

Proposal Subject: Vibrio Control Plans

Specific NSSP Chapter II @.05 *Vibrio vulnificus* Control Plan

Guide Reference: Chapter II @.06 *Vibrio parahaemolyticus* Plan

**Text of Proposal/
Requested Action** @.05 *Vibrio vulnificus* Control Plan (~~Effective January 1, 2012~~)

A. Risk Evaluation

Each shellfish producing State that is not currently implementing a *Vibrio vulnificus* (~~V.v.~~) control plan for purposes of controlling the risk of *Vibrio vulnificus* (V.v.) and/or *Vibrio parahaemolyticus* (V.p.) shall conduct a *Vibrio vulnificus* risk evaluation annually. The evaluation ~~shall~~ should consider factors deemed appropriate by the State Authority for effectively assessing whether or not each of the following factors, including seasonal variations in the factors, in determining the risk of *Vibrio vulnificus* or *Vibrio parahaemolyticus* infection from the consumption of shellfish harvested from the State's growing waters is reasonably likely.

(1) In conducting the risk evaluation the State Authority ~~may~~ will at a minimum consider any number of factors, for example the following:

- (a) The number of *Vibrio vulnificus* and *Vibrio parahaemolyticus* cases etiologically confirmed and epidemiologically linked to the consumption of commercially harvested shellfish from the State; and
- (b) Levels of *Vibrio vulnificus* and *Vibrio parahaemolyticus* in the growing waters and in shellfish, to the extent that such data exists; and

(c) Levels of tdh+ and trh+ *Vibrio parahaemolyticus* in the growing area to the extent that such data exists; and

(d) The water temperatures in the growing area; and

(e) The air temperatures in the growing area; and

(f) Salinity in the growing area; and

(g) Harvesting techniques in the growing area; and

(h) The quantity of harvest from the area and its uses i.e. shucking, half shell, PHP.

B. The State shall develop a *Vibrio* Contingency Plan should the risk evaluation indicate:

(1) Any etiologically confirmed shellfish-borne *Vibrio vulnificus* or *Vibrio parahaemolyticus* illness from the growing waters of that State but the number of cases does not reach the illness threshold established in Chapter II @.05 D or E; and

(2) Information on Levels of *Vibrio vulnificus* or *Vibrio parahaemolyticus*, if available, in the growing waters or in shellfish that is reasonably likely to cause an illness;

BC. States which have previously met the illness threshold for *Vibrio vulnificus* and/or *Vibrio parahaemolyticus* requiring a *Vibrio vulnificus* Control Plan will continue to maintain and implement a *Vibrio vulnificus* Control Plan

CD. All States not currently implementing a *Vibrio vulnificus* Control Plan shall develop and implement a *Vibrio vulnificus* Control Plan should the risk evaluation indicate two (2) or more etiologically confirmed, and epidemiologically linked *Vibrio vulnificus* septicemia illnesses from the consumption of commercially harvested raw or undercooked oysters that originated from the growing waters of that state within the previous ten (10) years.

E. All states not currently implementing a *Vibrio* Control Plan shall develop and implement a *Vibrio* Control Plan should the risk evaluation indicate that the State has a shellfish growing area that was the source of oysters or hard clams (*Mercenaria mercenaria*) that were epidemiologically linked to an outbreak of *Vibrio parahaemolyticus* within the prior five (5) years.

~~D. The State shall develop a *Vibrio vulnificus* Contingency Plan should the risk evaluation indicate:~~

- ~~(1) Any etiologically confirmed shellfish borne *Vibrio vulnificus* illness from the growing waters of that State but the number of cases does not reach the threshold established in @.04 C.; and~~
- ~~(2) Information on Levels of *Vibrio vulnificus*, if available in the growing waters or in shellfish that is reasonably likely to cause an illness;~~

EF. *Vibrio* 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* and/or *Vibrio parahaemolyticus* illness:

(i) Labeling oysters and/or hard clams, "For shucking by a certified dealer", when the ~~Average Monthly Maximum W~~water Ttemperature exceeds the temperature associated with *Vibrio* illnesses that caused the State to meet the illness threshold ~~70°F.~~

(ii) Subjecting all oysters and/or hard clams intended for the raw, half-shell market to Authority approved post-harvest processing when the ~~Average Monthly Maximum W~~water Ttemperature exceeds the temperature associated with *Vibrio* illnesses that caused the State to meet the illness threshold ~~70°F.~~

(iii) Cooling oysters and/or hard clams to 50°F within one hour of harvest when the water temperature exceeds the temperature associated with *Vibrio* illnesses that caused the State to meet the illness threshold. When deemed appropriate by the Authority an exception may be permitted for hard clams to allow for tempering.

~~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 W~~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.~~

(iv) Prohibiting the harvest of oysters and/or hard clams when water temperature exceeds the temperature associated with *Vibrio* illnesses that caused the State to meet the illness threshold. ~~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) In consultation with FDA the Authority will evaluate the implementation and effectiveness of their Control Plan.~~ The State Authority will conduct an evaluation of the plan. At a minimum the Authority will consider:

- (i) Changes in the annual number of *Vibrio vulnificus* and/or *Vibrio parahaemolyticus* cases associated with the State's growing waters.
- (ii) Environmental changes which could affect total *Vibrio vulnificus* and/or *Vibrio parahaemolyticus* 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 to determine the following:

- (i) Authority compliance with the *Vibrio* Risk Evaluation as required in Chapter II @ .05 A.
- (ii) For States required to develop and implement a *Vibrio* Control Plan, compliance with Control Plan requirements of Chapter II @ .05 F. (1). The evaluation shall determine:
 - a. Did the Authority implement one or more of the control measures required in Chapter II @ .05 F. (1)?
- (iii) For Authorities required to develop *Vibrio* Contingency Plans the evaluation shall determine:
 - a. Did the risk evaluation indicate the need for a Contingency Plan?
 - b. Does the plan include the regulatory steps to be implemented should the number of illnesses reach

the illness threshold requiring implementation of a Vibrio Control Plan?

- (c) The results of the State and USFDA 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.

FG. Contingency Plan

- (1) The Contingency Plan shall include a detailed plan outlining the regulatory steps that will be implemented should the number of illnesses reach the threshold established for development and implementation of a Vibrio Control Plan.
- (2) Contingency Plan Evaluation
In consultation with FDA the Authority will evaluate the adequacy of their Contingency Plan.

~~@.06 Vibrio parahaemolyticus Control Plan~~

~~A. Risk Evaluation.~~

~~Every State from which oysters and/are harvested shall conduct a Vibrio parahaemolyticus risk evaluation annually. The evaluation shall consider each of the following factors, including seasonal variations in the factors, in determining whether the risk of Vibrio parahaemolyticus infection from the consumption of oysters and/ harvested from an area (hydrological, geographical, or growing) is reasonably likely to occur. (For the purposes of this section, "reasonably likely to occur" shall mean that the risk constitutes an annual occurrence)~~

- ~~(1) The number of Vibrio parahaemolyticus cases epidemiologically linked to the consumption of oysters commercially harvested from the State; and~~
- ~~(2) Levels of total and tdh+ Vibrio parahaemolyticus in the area, to the extent that such data exists; and~~
- ~~(3) The water temperatures in the area; and~~
- ~~(4) The air temperatures in the area; and~~
- ~~(5) Salinity in the area; and~~
- ~~(6) Harvesting techniques in the area; and~~
- ~~(7) The quantity of harvest from the area and its uses i.e. shucking, half shell, PHP.~~

~~B. Control Plan~~

- ~~(1) If a State's Vibrio parahaemolyticus risk evaluation determines that the risk of Vibrio parahaemolyticus illness from the consumption of oysters and/ harvested from a growing area is reasonably likely to occur, the State shall develop and implement a Vibrio parahaemolyticus Control Plan; or~~
- ~~(2) If a State has a shellfish growing area in which harvesting occurs at a time when average monthly daytime water temperatures exceed those listed below, the State shall develop and implement a Vibrio parahaemolyticus Control Plan. The average water temperatures representative of harvesting conditions (for a period not to exceed thirty (30) days) that prompt the need for a Control Plan are:~~
 - ~~(a) Waters bordering the Pacific Ocean : 60°F.~~
 - ~~(b) Waters bordering the Gulf of Mexico and Atlantic Ocean (NJ and south): 81°F.~~
 - ~~(c) However, development of a Plan is not necessary if the State conducts a risk evaluation, as described in Section A. that determines that it is not reasonably likely that Vibrio parahaemolyticus illness will occur from the consumption of oysters harvested from those~~

~~areas:~~

- ~~(i) In conducting the evaluation, the State shall evaluate the factors listed in Section A. for the area during periods when the temperatures exceed those listed in this section;~~
- ~~(ii) In concluding that the risk is not reasonably likely to occur, the State shall consider how the factors listed in Section A. differ in the area being assessed from other areas in the state and adjoining states that have been the source of shellfish that have been epidemiologically linked to cases of *Vibrio parahaemolyticus* illness; or~~
- ~~(3) If a State has a shellfish growing area that was the source of oysters and that were epidemiologically linked to an outbreak of *Vibrio parahaemolyticus* within the prior five (5) years, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan for the area.~~
- ~~(4) For States required to implement *Vibrio parahaemolyticus* Control Plans, the Plan shall include the administrative procedures and resources necessary to accomplish the following:~~
 - ~~(a) Establish one or more triggers for when control measures are needed. These triggers shall be the temperatures in Section B. (2) where they apply, or other triggers as determined by the risk evaluation.~~
 - ~~(b) Implement one or more control measures to reduce the risk of *Vibrio parahaemolyticus* illness at times when it is reasonably likely to occur. The control measures may include:~~
 - ~~(i) Post harvest processing using a process that has been validated to achieve a two (2) log reduction in the levels of total *Vibrio parahaemolyticus* for Gulf and Atlantic Coast oysters and a three (3) log reduction for the Pacific Coast oysters;~~
 - ~~(ii) Closing the area to oyster harvest;~~
 - ~~(iii) Restricting oyster harvest to product that is labeled for shucking by a certified dealer, or other means to allow the hazard to be addressed by further processing;~~
 - ~~(iv) Limiting time from harvest to refrigeration to no more than five (5) hours, or other times based on modeling or sampling, as determined by the Authority in consultation with FDA;~~
 - ~~(v) Limiting time from harvest to refrigeration such that the levels of total *Vibrio parahaemolyticus* after the completion of initial cooling to 60°F (internal temperature of the oysters) do not exceed the average levels from the harvest water at time of harvest by more than 0.75 logarithms, based on sampling or modeling, as approved by the Authority;~~
 - ~~(vi) Other control measures that based on appropriate scientific studies are designed to ensure that the risk of *V.p.* illness is no longer reasonably likely to occur, as approved by the Authority.~~
 - ~~(c) Require the original dealer to cool oysters to an internal temperature of 50°F (10°C) or below within ten (10) hours or less as determined by the Authority after placement into refrigeration during periods when the risk of *Vibrio parahaemolyticus* illness is reasonably likely to occur. The dealer's HACCP Plan shall include controls necessary to ensure, document and verify that the internal temperature of oysters has reached 50°F (10°C) or below within ten~~

~~(10) hours or less as determined by the Authority of being placed into refrigeration. Oysters without proper HACCP records demonstrating compliance with this cooling requirement shall be diverted to PHP or labeled "for shucking only", or other means to allow the hazard to be addressed by further processing.~~

~~(d) Evaluate the effectiveness of the Plan.~~

~~(e) Modify the Control Plan when the evaluation shows the Plan is ineffective, or when new information is available or new technology makes this prudent as determined by the Authority.~~

~~(f) Optional cost benefit analysis of the *Vibrio parahaemolyticus* Control Plan.~~

~~C. The Time When Harvest Begins For the purpose of time to temperature control, time begins once the first shellstock harvested is no longer submerged.~~

Public Health Significance:

While *Vibrio parahaemolyticus* and *Vibrio vulnificus* Control plans (VPCP and VVCP) rely primarily on time and temperature controls to reduce post-harvest vibrio growth, the controls implemented vary widely from state to state. States requiring *V.v.* controls generally must implement more restrictive harvest controls than states which only require *V.p.* control plans. Additionally, risk per serving standards associated with VVCP require corrective actions that are absent in VPCP. This disparity creates an economic advantage for industry in states with less stringent requirements and favors higher production of more risky product. This may partially explain the increases in reported *V.v.* illnesses in recent years while *V.v.* cases have remained relatively static over this same period. Post-harvest growth increases the risk of *V.p.*, *V.v.* and likely other *Vibrio* spp. and shall be prevented by any reasonable means. Enforcement of current time and temperature controls is problematic as it is difficult to determine when the product was harvested. Immediate cooling would prevent any vibrio growth and maintain the vibrio levels at harvest providing enhanced public health protection relative to the current control plans. Immediate cooling would also facilitate enforcement and improve compliance. This approach is consistent with Codex Guidance for bivalve mollusks and industry cooling practices with other seafood products that are inherently less risky. Environmental monitoring with the current capabilities and capacity is not an effective means for mitigating vibrio risk. While immediate cooling is not as effective as Post Harvest Processing (PHP) or closures, it is far less disruptive to industry than these approaches. Acceptance of this proposal would unify and simplify the control approach used for *V.p.* and *V.v.* and provide a level playing field for industry.

FDA intends to provide additional information in support of this Proposal in advance of the ISSC 2013 Biennial Meeting.

Cost Information (if available):

Research Needs

The purpose of this section is to allow the submitter to identify research needs associated with the proposal. Please use additional pages as necessary.

Proposed Specific Research Need/Problem to be Addressed:

Quantity of ice needed to cool oysters to 50F at various ambient temperatures

Please explain the relationship between the proposed research need and the program change recommended in the proposal. Support need with literature citations as appropriate.

Estimated Cost: \$

Proposed Sources of Funding/Support:

Time Frame Anticipated:

For Research Guidance Committee Use Only

Relative Priority Rank in Terms of Resolving Research Need:

- Immediate Required Valuable Important
 Other

**Action by 2013
Task Force II**

Recommended adoption of Proposal 13-204 as substituted.

The ISSC Executive Board is tasked to work with states to seek and obtain funding for the purpose of assessing the efficacy of time and temperature controls on post-harvest Vibrio growth. Efforts shall be directed at developing robust science to define the combination(s) of prevention and post-harvest time and temperature controls that, when fully implemented, will minimize post-harvest Vibrio growth. The ISSC Executive Director, ISSC Chair, in consultation with an appropriate work group including some members of the Vibrio Management Committee shall provide guidance and administrative oversight to promote a coordinated effort among states, industry and the FDA to:

1. Assess regional and environmental differences that may better define the combination(s) of post-harvest time and temperature controls that will be most effective for a given region or state and;
2. Ensure that the results of research efforts will be fully considered by the membership of the ISSC.

In addition to new research activities directed at scientifically defining effective time and temperature controls, the Executive Office shall request that states and industry submit to the VMC data and information relative to efforts in their respective state associated with time and temperature assessment and control activities. This work shall be conducted over the next one to two years and the science that is generated and compiled shall be used to compose an ISSC Proposal for consideration at the 2015 biennial meeting of the ISSC for controlling the post-harvest growth of Vibrios. The Executive Board shall be briefed at each of its semiannual meetings regarding all ongoing work associated with this effort.

Additionally FDA requested that the remaining Vibrio Proposals be debated as submitted.

**Action by 2013
General Assembly**

Adopted recommendation of 2013 Task Force II on Proposal 13-204.

**Action by FDA
May 5, 2014**

FDA concurred with Conference action on Proposal 13-204 with the following comments and recommendations.

Prior to and during the 2013 Conference, FDA reached out to a number of States experiencing increasing Vibriosis in recent years for input regarding Proposal 13-204. The calculated illness reduction and associated public health benefit associated

with immediate icing and temperature reduction to 50°F within one hour of harvest was questioned by State and industry representatives. It became evident that the majority of State voting delegates were not willing to support the adoption of Proposal 13-204. As a result, FDA submitted and the Conference adopted substitute Proposal 13-204. Proposal 13-204 tasks the ISSC with obtaining funds to support studies that will further the science and public health benefits of existing and potential Vibrio control strategies. It also calls for the compilation of existing data and information available from States and industry regarding the science and impact of various control measures currently in place or previously tested.

FDA has secured initial funds for the ISSC to begin implementation of Proposal 13-204. These funds will serve to assist States with studies that support the intent of the substitute proposal. FDA is also looking at ways to provide resources and expertise from its Gulf Coast Seafood Laboratory to assist States with additional studies. Looking forward, FDA urges the ISSC to consider that the evidence most needed for determining the public health benefit of various control strategies would be to compare Vibrio levels at harvest to levels achieved with currently implemented time to temperature control measures and levels achieved using various other control strategies, including immediate cooling. If funding allows, it would be beneficial to conduct a follow-up to the 2007 market survey for purposes of comparing Vibrio levels from the 2007 survey to levels achieved under current V_p and V_v control plans. To expand further, a more comprehensive approach could examine changes in Vibrio levels as half shell product moves from harvest through processing and distribution. These data could inform allocation of regulatory resources to achieve the greatest public health benefit. Efforts outlined above are intended to help improve existing Vibrio controls, identify additional approaches for reducing risk and improve the effectiveness of the National Shellfish Sanitation Program (NSSP).