

Proposal Subject: Annual Assessment of Shellfish Production and Utilization

Specific NSSP Guide Reference: NSSP Section II Model Ordinance Chapter II Risk Assessment and Risk Management

Text of Proposal/ Requested Action @ .02 Annual Assessment of *Vibrio vulnificus* and *Vibrio parahaemolyticus* Illnesses and Shellfish Production

- A. The Authority shall assess annually *Vibrio vulnificus* and *Vibrio parahaemolyticus* illnesses associated with the consumption of molluscan shellfish. The assessment will include a record of all *Vibrio vulnificus* and *Vibrio parahaemolyticus* 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 determine annually, and report to the ISSC, the volume of shellfish harvested in the State. The report shall include the volume of shellfish harvested for each species associated with *Vibrio* illnesses, including a volume breakdown by utilization type (raw, shucked, PHP, etc.).

Public Health Significance: *Vibrio parahaemolyticus* and *V. vulnificus* control plans are based on risk per serving as determined by risk calculators developed by FDA. The predicted risk is applicable to consumption of raw oysters as this product use is assumed to present the greatest risk and is associated with the majority of seafood related illnesses. However predicted risk per serving levels in raw or half-shell oysters cannot currently be validated using observed data because only total landings are reported. The risk assessments assume that 50% of oysters are consumed raw but this can vary greatly from state to state and seasonally. A breakdown of total landings by product utilization would allow more accurate assessment of the associated risk of the various product categories.

Cost Information (if available):

Action by 2013 Task Force II Recommended adoption of Proposal 13-203 as amended.

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Action by 2013 General Assembly Adopted recommendation of 2013 Task Force II on Proposal 13-203.

**Action by FDA
May 5, 2014**

FDA concurred with Conference action on Proposal 13-203 with the following comments and recommendations.

FDA concurs with adoption of Proposal 13-203 to make annual reporting of harvest volume by species a requirement of each shellfish producing state. Having these numbers will assist the ISSC in better defining the risk per serving associated with individual shellfish species for *V. vulnificus* (*Vv*) and *Vp*. Although not required by Proposal 13-203 as adopted, reporting landings by product category (half shell, post-harvest processing, shucked, etc.) would enable greater refinement to risk per serving calculations associated with shellfish intended for the half shell market. While Proposal 13-203 as submitted was intended to require reporting by product category, FDA recognizes the additional burden that detail of reporting places on States already facing limited resources. For States that do not have landings data by product category, the 50% raw consumption value used in the *Vp* and *Vv* risk assessments will continue to be used as the default for calculating risk per serving.