

Proposal for Consideration at the Interstate Shellfish Sanitation Conference 2011 Biennial Meeting	<input checked="" type="checkbox"/> Growing Area <input type="checkbox"/> Harvesting/Handling/Distribution <input type="checkbox"/> Administrative
Name of Submitter:	Laboratory Methods Review Committee/Patti Fowler Chair
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Proposal Subject:	Use of analytical methods other than NSSP methods
Specific NSSP Guide Reference:	2009 NSSP Section II Model Ordinance Chapter III Laboratory @ .02 Methods, Paragraphs A, C, D (1) and (2)
Text of Proposal/ Requested Action	<p>Revise Chapter III @.02 Methods, Paragraphs A, C and D as follows.</p> <p>Chapter III @ .02 Methods</p> <p>A. Microbiological. Methods, practices, and procedures for the analyses of shellfish and shellfish growing or harvest waters shall be the methods validated for use in the National Shellfish Sanitation Program under Procedure XVI of the Constitution, Bylaws and Procedures of the ISSC and/or cited in the Guidance Documents, Chapter II. Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests. <u>for the analyses of shellfish and shellfish harvest waters shall be:</u></p> <p>(1) <u>The methods validated for use in the National Shellfish Sanitation Program under Procedure XVI of the Constitution, Bylaws and Procedures of the ISSC and listed in the Guidance Documents, Chpater II. Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests.</u></p> <p>(2) <u>When there is an immediate need for a method of analysis and no NSSP approved analytical method exists, a validated AOAC, BAM or EPA method may be used.</u></p> <p>(3) <u>When there is an ongoing critical need for a method of analysis and no NSSP approved analytical method exista an emergent method may be used pursuant to .02 D (1) and (2) below.</u></p> <p>B. Chemical and Physical</p> <p>(1) Methods for the analysis</p> <p>(a) Be the current</p> <p>(b) Express results of all</p> <p>(2) When an AOAC.....</p> <p>(3) If a method is not</p> <p>C. Biotxin. Methods for the analyses of shellfish and shellfish harvest waters shall be:</p> <p>(1) The current AOAC and APHA</p> <p>(2) The current APHA method</p> <p>(3) Methods validated for use in the National Shellfish Sanitation Program under</p>

	<p>Procedure XVI of the Constitution, Bylaws and Procedures of the ISSC and/or listed <u>listed</u> in the Guidance Documents, Chapter II. Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests.</p> <p><u>(4) When there is an immediate need for a method of analysis and no NSSP approved method exists, a validated AOAC method may be used.</u></p> <p><u>(5) When there is an ongoing critical need for a method of analysis and no NSSP approved method exists, an emergent method may be used pursuant to .02 D (1) and (2) below.</u></p> <p>D. Emerging Methods.</p> <p>(1) When there is an immediate or <u>ongoing</u> critical need <u>for a method of analysis</u> and no NSSP approved method exists, and the ISSC Executive Board <u>may</u> considers allowing an unapproved or non-validated method to be used for a specific purpose; The minimum requirements as defined in the <u>Laboratory Methods Review Committee Advisory for Emerging Methods</u> will be provided to the Executive Board and shall contain the following <u>criteria</u>:</p> <p>Name of Method;</p> <p>Date of Submission;</p> <p>Specific purpose or intent of the method for use in the NSSP;</p> <p>Step by step procedure including equipment, reagents and safety requirements necessary to run the method;</p> <p>Data generated in the development and/or comparing to approved methods if applicable <u>support of the efficacy of the method if available</u>;</p> <p>Any peer reviewed articles detailing the method and its efficacy;</p> <p>Name of the developer(s)/submitters <u>or SSCA submitter</u>;</p> <p>Developer/submitter contact information.</p> <p>(2) Within two years of the initial allowed use of the <u>emerging</u> method, the entire Single Lab Validation Protocol should be <u>completed and submitted to the ISSC for consideration as an approved method</u>. The Laboratory Methods Review Committee <u>will review the submission and</u> report to the Executive Board on <u>its Status of the single Lab Validation data submission</u>.</p>
<p>Public Health Significance:</p>	
<p>Cost Information (if available):</p>	<p>None</p>