Interstate Shellfish Sanitation Conference

Task Force III Report

2013 Biennial Meeting
January 25 – January 31, 2014

Kirk Wiles
Chair

Margaret Barrette
Vice Chair

Johnathan Gerhardt
Non-Producing Regulatory

Mike Hickey
Region 1 Regulatory

Steve Fleetwood
Region 2 Industry

Erin Butler
Region 3 Regulatory

Tim Parsons
Region 3 Industry

Sandy Shepherd
Region 4 Regulatory

Clifford Hillman
Region 5 Regulatory

Maryanne Guichard
Board Consultant

Paul DiStefano
FDA

Cheryl Lassiter
NOAA

The St. Anthony Riverwalk Hotel
"a national historic landmark"

Proposal Subject:	Press Releases
Specific NSSP Guide Reference:	Section II Model Ordinance Chapter II. Risk Assessment and Risk Management
Text of Proposal/ Requested Action:	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. Use of press is to inform consumers. 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.
Public Health Significance:	
Cost Information (if available):	
Action by 2007 Use of Press Committee	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.
Action by 2007 Task Force III	Recommended adoption of the Press Release Committee recommendation on Proposal 07-305.
Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force III.
Action by USFDA	December 20, 2007 Concurred with Conference action
Action by 2009 Use of Press Committee	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. 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 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.

Action by 2009 Task Force III	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. 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.
Action by 2009 General Assembly	Adopted recommendation of 2009 Task Force III on Proposal 07-305.
Action by USFDA 02/16/2010	Concurred with Conference action on Proposal 07-305.
Action by 2011 Use of Press Committee	Recommended to the Executive Board that the ISSC request that the FDA Core Group coordinate with the ISSC Use of Press Committee concerning use of press protocols. Criteria should include whether suspect product has been accounted for and the degree of public health risk. The Code of Federal Regulations protocols for use of press should be a guiding document as was the case for recall protocols developed by ISSC and FDA. The Committee requested that a work group be appointed to craft a decision tree using the work done to date and the CFR guidance. Members of the Committee that have volunteered for the work group include: Leslie Palmer, Chair; Maryanne Guichard; Don Ulstrom; Bill Dewey; Mike Antee; Tom Mahan; Lori Howell; and Mike Hickey.
Action by 2011 Task Force III	Recommended referral of Proposal 07-305 to an appropriate committee as determined by the Conference Chairman to continue to address the recommendations outlined in the 2011 Use of Press Committee report.
Action by 2011 General Assembly	Adopted the recommendation of Task Force III on Proposal 07-305.
Action by FDA February 26, 2012	Concurred with Conference action on Proposal 07-305.
Action by 2013 Use of Press Committee	Developed recommendation on use of press which were submitted to the USFDA for incorporation into the CORE SOP. The committee further recommends: 1) the committee review and discuss the new CORE document which was effective on 01/16-2014. 2) the committee continue to monitor use of press under the CORE SOP
Action by 2013 Task Force III	Recommends adoption of committee recommendations on Proposal 07-305. The Task further recommends that the committee report its findings to Executive Board.

Proposal Subject:	ISSC State Membership Fees
Specific NSSP Guide Reference:	ISSC Constitution, Bylaws, and Procedures Article III. Registration and Fees
Text of Proposal/ Requested Action:	Section 4. There shall be two (2) categories of membership: Subdivision a. State Subdivision i. Shellfish producing states Subdivision ii. Non-producing states Subdivision b. Individual Member 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. 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. Persons other than Voting Delegates shall be considered members by payment of the individual membership fee. 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.
Public Health Significance:	
Cost Information (if available):	
Action by 2011 Task Force III	Recommended referral of Proposal 11-302 to the appropriate committee as determined by the Conference Chairman.
Action by 2011 General Assembly	Adopted the recommendation of Task Force III on Proposal 11-302.
Action by FDA February 26, 2012	Concurred with Conference action on Proposal 11-302.
Action by 2013 Executive Committee	**Note: The Executive Committee consulted with the Executive Board in the development of the committee recommendations on Proposal 11-302** **Executive Board Policy on Use of Membership Funds** The purpose of this policy is to outline how the ISSC will utilize state membership funds. The recommended state membership fees are established to support 10% of the ISSC projected budget. Presently the majority of ISSC funding is made available from NOAA and USFDA. Should the present federal funding continue to support the ISSC projected budget, state membership fees will be made available to states in the form of travel assistance to the biennial meeting or Executive Board meeting. The level of travel assistance will not exceed the amount of the state membership fees paid.

	Biennial Meeting Year	Non-Biennial Meeting Year
Producing States	1350	1000
Non-Producing States	1000	1000

Article III. Membership and Registration ~~and Fees~~

Procedure XVIII. Executive Board Procedures for Establishing Membership Fees

ARTICLE III. MEMBERSHIP AND REGISTRATION ~~AND FEES~~

Section 1. The membership and registration fees shall be set by the Executive Board as necessary to defray the costs of the Biennial Meeting and the operating costs of the Conference.

Section 2. Membership Fees

Subdivision a. The fee for each category of membership and the membership period shall be set by the Executive Board. State membership fees will be established as necessary to provide, at a minimum, ten percent (10%) of the operating budget of the Conference. The Executive Board will follow the guidelines of Procedure XVIII in establishing membership fees.

Subdivision b. There shall be two (2) categories of membership:

Subdivision i. State

Subdivision (a) Shellfish producing states

Subdivision (b) Non-producing states

Subdivision ii. Individual member

Subdivision c. The membership fees may be paid annually or biennially.

Subdivision d. The State authority membership fees shall include membership for one Voting Delegate. Persons other than Voting Delegates shall be considered members by payment of the membership fee.

Subdivision e. The membership period shall coincide with the calendar year.

Subdivision f. 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.

Section 3. Registration Fees

Subdivision a. Registration fees shall include those amounts required by Article V. Section 9. of this Constitution.

Subdivision b. Any person who is interested in promoting the availability of safe, wholesome shellfish may register at the Conference meeting.

Subdivision c. Persons attending and participating in a Conference

meeting must first register their name, address, and affiliation with the Executive Director and pay the appropriate registration fee.

~~**Section 1.** Any person who is interested in promoting the availability of safe, wholesome shellfish may register at the Conference meeting.~~

~~**Section 2.** Persons attending and participating in a Conference meeting must first register their name, address, and affiliation with the Executive Director and pay the appropriate registration fee.~~

~~**Section 3.** Registration fees shall include those amounts required by Article V., Section 9. of this Constitution.~~

~~**Section 4.** There shall be two (2) categories of membership:~~

~~Subdivision a. State~~
~~Subdivision i. Shellfish producing states~~
~~Subdivision ii. Non-producing states~~
~~Subdivision b Individual Member~~

~~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. Persons other than Voting Delegates shall be considered members by payment of the membership fee. 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.~~

Section 5. The Board Chairperson, with the approval of the Board, shall appoint a non-voting Consumer Advisory representative. The Consumer Advisor shall serve a two (2) year term. The initial Consumer Advisory term shall be one (1) year to coincide with the Biennial meeting schedule.

Section 6. Each Board member and alternate must be a member when elected. For producing state and non-producing state elections, each state may cast one (1) vote by the authorized ISSC Voting Delegates (or alternates). For industry elections, industry registrants within each state may cast one (1) collective vote. Industry may caucus among its registrants in order to determine the voting member.

Section 7. Elected Board members shall serve four-year terms. Terms of the elected Board members shall expire at the end of the voting General Assembly of the regular Biennial Conference meeting.

Section 8. The Board shall elect a Chairperson and Vice-Chairperson for a two, (2) year term at the Executive Board meeting following the voting General Assembly of the regular Biennial Conference meeting. New officers shall take office at the beginning of the Spring Executive Board meeting.

~~**Section 9.**~~ The Board shall direct the Executive Director to collect membership

	and registration fees. ~~as necessary to defray the costs of the meeting and operation of the Conference.~~ The Executive Director shall pay all bills approved by the Board. ~~The registration fee amount shall be set by the Board.~~ The Board shall cause an audit to be made of the Executive Director's financial report annually. The Board shall direct the Executive Director to prepare annually a written financial report listing all receipts, expenditures, and financial balance of the ISSC for the previous year. A copy of the financial report shall be distributed to the membership at each Biennial Meeting. **Section 10**. The Board shall authorize the form used to tally and record votes in Board meetings and Conference meetings. **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 on the ISSC website at www.issc.org. PROCEDURE XVIII. EXECUTIVE BOARD PROCEDURES FOR ESTABLISHING MEMBERSHIP FEES Section 1. The ISSC Executive Board will follow the guidelines of Procedure XVIII in establishing membership fees for State and individual members. Subdivision a. Membership fees will be established as necessary to provide at a minimum, ten (10) percent of the operating costs of the ISSC. Subdivision b. The Executive Board will consider appropriate changes to the minimum of ten percent (10%) should decreases in other funding sources occur. Subdivision c. The Executive Board will allocate travel assistance to member States when the revenue acquired from membership fees is not critical to supporting the Conference operating budget.
Action by 2013 Task Force III	Recommended adoption of the Executive Committee recommendation on Proposal 11-302.

Proposal Subject:	ISSC Constitutional Cost-Benefit Requirement for New Proposals that have a Significant Financial Impact on the States and Shellfish Industry
Specific NSSP Guide Reference:	
Text of Proposal/ Requested Action:	Article XIII. Procedure for the Submission of Proposals 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. Section 2. All proposals must be submitted to the Executive Office no later than one hundred twenty (120) days prior to the Conference meeting. 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. Section 4. 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. Section 5~~4~~. 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. Section 4., Section 5., Section 6., and Section 7. of the Constitution of the Conference. Section 6~~5~~. 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. Section 7~~6~~. 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, training and research, or similar items concerning processing and distribution shall be assigned to Task Force II by the Executive Director. Section 8~~7~~. 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. Section 9~~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. Section 10~~9~~. 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. Subdivision a. Why is the proposal being submitted after the deadline? Subdivision b. Was the information available prior to the deadline? Subdivision c. What is the criticality of the proposal to the safety of molluscan shellfish or the future of the ISSC? Subdivision d. Does the proposal involve an NSSP Guide for the Control of Molluscan Shellfish change or an ISSC administrative change? Section 11~~10~~. The Executive Director will consult with the Proposal Review Committee before declaring any problem or proposal invalid. Section 12~~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.
Public Health Significance:	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.
Cost Information (if available):	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.
Action by 2011 Task Force III	Recommended referral of Proposal 11-305 to the appropriate committee as determined by the Conference Chairman. The committee is instructed to identify ways to better utilize the cost information portion of the proposal submission form.
Action by 2011 General Assembly	Adopted the recommendation of Task Force III on Proposal 11-305.
Action by FDA February 26, 2012	Concurred with Conference action on Proposal 11-305.
Action by 2013 Proposal Review Committee	Recommended no action on the proposed change to the procedures for submission of Proposals. The committee further recommended that an appropriate committee, as determined by the Conference Chair, work with the Executive Office to develop Proposal Submission Instructions. In addition to technical instructions about how to use the form, the instructions should address each field of the submission form and shall be completed prior to the next call for proposals. The instructions for the "cost" field should provide further guidance, including examples, of the type of cost information that may be useful to those reviewing the proposal.
Action by 2013 Task Force III	Recommends adoption of the Proposal Review Committee recommendations.

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

Proposal Subject:	Determining Effectiveness of NSSP Changes
Specific NSSP Guide Reference:	ISSC Constitution, Bylaws, and Procedures Article I. Task Forces Procedure X. Procedure for Handling ISSC Summary of Actions
Text of Proposal/ Requested Action:	Article I. Task Forces 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> <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> Procedure X. Procedure for Handling ISSC Summary of Actions <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>
Public Health Significance:	N/A
Cost Information (if available):	
Action by 2011 Task Force III	Recommended referral of Proposal 11-306 to the appropriate committee as determined by the Conference Chairman.
Action by 2011 General Assembly	Adopted the recommendation of Task Force III on Proposal 11-306.
Action by FDA February 26, 2012	Concurred with Conference action on Proposal 11-306.
Action by 2013 Program Review Committee	Recommends the adoption 11-306 with the following substitute language: **<u>ARTICLE IV. EXECUTIVE BOARD, OFFICERS, COMMITTEES</u>** **Section 10**. The Board may appoint committees from industry, educational institutions, research fields, or any other areas as needed to report to the Board and advise the Conference on proposals under

	consideration. Committee appointments will be made from the Conference membership by the Executive Board Chairman. The following committees shall be designated as standing committees and shall convene as needed or as directed by the Executive Board or Chairperson of the Conference: Education, Foreign Relations, Proposal Review, Patrol, Research Guidance, Resolutions, Shellfish Restoration, *Vibrio* Management Committee, and Model Ordinance Effectiveness Review Committee. The Vice-Chairperson of the Conference shall assist the Executive Director in encouraging development of committee work plans and completion of subcommittee assignments prior to convention of the Biennial Meeting. **Section 15.** The Executive Board Chairperson shall appoint a thirteen (13) member Model Ordinance Effectiveness Review Committee. The Committee will be comprised of a Chairperson with at least (1) industry members from the East, Gulf and West coasts, at least one (1) state regulatory from each of the ISSC regions and at least one (1) state regulatory person from a non-producing state. The Committee will also include one voting member from NOAA, one voting member from FDA and one voting member from EPA. The Federal entities will appoint these members. This Committee will review the requirements of the NSSP Model Ordinance and identify requirements that are deemed to be ineffective. The Committee will present recommendations in proposal form to the appropriate Task Force for the deletion or modification of ineffective requirements; or requirements that are excessively costly for the intended public health benefit. New requirements will not be reviewed until the fourth year following the implementation date. A four year waiting period will provide adequate time to determine effectiveness of new controls. Note: Initially the Committee will review all of the requirements in the NSSP that have been in existence for four (4) years or more. Following the initial review, the procedure outlined above would be followed by the Committee prior to the proposal submission deadline.
Action by 2013 Task Force III	Recommends adoption of the recommendation of the Program Review Committee as amended. **ARTICLE IV. EXECUTIVE BOARD, OFFICERS, COMMITTEES** **Section 10**. The Board may appoint committees from industry, educational institutions, research fields, or any other areas as needed to report to the Board and advise the Conference on proposals under consideration. Committee appointments will be made from the Conference membership by the Executive Board Chairman. The following committees shall be designated as standing committees and shall convene as needed or as directed by the Executive Board or Chairperson of the Conference: Education, Foreign Relations, Proposal Review, Patrol, Research Guidance, Resolutions, Shellfish Restoration, *Vibrio* Management Committee, and Model Ordinance Effectiveness Review Committee. The Vice-Chairperson of the

		Conference shall assist the Executive Director in encouraging development of committee work plans and completion of subcommittee assignments prior to convention of the Biennial Meeting.
	Section 15.	The Executive Board Chairperson shall appoint a thirteen (13) member Model Ordinance Effectiveness Review Committee. The Committee will be comprised of a Chairperson with at least (1) industry members from the East, Gulf and West coasts, at least one (1) state regulatory from each of the ISSC regions and at least one (1) state regulatory person from a non-producing state. The Committee will also include one voting member from NOAA, one voting member from FDA and one voting member from EPA. The Federal entities will appoint these members. This Committee will review the requirements of the NSSP Model Ordinance and identify requirements that are deemed to be ineffective. The Committee will present recommendations in proposal form to the appropriate Task Force for the deletion or modification of ineffective requirements; or requirements~~, that are excessively costly for the intended public health benefit.~~ New requirements will not be reviewed until the fourth year following the implementation date. A four year waiting period will provide adequate time to determine effectiveness of new controls. Note: Initially the Committee will review all of the requirements in the NSSP that have been in existence for four (4) years or more. Following the initial review, the procedure outlined above would be followed by the Committee prior to the proposal submission deadline.

Proposal Subject:	Internal Authority Self-Assessment Using a National Program Standards Manual
Specific NSSP Guide Reference:	Section II Model Ordinance Chapter I Shellfish Sanitation Program Requirements for the Authority @.01 Administration
Text of Proposal/ Requested Action	@.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… 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.
Public Health Significance:	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
Cost Information (if available)	
Action by 2011 Task Force III	Recommended referral of Proposal 11-310 to the appropriate committee as determined by the Conference Chairman.
Action by 2011 General Assembly	Adopted the recommendation of Task Force III on Proposal 11-310.
Action by FDA February 26, 2012	Concurred with Conference action on Proposal 11-310.
Action by 2013 NSSP Evaluation Criteria Committee	Recommended referral of Proposal 11-310 to the appropriate committee as determined by the Conference Chairperson with the following instructions. Establish a workgroup to evaluate the Manufactured Food Standards and determine the applicability of and/or use of these Manufactured Standards to the National Shellfish Sanitation Model Ordinance requirements and report their findings and recommendations to the NSSP Evaluation Criteria Committee at the next ISSC Meeting. The Committee further recommended that self-assessments should be voluntary and that the word "shall" should be replaced with the word "may".

Action by 2013 Task Force III	Recommends adoption of the NSSP Evaluation Criteria committee recommendation on Proposal 11-310.

Proposal Subject:	State Program Evaluation Criteria
Specific NSSP Guide Reference:	ISSC Constitution, Bylaws, and Procedures NSSP Guide Model Ordinance Chapters and Guidance Documents
Text of Proposal/ Requested Action	The ISSC has adopted State Program Evaluation Criteria for several program elements including laboratory, patrol, and processing plants. These evaluation criteria are incorporated into the NSSP as follows: Laboratory: Model Ordinance Chapter II and Guidance Documents Chapter II Growing Areas .12 and Shellfish Laboratory Evaluation Checklists Patrol: Model Ordinance Chapter VIII; Guidance Documents Chapter I General .03; and Guidance Documents Chapter II Growing Areas .09 Shellfish Plant Inspection Program: ISSC Constitution, Bylaws, and Procedures Procedure XV The purpose of this proposal is to move all NSSP evaluation criteria used by the USFDA to evaluate State program elements into a new Model Ordinance Chapter XVII. This proposed change will not involve modification of any criteria. The purpose is to locate all State evaluation criteria into one central location. Presently the criteria are difficult to locate.
Public Health Significance:	The proposed change does not have public health significance.
Cost Information (if available):	
Action by 2013 Task Force III	Recommends referral of Proposal 13-300 to an appropriate committee as determined by the Conference Chairman.

Proposal Subject:	Growing Area Classification Criteria
Specific NSSP Guide Reference:	To Be Determined
Text of Proposal/ Requested Action	The ISSC has adopted evaluation criteria for several program elements within the NSSP. These include laboratories, plant sanitation, and patrol. The development of these criteria has seemed to provide a better understanding of expectations, improve uniformity in State evaluations and enhance compliance. The ISSC should expand its evaluation criteria efforts to include growing area classification. Most illnesses associated with molluscan shellfish can be traced to problems associated with growing area classification. Although more complex, this element of the program could benefit from the development of evaluation criteria. The purpose of this proposal is to request the Evaluation Criteria Committee be charged with the task of developing evaluation criteria for the growing area element.
Public Health Significance:	Growing area classification criteria will enhance State classification efforts and ensure a high level of uniformity and effectiveness in FDA evaluations.
Cost Information (if available):	
Action by 2013 Task Force III	The submitter of proposal 13-301 requested that the following sentence be deleted from the proposal. ~~Most illnesses associated with molluscan shellfish can be traced to problems associated with growing area classification.~~ The Task Force recommends adoption of Proposal 13-301 with the amendment as requested by the submitter.

Proposal Subject:	Executive Board Voting
Specific NSSP Guide Reference:	ISSC Constitution, Bylaws and Procedures, Article IV. Executive Board Officers, Committees Section 2.
Text of Proposal/ Requested Action	The Board shall be comprised of eighteen (18) voting members selected as follows……. Only those members of the Executive Board representing shellfish producing states and non-producing states will have a vote for recommended changes to the NSSP Model Ordinance. Each shellfish producing state Executive Board member shall be entitled to one (1) full vote and each non-producing state shall be entitled to (1) vote in Executive Board meetings with the exception of issues involving recommendations Task Force I.
Public Health Significance:	Voting with regard to changes to the NSSP Model Ordinance by the Executive Board should be the same as the Biennial Meeting of the ISSC Voting Delegates.
Cost Information (if available):	
Action by 2013 Task Force III	Recommends no action on Proposal 13-302. Rationale: The Constitution, Bylaws and Procedures adequately addresses Executive Board voting.

Proposal Subject:	ISSC Executive Board Retail Advisor
Specific NSSP Guide Reference:	ISSC Constitution, Bylaws, and Procedures Article IV. Executive Board, Officers, Committees
Text of Proposal/ Requested Action	Section 5. The Board Chairperson, with the approval of the Board, shall appoint a non-voting Consumer Advisory representative and a Retail Advisory representative. The Consumer Advisor and the Retail Advisor shall serve a two (2) year term. The ~~initial~~ Consumer Advisory term and Retail Advisor term shall ~~be one (1) year to~~ coincide with the Biennial meeting schedule.
Public Health Significance:	
Cost Information (if available):	
Action by 2013 Task Force III	Recommends adoption of Proposal 13-303 as submitted.

Proposal Subject:	ISSC Proposal Review Committee
Specific NSSP Guide Reference:	ISSC Constitution, Bylaws, and Procedures Article IV. Executive Board, Officers, Committees
Text of Proposal/ Requested Action	Section 13. The Executive Board Chairperson shall appoint a 12-member Proposal Review Committee. The Committee will be comprised of a Chairperson and four (4) regulatory members, four (4) industry members, and a representative from the FDA, NOAA, and EPA. The Committee will review and link ~~prioritize~~ proposals for Conference consideration. The Committee will also provide consultation as needed to the Executive Director in assigning proposals to Task Forces.
Public Health Significance:	
Cost Information (if available):	
Action by 2013 Task Force III	Recommends adoption of Proposal 13-304 as submitted

Proposal Subject:	Executive Board Interim Changes to NSSP Model Ordinance
Specific NSSP Guide Reference:	ISSC Constitution, Bylaws & Procedures
Text of Proposal/ Requested Action	Article V. Duties of the Board Section 1. The Board shall manage the affairs of the Conference. The Board may not act on behalf of the Voting Delegates between voting Conference meetings unless directed to do so by 2/3 vote from the voting delegates at the general assembly of the last meeting. The Board may act on behalf of the Voting Delegates in the case of a public health emergency or event that requires changes in the NSSP. ~~in keeping with the spirit and intent of the delegates.~~ Any decision or action taken by the Board which would require Voting Delegate approval in accordance with the remainder of this Constitution, By-Laws, or Procedures, shall be submitted as a proposal to the next voting meeting for concurrence or correction.
Public Health Significance:	Interim changes to the Model Ordinance implemented by the Executive Board between Biennial Meetings of the ISSC have caused angst to some of the voting members of the conference. Changes to the Model Ordinance should be deliberated by the full Conference prior to implementation and evaluation of a State program by USFDA for compliance. Many changes require regulatory changes that States have difficulty promulgating since there has not been an opportunity to fully understand or embrace these changes or the possibility of these interim requirements to change at the next Biennial Meeting of the ISSC. It makes it extremely difficult for States to consider the sometimes long and tedious process of regulatory change when in fact the Voting Delegates might change the items implemented by the Board. Changes to the NSSP Model Ordinance need to be deliberated and considered by full participation of the Voting Delegates of the ISSC.
Cost Information (if available):	This change could possibly be a cost savings since States would not have to change regulations as often and regulation changes would be thoroughly vetted by the Voting Delegates of the ISSC.
Action by 2013 Task Force III	Recommends no action on Proposal 13-305. Rationale: The Constitution, Bylaws and Procedures adequately address Executive Board voting.

Proposal Subject:	ISSC Biennial Meeting
Specific NSSP Guide Reference:	ISSC Constitution, Bylaws, and Procedures Article XI. Rules of Biennial Conference Meetings
Text of Proposal/ Requested Action	ARTICLE XI. Rules of Annual~~Biennial~~ Conference Meetings Section 1. Except for special meetings, as provided for in Article V., Section 5. of this Constitution, the Conference will convene a meeting annually ~~through 1999 and biennially during the odd numbered years thereafter~~ and will rotate it among the different Regions of the country. NOTE: If adopted, all other references to Biennial in the ISSC Constitution, Bylaws, and Procedures will be changed to annual.
Public Health Significance:	
Cost Information (if available):	
Action by 2013 Task Force III	Recommends adoption of Proposal 13-306 as submitted. The Task Force further recommends an implementation date of 2016. The next Biennial Meeting will be held in 2015 and subsequent meetings would then be held annually. The Task Force recommends that the Executive Board explore condensing the meeting schedule to reduce the number of meeting days.

Proposal Subject:	Voting by the State Delegates
Specific NSSP Guide Reference:	Constitution, Bylaws & Procedures of the ISSC (Updated March 28, 2013) Constitution of the Interstate Shellfish Sanitation Conference Article XI. Rules of Biennial Conference Meetings
Text of Proposal/ Requested Action	Article XI. Rules of Biennial Conference Meetings Section 3. Business Rules of Conference Meetings Subdivision a. Robert's Rules of Order shall prevail, unless specific rules are established by the Conference. Subdivision b. Each shellfish producing State shall be entitled to one (1) full vote in the Conference meeting general assembly and each nonproducing State shall be entitled to one (1) vote in the Conference meeting General Assembly with the exception of ~~issues~~ proposals involving Task Force I recommendations and Task Force II proposals involving harvesters or their activities. Non-producing States shall be entitled to one-half (1/2) vote on proposals involving Task Force I recommendations or Task Force II proposals involving harvesters or their activities.
Public Health Significance:	Non-producing States may not have the necessary insight and experience related to factors that impact harvesters and those responsible for regulating/enforcing them. For proposals that require State Regulatory changes impacting harvesters, more weight of the vote should be given to growing area States.
Cost Information (if available):	This change could possibly be a cost savings since State agencies must consider economic impact to businesses when promulgating new regulations.
Action by 2013 Task Force III	Recommends no action on Proposal 13-307. Rationale: The Constitution, Bylaws and Procedures adequately address Delegate voting.

Proposal Subject:	Changes to Procedure for Evaluation of Shellfish Sanitation Program Elements.
Specific NSSP Guide Reference:	ISSC Constitution, Bylaws & Procedures Procedure XV. Procedure for Evaluation of Shellfish Sanitation Program Elements
Text of Proposal/ Requested Action	**Refer to the *Proposals for Consideration at the 2013Biennial Meeting.***
Public Health Significance:	Current Infield Plant criteria automatically "fails" a plant even if the critical deficiency is address and corrected. This puts a plant in non-compliance but still operating which is inconsistent with the evaluation of deficiency follow-up in Subdivision v (f). States are deemed in compliance when evaluating deficiency follow-up when critical deficiencies have been addressed. During a plant inspection, the professional discretion of the inspector is used to determine the severity of the critical deficiency. In some cases a critical deficiency that is addressed and corrected at the time of inspection allows the plant to legally continue to process and sell product. Critical deficiencies that are addressed and corrected at the time of the infield Plant Sanitation Element should be consistent with this. Deficiencies with a criticality code of "Other" vary widely in public health significance and in many cases may be the result of normal wear or use during the operating season. This is especially true with items in Item 17; Plants and Grounds, and Item 21; Equipment Condition, Cleaning, Maintenance and Construction of Non-Food Contact Surfaces. Many of these "other" deficiencies are addressed prior to re-certification for the following season.
Cost Information (if available):	No cost to states or industry.
Action by 2013 Task Force III	Recommends referral of Proposal 13-308 to the NSSP Evaluation Criteria Committee.

Proposal Subject:	NSSP Method Approval Review Process
Specific NSSP Guide Reference:	ISSC Constitution, Bylaws, and Procedures Procedure XVI. Procedure for the Approval of Analytical Methods for the NSSP
Text of Proposal/ Requested Action	Section 1. Prior to NSSP adoption, all laboratory methods shall be evaluated by the ISSC~~ using the validation criteria developed as detailed in the Single Laboratory Validation Protocol;~~ Persons interested in submitting a method for inclusion in the NSSP must submit a pre-proposal outlining the following: a. Description of Method; b. Proposed Use of Method; c. Time Table for SLV. ~~Section 2. All methods shall be submitted to the ISSC in proposal form requesting approval of the analytical method for use in the NSSP~~ ~~Subdivision a. Proposals shall include a completed Single Laboratory Validation Method Application and Checklist.~~ ~~Subdivision b. The ISSC Executive Director shall submit the proposal to the Laboratory Methods Review Committee for review and development of recommendations to Task Force I.~~ Section 2. The submitter of the proposal will be notified by the ISSC Executive Office of the action taken on the pre-proposal by the ISSC. Section 3. Submitters of pre-proposals receiving approval will be requested to submit a full proposal to the ISSC and a liaison from the Laboratory Methods Review Committee will be assigned. Section 4. The full proposal shall be submitted to the ISSC in proposal form requesting approval of the analytical method for use in the NSSP. Subdivision a. All proposals shall include a completed Single Laboratory Validation Method Application and Checklist. AOAC approved methods that have undergone the AOAC Official Methods of Analysis (OMA) or FDA Office of Foods Level 3 or 4 validations may be accepted as an NSSP method without Single Lab Validation providing the AOAC or FDA multi-laboratory validation was performed in the raw molluscan shellfish matrix for which the Conference intends it to be used, and is deemed by ISSC as fit for purpose. Submitters of AOAC and FDA validated methods will provide a Single Laboratory Validation Method Application and Checklist along with the AOAC OMA or FDA Office of Foods Level 3 or 4 validation.

Subdivision b. The ISSC Executive Director shall submit the proposal to the Laboratory Methods Review and Quality Assurance Committee for review and development of recommendations to Task Force I.

Section 5. Within six (6) months of receipt the Laboratory Method Review and Quality Assurance Committee will review the proposal package for completeness and recommend to the Executive Board the suitability of the method for a full review for possible inclusion into the NSSP. The recommendation of the Executive Board will be presented to the ISSC Voting Delegates for approval.

Section ~~3~~6. Review by Laboratory Methods Review Committee;

Subdivision a. Within six (6) months of receipt of a complete application proposal, ~~T~~the Laboratory Methods Review Committee shall conduct an evaluation of the data which describes the performance characteristics of the ~~method~~ new proposal, the AOAC approved method or FDA Office of Foods Level 3 or 4 method;

Subdivision i. These performance characteristics include:

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 (comparison of the performance of the new/modified method to the accepted method.

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. Subdivision iii. Specific application(s); Subdivision b. Review of need for the method; Subdivision i. Method meets an immediate or continuing need; Subdivision ii. Improves analytical capability under the NSSP as an alternative to an accepted method(s); . Subdivision iii Replaces other approved or accepted method(s). Section ~~4~~7. The Laboratory Methods Review Committee shall submit one of the following recommendations to Task Force I within six (6) months of receiving a complete proposal application for a method: Subdivision a. Non-acceptance pending further information as defined by the Committee; Subdivision b. Accept as an Approved NSSP Method; Subdivision c. Accept as an Approved Limited Use NSSP

Method;

Subdivision d. Accept as an Emergency Use NSSP Method.

Section ~~5~~8. 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.

Section ~~6~~9. 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 .11 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 .11 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; Subdivision 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, re-agents 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.
Public Health Significance:	
Cost Information (if available):	
Action by 2013 Task Force III	Recommends adoption of Proposal 13-310 as submitted.

Proposal Subject:	*V.v.* Illness Review Subcommittee Procedures Procedure XVII.
Specific NSSP Guide Reference:	Constitution, Bylaws, and Procedures
Text of Proposal/ Requested Action	Procedure XVII. ~~Reciprocity~~ Procedure for *Vibrio vulnificus (V.v.)* Illness Review Committee Procedures Section 1. Charge. The *V.v.* Illness Review Committee will annually review all *V.v.* cases involving the consumption of shellfish which are reported to FDA regional specialists and the Center for Disease Control (CDC). The Committee will determine which cases meet the case definition of a National Shellfish Sanitation Program (NSSP) *V.v.* case as outlined in Model Ordinance Section II Chapter II @.05. All cases meeting the NSSP definition will be included in an annual report which will be presented to the Interstate Shellfish Sanitation Conference (ISSC) Executive Board and the Vibrio Management Committee. Following ISSC Executive Board approval the report will be made available to the ISSC membership and posted on the ISSC website. This data is expected to be used by USFDA, State Authorities, and the ISSC for the following purposes: Subdivision a. Conducting annual *V.v.* Risk Evaluations; Subdivision b. Risk per serving determinations; Subdivision c. *V.v.* Control Plan Evaluations; Subdivision d. *V.v.* Contingency Plan Evaluations; and Subdivision e. Reviewing illness trends. Section 2. Procedures. Subdivision a. The Committee will only consider cases that are reported on a CDC and Prevention Cholera Vibrio Illness Surveillance Report (COVIS) Form CDC 52.79 or other means. Subdivision b. FDA (currently Shellfish Specialist Mark Glatzer) will coordinate the collection of cases and COVIS forms, and other information and after redacting identifying information will make this information available to the Committee. Subdivision c. The information from the COVIS forms will be shared with the *V.v.* Illness Review Committee for review. Subdivision d. The *V.v.* Illness Review Committee will review the cases and incorporate the appropriate information into a chart (see attachment A) which will serve as the Committee report. Subdivision e. The report will be presented to the ISSC Executive Board for approval and then forwarded to the Vibrio Management Committee. Subdivision f. The availability of the report will be announced to the ISSC membership. Section 3. A copy of the report will be posted on the ISSC website.

Criteria and Guidelines. The Committee will use the following criteria and guidelines in reviewing reported cases:

Subdivision a. Was the illness etiologically confirmed? In this context "etiologically confirmed "shall mean laboratory confirmation by wound, stool or blood culture. Confirmation may be by a laboratory other than a State laboratory."

Subdivision b. Was the illness epidemiologically linked to shellfish? Epidemiologically linked will mean "associated with" the consumption of oysters. Consumption means ingested; eaten within 7 days of onset of symptoms. Date of onset may be before hospitalization. Further information may be warranted; discretion may be exercised.

Subdivision c. Were the shellfish commercially harvested? Commercially harvested shall mean the shellfish were intended for sale or distribution in commerce. Commercial harvest will include those cases involving a foreign state.

Subdivision d. Were the shellfish raw or undercooked? If the victim developed *V.v.* septicemia after consumption the shellfish are considered to have been raw or undercooked.

Subdivision e. From what State was the shellfish harvested?

Subdivision f. Did the case involve septicemia from consumption: The following guidance will be used in determining if the case is a septicemia or a gastroenteritis case. Clinical signs and symptoms *V.v.* septicemia include:

Subdivision i. *V.v.* bacteria isolated from blood.

Subdivision ii. Fever measured as above 100 degree Fahrenheit.

Subdivision iii. Death as outcome (septicemia has a mortality rate of over 50% - 70%).

Subdivision iv. Bullae (blood filled blisters) but this also can occur after a wound infection which becomes septic.

Subdivision v. Shock because of the sepsis (again this can happen also because of a wound infection).

Subdivision g. Indications case may not be *V.v.* septicemia from consumption:

Subdivision i. Bacteria are only isolated from wound fluid or stool and no clinical evidence of septicemia

Subdivision ii. Cellulitis. Since cellulitis is a localized or diffuse inflammation of connective tissue with severe inflammation of dermal and subcutaneous layers of the skin (bacteria entering bodies through

	the skin, there might be a visible wound or just a small scratch), therefore more likely a wound infection. Subdivision iii. History of pre-existing and sustained wound infection (If both wound and oyster/seafood consumption is documented and happened within the incubation period, there is no way to differentiate why the patient is septic.) Subdivision iv. Septicemia has a much shorter incubation period compared to gastroenteritis, according to CDC data, *V.v.* septicemia has an incubation period between 12-72 hours, although we have seen cases with shorter incubation periods. Section 4. Challenges to Committee Findings Persons wishing to challenge the information included in the report must notify the ISSC Executive Director within sixty (60) days of the posting of the report on the ISSC website. The ISSC Executive Board will review all challenges at the next scheduled Executive Board meeting. *Vibrio Vulnificus* Illness Review Criteria Table on next page. Procedure XVIII. Reciprocity
Public Health Significance:	
Cost Information (if available):	
Action by 2013 Task Force III	Recommends adoption of proposal 13-310 as submitted.

Vibrio vulnificus Illness Review Criteria Table

Review Date: _____

Case Identifier/Number:	**Criteria Status Determination**		
Criteria	**Yes**	**No**	**Unknown**
1. Etiologically Confirmed Blood Stool			
2. Epidemiologically Linked?			
3. Septicemia Illness?			
4. Reporting State?			
5. Commercial Harvest?			
6. Were shellfish consumed?			
a. Specify shellfish consumed:	**Oysters**	**Clams**	**Specify Other**
b. Date of consumption: _____			
c. Is onset consistent with consumption of shellfish? Date of onset _____			
7. Trace-back Information			
a. Were shipping tags available? If other trace-back information reported, list:			
b. State of harvest, harvest area (s), and harvest date (list all reported).			

Harvest Area	Harvest State	Harvest Date	Species	Comment

ISSC *V.v.* Illness Review Subcommittee Form (06/28/2013)