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

ISSC

November 2, 2009

Mr. Donald W. Kraemer, Deputy Director
Office of Food Safety CFSAN
US Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

Dear Mr. Kraemer:

On October 16, 2009, the US Food and Drug Administration (USFDA) submitted a letter to the Interstate Shellfish Sanitation Conference (ISSC) outlining plans to reformulate USFDA policy regarding the control of *Vibrio vulnificus (Vv)* in raw oysters intended for half shell consumption. USFDA spokesperson Michael Taylor provided a rationale for the policy change in a presentation to the ISSC membership on October 17, 2009. The ISSC was surprised, confused, and very disappointed by the timing and the actions proposed in the USFDA letter. The ISSC has a working Memorandum of Understanding (MOU) with the USFDA which recognizes the ISSC as the primary body for consultation on matters involving molluscan shellfish. The USFDA did not consult with the ISSC prior to deciding to reformulate policy. The National Shellfish Sanitation Program (NSSP) is a cooperative program with recognized roles for State shellfish regulatory agencies, the USFDA and the ISSC. The proposed action by the USFDA is inconsistent with the established role for the USFDA and is counterproductive to ISSC efforts to address *Vv* illnesses associated with shellfish consumption.

In 2001, with the assistance and concurrence of the USFDA, the ISSC adopted a *Vv* Control Plan. This Plan was modeled from the USFDA Egg Safety Action Plan. The ISSC Plan established goals and included control strategies for the reduction of *Vv* illnesses. The 2007/2008 established goal was not met and more stringent measures were to be implemented in May of 2010. The control measures were developed cooperatively by the USFDA, the States, and the shellfish industry. The USFDA stated in the October 16, 2009, correspondence that the goals of the Plan were no longer acceptable and many of the control measures in the Plan were inadequate to sufficiently reduce *Vv* illnesses. The USFDA has now recommended the ISSC abandon the *Vv* Plan adopted in 2001 and adopt mandatory NSSP requirements for post harvest processing with an effective date of May 2011. The ISSC Voting Delegates unanimously disagree with this approach and believe controls should be implemented in 2010 as outlined in the current *Vv* Plan. Should the control measures implemented in 2010 prove to be ineffective the Plan requires that States adopt additional measures to achieve the established goal. These additional measures could include PHP.

The ISSC is disturbed by the new USFDA policy shift which could jeopardize the existing *Vv* Plan and implementation strategy. The USFDA premise that the goals of the present Plan are not ambitious enough to meet the present standard for US policy on food safety may have merit given the present position of the Administration and recent Congressional actions; however, the USFDA is obligated to communicate concerns prior to a unilateral decision to develop policy to federally regulate molluscan shellfish. Should the USFDA continue this effort without ISSC support it is likely that many States will choose not to enforce the Federal policy and Gulf States may implement intrastate programs that will lack the consistency and effectiveness to reduce *Vv* illnesses nationally. These intrastate programs could allow consumption of oysters in the state of harvest without adequate controls to substantially reduce *Vv* illnesses. The goals of the ISSC Plan are intended to address distribution of all molluscan shellfish both interstate and intrastate. During the ISSC biennial meeting the ISSC extensively discussed approaches for addressing *Vv* illness reduction and USFDA concerns regarding the present ISSC *Vv* Plan. The ISSC continues to be committed to reducing *Vv* illnesses and voted to continue efforts to implement the control measures of the *Vv* Illness Reduction Plan in 2010. Additionally, the ISSC offers the following recommendations to the USFDA:

1. The USFDA should support ISSC efforts to implement the control measures of the *Vv* Illness Reduction Plan in 2010.

2. The USFDA should develop and submit a proposal to the ISSC outlining how the reformulated policy could be integrated into the NSSP Model Ordinance and guidance documents.

3. The USFDA should fund a robust economic analysis study based on input from the ISSC Economic Analysis Workgroup. This information will be helpful for the USFDA and ISSC in determining the impacts of implementing mandatory PHP requirements.

Should the USFDA agree to submit a proposal, the ISSC *Vibrio Management Committee* (VMC) will review the proposal at the spring and/or fall 2010 Executive Board meetings. The ISSC Executive Board with assistance from the VMC will address the USFDA concerns, as directed by the voting delegates, as well as evaluate the effectiveness of the 2010 control measures and propose changes to the plan. This evaluation will include discussions regarding the appropriateness of the present goals as written in the current *Vv* Plan.

Sincerely,

J. Michael Hickey, Chairman
ISSC Executive Board

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cc: ISSC Executive Board