Proposal Subject Post Harvest Processing

Specific NSSP Model Ordinance Chapter I. Definitions **Guide Reference:** Model Ordinance Chapter IX. Transportation

Model Ordinance Chapter X. General Requirements for Dealers

Model Ordinance Chapter XVI. Post Harvest Treatment

Text of Proposal/ Requested Action

During its March 2004 meeting the ISSC Executive Board was made aware that changes were needed to address confusion associated with the handling and labeling of post harvest processed shellfish. A committee was appointed and recommendations developed for Board consideration at the August 2004 Executive Board meeting. The Board approved the following interim changes to the NSSP Model Ordinance. Included in the Model Ordinance changes adopted by the Executive Board is language in *Chapter X. General Requirements for Dealers .05 Shellstock Identification B. Tags*, which allows for inclusion of language, associated with USDA requirements for Country of Origin Labeling (COOL). The new Model Ordinance language does not require Country of Origin labeling but does allow dealers to include this information on tags and labels.

CHAPTER I. DEFINITIONS

Post Harvest Processing means processing of shellfish for the purpose of added safety or quality that involve hazards not addressed by controls in NSSP Model Ordinance Chapters XI. through XIV.

Raw means shellfish that have not been thermally processed:

- (a) to an internal temperature of 145°F or greater for 15 seconds (or equivalent); or
- (b) altering the organoleptic characteristics.

Shellfish means all species of:

- (a) Oysters, clams or mussels, whether:
 - (i) Shucked or in the shell;
 - (ii) Raw, including post harvest processed;
 - (ii)(iii) Frozen or unfrozen;
 - (iii)(iv) Whole or in part; and
- (b) Scallops in any form, except when the final product form is the adductor muscle only.

CHAPTER IX. TRANSPORTATION

Requirements for the Authority

- @ .02 Shipment Acceptability
 - A. Shipments are properly identified with tags <u>and/or labels</u> and shipping documents;
 - B. Shellstock is alive...
 - C. Shucked <u>or post harvest processed</u> shellfish <u>are</u> is cooled to a temperature of 45° Fahrenheit (7.2° Centigrade) or less; and
 - D. The time-temperature...
 - E. All other conditions...

CHAPTER X. GENERAL REQUIREMENTS FOR DEALERS

- .05 Shellstock Identification
 - B. Tags
 - (5) <u>The statement "Keep Refrigerated" or an equivalent statement must be included on the tag.</u>
 - (6) Country of origin information (USDA 2004) may be included on the dealer tag.
- .06 Shucked Shellfish Labeling
 - A. Shellfish Labeling
 - (5) The dealer shall assure that:
 - (a) The shucker-packer's or repacker's certification number is on the label of each package of fresh or frozen shellfish;
 - (b) The statement "Keep Refrigerated" or an equivalent statement appears on the label;
 - (c) Packages containing less than 64 fluid ounces have:
 - (i) A "SELL BY DATE" which is a reasonable subsequent shelf-life or the words "BEST IF USED BY" followed by a date when the product would be expected to reach the end of its shelf-life; and
 - (ii) The date as a month and day of the month.
 - (d) Packages containing 64 fluid ounces or more have on the lid and sidewall or bottom the "DATE SHUCKED" indicated as the number of the day of the year or the month and day of the month.

.07 Post Harvest Process Labeling

- A. If a dealer elects to post harvest process shellfish and the final product form is live, the dealer shall label in accordance with Chapter X. . 05.
- B. If a dealer elects to post harvest process shellfish and the final product form is not live, the dealer shall label in accordance with Chapter X. .06 and include the following, or equivalent statement: These shellfish have been post harvest processed.

NOTE: The Consumer Advisory shall be required for both A and B.

.08 Shipping Documents and Records.

.09 Wet Storage in Artificial Bodies of Water.

CHAPTER XVI. POST HARVEST **PROCESSING** TREATMENT

All References in Chapter XVI. to post harvest treatment will be changed to post harvest processing.

Public Health Significance:

None submitted

Cost Information (if available):

Although these changes have immediate effective dates, the Executive Board recognizes the financial impact associated with tagging and labeling changes. The

Executive Board requests states to establish reasonable implementation schedules to allow the shellfish industry to incorporate these changes into their tagging and labeling programs.

Action by 2005 PHP Committee

The PHP Committee reviewed Proposal 05-200 and acknowledged implementation concerns associated with Chapter X. .07 and directed a workgroup to propose language to address the concerns to Task Force II.

Action by 2005 Task Force II

Amended Proposal 05-200 by substituting the following language submitted by the PHP Workgroup to replace Chapter X. .07.

Chapter X. .07 Processed Shellstock Labeling

- A. The dealer shall label all processed shellstock with tags meeting the requirements of § .05 B. (1).
- **B.** Processed Shellstock Tags
- (1) The dealer tag on processed shellstock shall contain the following indelible, legible information in the order specified below:
- (a) The dealer's name and address;
- (b) The dealer's certification number as assigned by the Authority;
- (c) The original shellstock shipper's certification number. If depurated the original shellstock shipper's certification number is not required;
- (d) A "SELL BY DATE" which is a reasonable subsequent shelf-life or the
 words "BEST IF USED BY" followed by a date when the product would be
 expected to reach the end of its shelf-life. The date shall include, month,
 day and year;
- (e) If depurated, the depuration cycle number or lot number;
- (f) The most precise identification of the harvest location as is practicable including the initials of the state of harvest, and the Authority's designation of the growing area by indexing, administrative or geographic designation.

 If the Authority has not indexed growing areas, then an appropriate geographical or administrative designation must be used (e.g. Long Bay, Decadent County, lease number, bed, or lot number).
- (g) When the shellstock has been transported across state lines and placed in wet storage in a dealer's operation, the statement: "THIS PRODUCT IS A PRODUCT OF (NAME AND STATE) AND WAS WET STORED AT (FACILITY CERTIFICATION NUMBER) FROM (DATE) TO (DATE)";
- (h) The type and quantity of processed shellstock; and
- (i) The following statement in bold capitalized type on each tag: "THIS TAG

 IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY

 OR IS RETAGGED AND THEREAFTER KEPT ON FILE FOR 90

 DAYS."
- (j) All processed shellstock intended for raw consumption shall include a consumer advisory. The following statement, from Section 3-602.11 of the 1999 Food Code, or an equivalent statement, shall be included on all shellstock: "RETAILERS, INFORM YOUR CUSTOMERS"

 "Consuming raw or undercooked meats, poultry, seafood, shellfish or eggs may increase your risk of foodborne illness, especially if you have certain medical conditions."

- (k) The statement "Keep Refrigerated" or an equivalent statement must be included on the tag.
- (2) If the processed shellstock is removed from the original container, the tag on the new container shall meet the requirements in §.07B.
- (3) <u>Country of origin information (USDA 2004) may be included on the shucker-packer or reshipper tag.</u>

Additionally, the Task Force added the following definition to Proposal 05-200:

Chapter I - Definitions

(80) Processed shellstock means shellstock that has been Post Harvest

Processed with a validated or non-validated process which results in a
frozen or unfrozen end product which is no longer alive, and that is sold
in the whole or half shell.

Task Force II recommended that Proposal 05-200, as amended by the PHP Workgroup, be referred to the appropriate committee as determined by the Conference Chairman for further deliberation and Proposal 05-200 as amended remain interim pending further Conference action.

Action by 2005 General Assembly

Adopted recommendation of 2005 Task Force II.

Action by 2005 USFDA

FDA concurs with action by the Conference to refer Proposal 05-200 to an appropriate committee for further deliberation. However, FDA does not concur with interim adoption of Proposal 05-200 language, as amended by Task Force II, pending further Conference action. FDA finds that the interim language needs clarification prior to inclusion in the NSSP Model Ordinance. Task Force II, in its decision to refer this Proposal back to committee, recognized the need for clarification relative to the "post harvest processing" and "processed shellstock" definitions and the potential confusion associated with labeling of such products. The concept of PHP has been expanded from its original intent, which focused on processing to reduce Vibrio levels to non-detect, to include other processes that do not necessarily achieve pathogen reduction of public health significance. As a result the ISSC is continuing to examine how the Model Ordinance can best address this broader approach to PHP and its associated labeling requirements. Until the ISSC has completed its deliberations on Proposal 05-200 it is in the best interest of industry and regulatory authorities not to include Proposal 05-200 interim language in the NSSP Model Ordinance at this time.

Action by 2007 Post Harvest Processing Committee

Recommended adoption of Proposal 05-200 as amended

- 1. Change the title of Chapter X. 07 from Processed Shellstock Labeling to In-shell Product or Post Harvest Processed In-Shell Product labeling. Replace all references to processed shellstock in the language adopted by the Conference in 2005 with "in-shell product".
- Add a definition for "in shell product" to Chapter I (Definitions):
 "In Shell Product means non-living, processed shellfish with one or both shells present."

- 3. The Conference should appoint a work group to review Chapters VII. (Wet Storage in Approved and Conditionally Approved Growing Areas), XV. (Depuration), and XVI. (Post Harvest Processing) to determine if requirements are consistent for the risks involved with each process.
- 4. A transition period of up to 12 months should be allowed to allow dealers to utilize their current inventory of shellfish and supplies before the new labeling requirements must be met.

Action by 2007 Task Force II

Recommended adoption of the Post Harvest Processing Committee recommendation on Proposal 05-200.

Action by 2007 General Assembly

Adopted recommendation of 2007 Task Force II.

Action by USFDA

December 20, 2007

Concurred with Conference action.

2009 Action

No activity

Action by 2011 Post Harvest Processing Committee Recommended no action on Proposal 05-200.

Rationale: After reviewing the current NSSP controls and monitoring requirements for the processes listed above, the Committee determined that the controls and monitoring requirements for each process are not equivalent, but that public health risks are adequately addressed by NSSP controls. Therefore, no changes to the controls and monitoring in the Model Ordinance are warranted at this time.

Action by 2011 Task Force II

Recommended adoption of Post Harvest Processing Committee recommendation of no action on Proposal 05-200.

Rationale: No changes to the controls and monitoring in the Model Ordinance are warranted at this time

Action by 2011 General Assembly

Adopted recommendation of 2011 Task Force II on Proposal 05-200.

Action by FDA February 26, 2012

Concurred with Conference action on Proposal 05-200.