Proposal Subject Validation/Verification Process for PHT Product

Specific NSSP Guide Reference None Referenced

Text of Proposal/ Requested Action

VALIDATION/VERIFICATION INTERIM GUIDANCE:

Validation (level 1) – used for the initial validation of a 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 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.)**
- For Vibrio parahaemolyticus, the 03:K6 serotype shall be used for the initial load through an inoculation process.
- Analytical methodology to determine Vibrio levels should be the official methods previously endorsed by the ISSC.
- Microbiological testing for processed samples will be by a single dilution five-tube MPN, inoculating with 0.1 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 3 per gram.
- For the process to be validated, no more than three samples out of 30 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, the validation process will fail.

Validation (level 2) – used when a validated process is changed or when verification sampling indicates a failure in the process

- 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 0.1 g of shellfish per tube.
- For level 2 validation, 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, the validation process will fail.

Initial Load Testing

Initial level of vibrios in shellfish for each lot of shellfish used in validation shall be 100,000 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.

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.

See Attachment

Public Health Significance

None Submitted

Cost Information (if available)

None Submitted

Action by 2003 Vibrio vulnificus Subcommittee

Recommended that amended Proposal 03-212 (below) be substituted for Proposal 03-212. This recommendation includes a recommendation from the Post-Harvest Vv Levels Workgroup. The workgroup recommended the <3 MPN level for Post-harvest labeling be changed to 30 MPN. The 30 MPN will become the non-detect level. Post-harvest treatment labeling claims can be made for non-detect at 30 MPN. Additionally, it is recommended that the Executive Board be given the authority to increase the level up to a level no higher than 100 upon recommendation by the Vv Subcommittee.

Additionally, recommended modification of Model Ordinance Chapter XVI.A. (1)(a) to change the non-detect level from <3 MPN/gram to <30 MPN/gram.

VALIDATION/VERIFICATION INTERIM GUIDANCE:

Process Validation ~~(level 1)~~ – 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 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.)**
- ~~For Vibrio parahaemolyticus, the 03:K6 serotype shall be used for the initial load through an inoculation process.~~
- Analytical methodology to determine Vibrio levels should be the official methods previously endorsed by the ISSC.
- 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 the process to be validated, no more than three samples out of 30 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, the validation process will fail.

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.

ReV~~V~~alidation ~~(level 2)~~ – used when ~~a validated process is changed or when~~ verification sampling indicates a failure in the process

- 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 ~~level 2~~ 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, ~~the~~ revalidation ~~process~~ will fail.

Initial Load Testing

Initial level of vibrios in shellfish for each lot of shellfish used in validation shall be 100,000 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.

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.

Action by 2003 Task Force II	Recommended adoption of Proposal 03-211 as amended by the Import Assessment Committee.
Action by 2003 Vibrio Management Committee	Recommended adoption of the Vv Subcommittee recommendations on Proposal 03-212.
Action by 2003 Task Force II	Recommended adoption of Vibrio Management Committee recommendations on Proposal 03-212. Additionally, Task Force II recommended that Model Ordinance Chapter XVI (A)(1)(b) be amended as follows: (A)(1)(b) For processes that target *Vibrio parahaemolyticus* (the 03:K6 serotype shall be used for validation), the level of *Vibrio parahaemolyticus* in product that has been subjected to the process shall be non-detectable (<1 CFU/0.1 gram).
Action by 2003 General Assembly	Adopted recommendations of 2003 Task Force II.
Action by USFDA	Concurred with Conference action.
Action by 2005 Vibrio Management Committee	Recommended the PHP Workgroup continue to work on a revised approach and when completed, that it be considered by the Executive Board as an interim measure. Executive Board approval should be considered at its next scheduled meeting in March 2006 or sooner if the new approach can be completed well in advance of its next meeting in March.
Action by 2005 Task Force II	Recommended adoption of the Vibrio Management Committee recommendation on Proposal 03-212.
Action by 2005 General Assembly	Adopted recommendation of 2005 Task Force II.
Action by USFDA	Concurred with Conference action.

Verification Sampling Protocol Decision Tree