Proposal No. 2 7 - 2 1 5 _____

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Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. X Harvesting/Handling/Distribution c. ☐ Administrative
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9. Proposal Subject	Outbreak Determination & Response Clarification
10. Specific NSSP Guide Reference	Section II Model Ordinance, Chapter II. Risk Assessment & 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~~shellfish were consumed. 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. B. When the state or local epidemiologist in the state in which the ~~outbreak occurs~~shellfish were consumed has determined an epidemiological association between an illness outbreak meeting the definition of the NSSP and shellfish consumption~~, the appropriate Authorities shall~~: (1) The Authority of the state in which shellfish were consumed shall ~~N~~notify the FDA Shellfish Specialist that a shellfish related outbreak has occurred. (2) The appropriate Authorities shall, ~~W~~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 ~~a~~Authorities in multiple states. The determination of the illness being growing area related will be conducted by the ~~source state~~Authority of the state in which shellfish were harvested. 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 of the state in which shellfish were consumed shall determine if the outbreak is from a single source or multiple sources. (1) When the Authority of the state in which shellfish were consumed determines that a single source outbreak has occurred, the Authority of the state where shellfish were harvested 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 of the state in which shellfish were consumed determines that a multiple source outbreak has occurred, the Authority~~ies~~ of the state in which shellfish were harvested 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 by the Authority of the state in which shellfish were consumed, conducted in consultation with epidemiologist(s) in the state(s) in which the ~~outbreak occurs~~shellfish were consumed, 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 by the Authority of the state in which shellfish were harvested, 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~~shellfish were consumed and the Authorities ~~in~~of the state ~~from~~ in 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~~of 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 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 of the state in which shellfish were consumed cannot complete the determination outlined in Chapter II. @.01 B. within 24 hours, the Authority ~~in the source state~~of the state in which shellfish were harvested 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 ~~a~~Authority deems appropriate.
(3) Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7, when the ~~a~~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 (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 by the Authority in which shellfish were harvested, 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 of the state in which shellfish were harvested 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 appropriate Authority~~y~~ies 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. The determination of post-harvest abuse or mishandling may involve multiple Authorities in multiple states

(a) If the conditions in Chapter II @.02 A. (2) or (3) are met and the investigation cannot be completed within 72 hours, the Authority of the state in which shellfish were harvested shall 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 of the state in which the post-harvest contamination or mishandling occurred 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 of the state in which shellfish were harvested 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~~in which the shellfish was consumed 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.
12. Public Health Significance	This proposal is meant to clarify who does what during illness investigations, not to add or alter any existing requirements. When reading this chapter, it has been unclear to me which states (the state where the shellfish implicated in an illness were consumed, versus the states where the shellfish were harvested) were responsible for the actions required by this chapter. This proposal is intended to ensure that the responsibilities for illness response outlined in this chapter are clearly delineated. It is not meant to add or change any existing requirements, just to provide clarity so that illness response are handled as intended to ensure that outbreak investigation and response can be successful in preventing further illnesses.
13. Cost Information	None
14. Changes Needed to Guidance (if proposed change is adopted)	None