

Proposal Subject *Vibrio parahaemolyticus (Vp)* Control Plan

Specific NSSP Guide Reference Model Ordinance Chapter II. Risk Assessment and Risk Management
Add New @ .05 *Vibrio parahaemolyticus (Vp)* Control Plan

Text of Proposal/ Requested Action @ .05 *Vibrio parahaemolyticus* Control Plan.

The goal of the Control Plan is to reduce the likelihood of occurrence of *Vibrio parahaemolyticus* illness during periods that have been historically associated with predictable annual illnesses. The Plan is to be implemented as part of a comprehensive program which includes all the time and temperature requirements contained in the Model Ordinance.

A. Risk Evaluation.

Every State from which oysters 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 harvested from an area (hydrological, geographical, or growing) is reasonably likely to occur: (For the purposes of this sections reasonably likely to occur shall mean that the risk constitutes a predictable annual occurrence)

- (1) The number of *Vibrio parahaemolyticus* cases epidemiologically linked to the consumption of oysters harvested from the State to the area from which they are harvested; 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, halfshell, 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 harvested from a growing area is reasonably likely to occur, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan for that area.
- (2) If a State has a shellfish growing area that is in approved or conditionally approved status at a time when average monthly daytime water temperatures* exceed those listed in (a), the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan for the area.
 - (a) 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:
 - (i) Waters bordering the Pacific Ocean 61°F*
 - (ii) Waters bordering the Gulf of Mexico 81°F*
 - (iii) Waters bordering the Atlantic Ocean 81°F*
 - (b) However, development of a Plan is not necessary if the State conducts a risk evaluation, as described in 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 A. for the area during periods when the temperatures exceed those listed in B. (2) (a);
 - (ii) In concluding that the risk is not reasonably likely to

- occur, the State shall consider how the factors listed in B. (2) (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; and
- (c) If a State has a shellfish growing area that was the source of oysters 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.
- (3) For States required to implement *Vibrio parahaemolyticus* Control Plans, the Plan shall include the administrative procedures and resources necessary to accomplish the following:
- (a) Implement measures to reduce the risk of *Vibrio parahaemolyticus* illness, under the circumstances determined by A. and B. (2) and (3). The measures may include:
 - (i) Post harvest processing using a process that has been validated to ensure that levels of total *Vibrio parahaemolyticus* after processing do not exceed the average levels found in the area at times of the year when the State has determined that *Vibrio parahaemolyticus* illness is not reasonably likely to occur;
 - (ii) Closure of the area to oyster harvest;
 - (iii) Restricting oyster harvest to product that is labeled “For Cooking Only;”
 - (iv) Other measures (e.g., reduction in time from harvest to refrigeration) that based on appropriate scientific studies, are designed to ensure that the levels of total *Vibrio parahaemolyticus* after the completion of initial cooling to 60°F do not exceed the average levels from the harvest water by more than 0.5 logarithms.
 - (v) Other measures that based on appropriate scientific studies, are designed to ensure that the risk of *Vibrio parahaemolyticus* illness is no longer reasonably likely to occur (e.g., sampling, based on a statistically valid sampling plan, that demonstrates the absence of tdh+ *Vibrio parahaemolyticus* in the shellfish growing area)
 - (b) When measures provided in B. (3) (a) (iv) are included in a State’s *Vibrio parahaemolyticus* Control Plan, the State shall annually demonstrate the effectiveness of the Plan for each area under the circumstances determined by A. and B. (2) and (3), to ensure that the levels of total *Vibrio parahaemolyticus* after the completion of initial cooling to 60°F do not exceed the average levels from the harvest water by more than 0.5 logarithms. Alternatively, the State may require that individual dealers perform such verification.
 - (c) Modify the Control Plan when verification shows the Plan is ineffective.

* Further analysis is necessary to finalize these temperatures and definition is required for Average Water Temperature (e.g., tide status, source of data, time of day).

Public Health
Significance

Cost Information
(if available)

Action by 2007
Vibrio Management
Committee

@ .05 *Vibrio parahaemolyticus* Control Plan.

The goal of the Control Plan is to reduce the ~~probability likelihood~~ of occurrence of *Vibrio parahaemolyticus* illness during periods that have been historically associated with ~~predictable~~ annual illnesses. The Plan is to be implemented as part of a comprehensive program which includes all the time and temperature requirements contained in the Model Ordinance.

A. Risk Evaluation.

Every State from which oysters 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 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 ~~predictable~~ annual occurrence)

- (1) The number of *Vibrio parahaemolyticus* cases epidemiologically linked to the consumption of oysters ~~commercially~~ harvested from the State, ~~to the area from which they are harvested~~; 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, halfshell, PHP.

B. Control Plan

(3) If a State’s *Vibrio parahaemolyticus* risk evaluation determines that the risk of *Vibrio parahaemolyticus* illness from the consumption of oysters harvested from a growing area is reasonably likely to occur, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan ~~for that area~~.

(4) If a State has a shellfish growing area ~~that is in approved or conditionally approved status~~ in which harvesting occurs ~~that is in approved or conditionally approved status~~ at a time when average monthly daytime water temperatures* exceed those listed ~~in (a) below~~, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan ~~for the area~~.

(a) —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:

- (i) Waters bordering the Pacific Ocean 6460°F*
- (ii) Waters bordering the Gulf of Mexico and Atlantic Ocean (SC and south) 81°F*
- (iii) Waters bordering the Atlantic Ocean (NJ to NC, inclusive) 8168168°F*

(b) However, development of a Plan is not necessary if the State conducts a risk evaluation, as described in A. that determines that it is not reasonably likely that *Vibrio parahaemolyticus* illness will occur from the consumption of oysters harvested from those areas.

- (a~~i~~) In conducting the evaluation, the State shall evaluate the factors listed in A. for the area during periods when the temperatures exceed those listed in ~~B. (2) (a)~~ this section;
- (b~~ii~~) In concluding that the risk is not reasonably likely to

- occur, the State shall consider how the factors listed in ~~AB. (2) (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; and
- (3e) If a State has a shellfish growing area that was the source of oysters 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.
- (43) 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 (Bb)(2) where they apply, or other triggers as determined by the risk evaluation.
- (ba) Implement one or more control measures to reduce the risk of *Vibrio parahaemolyticus* illness, under the circumstances determined by A. and B. (2) and (3) 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 ensure that levels of total *Vibrio parahaemolyticus* after processing do not exceed the average levels found in the area at times of the year when the State has determined that *Vibrio parahaemolyticus* illness is not reasonably likely to occur;
 - (ii) ~~Closure~~ing of the area to oyster harvest;
 - (iii) Restricting oyster harvest to product that is labeled "For Cooking Only;"
 - (iv) ~~Other measures (e.g., r~~Reduction in Limiting time from harvest to refrigeration to no more than five hours, or other times based on modeling or sampling, as determined by the Authority in consultation with FDA;
~~) that based on appropriate scientific studies, are designed to ensure that the levels of total *Vibrio parahaemolyticus* after the completion of initial cooling to 60°F do not exceed the average levels from the harvest water by more than 0.5 logarithms.~~
 - (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 Vp illness is no longer reasonably likely to occur, as approved by the authority.~~Other measures that based on appropriate scientific studies, are designed to ensure that the risk of *Vibrio parahaemolyticus* illness is no longer reasonably likely to occur (e.g., sampling, based on a statistically valid sampling plan, that demonstrates the absence of tdh+ *Vibrio parahaemolyticus* in the shellfish growing area)~~
- (b)(c) When measures provided in B. (43) (ba) (iv) are included in a

~~State's *Vibrio parahaemolyticus* Control Plan, the State shall annually demonstrate Evaluate the effectiveness of the Plan for each area under the circumstances determined by A. and B. (2) and (3), to ensure that the levels of total *Vibrio parahaemolyticus* after the completion of initial cooling to 60°F do not exceed the average levels from the harvest water by more than 0.5 logarithms. Alternatively, the State may require that individual dealers perform such verification.~~

- (d) Modify the Control Plan when verification the evaluation shows the Plan is ineffective, or when new information is available or new technology makes this prudent as determined by the Authority.;
- (e) Optional cost benefit analysis of the *Vibrio parahaemolyticus* Control Plan.

~~* Further analysis is necessary to finalize these temperatures and definition is required for Average Water Temperature (e.g., tide status, source of data, time of day).~~

Action by 2007 Task Forces I & II

Recommended adoption of Vibrio Management Committee recommendation on Proposal 07-202 as amended.

@ .05 *Vibrio parahaemolyticus* Control Plan.

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A. Risk Evaluation.

Every State from which oysters 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 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, halfshell, PHP.

B. Control Plan

- (5) If a State's *Vibrio parahaemolyticus* risk evaluation determines that the risk of *Vibrio parahaemolyticus* illness from the consumption of oysters harvested from a growing area is reasonably likely to occur, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan or.
- (6) 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:

- (i) Waters bordering the Pacific Ocean 60°F*
- (ii) Waters bordering the Gulf of Mexico and Atlantic Ocean (NJ and south) 81°F*

However, development of a Plan is not necessary if the State conducts a risk evaluation, as described in A. that determines that it is not reasonably likely that *Vibrio parahaemolyticus* illness will occur from the consumption of oysters harvested from those areas.

- (a) In conducting the evaluation, the State shall evaluate the factors listed in A. for the area during periods when the temperatures exceed those listed in this section;
 - (b) In concluding that the risk is not reasonably likely to occur, the State shall consider how the factors listed in 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 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 (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 ensure that levels of total *Vibrio parahaemolyticus* after processing do not exceed the average levels found in the area at times of the year when the State has determined that *Vibrio parahaemolyticus* illness is not reasonably likely to occur;
 - (ii) Closing the area to oyster harvest;
 - (iii) Restricting oyster harvest to product that is labeled “For Cooking Only;”
 - (iv) Limiting time from harvest to refrigeration to no more than five 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 Vp illness is no longer reasonably likely to occur, as approved by the authority.
 - (c) Evaluate the effectiveness of the Plan.
 - (d) 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.
 - (e) Optional cost benefit analysis of the *Vibrio parahaemolyticus*

Control Plan.

- C. Effective Date
To be effective six (6) months following FDA concurrence.

**Action by 2007
General Assembly**

Adopted recommendation of 2007 Task Force II.

**Action by
USFDA**

December 20, 2007

Concurred with Conference action with the following comments and recommendations for ISSC consideration.

FDA commends the ISSC for its proactive efforts in addressing *Vibrio parahaemolyticus* illnesses associated with consumption of raw oysters. FDA urges the Conference to advise states of the requirements of the *Vibrio parahaemolyticus* Control Plan as adopted in Proposal 07-202. These requirements will impact many areas of the country and timely communication between ISSC and the states will help them prepare for compliance in 2008. FDA requests that in those communications the ISSC emphasize that the *Vibrio parahaemolyticus* Control Plan focuses on harvest areas where a risk evaluation determines that the risk of illness from oyster consumption is “**reasonably likely to occur.**” “**Reasonably likely to occur**” as defined in the Control Plan means “**the risk constitutes and annual occurrence**”. It is essential that states and industry understand that “**annual occurrence**” shall not be interpreted to mean the annual occurrence of confirmed illnesses but rather the annual occurrence of conditions that create an elevated risk of illness from oyster consumption. FDA also wishes to engage the Conference in a dialogue to discuss effective ways in which state programs could be evaluated for compliance with the requirements of Proposal 07-202.