DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

Food and Drug Administration
College Park, MD 20740

May 29, 2013

Mr. Keith Skiles, Chairman
Interstate Shellfish Sanitation Conference
209-2 Dawson Road
Columbia, South Carolina 29223

Dear Mr. Skiles:

This letter is in response to your November 26, 2012 letter to FDA regarding the Agency's concurrence with the Interstate Shellfish Sanitation Conference (ISSC) adoption of Proposal 11-201A establishing a new National Shellfish Sanitation Program (NSSP) *Vibrio vulnificus* (*Vv*) control plan for reducing illnesses associated with raw oyster consumption. In your letter you requested that FDA submit to the ISSC the Agency's plan for conducting state *Vv* evaluations beginning in 2013.

Establishment of risk per serving standards in Proposal 11-201A is in keeping with Proposal 09-207, adopted in 2009 with FDA concurrence, which shifted the ISSC *Vv* Risk Management Plan from an illness rate reduction goal to a risk per serving goal. Moving to a risk per serving goal embraced a more direct and accurate approach to measuring illness reduction. Determining compliance with the risk per serving standards adopted under Proposal 11-201A requires a comparison of the number of *Vv* illnesses to the number of raw oyster servings. It eliminates flaws in the ISSC's 2001 *Vv* control plan inherently associated with measuring illness rate reductions based on illnesses reported in just four states (Texas, Louisiana, Florida, California). Because of California's 2003 ban on the sale of untreated Gulf oysters from April through October, which virtually eliminated oyster related *Vv* illnesses in the state, the use of California illness data dramatically skewed illness rate reduction calculations and presented the ISSC with a false sense of achievement. Additionally, in calculating illness rates, the use of population increases relative to limited increases in oyster production further exaggerated the true level of illness reduction, particularly when considering that the number of *Vv* illnesses occurring each year has been relatively constant. Adoption of Proposal 11-201A appropriately places emphasis on the number of illnesses that occur nationally relative to the number of raw oyster servings produced by states whose oysters are confirmed to cause *Vv* illness.

As stated in the Agency's February 26, 2012 response to the 2011 ISSC Summary of Actions, evaluation of the risk per serving standards is imperative to demonstrate achievement of the intended 60 percent illness rate reduction. Also expressed was FDA's concern regarding the lack of criteria for evaluating state compliance as well as the absence of specific actions or sanctions as a consequence of non-compliance. In an effort to address those concerns, FDA worked with members of the ISSC *Vibrio* Plan Evaluation Committee to come to consensus on an effective and reasonable process for determining the effectiveness of state *Vv* control plans to achieve the risk per serving standards. Although discussion within the committee was helpful in understanding state and industry unease relative to risk per serving calculations, case attribution and compliance evaluation, it became evident that discussions intended to bring resolution to varying opinions among committee members were marginally productive at best. Without clear *Vv* control plan evaluation criteria, FDA realized that it could not fulfill its obligation under the 1984 ISSC/FDA Memorandum of Understanding for conducting state program evaluations. Therefore, in the interest of public health and to avoid further delays in evaluating the effectiveness of state *Vv* control plans and implementation of risk per serving standards in reducing illnesses nationally, the Agency will move forward with the evaluation process presented below.

The attached documents, "*Determination of Risk/Serving for Vibrio vulnificus in Raw Oysters*" and "*Risk per Serving Calculation,*" provide details regarding the assumptions, criteria, and formula that FDA will use for conducting state *Vv* risk per serving assessments. Although the approach to be used has similarities to that discussed by the *Vv* Evaluation Plan Committee in June 2012, it also includes significant latitude in response to committee member objections to certain assumptions and criteria initially proposed by FDA, such as case attribution, the use of confidence intervals, and risk per serving determinations. Accordingly, cases not attributed to commercially harvested oysters from a *Vv* control plan state(s) (Texas, Louisiana, Florida, Mississippi, Alabama, Virginia)) will not be counted in determining individual state compliance with risk per serving standards. FDA will also conduct annual evaluations of *Vv* control plan states collectively to assess risk per serving levels nationally. For the collective assessment FDA will include all *Vv* cases except those not specifically attributed to a *Vv* control plan state(s).

The numbers of *V. vulnificus* cases reported to CDC nationally have remained relatively constant since the ISSC adopted a 60 percent illness rate reduction plan in 2001. Preliminary analysis of risk per serving indicates that the strict time and temperature controls adopted in 2008 and 2010 in *V. parahaemolyticus* and *V. vulnificus* control plans have not achieved the intended risk reductions. FDA believes the shortfall of these plans may be attributed to several factors, including industry non-compliance associated with allowances for possession of both unrestricted and restricted use tags by harvesters, failure to comply with time to temperature requirements as well as lenient state penalties and enforcement. Therefore, in addition to evaluating compliance with risk per serving standards, FDA will more closely

evaluate efforts by states to enforce state *Vv* control plans to ensure industry compliance with time and temperature controls. The attached "*Vibrio Evaluation Reference*" document, for use by FDA regional shellfish specialists, provides detail regarding FDA's evaluation of state and industry efforts to comply with NSSP and state *Vibrio* Control Plan requirements.

If unsatisfactory compliance with *Vv* control plans or an inability to achieve risk per serving standards is identified during FDA evaluations, the state(s) will be expected to develop and implement a strict corrective action plan. The corrective action plan shall establish controls to correct deficiencies and reduce the risk per serving to levels adopted in Proposal 11-201A. Corrective action plans will be jointly reviewed by FDA and the ISSC for concurrence. Remediation efforts should be proportional to the severity of the compliance deficiencies and/or shortfall in achieving risk per serving standards.

While FDA considers *Vv* illnesses to be preventable using controls such as harvest restrictions and post-harvest processing technologies, the Agency is committed to working with states and industry to achieve the risk per serving standards agreed upon by the ISSC state voting delegates in Proposal 11-201A. Achievement of those standards through strict implementation of time and temperature controls is intended to provide an equivalent 60 percent illness rate reduction in accordance with conference action in 2009 to move from an illness rate reduction to a risk per serving standard. If based on FDA's 2013 evaluation results, such efforts have not achieved the intended outcome, FDA will work with the ISSC partners to explore and implement more effective approaches for controlling *Vv* illnesses.

Sincerely yours,

N for Bill Jones

William Jones, Acting Deputy Director
Office of Food Safety
Center for Food Safety
and Applied Nutrition

Enclosures:
Determination of Risk/Serving for *Vibrio vulnificus*
Risk per Serving Calculation
Vibrio Evaluation Reference

cc:
Ken Moore, ISSC Executive Director
HFS-001, M. Landa, M. Roosevelt
HFS-300, N. Beru
HFS-325, D. Benjamin, M. Ellwanger, P. DiStefano, F. Burditt
HFS-400, W. Burkhardt, A. Depaola
HFS-009, S. Cianci
ORA Shellfish Specialists
ORA Cooperative Program Directors
ORA Shellfish Steering Committee