Proposal Subject: Control Plan Evaluation

Specific NSSP Guide Reference: NSSP Guide for Control of Molluscan Shellfish, Section II. Chapter II @ .05 E. (1) and (2)

Text of Proposal/ Requested Action Section II. Chapter II @ .05 E. (1) and (2)

E. Control Plan

(1) The *Vibrio vulnificus* Control Plan shall include the following:

(a) Identification of triggers which address factors that affect risks. The triggers will be used to indicate when control measures are needed. One or more of the following triggers will be used:

(i) The water temperatures in the area; and

(ii) The air temperatures in the area; and

(iii) Salinity in the area; and

(iv) Harvesting techniques in the area; and

(v) Other factors which affect risk which can be used as a basis for reducing risk.

(b) Implementation of one or more of the following control measures to reduce the risk of *Vibrio vulnificus* illness:

(i) Labeling oysters, "For shucking by a certified dealer", when the Average Monthly Maximum Water Temperature exceeds 70°F.

(ii) Subjecting all oysters intended for the raw, half-shell market to Authority approved post-harvest processing when the Average Monthly Maximum Water Temperature exceeds 70°F.

(iii) Reducing time of exposure to ambient air temperature prior to delivery to the initial certified dealer based on modeling or sampling, as determined by the Authority in consultation with FDA. For the purpose of time to temperature control, time begins once the first shellstock harvested is no longer submerged. When this control measure is selected, State *V.v.* plans will include controls when water temperature promotes *V.v.* levels and risk of illness increases. The controls will minimize risk to less than three (3) illnesses per 100,000 servings when Average Monthly Maximum Water Temperature exceeds 80°F. Authority approved Best Management Practices (BMPs) will be applied to minimize *V.v.* growth to the extent possible when Average Monthly Maximum Water temperature exceeds 70°F but is less than or equal to 80 °F. BMPs will ensure that when the water temperature exceeds 70°F but is less than or equal to 75°F risk is minimized to less than 1.75 illnesses per 100,000 servings and when water temperature exceeds 75°F but is less than or equal 80 °F the risk will not exceed 2.5 illnesses per 100,000 servings. These risks per serving will be determined using the FDA developed *Vibrio vulnificus* calculator. A state is in compliance with the NSSP when it effectively implements the controls established in its plan using the FDA calculator to determine the risk per serving for the established water temperatures.

(iv) The State Authority may implement alternative controls that will reduce the risk to a level comparable to the risk per serving identified above in @.05 E. (1) (b) (iii) when water temperatures exceed 70°F.

(2) Control Plan Evaluation

(a) The State Authority will conduct an evaluation of the plan.

At a minimum the Authority will consider:~~In consultation with FDA the Authority will evaluate the implementation and effectiveness of their Control Plan.~~:

(i) ~~Changes in t~~The annual number of *Vibrio vulnificus* cases associated with the State's growing waters and the amount of shellstock sold for half shell consumption to determine risk per servings for each temperature period.

(ii) Environmental changes which could affect total *Vibrio vulnificus* in shellfish pre and post-harvest.

(iii) Industry compliance with existing controls.

(iv) The Authorities enforcement of industries' implementation of the controls.

(b) ~~The Control Plan shall be modified when the evaluation shows the Plan is ineffective, or when new information or more effective technology is available as determined by the Authority.~~For the purposes of determining Authority compliance the FDA will conduct an annual Vibrio evaluation of Authority to determine the following:

(i) Authority compliance with *V.v.* Risk Evaluation as required in Chapter II @ .05 A.

(ii) For States requiring the development of *V.v.* Control Plans, compliance with Control Plan requirements of Chapter II @ .05 E. (1) Control Plan. The evaluation should determine:

b. Appropriate identification of trigger to determine when control measures are needed.

c. Did the Authority implement one or more of the control measures required in Chapter II @ .05 E. (1) (b).

d. For Authority implementing Chapter II @ .05 E. (1) (b) (i) or (ii), were the controls implemented adequately.

e. For Authority implementing Chapter II @ .05 E. (1) (b) (iii) (time and temperature control), did the Authority establish controls consistent with water temperature and was the FDA developed *V.v.* calculator used correctly.

(iv) For Authorities required to develop *V.v.* Contingency Plans the evaluation should determine:

c. Did the risk evaluation indicate the need for a Contingency Plan.

d. For States requiring the development of a Contingency Plan, does the plan include the regulatory steps to be implemented should the number of illnesses reach the threshold for a *V.v.* Plan.

(c) Should the findings of the State evaluation indicate that the Authority was in compliance with the items audited in (2) (b)

and the observed risk per servings exceeded established risk per serving for one or more water temperature, the Authority will be deemed in compliance with the NSSP Model Ordinance. The FDA will include this finding in a report to the ISSC.

(d) The results of the State and USFDA risk per serving evaluations will be shared with the ISSC Vibrio Management Committee for use in conducting trend evaluations as stated in the ISSC Constitution, Bylaws, and Procedures.

Public Health Significance:

In 2001 the Interstate Shellfish Sanitation Conference (ISSC) adopted a *Vibrio vulnificus* (*V.v.*) illness reduction strategy (Proposal 00-201). This proposal established illness rate reduction goals that were based on actual *V.v.* illnesses reported by four (4) States. The implementation of this strategy has been controversial since its inception and there has never been consensus from the participants of the ISSC regarding an appropriate and effective evaluation strategy.

The initial goal of 40% was met, the 60% goal has never been achieved. The USFDA has been very critical of State efforts to meet the established illness rate reduction goal of 60% and in 2009 publicly withdrew its support for the illness rate reduction strategy, stating that the USFDA would pursue a requirement that oysters harvested from the Gulf of Mexico during periods of high risk could only be shipped in interstate commerce if post-harvest processed to reduce *V.v.* to non-detectable levels. The USFDA was requested to conduct an economic analysis of the impact of the proposed requirement. The study was conducted and the results indicated that the PHP requirement would financially devastate the industry and was not a viable option.

In 2009, the ISSC passed Proposal 09-207 which converted the illness rate reduction approach adopted in Proposal 00-201 to a risk per serving approach. The ISSC followed adoption of Proposal 09-207 with the adoption of Proposal 11-201A which established risk per serving based on the USFDA *V.v.* Risk Calculator. The established risk per servings was equivalent to the 60% illness rate reduction goal. The primary reason for ISSC adoption of Proposal 09-207 and Proposal 11-201A was the recognition of the many problems encountered by the ISSC in an attempt to use actual illness numbers to evaluate effectiveness and determine State compliance. Food safety programs have historically used illness trends to evaluate the effectiveness of food safety controls and this approved should be used rather than critiquing each illness and determine State compliance using actual reported illnesses. The adoption of Proposal 09-207 and Proposal 11-201A by the ISSC Voting Delegates was an acknowledgement of the need to move the focus of ISSC efforts to evaluation of controls rather than determinations of State compliance based on reported illnesses. This shift in focus would allow full ISSC debate of the effectiveness of controls and a collective review of the appropriateness of new controls. The results of State evaluations of *V.v.* Control Plans and USFDA evaluation of State programs would provide the ISSC with the necessary information to make decisions regarding other economically viable approaches that could be applied to the *V.v.* problem.

The language of Proposal 11-201A outlined controls that were to be implemented by Authorities to achieve the established risk per serving levels. The proposal did not include additional control or a means of evaluating the scientific basis or the economic impacts of additional controls should States not meet the established risk per serving levels. It is unrealistic to expect States to adopt controls that are not economically feasible or have not been adopted as a control of the NSSP. This unrealistic expectation has resulted in much controversy between the ISSC and the

USFDA.

The ISSC has imposed severe harvesting restrictions on the shellfish industry in Texas, Louisiana, Mississippi, Alabama, Florida, and Virginia, which has resulted in significant economic hardship to those industries.

Although not required, States were requested to implement the control of Proposal 11-201A in 2012 and the implementation of these controls were evaluated by the USFDA in 2012. The present number of *V.v.* illnesses from 2012 is much lower than in any year since 2001. Should this reduction become a trend, additional controls may not be needed. Should that not be the case, ISSC should fully debate additional controls to assure that they are scientifically based and economically feasible.

In correspondence dated May 29, 2013, the USFDA shared criteria which were developed by the USFDA for evaluating compliance with the established risk per serving outlined in Chapter II. @ .05 E. This criteria was shared with the ISSC Executive Board and Authorities for comments. Every comment received indicated disagreement with the USFDA criteria. Many commenters are concerned with the rigid evaluation approach of the USFDA. Host susceptibility issues, retail and consumer handling, and the very small number of cases continue to be issues of concern.

It appears there is agreement regarding the interpretation of the requirements outlined in Chapter II @ .05 E. (1) (a) and (b). The disagreement involves the interpretation of Chapter II @ .05 E. (2) and how the USFDA should evaluate States when the established risk per serving is not achieved for one or more water temperature periods. The USFDA has indicated it will deem a State in non-compliance if the risk per serving is not achieved for one or more water temperature periods and the State will be requested to develop an action plan. It is the opinion of States that conformance with the controls of Chapter II @ .05 E. (1) would indicate State compliance. Additionally States believe that modification of V.v. Control Plans to include additional controls should not occur without ISSC debate to allow discussion of effectiveness, scientific basis and economic feasibility. This proposal is being submitted by the VMC to allow full Conference debate regarding the intent and scope of the USFDA evaluation on State *V.v.* Plans.

Cost Information (if available):

Action by 2013 Task Force II Recommended adoption of Proposal 13-205 as submitted.

Action by 2013 General Assembly Adopted recommendation of Task Force II on Proposal 13-205.