Proposal Subject: Requirements to Conduct Product Recall

Specific NSSP Guide Reference: NSSP Guide Section II. Model Ordinance
Chapter II. Risk Assessment and Risk Management
@.02 Presence of Human Pathogens in Shellfish Meats

Text of Proposal/ Requested Action

B. Growing Area Investigation
- (1) The Authority shall…
- (2) The Authority shall …
- (3) When the Authority determines that the growing area is not properly classified **or that the growing area may be the source of the pathogens** the Authority shall take immediate action to:
  - (a) Change the existing classification to the correct classifications; or
  - (b) Close the growing area until the correct classification can be determined~~.~~**; and**
  - **(c) Promptly initiate recall procedures consistent with the Recall Enforcement Policy Title 21 of Code of Federal Regulations Part 7.**
- **(4) When the Authority determines that illegal harvesting is taking place, the Authority shall promptly initiate recall procedures consistent with the Recall Enforcement Policy Title 21 Code of Federal Regulations Part 7 for all shellfish that may be falsely represented.**

C. Distribution and Processing
- (1) The Authority shall …
- (2) The Authority shall …
- (3) When the Authority determines that a problem exists in the distribution or processing of the shellfish, the Authority shall take immediate steps to correct the problem **and promptly initiate recall procedures consistent with the Recall Enforcement Policy Title 21 of Code of Federal Regulation Part 7**.

Public Health Significance: The Model Ordinance is not clear regarding the disposition of shellfish that have been harvested and then found positive for the presence of human pathogens. Failure to initiate recall procedures when human pathogens are known to be present in shellfish meats is inconsistent with the conservative public health approach of the NSSP and jeopardizes consumer health. Furthermore, while the Model Ordinance addresses a finding of no illegal harvesting (@.02 B. (2)), it is silent regarding what happens when illegal harvesting is determined. Adoption of the proposed language clarifies what action is to be taken when human pathogens are found present in shellfish meats.

Cost Information (if available): N/A

Action by 2007 Task Force II Recommended referral of Proposal 07-200 to an appropriate committee as determined by the Conference Chairman.

Action by 2007 General Assembly Adopted recommendation of 2007 Task Force II.

Action by USFDA December 20, 2007
Concurred with Conference action.

Action by 2009 Product Recall Committee

Recommended adoption of Proposal 07-200 as amended by the Committee.

B. Growing Area Investigation

(1) The Authority shall…

(2) The Authority shall …

(3) When the Authority determines that the growing area is not properly classified ~~or that the growing area may be the source of the pathogens~~ the Authority shall take immediate action to:

(a) Change the existing classification to the correct classifications; or

(b) Close the growing area until the correct classification can be determined; and

(c) Promptly initiate recall procedures consistent with the Recall Enforcement Policy Title 21 of Code of Federal Regulations Part 7.

(4) When the Authority determines that the growing area may be the source of pathogens the Authority shall promptly initiate recall procedures consistent with the Recall Enforcement Policy title 21 of Code of Federal Regulations Part 7 if the pathogens exceed tolerance levels.

~~(4~~(5) When the Authority determines that illegal harvesting is taking place, the Authority shall promptly initiate recall procedures consistent with the Recall Enforcement Policy Title 21 Code of Federal Regulations Part 7 for all shellfish that may be falsely represented.

C. Distribution and Processing

(1) The Authority shall …

(2) The Authority shall …

(3) When the Authority determines that a problem exists in the distribution or processing of the shellfish, the Authority shall take immediate steps to correct the problem and promptly initiate recall procedures consistent with the Recall Enforcement Policy Title 21 of Code of Federal Regulation Part 7.

Action by 2009 Task Force II

Recommended adoption of Product Recall Committee recommendation on Proposal 07-200.

Action by 2009 General Assembly

Adopted recommendation of 2009 Task Force II on Proposal 07-200.

Action by USFDA 02/16/2010

Concurred with Conference action on Proposal 07-200.