

The Executive Board of the ISSC adopted as interim guidance the following Verification/Validation procedures for post harvest processing.

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.
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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 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 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/subsamples 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.

Verification Sampling Protocol Decision Tree

