

**Proposal Subject:** *Vibrio vulnificus* Risk Management Plan for Oysters exemption for licensed shellfish harvesters and certified dealers who produce fewer than 1.5 million raw oysters per year and/or sell all of their oysters directly to retailers.

**Specific NSSP Guide Reference:** Section II, Chapter II Risk Assessment and Risk Management @.04 *Vibrio vulnificus* Risk Management for Oysters, New B.

**Text of Proposal/ Requested Action** Add a new section; Section II, Chapter II Risk Assessment and Risk Management @.04 B. *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* Management Plan.

B. Exemptions. This section does not apply to licensed shellfish harvesters and certified shellfish dealers who produce fewer than 1.5 million raw oysters per year and/or sell all of their oysters directly to retailers.

~~B.C.~~ The Source State's *Vibrio vulnificus* 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 reduction program. The goal of the *Vibrio vulnificus* Management Plan will be to reduce the 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 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.

**Public Health Significance:** The *Vibrio vulnificus* Risk Management Plan for Oysters was introduced to the ISSC as being modeled after the U.S. Egg Safety Action Plan. The NSSP which has been in existence since 1925 is far more restrictive than FDA's October 2004 proposed rule for Egg Safety and the Prevention of Salmonella Enteritidis in Shell Eggs During Production and certain egg producers.

The most recent data from the Centers for Disease Control and Prevention (CDC) show that SE illnesses have essentially remained steady for the past several years. CDC estimated that 118,000 illnesses were caused by consumption of SE-contaminated eggs in 2001. Accordingly, FDA believes that further actions to improve egg safety—building upon the safe consumer handling labeling and egg refrigeration at retail rule of 2000—are the most effective way to achieve our public health goals of a 50% reduction in overall salmonellosis and a 50% reduction in SE outbreaks by 2010.

In comparison to an annual average of less than 40 *V.v.* infections to high-risk consumers that are attributed to shellfish, approximately half of those persons infected die, there are approximately 40,000 cases of salmonellosis reported in the United States annually. Because many milder S.E. cases are not diagnosed or reported, the actual number of S.E. infections may be thirty or more times greater. It is estimated that approximately 600 persons die each year with acute salmonellosis. Just as with *V.v.* infections, Salmonellosis infections are more common in the summer than winter. Young children, the elderly, and the immunocompromised are the most likely to have severe S.E. infections.

Since the FDA has proposed a rule that exempts certain egg producers from the rule and the rule is far less burdensome to the egg industry than the *Vibrio vulnificus* Risk Management Plan for Oysters is on the Gulf oyster industry, an exemption should be given to oyster producers as suggested.

<b>Cost Information (if available):</b>	None
<b>Action by 2005 Task Force I</b>	Recommended referral of Proposal 05-100 to the appropriate committee as determined by the Conference Chairperson.
<b>Action by 2005 General Assembly</b>	Adopted recommendation of 2005 Task Force I.
<b>Action by USFDA</b>	Concurred with Conference action.
<b>Action by 2007 Vibrio Management Committee</b>	Recommended adoption of Proposal 05-100 as a research need. More data is needed on the number of small harvesters and the number of small dealers; the percentage of all harvesters and dealers in the affected states that are in this category; the number of illnesses attributable to these small harvesters or dealers; other food commodities that allow exemptions from public health requirements based on the small size of the harvester/producer/processor; and the pathogens of concern with these other foods.
<b>Action by 2007 Task Force I</b>	Recommended adoption of the Vibrio Management Committee recommendation on Proposal 05-100.
<b>Action by 2007 General Assembly</b>	Adopted recommendation of 2007 Task Force I.
<b>Action by USFDA</b>	December 20, 2007 Concurred with Conference action.
<b>Action by 2009 Research Guidance Committee</b>	Recommended no action. Rationale: No data presented.
<b>Action by 2009 Task Force I</b>	Recommended referral of Proposal 05-100 to the Executive Board. The Task Force strongly urges the Executive Board to identify approaches to gather the information necessary for further deliberation of the issue.
<b>Action by 2009 General Assembly</b>	Adopted recommendation of 2009 Task Force I on Proposal 05-100.

**Action by Executive Board 10/23/2009** Approved referral of Proposal 05-100 to the *Vibrio* Management Committee. The *Vibrio* Management Committee will be asked to hold a conference call within the next 30 days to identify the types of information needed and who best can acquire that data.

**Action by USFDA 02/16/2010** Concurred with Conference action on Proposal 05-100 with the following comments and recommendations for ISSC consideration.

While FDA agrees to participate in *Vibrio* Management Committee discussions to identify approaches for gathering information that may further deliberation on Proposal 05-100, it is the Agency's current thinking that exemption of any harvester or dealer, regardless of operational size, from NSSP *Vv* controls is not an appropriate public health approach. FDA considers it essential that all harvesters and all dealers employ NSSP *Vv* control measures. Any allowance for exemption would be contrary to the food safety and public health protection initiatives of the NSSP. In consideration of the ongoing and developing efforts to address *Vv* illnesses and deaths, FDA believes it would be more prudent for the Executive Board to take no action on Proposal 05-100, or at least table further consideration pending consideration of Proposal 00-201.