DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
College Park, MD 20740

January 26, 2010

Mr. J. Michael Hickey, Chairman
Executive Board
Interstate Shellfish Sanitation Conference
209-2 Dawson Road
Columbia, SC 29223

Dear Mr. Hickey:

I am in receipt of your letter of November 2, 2009 in which you addressed my letter of October 16, 2009 to Interstate Shellfish Sanitation Conference (ISSC) members describing the U.S. Food and Drug Administration's (FDA) intent to reformulate its policy on the control of *Vibrio vulnificus* (Vv). In your letter, you expressed the ISSC's concern with FDA's announced intention to take unilateral steps to address the control of Vv and recommended that FDA:

- Support ISSC efforts to implement the ISSC Vv Illness Reduction Plan;
- Develop and submit to the ISSC a proposal describing how FDA's reformulated policy could be integrated into the National Shellfish Sanitation Program (NSSP) Model Ordinance and guidance documents; and,
- Fund a robust economic analysis on the implementation of mandatory post harvest processing (PHP).

On November 13, 2009 FDA released a statement acknowledging the concerns of ISSC members and others. The statement also concluded that there was a need to further examine the process and timing for industry adoption of PHP technology or equivalent Vv controls. Further, FDA committed to the following actions before proceeding with policy reformulation:

1. Funding an independent study to assess how PHP or equivalent controls can be implemented in the fastest, safest and most economical way;
2. Continuing dialog with the ISSC, State authorities and the Gulf Coast oyster industry on the control of Vv;
3. Working with the National Marine Fisheries Service to provide technical assistance relative to PHP implementation, including process validation, alternative technologies (e.g., off-shore relaying) and HACCP plan development;
4. Working with the U.S. Department of Agriculture and the U.S. Department of Commerce to review what forms of economic assistance may be available to assist PHP implementation; and,
5. Working with the U.S. Trade Representative to facilitate access to international trade for Gulf Coast oysters in which the Vv risk has been adequately addressed.

In response to item #2, above, FDA would like to work with the ISSC to coordinate visits by FDA officials to key locations in the Gulf Coast region to gather information on current practices, challenges to implementing PHP or equivalent controls, and possible solutions to ensuring the safety of warm weather Gulf Coast oysters in the fastest, safest and most economical way. We believe that these visits and opportunity for dialogue would inform FDA and the ISSC in setting Vv controls standards as well as provide useful information and contacts for the PHP study mentioned in item #1, above. FDA's goal is to have the study completed at least one month in advance of the ISSC's fall 2010 Executive Board meeting, so that its findings can be considered at that time. As such, we would like to have the visits accomplished in early 2010.

I would also like to acknowledge a meeting on January 18, 2010 between FDA and representatives of the ISSC Executive Board and the shellfish industry from the East, Gulf and West Coasts. During that meeting the delegation requested that FDA delay development of a proposal to the ISSC describing how FDA's reformulated policy could be integrated into the NSSP Model Ordinance and guidance documents until after the visits have been completed. FDA agrees that information obtained during the visits may be useful in refining the FDA proposal, and will therefore delay submission until Spring 2010, which should still give sufficient time for its consideration during the fall Executive Board meeting.

Through your letter of November 2, 2009 and subsequent discussions you have assured me that the ISSC voting delegates have empowered the Executive Board, with the assistance of the Vibrio Management Committee (VMC) to address the concerns raised in my letter of October 16, 2009 and to respond to an FDA proposal for improved Vv controls in the Model Ordinance. Given the timetable of events outlined in this letter and with aggressive engagement by the VMC over the next year, FDA believes that the essential elements will be in place for the Executive Board to take action during its fall 2010 meeting to protect all U.S. consumers from Vv illness and death. FDA is committed to that process as it moves forward on oyster safety and looks forward to working with the ISSC.

Sincerely,

Donald W. Kraemer
Deputy Director
Office of Food Safety
Center for Food Safety
and Applied Nutrition
Food and Drug Administration