Proposal Subject: Validation and Verification for Process Studies for Time and Temperature Requirements Related to *Vibrio* Management Plan Controls

Specific NSSP Guide Reference: NSSP Guide Section IV. Guidance Documents
Chapter IV. Naturally Occurring Pathogens
.04 Post Harvest Processing (PHP) Validation/Verification Guidance for *Vibrio vulnificus* and *Vibrio parahaemolyticus*

Text of Proposal/ Requested Action

A. Process Validation

B. Equipment Validation

C. Initial Load Testing

D. Verification

9. Time to temperature controls shall be evaluated using standard protocols for measuring temperatures in shellfish. A protocol shall include the number of samples, when and where samples will be collected and temperatures measured. The protocols will include procedures that can be included in harvester and dealer record keeping to document compliance with time to temperature requirements.

Public Health Significance: Implementation of the *Vibrio vulnificus* Management Plans will require establishing times to refrigeration and times to cool down to 55 degrees. It is important that standardized measuring methods be agreed upon in order to be sure that time to temperature requirements are being accomplished by harvesters and dealers. Additionally, agreed upon validation and verification activities will lead to greater uniformity in implementing *Vibrio* controls.

Cost Information (if available): None available

Action by 2009 Task Force II: Recommended approval of substituted language for Proposal 09-233.

.05 Guidance for Demonstrating the Effectiveness of Time to Temperature Reduction Criteria for *Vibrio vulnificus* and *Vibrio parahaemolyticus*

Time-to-Temperature Protocol

~~(3)~~(1) Identify the target time/temperature requirements for the specific cooling system/unit.

(2) Demonstrate that each cooling method and unit is capable of meeting the target time/temperature by conducting a process study under worst case conditions for that unit. The following parameters should be considered and utilized in conducting the process study:

a. maximum load for the cooling unit

b. initial product temperature (studies have demonstrated that measurement of the external temperature and the internal meat temperatures are comparable and either can be used)

c. location of hot spot(s)

d. thermostat setting(s)

e. cooling method(s) used
f. method of loading the cooling unit
(3) Include a description of the process; a record of the process study conducted; and monitoring records in a HACCP Plan.
(4) The protocol should be applied at the first point of refrigeration

Action by 2009 General Assembly Adopted recommendation of 2009 Task Force II on Proposal 09-233.

Action by USFDA 02/16/2010 Concurred with Conference action on Proposal 09-233.