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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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Highlights

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.
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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.