

Proposal for Task Force Consideration at the 2009 Biennial Meeting Interstate Shellfish Sanitation Conference		<input type="checkbox"/> Growing Area <input type="checkbox"/> Harvesting/Handling/Distribution <input checked="" type="checkbox"/> Administrative
Name of Submitter:	John Karolus	
Affiliation:	Northeast Laboratory Examination Officers and Laboratory Management (NELEOM)	
Address:	Connecticut State Department of Agriculture Bureau of Agriculture PO Box 97 Milford, CT 06460	
Phone:	203-874-0696	
Fax:	203-783-9976	
Email:	jjkarolus@snet.net	
Proposal Subject:	Laboratory Methods	
Specific NSSP Guide Reference:	NSSP Guide Model Ordinance Chapter XVI. Post-Harvest Processing A. (1) (a)	
Text of Proposal/ Requested Action	<p>2003 NSSP Model Ordinance Chapter XVI Post Harvest Processing A (1) (a)</p> <p>For processes that target <i>Vibrio vulnificus</i>, the level of <i>Vibrio vulnificus</i> in the product that has been subjected to the process shall be non-detectable (<30 MPN/gram), to be determined by the use of the <i>Vibrio vulnificus</i> FDA approved EIA procedure of Tamplin, et al., as described in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, 1992, or other methods approved <u>by the Laboratory Methods Review Committee</u> for NSSP use.</p> <p>It has been reported by laboratories that the reagents for the Tamplin EIA test are not readily available. Other testing procedures are needed to do perform the analysis of <i>Vibrio vulnificus</i>. However, since not all methods listed in the <i>Bacteriological Analytical Manual</i> (BAM) are collaboratively tested and approved, methods that appear in the BAM cannot be accepted into the program based solely on the method's inclusion in the BAM. The Laboratory Methods Review Committee must review laboratory methods that are to be accepted into the ISSC program.</p>	
Public Health Significance:	Laboratory methods detecting the direct or indirect presence of human pathogens must be proven to consistently work at various laboratories throughout the country and in participating MOU countries. Detailed review of scientific data (preferably from collaborative studies) by the Laboratory Methods Review Committee must be done.	
Cost Information (if available):	None	
Action by 2005 Task Force III	Recommended referral of Proposal 05-305 to the Executive Board to investigate ISSC approaches to adopting laboratory methods for use in the NSSP.	
Action by 2005 General Assembly	Adopted recommendation of 2005 Task Force III.	
Action by ISSC Executive Board August 19, 2005	Recommended appointment of a workgroup to determine what the role of the ISSC should be in adoption of laboratory methods. The workgroup is also directed to look at similar conferences' procedures regarding laboratory methods approval. The workgroup will report their findings to the Executive Board at the March 2006 meeting.	

Action by USFDA	Concurred with Conference action.
Action by 2007 Laboratory Methods Review Committee	Recommended referral of Proposal 05-305 to an appropriate committee as determined by the Conference Chairman.
Action by 2007 Task Force III	Recommended adoption of Laboratory Methods Review Committee recommendation on Proposal 05-305.
Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force III.
Action by USFDA	December 20, 2007 Concurred with Conference action.