

<b>Proposal Subject</b>	Post Harvest Processing
<b>Specific NSSP Guide Reference</b>	NSSP Guide Model Ordinance Chapter X. Section .09
<b>Text of Proposal/ Requested Action</b>	<p>Move the contents of existing Chapter X, section .09 to a new Chapter XVI and rewrite as follows:</p> <p>CHAPTER XVI</p> <p>POST HARVEST PROCESSING</p> <p>.01 Post-Harvest Processing.</p> <p>(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:</p> <ol style="list-style-type: none"> <li>(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. <ol style="list-style-type: none"> <li>(a) For processes that target <i>Vibrio vulnificus</i>, the level of <i>Vibrio vulnificus</i> in product that has been subjected to the process shall be non-detectable (&lt;3 MPN/gram), to be determined by use of the <i>Vibrio vulnificus</i> FDA approved EIA procedure of Tamplin, et al, as described in Chapter 9 of the FDA <i>Bacteriological Analytical Manual</i>, 7th Edition, 1992.</li> <li>(b) For processes that target <i>Vibrio parahaemolyticus</i>, the level of <i>Vibrio parahaemolyticus</i> in product that has been subjected to the process shall be non-detectable (&lt;1 CFU/0.1 gram).</li> <li>(c) For processes that target other pathogens, the level of those pathogens in product that has been subjected to the process shall be below the appropriate FDA action level, or, in the absence of such a level, below the appropriate level as determined by the ISSC.</li> <li>(d) The ability of the process to reliably achieve the appropriate reduction in the target pathogen(s) shall be validated by a study approved by the Authority, with the concurrence of FDA.</li> <li>(e) The HACCP plan shall include: <ol style="list-style-type: none"> <li>(i) Process controls to ensure that the end point criteria are met for every lot; and,</li> <li>(ii) A sampling program to periodically verify that the end point criteria are met.</li> </ol> </li> </ol> </li> <li>(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.</li> <li>(3) Keep records in accordance with Chapter X.07.</li> </ol> <p>(B) A dealer who meets the requirements of this section may label product that has been subjected to the reduction process as:</p> <ol style="list-style-type: none"> <li>(1) "Processed for added safety," if the process reduces the levels of all pathogens of public health concern to safe levels for the at risk population;</li> <li>(2) "Processed to reduce [name of target pathogen(s)] to non-detectable levels," if the process reduces one or more, but not all, pathogens of public health concern to safe levels for the at risk population, and if that level is non-detectable; or</li> <li>(3) "Processed to reduce [name of target pathogen(s)] to non-detectable levels for added safety," if the process reduces one or more, but not all, pathogens of public health concern to safe levels for the at risk population, and if that level is non-detectable; or</li> <li>(4) A term that describes the type of process applied (e.g. "pasteurized,"</li> </ol>

"individually quick frozen," "pressure treated") may be substituted for the word "processed" in the options contained in (B)(1)-(3).

(C) For the purposes of refrigeration, if the end product is dead, the product shall be treated as shucked product. If the end product is live, the product shall be treated as shellstock.

Eliminate Chapter X, section .10, "Processed Products with Labeling Claims for Safety."

**Public Health Significance**

Protection of at-risk consumers and added incentives for post-harvest labeling.

**Cost Information (if available)**

None

**Action By 2001 Task Force I**

1. Recommended adoption of Issue 01-224 as submitted.
2. Recommended that an appropriate committee be established by the Conference Chairman with the following instructions: consider the establishment of a new PHT dealer classification and any other relevant topics.
3. Recommended an effective date of October 1, 2001 and request expedited FDA approval.
4. Recommended that FDA identify in the ICSSL those firms that have been identified by the SSCA as having an approved post harvest treatment process.

Note: Recommendation number four (4) on Issue 01-224 may be divided and debated separately.

**Action By 2001 General Assembly**

Adopted recommendations 1-3 of 2001 Task Force II. Referred recommendation 4 to appropriate committee as determined by Conference Chairman.

**Action By USFDA**

Concurs with Conference action.

FDA concurs with Conference action to adopt Issue 01-224 even though an important aspect of it was referred to committee for consideration at the next meeting. Issue 01-224 specifically outlined four recommendations for adoption, however only three were adopted. The fourth, recommendation number 4, which was referred to an appropriate committee, would have provided for identification, in the Interstate Certified Shellfish Shippers List (ICSSL), of firms having an approved post harvest treatment process. FDA considers the ability to identify such firms in the shippers list as an important component of a comprehensive NSSP PHT program. We firmly believe that such a measure provides an important incentive to processors who currently use or who are considering installation of, PHT processes to reduce the presence of specific pathogens.

**Action By 2003 Post-Harvest Processing Committee**

Recommended adoption of the following recommendations to address recommendation#4 as indicated in Action by 2001 Task Force II.

1. A PHT designation should be defined and included in the ICSSL. The PHT definition should be as follows: PHT designates a certified dealer with the capability to apply a validated process to reduce the level(s) of one target pathogen or some target pathogens, or all pathogens of public health concerns in shellfish.
2. It is recommended that an ISSC committee address how to distinguish PHT products beyond current Model Ordinance pathogen reduction statements.
3. The PHT designation in the ICSSL should be accompanied by a change in the title of chapter XVI of the Model Ordinance from the current title "Post Harvest Processing" to Post Harvest Treatments.

**Action By 2003 Task Force I**

Recommended adoption of Post-Harvest Processing Committee recommendation on Proposal 01-224 as amended:

1. ~~A PHT designation should be defined and included in the ICSSL. The PHT definition should be as follows: PHT designates a certified dealer with the capability to apply a validated process to reduce the level(s) of one target pathogen or some target pathogens, or all pathogens of public health concerns in shellfish.~~
2. It is recommended that an ISSC committee address how to distinguish PHT products beyond current Model Ordinance pathogen reduction statements.
3. ~~The PHT designation in the ICSSL should be accompanied by a~~ Change in the title of chapter XVI of the Model Ordinance from the current title "Post Harvest Processing" to Post Harvest Treatments.

**Action By 2003  
General Assembly**

Adopted recommendation of 2003 Task Force II.

**Action By  
USFDA**

Concurred with Conference action with the exception of “**no action**” on Post Harvest Processing Committee recommendation number one. FDA requests that Post Processing Committee recommendation number one be referred back to the Conference for deliberation by an appropriate committee.

Recommendation number one called for the establishment of a Post Harvest Treatment (PHT) designation for use in the Interstate Certified Shippers List (ICSSL). Such designation would identify dealers who utilize a validated process to reduce target pathogens in shellfish to safe levels. Recommendation number one also defined the PHY designation in a manner consistent with Model Ordinance requirements for PHT processing. FDA considers the ability to identify shellfish dealers that have a validated process for reducing target pathogens to safe levels an important component of a comprehensive NSSP program for PHT. We remain committed to the premise that ICSSL identification of PHT processors provides incentive to processors who currently employ or who are considering installation of PHT processes to improve shellfish safety.

**Action By ISSC  
Executive Board**

Concurred with the USFDA. Post Harvest Processing Committee recommendation number one will be referred back to the Conference for deliberation by an appropriate committee.

**Action by 2005  
Post Harvest  
Processing  
Committee**

Recommended a PHP designation should be defined and included in the ICSSL. The PHP definition should be as follows: PHP designates a certified dealer with the capability to apply a validated process to reduce the level(s) of one target pathogen or some target pathogens, or all pathogens of public health concerns in shellfish.

**Action by 2005  
Task Force II**

1. Recommended adoption of the Post Harvesting Processing Committee recommendation on Proposal 01-224 as amended:

PHP designation should be defined and included in the ICSSL. The PHP definition should be as follows: PHP designates a certified dealer with the capability to apply a validated post harvest process to reduce the level(s) of hazards not addressed by controls in the 2003 NSSP Guide for the Control of Molluscan Shellfish Chapters XI through XIV.

2. Recommended the Post Harvest Processing Committee address inconsistencies between the definition of post harvest processing currently found in the Model Ordinance and the PHP designation definition in the ICSSL as stated above.

**Action by 2005  
General Assembly**

Adopted recommendation of 2005 Task Force II.

**Action by  
USFDA**

Concurred with Conference action.

**Action by 2007 Post Harvest Processing Committee** . Recommended adoption of Proposal 01-224 as amended.

1. Change the definition of Post Harvest Processing in Chapter I and other places in the Model Ordinance to:  
“Post Harvest Processing means any process which has been validated using NSSP validation procedures which reduces the levels of pathogenic hazards to below the appropriate FDA action level or in the absence of such a level, below the appropriate level as determined by the ISSC.”
2. Add a new definition to Chapter I:  
“Post Harvest Processor means a designation given to a shellfish dealer that has incorporated a post harvest process.”
3. Replace the current PHP designation in the ICSSL with the definition in Recommendation 2.

**Action by 2007 Task Force II** Recommended adoption of Post Harvest Processing Committee recommendation on Proposal 01-224.

**Action by 2007 General Assembly** Adopted recommendation of 2007 Task Force II.

**Action by USFDA** December 20, 2007  
Concurred with Conference action.