Chapter II. Risk Assessment and Risk Management

Requirements for the Authority

[Note: The Authority must meet the requirements of this section even if the Authority does not formally adopt this section in regulation.]

@.01 Outbreaks of Shellfish-Related Illness.

A. When shellfish are implicated in an illness outbreak involving two (2) or more persons not from the same household (or one or more persons in the case of paralytic shellfish poisoning [PSP]), the Authority shall determine whether an epidemiological association exists between the illness and the shellfish consumption by reviewing:
   (1) Each consumer's food history;
   (2) Shellfish handling practices by the consumer and/or retailer;
   (3) Whether the disease has the potential or is known to be transmitted by shellfish; and
   (4) Whether the symptoms and incubation period of the illnesses are consistent with the suspected etiologic agent.

NOTE: For additional guidance refer to the International Association of Milk, Food, and Environmental Sanitarians' *Procedures to Investigate Food Borne Illness*.

Clarifications/Recommendations

- All shellfish related biotoxin poisoning is now considered an outbreak, not limited to PSP only. (Proposal 17-122)
- The term Authority is not limited to a state agency that is responsible for the primary program elements of the NSSP. The MO definition for Authority includes other authorities or designated agents which are responsible for the enforcement of the MO which includes the state entity which addresses illnesses and illness reporting. In most cases this would be the State Office of Epidemiology.
- Proposal 17-205 included requirements for development of a protocol between the State Epi Office and the Shellfish Program. This protocol will address the working agreement between the shellfish program and the office of epidemiology.
- This determination of an epidemiological association is the responsibility of the State in which the illness occurred.
- An epidemiological association is different from an etiological link and the terms should not be confused in the application of Chapter II
- (2) Is not an activity that would be part of a review to determine epidemiological association.
- All authorities and entities involved in epidemiological determination and investigations should openly share information to ensure an accurate and thorough response to the illness outbreak.

B. When the Authority has determined an epidemiological association between an illness outbreak and shellfish consumption, the Authority shall:
   (1) Conduct an investigation of the illness outbreak within 24 hours to determine whether the illness is growing area related or is the result of post-harvest contamination or mishandling.
   (2) Determine whether to initiate a voluntary recall by firms. If a firm(s) is requested by the Authority to recall, the firm will use procedures consistent with the Recall Enforcement Policy, Title 21Code of Federal Regulations (CFR) Part 7. The recall shall include all implicated products.

Clarifications/Recommendations

- The investigation referred to in B.(1) is a post-harvest contamination or mishandling investigation. If post-harvesting contamination or mishandling is not identified within 24 hours, the growing area is considered the source of the illness. The section is not intended to suggest that a complete investigation of the implicated growing area(s) can be conducted within 24 hours and used as a rationale for not closing the growing area(s).
- The investigation would also include a source investigation to verify sources and, in the case of multiple sources, to eliminate growing areas that should not be implicated.
- Within 24 hours means within 24 hours of the authority being notified that an association has been determined by a state epidemiologist
- Section IV. Chapter V. provides a considerable amount of guidance for conducting recalls (28 pages) which includes several types of forms for conducting recalls.
- Chapter X of the MO requires that all dealers have written recall procedures and dealers are required to follow those procedures when recalls are necessary

C. When the investigation outlined in Model Ordinance Chapter II. @.04 B. 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, the ISSC 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 CFR Part 7. The recall shall include all implicated products.

Clarifications/Recommendations

- The investigation referred to in C. is a post-harvest contamination or mishandling investigation.
- Section C. addresses situations when the post-harvest contamination investigation can be conducted within 24 hours.
- Chapter II. @.04 B. is an incorrect reference. This section is entitled Presence of Human Pathogens in Shellfish Meats and does not include any reference to a post-harvest contamination investigation. The only information in the NSSP Guide that addresses post-harvest contamination investigation is in Section IV. Guidance Documents Chapter V.

D. When the investigation outlined in Model Ordinance Chapter II. @.04 B. 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, the ISSC and the FDA Regional Shellfish Specialist of the problem; and
   (2) Initiate a voluntary recall by firms. If a firm or firms is requested by the Authority to recall, the firm will use procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7. The recall shall include all implicated products.

Clarifications/Recommendations

- Section D. addresses situations when a post-harvest contamination or mishandling investigation can be completed within 24 hours and post-harvesting contamination or mishandling is the cause of the outbreak.
- Chapter II. @.04 B. reference is incorrect. This section is entitled Presence of Human Pathogens in Shellfish Meats and does not include any reference to a post-harvest contamination investigation. The only information in the NSSP Guide that addresses post-harvest contamination investigation is in Section IV. Guidance Documents Chapter V.

E. When the investigation outlined in Model Ordinance Chapter II. @.04 B. cannot be completed within 24 hours, the Authority shall:

(1) Follow the closure procedure outlined in Chapter II @.01 C.; and if the investigation does not indicate a growing area problem, the area shall be immediately reopened and product recall terminated.

Clarifications/Recommendations

- Section E. addresses situations when a post-harvest contamination or mishandling investigation cannot be completed within 24 hours.
- The investigation referenced in E. (1) is the post-harvesting contamination or mishandling investigation that would be conducted following the closure.
- In Section E., a precautionary closure could be implemented to allow time for the post-harvest contamination or mishandling investigation to be completed. Should the post-harvest contamination or mishandling investigation reveal that post-harvest contamination or mishandling caused the illness, the growing area can be immediately reopened. The need for recall can be assessed independently of a precautionary closure.
- Should the investigation reveal post-harvest contamination or mishandling, the growing area should be reopened and product recall from the growing area terminated. Product recall should then focus on product subjected to the post-harvest contamination or mishandling.

F. Upon closing an implicated area for problems other than natural occurring pathogens and/or Biotoxins, the Authority shall review the growing area classification and determine if a growing area classification problem exists. The review shall include at a minimum:

(1) A review of the growing area classification file records;
(2) A field review of existing pollution sources;
(3) A review of actual and potential intermittent pollution sources, such as vessel waste discharge and wastewater discharge from treatment plant collection systems; and
(4) Examination of water quality subsequent to the illness outbreak.

Clarifications/Recommendations

- This review is to be conducted prior to reopening an implicated growing area when the area is closed for problems other than naturally occurring pathogens and/or biotoxins.
- Guidance for conducting a growing area investigation following a closure can be found in Section IV Guidance Documents Chapter V .01.
- The growing area that has been closed as a precautionary measure may be opened sooner than 21 days should the review support reopening.

G. Upon closing an implicated portion(s) of the harvest area(s) for naturally occurring pathogens and/or Biotoxins, the Authority:

(1) Shall follow an existing marine Biotoxin contingency plan, if appropriate.

(2) Shall collect and analyze samples relevant to the investigation, if appropriate.

(3) Shall keep the area closed until it has been determined that levels of naturally occurring pathogens and/or Biotoxins are not a public health concern.

(4) May limit the closure to specific shellfish species when FDA concurs that the threat of illness is species specific.

Clarifications/Recommendations

- Section G. outlines reopening criteria for growing areas closed for naturally occurring pathogen or biotoxins.

H. When the growing area is determined the problem, the Authority shall:

(1) Place the growing area in the closed status until:

(a) The Authority verifies that the area is properly classified, using current data, in compliance with the NSSP Model Ordinance; or

(b) Shellfish from the growing area are confirmed as the cause of illness but it has been determined that the event which caused the contamination no longer exists;

(2) Keep the area closed for a minimum of 21 days if the illness is consistent with viral etiology; and

(3) Develop a written report summarizing the findings of the investigation and actions taken.

Clarifications/Recommendations

- Section H. includes additional reopening requirements when the growing area is determined to be the source of the contamination.
- Section H is to ensure that the risk of illness no longer exists

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, ISSC 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 CFR Part 7, Subpart C, Section 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.

Clarifications/Recommendations

- Section I. includes requirements for conducting recalls when a recall is initiated.
- Section IV. Chapter V. provides a considerable amount of guidance for conducting recalls (28 pages) which includes several types of forms for conducting recalls.
- Chapter X of the MO requires that all dealers have written recall procedures and dealers are required to follow those procedures when recalls are necessary

J. Molluscan shellfish product that is recalled as a result of an illness outbreak associated with *V.v.* or *V.p.* may be reconditioned. Validated reconditioning processes include subjecting product to validated PHPs or placing product into approved, conditionally approved, conditionally restricted, or restricted growing areas for an appropriate period of time, not less than fourteen (14) days, with appropriate controls and documentation to be determined by the State Shellfish Control Authority (SSCA).

Clarifications/Recommendations

No comments

Section IV. Chapter V. Illness Outbreaks and Recall Guidance Document Section A. p. 373

Clarifications/Recommendations

The following language includes errors which were never intended to be included into this guidance document. (See highlights)

A product recall may not be appropriate when an illness outbreak investigation reveals the following, including but not limited to:

1. When the etiological and epidemiological evidence confirms that shellfish from a specific growing area or lease area are the cause of the illnesses

2. When it has been determined that a specific process conducted by a dealer is the cause of the illnesses

A product recall may not be appropriate when an illness outbreak investigation reveals, but is not limited to, the implicated product is no longer available in the market.

In 2009 the ISSC adopted Proposal 09-236 which included the following language.

A product recall is appropriate when an illness outbreak investigation reveals the following, including but not limited to:

1. When the etiological and epidemiological evidence confirms that shellfish from a specific growing area or lease area are the cause of the illnesses

2. When it has been determined that a specific process conducted by a dealer is the cause of the illnesses

A product recall may not be appropriate when an illness outbreak investigation reveals, but is not limited to, the implicated product is no longer available in the market.