Proposal for Task Force Consideration at the Interstate Shellfish Sanitation Conference 2013 Biennial Meeting	☐ **Growing Area** ☒ **Harvesting/Handling/Distribution** ☐ **Administrative**
Submitter:	US Food and Drug Administration
Affiliation:	US Food and Drug Administration
Address	Center for Food Safety and Applied Nutrition 5100 Paint Branch Parkway College Park, Maryland 20740
Phone: **Fax:** **Email:**	240 402-2300 301 436-2601 paul.distefano@fda.hhs.gov
Proposal Subject:	*Vibrio parahaemolyticus* Control Plan Water Temperatures
Specific NSSP Guide Reference:	NSSP Guide Section II Chapter II Risk Assessment and Risk Management Section @.06 *Vibrio parahaemolyticus* Control Plan B. Control Plan (2)
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) Waters bordering the Atlantic Ocean (NY and north): 60°F.

(~~c~~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 *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)

(ii) Closing the area to oyster harvest;

(iii) 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;

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

(vi) Other control measures that based on appropriate scientific studies are designed to ensure that the risk of *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.
Public Health Significance:	Presently Chapter II. Section @.06 B. (2) does not include a water temperature for New York and north.
Cost Information (if available):	