Proposal Subject: *Vibrio vulnificus* Management

Specific NSSP Guide Reference: Section II Model Ordinance Chapter II Risk Assessment and Risk Management @04 *Vibrio vulnificus* Risk Management for Oysters

Text of Proposal/ Requested Action: Effective January 1, 2012:

@.04 *Vibrio vulnificus* Risk Management for Oysters

A. For states having 2 or more etiologically confirmed shellfish-borne *Vibrio vulnificus* illnesses since 1995 traced to the consumption of commercially harvested raw or undercooked oysters that originated from the waters of that state (Source State), the Authority shall develop and implement *a Vibrio vulnificus* Risk Management Plan.

B. The Source State's *Vibrio vulnificus* Risk Management Plan shall define the administrative procedures and resources necessary to accomplish (i.e. establish and maintain) involvement by the state in a collective illness risk reduction program. The goal of the *Vibrio vulnificus* Risk Management Plan will be to reduce the risk per serving to a 60% illness rate reduction for etiologically confirmed shellfish-borne *Vibrio vulnificus* septicemia illnesses reported collectively by California, Florida, Louisiana, and Texas, from the consumption of commercially harvested raw or undercooked oysters to a level equivalent to a 60% illness rate reduction from 1995 – 1999 baseline average illness rate of 0.278 per million.

C. The Source State's *Vibrio vulnificus* Risk Management Plan shall include, at a minimum:

(1) The ISSC Consumer Education Program targeted toward individuals who consume raw oysters and whose health condition(s) increase their risk for *Vibrio vulnificus* illnesses;

(2) A process to collect standardized information for each *Vibrio vulnificus* illness: including underlying medical conditions; knowledge of disease status; prior counseling on avoidance of high risk foods, including raw oysters; existence of consumer advisories at point of purchase or consumption; and, if possible, whether consumer was aware and understood the advisories;

(3) A standardized process for tracking products implicated in *Vibrio vulnificus* illnesses; and

(4) Identification and implementation of the controls, or equivalent controls, which produced an illness per serving equivalent to a 60% illness rate reduction in the core states. These controls include:

(a) Labeling all oysters, "For shucking by a certified dealer", when the Average Monthly Maximum Water Temperature exceeds 75°F;

(b) Subjecting all oysters intended for the raw, half-shell market to an Authority- approved post harvest processing that reduces the *Vibrio vulnificus* levels to <1000 MPN/gram when the Average Monthly Maximum Water Temperature exceeds 75°F;

(c) Closing shellfish growing areas for the purpose of harvest of oysters intended for the raw, half-shell market when the Average Monthly Maximum Water Temperature exceeds 75°F;

(d) Labeling all oysters, "For shucking by a certified dealer", during the months of May through September, inclusive;
(e) Subjecting all oysters intended for the raw, half-shell market to an Authority-approved post harvest processing that reduces the *Vibrio vulnificus* levels to <1000 MPN/gram when the Average Monthly Maximum Water Temperature exceeds 75°F; and
(f) Closing shellfish growing areas for the purpose of harvesting oysters intended for the raw, half-shell market during the months of May through September, inclusive.

Public Health Significance: A control standard that is easier to achieve will encourage industry acceptance by allowing for more PHP options (ie. high-salinity relay, and depuration). This would still very likely have a significant impact on reducing illnesses (considering the quagmire that the conference is in when dealing with V.v management). For the scientists: The <1000 MPN/gram level of V.v. may not be proven to reduce all risk of V.v. illness, but it is not disproven, either, that such a control level would help to significantly reduce the number of illnesses.

Cost Information (if available): None

Action by 2011 Task Force II Recommended adoption of Proposal 11-203 as amended.

Task Force II further recommended:

1. That the language of this proposal be incorporated into @.04 E. (1) (b) should Proposal 11-201-A be adopted.

2. The Executive Board appoint a committee to review the definition of post harvest processing to incorporate processing to achieve reductions to levels other than <30 MPN/g.

3. An effective date of January 1, 2012 be established for the Proposal.

Effective January 1, 2012:

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B. The Source State's *Vibrio vulnificus* Risk Management Plan shall define the administrative procedures and resources necessary to accomplish (i.e. establish and maintain) involvement by the state in a collective illness risk reduction program. The goal of the *Vibrio vulnificus* Risk Management Plan will be to reduce the risk per serving to a 60% illness rate reduction for etiologically confirmed shellfish-borne *Vibrio vulnificus* septicemia illnesses reported collectively by California, Florida, Louisiana, and Texas, from the

consumption of commercially harvested raw or undercooked oysters to a level equivalent to a 60% illness rate reduction from 1995 – 1999 baseline average illness rate of 0.278 per million.

C. The Source State's *Vibrio vulnificus* Risk Management Plan shall include, at a minimum:

(1) The ISSC Consumer Education Program targeted toward individuals who consume raw oysters and whose health condition(s) increase their risk for *Vibrio vulnificus* illnesses;
(2) A process to collect standardized information for each *Vibrio vulnificus* illness: including underlying medical conditions; knowledge of disease status; prior counseling on avoidance of high risk foods, including raw oysters; existence of consumer advisories at point of purchase or consumption; and, if possible, whether consumer was aware and understood the advisories;
(3) A standardized process for tracking products implicated in *Vibrio vulnificus* illnesses; and
(4) Identification and implementation of the controls, or equivalent controls, which produced an illness per serving equivalent to a 60% illness rate reduction in the core states. These ~~controls~~ include one or more of the following control measures:
   (a) Labeling all oysters, "For shucking by a certified dealer", when the Average Monthly Maximum Water Temperature exceeds 75°F;
   (b) Subjecting all oysters intended for the raw, half-shell market to an Authority- approved post harvest processing that reduces the *Vibrio vulnificus* levels to <0 MPN/gram when the Average Monthly Maximum Water Temperature exceeds 75°F;
   (c) Closing shellfish growing areas for the purpose of harvest of oysters intended for the raw, half-shell market when the Average Monthly Maximum Water Temperature exceeds 75°F;
   (d) Labeling all oysters, "For shucking by a certified dealer", during the months of May through September, inclusive;
   (e) Subjecting all oysters intended for the raw, half-shell market to an Authority-approved post harvest processing that reduces the *Vibrio vulnificus* levels to <1000 MPN/gram when the Average Monthly Maximum Water Temperature exceeds 70~~5~~°F (product meeting this requirement does not meet the minimum requirements for labeling claims); ~~and~~
   (f) Closing shellfish growing areas for the purpose of harvesting oysters intended for the raw, half-shell market during the months of May through September, inclusive.

Action by 2011 General Assembly

Adopted Section @.04 C. (4) (e) of Proposal 11-203 as amended by Task Force II.

The remainder of Proposal 11-203 was addressed by General Assembly action on Proposal 11-201A.

Action by FDA February 26, 2012

Concurred with Conference action on Proposal 11-203.