Proposal Subject: *Vibrio vulnificus* Controls

Specific NSSP Guide Reference: Section II Model Ordinance Chapter II Risk Assessment and Risk Management
@.04 *Vibrio vulnificus* Risk Management for Oysters

Section IV Guidance Documents Chapter IV Naturally Occurring Pathogens
.04 Naturally Occurring Pathogens

Text of Proposal/ Requested Action: During the January 2011 VMC meeting the Committee conducted an assessment of the effects of the 2010 *Vv* controls implemented by the *Vv* source states. The Committee also reviewed the *Vv* illness rate reductions for 2009 and 2010. The Committee concluded that the 60% goal had not been achieved for 2009, 2010 or 2009 and 2010 average. After a lengthy discussion which is described below, The VMC recommended, with Executive Board approval, the appointment of a workgroup to develop other *Vv* control options which would be included in a VMC proposal to the ISSC. The workgroup has been appointed and is working to develop new concepts. The workgroup will include Proposal 09-207, which was adopted in 2009, as a part of their discussions. The purpose of the proposal is to provide notice to the ISSC membership of this activity. The ISSC membership will be provided the full details of final recommendations when available.

Points of Discussion by the VMC during the January 2011 Meeting:

Chapter II @.04 includes requirements for States that have had two (2) or more etiologically confirmed shellfish borne *Vv* illnesses since 1995. Section IV Guidance Documents Chapter IV Naturally Occurring Pathogens includes guidance for implementation of the Chapter II Model Ordinance requirements. The ISSC adopted these requirements after years of encouragement by the USFDA. The very controversial *Vv* debate began in 1994 and after much resistance the ISSC adopted Proposal 00-201 in 2001. The controls of Proposal 00-201 were premised around illness rate reduction to be achieved by 2008.

Proposal 00-201 included the following three (3) major components:

(1) Consumer education: Each State *Vv* Management Plan was required to include a consumer education program.
(2) The development of PHP capacity to treat 50% of Gulf oysters intended for raw half-shall consumption. The capacity was to be available should the 60% goals not be achieved.
(3) Control strategies that could be implemented if the 40% and 60% goals were not met.

The implementation of Proposal 00-201 has been very controversial and problematic since 2001. The problems include:

(1) Our efforts to count cases for determining goal compliance has proven that illness reporting as it presently exists does not provide an adequate tool for determining the effectiveness of controls to lower risk for *Vv*.
(2) The use of four (4) states, especially California, has been publicly controversial. The FDA has stated that national illnesses should be used.
(3) In October 2009 FDA publicly announced that the agency no longer supported ISSC efforts to address *Vv*. The FDA stated its intent to reformulate policy and use the Fish and Fishery Product Hazards and Control Guidance 4th Edition to regulate *Vv* in raw oysters.

(4) States have had difficulty enforcing industry compliance.
(5) Restricted use shellstock has been diverted to restaurants and sold raw. Two (2) deaths have been attributed.
(6) FDA and ISSC have had disagreements regarding the responsibility for evaluating State compliance with *Vv* controls.
(7) The goal is a collective five (5) State goal. Determining compliance by individual States is problematic. The *Vibrio* Management Committee (VMC) concluded at the January 2011 meeting that the 60% goal has not been achieved.
(8) Results of Consumer Acceptance Study suggest consumers prefer traditional raw oysters at seven (7) days and PHP oysters at fourteen (14) days. Report indicates that most consumers would be unwilling to pay higher price for PHP oysters. RTI report suggests FDA should slow its efforts to mandate PHP.
(9) Congress passed the Food Safety Modernization Act which specifically addresses PHP in Section 114. The Senate authors of Section 114 of the Food Safety Modernization Act (FSMA) correspond with ISSC providing clarification of the intent of Congress and the Administration.
(10) The present goal approach for measuring success is not consistent with the other elements of the National Shellfish Sanitation Program (NSSP).

The Committee recommended additional time/temperature controls for April and November and recognized serious noncompliance issues in one Gulf State.

Public Health Significance:

Vibrio vulnificus is a naturally occurring bacterium found in seawater along the Gulf, Atlantic, and Pacific coasts, although it is most prevalent in the warm waters of the Gulf of Mexico. *Vibrio vulnificus* can be transmitted to humans through the consumption of raw shellfish harvested from waters containing the organism. Oysters from the Gulf of Mexico have been recognized as the primary species of molluscan shellfish associated with *Vibrio vulnificus* illnesses in consumers. *Vibrio vulnificus* does not normally affect healthy individuals, but persons who are immunocompromised, especially those with chronic liver disease, are at greater risk for contracting *Vibrio vulnificus* from oyster consumption. In immunocompromised individuals, there is a risk for the organism to invade the bloodstream, resulting in potentially fatal septicemia. Although the annual number in the US of reported *Vibrio vulnificus* illnesses associated with oyster consumption is low, generally in the range of 30 to 35, the incidence of death among those individuals who contract the disease is high. Between 2001 and 2010 (10 years) there were 335 cases of illnesses with 157 deaths reported to CDC.

Prior to 2001 the NSSP controls did not offer a strategy for controlling *Vibrio vulnificus*. In an effort to better control *Vibrio vulnificus* in oysters, in 2001 the Interstate Shellfish Sanitation Conference (ISSC) developed a *Vibrio vulnificus* Control Plan for inclusion in the NSSP.

The Plan adopted by the ISSC included a 60% illness rate reduction goal that was to be achieved by the end of 2008. To present the goal has not been achieved. The Plan also included several mandatory controls which could be implemented if necessary to achieve the 60% goal. Recognizing the potential economic damage of these controls to the industry the ISSC has continued to investigate other controls that could potentially assist the Gulf States in achieving the 60% goal. Very stringent time to

temperature controls were implemented in 2010. However, the implementation of these controls did not result in goal attainment.

The identified mandatory requirements included Post Harvest Processing (PHP) and closures. To evaluate the impact of requiring PHP, FDA contracted with RTI to conduct an economic assessment. The report entitled "Analysis of How Post-Harvest Processing Technologies for Controlling *Vibrio vulnificus* Can Be Implemented" suggest that it would take a minimum of 3 years and significant financial investment both by private and public sectors to prepare the industry for a PHP requirement. The other listed mandatory control which would likely result in 60% illness rate reduction was closure. Those supported the inclusion of closures thought that PHP would be a viable option by 2008.

Concerns for the economic impact of *Vibrio vulnificus* control prompted Congress and the Administration to include inclusion of Section 114 in the Food Safety Modernization Act. Although Section 114 is directed to FDA, the authors of the Section have communicated that they expect ISSC to consider economic effects in addressing *Vibrio vulnificus*. These directives make it very difficult to impose mandatory PHP or closures should the present expanded time to temperature approach prove ineffective in meeting the intended goals of 00-201. The VMC Proposal Workgroup will use the guidance of Procedure XIV and the ISSC Policy Statement on Consumption of Raw Molluscan Shellfish in characterizing the *Vibrio vulnificus* problem. From this characterization the workgroup will develop *Vibrio vulnificus* recommendations for VMC consideration.

Cost Information (if available):

Action by 2011 Task Force II

Recommended adoption of *Vibrio* Management Committee Substitute Proposal 11-201-A as amended.

Additionally, Task Force II recommended:

1. That a committee be established to consider options for water temperature determinations which can be used in the implementation of Proposal 11-201-A.

2. That a Committee be established to develop criteria for verifying reduction in harvest for raw consumption and the percentage of post harvest processed product on a monthly basis for those States required to have a *Vibrio vulnificus* Control Plan.

3. An implementation date of January 1, 2012 for Proposal 11-201-A.

Recommended referral of Proposal 11-201-B to an appropriate committee with representation from all regions to develop Model Ordinance language changes to support the time temperature requirements of the State's *Vibrio* Management Plans. This committee will be appointed and approved by the Executive Board at its closing Board meeting. The committee will be expected to meet within two (2) weeks of the close of the Conference. After its initial meeting, the committee shall meet by teleconference biweekly prior to an Executive Board meeting until the proposal is completed and at least once subsequent to the dissemination of the proposal and prior to an Executive Board meeting. The draft proposal that is to be considered by the Executive Board shall be disseminated to the ISSC membership a minimum of three

(3) weeks prior to the next Executive Board meeting and posted on the ISSC web site.

The Committee is directed to make recommendations to the Executive Board for interim approval with an effective date prior to the 2012 *Vibrio* season. The State's Authorities are requested to begin advising and educating their industries of these changes. Additionally, the committee will develop guidance for implementation of these controls.

Action by 2011 General Assembly

Adopted recommendation of 2011 Task Force II on Proposal 11-201 Part A.
Adopted recommendation of 2011 Task Force II on Proposal 11-201 Part B.

Action by FDA February 26, 2012

FDA concurred with Conference action on Proposal 11-201Part B but did not concur with Conference action on Proposal 11-201 part A.

FDA comments and recommendations in response to Proposal 11-201 Part A:

In October of 2009, the Food and Drug Administration (FDA) informed the Interstate Shellfish Sanitation Conference (ISSC) of its intention to reformulate the Agency's policy regarding implementation of the Seafood HACCP Regulation with the intent that post harvest processing (PHP) or equivalent measures be implemented for the control of *Vibrio vulnificus (Vv).* The new policy would require that oysters harvested from the Gulf of Mexico and intended for the raw half shell market be post harvest processed during those months when illness from *Vv* is reasonably likely to occur. Given that PHP can largely eliminate *Vv* while preserving the sensory qualities of raw untreated product FDA remains committed to this approach as the most prudent means of reducing the risk of illness from *Vv.* The efficacy of PHP is evidenced by the fact that since 2003, when the State of California banned the sale of untreated Gulf oysters harvested between April and October, there has been only one *Vv* illness in the State. Prior to 2003 California reported on average six *Vv* related illnesses per year.

In November 2009, having heard from elected State and Federal representatives, the oyster industry and State regulatory officials regarding the feasibility of implementing PHP or other equivalent controls, FDA acknowledged the need to further examine the process and timing of industry adoption of PHP technology and placed in abeyance the Agency's intent to change its policy for controlling *Vv* while taking steps to complete an independent study to assess how PHP controls can be implemented. In the interim, FDA has expressed its intention to continue working cooperatively with the ISSC to implement alternate controls which would reduce illnesses and meet the goals adopted by the ISSC in Proposal 00-201. Since adoption of Proposal 00-201 FDA has repeatedly expressed concerns relative to its implementation by the ISSC, including failure to consider national illness numbers and the lack of success in achieving the 60% illness rate reduction goal. FDA reiterated its concerns during ISSC deliberation of Proposal 11-201 at the October 2011 biennial meeting and those concerns were not adequately addressed by Conference action on Proposal 11-201. It is the position of FDA that Proposa111-201 deviates from current FDA policy in that it weakens the control measures adopted by the ISSC in Proposal 00-201. Therefore, FDA cannot concur with Proposal11-201 without further Conference action. FDA requests that the ISSC address the following issues and concerns.

1. ISSC adoption of Proposal 00-201 in 2001 established a 60% illness rate reduction goal. Although FDA no longer considers this the most appropriate goal given the efficacy of PHP, FDA has continued to recognize and support

ISSC efforts to achieve this level of illness reduction. However, the level of reduction reported by the ISSC *Vibrio* Management Committee (VMC) indicates only marginal success in moving toward that goal.

a. Proposal 00-201 included specific control measures to be taken by the *Vv* Source States if the 60% goal was not met. Those measures, intended for all oysters harvested during periods of risk included; closing shellfish growing areas to harvest, labeling oysters for shucking by a certified dealer, and subjecting oysters to PHP. Although the 60% illness rate reduction goal has not been achieved, none of these control measures have been implemented. Disagreement by States and the ISSC to pursue these more effective control measures has been a significant concern to FDA. That concern is further exacerbated by the fact that Source States, with ISSC support, have now adopted a policy that focuses control efforts toward more stringent time to temperature controls, for which compliance by industry is proving difficult. Section @.05 E. (1) (b) (iii) ofProposal11-201 establishes risk per serving standards for States using time/temperature controls and Section @.05 E. (1) (b) (iv) allows for alternative controls that achieve those same risk per servings standards. The risk per serving standards in Proposal11-201 are based on controls that were derived from the FDA developed *Vv* calculator. These controls have not yet been demonstrated to achieve a 60% illness rate reduction. The FDA maintains that until these risk per serving standards are demonstrated to achieve the intended 60% illness rate reduction, evaluation of their effectiveness is imperative. Guidance needs to be developed for how to evaluate State programs to determine if risk per serving standards are being achieved. Section @.05 E. (2) (a) ofProposal11-201 States that the State Authority in conjunction with FDA will evaluate the implementation and effectiveness of these controls. As written, FDA would consider a State to be in non-compliance when there is ineffective implementation due to industry noncompliance or when the controls are determined ineffective in achieving the risk per serving standards. FDA would expect a State to discontinue the use of the time/temperature control measures and implement other control options outlined in @.05 E. (1) (b) should the State evaluation indicate that the State is not meeting the risk per serving standards.

b. Proposal 11-201, based on temperature modeling using the *Vv* calculator, establishes risk per serving standards that are intended to achieve a 60% illness rate reduction. Determining the ability of the ISSC control strategy, based on implementing risk per serving standards, will focus on the number of nationally reported illnesses associated with oysters from the Source States. FDA expects that if the risk per serving standards established in Proposal 11-201 prove to be effective, the number of nationally reported *Vv* illnesses associated with Gulf oysters will be reduced by 60%.

c. The Source States have generically incorporated as part of their risk reduction measurement a 10% reduction in harvest attributed to stricter time/ temperature controls and a 15% reduction attributed to product diversion to PHP. Actual percentages are certain to vary from State to State and year to year, making it necessary that each State provide data supporting the use of these assumptions.

2. FDA is concerned that efforts to assess the effectiveness of time/temperature

controls in achieving risk per serving standards will be difficult. Given the small number of illnesses associated with oysters from an individual State, annual fluctuation of those numbers, and fluctuations in oyster production from year to year, calculating achievement of risk per serving numbers using national illness data and oyster production data from each *Vv* Source State will be challenging.

3. Beginning with the April2012 *Vv* season, FDA will be evaluating State *Vv* Control Plans, industry compliance, and State enforcement. While FDA is developing guidance regarding what Shellfish Specialists should consider when conducting *Vv* evaluations, presently neither FDA nor the ISSC has developed specific criteria for determining compliance with State *Vv* plan goals. FDA requests that an ISSC committee be appointed to work with FDA to develop State evaluation criteria. FDA requests development of:
    a. Evaluation criteria for determining proper and effective use of the *Vv* calculator;
    b. Evaluation criteria for determining State *Vv* control plan compliance with NSSP requirements;
    c. Evaluation criteria for determining the effectiveness of State regulatory efforts to ensure industry compliance with State *Vv* Control Plan requirements;
    d. A formula for calculating State compliance with risk per serving standards; and
    e. Actions and sanctions should a State be found out of compliance. In this regard FDA envisions that the established ISSC noncompliance process would be followed, which could result in advising receiving States of issues of noncompliance and recommending that shipments of oysters intended for raw consumption from non-compliant States not be accepted.

FDA remains committed to addressing *Vv* illnesses associated with consumption of raw Gulf oysters. As stated, FDA considers these illnesses to be preventable utilizing PHP technology. FDA will continue to support ISSC efforts to better control the risk of *Vv* until the obstacles associated with full implementation of PHP are addressed. In the interim, however, FDA cannot support Conference action to change existing *Vv* control requirements in such a way that they are less likely to achieve the existing 60% illness rate reduction goal. As adopted, FDA considers Proposal 11-201 a less effective approach to preventing *Vv* illnesses.