Proposal Subject: Post Harvest Processing

Specific NSSP Guide Reference: NSSP Guide Section II Model Ordinance
Chapter XVI. Post Harvest Processing

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, **and wishes to make labeling claims regarding the reduction of pathogens,** 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. **The HACCP Plan shall include:**

(a) **Process controls to ensure that the end point criteria are met for every lot; and** ~~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) **A sampling program to periodically verify that the end point criteria are met.** ~~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~~

(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.~~

~~(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.~~

~~(2) Package and label all shellfish in accordance with all requirements of this Ordinance. This includes labeling all shellfish which have been subjected to the process but which are not frozen in accordance with applicable~~

~~shellfish tagging and labeling requirements in Chapter X.05 and X.06.~~

~~(3) Keep records in accordance with Chapter X.07.~~

(2) Validate the Process by demonstrating that the process will reliably achieve the appropriate reduction in the target pathogen(s). The process shall be validated by a study as outlined in Guidance Documents Chapter IV, Naturally Occurring Pathogens, Section .04 and be approved by the Authority, with concurrence of FDA.

(a) The dealer must demonstrate that the process reduces the level of *Vibrio vulnificus* and/or *Vibrio parahaemolyticus* in the processed product to non-detectable (<30MPN/gram) and the process achieves a minimum 3.52 log reduction. Determination of *V. vulnificus* and/or *V. parahaemolyticus* levels must be done using the MPN protocols described in Guidance Documents, Chapter IV, Naturally Occurring Pathogens, Section .04 followed by confirmation using methods approved for use in the NSSP.

(b) 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.

(3) Conduct verification sampling to verify that the validated process is working properly. Verification sampling shall be at least equivalent to the verification protocol found in Guidance Documents, Chapter IV, Naturally Occurring Pathogens, Section .04 as determined by the Authority and shall be reviewed annually by the Authority.

(4) Package and label all shellfish in accordance with all requirements of this Ordinance. This includes labeling all shellfish which have been subjected to the process but which are not frozen in accordance with applicable shellfish tagging and labeling requirements in Chapter X.05 and X.06.

(5) Keep records in accordance with Chapter X.07.

Public Health Significance: Requirements for Post Harvest Processes to reduce the levels of pathogen(s) were re-organized for better flow.

Guidance for validation and verification of a process used to reduce levels of pathogen(s) has been developed and appear in the Guidance Documents, Chapter IV. This proposal provides specific requirements of the dealer and SSCA to ensure that companies wishing to use labeling claims concerning the reduction of pathogen(s) validate and verify the process using a protocol that is at least equivalent in public health protection as that listed in the Guidance Document.

Cost Information (if available):

Action by 2009 Task Force II

Recommended adoption of Proposal 09-229 as submitted with the following additional recommendations.

Recommended adoption of recommendation to verify references for NSSP Guide Section II Model Ordinance Chapter X. @.05 Post Harvest Processing A. Sections 4. and 5. (Editorial – does not require Conference action.)

Recommended adoption of recommendation to have Executive Board verify the exclusion of frozen shellfish in the labeling requirements in NSSP Guide Section II Model Ordinance Chapter X. Post Harvest Processing Section A. Section 4. (Editorial – does not require Conference action.)

Recommended adoption of recommendation that an "Additional Guidance Box" be added at (2) (a) to include a reference to the methods that have been approved by the Conference for use in the NSSP. The specific Guide reference to be included in the box is Section IV. Guidance Documents, Chapter II. Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests: Microbiological and Biotoxin Analytical Methods. (Editorial – does not require Conference action.)

Recommended adoption of recommendation that approved changes as a result of Proposal 09-229 will be reflected in the update for the 2009 NSSP Guide for the Control of Molluscan Shellfish Section III. Public Health Reasons and Explanations. (Editorial – does not require Conference action.)

Action by 2009 General Assembly

Adopted recommendation of Task Force II on Proposal 09-229.

Action by USFDA 02/16/2010

Concurred with Conference action on Proposal 09-229.