



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

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Mr. J. Michael Hickey, Chairman  
Interstate Shellfish Sanitation Conference  
209-2 Dawson Road  
Columbia, South Carolina 29223

Dear Mr. Hickey:

In response to discussions at the March 2010 Vibrio Management Committee (VMC) and ISSC Executive Board meetings in Denver, Colorado, I am writing to inform you that, based on discussions during the March 2010 meetings, FDA now supports ISSC efforts under Proposal 09-207 to shift from an "illness rate reduction" goal to a "risk reduction" approach for *Vv*, based on risk per serving<sup>1</sup>. Therefore, I am formally rescinding the Food and Drug Administration's (FDA) non-concurrence with adoption of Proposal 09-207.

I also would like to take this opportunity to reiterate comments that I made during the March 2010 meetings: First, while FDA remains committed to reducing to the extent practical *Vv* illnesses associated with the consumption of raw oysters, the Agency formally acknowledges concerns raised by the ISSC, State officials, the shellfish industry, and members of Congress about the feasibility of implementing post-harvest processing (PHP) for half shell Gulf Coast oysters harvested during warm months.

Second, as stated in earlier written and oral communication to the ISSC, FDA remains committed to:

- 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, States, and the Gulf oyster industry regarding *Vv* control, including visits by top FDA officials to the Gulf and Atlantic regions to meet with industry and other stakeholders to inform FDA about current industry practices, challenges to implementing PHP or equivalent controls, and solutions for such problems;
- 3.) Placing in abeyance any decision to reformulate policy relative to *Vv* while taking the steps listed under items 1 and 2 and utilizing the information obtained through those steps in making a decision on whether, when, and how to reformulate its *Vv* policy; and


- 4.) Submitting a proposal to the ISSC describing how that policy could be integrated into the National Shellfish Sanitation Program (NSSP) Model Ordinance and guidance documents before making any such policy change.

Finally, I would like to take this opportunity to ensure that the record is clear on several other *Vibrio*-related issues. As has been widely reported, in September 2009, FDA did consider policy changes relating to control of *Vibrio parahaemolyticus* (*Vp*) in oysters and clams through PHP. However, FDA decided such measures were not warranted based on an assessment of the current public health and economic considerations associated with *Vp* illnesses. That remains our position.

As you are aware, FDA did share with the VMC and Executive Board a preliminary table of *Vp* illnesses suggesting a relationship between hard clams (*Mercenaria mercenaria*) from the northeast and *Vp* illnesses. Providing such data is part of FDA's role of keeping the ISSC informed on current scientific developments related to the safety of molluscan shellfish. FDA was careful to explain that it was not seeking any specific action by the ISSC in response to the data.

As always, FDA is committed to a process to move forward on oyster safety and looks forward to working with the ISSC and other stakeholders with that goal in mind.

Sincerely yours,



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

<sup>1</sup> Such an approach is in keeping with the ISSC's current approach for managing *Vibrio parahaemolyticus* (*Vp*) using the FDA *Vp* risk calculator to achieve a risk per serving goal of 1 in 100,000 ( $10^{-5}$ ). Moving from an illness rate reduction that is based on illness counting and shifting to a "risk reduction," based on modeling risk per serving, would eliminate the problems associated with the current *Vv* illness rate reduction goal (e.g., crediting illness reductions resulting from the California post-harvest processing action, crediting the apparent rate reduction associated with population increases, and crediting illness rate reductions in a few reporting states while at the same time the incidence of *Vv* nationally remains at a relatively constant level).