Proposal No. 2 7 - 2 6 4

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting	1. a. ☐ Growing Area b. ☒ Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	U.S. Food & Drug Administration (FDA)
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9. Proposal Subject	Molluscan shellfish pathogen reduction
10. Specific NSSP Guide Reference	Section II Model Ordinance, Chapter XVI. .01 A. (2) (a), (3), and (4)
11. Text of Proposal/ Requested Action	(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 Section IV Guidance Documents – Chapter XVI. Processes and Procedures for Pathogen Reduction, .01 - .03 ~~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 *V.v.* ~~and/~~or *V.p.* in the process to non-detectable (<30 MPN/g) and the process achieves a minimum 3.52 log reduction. Determination of *V.v.* and~~/or~~ *V.p.* levels must be done using the MPN protocols described in Section IV Guidance Documents – Chapter XVI. Processes and Procedures for Pathogen Reduction, .01 - .03 ~~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 Section IV Guidance Documents – Chapter XVI. Processes and Procedures for Pathogen Reduction, .01 - .03~~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, X. .06, and X. .07~~6~~. (5) Keep records in accordance with Chapter X. .08.
12. Public Health Significance	The references to Post- Harvest Processing (PHP) Validation/Verification Guidance for *Vibrio vulnificus* (*V.v.*) and *Vibrio parahaemolyticus* (*V.p.*), .02 Method for Validation and Verification of a Two (2) or Three (3) Log Reduction of *Vibrio parahaemolyticus* (*V.p.*) in Oysters, and .03 Template for Submission of Post-Harvest Process Validation Studies were not updated in the Chapter XVI. text after the guidance was updated. Also, the requirements for labeling in-shell product or post-harvest processed in-shell labeling was not included in the text.

13. Cost Information	No cost.
14. Changes Needed to Guidance (if proposed change is adopted)	TBD