the estimated number of *V. vulnificus* illnesses.

The Structure of the WHO/FAO Risk Simulation Model

The WHO/FAO, in partnership with the Food and Drug Administration (FDA), developed a risk simulation model that estimates levels of *V. vulnificus* in raw oysters and the subsequent impact of these levels on the risk of illness.² The risk simulation model was presented in a WHO/FAO report on the assessment of risk of *V. vulnificus* in raw oysters.³ To estimate the impact of time and temperature controls on the risk of *V. vulnificus* illnesses, we replicated this model and modified it to account for potential changes to harvesting and storage practices in response to the

¹Both WHO and FAO are located within the United Nations system. WHO is the directing and coordinating authority for health and is responsible, among other things, for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries, and monitoring and assessing health trends. FAO serves both developed and developing countries by acting as a neutral forum where all nations meet as equals to negotiate agreements and debate policy and helps developing countries and countries in transition modernize and improve agriculture, forestry, and fisheries practices and ensure good nutrition for all.

²The risk of illness represents the probability that an individual in the susceptible population will become ill from eating a serving of raw oysters. The estimated number of illnesses per 100,000 servings consumed by the susceptible population can be obtained by multiplying 100,000 by the risk of illness per serving. Following the WHO/FAO risk assessment, the susceptible population includes people with certain medical conditions, including chronic liver disease, cancer, kidney disease, diabetes, and human immunodeficiency virus/acquired immune deficiency syndrome, who are at risk of developing a potentially fatal bloodstream infection known as septicemia.

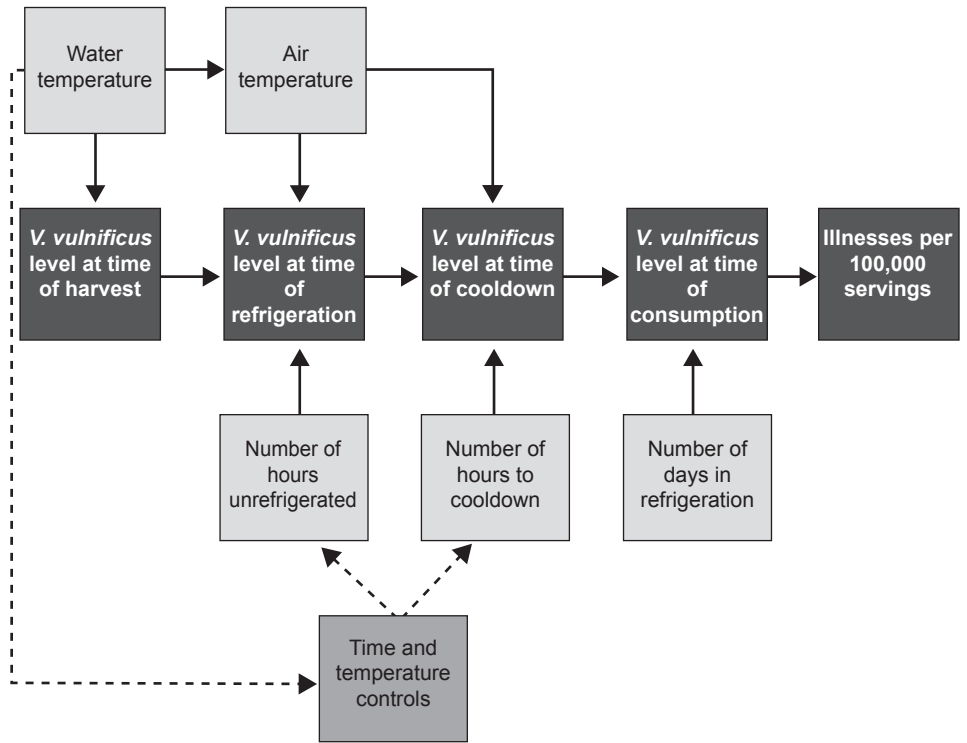
³World Health Organization and Food and Agriculture Organization of the United Nations, *Risk Assessment of Vibrio Vulnificus in Raw Oysters: Interpretive Summary and Technical Report*, Microbial Risk Assessment Series, 8 (Geneva, Switzerland and Rome, Italy: 2005).

imposition of time and temperature controls and to analyze various rates of compliance with these controls.

The WHO/FAO risk simulation model is a Monte Carlo simulation, a type of numerical analysis that produces a range of estimates to account for the natural variability in the model's data inputs and the statistical uncertainty in the parameters of the model's equations. Data inputs, such as water temperature, vary naturally from day to day within a month and from year to year for a given month. Similarly, the parameters in the model's equations that estimate *V. vulnificus* levels based on data inputs and that predict the risk of illness based on estimated *V. vulnificus* levels, while based on scientific studies, are subject to statistical uncertainty. To account for the variability in data inputs and the uncertainty in the parameters of the model's equations, the WHO/FAO risk simulation model calculates a range in possible estimates of risk, each using slightly different values of the data inputs and slightly different values of the parameters. To produce a single estimate of the risk of illness, the model first estimates levels of *V. vulnificus* at each of four stages in the production process—from harvest to first refrigeration to cooldown to consumption. The model then estimates the overall risk of illness based on the estimated levels of *V. vulnificus* at the four stages.

Figure 8 illustrates each of the stages of the model and the factors that influence them. In this figure, the light gray boxes represent the input factors, the black boxes represent calculations based on those factors, and the arrows indicate which factor influences which calculation. For example, water temperature, air temperature and the number of hours that oysters are left unrefrigerated are input factors that influence the level of *V. vulnificus* in oysters at the time they are first refrigerated. The dark gray box and the dotted arrows represent our modification of the WHO/FAO risk simulation model. Specifically, we modified the way in which the model determines the number of hours that oysters are left unrefrigerated, which will then impact the level of *V. vulnificus* in oysters at the time of cooldown. Finally, because *V. vulnificus* has been found to stop growing and to begin dying off when refrigerated at 55 degrees Fahrenheit or below, the number of days oysters are refrigerated affects the *V. vulnificus* level at the time oysters are consumed, which affects the number of *V. vulnificus* illnesses that are likely to occur.

Figure 8: Key Components of WHO/FAO Risk Simulation Model and GAO Modifications



- Legend**
- Data inputs used in WHO/FAO model
 - GAO modification to WHO/FAO model
 - Estimates made by WHO/FAO model
 - Relationships in WHO/FAO model
 - GAO modification to WHO/FAO model

Source: GAO replication of and modification to WHO/FAO risk simulation model.

Note: The arrow from water temperature to time and temperature controls indicates that time and temperature controls vary from month to month—the controls are stricter during warmer months and less strict during cooler months.

Our Replication and Modification of the WHO/FAO Risk Simulation Model

To replicate the WHO/FAO risk simulation model, we took several steps. We reviewed the WHO/FAO risk assessment and documented the model’s key data inputs, assumptions, and equations. We asked FDA modelers, who led the development of the WHO/FAO risk simulation model, to review our documentation, and we revised our version of the model based on their comments. We programmed the model in Statistical

Analysis Software, generated preliminary estimates, and asked FDA modelers to review these estimates, and we compared these estimates to identify remaining differences between our version of the model and the version used in the WHO/FAO risk assessment. We used the same data inputs as reported in the WHO/FAO risk assessment, including the statistical distributions of water temperature, the difference between water temperature and air temperature, the number of hours that oysters are unrefrigerated, the number of hours until oysters cool down to 55 degrees Fahrenheit, and the number of days that oysters remain in refrigeration. We also used the same values as the WHO/FAO risk assessment for parameters that convert these data inputs into the model's estimates, such as the parameters that define the relationship between water temperature and *V. vulnificus* levels at harvest and the parameters that define the relationship between *V. vulnificus* levels at consumption and the risk of illness.⁴

To verify that we correctly replicated the WHO/FAO risk simulation model, we compared our estimates to the estimates reported in the WHO/FAO risk assessment for each of the four seasons. Using the same data inputs, model parameters, and assumptions, our estimates of the risk of illness differ from the estimates reported in the WHO/FAO risk assessment by less than 1 percent in the spring, less than 1 percent in the summer, 4 percent in the fall, and 42 percent in the winter.⁵ We report only our estimates from the summer months because the risk of *V. vulnificus* illness is greatest during these months and because estimates from our model are most similar to the estimates from the WHO/FAO model during these months. See table 2 for a comparison between the WHO/FAO and GAO estimates for key stages of the model for the summer months.

⁴For these two parameters in particular, we obtained from the FDA additional information that was consistent with but more detailed than the information reported in the WHO/FAO risk assessment.

⁵Spring is defined as April, May, and June; summer is July, August, and September; fall is October, November, and December; and winter is January, February, and March. Although the difference in our estimates for winter is 42 percent, this represents a difference of about only one illness per 1 million oyster servings in absolute terms.

Appendix I: Estimating the Impact of Time and Temperature Controls on the Number of Illnesses from *V. vulnificus*

Table 2: Comparison of Estimates between WHO/FAO Risk Simulation Model and GAO Replication of the Model for July, August, and September

Variables	WHO/FAO risk simulation model		GAO replication of risk simulation model		Percentage difference ^a	
	Mean	Standard deviation	Mean	Standard deviation	Mean	Standard deviation
Log ₁₀ <i>V. vulnificus</i> per gram at time of harvest	3.27	0.64	3.27	0.65	0.00	1.50
Log ₁₀ <i>V. vulnificus</i> per gram growth prior to refrigeration	0.68	0.35	0.69	0.34	1.45	-2.86
Log ₁₀ <i>V. vulnificus</i> per gram growth during cooldown	0.50	0.22	0.50	0.22	0.00	0.00
Log ₁₀ <i>V. vulnificus</i> per gram die-off during refrigeration ^b	0.31	na ^d	0.32	0.15	3.13	na ^d
Number of <i>V. vulnificus</i> illnesses per 100,000 Servings	4.28	90 percent uncertainty interval (3.69-4.97) ^c	4.30	90 percent uncertainty interval (3.62-5.19) ^c	0.47	na ^e

Source: WHO/FAO risk assessment and GAO replication of WHO/FAO risk simulation model.

^aEstimates reported in the WHO/FAO risk assessment were rounded to two numbers past the decimal point. As a result, the calculations of percentage difference between the WHO/FAO estimates and the GAO estimates may be subject to rounding errors.

^b*V. vulnificus* per gram die-off implies a reduction in bacterial levels during refrigeration. Therefore, although the estimates are presented as positive numbers, they refer to a decrease in *V. vulnificus* levels.

^cTo be consistent with the estimates in the WHO/FAO risk assessment, we present the 90 percent uncertainty interval for the number of *V. vulnificus* illnesses per 100,000 servings, rather than the standard deviation.

^dThe standard deviation of the Log₁₀ *V. vulnificus* per gram die-off rate during refrigeration was not reported in the WHO/FAO risk assessment.

^eFor simplicity, the percentage differences between the upper and lower bound of the 90 percent uncertainty intervals are omitted, although the information provided in the table allows these percentage differences to be calculated.

After verifying that we replicated the WHO/FAO risk simulation model, we modified it to simulate the impact of time and temperature controls in Florida, Louisiana, and Texas. Since time and temperature controls are specific to each state and each month, we modified the model to provide the estimated risk of *V. vulnificus* illness for each state and each month. In particular, we used monthly, rather than seasonal, parameters that were reported in the WHO/FAO risk assessment to estimate water temperature and the difference between water temperature and air temperature. In addition, the WHO/FAO risk assessment reported parameters for the distribution of the number of hours that oysters are left unrefrigerated separately for Louisiana and for the rest of the Gulf Coast states. We applied these parameters to our simulation, using one set of parameters for Louisiana and another set of parameters for Florida and Texas. The WHO/FAO risk assessment model's

estimates are based on the average of 100 samples of 10,000 observations each. To provide more reliable uncertainty intervals for these estimates, our modification of the WHO/FAO model uses 1,000 samples.

Time and Temperature Controls for Florida, Louisiana, and Texas and Our Simulations of Various Compliance Rates with the Controls

Effective May 1, 2010, Florida, Louisiana, and Texas implemented new, more stringent time and temperature controls that specify (1) the maximum number of hours that oysters are allowed to be unrefrigerated after being harvested and (2) the maximum number of hours before refrigerated oysters must cool down to 55 degrees Fahrenheit. The new more stringent controls established by the three states for 2010 and incorporated in their risk management plans are presented in table 3 for each state and each month. These controls are stricter during the warmer months when *V. vulnificus* bacteria multiply more quickly. In August, for example, Louisiana and Texas have the most restrictive controls for the time oysters could remain unrefrigerated, allowing 1 hour from harvest until refrigeration, and Florida has the most restrictive controls for the time until refrigerated oysters must cool down, allowing 2 hours from when they are first refrigerated until they reach 55 degrees Fahrenheit.

Table 3: Time and Temperature Controls for 2010, by State and Month

Month	Maximum number of hours					
	From harvest to refrigeration			From refrigeration to cooldown to 55 degrees Fahrenheit		
	Florida	Louisiana	Texas	Florida ^a	Louisiana	Texas
January	18	36	18	10	10	10
February	18	36	18	10	10	10
March	18	8	18	10	10	10
April	12	8	10	10	10	10
May	6	1	4	2	6	6
June	6	1	3	2	6	6
July	6	1	1	2	6	6
August	6	1	1	2	6	6
September	6	1	3	2	6	6
October	6	1	4	2	6	6
November	18	8	10	10	10	10
December	18	36	18	10	10	10

Source: GAO analysis of Florida, Louisiana, and Texas 2010 risk management plans.

^aThe number of hours to cooldown for Florida refers to the rapid cooling control option, one of four time and temperature control options authorized in Florida's *V. vulnificus* risk management plan and the only option used during the summer of 2010 by the Florida oyster industry, according to a senior Florida regulatory official.

For the purpose of this analysis, we define the baseline scenario as the risk of illness in the absence of the new, more stringent time and temperature controls. Under the baseline scenario, the WHO/FAO risk simulation model assumes a certain statistical distribution in the number of hours that oysters ordinarily would be left unrefrigerated. The values in the statistical distribution, which is based on assumptions in the risk simulation model, range from 1 hour to 10 or more hours, depending upon the state and the month, and specifies the percentage of oysters that ordinarily would be left unrefrigerated for any given number of hours within this range. Based on this statistical distribution, we estimated the percentage of oysters that ordinarily—that is, in the absence of the new, more stringent time and temperature controls—would be refrigerated within the maximum number of hours established by time and temperature controls for each state and each month. In states and months with the least stringent controls, a majority of oysters ordinarily would be refrigerated within these time limits, even in the absence of these time and temperature controls. For example, in Florida during the three summer months, according to the assumed statistical distribution, approximately 85 percent of oysters harvested ordinarily would be refrigerated within the 6-hour limit established by the new, more stringent time and temperature controls. By contrast, in states and months with the most stringent controls, fewer oysters harvested would ordinarily be refrigerated within these limits. For example, in Louisiana and Texas in August, virtually none of the harvested oysters ordinarily would be refrigerated within the 1-hour limit established by these time and temperature controls, according to the assumed statistical distribution.

To simulate compliance with the maximum number of hours that oysters are allowed to be unrefrigerated under applicable time and temperature controls, we make the following assumptions about the behavior of oyster harvesters. First, harvesters that ordinarily—that is, under the baseline scenario—would leave oysters unrefrigerated for less than the maximum number of hours would continue to leave them unrefrigerated for the same number of hours that they ordinarily would have. Second, harvesters who ordinarily would leave oysters unrefrigerated for more than the maximum number of hours, and who decide to change to comply with time and temperature controls, would leave oysters unrefrigerated for no more than the maximum allowed number of hours. Third, harvesters who ordinarily would leave oysters unrefrigerated for more than the maximum number of hours, but who decide not to change to comply with time and temperature controls, would continue to leave oysters unrefrigerated for the same number of hours that they ordinarily would have. Similarly, to model the impact of compliance on the number of

hours until oysters reach the desired 55 degrees Fahrenheit, we assumed that producers would facilitate more rapid cooling so that oysters would take no longer than the maximum number of hours to cooldown.

Using these assumptions, we developed 10 compliance scenarios for each state and each month. These scenarios correspond to estimated compliance rates of 10 percent through 100 percent in increments of 10. Under these scenarios, the model first estimates the percentage of oysters that ordinarily would be refrigerated within the maximum number of hours established by time and temperature controls for each state and each month. To obtain a given compliance rate, the model calculates the additional percentage of oysters that would need to be refrigerated within the maximum number of hours by time and temperature controls to reach a given rate of compliance with regard to the maximum time allowed to be unrefrigerated. For this additional percentage of oysters, the model assumes that oysters would be refrigerated within the maximum number of hours allowed by the controls for that state and month. In Florida during the three summer months, for example, 85 percent of oysters are assumed to be refrigerated within the 6-hour limit in the absence of time and temperature controls, based on the assumed statistical distribution. To attain a 90 percent compliance rate, the model would select the additional 5 percent of oysters, from among the 15 percent that exceed the limit, and would assume that these oysters would be unrefrigerated for no longer than 6 hours. Since actual compliance rates are unknown, these calculations allow us to estimate the number of hours that oysters would be unrefrigerated assuming various compliance rates.

Estimates of the Number of *V. Vulnificus* Illnesses Using FDA's Risk Calculator

The three states used FDA's risk calculator and their own input data, including water temperature and air temperature for each month, to establish the specific limits for time and temperature controls. The risk calculator, which was developed by FDA, is a simplified version of the WHO/FAO risk simulation model and operates in a computer spreadsheet. It allows the user to estimate the risk of illness from *V. vulnificus* under various scenarios, such as different limits for the maximum number of hours that oysters can left be unrefrigerated. To determine the estimated number of illnesses per 100,000 servings of raw oysters (i.e., risk of illness) consumed by the susceptible population for each state and month under time and temperature controls, we used FDA's risk calculator. To make the results of our analysis comparable across the states and consistent with the assumptions of the baseline scenario, we used the input data for water temperature and air temperature from the WHO/FAO risk simulation model, rather than the

data used by the states. As a result, our estimates of the risk of illness differ somewhat from the estimates that the states made in using the risk calculator to develop their risk management plans.

Unlike the states, we estimated the number of illnesses per 100,000 servings of raw oysters consumed by the susceptible population, rather than the total number of illnesses, because (1) time and temperature controls are designed to affect the risk of illness per serving, not the total number of raw oyster servings consumed and (2) complete state-by-state and month-by-month data on the number of raw oyster servings consumed were not available. The estimated number of illnesses per 100,000 servings for each state and each month, as computed by the risk calculator, is presented in table 4. These estimates represent the number of illnesses that states would expect, based on the risk calculator, as a result of time and temperature controls. We compared these estimated numbers of illnesses, for each state and each month, to the estimates of our modification of the risk simulation model, which accounts for uncertainty in the estimates and for various compliance rates.

Effect of Uncertainty and Compliance Rates on the Likely Impact of Time and Temperature Controls on the Number of *V. vulnificus* Illnesses

FDA's risk calculator estimates the same number of *V. vulnificus* illnesses as the WHO/FAO risk simulation model, on average. Unlike the risk simulation model, however, the risk calculator does not provide uncertainty distributions associated with these estimates. Using our modification of the WHO/FAO risk simulation model, we computed the amount of uncertainty associated with estimates made by FDA's risk calculator. In any given month and in any given state, uncertainty in model assumptions may cause the actual number of illnesses to differ from the number estimated by the risk calculator. For example, in Texas in the month of August, FDA's risk calculator estimates that time and temperature controls will lead to 2.84 illnesses per 100,000 raw oyster servings consumed by the susceptible population. While this is true on average, the number of illnesses per 100,000 servings could vary from the lower bound of 2.44 to the upper bound 3.63 (for a 90 percent uncertainty interval), according to our analysis. We find a similar range of uncertainty in the estimated number of *V. vulnificus* illnesses for Florida and Louisiana. Table 4 presents our estimates compared with estimates made by the risk calculator, assuming 100 percent compliance with time and temperature controls for the three states during the summer months.

Appendix I: Estimating the Impact of Time and Temperature Controls on the Number of Illnesses from *V. Vulnificus*

Table 4: Comparison of FDA’s Risk Calculator and GAO’s Modification of WHO/FAO Risk Simulation Model Concerning Estimated Number of *V. Vulnificus* Illnesses per 100,000 Servings of Oysters at Baseline

Month	FDA risk calculator—mean ^a	GAO’s modification of WHO/FAO risk simulation model—lower bound ^b	GAO’s modification of WHO/FAO risk simulation model—mean	GAO’s modification of WHO/FAO risk simulation model—upper bound ^c
Florida				
July	3.46	2.87	3.47	4.23
August	3.45	3.00	3.53	4.30
September	3.05	2.51	3.05	3.69
Louisiana				
July	2.84	2.33	2.89	3.53
August	2.84	2.44	2.95	3.63
September	2.52	2.02	2.54	3.11
Texas				
July	2.84	2.33	2.89	3.53
August	2.84	2.44	2.95	3.63
September	2.85	2.33	2.86	3.48

Source: GAO analysis with FDA’s risk calculator and GAO’s modification of the WHO/FAO risk simulation model.

Notes: These estimates assume 100 percent compliance with state time and temperature controls.

^aEstimates made with the FDA’s risk calculator do not produce uncertainty intervals, so we only report a mean estimate, rather than a mean plus a lower bound and an upper bound.

^bThe lower bound is based on the 5th percentile of the distribution of risk calculations from our modification of the WHO/FAO risk simulation model.

^cThe upper bound is based on the 95th percentile of the distribution of risk calculations from our modification of the WHO/FAO risk simulation model.

Furthermore, we estimate that time and temperature controls would result in a smaller reduction in the number of *V. vulnificus* illnesses if compliance rates are less than 100 percent. Table 5 shows the estimated reduction in *V. vulnificus* illnesses as a result of time and temperature controls for various compliance rates for each of the three states during the summer months, based on our modification of the WHO/FAO risk simulation model. For example, during August, assuming that 100 percent of oysters are harvested in compliance with time and temperature controls, our analysis estimates these controls will reduce illnesses by between 16 percent and 27 percent in Florida, between 30 percent and 47 percent in Louisiana, and between 26 percent and 43 percent in Texas. If compliance is less than 100 percent, however, we estimate that these controls will lead to a much smaller reduction in illnesses. As can be seen in table 5, if 90 percent of oysters are harvested in compliance with time and temperature controls—meaning a noncompliance rate of 10 percent—the illness reduction is smaller than the illness reduction under

Appendix I: Estimating the Impact of Time and Temperature Controls on the Number of Illnesses from *V. Vulnificus*

the assumption of 100 percent compliance. For example, in the month of August, we estimate that illnesses would be reduced between 11 percent and 18 percent in Florida, between 21 percent and 32 percent in Louisiana, and between 19 percent and 31 percent in Texas, assuming 90 percent compliance. Furthermore, if 80 percent of oysters are harvested in compliance with these controls—meaning that noncompliance rates are 20 percent—the estimated illness reduction is smaller still. In particular, we estimate that illnesses would be reduced between 8 percent and 14 percent in Florida, between 15 percent and 23 percent in Louisiana, and between 14 percent and 22 percent in Texas. At lower levels of compliance, an even smaller reduction in the number of *V. vulnificus* illnesses is likely.

Table 5: Estimated Percentage Reduction in the Number of *V. Vulnificus* Illnesses as a Result of Time and Temperature Controls, by State and Month

	100 percent compliance			90 percent compliance			80 percent compliance ^c			70 percent compliance ^c		
	Lower bound ^a	Mean	Upper bound ^b	Lower bound ^a	Mean	Upper bound ^b	Lower bound ^a	Mean	Upper bound ^b	Lower bound ^a	Mean	Upper bound ^b
Florida												
July	17	22	27	11	15	18	8	11	14	7	9	11
August	16	21	27	11	14	18	8	11	14	7	9	11
September	17	22	29	12	16	20	9	11	15	7	9	12
Louisiana												
July	31	39	48	21	26	32	15	19	23	11	14	17
August	30	38	47	21	26	32	15	19	24	11	14	17
September	31	39	49	23	28	35	16	20	25	11	14	18
Texas												
July	27	35	43	19	24	30	14	18	22	10	13	15
August	26	34	43	19	25	31	14	18	22	10	13	16
September	21	27	34	15	19	24	10	13	17	6	8	11

Source: GAO modification of the WHO/FAO risk simulation model.

^aThe lower bound is based on the 5th percentile of the distribution of calculations.

^bThe upper bound is based on the 95th percentile of the distribution of calculations.

^cUnder the baseline scenario, approximately 85 percent of oysters in Florida in July, August, and September are assumed to be refrigerated within the maximum number of hours allowed by time and temperature controls. As a result, we assume that compliance rates for Florida during the summer will be no lower than 85 percent for time-to-refrigeration controls. Therefore, the 80 percent and 70 percent compliance scenarios for Florida refer only to compliance with refrigeration to cooldown controls.

Because time and temperature controls are less effective at lower compliance rates, the probability that these controls will lead to the illness reduction estimated by the risk calculator is also lower when compliance rates are lower. Table 6 shows the probability that time and temperature controls will reduce *V. vulnificus* illnesses to the number estimated by FDA's risk calculator or lower for various compliance rates for each of the three states, based on our risk simulation model. During the summer, assuming that 100 percent of oysters are harvested in compliance with time and temperature controls, as would be expected with the risk calculator's design, there is between a 43 percent chance and a 55 percent chance that these controls will reduce illnesses to the number estimated by the risk calculator or lower, depending on the state and the month. If compliance is less than 100 percent, however, our analysis shows that it is unlikely that time and temperature controls will reduce illnesses to the number estimated by the risk calculator or lower. As can be seen in table 5, if 90 percent of oysters are harvested in compliance with time and temperature controls—meaning a noncompliance rate of 10 percent—the chances that these controls will reduce illnesses to the estimated number or lower drop substantially when compared with the chances under the assumption of 100 percent compliance. In particular, for the month of August, we estimate that the probability drops from 48 percent to 18 percent in Florida, from 43 percent to 2 percent in Louisiana, and from 43 percent to 4 percent in Texas. Furthermore, if 80 percent of oysters are harvested in compliance with these controls—meaning that noncompliance rates are 20 percent—the likelihood of success is smaller still. In particular, we estimate that the probability that these controls will reduce illnesses to the number estimated by the risk calculator or lower drops to 7 percent in Florida, less than 1 percent in Louisiana, and 1 percent in Texas.

Table 6: Probability That the Time and Temperature Controls Will Reduce *V. Vulnificus* Illnesses to the Number Estimated by FDA’s Risk Calculator or Lower, by Estimated Compliance Rate^a

Month	Estimated compliance rate ^b			
	100 percent	90 percent	80 percent	70 percent
Florida				
July	0.54	0.22	0.11 ^c	0.08 ^c
August	0.48	0.18	0.07 ^c	0.05
September	0.55	0.24	0.10 ^c	0.07 ^c
Louisiana				
July	0.47	0.03	0.00	0.00
August	0.43	0.02	0.00	0.00
September	0.50	0.06	0.00	0.00
Texas				
July	0.47	0.07	0.01	0.00
August	0.43	0.04	0.01	0.00
September	0.52	0.17	0.04	0.01

Source: GAO modification of the WHO/FAO risk simulation model.

^aProbabilities are expressed between 0.00 and 1.00, with values close to 0.00 being highly unlikely and values close to 1.00 being highly likely.

^bCompliance rates are estimated based on the distribution of time to refrigeration and time to cooldown, which is used in both the WHO/FAO risk simulation and in GAO’s modification of the WHO/FAO risk simulation model, in combination with the thresholds established by time and temperature controls.

^cUnder the baseline scenario, approximately 85 percent of oysters in Florida in July, August, and September are assumed to be refrigerated within the maximum number of hours allowed by time and temperature controls. As a result, we assume that compliance rates for Florida during the summer will be no lower than 85 percent for time-to-refrigeration controls. Therefore, the 80 percent and 70 percent compliance scenarios for Florida refer only to compliance with refrigeration to cooldown controls.

Limitations to Our Analysis

Like all quantitative models, our analysis is subject to certain limitations. First, our analysis is subject to all of the limitations to which the WHO/FAO risk simulation model is subject. Though the WHO/FAO model is based on credible scientific studies, uses a valid and reliable methodology, and predicts actual illnesses rates with reasonable accuracy, it is subject to limitations just as all quantitative models are. For example, the model assumes that *V. vulnificus* levels at harvest are only determined by water temperature, that all strains of *V. vulnificus* are equally virulent, and that the risk of infection is identical for all members of the susceptible population, though these are simplifications. Furthermore, the exact relationship between levels of *V. vulnificus* and the observed

number of illness is not known, and there are no precise estimates of the size of the susceptible population. Second, our simulations of compliance rates are based on certain assumptions about handling of oysters under the baseline scenario—including the number of hours that oysters would be unrefrigerated and the number of hours until oysters cool down—and on certain assumptions about how producers might respond to time and temperature controls under various compliance scenarios. Since we do not have direct data on actual compliance rates, however, our estimates are only an approximation and cannot be validated against observed data. Third, our estimates of the probability that time and temperature controls will lead to the levels of illness estimated by the risk calculator are approximations and are a function of the data inputs, assumptions, and equations in the risk simulation model. In spite of these limitations, however, we believe our estimates are sufficiently reliable to demonstrate that there is a substantial chance that time and temperature controls will not lead to the number of *V. vulnificus* illnesses estimated by the risk calculator or lower, especially with less than perfect compliance rates.

Appendix II: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

Lisa Shames
Director, Natural Resources and Environment
U.S. Government Accountability Office
441 G Street N.W.
Washington, DC 20548

AUG 15 2011

Dear Mr. Kohn:

Attached are comments on the U.S. Government Accountability Office's (GAO) draft report entitled: "FOOD SAFETY: FDA Needs to Reassess Its Approach to Reducing an Illness Caused by Eating Raw Oysters" (GAO-11-607).

The Department appreciates the opportunity to review this report before its publication.

Sincerely,

A handwritten signature in black ink that reads "Jim R. Esquea".

Jim R. Esquea
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "FOOD SAFETY: FDA NEEDS TO REASSESS ITS APPROACH TO REDUCING AN ILLNESS CAUSED BY EATING RAW OYSTERS" (GAO-11-607)

The Department appreciates the opportunity to review and comment on this draft report. *Vibrio Vulnificus* (*V. vulnificus*) is a naturally occurring bacterium that can cause a severe and life threatening illness that is fatal about 50 % of the time, generally causing about 15 deaths per year. *V. vulnificus* is associated with the consumption of raw oysters and characterized by fever and chills, decreased blood pressure (septic shock), and blistering skin lesions. At greatest risk are individuals whose immune systems have been compromised or who have certain health conditions, such as liver, stomach, or blood disorders; cancer; AIDS; diabetes; kidney disease; and chronic alcohol abuse.

Effective technologies have been developed that can largely eliminate the hazard of *V. vulnificus* while producing oysters that retain the sensory qualities of untreated product. These technologies, known as Post Harvest Processing (PHP), include individual quick freezing (IQF) with extended frozen storage, high hydrostatic pressure, mild heat, and low dose gamma irradiation. PHP technologies have proven to be effective in eradicating *V. vulnificus* associated illness. For example, in 2003, the State of California prohibited Gulf Coast oysters from entering the state during the season of greatest risk unless they had undergone PHP. Once PHP was required in California, the number of deaths in the state fell from 40, between 1991 to 2001, to nearly zero since then. California's PHP requirement has virtually eliminated the state's *V. vulnificus*-related deaths and illness from consuming raw oysters.

The Food and Drug Administration (FDA) has collaborated with the Interstate Shellfish Sanitation Conference (ISSC) for years to reduce *V. vulnificus* illness through improving consumer education and refrigeration practices, but these practices have failed to achieve measurable reductions of *V. vulnificus* illnesses nationally. FDA has proposed the implementation of PHP, or other equivalent controls, to substantially reduce *V. vulnificus* illness, but the Gulf Coast industry, state officials, and elected representatives have raised concerns about implementing PHP controls. FDA has considered these concerns and recognizes the need to further examine the timing and processes for oyster harvesters to gain access to PHP facilities or equivalent controls. To that end, FDA commissioned an independent study to assess how PHP or other equivalent controls can be implemented in a safe, efficient, and economic manner and will be addressing the concerns related to that study raised by GAO in an addendum to that study. FDA will continue to collaborate and dialogue with industry, state officials, and the ISSC to explore reasonable and workable approaches to substantially reduce *V. vulnificus* illness and protect the American people from this painful, deadly and preventable disease.

FDA's responses to GAO's recommendation are set forth below:

GAO Recommendations

To better ensure the safety of oysters from the Gulf of Mexico that are sold for raw consumption, we recommend that the Commissioner of FDA work with the Executive Board of the ISSC to take the following four actions:

- *agree on a nationwide goal for reducing the number of *V. vulnificus* illnesses caused by the consumption of Gulf Coast raw oysters and develop strategies to achieve that goal,*

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "FOOD SAFETY: FDA NEEDS TO REASSESS ITS APPROACH TO REDUCING AN ILLNESS CAUSED BY EATING RAW OYSTERS" (GAO-11-607)

*recognizing that consumer education and time and temperature controls have not resulted in achievement of the 60 percent *V. vulnificus* illness rate reduction goal and that the capacity to use post-harvest processing (PHP) on Gulf Coast oysters harvested from April through October that are intended for raw consumption does not currently exist;*

FDA Response

The ISSC has attempted to achieve the 60% illness reduction goal that had been established in 2001 through improved refrigeration practices, limited PHP and consumer education, but these efforts have not succeeded. FDA recognizes the efforts that went into these undertakings and will continue to collaborate with the ISSC to find strategies and explore approaches to establishing reasonable and workable goals for reducing *V. vulnificus* illness and protecting Americans from this deadly and preventable disease. As FDA continues in these efforts the agency remains mindful that effective technologies have been developed that can largely eliminate the hazard of *V. vulnificus* while producing oysters that retain the sensory qualities of untreated product.

- *correct the limitations in the current approach to measuring progress toward the 60 percent *V. vulnificus* illness rate reduction goal or design and implement a new approach that does not have the limitations of the current one;*

FDA Response

FDA agrees that the current approach used by the ISSC to count *V. vulnificus* illnesses and assess illness rate reduction is defective and should be corrected. The evaluation of success of existing control measures is based on counting illnesses reported in four "core" states (CA, LA, TX, FL). For a number of years, FDA has advised the ISSC of concerns with that approach. While the ISSC has claimed some success in its effort to reduce *V. vulnificus* illnesses, using numbers for the four "core" states, the rate of illness at the national level has remained relatively static. Much of the success claimed by the ISSC is directly attributable to the 2003 California ban on raw, untreated Gulf oysters. That ban virtually eliminated oyster associated *V. vulnificus* illnesses in California, which previously reported 5 to 6 annually. Continued use of California as a "core" state in the ISSC's illness counting system biases the calculated illness reduction rate. Even if the ISSC's 60% goal had been achieved, it is unlikely that a measurable reduction in the rate of illness nationally would have been realized. This presented itself as a significant factor in FDA's announcement of its intent to revise its policy and issue guidance regarding PHP. FDA wishes to continue working with the ISSC to develop a counting formula that accounts for illness nationally and that realistically defines how effective *V. vulnificus* control measures are, whatever they include.

- *regularly evaluate the effectiveness of *V. vulnificus* illness reduction strategies, such as consumer education and time and temperature controls, to determine whether they are successful and should be continued or are ineffective and should be stopped;*

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "FOOD SAFETY: FDA NEEDS TO REASSESS ITS APPROACH TO REDUCING AN ILLNESS CAUSED BY EATING RAW OYSTERS" (GAO-11-607)

FDA Response

FDA agrees with GAO that the approach that has been used to evaluate the effectiveness of illness reduction strategies has limitations that undermine its credibility, including the limited number of states used in determining *V. vulnificus* illness reduction, and the overstatement of the effectiveness of the primary *V. vulnificus* illness reduction strategies, consumer education and time and temperature controls—by including *V. vulnificus* illness data from California.

Historically FDA, ISSC and the States have devoted significant resources to conducting *V. vulnificus* education campaigns. Directed at the consuming public, these activities have been aimed at informing at-risk consumers about the risks of consuming raw molluscan shellfish. Campaign efforts have also targeted health professionals who provide care to at risk individuals, including those with underlying medical conditions, such as liver disease and chronic alcohol abuse. While FDA has not undertaken a study to specifically examine the impact of educational programs, there is no indication that they have resulted in any substantial reduction in the occurrence of *V. vulnificus* illnesses, as evidenced by the relatively static level of illnesses and deaths occurring each year nationally. A survey commissioned by the ISSC in 2004 does not suggest a reduction in the number of at-risk consumers who are consuming raw oysters and there is no evidence of illness reduction at the national level. Furthermore, even though the independent impact of education on the rate of illness cannot be measured, the impact appears to be marginal at best given that the current illness reduction rate (based on 2009 and 2010 data) is only 38.8% in the "core" states. That rate of reduction is significantly skewed by the use of California as a counting state. FDA has concluded that additional efforts to educate will have little if any beneficial outcome.

With regard to assessing the effectiveness of existing controls on illness reduction, it is extremely difficult, and perhaps impossible, to tease out the contribution of one control measure versus another. For that reason, ISSC goals have relied on illness counting to determine their success. Unfortunately, the counting strategy employed by the ISSC is flawed, for reasons previously discussed and pointed out by GAO. Studies to compare *V. vulnificus* levels in retail oysters subsequent to states' implementation of time and temperature controls to levels found in previous retail studies may help identify levels of consumer exposure. However, FDA has no plans to conduct additional studies given existing budgetary and competing priority considerations. One thing that remains clear is implementation of strict time and temperature controls by states has not achieved the ISSC 60% illness rate reduction goal. Nor have these controls resulted in any illness reduction at the national level. Arguments have been put forth suggesting that industry compliance is problematic and that increased effort by states and FDA to enforce compliance is needed. Toward that end, FDA is moving from biennial to annual evaluation of *V. vulnificus* control plans being used by states and industry. As part of its increased compliance evaluation, FDA will conduct annual onsite checks at oyster landing sites and processing plants to examine compliance with *V. vulnificus* HACCP controls, harvester records, time/temperature logs, and actual product temperatures. Such efforts will help address concerns that the goal has not been met due to inadequate implementation and enforcement of controls.

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "FOOD SAFETY: FDA NEEDS TO REASSESS ITS APPROACH TO REDUCING AN ILLNESS CAUSED BY EATING RAW OYSTERS" (GAO-11-607)

- *conduct further study of the six issues of concern that we identified regarding the RTI report's economic analysis to ensure a more accurate assessment of the feasibility of developing adequate capacity and before FDA and the ISSC move forward with revising the National Shellfish Sanitation Program's shellfish safety guidelines to provide post-harvest processing for oysters harvested from Gulf Coast waters during warmer months and intended for raw consumption.*

FDA Response

The 6 issues of concern identified by GAO are as follows:

- *Baseline data may not be representative of industry;*

FDA disagrees with the argument that baseline data, upon which the study is premised, is not representative. Data for 2008 are representative of a typical year, in which natural or manmade disasters are not of impact. As such, 2008 serves well as a baseline for what a "normal" year in the Gulf historically represents. Use of data for 2010 would not have represented a typical harvest year due to the Gulf oil spill disaster that reduced harvest levels due to closures in many Gulf Coast harvest areas. This circumstance would have skewed the results, possibly underestimating the impact and cost associated with PHP. Furthermore, to have waited until more recent data was available, and for what would be representative of a "normal" year, would have delayed efforts by FDA to examine the feasibility of PHP. Moreover, according to RTI, the overall conclusions of their study likely would not have changed.

- *Key costs are excluded;*

FDA recognizes that exclusion of certain costs can and have affected final cost outcomes presented in the RTI report. In an effort to better assess how costs associated with needs such as land purchase, new facility construction, transportation, and insurance, FDA has commissioned additional work to address these cost considerations.

- *Who should pay to expand processing capacity is not clear;*

FDA recognizes the importance to industry of identifying financing opportunities to consider and tap to partially defray the costs of implementing the PHP. FDA has commissioned additional analysis to be performed by Research Triangle Institute to develop information to fill this gap. FDA does not consider identification of funding opportunities to be principally the responsibility of the Agency.

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "FOOD SAFETY: FDA NEEDS TO REASSESS ITS APPROACH TO REDUCING AN ILLNESS CAUSED BY EATING RAW OYSTERS" (GAO-11-607)

- *Limited support exists for estimated time frame for increasing post-harvest processing capacity;*

The report presents what are considered minimum time frames for meeting the needed PHP capacity and its implementation. As a baseline minimum, it provides FDA with guidance on what the general time frame for full implementation may be. FDA recognizes that there may be additional time needs and constraints. The Agency stands ready to engage the industry and states in dialogue regarding time frames.

- *Assumptions about post-harvest processing for oysters shipped within state borders are likely inaccurate;*

FDA and RTI recognize that the study did not consider the possibility of Gulf States allowing for the intrastate sale of untreated oysters. FDA has commissioned additional analysis to be performed by Research Triangle Institute to address this concern. It may be possible that analysis could be done to account for intrastate shipment and sale of oysters for raw half-shell consumption that have not undergone PHP. It may also be possible that costs could be recalculated assuming that private processors would only post-harvest process interstate half-shell oyster shipments. In addition, the economic impact model used to assess the price and quantity effects of PHP requirements could be altered to assume that only interstate shipments of oysters intended for raw half-shell consumption would be post-harvest processed. It has been pointed out however, that to make these alterations to the model would require development of assumptions regarding numerous values in the model given the lack of data (e.g., estimates of the degree to which consumers in each of the Gulf states would substitute between oysters that have and have not been post-harvest processed).

- *Post-harvest processing costs may not be able to be passed on to consumers.*

PHP Gulf oysters are currently marketed at premium prices, according to the report. However, if PHP becomes the standard for Gulf oysters, the ability to gain premium prices to offset PHP processing costs becomes less likely. There are many uncertainties around the question of price. RTI indicated to FDA that, "If it is indeed the case that none of the costs of PHP could be passed along to consumers, an economic impact model is not an appropriate tool for assessing effects of the PHP requirements because the main purpose of this type of model is to determine the extent to which prices in the market would adjust to a change. In this case, the results of the economic impact model (Section 5.2 of the report) should simply be disregarded, and the closure analysis (Section 5.1 of the report), which includes estimates of the total costs of complying with PHP requirements, should be the focus of the economic analysis."

Appendix III: Comments from the Interstate Shellfish Sanitation Conference



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

August 22, 2011

Mr. Steve Secrist, Assistant Director
United States Government Accountability Office
Natural Resources & Environment
Western Region, San Francisco Office
301 Howard Street, Suite 1200
San Francisco, CA 94105

Dear Mr. Secrist:

Thank you for providing the Interstate Shellfish Sanitation Conference (ISSC) an opportunity to review and comment on your draft report entitled, Food Safety: FDA Needs to Reassess Its Approach to Reducing an Illness Caused by Eating Raw Oysters (GAO-11-607).

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 ISSC efforts to reduce *Vibrio vulnificus* (*Vv*) related illnesses and deaths. The comments are formatted consistent with the draft report.

The ISSC is in general agreement with the recommendations of your report. However, the scope of your investigation did not allow for a review of the history of involvement by ISSC and FDA on this issue. The scope did not allow for a full explanation of the many issues associated with *Vv* that makes this problem very unique. Regardless, we will continue to work with FDA to develop risk-based, cost effective ways to improve the safety of raw molluscan shellfish. We continue to be committed to reducing illness associated with *Vv* and will continue our efforts to explore cost effective appropriate measures which can be implemented to address illnesses associated with this naturally occurring *Vibrio*.

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) 990-2860 extension 122.

Sincerely,

A handwritten signature in cursive script that reads "J. Michael Hickey".

J. Michael Hickey, Chairman
ISSC Executive Board

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

**Appendix III: Comments from the Interstate
Shellfish Sanitation Conference**

INTERSTATE SHELLFISH SANITATION CONFERENCE COMMENTS ON THE
GOVERNMENT ACCOUNTABILITY OFFICE DRAFT REPORT
Food Safety: FDA Needs to Reassess Its Approach to Reducing an Illness Caused by Eating Raw Oysters
GAO-11-607

The Interstate Shellfish Sanitation Conference (ISSC) welcomes and appreciates the opportunity to review and comment on the Government Accountability Office's (GAO) draft report. The ISSC is in general agreement with the four (4) recommendations of the report. Provided below are general comments and specific comments to the report.

BACKGROUND OF ISSC

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 [FDA]) 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 Guide for the Control of Molluscan Shellfish 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* (*Vp*) and *Vibrio vulnificus* (*Vv*) is 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.

GENERAL COMMENTS

The ISSC applauds the effort of the GAO to examine the *Vv* problem. However, the scope of your investigation did not allow for a broader explanation of the uniqueness of the *Vv* issue. An understanding of the uniqueness is critical for a full understanding of the present controls that exist for addressing *Vv* illnesses.

The controls which have been incorporated into the NSSP since 1987 to address *Vv* were developed by ISSC and supported by FDA. FDA was fully engaged in the development of many of the approaches. Together, we recognize the limited success of several of our programs. In the late 1980s we agreed that with the small number of illnesses that physician and consumer education was more prudent than regulation. We now know that while education has benefits it will not significantly reduce national *Vv* illnesses. In 2001 we agreed that if the industry was allowed to process oysters to reduce *Vv* to non detectable levels and label the product safe that consumers would demand the safer product and the market place would encourage the industry to Post Harvest Process (PHP) oysters. This has not been the case. Consumer demand for PHP product has not created the financial incentive to encourage the majority of the industry to pursue PHP.

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Your report provides an accurate estimate of the prevalence of *Vv* illnesses which is approximately 32 illnesses per year. When compared to other food borne illnesses, this number is very small. This number has remained virtually unchanged since the early 1990s. During this period the number of reporting states has nearly doubled. The Centers for Disease Control and Prevention (CDC) reports that due to the severity of the illness, practically all cases are reported. The State Voting Delegates of ISSC, responsible for implementing controls in their respective States, have struggled to identify controls to address a naturally occurring organism that affects only 32 individuals annually. It is also important to note that the general population is not at risk.

Vv poses a risk to immuno-compromised individuals. Approximately 7% of the US population is immuno-compromised. Only a small number of that 7% is affected. Most food safety concerns place all consumers at risk. States prioritize resources to address food safety issues which pose the greatest threat of illness to consumers. Implementing regulatory controls which cause industry financial hardship make regulating this problem very problematic.

The inability to identify other food safety issues with similar illness burdens that have been regulated with similar costs to an industry has made consensus on this issue difficult. The cost benefit debate on *Vv* has always been an obstacle for the ISSC in agreeing on controls. Yet the ISSC has continued to be proactive in its efforts to reduce *Vv* illnesses. The report recommends that the ISSC and FDA agree on an appropriate *Vv* illness reduction goal. To accomplish this, ISSC and FDA must address the two broad questions: (1) what should be the goal of a public funded regulatory program for addressing a food safety issue which affects 32 persons annually; and (2) to what extent should a program of this type impose economic hardship to the industry.

Your report outlines several areas of disagreement between the FDA and ISSC. There is agreement between FDA and ISSC in several areas that provide a foundation for identifying approach for addressing the problem. The FDA and ISSC agree that *Vv* illnesses pose a health risk which requires public health intervention. There is agreement on the scope of the problem and the ability of known controls to reduce risk. The only major disagreement is the extent of public health interventions that will appropriately address the problem. The extent of the interventions dictates the financial impact to the shellfish industry. The present controls adopted by the ISSC recognize a risk at harvest and are intended to minimize any increase in risk as a result of post harvest growth. Although these controls pose significant fiscal challenges for the industry, states have imposed these controls. The FDA is proposing an approach requiring PHP, which would reduce the levels of *Vv* post harvest and further reduce the risk. While this approach seems plausible it can not be implemented without financial devastation to the industry (see Research Triangle Institute (RTI) report).

The FDA announced in 2009, intentions to reformulate policy to require post harvest processing or equivalent controls. This FDA announcement exacerbated the controversy associated with *Vv* controls. The cooperative nature of the NSSP requires support from all participants. The announcement of FDA was unilateral and has alienated the industry and states. Since the announcement FDA has been reluctant to engage in discussions regarding *Vv* goals and strategies to achieve those goals.

It appears that all interested parties are fully engaged in the *Vv* issue but as you indicate in your report, we must work together to find agreement. The major challenge for FDA and ISSC is to find a middle ground approach that can be supported by all interested parties. It seems apparent from Congressional involvement on this issue that the members of Congress have a desire for mutual agreement on an

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acceptable risk for at-risk consumers choosing to eat raw molluscan shellfish. For that reason the ISSC firmly supports the recommendations of GAO.

Specific Comments to the GAO Report

Page 2:

“The shellfish safety guidelines also included goals for reducing the rate of illness for four reporting states”

ISSC Comments:

The goal of the ISSC *V* Management Plan was to reduce illnesses nationally. The four (4) states of California, Florida, Louisiana, and Texas were used to measure effectiveness. These states were chosen because of their history in reporting *V* cases.

Page 24:

“A senior FDA official told us that this motion is unlikely to be implemented in any meaningful way given limited state enforcement capacity.”

ISSC Comments:

The FDA is responsible for ensuring compliance. The FDA should not have concurred with ISSC adoption of time temperature controls if there were concerns regarding implementation and compliance. The ISSC expects that the 2011 focused efforts of FDA to evaluate State compliance will result in effective implementation.

Appendix IV: GAO Contact and Staff Acknowledgments

GAO Contact

Lisa Shames, (202) 512-3841 or shamesl@gao.gov

Staff Acknowledgments

In addition to the contact named above, Stephen D. Secrist, Assistant Director; Leo G. Acosta, Analyst in Charge; Kevin Bray; Mark A. Braza; Allen T. Chan; Nancy L. Crothers; Barbara J. El Osta; Lorraine R. Ettaro; Mitchell B. Karpman; Anthony R. Padilla; Emmy L. Rhine; Anne O. Stevens; Kiki Theodoropoulos; and Nimish D. Verma made key contributions to this report. Also contributing to this report were Michael D. Derr, Katherine M. Raheb, and Jena Y. Sinkfield.

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