Proposal Subject: Approval of the Use of End-Product Testing as an Alternative to Validation of Post Harvest Processes

Specific NSSP Guide Reference: Section IV. Guidance Documents
Chapter IV. Naturally Occurring Pathogens

Text of Proposal/ Requested Action

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

C. End Product Testing

Used as an alternative to validation of new shellfish processes to ensure that the end-product contains less than 30 MPN/g of Vv and/or Vp.

Prior to adding labeling claims to the product, the processor must analyze each lot of the finished product in accordance with the NSSP guidance document.

Only lots having less than 30 MPN/g will be allowed to be labeled as PHP. Processor must incorporate the sampling and testing into their HACCP plan and maintain records of HACCP controls as well as laboratory analytical results for all lots tested.

~~C~~D. 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.

~~D~~E. Verification

Public Health Significance: None

Cost Information (if available): None

Action by 2009 Task Force II: Recommended referral of Proposal 09-235 to an appropriate committee as determined by the Conference Chairman.

Action by 2009 General Assembly Adopted recommendation of 2009 Task Force II on Proposal 09-235.

Action by USFDA	Concurred with Conference action on Proposal 09-235.
Action by 2011 Post Harvest Processing Committee	Recommended no action on Proposal 09-235. Rationale: Validation is a requirement for labeling claims.
Action by 2011 Task Force II	Recommended adoption of Post Harvest Processing Committee recommendation of no action on Proposal 09-235. Rationale: Validation is a requirement for processing shellfish with labeling claims.
Action by 2011 General Assembly	Adopted recommendation of 2011 Task Force II on Proposal 09-235.
Action by FDA February 26, 2012	Concurred with Conference action on Proposal 09-235.