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 Paragraph C.

Text of Proposal/ Requested Action

C. When the investigation outlined in §.02B. does not indicates a growing area problem: post-harvest contamination problem, or illegal harvesting from a closed area, the Authority shall:

- (1) Immediately place the implicated portion(s) of the harvest area(s) in the closed status;
- (2) Notify receiving states and the FDA Regional Shellfish Specialist that a potential health risk is associated with shellfish harvested from the implicated growing area;
- (3) As soon as determined by the Authority, transmit to the FDA and receiving states information identifying the dealers shipping the implicated shellfish; and
- (4) Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 Code of Federal Regulations Part 7. The recall shall include all implicated products.

Public Health Significance:

The basis for this addition is to allow the Authority time to determine if suspected shellfish related outbreak is due to growing area problems or problems associated with the location where the shellfish were served. It would be expected that if the suspected outbreak were growing area related, illnesses would be seen at more than one location. It is difficult to determine the actual cause within 24 hours when faced with illness reported from a single location.

Cost Information (if available):

None

Research Needs:

There is a need of one type of post harvest processing technology that could be used as a determining factor that when applied as a process to recondition a batch of recalled oysters whether shucked, shellstock and post harvest processed oysters, all the rest of the oyster related pathogens causing foodborne illnesses are deemed clean. It is patterned after the analysis of water using fecal coliform as an identifier of the presence of pathogens in the water.

In any oyster recall, dealers and processors often experience financially devastating product recalls and experience the loss of their investments on the product. The number of oyster dealers had decreased over the years for various reasons. Those remaining are finding it difficult to cope without alternatives to destruction of product.

Estimated Cost: Not available at this time.

Proposed Source of Funding/Support:

Not available at this time.

Time Frame Anticipated:

Not available at this time.

Action by 2011 Task Force I Recommended no action on Proposal 11-113.

Rationale: Adequately addressed in Proposal 11-114.

Action by 2011 General Assembly Adopted recommendation of 2011 Task Force I on Proposal 11-113.

Action by FDA February 26, 2012 Concurred with Conference action on Proposal 11-113.