Proposal Subject: Addition of the Requirements for the Authority During a Suspected Oyster Related Outbreak of *Norovirus*

Specific NSSP Guide Reference: Section II Model Ordinance Chapter II. Risk Assessment and Risk Management @.01 Outbreaks of Shellfish Related Illness

Key Words: *Norovirus*

Text of Proposal/ Requested Action: @.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]), and in the case of *Norovirus* being reported for more than one retail outlet or location of consumption), 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.

Public Health Significance: The basis for this addition is to allow the authority time to determine if the suspected oyster-related *Norovirus* outbreak is due to growing area problems or problems associated with the location where the oysters were served. Due to the nature of *Norovirus*, it would be expected that if the suspected outbreak were growing area related, illnesses would be seen at more than one location. With the known prevalence of *Norovirus* and the ease with which it can be spread by human to human and human to food contact, it is difficult to determine the actual cause within 24 hours when faced with illness reported from a single location.

The Centers for Disease Control and Prevention (CDC) estimates that *Norovirus* cause 23 million cases of acute gastroenteritis annually, making *Norovirus* the leading cause of gastroenteritis in the United States (CDC, 2006; Fankhauser, et al., 2002, Mead, et al., 1999).

Of viruses, only the common cold is reported more often than viral gastroenteritis (N*orovirus)* (Benson & Merano, 1998).
According to the CDC:

Food and drinks can very easily become contaminated with *Norovirus* because the virus is so small and because it probably takes fewer than 100 *Norovirus* particles to make a person sick. Food can be contaminated either by direct contact with contaminated hands or work surfaces that are contaminated with stool or vomit, or by tiny droplets from nearby vomit that can travel through air to land on food. Although the virus cannot multiply outside of human bodies, once on food or in water, it can cause illness.

People working with food who are sick with *Norovirus* gastroenteritis are a particular risk to others, because they handle the food and drink many other people will consume.

Since the virus is so small, a sick food handler can easily – without meaning to – contaminate the food he or she is handling. Many of those eating the contaminated food may become ill, causing an outbreak.

Outbreaks of *Norovirus* gastroenteritis have taken place in restaurants, cruise ships, nursing homes, hospitals, schools, banquet halls, summer camps, and family dinners – in other words, places where often people have consumed water and/or food prepared or handled by others. It is estimated that as many as half of all food-related outbreaks of illness may be caused by *Norovirus*. In many of these cases, sick food handlers were thought to be implicated.

Cost Information (if available):

Action by 2011 Growing Area Classification Committee

Recommended adoption of the suggested language to Chapter II @ .01 Outbreaks of Shellfish – Related Illness, B., C., D. and @ .02 Presence of Human Pathogens in Shellfish Meats. B. Growing Area Investigation (3), (4) & (5) as submitted by the Executive Office.

Modify Model Ordinance Chapter II. Risk Assessment and Risk Management:

@.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*.

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 if the Authority should request 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.

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, 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 Code of Federal Regulations Part 7. The recall shall include all implicated products.

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, the ISSC and the FDA Regional Shellfish Specialist of the problem; and
~~(2)Promptly initiate recall procedures consistent with the Recall Enforcement Policy Title 21Code of Federal Regulations Part 7. The recall shall include all implicated products.~~
(2) Determine if the Authority should request 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.

@. 02 Presence of Human Pathogens in Shellfish Meats.

B. Growing Area Investigation.
(1) The Authority shall review the following factors:
(a) The documentation to trace the shellfish to its source;
(b) (The classification assigned to the growing area and whether the sanitary survey data supporting that classification is current; and
(c) The probability of illegal harvesting from areas classified as restricted or prohibited, or in the closed status.
(2) The Authority shall take no further action when the Authority determines that:
(a) The growing area is properly classified;
(b) No illegal harvesting is taking place; and
(c) There is no reason to believe that the growing area is the source of the pathogens.
(3) When the Authority determines that the growing area is not properly classified, the Authority shall take immediate action to:
(a) Change the existing classification to the correct classification; or
(b) Close the growing area until the correct classification can be determined; and
~~(4)~~ (c) ~~Promptly initiate recall procedures consistent with the Recall Enforcement Policy Title 21 of Code of Federal Regulations Part 7.~~ Determine if the Authority should request 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.
(4)When the Authority determines that the growing area may be the source of pathogens and~~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, the Authority shall request a voluntary recall by firms. The firms will use procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7. The recall shall include all implicated products.

(5) When the Authority determines that illegal harvesting is taking place, the Authority shall determine if the Authority should request a voluntary recall by firms The firms will use procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7. The recall shall include all implicated products. ~~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 Investigation.

(1) The Authority shall evaluate the distribution and processing of the shellfish. This investigation may include collection of additional meat samples.

(2) The Authority shall take no further action when the Authority determines that there is no reason to believe a problem exists in the distribution or processing of the shellfish.

(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 determine if the Authority should request 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.

~~(3)promptly initiate recall procedures consistent with the Recall Enforcement Policy Title 21of Code of Federal Regulations Part 7.~~

Action by 2011 Task Force I

Recommended adoption of Substitute Proposal 11-114 as amended.

Modify Model Ordinance Chapter II. Risk Assessment and Risk Management:

@.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;

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(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*.

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 ~~if the Authority should request~~ 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.

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, 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 Code of Federal Regulations Part 7. The recall shall include all implicated products.

D. When the investigation outlined in §.02B demonstrates that the illnesses are related to postharvesting 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) ~~Determine~~ Initiate a ~~if the Authority should request~~ 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.

@. 02 Presence of Human Pathogens in Shellfish Meats.

B. Growing Area Investigation.

(1) The Authority shall review the following factors:

(a) The documentation to trace the shellfish to its source;

(b) (The classification assigned to the growing area and whether the sanitary survey data supporting that classification is current; and

(c) The probability of illegal harvesting from areas classified as restricted or prohibited, or in the closed status.

(2) The Authority shall take no further action when the Authority determines that:

(a) The growing area is properly classified;

(b) No illegal harvesting is taking place; and

(c) There is no reason to believe that the growing area is the source of the pathogens.

(3) When the Authority determines that the growing area is not properly classified, the Authority shall take immediate action to:

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

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

(c) Determine whether to initiate a ~~if the Authority should request~~ 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.

(4) When the Authority determines that the growing area may be the source of pathogens and the pathogens exceed tolerance levels, the Authority shall request a voluntary recall by firms. The firms will use procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7. The recall shall include all implicated products.

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(2) The Authority shall take no further action when the Authority determines that there is no reason to believe a problem exists in the distribution or processing of the shellfish.

(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 determine whether to initiate a~~if the Authority should request~~ 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.

Action by 2011 General Assembly Adopted recommendation of 2011 Task Force I on Proposal 11-114.

Action by FDA February 26, 2012 Concurred with Conference action on Proposal 11-114.