Proposal Subject: Analytical Capability and Capacity for Vibrio Testing

Specific NSSP Guide Reference: Model Ordinance Chapter II Section @.05 and Section @.06

Text of Proposal/ Requested Action

Chapter II Section @.05 add new G.

F. Contingency Plan

(1) The Contingency Plan shall include a detailed plan outlining the regulatory steps that will be implemented should the number of illnesses reach the threshold established for development and implementation of a *V.v.* Control Plan.

(2) Contingency Plan Evaluation

In consultation with FDA the Authority will evaluate the adequacy of their Contingency Plan.

G. States required to implement a *Vibrio vulnificus* Control Plan shall develop analytical capability and capacity to monitor *V.v.* levels with corresponding environmental data (water temperature and salinity) to determine and establish baseline data.

Chapter II Section @.06 add new D.

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.

D. States required to implement a *Vibrio parahaemolyticus* Control Plan shall develop analytical capability and capacity to monitor total and pathogenic *V.p.* levels with corresponding environmental data (water temperature and salinity) to determine and establish baseline data.

Public Health Significance: Most shellfish producing states have environmental conditions in their growing areas at certain times that present a vibrio risk. Development of the analytical capability and capacity within each state will greatly facilitate the characterization and control of this risk with regard to season, location, conditions and practices.

Cost Information (if available): Depending on the analytical method of choice, cost per sample for one organism (either *V.v.* or *V. p.*) is ~$10-75.

Action by 2013 Task Force II Recommended no action on Proposal 13-206.

Rationale: The cost of implementation is too expensive.

Action by 2013 General Assembly Adopted recommendation of 2013 Task Force II on Proposal 13-206.

Action by FDA May 5, 2014 FDA concurred with Conference action on Proposal 13-206 with the following comments and recommendations.

Most shellfish producing States experience environmental conditions within their shellfish growing areas at certain times that present a greater Vibrio risk. Development of the analytical capability and capacity to test for Vibrio within each state will greatly facilitate the characterization and control of this risk with regard to season, location, environmental conditions and industry practices. While Proposal 13-206 was not

adopted by the Conference, FDA continues to encourage States required to implement a Vp or Vv Control Plan to develop analytical capability and capacity to monitor total and pathogenic Vibrio levels. States are further encouraged to link Vibrio levels to corresponding environmental data, including air temperature, water temperature and salinity. This will help establish baseline data that can be used to assess the effectiveness of Vibrio Control Plans and to make Vibrio management and control decisions. FDA has assisted a number of States with enhancing their Vibrio analytical capability and capacity by providing guidance, training and performance assessment. It is the intent of the Agency to continue to make this assistance available to ISSC stakeholders.