Proposal Subject: Addition to the Requirements for the Authority During a Suspected Shellfish Related Outbreak

Specific NSSP Guide Reference: 2009 NSSP Section II Model Ordinance
Chapter II @.01 Outbreaks of Shellfish-Related Illness J.

Text of Proposal/ Requested Action:

I. Whenever an Authority or dealer initiates a recall of shellfish products because of public health concerns, the Authority will monitor the progress and success of the recall. The Authority will immediately notify the FDA and the Authorities in other states involved in the recall. The Authority shall submit periodic recall status reports to the FDA Regional Shellfish Specialist consistent with the Recall Enforcement Policy Title 21 Code of Federal Regulations Part 7, Subpart C, §7.53 (b) (1-6) until such time that the Authority deems the recall to be completed. Each Authority involved in a recall will implement actions to ensure removal of recalled product from the market, issue public warnings if necessary to protect public health and provide periodic reports to the Authority in the state of product origin regarding recall efforts within their state until such time that the Authority in the state of product origin deems the recall to be completed. FDA will decide whether to audit or issue public warnings after consultation with the Authority/Authorities, and after taking into account the scope of the product distribution and other related factors. If the FDA determines that the Authority in any state involved in the recall fails to implement effective actions to protect public health, the FDA may classify, publish and audit the recall, including issuance of public warnings when appropriate.

J. Whenever the Molluscan shellfish products are deemed to be contaminated with a pathogen that would subject it to a recall, reconditioning of the product will be permitted as an alternative to control the hazard. Any such reconditioning process that is used must be validated to reduce the level of the pathogen in question to a level which is not reasonably likely to cause illness or alter the product to a form that is intended to be cooked.

~~J~~K. The Authority shall assess annually Vibrio parahaemolyticus illnesses associated with the consumption of molluscan shellfish. The assessment will include a record of all V. parahaemolyticus shellfish-associated illnesses reported within the state and from receiving states, the numbers of illnesses per event, and actions taken by the Authority in response to the illnesses.

Public Health Significance:

Cost Information (if available):

Action by 2011 Task Force I Recommended referral of Proposal 11-115 to the appropriate committee as determined by the Conference Chairman.

Action by 2011 General Assembly Adopted recommendation of 2011 Task Force I on Proposal 11-115.

Action by FDA February 26, 2012 Concurred with Conference action on Proposal 11-115.