Proposal No. 2 7 - 1 0 9

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	Model Ordinance Effectiveness Review Committee
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9. Proposal Subject	Model Ordinance Effectiveness
10. Specific NSSP Guide Reference	Chapter II. Risk Assessment and Risk Management
11. Text of Proposal/ Requested Action	**@.01 Outbreaks of Shellfish-Related Illness** A. **When shellfish are implicated in an illness outbreak involving two (2) or more persons not from the same household (or one (1) or more persons in the case of shellfish toxicity poisoning associated with marine biotoxins), the determination of whether an epidemiological association exists between the illness and the shellfish consumption will be made by the state or local epidemiologist in the state in which the outbreak occurs. The determination will be made by reviewing:** (1) **Food history;** (2) **Whether the disease has the potential or is known to be transmitted by shellfish; and** (3) **Whether the symptoms and incubation period of the illnesses are consistent with the suspected etiologic agent.** **NOTE: For additional guidance refer to the International Association for Food Protection *Procedures to Investigate Food Borne Illness*.** B. **When the state or local epidemiologist in the state in which the outbreak occurs has determined an epidemiological association between an illness outbreak meeting the definition of the NSSP and shellfish consumption, the appropriate Authorities shall:** (1) **Notify the FDA Shellfish Specialist that a shellfish related outbreak has occurred.** (2) **Within twenty-four (24) hours determine whether the illness is growing area related or is the result of post-harvest contamination, mishandling or illegal harvesting from a closed area. The determination of post-harvest contamination may involve multiple authorities in multiple states. The determination of the illness being growing area related will be conducted by the source**

	state. C. **When the Authorities determine that the outbreak is not the result of a post-harvest contamination problem or illegal harvesting from a closed area, the Authority shall determine if the outbreak is from a single source or multiple sources.** (1) **When the Authority determines that a single source outbreak has occurred, the Authority shall:** (a) **Immediately place the implicated portion(s) of the harvest area(s) in the closed status;** (b) **Notify the ISSC and the FDA Shellfish Specialist that a potential health risk is associated with shellfish harvested from the implicated growing area;** (c) **Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7, when a recall is deemed appropriate by the Authority. The recall shall include all implicated products.** (d) **Transmit to the ISSC and FDA information identifying the dealers shipping the implicated shellfish.** (e) **The ISSC will notify States and FDA Shellfish Specialists of growing area closures and recalls. In the case of recalls, ISSC will notify States with information identifying dealers shipping the implicated shellfish. Closure and recall notices (not to include dealers) will be posted on the ISSC website. ISSC will maintain an inventory of closure and recall information.** (2) **When the Authority determines that a multiple source outbreak has occurred, the Authority shall immediately place the implicated portion(s) of the harvest area(s) in a precautionary closure. A specific growing area placed in a precautionary closed status under this section can be immediately re- opened when one (1) or more of the following conditions are met:** **(a) When the investigation, conducted in consultation with epidemiologist(s) in the state(s) in which the outbreak occurs, determines that the shellfish which caused the outbreak did not come from one (1) or more of the implicated growing areas in question based on consumption data provided by victims or other relevant data provided by state investigators. This would include an additional illness(es) that matches one (1) or more of the implicated areas and allows for a more precise identification of the growing area(s) which caused the outbreak.** **(b) When an investigation, in accordance with Chapter II @ .01 H, of an implicated growing area identifies an actual or potential pollution source(s) in a specific growing area and no source(s) are identified in other implicated**

growing areas, the precautionary closures in other implicated growing areas can be reopened. The reopening can only occur in a growing area after the investigation referenced above does not indicate an actual or potential pollution source that could be the cause of the outbreak.

(c) When the investigation, conducted in consultation with the epidemiologists in the state(s) in which the illnesses occur and the Authorities in the state from which the shellfish were harvested, provides information that may include but shall not be limited to:

(i) Volume or distribution information which would implicate a specific growing area;

(ii) Illness reporting from immediately adjacent growing areas;

(iii) Pollution source investigation in conjunction with growing area evaluation does not identify a pollution source.

(iv) Epidemiological tools that would link cases based on genetic similarity.

(3) When precautionary closures are established to address an illness outbreak involving multiple sources, Authorities will not be required to initiate voluntary recalls until the investigations indicate a single source.

D. **When the appropriate Authorities determine that the illnesses are related to post- harvesting contamination or mishandling, growing area closure is not required. However, the Authority in the state where the post-harvest contamination, mishandling or illegal harvesting from a closed area occurred shall:**

(1) **Notify the ISSC and the FDA Shellfish Specialist of the problem; and**

(2) **Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7 when a recall is deemed appropriate by the Authority . The recall shall include all implicated products.**

(3) **Transmit to the ISSC and FDA information identifying the dealers shipping the implicated shellfish.**

(4) **The ISSC will notify States and FDA Shellfish Specialists of ~~growing area closures and~~ recalls. In the case of recalls, ISSC will notify States with information identifying dealers shipping the implicated shellfish. ~~Closure and r~~Recall notices (not to include dealers) will be posted on the ISSC website. ISSC will maintain an inventory of ~~closure and~~ recall information.**

E. **When the Authority can not complete the determination outlined in Chapter II. @.01 B. within 24 hours, the Authority in the source state shall:**

(1) **Immediately place the implicated portion(s) of the**

harvest area(s) in a precautionary closed status. Should the Authorities later determine that the illnesses are related to post-harvest contamination, or mishandling, or harvested from a closed area, the suspected growing area can be reopened.

(2) Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7, when the authority deems appropriate.

(3) Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7, when the authority can document a rationale that a recall would be effective.

F. **Upon closing an implicated portion(s) of the harvest area(s) for naturally occurring pathogens and/or biotoxins, the Authority:**

(1) Shall follow an existing marine biotoxin contingency/management plan, if appropriate.

(2) Shall collect and analyze samples relevant to the investigation, if appropriate.

(3) Shall keep the area closed until it has been determined that levels of naturally occurring pathogens and/or biotoxins are not a public health concern.

(4) Shall follow the procedure outlined in Chapter II @ .02 A. (10)(a) or (b) for closures resulting from *V.p.* illnesses.

(5) May limit the closure to specific shellfish species when FDA concurs that the threat of illness is species specific.

G. **When the growing area is determined the problem, the Authority shall:**

(1) Place the growing area in the closed status until:

(a) The Authority verifies that the area is properly classified by conducting a review of the growing area to include:

i. current data, in compliance with the NSSP Model Ordinance;

ii. A field review of existing pollution sources;

iii. A review of actual and potential intermittent pollution sources, such as vessel waste discharge and wastewater discharge from treatment plant collection systems. If a previously unknown pollution source can be corrected, the closure period shall be extended to allow for natural depuration following correction of the pollution source; and

iv. Examination of water quality subsequent to the illness outbreak.

(b) It has been determined that the event which caused the contamination no longer exists and sufficient time has elapsed for natural depuration;

(2) Keep the area closed until at least 21 days have passed from the last date of harvest of the implicated shellstock if the illness is consistent with viral etiology; and

(3) Develop a written report summarizing the findings of the

investigation and actions taken.

H. **Whenever an Authority or dealer initiates a recall of shellfish products because of public health concerns, the Authority will monitor the progress and success of the recall. The Authority will immediately notify the FDA, ISSC and the Authorities in other States involved in the recall. The Authority shall submit periodic recall status reports to the FDA Shellfish Specialist consistent with the Recall Enforcement Policy Title 21 CFR Part 7, Subpart C, Section 7.53 (b) (1- 6) until such time that the Authority deems the recall to be completed. Each Authority involved in a recall will implement actions to ensure removal of recalled product from the market, issue public warnings if necessary to protect public health and provide periodic reports to the Authority in the State of product origin regarding recall efforts within their State until such time that the Authority in the State of product origin deems the recall to be completed. FDA will decide whether to audit or issue public warnings after consultation with the Authority/Authorities and after taking into account the scope of the product distribution and other related factors. If the FDA determines that the Authority in any State involved in the recall fails to implement effective actions to protect public health, the FDA may classify, publish and audit the recall, including issuance of public warnings when appropriate.**

I. **Molluscan shellfish product that is recalled as a result of an illness outbreak associated with *V.v., V.p.* or Norovirus may be reconditioned.**

(1) **Validated reconditioning processes for *V.v.* and *V.p.* include subjecting product to validated post-harvest processing (PHP) or placing product into approved, conditionally approved, conditionally restricted, or restricted growing areas for an appropriate period of time, not less than fourteen (14) days, with appropriate controls and documentation to be determined by the Authority.**

(2) **Product associated with a Norovirus outbreak may be reconditioned by returning the product, within ten (10) days of harvest, to the area from which it was harvested for an appropriate period of time. Environmental conditions in the harvest area must be conducive for pumping and feeding. The period of time shall not be less than sixty (60) days. The Authority shall ensure appropriate controls and provide documentation of the activity**

@.02 Shellfish Related Illnesses Associated with *Vibrio parahaemolyticus (V.p.)*

A. **When the investigation outlined in Section @.01 A. indicates the illness(es) are associated with the naturally occurring pathogen *Vibrio parahaemolyticus (V.p.)*, the Authority shall determine the number of laboratory confirmed cases epidemiologically**

associated with the implicated area. States will not be expected to close growing areas based on *V.p.* cases that are reported more than thirty (30) days after harvest or when environmental parameters have changed or monitoring indicates the *V.p.* risk is reduced. Actions taken by the Authority will be based on the number of cases and the span of time as follows.

(1) **When sporadic cases do not exceed a risk of one (1) illness per 100,000 servings or involves at least two (2) but not more than four (4) cases occurring within a thirty (30) day period from an implicated area in which no two (2) cases occurred from a single harvest day, the Authority shall determine the extent of the implicated area. The Authority will make reasonable attempts to ensure compliance with the existing Vibrio Management Plan.**

(2) **When the risk exceeds one (1) illness per 100,000 servings within a thirty (30) day period or when cases exceed four (4) but not more than ten (10) over a thirty (30) day period from the implicated area or two (2) or more cases but less than four (4) cases occur from a single harvest day from the implicated area, the Authority shall:**

- (a) **Determine the extent of the implicated area; and**
- (b) **Immediately place the implicated portion(s) of the harvest area(s) in the closed status; and**
- (c) **As soon as determined by the Authority, transmit to the FDA and receiving States information identifying the dealers shipping the implicated shellfish.**

(3) **When the number of cases exceeds ten (10) illnesses within a thirty (30) day period from the implicated area or four (4) or more cases occurred from a single harvest date from the implicated area, The Authority shall:**

- (a) **Determine the extent of the implicated area; and**
- (b) **Immediately place the implicated portion(s) of the harvest area(s) in the closed status; and**
- (c) **Promptly initiate a voluntary industry recall consistent with the Recall Enforcement Policy, Title 21 CFR Part 7 unless the Authority determines that a recall is not required where the implicated product is no longer available on the market or when the Authority determines that a recall would not be effective in preventing additional illnesses. The recall shall include all implicated products.**
- (d) **Issue a consumer advisory for all shellfish (or species implicated in the illness).**

(4) **When the number of cases and the span of time reach the thresholds outlined above, prior to implementing the controls above, the Authority shall conduct an investigation of the illnesses within seventy-two (72) hours of reaching any one (1) of the thresholds of Chapter II @.02 A. (1), (2) or (3) to determine whether**

	the illness is growing area related or is the result of post-harvest abuse or mishandling such as time temperature abuse. (a) **If the conditions in Chapter II @.02 A. (2) or (3) are met and the investigation cannot be completed within 72 hours, immediately place the implicated portion(s) of the harvest area(s) in a precautionary closed status.** (b) **Should the Authority later determine that the illnesses are related to post harvest abuse or mishandling the implicated harvest area(s) can be immediately reopened.** **(5) When the investigation outlined in Model Ordinance Chapter II. @.02 A. (4) demonstrates that the illnesses are related to post- harvesting contamination or mishandling, growing area closure is not required. However, the Authority shall:** (a) **Notify the ISSC and the FDA Shellfish Specialist of the problem; and** (b) **Determine the appropriateness of initiating a voluntary recall by firms. If a firm or firms is requested by the Authority to recall, the firm will use procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7. The recall shall include all implicated products.** (c) **Transmit to the ISSC and FDA information identifying the dealers shipping the implicated shellfish; Should closures and recalls be necessary the ISSC will notify States and FDA Shellfish Specialists of growing area closures and recalls. In the case of recalls, ISSC will notify States with information identifying dealers shipping the implicated shellfish. Closure and recall notices (not to include dealers) will be posted on the ISSC website. ISSC will maintain an inventory of closure and recall information.** (6) **When the investigation outlined in Model Ordinance Chapter II. @.02 A.(4) does not indicate a post-harvest contamination problem, or illegal harvesting from a closed area, the Authority shall:** (a) **Follow the procedures outlined in Chapter II @.02 A. (1), (2) and (3).** (b) **Notify the ISSC and the FDA Shellfish Specialist that a potential health risk is associated with shellfish harvested from the implicated growing area;** (c) **If a recall is required by Chapter II @.02 A. (3)** i. **Transmit to the ISSC and FDA information identifying the dealers shipping the implicated shellfish.**

ii. **The ISSC will notify States and FDA Shellfish Specialists of growing area closures and recalls. In the case of recalls, ISSC will notify States with information identifying dealers shipping the implicated shellfish. Closure and recall notices (not to include dealers) will be posted on the ISSC website. ISSC will maintain an inventory of closure and recall information.**

(7) **When the State Authority investigating the laboratory confirmed *V.p.* cases does not provide information to identify a single growing area and multiple growing areas are implicated, the State Authorities in the states with implicated growing areas shall evaluate to determine if the illness should be attributed to the implicated area(s). Evaluations may include but are not limited to:**

(a) Vibrio levels in the growing area around the time and date of harvest

(b) Comparison of other single source illnesses attributed to a growing area(s) involved in a multiple source outbreak. The purpose of this comparison would be to determine if a common growing area can be identified.

(c) Environmental conditions which could increase the risk of *V.p.* at the time of harvest. This could include conditions such as water temperature, air temperature and tidal stage.

(d) Genetic typing of clinical isolates implicates a common growing area or rules out implicated growing areas

(8) **If the evaluation in (7) provides sufficient information to implicate a single area, then the Shellfish Authority shall take actions outlined in A. (6), above.**

(9) **When a growing area has been closed as a result of *V.p.* cases, the Authority shall keep the area closed for the following periods of time to determine if additional illnesses have occurred:**

(a) **The area will remain closed for a minimum of fourteen (14) days when the risk exceeds one (1) illness per 100,000 servings within a thirty (30) day period or cases exceed four (4) but not more than ten (10) cases over a thirty (30) day period from the implicated area or two (2) or more cases but less than four (4) cases occur from a single harvest date from the implicated area.**

(b) **The area will remain closed for a minimum of twenty-one (21) days when the number of cases exceeds ten (10) illnesses within thirty (30) days or four (4) cases occur from a single harvest date from the implicated area**

(10) **Prior to reopening an area closed as a result of @.02 A. (9)(a) or (b), the Authority shall:**

(a) **Collect and analyze samples to ensure that tdh does**

not exceed 10/g and trh does not exceed 10/g; or other such values as determined appropriate by the Authority based on studies.

(i) **Samples shall be collected to be representative of the area and shellfish types.; and**

(ii) **Multiple sample collection events shall span the closure time period in @.02 A. (9)(a) or (b) and be collected at intervals necessary to determine trends in the implicated area.**

;or

(b) **Ensure that environmental conditions have returned to levels not associated with *V.p.* cases.**

(11) **Shellfish harvesting may occur in an area closed as a result of *V.p.* illnesses when the Authority implements one (1) or more of the following controls:**

(a) **PHP using a process that has been validated to achieve a two (2) log reduction in the levels of total *V.p.* for Gulf and Atlantic Coast oysters and/or hard clams and a three (3) log reduction for Pacific Coast oysters and/or hard clams;**

(b) **Restricting oyster and/or hard clam 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;**

(c) **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.**

@. 03 Annual Assessment of *Vibrio vulnificus* and *Vibrio parahaemolyticus* Illnesses and Shellfish Production

A. **The Authority shall assess annually *Vibrio vulnificus (V.v.)* and *Vibrio parahaemolyticus (V.p.)* CIDT cases or culture confirmed illnesses associated with the consumption of molluscan shellfish. The assessment will include a record of all *V.v.* and *V.p.* shellfish-associated illnesses reported within the State and from receiving States, the numbers of illnesses per event, and actions taken by the Authority in response to the illnesses.**

B. **The Authority shall collect by month and report annually to the ISSC the volume of shellfish harvested in the State. The report shall include the volume of shellfish harvested for each species. Where available the volume breakdown of the production data will be reported by utilization type (raw, shucked, PHP, etc.).**

@.04 Presence of Human Pathogens in Shellfish Meats

A. **Finding. Upon determination that human pathogens are present in shellfish meats, the Authority shall investigate the harvesting, the distribution, and the processing of the shellfish.**

B. **Growing Area Investigation.**

(1) **The Authority shall review the following factors:**

(a) **The documentation to trace the shellfish to its source;**

(b) **The classification assigned to the growing area and whether the sanitary survey data supporting that classification is current; and**

(c) **The probability of illegal harvesting from areas classified as restricted or prohibited, or in the closed status.**

(2) **The Authority shall not be required to~~shall~~ take ~~no~~ further action when the Authority determines that:**

(a) **The growing area is properly classified;**

(b) **No evidence that illegal harvesting is taking place; and**

(c) **There is an absence of evidence~~no reason to believe~~ that the growing area is the source of the pathogens.**

(3) **When the Authority determines that the growing area is not properly classified, the Authority shall take immediate action to:**

(a) **Change the existing classification to the correct classification; or**

(b) **Close the growing area until the correct classification can be determined; and**

(c) **Determine whether to initiate a voluntary recall by firms. If a firm or firms is requested by the Authority to recall, the firm will use procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7. The recall shall include all implicated products.**

(4) **When the Authority determines that the growing area may be the source of pathogens and the pathogens exceed tolerance levels, the Authority shall request a voluntary recall by firms. The firms will use procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7. The recall shall include all implicated products.**

(5) **When the Authority determines that illegal harvesting is taking place, the Authority shall determine whether to initiate a voluntary recall by firms. The firm will use procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7. The recall shall include all implicated products.**

C. **Distribution and Processing Investigation.**

(1) **The Authority shall evaluate the distribution and processing of the shellfish. This investigation may include collection of additional meat samples.**

(2) **The Authority shall not be required to take ~~no~~ further**

	action when the Authority determines that there is no reason to believe a problem exists in the distribution or processing of the shellfish. (3) **When the Authority determines that a problem exists in the distribution or processing of the shellfish, the Authority shall take immediate steps to correct the problem and determine whether to initiate a voluntary recall by firms. If a firm(s) is requested by the Authority to recall, the firm will use procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7. The recall shall include all implicated products.** D. **Risk Management and Tolerance Levels.** (1) **Pathogen Present. When a growing area continues to demonstrate the presence of human pathogen isolates in shellfish meats in the absence of illness, the Authority shall perform a risk assessment to determine the correct classification for an area.** (2) **Established Tolerance Levels.** (a) **When the established tolerance level for a particular pathogen isolate is not exceeded, the Authority:** (i) **Shall maintain a written summary of its finding and the data supporting its finding in its central file; and** (ii) **May leave the growing area in its present classification.** (b) **When the established tolerance level for a particular pathogen isolate is known and there are no known outbreaks of shellfish associated disease caused by that pathogen in a particular growing area, the Authority shall:** (i) **Leave the area in the open status of its classification when the tolerance level is not exceeded; and** (ii) **Place the area in the closed status of its classification when the tolerance level is exceeded.** (c) **When the tolerance level is exceeded, the Authority may:** (i) **Maintain the growing area in the closed status of its current classification;** (ii) **Reclassify the growing area to the restricted or prohibited classification; or** (iii) **Reclassify the growing area to the conditionally restricted classification and establish a management plan.** (d) **Any management plan based on shellstock exceeding established tolerance levels shall:** (i) **Meet all appropriate requirements for a management plan for the conditionally approved or conditionally restricted classification;** (ii) **Specify the additional criteria associated with the particular pathogen isolate that the growing area must meet to be in the open status of its classification;**

(iii) **Document the scientific basis for the additional criteria;**

(iv) **Provide for periodic retesting of the shellfish meats; and**

(v) **Provide for the growing area to be placed in the closed status if the criteria are exceeded.**

(3) **Established Tolerance Levels Not Known.**

(a) **When an established tolerance level does not exist for the particular pathogen isolated, the Authority shall assess the public health significance of the levels of the pathogen found in the growing area shellfish meats. The Authority may consider FDA recommended action levels or levels of concern in this determination. When the Authority determines that:**

(i) **The levels are acceptable, the growing area ~~shall~~ may remain in the open status of its classification; or**

(ii) **The levels are unacceptable; the growing area shall be placed in the closed status of its classification.**

(b) **If a growing area is placed in the closed status, the Authority may elect to**

(i) **Maintain that status indefinitely;**

(ii) **Reclassify the area to the restricted or prohibited classification; or**

(iii) **Reclassify the area to the conditionally restricted classification and establish a management plan. The management plan shall meet the requirements of Section D. (2) (d).**

@.05 Presence of Toxic Substances in Shellfish Meats

A. **Upon determination that toxic substances, including but not limited to heavy metals, chlorinated hydrocarbons, and natural toxins are present in levels of public health significance in shellfish meats, the Authority shall investigate the harvesting, distribution, and processing of shellfish and take necessary corrective action in accordance with the procedures described in Section @.04.**

B. **When a growing area continues to demonstrate the presence of toxic substances in the absence of illness, the Authority shall perform a risk assessment to determine the correct classification of the area. The risk assessment and subsequent risk management shall follow the procedures outlined in Section @.04 D., Risk Management and Tolerance Levels.**

@.06 *Vibrio vulnificus* Control Plan

A. **Risk Evaluation**

Each shellfish producing State that is not currently implementing

	a *V.v.* Control Plan shall conduct a *V.v.* risk evaluation annually. The evaluation shall consider each of the following factors, including seasonal variations in the factors, in determining the risk of *V.v.* infection from the consumption of shellfish harvested from the State's growing waters. **(1) In conducting the risk evaluation, the Authority will at a minimum consider the following:** **(a) The number of *V.v.* cases etiologically confirmed and epidemiologically linked to the consumption of commercially harvested shellfish from the State; and** **(b) Levels of *V.v.* in the growing waters and in shellfish, to the extent that such data exists; and** **(c) The quantity of harvest from the area and its uses i.e. shucking, half shell, PHP.** **B. States which have previously met the illness threshold requiring a *V.v.* Control Plan will continue to maintain and implement a *V.v.* Control Plan.** **C. All States not currently implementing a *V.v.* Control Plan shall develop and implement a *V.v.* Control Plan if the risk evaluation indicates two (2) or more etiologically confirmed, and epidemiologically linked *V.v.* illnesses from consumption of commercially harvested oysters that originated from the growing waters of that State within the previous ten (10) years** **D. The Authority shall develop a *V.v.* Contingency Plan should the risk evaluation indicate any etiologically confirmed shellfish-borne *V.v.* illness from the growing waters of that State but the number of cases does not reach the threshold established in @.06 C.** **E. Control Plan** **(1) The *V.v.* 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 (1) or more of the following triggers will be used:** **(i) The water temperatures in the area;** **(ii) The air temperatures in the area;** **(iii) Salinity in the area;** **(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 (1) or more of the following control measures to reduce the risk of *V.v.* illness:** **(i) Labeling oysters as being for shucking by a certified dealer or for approved post-harvest processing to control the *Vibrio vulnificus* hazard when the Average Monthly Maximum Water Temperature exceeds 70 °F.** **(ii) Subjecting all oysters intended for the raw, half-shell market to Authority approved PHP 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 *V.v.* 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 @.06 E. (1) (b) (iii) when water temperatures exceed 70 °F.**

(c) **A state has the option to implement a *Vibrio vulnificus* Control Plan that includes time-temperature harvesting controls when Average Monthly Maximum water temperatures are below 70°F. If the state implements this option, shellstock intended for raw consumption shall comply with the matrix below:**

Action Level	Water Temperature	Max Expos

Level 1	**<65ºF**	**36 hours**
Level 2	**65ºF - 70ºF (18ºC - 23ºC)**	**14 hours**

(d) All shellstock harvested according to a *Vibrio vulnificus* control plan shall be cooled to an internal temperature of 55ºF (12.7ºC) or less within 10 hours of being placed into temperature control.

(e) When pre-harvest culture practices have the potential to elevate Vibrio levels in market size product intended for immediate harvest, the Authority shall establish Vibrio control measures and include the measures in the State Vibrio Control Plan. Such control measures may be implemented on a State-wide, regional, geographic, or farm or growing area-specific basis. When shellfish are re-immersed as a control measure the Authority should consider inclusion of record keeping requirements such as means of shellfish segregation/identification procedures, date re-immersed in water and date of final harvest. The Authority may require growers to have a control plan approved by the Authority.

(2) Control Plan Evaluation

(a) The State Authority will conduct annual evaluations of the plan. At a minimum the Authority will consider:

(i) 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 *V.v.* in shellfish pre and post-harvest.

(iii) Industry compliance with existing controls.

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

(b) For the purposes of determining Authority compliance the FDA will conduct an annual Vibrio evaluation of the Authority to determine the following:

(i) Authority compliance with *V.v.* Risk Evaluation as required in Chapter II. @.06 A.

(ii) For States requiring the development of *V.v.* Plans, compliance with Control Plan requirements of Chapter II. @.06 E. (1). The evaluation should determine:

(a) Appropriate identification of triggers to determine when control measures are needed.

(b) **Did the Authority implement one (1) or more of the control measures required in Chapter II. @.06 E. (1) (b).**

(c) **For Authorities implementing Chapter II. @.06 E. (1) (b) (i) and (ii), were the controls implemented adequately.**

(d) **For Authorities implementing Chapter II. @.06 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.**

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

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

b. **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 (1) 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 FDA 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.**

F. **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 *V.v.* Control Plan.**

(2) **Contingency Plan Evaluation**
In consultation with FDA the Authority will evaluate the adequacy of their Contingency Plan.

@.07 *Vibrio parahaemolyticus* Control Plan

The goal of the Control Plan is to reduce the probability of occurrence of *Vibrio parahaemolyticus* (*V.p.*) illness during periods that have been historically associated with 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. **Independent Species Specific Risk Evaluation.**
Every State from which oysters or hard clams (*Mercenaria mercenaria*) are harvested shall conduct a *V.p.* risk evaluation annually. The evaluation shall consider each of the following factors, including seasonal variations in the factors, in determining whether the risk of *V.p.* infection from the consumption of oysters or hard clams 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 *V.p.* cases epidemiologically linked to the consumption of oysters or hard clams commercially harvested from the State;**
(2) **Levels of total and tdh+ *V.p.* in the area, to the extent that such data exists;**
(3) **The water temperatures in the area;**
(4) **The air temperatures in the area;**
(5) **Salinity in the area;**
(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. **Independent Species Specific Control Plan**
(1) **If a State's *V.p.* risk evaluation determines that the risk of *V.p.* illness from the consumption of oysters or hard clams harvested from a growing area is reasonably likely to occur, the State shall develop and implement a *V.p.* Control Plan.**
(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 *V.p.* 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) **Waters bordering the Atlantic Ocean (NY and north): 60 °F.**
(d) **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 *V.p.* illness will occur from the consumption of oysters or hard clams 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 *V.p.* illness; or** (3) **If a State has a shellfish growing area that was the source of oysters or hard clams that were epidemiologically linked to an outbreak of *V.p.* within the prior five (5) years, the State shall develop and implement a *V.p.* Control Plan for the area.** (4) **For States required to implement *V.p.* Control Plans, the Plan shall include the administrative procedures and resources necessary to accomplish the following:** (a) **Establish one (1) 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 (1) or more control measures to reduce the risk of *V.p.* illness at times when it is reasonably likely to occur. The control measures may include:** (i) **PHP using a process that has been validated to achieve a two (2) log reduction in the levels of total *V.p.* for Gulf and Atlantic Coast oysters and hard clams and a three (3) log reduction for the Pacific Coast oysters;** (ii) **Closing the area to oyster and/or hard clam harvest;** (iii) **Restricting oyster and/or hard clam 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 *V.p.* after the completion of initial cooling to 60 °F (internal temperature of the oysters or hard clams) 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 and/or hard clams 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 *V.p.* 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 and/or hard clams has reached 50 °F (10 °C) or below within ten (10) hours or less as determined by the Authority of being placed into refrigeration. When deemed appropriate by the Authority an exception may be permitted for hard clams to allow for tempering. Oysters and/or hard clams without proper HACCP records demonstrating compliance with this cooling requirement shall be diverted to PHP or labeled as being for shucking by a certified dealer or for approved post-harvest processing to control the *Vibrio parahaemolyticus* hazard. **(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 *V.p.* Control Plan.** **(5) When pre-harvest culture practices have the potential to elevate *V.p.* levels in market size product intended for immediate harvest, the Authority shall establish *V.p.* control measures and include the measures in the State Vibrio Control Plan. Such control measures may be implemented on a State-wide, regional, geographic, or farm or growing area-specific basis. When shellfish are re-immersed as a control measure the Authority should consider inclusion of record keeping requirements such as means of shellfish segregation/identification procedures, date re-immersed in water and date of final harvest. The Authority may require growers to have a control plan approved by the Authority.** **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.**
12. Public Health Significance	N/A
13. Cost Information	N/A
14. Changes Needed to Guidance (if proposed change is adopted)	N/A