

**Interstate Shellfish  
Sanitation Conference**

***Task Force III***  
***(Administrative)***



**2011 Biennial Meeting**  
***Proposals for Consideration***  
**October 1 – 7, 2011**

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<b>Proposal for Consideration at the Interstate Shellfish Sanitation Conference 2011 Biennial Meeting</b>		<input type="checkbox"/> Growing Area <input type="checkbox"/> Harvesting/Handling/Distribution <input checked="" type="checkbox"/> Administrative
<b>Name of Submitter:</b>	Alfred R. Sunseri	
<b>Affiliation:</b>	P & J Oyster Company, Inc.	
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<b>Email:</b>	asunseri@bellsouth.net	
<b>Proposal Subject:</b>	ISSC Policy Statement on the "Consumption of Raw Oysters"	
<b>Specific NSSP Guide Reference:</b>	Section VI. NSSP Policy Setting Documents, ISSC Policy Statement, Paragraph 3	
<b>Key Words:</b>	Consumption; Raw; Oysters; Policy; Statement	
<b>Text of Proposal/ Requested Action:</b>	<p>"Certain medically compromised individuals are at increased risk from common marine bacteria that are unrelated to pollution. Therefore, it may not be possible to address this risk through environmental controls. Although the reported number of illnesses and fatalities from these bacteria in the United States each year is small in comparison with other food borne illnesses, <b><u>shellfish that have been processed to reduce the levels of all pathogens of public health concern to safe levels can be eaten by the at-risk population or the at-risk population should eat molluscan shellfish fully cooked or,</u></b> total abstinence from raw molluscan shellfish is the best advice for medically compromised."</p>	
<b>Public Health Significance:</b>	<p>This new ISSC policy setting language for the consumption of raw oysters will confirm the use of the labeling allowed for PHP shellfish listed in Chapter XVI. This new policy statement language will show the ISSC supports PHPs and that medically compromised individuals can choose safer post harvest processed shellfish rather than consume other raw shellfish that has not undergone a PHP and/or eat shellfish fully cooked.</p>	
<b>Cost Information (if available):</b>	None	
<b>Action by 2005 Task Force III</b>	Recommended referral of Proposal 05-308 to an appropriate committee as determined by the Conference Chairperson to investigate the possibility of a change to the ISSC Policy Statement on the Consumption of Raw Molluscan Shellfish.	
<b>Action by 2005 General Assembly</b>	Adopted recommendation of 2005 Task Force III.	
<b>Action by USFDA</b>	Concurred with Conference action.	
<b>Action by 2007 Executive Board</b>	Executive Board directed the Executive Director to discuss the ISSC Consumption Policy with the FDA. These discussions were not productive in identifying meaningful language for incorporating changes to the Policy Statement.	

<b>Action by 2007 Task Force III</b>	Recommended no action on the proposed changes to the ISSC Policy Statement on the Consumption of Raw Molluscan Shellfish but, recommends the Executive Board continue to pursue ways to acknowledge Post Harvest Processing in the National Shellfish Sanitation Program.
<b>Action by 2007 General Assembly</b>	Adopted recommendation of 2007 Task Force III.
<b>Action by USFDA</b>	December 20, 2007 Concurred with Conference action.
<b>Action by 2009 ISSC Executive Board</b>	The Executive Board has concluded that it is inappropriate to consider changes to the ISSC Policy Statement on the Consumption of Raw Molluscan Shellfish until the future of PHP is more clearly defined.
<b>Action by 2009 Task Force III</b>	Recommended no action on Proposal 05-308.  Rationale: The Conference is in a state of transition regarding PHP approval and it is inappropriate at this time to consider changes to the policy.
<b>Action by 2009 General Assembly</b>	Adopted recommendation of 2009 Task Force III on Proposal 05-308.
<b>Action by USFDA 02/16/2010</b>	Concurred with Conference action on Proposal 05-308.

<b>Proposal for Consideration at the Interstate Shellfish Sanitation Conference 2011 Biennial Meeting</b>		<input type="checkbox"/> <b>Growing Area</b> <input type="checkbox"/> <b>Harvesting/Handling/Distribution</b> <input checked="" type="checkbox"/> <b>Administrative</b>
<b>Name of Submitter:</b>	ISSC Executive Director	
<b>Affiliation:</b>	Interstate Shellfish Sanitation Conference	
<b>Address:</b>	209-2 Dawson Road Columbia, SC 29223	
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<b>Fax:</b>	803-788-7576	
<b>Email:</b>	issc@issc.org	
<b>Proposal Subject:</b>	Guidance on Equivalence Criteria for Food	
<b>Specific NSSP Guide Reference:</b>	N/A	
<b>Key Words:</b>	Equivalence; Criteria	
<b>Text of Proposal/ Requested Action:</b>	<p>Under Article 4 of the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) (the SPS Agreement), each member nation of the WTO, including the United States, is obligated to accept as equivalent a food regulatory system of another country if it provides the same level of health protection as is provided to consumers by its own system.</p> <p>Equivalent regulatory systems need not be identical. Under the concept of equivalence, the “sanitary or phytosanitary measures” used by an exporting country may differ from the measures applied domestically by an importing country as long as these measures “achieve the importing Member’s appropriate level of sanitary or phytosanitary protection”.</p> <p>Under the SPS Agreement, the burden of demonstrating that equivalence exists rests with the exporting country. The exporting country has the right to decide for itself whether the regulatory system of the exporting country is equivalent to its own or is inadequate to achieve “the importing Member’s appropriate level of sanitary or phytosanitary protection,” or that inadequate evidence has been provided to demonstrate equivalence.</p> <p>One of the roles of the USFDA in the National Sanitation Shellfish Program (NSSP) is the evaluation of foreign programs and the establishment of MOU’s with countries that meet the requirements of the NSSP. This responsibility of FDA is outlined in IV. A. 4. of the ISSC/FDA Memorandum of Understanding, March 14, 1984. Article 4 of the WTO Agreement obligates the FDA to accept equivalency in foreign programs. The Agreement requires that the USFDA consider acceptance of foreign shellfish safety programs that, while having a system of sanitary measures that differ from those applied domestically, are recognized as providing an equivalent level of public health protection.</p> <p>The FDA is seeking input from the ISSC for purposes of incorporating the concept of equivalency into the NSSP. Recognizing that FDA has a clear obligation under the WTO Agreement to take responsibility for equivalency determination, it is important to the Agency that this responsibility be recognized within the NSSP.</p>	

<b>Public Health Significance:</b>	N/A
<b>Cost Information (if available):</b>	N/A
<b>Action by 2007 Task Force III</b>	Recommended referral of Proposal 07-303 to Executive Board for developing short term and long term approaches to incorporating equivalency into the NSSP and the ISSC.
<b>Action by 2007 General Assembly</b>	Adopted recommendation of 2007 Task Force III.
<b>Action by USFDA</b>	December 20, 2007 Concurred with Conference action.
<b>Action by 2009 Executive Board</b>	Recommended the Executive Board continue discussions with FDA to address equivalency of food programs.
<b>Action by 2009 Task Force III</b>	Recommended adoption of the Executive Board recommendation on Proposal 07-303.
<b>Action by 2009 General Assembly</b>	Adopted recommendation of 2009 Task Force III on Proposal 07-303.
<b>Action by USFDA 02/16/2010</b>	Concurred with Conference action on Proposal 07-303.

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<b>Name of Submitter:</b>	ISSC Executive Board	
<b>Affiliation:</b>	Interstate Shellfish Sanitation Conference (ISSC)	
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<b>Fax:</b>	803-788-7576	
<b>Email:</b>	issc@issc.org	
<b>Proposal Subject:</b>	Press Releases	
<b>Specific NSSP Guide Reference:</b>	Section II Model Ordinance Chapter II. Risk Assessment and Risk Management	
<b>Key Words:</b>	Press Release	
<b>Text of Proposal/ Requested Action:</b>	<p>The US FDA issued press releases associated with outbreaks in the Pacific Northwest in the summer of 2006 and in Texas in March of 2007. These press releases created concern regarding the appropriateness and effectiveness of press releases as a public health measure to address an illness outbreak.</p> <p>Use of press is to inform consumers.</p> <p>The ISSC Executive Board discussed the issuance of these press releases and directed the formation of a working group to further investigate and review the use of press by state and federal agencies. The workgroup is to look for ways to coordinate use of press and provide recommendations for discussion at the 2007 Biennial Meeting.</p>	
<b>Public Health Significance:</b>		
<b>Cost Information (if available):</b>		
<b>Action by 2007 Use of Press Committee</b>	Recommended that this Committee continue its deliberations and that a meeting be held in January 2008 in conjunction with appropriate FDA officials and report back to the Executive Board in March 2008. In the interim FDA will consult with the involved state regulatory agency on the content and timing of the release of press.	
<b>Action by 2007 Task Force III</b>	Recommended adoption of the Press Release Committee recommendation on Proposal 07-305.	
<b>Action by 2007 General Assembly</b>	Adopted recommendation of 2007 Task Force III.	
<b>Action by USFDA</b>	December 20, 2007 Concurred with Conference action.	
<b>Action by 2009 Use of Press Committee</b>	The Committee held a conference call on March 13, 2008, and planned a meeting in Washington, DC for April 30, 2008. The plans for this meeting were reported to the Executive Board on April 3, 2008.	

	<p>On April 30, 2008, several members of the Committee and the ISSC Executive Director met with FDA officials at FDA headquarters and discussed agency procedures regarding use of press. The discussions of this meeting were presented to the Executive Board at the September 11, 2008, Executive Board meeting. The Committee reported that it is working to develop a press protocol for use in addressing press releases associated with outbreaks and product recall</p> <p>The Committee held a meeting at the 2009 Biennial Conference and is continuing to develop a press protocol. The Committee will continue to fine tune a list of issues to be considered when use of press is contemplated. This list should be incorporated into NSSP Guidance Documents that address outbreaks and product recall.</p>
<p><b>Action by 2009 Task Force III</b></p>	<p>Recommended adoption of the Use of Press Committee recommendations on Proposal 07-305. Additionally, the Task Force recommended the Committee address the use of press in situations where significant time lapses have occurred between the last reported illness and the proposed use of press. The protocol should address the rationale for using press in situations where product is not likely to still be available for consumption.</p> <p>Task Force III further recommended the Use of Press Committee complete the protocol and present the protocol to the Executive Board at the 2010 Spring Meeting. In the interim, as noted in the March 13, 2008, Use of Press Committee report, FDA should be requested to continue to consult with the involved State regulatory agencies on the content and timing of press releases.</p>
<p><b>Action by 2009 General Assembly</b></p>	<p>Adopted recommendation of 2009 Task Force III on Proposal 07-305.</p>
<p><b>Action by USFDA 02/16/2010</b></p>	<p>Concurred with Conference action on Proposal 07-305.</p>



<b>Proposal for Consideration at the Interstate Shellfish Sanitation Conference 2011 Biennial Meeting</b>		<input type="checkbox"/> Growing Area <input type="checkbox"/> Harvesting/Handling/Distribution <input checked="" type="checkbox"/> Administrative
<b>Name of Submitter:</b>	State Shellfish Control Authorities of Georgia, North Carolina, and South Carolina	
<b>Affiliation:</b>	Georgia Department of Agriculture Georgia Department of Natural Resources North Carolina Department of Environment and Natural Resources South Carolina Department of Health and Environmental Control	
<b>Address:</b>	See State Contact List on ISSC Web Site	
<b>Phone:</b>	See State Contact List on ISSC Web Site	
<b>Fax:</b>		
<b>Email:</b>		
<b>Proposal Subject:</b>	Changes to ISSC State Regions	
<b>Specific NSSP Guide Reference:</b>	ISSC Constitution, Bylaws, and Procedures, Definitions, (3) ISSC REGION, Page 3	
<b>Key Words:</b>	ISSC Region, Definitions	
<b>Text of Proposal/ Requested Action:</b>	<p>Change Region 4 to include only the States of North Carolina, South Carolina and Georgia and move Florida to Region 5.</p> <p>(3) ISSC REGION - geographical grouping of shellfish producing states with similar characteristics and interests, established to provide for fairly distributed representation. The ISSC Regions shall be:</p> <p>Region 1 - Maine, New Hampshire, Massachusetts, Rhode Island          Region 2 - Connecticut, New York, New Jersey          Region 3 - Maryland, Delaware, Virginia          Region 4 - North Carolina, South Carolina, Georgia, <del>Florida</del>          Region 5 - <u>Florida</u>, Alabama, Mississippi, Louisiana, Texas          Region 6 - Alaska, Washington, Oregon, California, Hawaii</p>	
<b>Public Health Significance:</b>	<p>The geographical grouping of shellfish producing states into ISSC Regions should be changed to reflect the environment and geographical area of those states. The current grouping includes Florida with the South Atlantic States of North Carolina, South Carolina and Georgia. Florida issues and interests are and have been Gulf Coast related. Changing this geographical grouping of these shellfish producing states would better align the states with similar characteristics and interests. The South Atlantic States of North Carolina, South Carolina and Georgia should be a separate region from Florida simply due to the geographical differences with the southeast coast.</p>	
<b>Cost Information (if available):</b>		

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<b>Name of Submitter:</b>	Executive Office	
<b>Affiliation:</b>	Interstate Shellfish Sanitation Conference (ISSC)	
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<b>Fax:</b>	803-788-7576	
<b>Email:</b>	issc@issc.org	
<b>Proposal Subject:</b>	ISSC Board Minutes	
<b>Specific NSSP Guide Reference:</b>	ISSC Constitution, Bylaws, and Procedures Article V. Duties of the Board	
<b>Key Words:</b>	Board Meeting Minutes	
<b>Text of Proposal/ Requested Action:</b>	Section 11. The Board shall direct the Executive Director to prepare written minutes of all Board meetings and make copies of such minutes for the previous two years available to the ISSC membership <del>at each Biennial Meeting</del> <u>on the ISSC web site at <a href="http://www.issc.org">www.issc.org</a>.</u>	
<b>Public Health Significance:</b>	N/A	
<b>Cost Information (if available):</b>		

<b>Proposal for Consideration at the Interstate Shellfish Sanitation Conference 2011 Biennial Meeting</b>		<input type="checkbox"/>	<b>Growing Area</b>
		<input type="checkbox"/>	<b>Harvesting/Handling/Distribution</b>
		<input checked="" type="checkbox"/>	<b>Administrative</b>
<b>Name of Submitter:</b>	Robert B. Rheault; Mike Voisin; and Margaret Barrette		
<b>Affiliation:</b>	East Coast Shellfish Growers' Association (ECSGA); Gulf Oyster Industry Council (GOIC); and Pacific Coast Shellfish Growers' Association (PCSGA);		
<b>Address:</b>	1121 Mooresfield Road, Wakefield, RI 02879; P.O. Box 3916 Houma, LA 703611; and 20 State Ave NE #142, Olympia, WA 98501		
<b>Phone:</b>	401-783-3360	985-868-7191	360-754-2744
<b>Fax:</b>	none	985-868-7472	360-754-2743
<b>Email:</b>	bob@ecsga.org	mike.voisin@motivait.com	margaretbarrette@pcsga.org
<b>Proposal Subject:</b>	ISSC State Membership Fees		
<b>Specific NSSP Guide Reference:</b>	ISSC Constitution, Bylaws, and Procedures Article III. Registration and Fees		
<b>Key Words:</b>	Membership; Fees; State; Individual		
<b>Text of Proposal/ Requested Action:</b>	<p>Section 4. There shall be two (2) categories of membership:</p> <p style="padding-left: 40px;"><u>Subdivision a.</u> State</p> <p style="padding-left: 80px;"><u>Subdivision i.</u> Shellfish producing states</p> <p style="padding-left: 80px;"><u>Subdivision ii.</u> Non-producing states</p> <p style="padding-left: 40px;"><u>Subdivision b.</u> Individual Member</p> <p>The fee for each category of membership and the membership period shall be set by the Executive Board. The membership fees may be paid annually or biennially. The state authority membership dues shall include membership for one Voting Delegate. <u>State membership shall be set to provide for forty (40%) per cent and individual membership shall be set to provide for five (5%) per cent of the previous ISSC fiscal year budget.</u> Persons other than Voting Delegates shall be considered members by payment of the <u>individual membership fee</u>. The membership period shall coincide with the calendar year. Applications for membership shall be mailed at least thirty (30) days prior to the beginning of the membership period to the two (2) previous years' membership rolls.</p>		
<b>Public Health Significance:</b>			
<b>Cost Information (if available):</b>			

<b>Proposal for Consideration at the Interstate Shellfish Sanitation Conference 2011 Biennial Meeting</b>		<input type="checkbox"/> Growing Area <input type="checkbox"/> Harvesting/Handling/Distribution <input checked="" type="checkbox"/> Administrative
<b>Name of Submitter:</b>	Executive Office	
<b>Affiliation:</b>	Interstate Shellfish Sanitation Conference (ISSC)	
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<b>Fax:</b>	803-788-7576	
<b>Email:</b>	issc@issc.org	
<b>Proposal Subject:</b>	ISSC Task Force Consultants	
<b>Specific NSSP Guide Reference:</b>	ISSC Constitution, Bylaws, and Procedures Article II. Task Force Consultant	
<b>Key Words:</b>	Task Force; Consultant; EPA	
<b>Text of Proposal/ Requested Action:</b>	<p>Section 1. The Board Chairperson shall appoint a consultant for each Task Force from the Board.</p> <p>Section 2. FDA and NMFS may provide a consultant for each Task Force. <u>EPA may provide a consultant to Task Force I and Task Force III.</u></p> <p>Section 3. Consultants will have no voting rights in Task Force action but will attend Task Force deliberations to offer advice as needed.</p>	
<b>Public Health Significance:</b>	N/A	
<b>Cost Information (if available):</b>		

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<b>Name of Submitter:</b>	US Food and Drug Administration (USFDA) Interstate Shellfish Sanitation Conference Executive Office (ISSC)	
<b>Affiliation:</b>	Same as Above	
<b>Address:</b>	5100 Paint Branch Parkway College Park, MD 20740	209-2 Dawson Road Columbia, SC 29223
<b>Phone:</b>	240-402-1410	803-788-7559
<b>Fax:</b>		803-788-7576
<b>Email:</b>	paul.distefano@fda.hhs.gov	issc@issc.org
<b>Proposal Subject:</b>	Procedure for Handling and Disseminating Interpretations of the Manual by FDA	
<b>Specific NSSP Guide Reference:</b>	ISSC Constitution, Bylaws, and Procedures Procedure XII.	
<b>Key Words:</b>	FDA; Interpretation; Dissemination	
<b>Text of Proposal/ Requested Action:</b>	<p>PROCEDURE XII. PROCEDURE FOR HANDLING AND DISSEMINATING INTERPRETATIONS OF THE <u>NSSP GUIDE FOR THE CONTROL OF MOLLUSCAN SHELLFISH MANUAL</u> BY FDA.</p> <p>Section 1. A request for Interpretation must be submitted to FDA Headquarters (Office of <u>Food Safety Field Programs</u>) through either an FDA Regional Office or the ISSC Executive Director according to the following routes:</p> <p style="padding-left: 40px;">Subdivision a. The interpretation request is submitted to the Office of <u>Food Safety Field Programs</u> following the administrative chain of communication from industry to the State <u>and</u>, to the FDA Regional Office, <del>to FDA Headquarters</del>; or</p> <p style="padding-left: 40px;">Subdivision b. The interpretation request is submitted to the ISSC Executive Director by industry, a State, or the general public. The ISSC forwards the interpretation request to Office of <u>Food Safety Field Programs</u> for a response.</p> <p>Section 2. The interpretation request submitted to Office of <u>Food Safety Field Programs</u> must be written and include the following:</p> <p style="padding-left: 40px;">Subdivision a. The question to be interpreted. Clearly state what the issue(s) is and include the NSSP Guide for the Control of Molluscan Shellfish reference(s) that is unclear and requires interpretation. Include any NSSP Guide for the Control of Molluscan Shellfish references related to the question.</p> <p style="padding-left: 40px;">Subdivision b. Who is requesting the interpretation? Give the name, state, area of interest (i.e., an industry person</p>	

	<p>who operates an oyster shucker/packer operation, a State Shellfish Standardization Officer, etc.) and his/her address and phone number.</p> <p>Subdivision c. The background surrounding the interpretation request. It is very important to understand the circumstances, motivation, and purpose for an interpretation to put it into context.</p> <p>Subdivision d. An opinion on resolving the problem. Include ideas on what the Interpretation should be. This includes what the NSSP Guide for the Control of Molluscan Shellfish means, the intent of the NSSP Guide for the Control of Molluscan Shellfish, how appropriate reference (CFR, EPA Guidance Document, etc.) should be interpreted.</p> <p>Section 3. Within seven (7) days, the Office of <del>Food Safety</del><u>Field Programs</u> will acknowledge receipt of the letter to the requestor and FDA's Division of Federal and State Relations (DFSR) <del>and report which branch in FDA is responsible for developing the interpretation.</del></p> <p>Section 4. All requests for interpretations must be sent to the Office of <del>Food Safety</del><u>Field Programs</u>. <del>The Office of Field Programs will decide if the request is a technical or policy issue. The Office of Field Programs will develop technical interpretations and the FDA Office of Seafood will develop policy interpretations. Therefore, in the following subdivisions, if the request is a policy issue, substitute FDA Office of Seafood for Office of Field Programs.</del></p> <p>Subdivision a. Within sixty (60) days of acknowledgment of the letter, the Office of <del>Food Safety</del><u>Field Programs</u> will provide a draft proposal to the FDA Regional Offices, the ISSC Executive Director, and DFSR for comment. The ISSC Executive Director shall distribute the draft proposal to the requestor and ISSC members from states, industry, and the general public.</p> <p>Subdivision b. An additional thirty (30) days may be permitted for draft development if circumstances warrant. The requestor must be notified of the additional development time.</p> <p>Section 5. Comments on the Draft Interpretation.</p> <p>Subdivision a. The FDA <del>Office of Seafood, the</del> Regional Offices, ISSC Executive Director, and <del>DFSR</del><u>A</u> have thirty (30) days from receipt to comment on the draft proposal to the Office of <del>Food Safety</del><u>Field Programs</u>. The ISSC Executive Director is responsible for receiving, consolidating, and forwarding to the Office of <del>Food Safety</del><u>Field</u></p>
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	<p><del>Programs</del> comments from ISSC members from states, industry, and the general public.</p> <p>Subdivision b. The FDA <del>Office of Seafood, the FDA Regional Offices</del>, ISSC Executive Director, and DFSR may request, in writing to the Office of <u>Food Safety</u><del>Field Programs</del>, an additional thirty (30) days to comment on the draft proposal.</p> <p>Section 6. Action on Draft Interpretation Comments.</p> <p>Subdivision a. The Office of <u>Food Safety</u><del>Field Programs</del> has thirty (30) days from receipt of comments to complete the final interpretation by:</p> <p style="padding-left: 40px;">Subdivision i. Incorporating the comments and issuing a final interpretation; or</p> <p style="padding-left: 40px;">Subdivision ii. Issuing the final interpretation without revision.</p> <p>Subdivision b. FDA may request an additional thirty (30) days for issuance of the final interpretation if circumstances warrant. The requestor and ISSC Executive Director must be notified of the additional development time.</p> <p>Section 7. The Office of <u>Food Safety</u><del>Field Programs</del> shall disseminate final interpretations to the ISSC and DFSR for dissemination as follows:</p> <p>Subdivision a. Upon receipt of the final interpretation, the ISSC Executive Director shall distribute it to the requestor and ISSC members from states, industry, and the general public.</p> <p>Subdivision b. Upon receipt of the final interpretation, DFSR shall distribute it to the FDA Regional Offices and the Office of <u>Food Safety</u><del>Field Programs</del>.</p> <p><u>Subdivision c. Final interpretation shall be incorporated into the NSSP Guide for the Control of Molluscan Shellfish.</u></p>
<p><b>Public Health Significance:</b></p>	
<p><b>Cost Information (if available):</b></p>	

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<b>Name of Submitter:</b>	Alfred R. Sunseri	
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<b>Email:</b>	asunseri@bellsouth.net	
<b>Proposal Subject:</b>	ISSC Constitutional Cost-Benefit Requirement for New Proposals that have a Significant Financial Impact on the States and Shellfish Industry	
<b>Specific NSSP Guide Reference:</b>		
<b>Key Words:</b>	Cost-Benefit Requirement for Proposals-New Information Attached	
<b>Text of Proposal/ Requested Action:</b>	<p>Article XIII. Procedure for the Submission of Proposals</p> <p>Section 1. The Executive Director shall provide each registrant of the preceding Conference meeting at least one hundred sixty-five (165) days prior to the next Conference meeting with forms on which proposal for problems are to be submitted to the Executive Director for assignment to the appropriate Task Force.</p> <p>Section 2. All proposals must be submitted to the Executive Office no later than one hundred twenty (120) days prior to the Conference meeting.</p> <p>Section 3. Proposals submitted by any Conference participants requiring Conference action are to be referred to the Executive Director for assignment to the appropriate Task Force.</p> <p><u>Section 4.</u> <u>Proposals submitted by any Conference participant that may have a significant cost to implement by either the SSCA or the shellfish industry must include an independent cost benefit analysis and an economic impact study.</u></p> <p>Section <u>54.</u> The Executive Director shall review and assign all problems or proposals received for Task Force and Conference deliberation. Problem or proposal assignment shall be made according to subject matter and in accordance with Article XIII. <u>Section 4.</u>, Section 5., Section 6., and Section 7. of the Constitution of the Conference.</p> <p>Section <u>65.</u> Task Force I - Growing Areas: all proposals submitted to the Conference dealing with the classification or patrol of shellfish growing waters, relaying, training and research, or similar items concerning growing areas shall be assigned to Task Force I by the Executive Director.</p> <p>Section <u>76.</u> Task Force II – Harvesting, Handling, and Distribution: all proposals submitted to the Conference dealing with the sanitation of harvesting, depuration, processing, labeling, transporting, storage, fill or content,</p>	



	<p>training and research, or similar items concerning processing and distribution shall be assigned to Task Force II by the Executive Director.</p> <p>Section <u>87</u>. Task Force III - Administration: all proposals submitted to the Conference dealing with Conference agreements, memorandums of understanding, complaints and challenges of reciprocity and program evaluations, or similar items, or items not specifically relating to Task Force I or II shall be assigned to Task Force III by the Executive Director.</p> <p>Section <u>98</u>. The Executive Director shall provide the appropriate shellfish control authorities in each state and all members, at least ninety (90) days prior to each Conference meeting, with the proposals to be discussed under the heading of Unfinished Business.</p> <p>Section <u>109</u>. Proposals submitted after the deadline, established in Article XIII Section 2 of the Constitution, will be reviewed and may be accepted by the Executive Board for Task Force Consideration. The Executive Board will use the following criteria in accepting late proposals.</p> <p>Subdivision a. Why is the proposal being submitted after the deadline?</p> <p>Subdivision b. Was the information available prior to the deadline?</p> <p>Subdivision c. What is the criticality of the proposal to the safety of molluscan shellfish or the future of the ISSC?</p> <p>Subdivision d. Does the proposal involve an NSSP Guide for the Control of Molluscan Shellfish change or an ISSC administrative change?</p> <p>Section <u>1140</u>. The Executive Director will consult with the Proposal Review Committee before declaring any problem or proposal invalid.</p> <p>Section <u>1211</u>. The Proposal Review Committee will review and prioritize proposals for Task Force consideration. The Committee will also provide consultation as needed to the Executive Director in assigning proposals to Task Forces.</p>
<p><b>Public Health Significance:</b></p>	<p>Cost-Benefit Analyses and Economic Impact Studies are required by Federal and State Agencies prior to imposing new regulations. For too many years the ISSC through amendments made to the NSSP without any regards to the costs imposed on the SSCA and Shellfish Industry to implement the new guidelines.</p>
<p><b>Cost Information (if available):</b></p>	<p>The cost to conduct cost-benefit analyses and economic impact studies will be much less on the SSCA'S and Shellfish Industry than the cost to implement by the SSCA's or by the shellfish industry.</p>

**H.R.2751**  
**FDA Food Safety Modernization Act**  
**SEC. 114. REQUIREMENT FOR GUIDANCE RELATING TO**  
**POST HARVEST PROCESSING OF RAW OYSTERS.**

- (a) In General- Not later than 90 days prior to the issuance of any guidance, regulation, or suggested amendment by the Food and Drug Administration to the National Shellfish Sanitation Program's Model Ordinance, or the issuance of any guidance or regulation by the Food and Drug Administration relating to the Seafood Hazard Analysis Critical Control Points Program of the Food and Drug Administration (parts 123 and 1240 of title 21, Code of Federal Regulations (or any successor regulations), where such guidance, regulation or suggested amendment relates to post harvest processing for raw oysters, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report which shall include--
- (1) an assessment of how post harvest processing or other equivalent controls feasibly may be implemented in the fastest, safest, and most economical manner;
  - (2) the projected public health benefits of any proposed post harvest processing;
  - (3) the projected costs of compliance with such post harvest processing measures;
  - (4) the impact post harvest processing is expected to have on the sales, cost, and availability of raw oysters;
  - (5) criteria for ensuring post harvest processing standards will be applied equally to shellfish imported from all nations of origin;
  - (6) an evaluation of alternative measures to prevent, eliminate, or reduce to an acceptable level the occurrence of foodborne illness; and
  - (7) the extent to which the Food and Drug Administration has consulted with the States and other regulatory agencies, as appropriate, with regard to post harvest processing measures.
- (b) Limitation- Subsection (a) shall not apply to the guidance described in section 103(h).
- (c) Review and Evaluation- Not later than 30 days after the Secretary issues a proposed regulation or guidance described in subsection (a), the Comptroller General of the United States shall--
- (1) review and evaluate the report described in (a) and report to Congress on the findings of the estimates and analysis in the report;
  - (2) compare such proposed regulation or guidance to similar regulations or guidance with respect to other regulated foods, including a comparison of risks the Secretary may find associated with seafood and the instances of those risks in such other regulated foods; and
  - (3) evaluate the impact of post harvest processing on the competitiveness of the domestic oyster industry in the United States and in international markets.
- (d) Waiver- The requirement of preparing a report under subsection (a) shall be waived if the Secretary issues a guidance that is adopted as a consensus agreement between Federal and State regulators and the oyster industry, acting through the Interstate Shellfish Sanitation Conference.
- (e) Public Access- Any report prepared under this section shall be made available to the public.

United States Senate  
WASHINGTON, DC 20510

January 25, 2011

Mr. Ken Moore  
Executive Director  
Interstate Shellfish Sanitation Conference  
209-2 Dawson Road  
Columbia, SC 29223

Dear Mr. Moore:

As you know, Congress recently passed P.L. 111-353 the "FDA Food Safety Modernization Act." We were proud to author section 114 of the law pertaining to the regulation of raw oysters. We wrote this language to provide the Secretary a waiver only if state regulators, the oyster industry, and Interstate Shellfish Sanitation Conference's, (ISSC), voting delegates approved the regulation or guideline proposed by the Food and Drug Administration or ISSC. As the ISSC moves forward, we wanted to clarify the intent of section 114(d) which states:

Waiver- The requirement of preparing a report under subsection (a) shall be waived if the Secretary issues a guidance that is adopted as a consensus agreement between Federal and State regulators and the oyster industry, acting through the Interstate Shellfish Sanitation Conference.

This clearly states that the oyster industry through ISSC should be an intricate part of the process. Specifically, the language is intended to ensure that new guidelines or regulations cannot move forward without the consensus from the oyster industry.

Thank you for the opportunity to clarify the intent of Congress in these matters. We look forward to working with you and the Interstate Shellfish Sanitation Conference on the implementation of the FDA Food Safety Modernization Act.

Sincerely,

  
\_\_\_\_\_  
David Vitter  
United States Senator

  
\_\_\_\_\_  
Mary Landrieu  
United States Senator

<b>Proposal for Consideration at the Interstate Shellfish Sanitation Conference 2011 Biennial Meeting</b>		<input type="checkbox"/> Growing Area <input type="checkbox"/> Harvesting/Handling/Distribution <input checked="" type="checkbox"/> Administrative
<b>Name of Submitter:</b>	Executive Office	
<b>Affiliation:</b>	Interstate Shellfish Sanitation Conference (ISSC)	
<b>Address:</b>	209-2 Dawson Road Columbia, SC 29223	
<b>Phone:</b>	803-788-7559	
<b>Fax:</b>	803-788-7576	
<b>Email:</b>	issc@issc.org	
<b>Proposal Subject:</b>	Determining Effectiveness of NSSP Changes	
<b>Specific NSSP Guide Reference:</b>	ISSC Constitution, Bylaws, and Procedures Article I. Task Forces Procedure X. Procedure for Handling ISSC Summary of Actions	
<b>Key Words:</b>	Task Forces; Summary of Actions	
<b>Text of Proposal/ Requested Action:</b>	<p>Article I. Task Forces</p> <p>Section 6. Each Task Force shall deliberate all proposals during the times specified at the Conference meeting. Each Task Force Chairperson shall report the actions recommended by his/her respective Task Force to the voting delegates at the Conference under the heading of New Business for final Conference consideration. Any "No Action" recommended by a Task Force shall contain the reasons for the "No Action" recommendation. <u>The Task Force will designate each proposal with a determination of cost of implementation. The designation will be all of the following:</u></p> <p style="padding-left: 40px;"> <u>Subdivision a. Significant costs to industry.</u>  <u>Subdivision b. Significant costs to State Shellfish Control Authority.</u>  <u>Subdivision c. Insignificant costs.</u> </p> <p>Procedure X. Procedure for Handling ISSC Summary of Actions</p> <p><u>Section 5. All NSSP changes that have significant costs will be reviewed and assessed for effectiveness. This assessment will occur as part of the Conference meeting held in the fourth calendar year following adoption of the change. Those changes that are determined to be ineffective will be deleted.</u></p>	
<b>Public Health Significance:</b>	N/A	
<b>Cost Information (if available):</b>		

<b>Proposal for Consideration at the Interstate Shellfish Sanitation Conference 2011 Biennial Meeting</b>		<input type="checkbox"/> Growing Area <input type="checkbox"/> Harvesting/Handling/Distribution <input checked="" type="checkbox"/> Administrative
<b>Name of Submitter:</b>	ISSC Executive Office Patti Fowler	
<b>Affiliation:</b>	Interstate Shellfish Sanitation Conference (ISSC) NC Shellfish Sanitation and Recreational Water Quality	
<b>Address:</b>	209-2 Dawson Road Columbia, SC 29223	PO Box 769 Morehead City, NC 18557
<b>Phone:</b>	803-788-7559	252-808-8147
<b>Fax:</b>	803-788-7576	252-726-8475
<b>Email:</b>	issc@issc.org patti.fowler@ncdenr.gov	
<b>Proposal Subject:</b>	Procedure for the Approval of Analytical Methods for the NSSP	
<b>Specific NSSP Guide Reference:</b>	ISSC Constitution, Bylaws, and Procedures Procedure XVI. Procedure for the Approval of Analytical Methods for the NSSP	
<b>Key Words:</b>	Proposal; Procedure; Analytical Methods	
<b>Text of Proposal/ Requested Action:</b>	<p>PROCEDURE XVI. Procedure for the Approval of Analytical Methods for the NSSP</p> <p>Section 1. <u>Prior to NSSP adoption, all laboratory methods shall be Systematic evaluationed by the ISSC of the analytical method</u> using the validation criteria developed <u>by the ISSC</u> as detailed in the Single Laboratory Validation Protocol;</p> <p>Section 2. <u>All methods shall be submitted Proposal to the ISSC in proposal form</u> requesting approval of the analytical method for use in the NSSP;</p> <p>Subdivision a. <u>Proposals shall include a Submission of the Proposal completed Single Laboratory Validation Method Application and Checklist.;</u></p> <p>Subdivision b. <u>The ISSC Proposal presented to Executive Director shall submit the proposal to the Laboratory Methods Review for Committee for review and development of recommendations to Task Force Jeonsideration for acceptance.</u></p> <p>Section 3. Review by Laboratory Methods Review Committee;</p> <p>Subdivision a. <u>The Laboratory Methods Review Committee shall conduct an review and evaluation of the data submitted which describesing the performance characteristics of the method;</u></p> <p>Subdivision i. These performance characteristics include:</p> <p style="padding-left: 40px;">Subdivision (a) Accuracy (Trueness);          Subdivision (b) Measurement uncertainty;          Subdivision (c) Precision;          Subdivision (d) Recovery;</p>	

	<p>Subdivision (e) Specificity;  Subdivision (f) Linear range;  Subdivision (g) Limit of detection;  Subdivision (h) Limit of quantitation (sensitivity);  Subdivision (i) Ruggedness;  Subdivision (j) Comparability if applicable (comparison of the performance of the new/modified method to the accepted method.</p> <p>Subdivision ii. Method documentation including:  Subdivision (a) Method title, scope and references;  Subdivision (b) Equipment and reagents required;  Subdivision (c) Sample collection, preservation and storage requirements;  Subdivision (d) Safety requirements;  Subdivision (e) Step by step procedure;  Subdivision (f) Specific quality control measures associated with the method;  Subdivision (g) Cost of the method;  Subdivision (h) Sample turnaround time.</p> <p>Subdivision iii. Specific application(s);</p> <p>Subdivision b. Review of need for the method;</p> <p>Subdivision i. Method meets an immediate or continuing need;</p> <p>Subdivision ii. Improves analytical capability under the NSSP as an alternative to an accepted method(s);</p> <p>Subdivision iii. Replaces other approved or accepted method(s).</p> <p>Section 4. <del>Possible Actions by</del> <u>The Laboratory Methods Review Committee shall submit one of the following recommendations to Task Force I;</u></p> <p>Subdivision a. Non-acceptance pending further information as defined by the Committee;</p> <p>Subdivision b. Accept as an <u>Approved NSSP</u> <del>Type IV</del> Method;</p> <p>Subdivision c. Accept as an <u>Approved Limited Use NSSP</u> <del>Type III</del> Method;</p>
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~~Subdivision d. Accept as an Emergency Use NSSP Type III Method, and recommend adoption as Type II or Type I Method;~~

~~Subdivision e. Rescind acceptance for cause (the need no longer exists, poor performance, equipment or reagents no longer available, etc.)~~

~~Section 5. Requests for ISSC recantation of an approved method shall be submitted using the ISSC proposal form. The request for recantation must include reason for the request, i.e. the need no longer exists, poor performance, equipment or reagents no longer available, etc. Task Force recommendation (or non recommendation) for adoption by ISSC;~~

~~Section 6. Adoption (or non adoption) by ISSC General Assembly; Types of NSSP analytical methods.~~

Subdivision a. Approved NSSP Methods.

Approved NSSP methods are those accepted for use as permanent methods and cited in the NSSP Guide for the Control of Molluscan Shellfish, Guidance Documents Chapter II. Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests. These methods have been long used in the NSSP or have completed the Single Laboratory Validation Method Protocol to show that the method is fit for purpose in the NSSP. Approved NSSP Methods have been:

Subdivision i. Described in a scientific or other peer-reviewed professional publication;

Subdivision ii. Used successfully to detect or quantify;

Subdivision iii. Evaluated and the performance characteristics for specific applications have been determined and found fit for purpose;

Subdivision iv. Collaboratively studied and/or collaboratively tested.

Subdivision b. Approved Limited Use Methods.

Approved Limited Use Methods are methods accepted for use in NSSP and listed in the NSSP Guide for the Control of Molluscan Shellfish, Guidance Documents Chapter II. Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests. These methods are alternative methods within the NSSP that can meet an immediate need of the NSSP, improve turnaround time, cost effectiveness, and / or increase analytical capacity. Approved Limited Use Methods can include screening, provisional, or methods with limitations as defined by the LMRC evaluation of the method.

Subdivision c. Emergency Use Methods.

Emergency Use Methods are methods used to meet an immediate or ongoing critical need for a method of analysis and no NSSP approved method exists. Emergency Use Methods may be given interim approval by the ISSC Executive Board provided the following criteria are provided:

Subdivision i. Name of Method;

Sudivision ii. Date of Submission;

Subdivision iii. Specific purpose or intent of the method for use in the NSSP;

Subdivision iv. Step by step procedure including equipment, reagents and safety requirements necessary to run the method;

Subdivision v. Data generated in support of the efficacy of the method if available;

Subdivision vi. Any peer reviewed articles detailing the method and its efficacy;

Subdivision vii. Name of the developer or SSCA submitter;

Subdivision viii. Developer or submitter contact information.

~~Section 7. Review and Acceptance by FDA Office of Food Safety in the Summary of Actions;~~

~~Section 8. Addition to/removal from the NSSP *Guide for the Control of Molluscan Shellfish*, Guidance Documents Chapter II. Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests: Microbiological and Biotoxin Analytical Methods.~~

~~Section 9. Types of NSSP analytical methods.~~

~~Subdivision a. Type I Methods. Type I methods are methods accepted for use in the NSSP and cited in the NSSP *Guide for the Control of Molluscan Shellfish*, Guidance Documents Chapter II. Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests: Microbiological and Biotoxin Analytical Methods that have been:~~

~~Subdivision i. Described in a scientific or other peer-reviewed professional publication;~~

~~Subdivision ii. Used successfully to detect or quantify;~~

~~Subdivision iii. Evaluated, and the performance characteristics for specific applications~~



	<p>have been determined and found fit for purpose;</p> <p>Subdivision iv. Collaboratively studied and/or collaboratively tested; and/or;</p> <p>Subdivision v. Long used as an accepted method in the NSSP. Examples: APHA MPNs for total and fecal coliforms, Modified A-1 MPN (MA-1), and the mouse bioassay for saxitoxins (PSP).</p> <p>Subdivision b. <del>Type II Methods. Type II methods are methods accepted for use in the NSSP and cited in the NSSP <i>Guide for the Control of Molluscan Shellfish</i>, Guidance Documents Chapter II, Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests: Microbiological and Biotxin Analytical Methods that have been:</del></p> <p>Subdivision i. <del>Described in a scientific or other peer-reviewed professional publication;</del></p> <p>Subdivision ii. <del>Used successfully to detect or quantify;</del></p> <p>Subdivision iii. <del>Evaluated, and the performance characteristics for specific applications have been determined and found fit for purpose;</del></p> <p>Subdivision iv. <del>Long used and accepted for use in the NSSP. Examples: Elevated temperature coliform pour plate method (ETCP) and the mouse bioassay for brevetoxins (NSP).</del></p> <p>Subdivision c. <del>Type III Methods. Type III methods include those methods accepted by unanimous vote of the Laboratory Methods Review Committee for use on an interim basis and cited in the NSSP <i>Guide for the Control of Molluscan Shellfish</i>, Guidance Documents, Chapter II, Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests: Microbiological and Biotxin Analytical Methods that have been:</del></p> <p>Subdivision i. <del>Described in a scientific or other peer-reviewed professional publication;</del></p> <p>Subdivision ii. <del>Used successfully to detect or quantify;</del></p> <p>Subdivision iii. <del>Evaluated, and the performance characteristics for specific applications have been determined and found fit for purpose;</del></p> <p>Subdivision iv. <del>Selected to fulfill a continuing need;</del></p> <p>Subdivision v. <del>Designated for review and assessment by the Laboratory Methods Review Committee for continued use, re-designation or deletion.</del></p> <p>Subdivision d. <del>Type IV Methods. Type IV methods include those methods accepted by majority vote of the Laboratory Methods Review Committee for use on an interim basis</del></p>
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	<p><del>and cited in the NSSP <i>Guide for the Control of Molluscan Shellfish</i>, Guidance Documents, Chapter II, Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests: Microbiological and Biotxin Analytical Methods that have been:</del></p> <p><del>Subdivision i. Described in a scientific or other peer-reviewed professional publication;</del></p> <p><del>Subdivision ii. Used successfully to detect or quantify;</del></p> <p><del>Subdivision iii. Evaluated, and the performance characteristics for specific applications have been determined and found fit for purpose;</del></p> <p><del>Subdivision iv. Selected to fulfill an immediate need;</del></p> <p><del>Subdivision v. Designated for review and assessment by the Laboratory Methods Review Committee for continued use, re-designation or deletion.</del></p>
<p><b>Public Health Significance:</b></p>	
<p><b>Cost Information (if available):</b></p>	

<b>Proposal for Consideration at the Interstate Shellfish Sanitation Conference 2011 Biennial Meeting</b>		<input type="checkbox"/> <b>Growing Area</b> <input type="checkbox"/> <b>Harvesting/Handling/Distribution</b> <input checked="" type="checkbox"/> <b>Administrative</b>
<b>Name of Submitter:</b>	Laboratory Methods Review Committee/Patti Fowler Chair	
<b>Affiliation:</b>	ISSC	
<b>Address:</b>	P.O. Box 769 Morehead City, NC 28557	
<b>Phone:</b>	252-808-8147	
<b>Fax:</b>	252-726-8475	
<b>Email:</b>	patti.fowler@ncdenr.gov	
<b>Proposal Subject:</b>	Revision of Procedure XVI of the ISSC's Constitution, Bylaws and Procedures	
<b>Specific NSSP Guide Reference:</b>	ISSC Constitution, Bylaws and Procedures Procedure XVI. Procedure for Acceptance and Approval of Analytical Methods for the NSSP (Section 3, subdivision b, b i, b ii, b iii, Section 4, subdivision a, subdivision b, subdivision c, subdivision d, subdivision e, subdivision f and subdivision g, Section 5, Section 6, Section 7, Section 8, Section 9, subdivision a, a ii, a iii, a iv, Subdivision b, b ii, b iii, b iv, Subdivision c, c ii, c iii, c iv, c v, Subdivision d, d ii, d iii, d iv, d v.)	
<b>Text of Proposal/ Requested Action</b>	<p>Revise Procedure XVI ISSC Constitution, Bylaws and Procedures as follows.</p> <p>Section 3 Review by Laboratory Methods Review Committee;</p> <p style="padding-left: 40px;">Subdivision a. Committee review .....</p> <p style="padding-left: 80px;">Subdivision i. These performance .....</p> <p style="padding-left: 120px;">Subdivision (a) Accuracy (Trueness);  Subdivision (b) Measurement uncertainty;  Subdivision (c) Precision;  Subdivision (d) Recovery;  Subdivision (e) Specificity;  Subdivision (f) Linear range;  Subdivision (g) Limit of detection;  Subdivision (h) Limit of quantitation (sensitivity);  Subdivision (i) Ruggedness;  Subdivision (j) Comparability if applicable.....</p> <p style="padding-left: 40px;">Subdivision ii. Method documentation including: .....</p> <p style="padding-left: 80px;">Subdivision (a) Method title.....  Subdivision (b) Equipment and.....  Subdivision (c) Sample collection .....</p> <p style="padding-left: 120px;">Subdivision (d) Safety requirements;  Subdivision (e) Step by step procedure;  Subdivision (f) Specific quality.....  Subdivision (g) Cost of the method;  Subdivision (h) Sample turnaround time.</p>	

Subdivision iii. Specific application(s);

Subdivision b. Review of the need for the method;

Subdivision i. ~~Method~~ Meets an immediate or continuing a critical need for a method of analysis where there is no existing NSSP method available;

Subdivision ii. Improves turnaround time, cost effectiveness or develops analytical capacity beyond existing NSSP methods; ~~capability under the NSSP as an alternative to an accepted method(s);~~

Subdivision iii. Replaces an obsolete NSSP method of analysis. ~~other approved or accepted method(s);~~

Section 4. Possible Actions by the Laboratory Methods Review Committee;

Subdivision a. Recommend non-adoption as the proposed method does not meet a critical need; does not replace an obsolete NSSP method or improve turnaround time, cost-effectiveness or develop analytical capacity beyond existing NSSP methods;

Subdivision b. Recommend non-adoption. ~~Non-acceptance~~ pending further information as ~~defined~~ required by the Committee;

Subdivision c. Recommend adoption ~~Accept~~ as a Type IV Method;

Subdivision d. Recommend adoption ~~Accept~~ as a Type III Method;

Subdivision e. ~~Accept as a Type III Method and~~ Recommend adoption as a Type II or Type I Method;

Subdivision f. Recommend adoption as a Type I Method;

Subdivision g. Rescind acceptance Recommend rescinding the method for cause (the need no longer exists, poor performance, equipment or reagents no longer available, little or unused etc.).

Subdivision h. Recommend no action as there has been no response to the Committee's request for further information or additional data.

Section 5. Task force Recommendation (or non-recommendation) for adoption by the ISSC;

Section 6. Adoption (or non-adoption) by the ISSC General Assembly;

Section 7. Review and concurrence (or non-concurrence) ~~Acceptance~~ by FDA Office of Food Safety in the Summary of Actions;

Section 8. If the Task Force’s action is adopted by the Conference and concurred with by FDA, the method is added ~~Addition to/removal removed~~ from the Table of Approved National Shellfish Sanitation Program Laboratory Tests in the NSSP Guide for the Control of Molluscan Shellfish, Guidance Documents Chapter II. Growing Areas .10. ~~Approved National Shellfish Sanitation Program Laboratory Tests: Microbiological and Biotoxin Analytical Methods.~~

Section 9. Types of NSSP analytical methods.

Subdivision a. Type I Methods. Core Methods. ~~Type I~~ Core methods are methods accepted for use in the NSSP and ~~cited~~ listed in the NSSP Guide for the Control of Molluscan Shellfish, Guidance Documents Chapter II. Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests: Microbiological and Biotoxin Analytical Methods that have been:

Subdivision i. Described in a scientific or other peer-reviewed professional publication;

Subdivision ii. Used successfully throughout the NSSP to detect or quantify;

Subdivision iii. Evaluated, and the performance characteristics for specific applications in the NSSP have been determined and found fit for purpose;

Subdivision iv. Collaboratively studied and/or collaboratively tested ; and/or,

Subdivision v. Long used as ~~an accepted method~~ the “gold standard” throughout in the NSSP to meet established Program requirements. Examples of Type I methods the: the APHA MPNs methods for both total and fecal coliforms, Modified A-1 MPN (MA-1) and the mouse bioassays for ~~saxitoxin~~ Paralytic shellfish toxins (PSP) and brevetoxins (NSP).

Subdivision b. Type II Methods. Permanent Methods. ~~Type II~~ Permanent methods are methods accepted for use in the NSSP and ~~cited~~ listed in the NSSP Guide for the Control of Molluscan Shellfish, Guidance Documents Chapter II Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests: Microbiological and Biotoxin Analytical Methods that have been:

Subdivision i. Described in a scientific or other peer-reviewed professional publication;

	<p>Subdivision ii. Used successfully <u>within the NSSP</u> to detect or quantify;</p> <p>Subdivision iii. <del>Evaluated</del> <u>NSSP validated</u> and the performance characteristics for specific applications <u>within the NSSP</u> have been determined and found fit for purpose;</p> <p>Subdivision iv. <del>Long</del> <u>Widely used and accepted for use within the NSSP as alternative methods to improve turnaround time, cost effectiveness or to develop analytical capacity beyond what is achieved by the core methods.</u> Examples of <u>Type II methods: the Elevated temperature coliform pour plate method (ETCP) for fecal coliform analysis and the mouse bioassay for brevetoxins (NSP) mTEC membrane filtration method for fecal coliforms.</u></p> <p>Subdivision c. Type III Methods.</p> <p><u>Interim Methods.</u> <del>Type III Interim methods are include those methods accepted by unanimous vote of the Laboratory Methods Review Committee for use in the NSSP on an interim basis and listed cited in the NSSP Guide for the Control of Molluscan Shellfish, Guidance Documents , Chapter II, Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests:- Microbiological and Biotoxin Analytical Methods that have been:</del></p> <p>Subdivision i. Described in a scientific or other peer-reviewed professional publication;</p> <p>Subdivision ii. Used <u>within the NSSP</u> to detect or quantify;</p> <p>Subdivision iii. <del>Evaluated</del> <u>NSSP validated</u> and the Performance characteristics for specific applications <u>within the NSSP</u> have been determined and found fit for purpose;</p> <p>Subdivision iv. Selected to fill <del>fulfill</del> <u>an ongoing NSSP Program continuing</u> need;</p> <p>Subdivision v. <u>Used effectively outside the laboratory in which the method was developed and/or validated;</u></p> <p>Subdivision vi. Designated for <u>periodic</u> review and assessment by the Laboratory Methods Review Committee <u>as to the</u> feasibility for continued use, re-designation or deletion <u>of the method.</u> <u>Examples of Type III methods: the Jellett Rapid Test (JRT) for PSP and the mEndo-LES</u></p>
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	<p style="text-align: center;"><u>membrane filtration method for UV treated process water.</u></p> <p>Subdivision d. Type IV Methods. <u>Provisional Methods.</u> <del>Type iv</del> <u>Provisional methods are include those methods accepted by majority vote of the Laboratory Methods Review Committee for use in the NSSP on an interim basis and cited listed in the NSSP Guide for the Control of Molluscan Shellfish , Guidance Documents, Chapter II Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests: Microbiological and Biotoxin Analytical Methods that: have been:</u></p> <p>Subdivision i. <u>Have been</u> described in a scientific or other peer-reviewed professional publication;</p> <p>Subdivision ii. <u>Can be used successfully within the NSSP to detect or quantify;</u></p> <p>Subdivision iii. <del>Evaluated,</del> <u>Have been NSSP validated</u> and the performance characteristics for specific applications <u>within the NSSP</u> have been determined and found fit for purpose;</p> <p>Subdivision iv. <u>Have been</u> selected to <del>fulfill</del> <u>fill an ongoing NSSP Program Immediate-need;</u></p> <p>Subdivision v. <u>Have been Newly accepted for use and/or not yet used for Program support outside the laboratory in which the method was developed and/or validated;</u></p> <p>Subdivision vi. Designated for <u>periodic</u> review and assessment by the Laboratory Methods Review Committee <u>as to the feasibility for continued use, redesignation or deletion of the method.</u> <u>Examples of Type IV methods: the HPLC post column oxidation (PCOX) method for paralytic shellfish toxins and the Male Specific Coliphage (MSC) method for soft shell clams and American Oysters.</u></p>
<p><b>Public Health Significance:</b></p>	<p>The revision of Procedure XVI is meant to clarify the overall process of analytical method acceptance into the NSSP and ensure that only proven methods of analysis are available for use to support NSSP Program requirements.</p>
<p><b>Cost Information (if available):</b></p>	<p>None</p>

<b>Proposal for Consideration at the Interstate Shellfish Sanitation Conference 2011 Biennial Meeting</b>		<input type="checkbox"/> Growing Area <input type="checkbox"/> Harvesting/Handling/Distribution <input checked="" type="checkbox"/> Administrative
<b>Name of Submitter:</b>	Executive Office	
<b>Affiliation:</b>	Interstate Shellfish Sanitation Conference (ISSC)	
<b>Address:</b>	209-2 Dawson Road Columbia, SC 29223	
<b>Phone:</b>	803-788-7559	
<b>Fax:</b>	803-788-7576	
<b>Email:</b>	issc@issc.org	
<b>Proposal Subject:</b>	ISSC Procedure for the Submission of Proposals	
<b>Specific NSSP Guide Reference:</b>	ISSC Constitution, Bylaws, and Procedures Article XIII. Procedure for the Submission of Proposals	
<b>Key Words:</b>	Proposals; Unfinished Business	
<b>Text of Proposal/ Requested Action:</b>	<p>Section 8. The Executive Director shall provide the appropriate shellfish control authorities in each state and all members, at least ninety (90) days prior to each Conference meeting, with the proposals to be discussed under the heading of Unfinished Business <u>or New Business</u>.</p> <p><del>Section 11. The Proposal Review Committee will review and prioritize proposals for Task Force consideration. The Committee will also provide consultation as needed to the Executive Director in assigning proposals to Task Forces.</del></p>	
<b>Public Health Significance:</b>	N/A	
<b>Cost Information (if available):</b>		



<b>Proposal for Consideration at the Interstate Shellfish Sanitation Conference 2011 Biennial Meeting</b>		<input type="checkbox"/> Growing Area <input type="checkbox"/> Harvesting/Handling/Distribution <input checked="" type="checkbox"/> Administrative
<b>Name of Submitter:</b>	Julie Henderson	
<b>Affiliation:</b>	Virginia Department of Health Division of Shellfish Sanitation	
<b>Address:</b>	109 Governor Street 6 <sup>th</sup> Floor Richmond, VA 23219	
<b>Phone:</b>	804-382-3223	
<b>Fax:</b>	804-864-7481	
<b>Email:</b>	julie.henderson@vdh.virginia.gov	
<b>Proposal Subject:</b>	Internal Authority Self-Assessment Using a National Program Standards Manual	
<b>Specific NSSP Guide Reference:</b>	Section II Model Ordinance Chapter I Shellfish Sanitation Program Requirements for the Authority @.01 Administration	
<b>Key Words:</b>	NSSP Program Evaluation; Comparability	
<b>Text of Proposal/ Requested Action</b>	@.01 Administration  A. Scope... B. State Law and Regulations... C. Records... D. Shared Responsibilities... E. Administrative Procedures... F. Epidemiologically Implicated Outbreaks of Shellfish-Related Illness... G. Commingling... <u>H. Program Evaluation. The Authority shall conduct a self-assessment using the National Program Standards Manual and report annually to the U.S. Food and Drug Administration the results of the assessment.</u>	
<b>Public Health Significance:</b>	The purpose of this proposal is to begin discussions on how a self-assessment can be used by Authorities to conduct a comprehensive evaluation of their ability to promote the protection of public health. An assessment conducted by an Authority may encourage continuous improvement and innovation and can assure that individual program activities provide comparability among other domestic and international shellfish programs. The evaluation can be used to assist both the FDA and shellfish Authorities in fulfilling regulatory obligations and ensuring the implementation of the requirements set forth in the NSSP Model Ordinance.	
<b>Cost Information (if available)</b>		