Proposal No. 2 7 - 2 1 6

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	Vibrio Management Program
10. Specific NSSP Guide Reference	Section II. Model Ordinance Chapter II. Risk Assessment and Risk Management @.01, @.02, @.03, @.06
11. Text of Proposal/ Requested Action	The below text is proposed to replace existing Ch II. @.01 where indicated, all of @.02, @.03, and @.06 as well as strike @.07 in its entirety. **@.01 Outbreaks of Shellfish-Related Illness** A. When shellfish are implicated in an illness outbreak involving two (2) or more persons (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… C. When the Authorities determine that the outbreak is not the result of a post-harvest contamination… D. When the appropriate Authorities determine that the illnesses are related to post-harvesting contamination… E. When the Authority can not complete the determination outlined in Chapter II. @.01 B. within 24 hours… F. Upon closing an implicated portion(s) of the harvest area(s) for 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 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 *Vibrio* 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… H. Whenever an Authority or dealer initiates a recall of shellfish products… I. Molluscan shellfish product that is recalled as a result of an illness outbreak associated with *Vibrio* or Norovirus may be reconditioned. (1) Validated reconditioning processes for *Vibrio* 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… **@.02 Shellfish Related Illnesses Associated with *Vibrio* Species** A. When the investigation outlined in Section @.01 A. indicates the illness(es) are associated with *Vibrio* spp., the Authority shall determine the number of culture-confirmed cases and the number of laboratory-confirmed cases and the number of *Vibrio* spp. cases diagnosed by culture-independent testing (CIDT) epidemiologically associated with the implicated area. States will not be expected to close growing areas based on vibriosis cases that are reported more than thirty (30) days after harvest or when environmental parameters have changed or monitoring indicates the *Vibrio* 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 at least two (2) cases occur within a thirty (30) day period and are from a single harvest day, the determination of whether the definition of an outbreak has been met should be made as described in @.01 A. If determined to be an outbreak, the requirements of @.01 B.-I. shall be met. (2) 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. (3) 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. (4) 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). (5) If at least one (1) culture-confirmed *Vibrio* case has been epidemiologically associated with an implicated area, every two (2) *Vibrio* spp. cases diagnosed via CIDT and epidemiologically associated with the implicated area within a 30-day period will be individually enumerated as one (1) case under sections @.02 A.(1)-(4). (6)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. (7) 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. (8) 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. (9) When the State Authority investigating the laboratory confirmed *Vibrio* 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 *Vibrio* 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. (9) If the evaluation in (8) provides sufficient information to implicate a single area, then the Shellfish Authority shall take actions outlined in A. (7), above. (10) When a growing area has been closed as a result of vibriosis 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 at least two (2) cases occur from a single harvest date from the implicated area. (11) 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 *Vibrio* levels are less than those associated with illness (for *V. parahaemolyticus*, tdh does not exceed 10/g and trh does not exceed 10/g) 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 vibriosis cases for a minimum of 14 days. (12) Shellfish harvesting may occur in an area closed as a result of *Vibrio* 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; (c) Other control measures that based on appropriate scientific studies are designed to ensure that the risk of *Vibrio* illness is no longer reasonably likely to occur, as approved by the Authority.

@. 03 Annual Assessment of *Vibrio* spp. Illnesses and Shellfish Production
A. The Authority shall assess annually vibriosis cases associated with the consumption of molluscan shellfish. The assessment will include a record of all vibriosis shellfish-associated cases, culture-confirmed and CIDT-positive, 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…

@.05 Presence of Toxic Substances in Shellfish Meats…

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

A. Determination of Need for *Vibrio* Control Plan
(1) Risk Evaluation
Every State from which shellfish are harvested shall conduct a *Vibrio* risk evaluation annually for each species of commercially harvested shellfish. The evaluation shall consider each of the following factors, including seasonal variations in the factors, in determining whether the risk of vibriosis from the consumption of shellfish 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):
(a) The number of vibriosis cases, culture-confirmed and CIDT-positive, linked to the consumption of commercially harvested shellfish from the State;
(b) Levels of *Vibrio* spp. in the growing waters and in shellfish, to the extent that such data exists;
(c) The water temperatures in the area;
(d) The air temperatures in the area;
(e) Salinity in the area;
(f) Harvest techniques in the area; and
(g) The quantity of harvest from the area and its uses, i.e., raw market, half shell, PHP.
(2) States which have previously met the threshold requiring a *Vibrio* Control Plan will continue to maintain and implement a *Vibrio* Control Plan.
(3) All States not currently implementing a *Vibrio* Control Plan shall develop and implement a *Vibrio* Control Plan if the risk evaluation indicates:
(a) Two (2) or more etiologically confirmed, and epidemiologically linked *V. vulnificus* illnesses from consumption of commercially harvested oysters that originated from the growing waters of that State within the previous ten (10) years; or
(b) Shellfish from the growing waters within the State were epidemiologically linked

	to an outbreak of *Vibiro* within the prior five (5) years; (c) Shellfish from the growing waters within the State were closed due to triggers in @.02 more than 3 times within the prior five (5) years; or (c) The risk of vibriosis from the consumption of shellfish harvested from a growing area is reasonably likely to occur; or (d) A shellfish growing area in which harvesting occurs at a time when average monthly daytime water temperatures exceed those listed below, unless the risk evaluation determines that vibriosis is not reasonably likely to occur from the consumption of shellfish harvested from those areas and rationale is documented: (i) Waters bordering the Pacific Ocean: 60 °F. (ii) Waters bordering the Gulf of Mexico and Atlantic Ocean (NJ and south): 81 °F. (iii) Waters bordering the Atlantic Ocean (NY and north): 60 °F. B. *Vibrio* Control Plan (1) For States required to implement a *Vibrio* Control Plan (VCP), the VCP 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 average monthly daytime water temperatures in @.06 A(3)(d) where they apply, or other triggers as determined by the risk evaluation, which may include: (i) The air temperatures in the area; when the Average Monthly Maximum Water Temperature (AMMWT) exceeds: a) 60°F for waters bordering the Pacific Ocean or Atlantic Ocean (NY and north) b) 81°F for waters bordering the Gulf of Mexico or Atlantic Ocean (NJ and south) (ii) Salinity in the area; or (iii) Other factors that affect risk which can be used as a basis for reducing risk. (b) Implement one (1) or more control measures to reduce the risk of vibriosis at times when it is reasonably likely to occur. The control measures may include: (i) Closing the area to shellfish harvest; (ii) 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 shellfish and a three (3) log reduction for the Pacific Coast oysters; (iii) Subjecting all oysters intended for the raw, half-shell market to approved PHP when the AMMWT exceeds temperatures in B.(1)(a)(i). (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. . 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, the State VCP will include controls when water temperature promotes *Vibrio* levels and risk of vibriosis increases. (v) Limiting time from harvest to refrigeration such that the *Vibrio* levels after the completion of initial cooling to 50F (internal temperature of shellfish) 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) Require the original dealer to cool shellfish 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* 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. Shellfish without proper HACCP records demonstrating compliance with this cooling requirement shall be diverted to PHP or labeled for approved post-harvest processing to control the *Vibrio* hazard. (d) 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 VCP. 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 shall include 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. (e) Evaluate the effectiveness of the Plan. (f) 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. (2) 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 VCP. 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. Control Plan Evaluation (1) The State Authority will conduct annual evaluations of the VCP. At a minimum the Authority will consider: (a) The annual number of vibriosis cases associated with the State's growing waters and the amount of shellstock sold to determine risk per servings for each temperature period. (b) Environmental changes which could affect total *Vibrio* levels in shellfish pre- and post-harvest. (c) Industry compliance with existing controls. (d) The Authority's enforcement of industries' implementation of the controls. (2) For the purposes of determining Authority compliance with VCP requirement, the FDA will conduct an annual RARM evaluation of the Authority to determine the following: (a) Authority compliance with *Vibio* Risk Evaluation as required in Chapter II. @.06 A. (b) For States requiring the development of VCPs, compliance with Control Plan requirements of Chapter II. @.06 E. (1). The evaluation should determine:

	(i) Appropriate identification of triggers to determine when control measures are needed. (ii) Appropriate implementation of one (1) or more of the control measures required in Chapter II. @.06 B. (1) (b).
12. Public Health Significance	Note that this proposal is being submitted to start the discussion. Due to increases in vibriosis cases and the use of CIDT, which does not align with current Vibrio management strategies, a total vibrio program is being proposed. In recent years, the total number of vibriosis cases continues to increase. According to the CDC BEAM Dashboard, culture confirmed vibrio cases increased from 1,284 (648 foodborne) in 2022 to 1,449 (736 foodborne) in 2024, the most recent year for which data are available. During these year, Vibrio parahaemolyticus and V. vulnificus cases (606 combined in 2022 and 682 combined in 2024) do not account for this increase alone. While not all vibriosis-causing species are reported through the BEAM dashboard, the other species reposnsible for foodborne infections, V. cholerae and V. fluvialis, also increased from 246 combined in 2022 to 300 in 2024, with 63-77% of cases reporting seafood consumption. In addition, the use of CIDT continues to increase. 1,276 CIDT vibrio cases were reported in 2022, with 2,231 reported cases in 2024. When looking only a foodborne associated CIDT cases, there were 1,175 in 2022 and 2,110 in 2024. CIDTs can detect multiple species of vibrio, there is an increasing use of CIDT, and species other than V. parahaemolyticus and V. vulnificus are increasingly identified as causes of vibriosis. Taken together, this indicated the need to update the strategy for evaluating and managing the public health risk associated with vibrios.
13. Cost Information	Unknown.
14. Changes Needed to Guidance (if proposed change is adopted)	TBD