Proposal Subject: Extent of Product to be Included Under a Recall and Requirement for Recall Status Reports

Specific NSSP Guide Reference: NSSP Guide Section II. Model Ordinance
Chapter II. Risk Assessment and Risk Management
@. 01. Outbreaks of Shellfish Related Illnesses Sections C., D., and I.

Text of Proposal/ Requested Action

A. When…

B. When…

C. When the investigation outlined in §.02B. does not indicate a 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 products that have not undergone a 6D thermal process for *Listeria monocytogenes*.**

D. When the investigation outlined in §.02B demonstrates that the illnesses are related to post-harvesting contamination or mishandling, growing area closure is not required. However, the Authority shall:

(1) Notify receiving states **and the FDA Regional Shellfish Specialist** of the problem; and

(2) 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. that have not undergone a 6D thermal process for *Listeria monocytogenes*.**

E. When …

F. Upon ...

G. Upon …

H. When ...

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 weekly 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, ~~and~~ issue public warnings if necessary to protect public health **and provide weekly 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. The…

Public Health Significance:

The Model Ordinance provides no guidance concerning the extent of products that are to be included in a shellfish recall. Adding language specifying that recalls are to include all products that have not been thermally processed to achieve a 6D treatment for *Listeria monocytogenes* defines the extent of shellfish products to be included in a recall. Although value added products, such as frozen breaded shellfish, are intended for cooking prior to consumption, their associated hazards are required to be controlled prior to their distribution for retail sale. In accordance with the FDA Seafood HACCP Regulation, processors must control food safety hazards before the product is marketed. Processors are not permitted to pass the control of food safety hazards onto the consumer.

While the Model Ordinance states that recalls are to be initiated in accordance with the Federal Recall Enforcement Policy as outlined in 21 Code of Federal Regulations, Part 7, which includes requirements for recall status reports, it is not explicit regarding this requirement. The lack of recall status reports in the past has proven problematic in determining the extent and effectiveness of recalls and has hindered efforts by public health authorities to manage recalls effectively. Including specific Model Ordinance language clearly establishes importance and need for recall status reports.

Cost Information (if available):

Action by 2009 Task Force II:

Recommended adoption of Proposal 09-206 as amended.

C. When the investigation outlined in §.02B. does not indicate a 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 ~~that have not undergone a 6D thermal process for *Listeria monocytogenes*~~.

D. When the investigation outlined in §.02B demonstrates that the illnesses are related to post-harvesting contamination or mishandling, growing area closure is not required. However, the Authority shall:

(1) Notify receiving states and the FDA Regional Shellfish Specialist of the problem; and

(2) 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. ~~that have not undergone a 6D thermal process for *Listeria monocytogenes*.~~

E. When …

F. Upon ...

G. Upon …

H. When ...

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 ~~weekly~~ **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 ~~weekly~~ **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.

Action by 2009 General Assembly Adopted recommendation of 2009 Task Force II on Proposal 09-206.

Action by USFDA 02/16/2010 Concurred with Conference action on Proposal 09-206.