

Proposal for Task Force Consideration at the 2009 Biennial Meeting Interstate Shellfish Sanitation Conference		<input type="checkbox"/> Growing Area <input checked="" type="checkbox"/> Harvesting/Handling/Distribution <input type="checkbox"/> Administrative
Name of Submitter:	US Food and Drug Administration	
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Proposal Subject:	Revising Post Harvest Processing Control Measure for a <i>Vibrio parahaemolyticus</i> Control Plan	
Specific NSSP Guide Reference:	NSSP Guide Section II. Model Ordinance Chapter II. Risk Assessment and Risk Management @.05 <i>Vibrio parahaemolyticus</i> Control Plan	
Text of Proposal/ Requested Action	<p>B. Control Plan</p> <p>(4) For States required to implement <i>Vibrio parahaemolyticus</i> Control Plans, the Plan shall include the administrative procedures and resources necessary to accomplish the following:</p> <p>(a) Establish one or more triggers for when control measures are needed. These triggers shall be the temperatures in § B. (2) where they apply, or other triggers as determined by the risk evaluation.</p> <p>(b) Implement one or more control measures to reduce the risk of <i>Vibrio parahaemolyticus</i> illness at times when it is reasonably likely to occur. The control measures may include:</p> <p>(i) Post harvest processing using a process that has been validated to <u>achieve a 2 log reduction in the</u> ensure that levels of total <i>Vibrio parahaemolyticus</i> <u>for Gulf and Atlantic Coast oysters and a 3 log reduction for Pacific Coast oysters</u> after processing do not exceed the average levels found in the area at times of the year when the State has determined that <i>Vibrio parahaemolyticus</i> illness is not reasonably likely to occur;</p> <p>(ii) Closing the area to oyster harvest;</p> <p>(iii) Restricting oyster harvest to product that is labeled "For Cooking Only;"</p> <p>(iv) Limiting time from harvest to refrigeration to no more than five hours, or other times based on modeling or sampling, as determined by the Authority in consultation with FDA;</p>	

	<p>(v) Limiting time from harvest to refrigeration such that the levels of total <i>Vibrio parahaemolyticus</i> after the completion of initial cooling to 60 °F (internal temperature of the oysters) do not exceed the average levels from the harvest water at time of harvest by more than 0.75 logarithms, based on sampling or modeling, as approved by the Authority;</p> <p>(vi) Other control measures that based on appropriate scientific studies are designed to ensure that the risk of <i>Vp</i> illness is no longer reasonably likely to occur, as approved by the Authority.</p>
Public Health Significance:	<p>Levels of <i>Vibrio parahaemolyticus</i> in time temperature abused oysters are not likely to commonly exceed 100,000/gram. Subjecting temperature abused oysters to post harvest processing that achieves a 2 log reduction for the Gulf and Atlantic and a 3 log reduction for the Pacific would ensure that levels in processed oysters are somewhat more protective of public health than levels under control measures listed in Chapter II. @.05 B. (4) (b) (iv) and (v) but likely less protective than levels under (ii) and (iii). As such, it is consistent with the ISSC goal of substantial risk reduction, rather than that of near elimination of risk. The existing language is substantially more protective still, and is more in keeping with the level of control needed for “for added safety” labeling of post harvest processed product.</p>
Cost Information (if available):	None.