Proposal Subject: Outbreaks of Shellfish Related Illness

Specific NSSP Guide Reference: NSSP Guide Section II Model Ordinance Chapter I Shellfish Sanitation Program Requirements for the Authority

Text of Proposal/ Requested Action

@.01 Outbreaks of Shellfish-Related Illness.

D. When shellfish harvested within ten (10) days of each other from the same growing area are implicated in an illness outbreak involving ~~two (2)~~three (3) 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~~.~~ ; and
(5) Harvest tags, dealer tags and shipping and receiving records to determine the origin of shellfish implicated in an illness outbreak. Copies of harvest tags, dealer tags and shipping and receiving records are to be provided to the Authority. Failure to provide accurate harvest tags, dealer tags or shipping and receiving records substantiating the origin of the shellfish would preclude the existence of an epidemiological association.

E. 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.

F. When the investigation outlined in Section .02 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 (unless more than thirty (30) days have passed since the last reported illness and no additional illnesses have occurred;
(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 (unless more than thirty (30) days have passed since the last reported illness [associated date of harvest] and no implicated product is likely to remain in the market place).

Public Health Significance:

Cost Information (if available):

Action by 2013 Task Force II

Recommended adoption of Proposal 13-202 as substituted.

Chapter II. Risk Assessment and Risk Management

@.01 Outbreaks of Shellfish Related Illness

F. When the investigation outlined in Section @.01 A. indicates the illness(es) are associated with the naturally occurring pathogen *Vibrio parahaemolyticus (V.p.),* the Authority shall determine the number of laboratory confirmed cases epidemiologically associated with implicated area and actions taken by the Authority will be based on the number of cases and the span of time as follows.

(1) When sporadic cases do not exceed a risk of one (1) illness per 100,000 servings or involves at least two (2) but not more than four (4) cases occurring within a thirty (30) day period from an implicated area in which no two (2) cases occurred from a single harvest day, the Authority shall determine the extent of the implicated area. The Authority will make reasonable attempts to ensure compliance with the existing Vibrio Management Plan.

(2) When the risk exceeds one (1) illness per 100,000 servings within a thirty (30) day period or when cases exceed four (4) but not more than ten (10) over a thirty (30) day period from the implicated area and when two (2) or more cases but less than four (4) cases occur from a single harvest day from the implicated area, the Authority shall:

(a) Determine the extent of the implicated area; and
(b) Immediately place the implicated portion(s) of the harvest area(s) in the closed status; and
(c) As soon as determined by the Authority, transmit to the FDA and receiving States information identifying the dealers shipping the implicated shellfish.

(3) When the number of cases exceeds ten (10) illnesses within a thirty (30) day period from the implicated area or four (4) cases occurred from a single harvest date from the implicated area, The Authority shall:

(a) Determine the extent of the implicated area; and
(b) Immediately place the implicated portion(s) of the harvest area(s) in the closed status; and
(c) Promptly initiate a voluntary industry recall consistent with the Recall Enforcement Policy, Title 21 CFR Part 7 unless the Authority determines that a recall is not required where

the implicated product is no longer available on the market or when the Authority determines that a recall would not be effective in preventing additional illnesses. The recall shall include all implicated products.

(d) Issue a consumer advisory for all shellfish (or species implicated in the illness).

(4) When a growing area has been closed as a result of *V.p.* cases, the Authority shall keep the area closed for the following periods of time to determine if additional illnesses have occurred:

(a) The area will remain closed for a minimum of seven (7) days when sporadic cases do not exceed a risk of one (1) illness per 100,000 servings or involves four (4) or less cases occurring within a thirty (30) day period from the implicated area in which no two (2) cases occurred from a single harvest date from the implicated area.

(b) The area will remain closed for a minimum of fourteen (14) days when the risk exceeds one (1) illness per 100,000 servings within a thirty (30) day period or cases exceed four (4) but not more than ten (10) cases over a thirty (30) day period from the implicated area with two (2) or more cases but less than four (4) cases occurring from a single harvest date from the implicated area.

(c) The area will remain closed for a minimum of twenty-one (21) days when the number of cases exceeds ten (10) illnesses within thirty (30) days or four (4) cases occur from a single harvest date from the implicated area

(5) Prior to reopening an area closed as a result of the number of cases exceeding ten (10) illnesses within thirty (30) days or four (4) cases from a single harvest date from the implicated area, the Authority shall:

(a) Collect and analyze samples to ensure that tdh does not exceed 10/g and trh does not exceed 10/g; or other such values as determined appropriate by the Authority based on studies.

(b) Ensure that environmental conditions have returned to levels not associated with *V.p.* cases.

(6) Shellfish harvesting may occur in an area closed as a result of *V.p.* illnesses when the Authority implements one or more of the following controls:

(a) Post-harvest processing using a process that has been validated to achieve a two (2) log reduction in the levels of total *Vibrio parahaemolyticus* for Gulf and Atlantic Coast oysters and a three (3) log reduction for Pacific Coast oysters;

(b) Restricting oyster harvest to product that is labeled for shucking by a certified dealer, or other means to allow the hazard to be addressed by further processing;

(c) Other control measures that based on appropriate scientific studies are designed to ensure that the risk of *V.p.* illness is

no longer reasonably likely to occur, as approved by the Authority.

Action by 2013 General Assembly Adopted recommendation of 2013 Task Force II on Proposal 13-202.