Proposal for Task Force Consideration at the ISSC 2015 Biennial Meeting	☐ Growing Area ☒ Harvesting/Handling/Distribution ☐ Administrative

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Proposal Subject	*Vibrio parahaemolyticus(V.p.)* Control Plan Risk Per Serving
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter II. Risk Assessment and Risk Management
Text of Proposal/ Requested Action	@.06 *Vibrio parahaemolyticus* Control Plan A. Risk Evaluation. Every State from which oysters are harvested shall conduct a *Vibrio parahaemolyticus* risk evaluation annually. The evaluation shall consider each of the following factors, including seasonal variations in the factors, in determining whether the risk of *Vibrio parahaemolyticus* infection from the consumption of oysters harvested from an area (hydrological, geographical, or growing) is reasonably likely to occur: (For the purposes of this section, "reasonably likely to occur" shall mean that the risk constitutes an annual occurrence) (1) The number of *Vibrio parahaemolyticus* cases epidemiologically linked to the consumption of oysters commercially harvested from the State; and (2) Levels of total and tdh+ *Vibrio parahaemolyticus* in the area, to the extent that such data exists; and (3) The water temperatures in the area; and (4) The air temperatures in the area; and (5) Salinity in the area; and (6) Harvesting techniques in the area; and (7) The quantity of harvest from the area and its uses i.e. shucking, half-shell, PHP. B. Control Plan (1) If a State's *Vibrio parahaemolyticus* risk evaluation determines that the risk of *Vibrio parahaemolyticus* illness from the consumption of oysters harvested from a growing area is reasonably likely to occur, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan; or (2) If a State has a shellfish growing area in which harvesting occurs at a time when average monthly daytime water temperatures exceed those listed below, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan. The average water temperatures representative of harvesting conditions (for a period not to exceed thirty (30) days) that prompt the need for a Control Plan are: (a) Waters bordering the Pacific Ocean: 60°F. (b) Waters bordering the Gulf of Mexico and Atlantic Ocean (NJ and south): 81°F. (c) However, development of a Plan is not necessary if the State conducts a risk evaluation, as described in Section A. that determines that it is not reasonably likely that *Vibrio parahaemolyticus* illness will occur from the consumption of oysters harvested from those areas.

(i) In conducting the evaluation, the State shall evaluate the factors listed in Section A. for the area during periods when the temperatures exceed those listed in this section;

(ii) In concluding that the risk is not reasonably likely to occur, the State shall consider how the factors listed in Section A. differ in the area being assessed from other areas in the state and adjoining states that have been the source of shellfish that have been epidemiologically linked to cases of *Vibrio parahaemolyticus* illness; or

(3) If a State has a shellfish growing area that was the source of oysters that were epidemiologically linked to an outbreak of *Vibrio parahaemolyticus* within the prior five (5) years, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan for the area.

(4) For States required to implement *Vibrio parahaemolyticus* Control Plans, the Plan shall include the administrative procedures and resources necessary to accomplish the following:

(a) Establish one or more triggers for when control measures are needed. These triggers shall be the temperatures in Section B. (2) where they apply, or other triggers as determined by the risk evaluation.

(b) Implement one or more control measures to reduce the risk of *Vibrio parahaemolyticus* illness at times when it is reasonably likely to occur. The control measures may include: (i) Post-harvest processing using a process that has been validated to achieve a two (2) log reduction in the levels of total *Vibrio parahaemolyticus* for Gulf and Atlantic Coast oysters and a three (3) log reduction for the Pacific Coast oysters;

(i) Closing the area to oyster harvest;

(ii) Restricting oyster harvest to product that is labeled for shucking by a certified dealer, or other means to allow the hazard to be addressed by further processing;

(iii) 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;

(iv) Limiting time from harvest to refrigeration such that the levels of total *Vibrio parahaemolyticus* after the completion of initial cooling to 60°F (internal temperature of the oysters) do not exceed the average levels from the harvest water at time of harvest by more than 0.75 logarithms, based on sampling or modeling, as approved by the Authority;

(v) Other control measures that based on appropriate scientific studies are designed to ensure that the risk of *V.p.* illness is no longer reasonably likely to occur, as approved by the Authority.

(c) Require the original dealer to cool oysters to an internal temperature of 50°F (10°C) or below within ten (10) hours or less as determined by the Authority after placement into refrigeration during periods when the risk of *Vibrio parahaemolyticus* illness is reasonably likely to occur. The dealer's HACCP Plan shall include controls necessary to ensure, document and verify that the internal temperature of oysters has reached 50°F (10°C) or below within ten (10) hours or less as determined by the Authority of being placed into refrigeration. Oysters without proper HACCP records demonstrating compliance with this cooling requirement shall be

	diverted to PHP or labeled *"for shucking only"*, or other means to allow the hazard to be addressed by further processing. (d) Evaluate the effectiveness of the Plan. (e) Modify the Control Plan when the evaluation shows the Plan is ineffective, or when new information is available or new technology makes this prudent as determined by the Authority. (f) Optional cost benefit analysis of the *Vibrio parahaemolyticus* Control Plan. C. The Time When Harvest Begins For the purpose of time to temperature control, time begins once the first shellstock harvested is no longer submerged. States implementing a *Vibrio parahaemolyticus* Control Plan shall determine the level of protection afforded by calculating the observed risk per serving based on the number of annual illnesses attributed to shellfish harvested from the state and the state's annual oyster and/or hard clam production. Modify the Control Plan when the observed risk per serving is greater than 1 illness per 100,000 servings.
Public Health Significance	In the absence of a requirement for states to determine the observed risk per serving, it is not possible to verify that the level of protection offered by state Control Plans is consistent with the level of protection (≤1 illness per 100,000 servings) intended by time and temperature controls as defined by the *Vibrio parahaemolyticus* risk calculator. Requiring states to determine the observed risk per serving using annual illness data and annual production data will allow the ISSC to gauge the success of state control plans and engage states in developing additional controls where necessary. During periods of unacceptable risk, further restrictions on time and temperature controls, or other equivalent measures, should be considered to reduce risk to an acceptable level.
Cost Information	
Action by 2013 Task Force II	Recommended referral of Proposal 13-223 to an appropriate committee as determined by the Conference Chairman.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force II on Proposal 13-223.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-223.