Proposal Subject: Post-Harvest Handling

Specific NSSP Guide Reference: NSSP Guide Section II Model Ordinance Definitions and New Chapter XVII.

Text of Proposal/ Requested Action

Action #1

Add a new definition to B. Definition of Terms for Post-Harvest Handling and renumber Definitions Section accordingly.

Post-Harvest Handling means a control(s) employed by a dealer to further reduce, beyond controls currently in place under the NSSP, the post-harvest growth of naturally occurring pathogens for the purposes of handling product outside of as an alternative to the Authority's existing NSSP management plans.

Action #2:

Add a new chapter to the NSSP Guide Section II. Model Ordinance as follows:

Chapter XVII. Post-Harvest Handling

A. If a dealer elects to use a post-harvest handling control(s) to reduce the levels of post-harvest growth of a naturally occurring pathogen(s) of public health concern in shellfish, the dealer shall:

(1) Have a HACCP plan (approved by the Authority) for the control(s) that reduces post-harvest growth of the target pathogen(s).

(a) The dealer must validate that the post-harvest handling control(s) reduces the post-harvest growth of naturally occurring pathogen(s). The validation study must be approved by the State Shellfish Control Authority with FDA concurrence.

(b) The ability of the post-harvest handling control(s) to reliably achieve the appropriate reduction in post-harvest growth of the target pathogen(s) shall be routinely verified at a frequency determined by the State Shellfish Control Authority.

(2) Package and label all shellfish in accordance with the requirements of this Ordinance.

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

Public Health Significance: The changes recommended by this proposal provide added opportunities for shellfish dealers to meet the required State Control Plans for naturally occurring pathogens.

Cost Information (if available):

Action by 2009 Task Force II: Recommended referral of Proposal 09-231 to an appropriate committee as determined by the Conference Chairman.

Action by 2009 General Assembly Adopted recommendation of 2009 Task Force II on Proposal 09-231.

Action by USFDA 02/16/2010 Concurred with Conference action on Proposal 09-231.

Action by 2011 Post Harvest Processing Committee

Recommended no action on Proposal 09-231.

Rationale: The proposed new definition and new chapter are not necessary because the State *Vibrio* Management Plans already allow handling practices to reduce levels of naturally occurring pathogens. The recommended changes are adequately addressed in the Model Ordinance.

Action by 2011 Task Force II

Recommended referral of Proposal 09-231 to an appropriate Committee as determined by the Conference Chairman with instructions that the Committee establish validation protocols for activities that reduce levels of naturally occurring pathogens so that a dealer can work outside the Authority's *Vibrio* Management Plan. Additionally, the Committee is charged with ensuring the Post-Harvest Handling (PHH) definition and section in Chapter XVII is consistent so that they are directing a process that reduces levels not just growth.

The intent of Task Force II is that Post Harvest Handling activities are not intended to be used to support labeling claims.

Action by 2011 General Assembly

Adopted recommendation of 2011 Task Force II on Proposal 09-231.

Action by FDA February 26, 2012

Concurred with Conference action on Proposal 09-231.

Action by 2013 Post Harvest Processing Committee

The Post-Harvest Processing Committee recommended:

1. No action on proposal 09-231 as written.
2. Change the title of Model Ordinance Chapter XVI, Post-Harvest Processing to "Processes and Procedures for Pathogen Reduction" in order to include pathogen reduction processes that are not associated with labeling claims, which was the intent of Proposal 09-231.
3. Add a new section to the newly titled Chapter XVI (Recommendation 2) to be titled "Pathogen Reduction Processes that are not associated with Labeling Claims."
4. The committee recommended that a work group be established to develop language for the new section of Chapter XVI and report the findings to the appropriate committee as determined by the Conference Chairman. It is further recommended that the work group meet quarterly until the new section is complete so that it can be submitted as a proposal at the next ISSC meeting.
5. Requested the Conference Chairman to appoint an appropriate work group or committee to work with FDA to establish target levels for pathogen reduction processes that do not require labeling that will achieve the required risk reduction goals. (The intent of the committee is to use the information developed by this workgroup to determine if additional validation protocols are needed.)

Recommendation 5 should be done as soon as possible to allow validation protocols to be developed as necessary

Action by 2013 Task Force II

Recommended referral of Proposal 09-231 back to Committee with instructions to continue the work on the proposal which includes recommendations 2. – 5. as a charge to the Committee; with further instructions that recommendation 5. should be completed as soon as possible to allow validation protocols to be developed as necessary.

Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force II on Proposal 09-231.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 09-231.