Interstate Shellfish Sanitation Conference

2017 Biennial Meeting

Task Force III Report

South Carolina

the palmetto state

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NOAA

October 14 - 19, 2017
Sheraton Hotel

Proposal No. **11-310**

Submitter	Julie Henderson
Affiliation	Virginia Department of Health Division of Shellfish Sanitation
Email	julie.henderson@vdh.virginia.gov
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
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	
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	Recommended adoption of the NSSP Evaluation Criteria Committee recommendation on Proposal 11-310.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force III on Proposal 11-310.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 11-310.

Action by 2015 NSSP Evaluation Criteria Committee	Recommended that draft standards be developed for each program element. These draft standards will be developed using the standards from other programs and the FDA draft. It is further recommended that the ISSC identify volunteer states to pilot the standards once developed. The committee will review results from the pilot and submit a proposal for conference consideration.
Action by 2015 Task Force III	Recommended adoption of the NSSP Evaluation Criteria Committee recommendation on Proposal 11-210.
Action by 2015 General Assembly	Adopted recommendation of Task Force III on Proposal 11-310.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 11-310.
Action by 2017 NSSP Evaluation Committee	Recommended: 1. The full committee be allowed to review the Voluntary National Shellfish Regulatory Program Standards Plant Sanitation draft report. 2. This review should take place as soon as possible so that a decision can be made in January by the NSSP Evaluation Committee via a conference call. 3. If the full committee concurs, 2-4 state can move forward with a pilot study for the program standards as determined by the sub-committee chair.
Action by 2017 Task Force III	Recommends referral of Proposal 11-310 back to the NSSP Evaluation Criteria Committee with instructions to review the Plant Sanitation Standards developed by the Standards Subcommittee. The Committee is instructed to complete the review by January 31, 2018 and present recommendations to the ISSC Executive Board for interim approval and pilot testing.

Proposal No. **13-301**

Submitter	ISSC Executive Office
Affiliation	Interstate Shellfish Sanitation Conference
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	
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 recommended adoption of Proposal 13-301 with the amendment as requested by the submitter.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force III on Proposal 13-301.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-301.

Action by 2015 NSSP Evaluation Criteria Committee	Recommended: 1) The following criteria be used in evaluating the State Growing Area classification element 1. Written Sanitary Survey (A) Is there a written Sanitary Survey for each growing area that is classified other than prohibited? (B) Is the Sanitary Survey complete? A. Executive Summary B. Description of Growing Area C. Pollution Source Survey D. Hydrographic and Meteorological Characteristics E. Water Quality Studies F. Interpretation of Data in Determining Classification to Be Assigned to Growing Area: A discussion of how actual or potential pollution sources, wind, tide, rainfall, etc. affect or may affect water quality, that will address the following: G. Conclusions (C) Is the Sanitary Survey current? A. Annual B. Triennial C. 12 Year) 2. Shoreline Survey (A) Does Shoreline Survey include identification and evaluation of all actual and potential sources of pollution (B) Does Shoreline Survey include boundaries? (C) Does Shoreline Survey include unique designation? (D) Does Shoreline Survey include required maps? (E) Does Shoreline Survey include a summary of survey findings? 3. Adequate Sampling (A) Are the number and location of sampling stations adequate to effectively evaluate all pollution sources? (B) Were adequate samples collected for each area consistent with the classification and type of sampling approach used (i.e. Remote, Adverse Pollution, Systematic Random Sampling)? (C) Were samples collected under appropriate conditions consistent with the type of sampling approach? 4. Data to support Classification (A) The assigned classifications are based on data/information supporting the classification and performance standards? (B) Is appropriate data/information available to support the classification within each designated growing area? 5. Proper Classification (A) Are all growing areas properly classified? (B) Does SSCA have appropriate MOU(s) with appropriate parties for each area classified as conditional?

	2) The subcommittee will develop a scoring system which assigns appropriate significance to the criteria and establishes compliance standards which can be used to assign compliance designations as outlined in the other NSSP elements. 3) Field testing of the complete evaluation criteria including compliance designation will be field tested in one state in each ISSC region. The results will be reviewed by the NSSP Evaluation Committee, modified as appropriate and presented to the ISSC as a proposal.
Action by 2015 Task Force III	Recommended adoption of the NSSP Evaluation Criteria Committee recommendations on Proposal 13-301.
Action by 2015 General Assembly	Adopted recommendation of Task Force III on Proposal 13-301.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 13-301.
Action by 2017 NSSP Evaluation Criteria Committee	Recommended 1.The full committee be allowed to review the FDA proposed growing area evaluation criteria immediately, 2. Concur with FDA not to initiate a full pilot until the committee completes a review of the FDA proposed criteria.
Action by 2017 Task Force III	Recommends referralof Proposal 13-301 back to the NSSP Evaluation Criteria Committee with the following charge: Review the evaluation criteria provided to the NSSP Evaluation Criteria Committee and provide recommendation for interim approval by the ISSC Executive Board at the Spring Board meeting. The Executive Board is requested to coordinate the piloting of the criteria with FDA as soon as possible.

Proposal No. **17-300**

Submitter	ISSC Executive Office
Affiliation	Interstate Shellfish Sanitation Conference
Email	issc@issc.org
Proposal Subject	State Shellfish Control Authority (SSCA)
Specific NSSP Guide Reference	NSSP Guide for the Control of Molluscan Shellfish and ISSC Constitution, Bylaws, and Procedures
Text of Proposal/ Requested Action	Change all references in NSSP Guide for the Control of Molluscan Shellfish and the ISSC Constitution, Bylaws, and Procedures to include the term "Authority" for the purposes of identifying all government entities that are responsible for implementing the NSSP. Add the following definition to the ISSC Constitution, Bylaws, and Procedures: **(1) Authority** means the State or local shellfish control authority or authorities or its designated agents, which are responsible for the enforcement of this Code. Delete the following definition from the ISSC Constitution, Bylaws, and Procedures: ~~(11) STATE SHELLFISH CONTROL AUTHORITY (SSCA) - the state agency or agencies having the legal authority to classify shellfish growing waters, to issue certificates for the interstate shipment of shellfish and to regulate harvesting, processing and shipping in accordance with the NSSP Model Ordinance [effective January 1, 1998].~~
Public Health Significance	This change will create consistency in terminology.
Cost Information	
Action by 2017 Task Force III	Recommends adoption of Proposal 17-300 as submitted.

Proposal No. **17-301**

Submitter	ISSC Executive Office
Affiliation	Interstate Shellfish Sanitation Conference
Email	issc@issc.org
Proposal Subject	CDC and ORA Liaisons for ISSC Executive Board
Specific NSSP Guide Reference	ISSC Constitution, Bylaws, and Procedures
Text of Proposal/ Requested Action	ARTICLE IV. EXECUTIVE BOARD, OFFICERS, COMMITTEES Section 5. The Board Chairperson, with the approval of the Board, shall appoint a non-voting Consumer Advisory representative, ~~and~~ a non-voting Retail Advisory representative a non-voting CDC Liaison, and a non-voting FDA Office of Regulatory Affairs Liaison. The Consumer Advisory representative, ~~and~~ the Retail Advisory representative, ~~,~~ the CDC Liaison, and the FDA Office of Regulatory Affairs Liaison shall serve a two (2) year term. The two-year term ~~Consumer Advisory representative term and the Retail Advisory term~~ shall coincide with the Biennial meeting schedule.
Public Health Significance	Both CDC and the FDA ORA will provide important input to Executive Board discussions.
Cost Information	
Action by 2017 Task Force III	Recommends adoption of Proposal 17-301 as submitted.

Proposal No. **17-302**

Submitter	ISSC Executive Office
Affiliation	Interstate Shellfish Sanitation Conference
Email	issc@issc.org
Proposal Subject	NSSP Training Curriculum
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter I Section IV. Guidance Documents Chapter I
Text of Proposal/ Requested Action	Presently the NSSP does not have a well defined training curriculum for State Shellfish Authority staff that are implementing the requirements of the NSSP. There are two (2) required courses for Authority staff and FDA provides other training on an as needed basis. In 2016, the Association of Food and Drug Officials received a cooperative program grant to support training for shellfish regulatory staff. A joint advisory group (JAG) was created to provide oversight. The lack of an established NSSP curriculum made it difficult to develop funding selection criteria. In response, the ISSC appointed a training committee which discussed available training and provided recommendations to the JAG. The purpose of this proposal is to charge the Training Committee with development of an NSSP training curriculum for inclusion into either Chapter I of the Model Ordinance or as a Guidance Document.
Public Health Significance	Adequate training of Authority staff is fundamental to successful implementation of the elements of the NSSP. A NSSP training curriculum would be a helpful tool to guide Authorities in selection of appropriate and helpful training for staff.
Cost Information	
Action by 2017 Task Force III	Recommends adoption of Proposal 17-302 as submitted.

Proposal No. **17-303**

Submitter	ISSC Executive Office
Affiliation	Interstate Shellfish Sanitation Conference
Email	issc@issc.org
Proposal Subject	*V.v.* Case Appeal Procedure
Specific NSSP Guide Reference	ISSC Constitution, Bylaws, and Procedures Procedure XVI. Procedure for *Vibrio vulnificus (V.v.)* Illness Review Committee Procedures
Text of Proposal/ Requested Action	SECTION 5. *V.v.* Case Appeal Procedure 1. Appropriate V.v. information will be provided to the reporting and source States prior to review by the V.v. Illness Review Committee. 2. Following V.v. Illness Review Committee review, each source State with a countable case will be notified. 3. Should a source State disagree with the Committee determination on a specific case, the source State will be provided thirty (30) days to file an appeal. 4. Should the Committee, based on the information provided by the appellant, conclude that the original determination should be reversed, the appellant will be notified. 5. Should the Committee, based on the information provided by the appellant, conclude that the original determination was appropriate; the Committee will provide the appellant an opportunity to state their position. This opportunity will be either by telephone conference call or in person. The choice of venue will be determined by the Committee and will not exceed fifteen (15) minutes. 6. The Committee will consider information presented by the appellant in the oral presentation. The appellant will be notified of the final decision of the Committee. 7. The appellant will receive a final decision from the Committee no more than 30 days after the date the appeal is submitted; if a decision can NOT be made after 30 days, then an appeal extension must be granted by the committee, or the appeal will be considered denied.
Public Health Significance	This proposal outlines how the ISSC will handle *V.v.* case appeals.
Cost Information	

Action by 2017 Task Force III	Recommends adoption of Proposal 17-303 as amended. SECTION 5. *V.v.* Case Appeal Procedure 1. Appropriate V.v. information will be provided to the reporting and source States ~~prior to review~~ at least 60 days prior to committee review. The States will be given 30 days from the date of receipt to respond.~~by the V.v. Illness Review Committee~~. 2. Following V.v. Illness Review Committee review, each source State with a countable case will be notified. 3. Should a source State disagree with the Committee determination on a specific case, the source State will be provided thirty (30) days to file an appeal. 4. Should the Committee, based on the information provided by the appellant, conclude that the original determination should be reversed, the appellant will be notified. 5. Should the Committee, based on the information provided by the appellant, conclude that the original determination was appropriate; the Committee will provide the appellant an opportunity to state their position. This opportunity will be either by telephone conference call or in person. The choice of venue will be determined by the Committee and will not exceed fifteen (15) minutes. 6. The Committee will consider information presented by the appellant in the oral presentation. The appellant will be notified of the final decision of the Committee. 7. The appellant will receive a final decision from the Committee no more than 30 days after the date the appeal is submitted; if a decision can NOT be made after 30 days, then an appeal extension must be granted by the committee, or the appeal will be considered denied.

Proposal No. **17-304**

Submitter	ISSC Executive Office
Affiliation	Interstate Shellfish Sanitation Conference
Proposal Subject	Clarification of Model Ordinance Effectiveness Review Committee Responsibility
Specific NSSP Guide Reference	ISSC Constitution Bylaws & Procedures Article IV, Executive Board, Officers, Committees
Text of Proposal/ Requested Action	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 one (1) industry member from the East, Gulf, and West coasts; at least one (1) State regulatory person 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 (1) voting member from NOAA; one (1) voting member from FDA; and one (1) 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. New requirements will not be reviewed until after the second (2nd) ISSC Biennial Meeting ~~fourth (4th) year~~ following the implementation date. A four (4) year waiting period will provide adequate time to determine effectiveness of new controls. ~~NOTE: Initially the Committee will review all 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.~~
Public Health Significance	Requirements become effective when revisions to the NSSP Guide are published not when the requirement is adopted. Due to review processes, the requirements may not be implemented for some time following the ISSC General Assembly meeting at the Biennial Meeting. To ensure that a requirement has the intended 4 year implementation period for efficiency, requirements should not be reviewed until 2 full conference cycles have passed following its initial inception.
Cost Information	
Action by 2017 Task Force III	Recommends adoption of Proposal 17-304 as submitted.

Proposal No. **17-305**

Submitter	Kathy Brohawn Kathryn Busch Robin Henderson Debbie Rouse
Affiliation	Maryland Department of Environment, Natural Resources & Health & Mental Hygiene, DE Division of Natural Resources & Environmental Control
Email	kathy.brohawn@maryland.gov kathryn.busch@maryland.gov robin.henerson@maryland.gov debbie.rouse@state.de.us
Proposal Subject	Responsibilities of the FDA for Annual or Bi-Annual Evaluations
Specific NSSP Guide Reference	ISSC Constitution, Bylaws, and Procedures of the ISSC Procedure IV. Responsibilities of the FDA Section 3. and Model Ordinance Chapter I. @.03 (new) E.
Text of Proposal/ Requested Action	Procedures of the Interstate Shellfish Sanitation Conference Procedure IV. Responsibilities of the FDA Section 3. Subdivision a: FDA shall provide a description of all deficiencies/non-compliance or emerging concerns identified during the evaluation. FDA will include the specific NSSP Model Ordinance reference for each deficiency, non-compliance, or emerging concern. This can be accomplished during a close out session with state program officials or at any time during a field inspection or overall program evaluation and shall occur prior to finalizing the Program Element Evaluation Report (PEER) Subdivision b: FDA shall allow state program officials a minimum of 30 days to correct any deficiencies/non-compliance or emerging concerns (that do not pose an imminent health hazard) identified prior to finalizing the PEER. If state program officials correct the identified deficiencies during the 30 day time frame, the final PEER will acknowledge the corrections and reflect compliance with any deficiencies identified or noted during the evaluation as in Subdivision a, above. If corrections cannot be accomplished within 30 days an agreed upon timeframe or action plan is required and should be included in the PEER. Subdivision c: All deficiencies, non-compliance, or emerging concerns cited in a PEER will include the specific Model Ordinance references of the requirements. Once a State has corrected any non-compliance FDA shall acknowledge the correction in writing. Model Ordinance Chapter I. @.03 (new) E. E. When notifying the Authority of deficiencies cited as part of a Program Evaluation, the FDA will adhere to the following: (1) FDA shall provide a description of all deficiencies/non-compliance or emerging concerns identified during the evaluation and include the specific NSSP Model Ordinance reference for each.

	(2) FDA shall allow state program officials a minimum of 30 days to correct any deficiencies/non-compliance or emerging concerns (that do not pose a public health hazard) identified prior to finalizing the Program Element Evaluation Report (PEER). If State program officials correct the identified deficiencies during the 30 day time frame, the PEER will acknowledge and reflect compliance. (3) Once a State has corrected or addressed any non-compliance, deficiencies, or emerging concerns, FDA shall acknowledge the correction in writing.
Public Health Significance	Provides a mechanism to assure consistency and encourages corrections during the evaluation process so that correction of deficiencies occur in a timely manner. This is consistent with the existing FDA Compliance Program Guidance Manual. This language encourages the cooperative aspect of the NSSP by allowing FDA and State Authorities to work together to address problems sooner rather than later.
Cost Information	Would save time and resources for both FDA and State Regulators.
Action by 2017 Task Force III	Recommends referral of Proposal 17-305 to an appropriate committee as determined by the Conference Chairperson.

Proposal No. **17-306**

Submitter	ISSC Laboratory Committee
Affiliation	Interstate Shellfish Sanitation Conference
Email	issc@issc.org
Proposal Subject	Limitation for Inactive Laboratory Method Proposals
Specific NSSP Guide Reference	Constitution, Bylaws and Procedures of the ISSC, Procedure XV, Section 7
Text of Proposal/ Requested Action	Constitution, Bylaws and Procedures of the ISSC, Procedure XV, Section 7 Subdivision a. Non-acceptance (no action) pending further information as defined by the Committee~~;~~. . The method submitter has eighteen (18) months from the date of the written request from the ISSC to provide the information/data necessary to complete the evaluation of the method. If there is no response from the submitter within this timeframe, the Laboratory Committee will recommend no action on the proposal;
Public Health Significance	The Laboratory Committee expends time and resources tracking, reviewing and commenting on inactive method proposals. Limiting the lifespan of such proposals will allow Committee participants the time necessary to adequately consider active proposals to ensure their fitness for purpose.
Cost Information	
Action by 2017 Task Force III	Recommends adoption of Proposal 17-306 as submitted.