Proposal Subject Validation Verification Revision

Specific NSSP Guide Reference Guidance Documents Chapter IV @.04 Post Harvest Processing Validation/Verification Interim Guidance for *Vibrio vulnificus* and *Vibrio parahaemolyticus*

Text of Proposal/ Requested Action

.04 **Post Harvest Processing (PHP)** Validation/Verification Interim Guidance **for *Vibrio vulnificus* and *Vibrio parahaemolyticus***

A. Process Validation

Used for the initial validation of a process or when there has been a change to a previous validation process.

- Data on ten processed samples obtained on each of three processing days (total of 30 samples) are required.
- All samples used on a processing day must come from the same lot of shellfish and be determined to have an adjusted geometric mean (AGM) MPN of ~~100,000~~ **10,000** per gram or greater as described below for initial load testing. ~~(If some lower initial levels are used the process will only be validated for those maximum initial levels.)~~
- Samples should be distributed throughout the processing day. A sample will consist of a composite of 10 to 12 oysters processed at one time.
- The zero hour level may be achieved through naturally occurring Vibrio levels in shellfish and, where not practical, by time/temperature abuse. (Inoculated pack samples may be used as appropriate.)
- Analytical methodology to determine Vibrio levels should be the official methods previously endorsed by the ISSC **as indicated in Model Ordinance Chapter XVI. Post Harvest Processing**.
- Microbiological testing for processed samples will be by a single dilution five-tube MPN, inoculating with **either** 0.01 g **or 0.1 g** of shellfish per tube **based upon the table below**.
- The numerical value of the endpoint criteria should ~~represent the lowest sensitivity of the MPN method, which is~~ **be** less than 30 per gram **and achieves a minimum 3.52 log reduction**.
- For the process to be validated, no more than three samples out of 30 may fail. **Depending upon the initial load, ~~F~~failure of a single sample** is ~~indicated by more than two out of five MPN tubes in any sample being positive. If any one sample has all five MPN tubes positive, the validation process will fail.~~ **determined according to the table below.**

AGM Interval	Grams Per Tube	Positive Tubes Allowed
59,995 or Greater	.01	2
37,174 – 59,994	.01	1
23,449 – 37,173	.1	4
12,785 – 23,448	.1	3
10,000 – 12,784	.1	2

For example, if the AGM equals 50,000, then use the second row because 37,174 ≤50,000 < 59,994. the second row tells to inoculate with .01 grams of the original oyster homogenate in each tube and the test fails if more than one of the five tubes is positive.

B. Equipment Validation

Used to ensure that each unit of equipment will deliver the validated process. May be accomplished using either of two methods:

- The process described under "Revalidation," below:
- A physical test of the equipment (e.g., thermal distribution study) that is designed to ensure that, when properly operated, it will consistently deliver the validated process.

C. Revalidation

Used when verification sampling indicates a failure in the process.

Option 1:

- Data on ten processed samples obtained throughout a processing day are required.
- All samples used on a processing day must come form the same lot of shellfish and be determined to have an adjusted geometric mean (AGM) MPN of 100,000 per gram or greater as described below in initial load testing.
- A sample will consist of a composite of 10 to 12 oysters processed at one time.
- The zero hour level may be achieved through naturally occurring Vibrio levels in shellfish and, where not practical, by time/temperature abuse. (Inoculated pack samples may be used as appropriate).
- Microbiological testing for processed samples will be by a single dilution five-tube MPN, inoculating with 0.01 g of shellfish per tube.
- The numerical value of the endpoint criteria should represent the lowest sensitivity of the MPN method, which is less than 30 per gram.
- For revalidation, no more than one sample out of ten may fail. Failure is indicated by more than two out of five MPN tubes in any sample being positive. If any one sample has all five MPN tubes positive, revalidation will fail.

Option 2:

Repeat full validation when initial levels of 100,000 per gram can't be achieved.

D. Initial Load Testing

Initial level of vibrios in shellfish for each lot of shellfish used in validation shall be ~~100,000~~ 10,000 MPN per gram or greater based on the adjusted geometric mean (AGM) of the MPNs/g of four samples where the AGM is given by:

AGM = the geometric mean of the 4 MPNs/g multiplied by an adjustment factor of 1.3

Note: If 4 samples from a lot of shellfish with a true density of 100,000 cells per gram are examined by the MPN procedure, the probability of the geometric mean of the MPNs showing 100,000 or greater is about 50%. In an attempt to improve the probability of samples being accepted when the true density is 100,000/g an adjustment factor of 1.3 was selected based upon statistical analysis. ~~provided by Dr. Bob Blodgett.~~

E. Verification

Used to verify that a previously validated process is working properly.

- Process verification by microbiological testing should be done monthly
- The number of samples/sub samples for verification and the pass/fail criteria for the verification process will be determined by the validation/verification workgroup following evaluation of statistical data to be supplied by Dr. Bob Blodgett.
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- The dealer in conjunction with the SSCA shall annually evaluate the previous 12 months of data and the HACCP plan.
- The dealer may elect, with SSCA concurrence, to conduct quarterly sampling if the previous 12 verification samples pass.

Public Health Significance N/A

Cost Information (if available) N/A

Action by 2007 Validation/Verification Workgroup Recommended adoption of Proposal 07-209 as substituted.

.04 **Post Harvest Processing (PHP)** Validation/Verification Interim Guidance **for *Vibrio vulnificus* and *Vibrio parahaemolyticus***

A. Process Validation

Used for the initial validation of a process or when there has been a change to a previous validation process.

- Data on ten processed samples obtained on each of three processing days (total of 30 samples) are required.
- All samples used on a processing day must come from the same lot of shellfish and be determined to have an adjusted geometric mean (AGM) MPN of **10,000** per gram or greater as described below for initial load testing.
- Samples should be distributed throughout the processing day. A sample will consist of a composite of 10 to 12 oysters processed at one time.
- The zero hour level may be achieved through naturally occurring Vibrio levels in shellfish and, where not practical, by time/temperature abuse. (Inoculated pack samples may be used as appropriate.)
- Analytical methodology to determine Vibrio levels should be the official methods previously endorsed by the ISSC **as indicated in Model Ordinance Chapter XVI. Post Harvest Processing**.
- **Microbiological testing for initial levels will be by a 3 tube MPN using appropriate dilutions (10^{-1}- 10^{-6})**
- Microbiological testing for processed samples will be by a single dilution five-tube MPN, inoculating with **either** 0.01 g **or 0.1 g** of shellfish per tube **based upon the table below**.
- The numerical value of the endpoint criteria should be less than 30 per gram **and achieves a minimum 3.52 log reduction.**
- For the process to be validated, no more than three samples out of 30 may fail. **Depending upon the initial load, failure of a single sample** is **determined according to the table below.**

AGM Interval	Grams Per Tube	Positive Tubes Allowed
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B. Equipment Validation
Used to ensure that each **new or modified** unit of equipment will deliver the validated process. May be accomplished using ~~either of two methods:~~**the following:**

- ~~The process described under "Revalidation," below:~~
- A physical test of the equipment (e.g., thermal distribution study) that is designed to ensure that, when properly operated, it will consistently deliver the validated process.
- **The process needs to be verified according to section D. before labeling claims can be made.**

~~C.~~ ~~Revalidation~~

~~Used when verification sampling indicates a failure in the process.~~

~~**Option 1:**~~

- ~~Data on ten processed samples obtained throughout a processing day are required.~~
- ~~All samples used on a processing day must come form the same lot of shellfish and be determined to have an adjusted geometric mean (AGM) MPN of 100,000 per gram or greater as described below in initial load testing.~~
- ~~A sample will consist of a composite of 10 to 12 oysters processed at one time.~~
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- ~~The numerical value of the endpoint criteria should represent the lowest sensitivity of the MPN method, which is less than 30 per gram.~~
- ~~For revalidation, no more than one sample out of ten may fail. Failure is indicated by more than two out of five MPN tubes in any sample being positive. If any one sample has all five MPN tubes positive, revalidation will fail.~~

~~**Option 2:**~~

~~**Repeat full validation when initial levels of 100,000 per gram can't be achieved.**~~

~~D~~C. Initial Load Testing

Initial level of vibrios in shellfish for each lot of shellfish used in validation shall be 10,000 MPN per gram or greater based on the adjusted geometric mean (AGM) of the MPNs/g of four samples where the AGM is given by:

AGM = the geometric mean of the 4 MPNs/g multiplied by an adjustment factor of 1.3

Note: If 4 samples from a lot of shellfish with a true density of 100,000 cells per gram are examined by the MPN procedure, the probability of the geometric mean of the MPNs showing 100,000 or greater is about 50%. In an attempt to improve the probability of samples being accepted when the true density is 100,000/g an adjustment factor of 1.3 was selected based upon statistical analysis.

~~E~~D. Verification

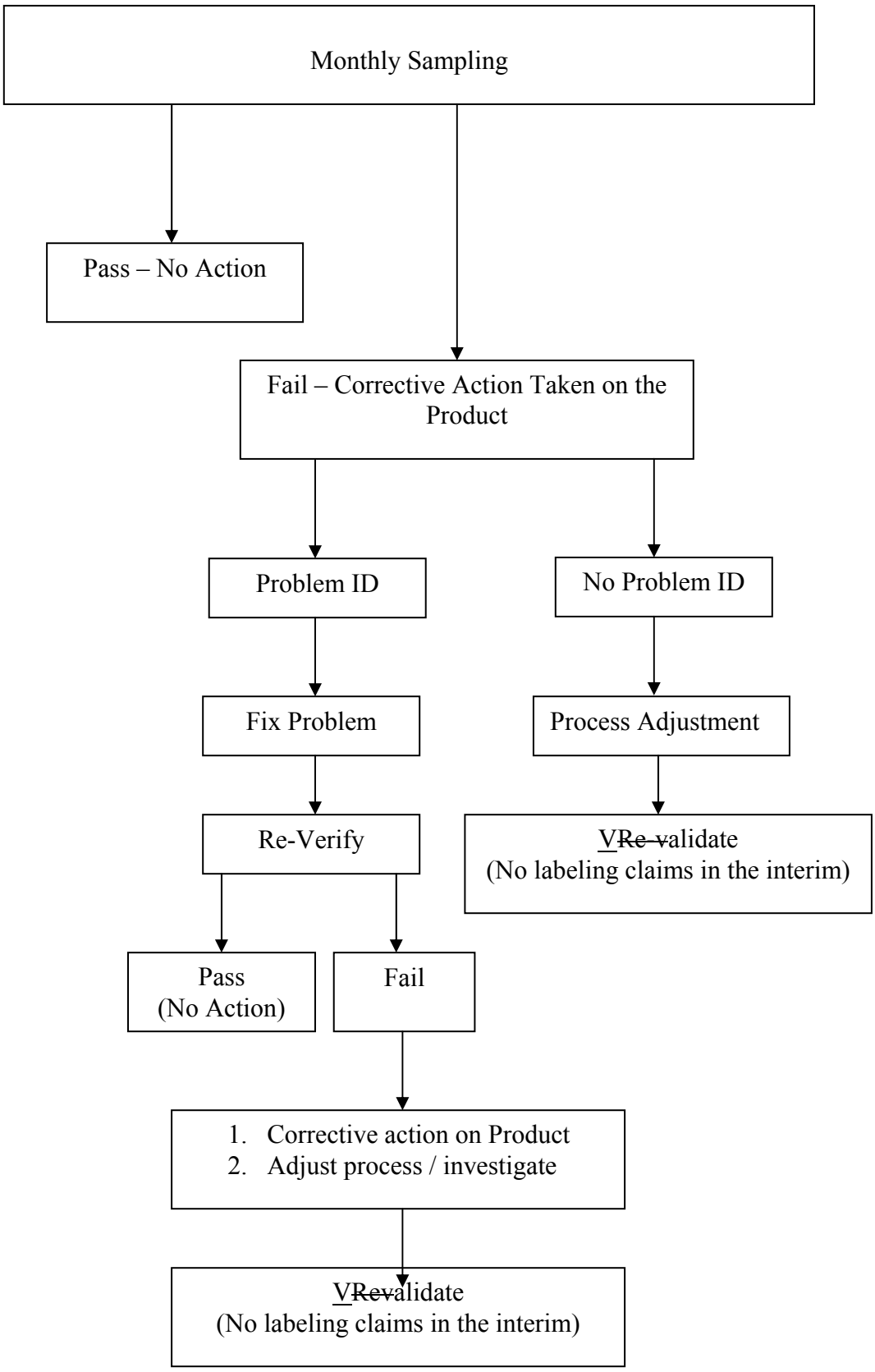
Used to verify that a previously validated process is working properly.

- Process verification by microbiological testing should be done monthly
- ~~The number of samples/sub-samples for verification and the pass/fail criteria for the verification process will be determined by the validation/verification workgroup following evaluation of statistical data to be supplied by Dr. Bob Blodgett.~~
- ~~The dealer in conjunction with the SSCA shall annually evaluate the previous 12 months of data and the HACCP plan.~~
- ~~The dealer may elect, with SSCA concurrence, to conduct quarterly sampling if the previous 12 verification samples pass.~~ **The monthly sampling shall consist of 30 tubes from a minimum of three samples of 10 tubes each with an innoculum of 0.01 grams. Ideally, this would**

be done on three separate days of production, spread throughout the month, using a 10 tube MPN each day. If this is not feasible, the 30 tubes can consist of 3 samples from three consecutive days or 3 samples from a given day (from three separate lots if possible)

- **Each sample will consist of 10-12 oysters**
- **If more than 11 tubes of the 30 most recent 3-10 tube samples within any calendar month are positive, then the process fails for that month. In this case, corrective actions as outlined in the Verification Sampling Plan Decision Tree must be taken and verification must be repeated within one week of the analysis indicating verification failure. Labeling claims may not be used during this time.**
- **If all ten tubes are positive for any given sample, this is considered a verification failure and corrective actions must be taken immediately regardless of the result of the other samples for that month.**
- **If verification fails twice during a twelve month period, revalidation is required and product should not be labeled until revalidation occurs.**
- **The dealer in conjunction with the SSCA shall annually evaluate the previous 12 months of data and the HACCP plan.**

Verification Sampling Protocol Decision Tree



NOTE: When a monthly verification fails, the verification must be repeated within one week of failure.

Action by 2007 Task Force II

Recommended adoption of substitute Proposal 07-209 submitted by the Validation/Verification Workgroup as amended by Task Force II. The substitute included changing Monthly Sampling to Verification Sampling in the Verification Sampling Protocol Decision Tree.

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- If verification fails twice during a twelve month period, revalidation is required and product should not be labeled until revalidation occurs.
- The dealer in conjunction with the SSCA shall annually evaluate the previous 12 months of data and the HACCP plan.
- ~~(81)~~ The dealer may elect, with SSCA concurrence, to conduct quarterly sampling if the previous 12 verification samples pass.

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

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