

NSSP Guide for the Control of Molluscan Shellfish

Section I. Model Ordinance

Chapter II. Risk Assessment and Risk Management

@.01 Outbreaks of Shellfish Related Illness

Insert New Section:

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 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 a hydrologically connected water body in which no two (2) cases occurred from a single harvest day, the Authority shall:
 - (a) Determine the extent of the hydrologically connected water body, and
 - (b) Issue a consumer advisory for all shellfish (or species implicated in the illness) from the implicated area; and
 - (c) 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, and
- (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 a hydrologically connected water body and when two (2) or more cases but less than four (4) cases occur from a single harvest day, the Authority shall:
 - (a) Determine the extent of the hydrologically connected water body; and
 - (b) Issue a consumer advisory for all shellfish (or species implicated in the illness) from the implicated growing area; and
 - (c) Immediately place the implicated portion(s) of the harvest area(s) in the closed status; and
 - (d) 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; and
 - (e) 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 a hydrologically connected growing area or four (4) cases occurred from a single harvest date, The Authority shall:
- (a) Determine the extent of the hydrologically connected water body; 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. The recall shall include all implicated products.
- (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 a hydrologically connected water body in which no two (2) cases occurred from a single harvest date.
 - (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 a hydrologically connected water body with two (2) or more cases but less than four (4) cases occurring from a single harvest date.
 - (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 a hydrologically connected growing area.
- (5) Prior to reopening an area closed as a result of *V.p.* cases, 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
 - (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) Limiting the time to one (1) hour from harvest to an internal temperature of 50°.
- (d) 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.