

Proposal Subject: *Vibrio vulnificus* Risk Management for Oysters

Specific NSSP Guide Reference: NSSP Guide Section II. Model Ordinance
Chapter II. Risk Assessment and Risk Management

Text of Proposal/ Requested Action The *Vibrio* Management Committee recommends that the existing language for Section @.04 *Vibrio vulnificus* Risk Management for Oysters remain in the 2009 update of the Guide.

The Committee also recommends that a new section be added to the 2009 update of the NSSP Guide as follows.

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** rate of 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.** by 40 percent for years 2005 and 2006 (average) and by 60 percent for years 2007 and 2008 (average) from the average illness rate for the years 1995 – 1999 of 0.303/million. The list of states (California, Florida, Louisiana, Texas) used to calculate rate reduction may be adjusted if after a thorough review, epidemiological and statistical data demonstrates that it would be appropriate. The illness rate shall be calculated as the number of illnesses per unit of population. The goal may be reevaluated prior to the year 2006 and adjusted in the event that new science, data, or information becomes available. State's compliance with the Plan will require States to maintain a minimum of 60% reduction in years subsequent to 2008. Determination and compliance after 2008 will be based on two year averages beginning in 2009.

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.** preparation for achieving a goal of post harvest processing capacity of 25 percent of all oysters intended for the raw, half-shell market during the months of May through September harvested from a Source State by the end of the third year (December 31, 2004). The percentage of post harvest processing will include the capacity of all operational plants and the capacity of plants under construction;
 - (5) Identification and preparation for implementation of required post harvest processing capacity of 50% of all oysters intended for the raw, half-shell market during the months of May through September, harvested from a Source State, which shall be implemented should the 40 percent illness reduction goal not be achieved by December 31, 2006. The percentage of post harvest processing will include the capacity of all operational plants and the capacity of plants under construction. In the alternative, the state may utilize the control measures, or equivalent control measures, listed in @.04, (C), (6) (a), (b), (c), and (d) below for such periods of time which, in combination with post harvest processing, will provide equivalent outcomes. This portion of the plan shall be completed no later than December 31, 2005; and
 - (46) Identification and preparation for implementation of one or more of the following controls, or equivalent controls, which shall be implemented should the 60 percent rate of illness reduction goal not be achieved collectively by 2008. The control measures identified in the plan shall be appropriate to the state and reflect that state's contribution to the number of Vv illnesses and the controls that have been implemented by each state. This portion of the Plan shall be completed no later than December 2007. The temperature and month of the year parameters identified in the following controls may be adjusted by the ISSC Executive Board as recommended by the Vibrio Management Committee (VMC) on a state by state basis, as needed to achieve the established illness reduction goal. The adjustment to the State's plan can take into account the illness rate reduction that has occurred since the last review of the plan.
 - (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 <30 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 a post harvest processing that is both approved by the Authority and reduces the *Vibrio vulnificus* levels to <30 MPN/gram during the months of May through September, inclusive; 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:	None submitted.
Cost Information (if available):	None submitted.
Action by 2009 Task Force II:	Recommended adoption of Proposal 09-207 as submitted.
Action by 2009 General Assembly	Adopted recommendation of 2009 Task Force II on Proposal 09-207.
Action by USFDA 02/16/2010	FDA does not concur with action by the Conference to adopt Proposal 09-207. Although FDA was initially supportive of the risk based approach set forth in Proposal 09-207, given the current situation regarding efforts to control <i>Vibrio vulnificus</i> (<i>Vv</i>) illnesses and deaths, and in consideration of activities and discussions planned in this area in the near future, FDA believes that this proposal is premature. For this reason, FDA recommends that Proposal 09-207 be referred back to the Conference for consideration after further consideration of Proposal 00-201.
Action by ISSC Executive Board March 2010	Appoint a workgroup to continue to explore implementation of Proposal 09-207 and look at types of controls to determine the risk reduction the controls could achieve with each type of control. USFDA stated that they will be withdrawing their non concurrence of Proposal 09-207.
Action by USFDA April 13, 2010	In response to discussions at the March 2010 Vibrio Management Committee (VMC) and ISSC Executive Board meetings in Denver, Colorado, and based on discussions during the March 2010 meetings, FDA now supports ISSC efforts under Proposal 09-207 to shift from an “illness rate reduction” goal to a “risk reduction” approach for <i>Vv</i> , based on risk per serving ¹ . Therefore, FDA rescinded the Food and Drug Administration’s (FDA) non-concurrence with adoption of Proposal 09-207. FDA reiterated comments made during the March 2010 meetings that first, while FDA remains committed to reducing to the extent practical <i>Vv</i> illnesses associated with the consumption of raw oysters, the Agency formally acknowledges concerns raised by the ISSC, State officials, the shellfish industry, and members of Congress about the feasibility of implementing post-harvest processing (PHP) for half shell Gulf Coast oysters harvested during warm months.
	¹ Such an approach is in keeping with the ISSC’s current approach for managing <i>Vibrio parahaemolyticus</i> (<i>Vp</i>) using the FDA <i>Vp</i> risk calculator to achieve a risk per serving goal of 1 in 100,000 (10^{-5}). Moving from an illness rate reduction that is based on illness counting and shifting to a “risk reduction,” based on modeling risk per serving, would eliminate the problems associated with the current <i>Vv</i> illness rate reduction goal (e.g., crediting illness reductions resulting from the California post-harvest processing action, crediting the apparent rate reduction associated with population increases, and crediting illness rate reductions in a few reporting states while at the same time the incidence of <i>Vv</i> nationally remains at a relatively constant level).