

Proposal for Consideration at the Interstate Shellfish Sanitation Conference 2011 Biennial Meeting		<input type="checkbox"/> Growing Area <input checked="" type="checkbox"/> Harvesting/Handling/Distribution <input type="checkbox"/> Administrative
Name of Submitter:	Vibrio Management Committee	
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Proposal Subject:	Vibrio vulnificus Controls	
Specific NSSP Guide Reference:	Section II Model Ordinance Chapter II Risk Assessment and Risk Management @.04 Vibrio vulnificus Risk Management for Oysters Section IV Guidance Documents Chapter IV Naturally Occurring Pathogens .04 Naturally Occurring Pathogens	
Key Words:	Vibrio vulnificus Controls	
Text of Proposal/ Requested Action:	<p>During the January 2011 VMC meeting the Committee conducted an assessment of the effects of the 2010 Vv controls implemented by the Vv source states. The Committee also reviewed the Vv illness rate reductions for 2009 and 2010. The Committee concluded that the 60% goal had not been achieved for 2009, 2010 or 2009 and 2010 average. After a lengthy discussion which is described below, The VMC recommended, with Executive Board approval, the appointment of a workgroup to develop other Vv control options which would be included in a VMC proposal to the ISSC. The workgroup has been appointed and is working to develop new concepts. The workgroup will include Proposal 09-207, which was adopted in 2009, as a part of their discussions. The purpose of the proposal is to provide notice to the ISSC membership of this activity. The ISSC membership will be provided the full details of final recommendations when available.</p> <p>Points of Discussion by the VMC during the January 2011 Meeting:</p> <p>Chapter II @.04 includes requirements for States that have had two (2) or more etiologically confirmed shellfish borne Vv illnesses since 1995. Section IV Guidance Documents Chapter IV Naturally Occurring Pathogens includes guidance for implementation of the Chapter II Model Ordinance requirements. The ISSC adopted these requirements after years of encouragement by the USFDA. The very controversial Vv debate began in 1994 and after much resistance the ISSC adopted Proposal 00-201 in 2001. The controls of Proposal 00-201 were premised around illness rate reduction to be achieved by 2008.</p> <p>Proposal 00-201 included the following three (3) major components:</p> <ol style="list-style-type: none"> (1) Consumer education: Each State Vv Management Plan was required to include a consumer education program. (2) The development of PHP capacity to treat 50% of Gulf oysters intended for raw half-shell consumption. The capacity was to be available should the 60% goals not be achieved. 	

	<p>(3) Control strategies that could be implemented if the 40% and 60% goals were not met.</p> <p>The implementation of Proposal 00-201 has been very controversial and problematic since 2001. The problems include:</p> <ol style="list-style-type: none"> (1) Our efforts to count cases for determining goal compliance has proven that illness reporting as it presently exists does not provide an adequate tool for determining the effectiveness of controls to lower risk for <i>Vv</i>. (2) The use of four (4) states, especially California, has been publicly controversial. The FDA has stated that national illnesses should be used. (3) In October 2009 FDA publicly announced that the agency no longer supported ISSC efforts to address <i>Vv</i>. The FDA stated its intent to reformulate policy and use the Fish and Fishery Product Hazards and Control Guidance 4th Edition to regulate <i>Vv</i> in raw oysters. (4) States have had difficulty enforcing industry compliance. (5) Restricted use shellstock has been diverted to restaurants and sold raw. Two (2) deaths have been attributed. (6) FDA and ISSC have had disagreements regarding the responsibility for evaluating State compliance with <i>Vv</i> controls. (7) The goal is a collective five (5) State goal. Determining compliance by individual States is problematic. The <i>Vibrio</i> Management Committee (VMC) concluded at the January 2011 meeting that the 60% goal has not been achieved. (8) Results of Consumer Acceptance Study suggest consumers prefer traditional raw oysters at seven (7) days and PHP oysters at fourteen (14) days. Report indicates that most consumers would be unwilling to pay higher price for PHP oysters. RTI report suggests FDA should slow its efforts to mandate PHP. (9) Congress passed the Food Safety Modernization Act which specifically addresses PHP in Section 114. The Senate authors of Section 114 of the Food Safety Modernization Act (FSMA) correspond with ISSC providing clarification of the intent of Congress and the Administration. (10) The present goal approach for measuring success is not consistent with the other elements of the National Shellfish Sanitation Program (NSSP). <p>The Committee recommended additional time/temperature controls for April and November and recognized serious noncompliance issues in one Gulf State.</p>
<p>Public Health Significance:</p>	<p><i>Vibrio vulnificus</i> is a naturally occurring bacterium found in seawater along the Gulf, Atlantic, and Pacific coasts, although it is most prevalent in the warm waters of the Gulf of Mexico. <i>Vibrio vulnificus</i> can be transmitted to humans through the consumption of raw shellfish harvested from waters containing the organism. Oysters from the Gulf of Mexico have been recognized as the primary species of molluscan shellfish associated with <i>Vibrio vulnificus</i> illnesses in consumers. <i>Vibrio vulnificus</i> does not normally affect healthy individuals, but persons who are immunocompromised, especially those with chronic liver disease, are at greater risk for contracting <i>Vibrio vulnificus</i> from oyster consumption. In immunocompromised individuals, there is a risk for the organism to invade the bloodstream, resulting in potentially fatal septicemia. Although the annual number in the US of reported <i>Vibrio vulnificus</i> illnesses associated</p>

	<p>with oyster consumption is low, generally in the range of 30 to 35, the incidence of death among those individuals who contract the disease is high. Between 2001 and 2010 (10 years) there were 335 cases of illnesses with 157 deaths reported to CDC.</p> <p>Prior to 2001 the NSSP controls did not offer a strategy for controlling <i>Vibrio vulnificus</i>. In an effort to better control <i>Vibrio vulnificus</i> in oysters, in 2001 the Interstate Shellfish Sanitation Conference (ISSC) developed a <i>Vibrio vulnificus</i> Control Plan for inclusion in the NSSP.</p> <p>The Plan adopted by the ISSC included a 60% illness rate reduction goal that was to be achieved by the end of 2008. To present the goal has not been achieved. The Plan also included several mandatory controls which could be implemented if necessary to achieve the 60% goal. Recognizing the potential economic damage of these controls to the industry the ISSC has continued to investigate other controls that could potentially assist the Gulf States in achieving the 60% goal. Very stringent time to temperature controls were implemented in 2010. However, the implementation of these controls did not result in goal attainment.</p> <p>The identified mandatory requirements included Post Harvest Processing (PHP) and closures. To evaluate the impact of requiring PHP, FDA contracted with RTI to conduct an economic assessment. The report entitled “Analysis of How Post-Harvest Processing Technologies for Controlling <i>Vibrio vulnificus</i> Can Be Implemented” suggest that it would take a minimum of 3 years and significant financial investment both by private and public sectors to prepare the industry for a PHP requirement. The other listed mandatory control which would likely result in 60% illness rate reduction was closure. Those supported the inclusion of closures thought that PHP would be a viable option by 2008.</p> <p>Concerns for the economic impact of <i>Vibrio vulnificus</i> control prompted Congress and the Administration to include inclusion of Section 114 in the Food Safety Modernization Act. Although Section 114 is directed to FDA, the authors of the Section have communicated that they expect ISSC to consider economic effects in addressing <i>Vibrio vulnificus</i>. These directives make it very difficult to impose mandatory PHP or closures should the present expanded time to temperature approach prove ineffective in meeting the intended goals of 00-201. The VMC Proposal Workgroup will use the guidance of Procedure XIV and the ISSC Policy Statement on Consumption of Raw Molluscan Shellfish in characterizing the <i>Vibrio vulnificus</i> problem. From this characterization the workgroup will develop <i>Vibrio vulnificus</i> recommendations for VMC consideration.</p>
<p>Cost Information (if available):</p>	