Proposal Subject: Guidance for Submission of Post-Harvest Process Validation Studies

Specific NSSP Guide Reference: NSSP Guide Section II Model Ordinance Chapter XVI. and Section IV Guidance Documents Chapter IV.

Text of Proposal/ Requested Action Add a new Section .05 Template for Submission of Post-Harvest Process Validation Studies as follows:

In the *National Shellfish Sanitation Program* (NSSP) *Model Ordinance Chapter XVI: Post Harvest Processing* (PHP) it states that if a dealer elects to utilize a PHP for the purpose of making safety added labeling claims they must conduct a validation study to demonstrate the ability of the PHP to reduce the target pathogen(s) to acceptable levels. Specifics on target levels and approved methods of detection for pathogens are found in the Model Ordinance. All laboratory analysis must be performed by a laboratory that has been evaluated by FDA or an FDA certified LEO and found to "conform" or "provisionally conform" with the requirements of the National Shellfish Sanitation Program (NSSP) Model Ordinance Chapter III and supporting Guidance Documents. Results of the validation study should be submitted in the following format for review and consideration by state and federal shellfish control authorities. For validation of *Vibrio vulnificus* or *Vibrio parahaemolyticus* methods, checklist may be used as a guide.

1) TITLE OF PHP METHOD VALIDATED
2) SUMMARY
3) OBJECTIVES (Study Purpose)
    a) Detailed description of the PHP method validated.
    b) Target pathogen(s) and prescribed reduction.
4) METHOD OF ANALYSIS
    a) Post-Harvest Process description.
        i) Identify temperatures, weights or other pertinent information for the PHP method. Methods of mollusk preparation, for example acclimation to temperature or salinity, include all details. All variables that could affect the outcome of the PHP must be detailed.
        ii) Identify number of animals used in study and number of trials performed.
    b) Laboratory: (Pre and post processing pathogen measurement and description of analytical procedure)
        i) Initial pathogen levels and pathogen detection model: microbiological or chemical analysis.
            (1) How was initial pathogen load achieved, i.e. naturally occurring population, inoculation or thermal abuse.
            (2) Provide adjusted Geometric Mean (AGM) calculations and unit of measure appropriate for target (i.e.: MPN/g for Vibrio or coliforms, CFU/100g for Elevated Temperature Coliform Plates (ETCP fecals).
            (3) Analytical methodology used for pathogen quantification and confirmation. This method must be recognized in the NSSP Guide for the Control of Molluscan Shellfish (Accepted methods listed in Section IV. Guidance Documents Chapter II.10 Approved National Shellfish Sanitation Program Laboratory Tests: Microbiological and Biotoxin Analytical Methods.)
        ii) Post Process Product Analysis: microbiological or chemical analysis

(1) Quantify pathogen level(s) in processed product utilizing the same analytical method used to attain initial load.

c) Validation Outcome:

i) Provide specific information regarding outcome measurements. Metric used to validate method (these will vary depending on targeted pathogen and are located in the Model Ordinance). Documentation that process achieved target reduction.

5) RESULTS

a) Graphs, tables and charts outlining the validation study results.

i) Data from validation demonstration; levels achieved in post process.

ii) Pathogen measurements (for example: AGM interval, grams per tube and the number of positive tubes as per the guidance document for verification/validation).

6) CONCLUSIONS:

a) Demonstrate reduction of the target pathogen to NSSP established standards.

7) APPENDIX

a) Tables or graphical interpretations of data.

8) OPTIONAL INFORMATION

a) If appropriate, include optional items such as interpretation of confounding factors or applicable industry limitations.

b) Acknowledgements, for example funding sources, technical help or bibliography.

Public Health Significance: The purpose of this proposal is to provide guidance for dealers conducting post-harvest processing validation studies for the purposes of labeling shellfish as outlined in Model Ordinance Chapter XVI.

Cost Information (if available):

Action by 2013 Task Force Recommended adoption of Proposal 13-225 as submitted.

Action by 2013 General Assembly Adopted recommendation of 2013 Task Force II on Proposal 13-225.

Action by FDA May 5, 2014 Concurred with Conference action on Proposal 13-225.

Draft- Checklist for Submission of Post-Harvest Process Validation Studies for *Vibrio vulnificus* and *Vibrio parahaemolyticus*	
	Explanation of PHP Method Validated
	1. Method name
	2. Specific information about machinery, equipment, or supplies necessary to perform the method of PHP is provided
	3. Standard operating procedures: Detailed description of the PHP method validated is provided
	4. What are the specific issues that must be accounted for during processing? For example, is there a limit to number of shellfish, spacing, hold times that are considered part of the
	5. Internal quality control measures for equipment calibration, maintenance, and repair and for performance checks are explained.
	Objectives to be Accomplished
	1. Does the process reduce the level of *Vibrio vulnificus* and/or *Vibrio parahaemolyticus* in the process to non-detectable (<30MPN/gram) and achieve a minimum 3.52 log reduction?
	2. Was the process validated by demonstrating that the process will reliably achieve the appropriate reduction in the target pathogen(s) in a study as outlined in Guidance Documents Chapter IV, Naturally Occurring Pathogens.
	Method of Analysis
	1. Was laboratory analysis performed by a laboratory that has been evaluated by FDA or an FDA certified LEO and found to "conform" or "provisionally conform" with the requirements of the National Shellfish Sanitation Program (NSSP) Model Ordinance Chapter III and supporting Guidance Documents? 2
	2. Are all variables that could affect the outcome of the PHP identified: temperatures, weights or other pertinent information?
	Pre Processed Samples to attain initial levels
	1. Microbiological testing for initial levels was done by a 3-tube MPN using appropriate dilutions (10-1 to 10-6).
	2. Was the initial level of Vibrios for each lot of shellfish used in the validation 10,000 MPN per gram or greater based on the adjusted geometric mean (AGM) of the MPNs/g of four samples?
	3. How were the zero hour levels achieved: through naturally occurring Vibrio levels in shellfish, time/temperature abuse, inoculation? (Inoculation is not preferred)
	Enumeration of or Processed Samples
	1. Does a sample consist of a composite of 10 to 12 oysters processed at one time from one day?
	2. Is there data on ten processed samples obtained on each of three processing days (total of 30 samples)?
	3. Microbiological testing for processed samples was done with a single dilution five-tube MPN, inoculating with either 0.01 g or 0.1 g of shellfish.
	4. Are only analytical methods to determine Vibrio levels previously endorsed by the ISSC as indicated in Model Ordinance Chapter XVI. Post-Harvest Processing?
	5. Was microbiological testing for processed samples done with a single dilution five-tube MPN, inoculating with either 0.01 g or 0.1 g of shellfish per tube?
	6. **For the process to be validated, no more than three samples out of 30 may fail**. Failure is based on the Guide for the Control of Molluscan Shellfish 2009 Section IV. Guidance Documents Chapter IV. Naturally Occurring Pathogens .04 Post Harvest Processing (PHP) Validation/Verification Guidance for *Vibrio vulnificus* and *Vibrio parahaemolyticus.*