Proposal Subject: Post Harvest Process Validation

Specific NSSP Guide Reference: NSSP Guide Section II. Model Ordinance
Chapter XVI. Post Harvest Processing A. (1) (d)

Text of Proposal/ Requested Action

A. If a dealer elects to use a process to reduce the level(s) of one target pathogen or some target pathogens, or all pathogens of public health concern in shellfish, the dealer shall:

(1) Have a HACCP plan approved by the Authority for the process that ensures that the target pathogen(s) are at safe levels for the at risk population in product that has been subjected to the process.

(a) The dealer must demonstrate that the process reduces the level of *Vibrio vulnificus* in the processed product to non-detectable (<30 MPN/gram) and the process achieves a minimum 3.52 log reduction, to be determined by use of the *Vibrio vulnificus* FDA approved EIA procedure of Tamplin, et al, as described in Chapter 9 of the FDA *Bacteriological Analytical Manual*, 7th Edition, 1992, or other method approved for NSSP use.

(b) The dealer must demonstrate that the process reduces the level of *Vibrio parahaemolyticus* in the processed product to non-detectable (<30 MPN/gram) and the process achieves a minimum 3.52 log reduction.

(c) For processes that target other pathogens the dealer must demonstrate that the level of those pathogens in processed product has been reduced to levels below the appropriate FDA action level, or, in the absence of such a level, below the appropriate level as determined by the ISSC.

(d) The ability of the process to reliably achieve the appropriate reduction in the target pathogen(s) shall be validated by a study as outlined in Guidance Documents Chapter IV. Naturally Occurring Pathogens, Section .04 approved by the Authority, with the concurrence of FDA. **Analytical results used for validation and verification of a PHP shall come from an analytical laboratory that is evaluated by the State and/or FDA and found to be in compliance with applicable NSSP laboratory requirements.**

(e) The HACCP plan shall include:
(i) Process controls to ensure that the end point criteria are met for every lot; and,
(ii) A sampling program to periodically verify that the end point criteria are met.

Public Health Significance: Laboratory results used in the NSSP should come from laboratories that have been evaluated and found to comply with NSSP laboratory requirements. Existing laboratory requirements and checklists do not include *Vibrio* analyses and may need to be revised to include evaluation criteria for laboratories conducting *Vibrio* analyses.

Cost Information (if available):

Action by 2009 Task Force III: Recommended adoption of Proposal 09-230 as submitted and further requests the Executive Board to work with states and the FDA to development requirements and a timetable for all laboratories providing data for NSSP requirements to become compliant with the laboratory requirements of the Model Ordinance.

Action by 2009 General Assembly Adopted recommendation of 2209 Task Force III on Proposal 09-230.

Action by USFDA 02/16/2010 Concurred with Conference action on Proposal 09-230.