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DeLauro Requests GAO Audit on Reducing Illnesses and Death Due to Contaminated Raw Oysters

Audit Would Determine Effectiveness of ISSC Risk Management Plan in Reducing Deaths Due to Raw Oysters Contaminated with *Vibrio Vulnificus*

Washington, DC— Congresswoman Rosa L. DeLauro (D-CT) today sent a letter to the Government Accountability Office (GAO) requesting an audit of the Interstate Shellfish Sanitation Conference's (ISSC) risk management plan for *Vibrio vulnificus* (Vv). The audit would determine whether the risk management plan being used by the oyster industry, and promoted by the ISSC, is effective in reducing illnesses and death due to oysters contaminated with the Vv bacteria.

On October 17, the Food and Drug Administration announced a new requirement for post-harvest processing for oysters after determining that the existing Vv risk management plan was not true to the spirit of food-borne illness prevention regulations. The FDA also questioned the reliability of the methods used by the ISSC to evaluate the effectiveness of the Vv risk management plan. After receiving significant negative feedback from the industry, the FDA announced on November 13 that the agency would not proceed with its policy regarding post-harvest processing until it conducted an independent study to assess how post-harvest processing or other equivalent controls can be feasibly implemented in the Gulf Coast in the fastest, safest and most economical way. "The FDA made the appropriate decision not to proceed with the new guidance and to work with industry to examine the process for oyster harvesters to access adequate controls to achieve this important public health goal," DeLauro stated. "However, the FDA's initial questioning of whether ISSC's Vv risk management plan is achieving its intended public health benefit is valid, and that is why I am requesting this audit. This GAO audit will provide independent, verifiable information about the effectiveness of the risk management plan and provide the FDA and the ISSC with some guidance on how to proceed toward the goal of reducing illnesses and death from raw oysters contaminated with Vv."

The full text of the letter is as follows:

November 17, 2009

Gene L. Dodaro Acting Comptroller General Government Accountability Office 441 G St.,
NW Washington, DC 20548

Dear Mr. Dodaro:

I am writing to request that the Government Accountability Office (GAO) conduct an audit of the Interstate Shellfish Sanitation Conference's (ISSC) *Vibrio vulnificus* (Vv) risk management plan. One of the primary purposes of this audit would be to determine whether this risk management plan being used by the oyster industry, and promoted by the ISSC, is effective in reducing illnesses and death due to oysters contaminated with the Vv bacteria.

The ISSC is a State/Federal conference responsible for coordinating State regulation of the shellfish industry under the National Shellfish Sanitation Program. The ISSC developed a Vv risk management plan as its principal tool for reducing illnesses and deaths caused by the consumption of Vv contaminated oysters. The plan set a target of reducing the incidence of illnesses associated with Vv by 60 percent over seven years, defined control interventions to achieve the target, and provided a methodology for measuring the effectiveness of control efforts. At this time, the target reduction has not been met.

On October 17, the Food and Drug Administration announced that the existing Vv risk management plan was not true to the spirit of HACCP regulations. The FDA claimed that affordable technology capable of eliminating Vv illnesses exists and because the goal of the seven-year plan (60 percent reduction in Vv illness) had not yet been met, the agency believed that it could no longer support the existing plan. In making this announcement, FDA also questioned the reliability of the methodology used by the ISSC to evaluate the effectiveness of the Vv risk management plan.

Subsequent to this announcement, the FDA issued a statement on November 13 that indicated the agency would not proceed with its policy regarding post-harvest processing until it conducts "an independent study to assess how post-harvest processing or other equivalent controls can be feasibly implemented in the Gulf Coast in the fastest, safest and most economical way." The FDA rightfully concluded that there was a need to further examine the process and timing for large and small oyster harvesters to gain access to processing facilities or equivalent controls in order to address this important public health goal.

However, the FDA's initial questioning of the plan raises serious doubts as to whether the ISSC's Vv risk management plan is achieving its intended public health benefits by reducing the number of people infected by Vv. The FDA indicated that there has been little documented success of the interventions encouraged by the plan – "modest increases in consumer awareness" and "essentially no change" in Vv illnesses from raw oysters in states allowing the sale of untreated Gulf Coast oysters during warm months. This announcement is troubling given that people continue to be infected with Vv when consuming raw oysters.

Therefore, I am requesting that GAO review the methodology used by the ISSC to determine if it produces meaningful data for assessing improvements in safety from

industry efforts under the Vv risk management plan. The purpose of this is two-fold: (1) to evaluate the reduction in illnesses and deaths achieved by the specific control methods encouraged by the Vv risk management plan and make recommendations, if appropriate, for improving the methodology; and (2) to determine, going forward, whether the effectiveness of time and temperature controls is properly evaluated.

The GAO also should evaluate the success of the plan to this date. When evaluating the Vv risk management plan, it is critical to identify and isolate confounding factors. For example, California has more stringent controls than those required by the Vv risk management plan, so it is appropriate to verify that the ISSC data set does not include California statistics when evaluating the efficacy of the plan. This has the potential to overestimate the success of the plan and should be avoided in your analysis of the success attributable specifically to the Vv risk management plan.

In reviewing the method used to evaluate the Vv risk management plan, the GAO also should evaluate whether the States have the resources to enforce time and temperature controls. This is important because FDA modeling predicts that any effectiveness of the controls depends on a high level of compliance by the States. The review should examine:

Whether reductions in State budgets may have an impact on the ability of the States to gather appropriate epidemiology data or to adequately oversee compliance with future control efforts (i.e. time and temperature controls).

Whether the States have appropriate systems in place to evaluate compliance by oyster harvesters.

Whether the ISSC will have sufficient data for evaluating the effectiveness of time and temperature controls at the end of the summer harvest season in 2010.

The ISSC voted in October to implement time and temperature controls by spring 2010 and evaluate their effectiveness at the end of summer 2010. Therefore, it is essential that GAO begin its work and complete its review at the earliest possible date. Thank you very much for your assistance on this issue. I look forward to hearing from you about how GAO intends to proceed with this audit.

Sincerely,

ROSA L. DeLAURO

Chairwoman House Appropriations Subcommittee on Agriculture Rural Development,
Food and Drug Administration, and Related Agencies