Proposal for Task Force Consideration at the ISSC 2015 Biennial Meeting	☐ Growing Area ☒ Harvesting/Handling/Distribution ☐ Administrative

Submitter	ISSC Post-Harvest Processing Review Committee
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Proposal Subject	Post-Harvest Processing
Specific NSSP Guide Reference	Section II Model Ordinance Chapter XVI. Post-Harvest Processing
Text of Proposal/ Requested Action	.01 Processes and Procedures Involving Labeling Claims. 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 (b) A sampling program to periodically verify that the end point criteria are met. (c) 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. (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 .02 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 process 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 .02 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 .02 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 subject 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. B. A dealer who meets the requirements of this section may label product that has been subjected to the reduction process as: (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; (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 (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 (4) A term that describes the type of process applied (e.g., "pasteurized," "individually quick frozen," "pressure treated") may be substituted for the word "processed" in the options contained in B. (1) - (3). C. For the purpose of product temperature the receiving and storage critical control points of Chapter XI., shall apply to shellstock prior to PHP processing. Following PHP processing, if the product is dead, the product shall be treated as in-shell or shucked product. If the product is live, the product shall be treated as shellstock. .02 Processes and Procedures Not Involving Labeling Claims. A. If a dealer elects to use a post-harvest process(es) to reduce the levels 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 the target pathogen(s). (a) The dealer must validate that the post-harvest process(es) reduces 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 process(es) to reliably achieve the appropriate reduction in the target pathogen(s) shall be 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	
Cost Information	