Interstate Shellfish Sanitation Conference

2023 Biennial Meeting

Task Force III Report

Baton Rouge, Louisiana

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March 18-23, 2023
Baton Rouge Marriott

Proposal No. **11-310**

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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	Recommended referral of Proposal 11-310 to the appropriate committee as determined by the Conference Chairperson with the following instructions.

Committee	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 stnadards from other programs and the FDA draft. It is further recommended that the ISSC identify volunteer states to ilot 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	Recommended 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.
Action by 2017	Adopted the recommendation of Task Force III on Proposal 11-310.

General Assembly	
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 11-310.
Action by 2019 Standards Committee	The Committee recommended Task Force III adopt the draft Voluntary National Shellfish Regulatory Program Standards (attached) for the Plant Sanitation element into Section IV Guidance Documents of the National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish.
Action by 2019 Task Force III	Recommended adoption of the Standards Committee recommendation on Proposal 11-310 as follows: 1) Adopt the draft Voluntary National Shellfish Regulatory Program Standards for the Plant Sanitation element into Section IV Guidance Documents of the National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish. 2) The committee complete the piloting and recommend any needed changes to the Conference at the 2021 Bienninal Meeting. 3) The committee begin the development of Program Standards for the Growing Area Classification Element for Conference consideration.
Action by 2019 General Assembly	Adopted recommendation of Task Force III on Proposal 11-310.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 11-310.
Action by 2023 Standards Committee	Recommend continued development of the voluntary program standards.
Action by 2023 Task Force III	Recommend adoption of the Standards Committee recommendation on proposal 11-310.

Proposal No. **13-301**

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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.

Proposal No. **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 NSS 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 is allowed to review the FDA proposed growing area evaluation criteria immediately. 2. Concurrence 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	Recommended adoption of NSSP Evaluation Criteria Committee recommendation to refer 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.
Action by 2017 General Assembly	Adopted the recommendation of Task Force III on Proposal 13-301.

Action by FDA February 7, 2018	Concurred with Conference action on Proposal 13-301.
Action by 2019 NSSP Evaluation Criteria Committee	Recommended Proposal 13-301 be referred to an appropriate committee as determined by the Conference Chairperson to continue the development of the growing area classification evaluation criteria and make recommendations to the conference on proposal 13-301. The committee will work with FDA to assure consistency and uniformity of evaluation criteria for all program elements. The committee requests the Conference Chairperson to instruct the committee to start deliberation as soon as possible.
Action by 2019 Task Force III	Recommended adoption of NSSP Evaluation Criteria Committee recommendation to refer Proposal 13-301 to the NSSP Evaluation Criteria Committee.
Action by 2019 General Assembly	Adopted recommendation of Task Force III on Proposal 13-301.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 13-301.
Action by Growing Area Evaluation Criteria Committee	Recommends referral of Proposal 13-301 to an appropriate committee as determined by the Conference Chairperson.
Action by 2023 Task Force III	Recommends adoption of the Growing Area Evaluation Criteria Committee recommendation on proposal 13-301.

Proposal No. 17-204

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Proposal Subject	Add in-field Compliance Criteria for Control of Harvest Element
Specific NSSP Guide Reference	Section II. Model Ordinance - Chapter I@03B.3
Text of Proposal/ Requested Action	3. ~~Patrol~~ Control of Harvest (Change "Patrol Element" to "Control of Harvest Element" in Chapter I@03B.3 Section.) a. Requirements for evaluation …. (new) i. In-field (Harvester) Compliance Criteria i. Each harvester shall have a valid license, and a special license if necessary, in his possession while engaged in shellstock harvesting activities. **95% of harvesters have valid license Critical** ii. Each harvester shall obtain Authority approved training at an interval to be determined by the Authority not to exceed five (5) years. The training shall include required harvest, handling, and transportation practices as determined by the Authority. A harvester shall be allowed ninety (90) days following initial licensing to obtain the required education. A harvester shall obtain proof of completion of the required training. Proof of training obtained by the harvester shall be presented to the Authority prior to certification, recertification, or licensing. At a minimum, one (1) individual involved in the shellfish operations shall obtain the required training. The harvester shall maintain record of the completed training. **100% of licensed harvesters have required training within specified time.Critical** iii. Harvesters. Any harvester who engages in shellfish packing as defined in this Ordinance shall: Be a dealer; or Pack shellstock for a dealer. **95% of harvesters engaging in shellfish packing meet this requirementCritical** iv. Non-Vessel Harvesting. Harvesters shall assure shellstock are harvested, handled, and transported to prevent contamination, deterioration, and decomposition. **95% of the non-vessel harvesters meet this requirement Key**

v. Vessels. The operator shall assure that all vessels used to harvest and transport shellstock are properly constructed, operated, and maintained to prevent contamination, deterioration, and decomposition of the shellstock.

95% of the harvest vessels meet this requirement Key

Cats, dogs, and other animals shall not be allowed on vessels.

95% of the harvest vessels meet this requirement Key

Human sewage shall not be discharged overboard from a vessel used in the harvesting of shellstock, or from vessels which buy shellstock while the vessels are in growing areas.

100% of harvest vessels meet this requirement Critical

As required by the Authority, in consultation with FDA, an approved marine sanitation device (MSD), portable toilet or other sewage disposal receptacle shall be provided on the vessel to contain human sewage.

95% of the harvest vessels meet this requirement Critical

~~i.~~vi. Shellstock Washing. The harvester shall be primarily responsible for washing shellstock.

If shellstock washing is not feasible at the time of harvest, the dealer shall assume this responsibility. Water used for shellstock washing shall be obtained from: A potable water source; or a growing area in the: Approved classification; or in the open status of the conditionally approved classification.

If the harvester or dealer elects to use tanks or a recirculating water system to wash shellstock, the shellstock washing activity shall be constructed, operated, and maintained in accordance with Chapter XI. 02 A. (3) and Chapter XIII. 02 A. (3).

95% of the harvesters meet this requirement Critical

vii. Shellstock Identification. Each harvester shall affix a tag that meets Chapter VIII.02.F to each container of shellstock which shall be in place while the shellstock is being transported to a dealer.

95% of the harvesters meet this requirement Critical

viii. Bulk tagging of a lot of shellstock during transport from harvest area to the dealer facilities meets the requirements of Chapter VIII02.F(7).

95% of the harvesters utilizing bulk tagging meet this requirementCritical

ix. Shellstock Temperature Control. All harvesters shall comply with the applicable time to temperature requirements of a State *V.v.* and *V.p.* Control Plans outlined

	in Chapter II. @.06 and @.07; or Chapter VIII. @.02 Shellstock Time to Temperature Controls A. (3). All harvesters shall provide trip records to the initial dealer demonstrating compliance with the time to temperature requirements. **95% of the harvesters meet these requirements Critical** ji. The following procedures will be implemented when an FDA evaluation identifies deficiencies with the above ~~patrol~~ Control of Harvest evaluation criteria. i. The overall ~~Patrol Program~~ Control of Harvest element will be assigned one of the following designations: (a) **Conformance:** The program is in compliance with all of the criteria listed above. (b) **Conformance with Deficiencies:** The program only has minor deficiencies associated with a key compliance item. (c) **Non-Conformance:** The program has: i. at least one (1) critical deficiency; ii. ~~two (2)~~ four (4) or more key deficiencies; or iii. a repeat **[Key]** deficiency from the previous evaluation. (d) **Major Non-Conformance:** The program has multiple deficiencies, key or critical, that suggests the program has become ineffective to control harvest in harvest restricted waters. ii. ….
Public Health Significance	Adds in-field compliance criteria to address Control of Harvest Element evaluation activities related to NSSP MO Chapter VIII Requirements for Harvesters. Proposal will bring in the in-field compliance criteria which is similar to plant compliance criteria which have administrative and in-field components.
Cost Information	NA
Action by 2017 Task Force II	Recommended referral of Proposal 17-204 to an appropriate committee as determined by the Conference Chair with instructions that this proposal be assigned to the appropriate multiple committees.
Action by 2017 General Assembly	Adopted the recommendation of Task Force II on Proposal 17-204.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 17-204.
Action by 2019 NSSP Evaluation Criteria	Recommends the Conference Chairperson establish a workgroup including members from the NSSP Evaluation Criteria Committee and the Patrol Committee to review and make recommendations to the conference on proposal 17-204 working with FDA to consider consistency and uniformity of evaluation criteria for all program elements.
Action by 2019 Task Force III	Recommended adoption of the NSSP Evaluation Criteria Committee recommendation on Proposal 17-204.
Action by 2019 General Assembly	Adopted recommendation of Task Force III on Proposal 17-204.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 17-204.

Action by 2023 Control of Harvest Evaluation Criteria	Recommends referral of Proposal 17-204 to an appropriate committee as determined by the Conference Chairperson.
Action by 2023 Task Force III	Recommend adoption of the Control of Harvest Evaluation Criteria Committee recommendation on proposal 17-204.

Proposal No. 19-305

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Proposal Subject	Evaluation of Shellfish Sanitation Program Elements
Specific NSSP Guide Reference	Section II Model Ordinance Chapter I. Shellfish Sanitation Program Requirements for the Authority @.03 Evaluation of Shellfish Sanitation Program Elements
Text of Proposal/ Requested Action	A. The goal of shellfish program evaluation shall be to monitor program implementation and work with States to determine where problems may exist and how to address them. 1. Shellfish program evaluation methodologies shall: a. Monitor State Program implementation; b. Assess State program effectiveness; and c. Evaluate the validity of the elements of the NSSP Guide for the Control of Molluscan Shellfish. 2. The minimum components of shellfish program evaluation shall include: a. A description of the program activity; b. A comparison of FDA observations with State observations; and c. A measurement of conformity of shellfish program activities with elements of the NSSP Guide for the Control of Molluscan Shellfish. 3. The focus of data collection shall be on measuring conformity of shellfish program activities with elements of the NSSP Guide for the Control of Molluscan Shellfish. 4. The types of date collected shall include the following: a. Program records; b. Direct observation made by the evaluator; and c. Data and information from the Authority or other pertinent sources. 5. FDA shall not evaluate Shellfish Sanitation Program Elements while simultaneously training and/or standardizing newly hired FDA Shellfish Specialists or potential candidates being considered for a position as an FDA Shellfish Specialist. 6. FDA shall not evaluate Shellfish Sanitation Program Elements of any firm or a specific growing area that has been utilized to train and/or standardize newly hired FDA Shellfish Specialists or potential candidates being considered for a position as an FDA Shellfish Specialist for at least three (3) years from the date the candidate has been standardized as an FDA Shellfish Specialist with the following exceptions: a. When the State used for FDA training consists of less than the State's total inventory of certified shellfish dealers necessary to achieve a 95% probability of detecting a greater than or equal defect level of 20% for the State's Plant and Shipping Program Element; or b. When the State used for FDA training consists of less than the State's representative sampling plan designed to provide a 95%

	probability of detecting a 20% or greater defect level for the State's Growing Area Classification Program Element. Request that the NSSP Evaluation Committee consider changes to the Evaluation of Shellfish Sanitation Program Elements related to the use of a States' Shellfish Sanitation Program Element Evaluation for the purpose of training and standardizing newly hired FDA Shellfish Specialists. It is requested that the committee consider these or other additions to Section II. Chapter I. @.03 in order to more specifically define the purpose of an FDA PEER as intended to evaluate a States' compliance with the elements of the NSSP Guide for the Control of Molluscan Shellfish versus using a "PEER-modeled" evaluation of an SSCA to conduct training/standardization of a newly hired FDA Shellfish Specialist.
Public Health Significance	There are existing requirements in the NSSP for Standardizing FDA Shellfish Specialists and State Standardization Officers to conduct Shellfish Plant Inspections, whereby the inspections of certified dealers' facilities are used not to conduct regulatory inspections of the facilities, but are rather used as an opportunity to train and standardize the skills of the inspector. Similarly, the concept presented here is that a "PEER-modeled" Shellfish Plant and Growing Area Evaluation used for the training and standardization of a newly hired FDA specialist would be defined and separated from the formal PEER evaluation process. The goals of these two types of evaluations should be clearly identified as distinct from one another. The goals of the Evaluation of Shellfish Program Elements, as defined under Section II. Chapter I. @.03. A. is to "monitor program implementation and work with States to determine where problems may exist and how to address them." The purpose of conducting training/standardization of a newly hired FDA specialist is to ensure that newly hired FDA Specialists have the knowledge and ability to evaluate a State program effectively and objectively across the wide rang of State shellfish programs, while ensuring that Shellfish Specialists are standardized amongst themselves in the evaluation of State programs. By separating these two types of evaluations, valuable discussions can occur which may lead to immediate corrective actions of critical deficiencies and ensure that, above all, public health is protected. This would also remove some of the stigma that has resulted from what is perceived as an increase in the number of deficiencies that have been identified in recent years in many States' PEERs in which multiple Specialists with differing levels of experience were evaluating a program. During the period in which a new FDA Specialist is being trained in how to conduct a PEER evaluation of a shellfish program element for the State, information gathered during the training would not be used to determine a States' regulatory compliance with the requirements of the NSSP, but would rather provide an opportunity for an experienced Shellfish Specialist to impart his/her knowledge about how to evaluate a State's compliance, communicate his/her perception of the relative severity of compliance issues, and allows for open communication between a Specialist and the Authority. Issues discussed during the training process may or may not reflect significant compliance issues, however through open discussion, all parties would

	have the opportunity to communicate where disagreements of NSSP interpretation occur. While the critical importance of training new hires in the role of FDA Shellfish Specialist is recognized, it should also be recognized that there are inherent differences between these two types of evaluations, and the existing application of the PEER Evaluation to the training and Standardization of new FDA hires may be creating unnecessary conflict between State Shellfish Authorities and the FDA Shellfish Specialists tasked with the difficult job of evaluating State programs.
Cost Information	No cost will be incurred by the industry or State regulatory agencies.
Action by 2019 Task Force III	Recommended referral of Proposal 19-305 to the Regulatory Relations Committee for resolution.
Action by 2019 General Assembly	Adopted recommendation of Task Force III on Proposal 19-305.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-305.
Action by 2023 Plant Evaluation Criteria Committee	Recommends no action on Proposal 19-305. Rationale: It is not appropriate Model Ordinance language and FDA Specialists are already instructed to work with each state concerning evaluations.
Action by 2023 Task Fore III	Recommend adoption of the Plant Evaluation Criteria Committee recommendation on proposal 19-305.

Proposal No. 19-310

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Proposal Subject	Plant Element Evaluation Criteria
Specific NSSP Guide Reference	Section II Model Ordinance – Chapter I. Shellfish Sanitation Program for the Authority
Text of Proposal/ Requested Action	4. Plants Requirements for evaluation of the shellfish plant inspection program elements shall include at a minimum: a. Records audit of past shellfish processing facility inspections for a time frame not to exceed two certification periods. The number of files to be reviewed shall be based upon a representative sampling plan designed to provide a 95 percent probability of detecting a 20 percent or greater defect level. The ratio should be based upon the certification type of plants within that State's inventory (i.e. if 50% of plants are Shucker Packers, then 50% of the plants selected for evaluation should be Shucker Packers). b. ~~Direct observation of current shellfish processing facility conditions;~~ Evaluations of SSO(s), either via maintenance inspections or actual standardization depending on the expiration date of current SSO(s) during the plant element evaluation following the standardization protocol outlined in the NSSP MO Section IV Guidance Documents- Chapter III Harvesting, Handling, Processing and Distribution. No more than two SSOs will be evaluated per evaluation and no more than five maintenance inspections will be performed per SSO, not to exceed a total of ten inspections. For states having less than five plants during years when actual standardization is not required, the existing number of plants will be used for the SSO maintenance inspections. c. Information collection from the Authority and other pertinent sources concerning shellfish processing facility inspection program. d. Shellfish sanitation program element criteria shall be used to evaluate consecutive full evaluations (not including follow up). If a violation of the same criteria is repeated, the program element is considered out of compliance. This program element compliance will be based on the following criteria evaluated during the file review: i. All dealers are required to be certified in accordance with the Guide for the Control of Molluscan Shellfish. ii. ~~95~~ 90% of the certified dealers evaluated in the file review must have been inspected by the State at the frequency required by the current Guide for

the Control of Molluscan Shellfish.

iii. Where compliance schedules are required, no more than 10% of the certified dealers evaluated in the file review will be without such schedules.

iv. States must demonstrate that they have performed proper follow up for compliance schedules for 90% of dealers evaluated during the file review, and if the compliance schedules were not met, that proper administrative action was taken by the State.

v. All critical deficiencies identified in the file review have been addressed by the State inspector in accordance with the Guide for the Control of Molluscan Shellfish.

e. Plant Evaluation Criteria

i. Legal Authority – Chapter I @ .01 B.

The plant sanitation element will be deemed in compliance if administrative laws and regulations exist that provide the administrative authority to implement the Dealer Certification requirements listed in Chapter I @ .01 and @ 02. [Critical]

ii. Initial Certification – Chapter I @ .02 B.

The Plant Sanitation Element will be deemed in compliance with this requirement when all plants reviewed in the file review are certified in accordance with criteria listed below:

(a) HACCP requirements:

(i) A HACCP plan accepted by the Authority

(ii) No critical deficiencies;

(iii) Not more than two (2) key deficiencies;

(iv) Not more than two (2) other deficiencies.

(b) Sanitation and additional Model Ordinance Requirements:

(i) No critical deficiencies;

(ii) Not more than two (2) key deficiencies;

(iii) Not more than three (3) other deficiencies.

iii. Inspection frequency– Chapter I @ .02 F. and G.

The Plant Sanitation Element will be deemed in compliance with this requirement when during the file review , ~~one (1) or~~ 10% or less of plants ~~inspected~~ do~~esn't~~not meet the required inspection frequency .

iv. Compliance schedules.

The Plant Sanitation Element will be deemed in compliance with this requirement when no more than 10% of the certified dealers evaluated during the file review are found to be without schedules.

v. Follow-Up.

The Plant Sanitation Element will be deemed in compliance with this requirement when the State demonstrates that they have performed proper follow-up for compliance schedules for 90% of dealers evaluated in the file review and if the compliance schedules were not met that administrative action was taken.

vi. Deficiency Follow-up.

The Plant Sanitation Element will be deemed in compliance with this requirement when the State demonstrates via the file review and/or other supporting documentation that all critical deficiencies have been addressed

vii. ~~In-Field Plant Criteria.~~SSO(s) Standardization Maintenance

~~Certified plants will be evaluated to determine compliance with the criteria listed below:~~

~~(a) Shucker/packers and repackers HACCP requirements:~~

~~(i) A HACCP plan accepted by the Authority;~~

~~(ii) No critical deficiencies; and~~

~~(iii) Not more than four (4) key deficiencies.~~

~~(b) Shucker/packers and repackers sanitation and additional Model Ordinance requirements:~~

~~(i) No critical deficiencies; and~~

~~(ii) Not more than four (4) key deficiencies.~~

~~(c) Shellstock shippers and reshippers HACCP requirements:~~

~~(i) A HACCP plan accepted by the authority;~~

~~(ii) No critical deficiencies; and~~

~~(iii)Not more than three (3) key deficiencies.~~

~~(d) Shellstock shippers and reshippers sanitation and additional Model Ordinance requirements~~

~~(i) No critical deficiencies; and~~

~~(ii) Not more than three (3) key deficiencies.~~

The Plant Sanitation Element will be deemed in compliance with this requirement when a SSO(s) achieves standardization and/or successfully meets the requirements for the Performance Criteria described in the NSSP MO Section IV Guidance Documents .02 Shellfish Plant Inspection Standardization Procedures

f. The overall Plant Sanitation Program element will be assigned one (1) of the following conformance designations based on compliance with the criteria listed in Chapter I. @03 B.4

i. Conformance: The program is in compliance with all of the criteria listed above and all plants evaluated are in compliance with Chapter I. @.03 B. 4. e. i-vii.

ii. Conformance with Deficiencies:

The program is in compliance with Chapter I. @ .03 B. 4. e. i ~~- vi. and has~~ ~~25% or less of plants with deficiencies associated with Chapter I. @ .03 B. 4. e. vii.~~

but does not meet the criteria in one (1) of Chapter I. @.03 B. 4. e. iii. or iv. or v. or vi. and the SSO is given a "Needs Improvement" classification in the sections inspectional equipment and communication as described in the NSSP

	MO Section IV Guidance Documents.02 Shellfish Plant Inspection Standardization Procedures but is still standardized iii. Nonconformance: The program is in compliance with Chapter I. @ .03 B. 4. e. i., but, does not meet the criteria in Chapter I. @.03 B. 4. e. ii. ~~or iii. or iv. or v. or vi. or has greater than 25% (but less than 51%) of plants with deficiencies associated with Chapter I. @.03 B. 4. e. vii~~ or does not meet the criteria in two (2) of Chapter I. @.03 B. 4. e. iii. or iv. or v. or vi. and the SSO is unable to meet the Performance Criteria described in the NSSP MO Section IV Guidance Documents.02 Shellfish Plant Inspection Standardization Procedures iv. Major Nonconformance: ~~C. The program has multiple deficiencies. It is non-compliant with Chapter I. @.03 B. 4. e. i., or two (2) or more of Chapter I. @.03 B. 4. e. ii., or iii., or iv., or v., or vi., or 51% or greater of plants with deficiencies associated with Chapter I. @.03 B. 4. e. vii.~~ The program is non-compliant with both Chapter I. @ .03 B. 4. e. i and Chapter 1. @03 B. 4. e. ii, or does not meet the criteria in three (3) of Chapter I. @.03 B. 4. e. iii. or iv. or v. or vi. and the SSO is unable to meet the Performance Criteria described in the NSSP MO Section IV Guidance Documents.02 Shellfish Plant Inspection Standardization Procedures FDA will follow the current compliance program for communication with the State agencies. ~~D. All deficiencies observed by FDA while conducting the in-plant inspection portion of the evaluation will be documented and included in the compliance determination outlined in Chapter I. @.03B.4.e.ii.~~
Public Health Significance	The Plant Element Evaluations conducted by FDA should be a comprehensive evaluation of the State Shellfish Control Authority's (SSCA) ability to promote the protection of public health as it relates to the handing of shellfish. State program audits should have a high level of uniformity and effectiveness in the actual audit criteria. The Plant Element Evaluation Criteria should focus on the actual SSCA's administration of the program with objective measurable items, which represent the SSCA work efforts along with a focus on the State Shellfish Standardization Officers (SSO). The SSCA SSO(s) are responsible for the standardization of the SSCA inspection staff and the NSSP MO already provides a methodology for the standardization and maintenance of the SSO staff which FDA can evaluate as part of the plant element evaluation criteria. The states participating in the ISSC do not all have the same amount or type of dealers. Geographic differences also exist in relation to producing states versus states consisting of mostly secondary processors. Because of this diversity in plant inventory amongst the States , the current in plant criteria element of the plant element evaluation in which FDA Specialist conduct actual inspections at a shellfish dealers facility cannot be uniform in implementation amongst States and does not uniformly assess a SSCA. The inclusion of actual plant inspections and the results of the individual dealer's compliance is not reflective of the SSCAs compliance with the NSSP as the in plant dealer evaluations are only

	assessments of the actual dealer, for which outside of a regulatory inspection or enforcement actions, the SSCA has no control. For example, a SSCA has no control over a refrigeration unit failing to maintain temperature on any particular day, a septic system failing due to age, a sewage back up, a roach infestation, and so on. Inspections of Shellfish dealer facilities are not true evaluations of the SSCA program's compliance with the NSSP. Focusing on the file review along with an evaluation of the State Shellfish Standardization Officer's (SSO) performance during actual standardization or standardization maintenance evaluations as a program element to be evaluated is key to assessing the uniform implementation of the NSSP MO.
Cost Information	None
Action by 2019 Task Force III	Recommended referral of 19-310 to the NSSP Evaluation committee. The NSSP Evaluation Committee is requested to immediately address concerns associated with the In-Field Plant Criteria and the development of recommendations for Executive Board interim action at the 2020 Spring Board meeting. Additionally, Task Force II recommends the suspension of In-Field Plant Criteria until the Executive Board provides modified criteria.
Action by 2019 General Assembly	Adopted recommendation of Task Force III on Proposal 19-310.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-310.
Action by 2022 Plant Evaluation Criteria Committee	Recommends adoption of Proposal 19-310 as amended with interim approval by the Executive Board. Replace language in proposed language 4. f with following. There are no other changes to suggested language. f. Conformance Designations i. The overall Plant Sanitation Program element will be assigned one (1) of the following conformance designations based on compliance with the criteria listed in Chapter I. @.03 B. 4.: a) Conformance: The program is in compliance with all of the criteria listed in Chapter I. @.03 B. 4. e. i.-vi. and has 25% or fewer of plants with deficiencies as outlined in Chapter I. @.03 B. 4. e. vii. b) Provisional Conformance: The program is in compliance with Chapter I. @ .03 B. 4. e. i - vi. and has 26% to 42% of plants with deficiencies as outlined in Chapter I. @ .03 B. 4. e. vii. For plant sanitation programs that have 26-42% deficiencies, the Authority can achieve a designation of conformance by successful completion of the actions listed in Chapter I. @.03 B. 4. f. ii. b). c) Nonconformance: The program is in compliance with Chapter I. @ .03 B. 4. e. i., but, does not meet the criteria in Chapter I. @.03 B. 4. e. ii. or iii. or iv. or v. or vi. or has greater than 42%of plants with deficiencies as outlined in Chapter I. @.03 B. 4. e. vii.. Two consecutive FDA audits of Provisional Conformance will result in a conformance designation of Non-Conformance. This conformance designation requires an action plan as outlined in Chapter I. @.03 B, 4. f. ii. c).

	the program has been deemed in Provisional Conformance on two consecutive FDA audits. d) Major Nonconformance: The program has multiple deficiencies. It is non-compliant with Chapter I. @.03 B. 4. e. i., or two (2) or more of Chapter I. @.03 B. 4. e. ii., or iii., or iv., or v., or vi., The failure of a state to develop and implement an acceptable and effective action plan. ii. Each conformance designation will require the actions listed below: a) Conformance: The Authority will work cooperatively with the individual firms to correct deficiencies or develop deficiency-specific compliance schedules in plants audited by FDA. b) Provisional Conformance: For plant sanitation programs that have 26-42% deficiencies, the Authority can achieve a designation of Conformance by successful completion of the actions listed below: 1. Correct deficiencies or develop deficiency-specific compliance schedules in plants audited by FDA within 30 days of the in-field closeout meeting. If there are any disagreements between the Authority and FDA an additional 15 days will be allowed to resolve differences. 2. The State must take one of the following actions. • Within 30 days, the SSO will conduct an audit of the same number of plants as the original FDA evaluation to determine compliance with Chapter I @.03 B. 4. e. vii., (The Authority will work with FDA to select the plants.); or • Conduct inspections of all certified dealers with 120 days to identify and correct deficiencies. Within 30 days of completion of the inspections, the SSO will conduct an audit of the same number of plants to determine compliance with Chapter I @.03 B. 4. e. vii. (The Authority will work with FDA to select the plants.) 3. Conduct a file review for the purpose of comparing FDA and SSO findings to previous inspections 4. Determine if inspector re-standardization or additional training is needed. 5. Re-standardize and provide additional training for inspectors as needed. Should the SSO audit outlined in Chapter I.@.03 B. 4. f. ii. b).2. above determine that compliance with Chapter I.@.03 B. 4. f. i. a) the program will be reassigned a conformance designation of Conformance. This reassignment will be acknowledged in FDA correspondence to the Authority. Should the SSO audit outlined in Chapter I.@.03 B. 4. f. ii. b).2. determine that the program is not in compliance with Chapter I.@.03 B. 4. f. i. a), the program will be reassigned a designation of nonconformance. This reassignment will be acknowledged in FDA correspondence to the Authority. c) Nonconformance: The Authority must develop and complete an action plan that includes a plan to specifically address any deficiencies associated with Chapter I @03 B.4.e. ii-vi. Should the designation of Nonconformance be the result of deficiencies associated with Chapter I @03 B.4.e.vii the action plan shall include the following: 1. Correct deficiencies or develop deficiency-specific compliance schedules in plants audited by FDA within 30 days of the in-field closeout meeting. Should the state disagree with FDA regarding an identified deficiency(s), an additional 15 days will be allowed for resolution and/or correction of those specific deficiencies.

	2. Within 10 days of correcting the deficiencies identified in the FDA audit, the Authority shall request re-standardization of state SSO(s) by FDA. 3. Within 60 days of SSO re-standardization by FDA, the SSO will conduct an abbreviated re-standardization of all inspectors using a minimum of 3 plants for the purpose of evaluating staff competency. 4. Provide additional inspector training as determined by the Authority. 5. Following re-standardization, the state will conduct a state-wide compliance inspection of all plants (excluding plants audited by FDA). This activity must be completed within 120 days or another timeframe mutually agreed upon by the Authority and FDA.. 6. Within 30 days of completion of the state-wide compliance effort, the SSO will conduct an audit of the same number of plants to determine compliance with Chapter I @.03 B. 4. E. (The Authority will work with FDA to select the plants) 7. The state SSO will conduct a file review for the purpose of comparing FDA and SSO findings to previous inspections Failure to complete an effective action plan will result in a Conformance designation of major Non-Conformance If Non-Conformance is the result of Provisional Conformance failure, an action plan would be required consistent with a conformance designation of Non-Conformance. d) Major Non-Conformance: All determinations of Major Non-Conformance and the identification of deficiencies that pose imminent health concerns will be immediately reported to the ISSC Executive Board for consideration for appropriate action. g. FDA will follow the current compliance program for communication with the State agencies. h. All deficiencies observed by FDA while conducting the in-plant inspection portion of the evaluation will be documented and included in the compliance determination outlined in Chapter I. @.03B.4.e.ii.
Action by 2022 ISSC Executive Board	Granted Interim Approval in effect until the Conference convenes at the 2023 ISSC Biennial Meeting.
Action by 2023 Task Force III	Recommend adoption of the Executive Board interim action on Proposal 19-310

Proposal No. 19-311

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Proposal Subject	NSSP Plant and Shipping Evaluation Criteria
Specific NSSP Guide Reference	Section II. Chapter I Shellfish Sanitation Program for the Authority @.02 Dealer Certification Section II. Chapter I Shellfish Sanitation Program for the Authority @.03 Evaluation of Shellfish Sanitation Program Elements
Text of Proposal/ Requested Action	Request that the NSSP Evaluation Committee consider changes to the Evaluation of Shellfish Sanitation Program Elements related to plants. It is requested that the committee review the Cooperative Milk Program State Evaluation process and consider incorporating pertinent aspects into the Shellfish Plant Program element evaluation of state programs. The committee should specifically consider changes to include but are not limited to: • Developing a numerical score for plant inspections. • Using the numerical score to provide an average score for plants during the FDA In-Field Evaluation. This would be a better reflection of the true status of the plants that considers high performing plants as well as low performing plants. • Evaluating a state on model ordinance requirements of the authority to establish an authority performance rating. • Separating plant performance from authority and establish a plant performance rating based on a numerical average score of plants. The current plant element state evaluation is primarily dependent on In-Field Plant criteria. The current designations are in most cases dependent upon plant performance based upon a one-day evaluation by FDA. The criteria is based on plant failures with no credit toward plants that are high performing. The Authorities have model ordinance requirements in the plant element. State performance should be evaluated on those requirements. Authority performance and industry performance should be evaluated separately.
Public Health Significance	Changing the focus of the plant element evaluation away from plant performance would ensure that states are following model ordinance requirements that protect public health. Using the current In-Field evaluation process represents a one-day snap shot of industry performance.

	It is not reflective of whether the authority is meeting requirement of the model ordinance. Separating industry performance from the performance of the authority will encourage long term improvement in state implementation of model ordinance plant element requirements.
Cost Information	No cost increases.
Action by 2019 Task Force III	Recommended referral of Proposal 19-311 to the NSSP Evaluation Criteria Committee.
Action by 2019 General Assembly	Adopted recommendation of Task Force III on Proposal 19-311.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-311.
Action by 2023 Plant Evaluation Criteria Committee	Recommended no action on Proposal 19-311. Rationale: This issue is resolved by action on Proposal 19-310.
Action by 2023 Task Force III	Recommends adoption of the Plant Evaluation Criteria Committee recommendation on Proposal 19-311.

Proposal No. 19-312

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Proposal Subject	Plant and Shipping Element Evaluation Criteria
Specific NSSP Guide Reference	Model Ordinance Chapter I. Shellfish Sanitation Program Requirements for the Authority @.03 B. 4.
Text of Proposal/ Requested Action	We have been using the plant and shipping evaluation criteria for approximately 10 years and have identified some areas that need review. FDA requests that the NSSP Evaluation Criteria Committee be charged with reviewing the criteria, especially with respect to these areas of concern: (1) In-field Plant Criteria (2) Compliance Schedules (3) Follow-Up for Compliance Schedules (4) Conformance Designations
Public Health Significance	Many states have expressed concerns to FDA and the ISSC Executive Office surrounding the Plant and Shipping evaluation criteria. In addition, FDA has identified its own concerns with the implementation of the criteria.
Cost Information	No additional cost
Action by 2019 Task Force III	Recommended referral of Proposal 19-312 to the NSSP Evaluation Criteria Committee
Action by 2019 General Assembly	Adopted recommendation of Task Force III on Proposal 19-312.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-312.
Action by Plant Evaluation Criteria Committee	Recommends referral of Proposal 19-312 to an appropriate committee as determined by the Conference Chairperson.
Action by 2023 Task Force III	Recommends adoption of the Plant Evaluation Criteria Committee recommendation on proposal 19-312

Proposal No. **23-300**

Submitter	US Food & Drug Administration (FDA)
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Proposal Subject	Definition of Shellfish
Specific NSSP Guide Reference	Section I. Purpose & Definitions Definitions B. (115) Shellfish
Text of Proposal/ Requested Action	Modify the definition of "Shellfish" as follows: **(115) Shellfish** means all species of: (a) Bivalve mollusks (e.g. ~~O~~oysters, clams, ~~or~~ mussels, cockles) whether: (i) Shucked or in the shell; (ii) Raw, including post-harvest processed; (iii) Frozen or unfrozen; (iv) Whole or in part; and (b) Scallops in any form, except when the final product form is the adductor muscle only.
Public Health Significance	As currently written in the Model Ordinance, the definition of "Shellfish" is exclusive to oysters, clams, mussels, and scallops and is not inclusive of all types of bivalve molluscan shellfish that may be encountered and that the Guide for the Control of Molluscan Shellfish must cover. This change will expand the definition to include all bivalve molluscan shellfish (such as cockles, penshells, etc) so that consumers are afforded the same protections from the risks that all raw bivalve molluscan shellfish can present. Whether these additional types of bivalve molluscan shellfish are aquacultured or imported from other countries, this change is needed to ensure the products are all covered by NSSP requirements.
Cost Information	N/A
Action by 2023 Task Force III	Recommends adoption of Proposal 23-300 as submitted.

Proposal No. **23-301**

Submitter	Eric Hickey, MA Department of Public Health Kathy Brohawn, MD Department of the Environment Jeff Kennedy, MA Division of Marine Fisheries Michael Bott, DE Department of Natural Resources and Environmental Control Bryant Lewis, ME Department of Marine Resources Chris Nash, NH Department of Environmental Services Danielle Schools, VA Department of Health, Division of Shellfish Safety
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Proposal Subject	Guidance Documents
Specific NSSP Guide Reference	ISSC Constitution and Bylaws Section I. Purpose & Definitions Section II Model Ordinance, Chapter I. Shellfish Sanitation Program Requirements for the Authority @03 A. (1) (c) and (3) Section IV. Guidance Documents
Text of Proposal/ Requested Action	**Section I. Purpose & Definitions** (50) **Guidance Document** means a document that provides ISSC current thinking and/or general applicability suggestions on a NSSP provision. Guidance documents do not create or confer any rights or requirements for or on any person that are beyond those outlined in the NSSP Model Ordinance and do not operate to bind FDA, the Authority, or the public. Guidance documents do not preclude the use of alternative approaches for the implementation of NSSP Model Ordinance requirements. ~~(50)~~(51) **HACCP** is an acronym that stands for Hazard Analysis Critical Control Point, a systematic, science-based approach used in food production as a means to assure food safety. The concept is built upon the seven principles identified by the National Advisory Committee on Microbiological Criteria for Foods (1992). ~~(51)~~(52) **HACCP Plan** means a written document that delineates the formal procedures that a dealer follows to implement the HACCP requirements set forth in 21 Code of Federal Regulations (CFR) 123.6 as adopted by the Interstate Shellfish Sanitation Conference.

	Section II. Model Ordinance **Ch. I @.03 Evaluation of Shellfish Sanitation Program Elements** A. The goal of shellfish program evaluation shall be to monitor program implementation and work with States to determine where problems may exist and how to address them. 1. Shellfish program evaluation methodologies shall: a. Monitor State program implementation; b. Assess State program effectiveness; c. Evaluate the validity of the elements of the NSSP ~~Guide to the Control of Molluscan Shellfish~~ Model Ordinance. **Ch. I @.03 Evaluation of Shellfish Sanitation Program Elements** A. 3. The focus of data collection shall be on measuring conformity of shellfish program activities with elements of the NSSP ~~Guide to the Control of Molluscan Shellfish~~ Model Ordinance. **ISSC Constitution Bylaws and Procedures Procedure IV Responsibilities of the FDA** 3. The FDA should prepare an annual evaluation of the shellfish program of each state in accordance with the Procedures of the NSSP Model Ordinance. This evaluation should consider the program as a whole and should also specifically address the legal authority, the classification of shellfish growing waters, the shellfish sanitation control and certification, personnel training, patrol, relaying, depuration and laboratory phases of the program, and the status of state authorities Memorandums of Understanding. The state evaluation prepared by the Regional Shellfish Specialist should be reviewed and discussed with the appropriate state shellfish officials prior to submission to FDA headquarters. A PEER deficiency item can only be found based on the Model Ordinance requirements (not guidance). INTRODUCTORY STATEMENT TO BE PLACED AT THE BEGINNING OF SECTION IV: Guidance documents are intended to provide supporting information on how to implement the criteria set forth in the Model Ordinance or the current thinking on topics referenced in the Model Ordinance. Alternative approaches that satisfy requirements of the Model Ordinance may be used. Guidance documents are not intended to be solely used by FDA as a reference to cite NSSP deficiencies in a PEER or determine program conformance with the requirements of the NSSP Model Ordinance.
Public Health Significance	The purpose of this proposal is to address concerns of state control authorities and to clarify areas of confusion which include, but are not limited to, guidance concerning marinas and moorings, biotoxin management strategies, and shellfish program element evaluations. Under 21 CFR Part 123 FDA's guidance documents

	do not establish legally enforceable responsibilities. Instead, guidance describes ISSC current thinking on relevant topics and should be viewed only as supporting information, recommendations, and NSSP implementation aids unless specific regulatory or statutory requirements are cited. The use of the word "should" in Agency guidance means that something is suggested or recommended, but not required. Guidance documents represent FDA's current thinking on a topic. They do not create or confer any rights for or on any person and do not operate to bind FDA or the public. The Authority can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. The same definition of guidance and how it is applied should be adopted in the NSSP MO to be consistent with FDA policy and definitions.
Cost Information	N/A
Action by 2023 Task Force III	Recommends referral of Proposal 23-301 to an appropriate Committee or Committees as determined by the Conference Chair. Further recommends that the committee(s) review NSSP Guidance to identify requirements that need to be moved from guidance into the Model Ordinance with completion of the review by the next ISSC Biennial meeting.

Proposal No. **23-302**

Submitter	ISSC Executive Office
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Proposal Subject	Removal of Office Manager and Program Chair Posistions
Specific NSSP Guide Reference	ISSC Constitution, Bylaws & Procedures, Article IV 3. & 9., Article V. 4., Article VI. 5, Article IX
Text of Proposal/ Requested Action	ARTICLE IV. EXECUTIVE BOARD, OFFICERS, COMMITTEES 1. The Conference shall… 2. The Board shall… 3. The immediate past Chairperson, ~~the Program Chairperson,~~ the three (3) Task Force Chairpersons, the Executive Director, and the Biennial Meeting Office Manager, except as otherwise provided, shall serve as non-voting members of the Board. 4. The Treaty Tribes… 5. The Board Chairperson… 6. Each Board member… 7. Elected Board members…. 8. The Board shall… 9. The Executive Committee, at a minimum, shall consist of the Board Chairperson, Vice Chairperson, Executive Director, ~~Office Manager, Program Chairperson,~~ one Industry Executive Board member, and the immediate past Board Chairperson. The function of the Executive Committee is to provide administrative guidance to the Executive Office of the ISSC for management of daily activities. Industry representation on the Executive Committee shall be appointed by the Chairperson of the Executive Board, at each Biennial Meeting, with recommendation from the industry members of the Board. 10. The Board may… 11. A quorum for… 12. The nine-member… 13. The Executive Board… 14. The Executive Board… 15. The Executive Board… 16. The Executive Board… 17. The Executive Board… ARTICLE V. DUTIES OF THE BOARD 1. The Board shall… 2. The Board shall… 3. The Board may… 4. The Board shall direct the Executive Director ~~and the Program Chairperson~~ in the preparation of programs for each General Assembly of the Biennial Conference meeting. 5. The Board shall…

	6. In the event… 7. If a member… 8. A Board member… 9. The Board shall… 10. The Board shall… 11. The Board shall… ARTICLE VI. DUTIES OF THE BOARD CHAIRPERSON 1. The Board Chairperson… 2. The Board Chairperson… 3. The Board Chairperson… 4. The Board Chairperson… ~~5. The Board Chairperson, with the approval of the Board, shall appoint a Program Chairperson and a Biennial Meeting Office Manager.~~ ~~6.~~5. The Board Chairperson… ~~7.~~6. The Board Chairperson… ~~ARTICLE IX. DUTIES OF THE PROGRAM CHAIRPERSON~~ ~~1. The Program Chairperson shall assist the Executive Director in planning and arranging for all Conference meetings.~~ ~~2. The Program Chairperson shall serve as a non-voting member of the Executive Board.~~
Public Health Significance	None. The positions of Office Manager and Program Chairperson have been vacant for numerous years and are unnecessary to the operations of the ISSC.
Cost Information	None
Action by 2023 Task Force III	Recommend adoption of Proposal 23-302 as submitted.

Proposal No. **23-303**

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Proposal Subject	Revision of Standing Committee List
Specific NSSP Guide Reference	ISSC Constitution, Bylaws & Procedures, Article IV 10
Text of Proposal/ Requested Action	ARTICLE IV. EXECUTIVE BOARD, OFFICERS, COMMITTEES 1. 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 Chairperson. 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: • ~~Audit Committee;~~ • Credentials Committee; • ~~Education Committee;~~ • ~~Foreign Relations Committee;~~ • Laboratory Committee • Model Ordinance Effectiveness Review Committee; • Pathogen Review Committee; • ~~Patrol Committee;~~ • Proposal Review Committee; • ~~Research Guidance Committee;~~ • ~~Research Management Committee;~~ • Resolutions Committee; • ~~Shellfish Restoration Committee;~~ • Study Design Guidance Committee; • ~~Training Committee;~~ • Unresolved Issues Committee; • ~~Vibrio~~Vibrio vulnificus Illness Review Committee; and • *Vibrio* Management 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.
Public Health Significance	Standing committees are committees that have been assigned charges by the ISSC Constitution, By-laws & Procedures. These committees are appointed either every Biennial Meeting cycle for ongoing charges or as needed as defined in the ISSC Constitution By-laws & Procedures. Committees should not be included in the standing committee list unless a purpose for the committee has been defined by the ISSC Constitution, By-laws & Procedures. The revisions to the standing committee list will remove committees that have not been defined by the ISSC Constitution, By-laws &

	Procedures and will add committees that are defined in the ISSC Constitution, By-laws & Procedures.
Cost Information	None
Action by 2023 Task Force III	Recommends referral of proposal 23-303 to an appropriate committee as determined by the Conference Chair.

Proposal No. **23-304**

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Proposal Subject	Remove Proposal Review Committee
Specific NSSP Guide Reference	ISSC Constitution, Bylaws & Procedures, Article IV 10. & 13., Article XIII. 3.
Text of Proposal/ Requested Action	ARTICLE IV. EXECUTIVE BOARD, OFFICERS, COMMITTEES 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 Chairperson. 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: • Audit Committee; • Education Committee; • Foreign Relations Committee; • Laboratory Committee • Model Ordinance Effectiveness Review Committee; • Patrol Committee; • ~~Proposal Review Committee;~~ • Research Guidance Committee; • Research Management Committee; • Resolutions Committee; • Shellfish Restoration Committee; • Study Design Guidance Committee; • Training Committee; • Vibrio Illness Review Committee; and • *Vibrio* Management 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. 11. A quorum for… 12. The Nine-member… 13. ~~The Executive Board Chairperson shall appoint a 12 member Proposal Review Committee. The Committee will be comprised of a Chairperson, four (4) regulatory members, four (4) industry members, and a representative from the FDA, NOAA, and EPA. The Committee will review and link proposals for Conference consideration. The Committee will also provide consultation as needed to the Executive Director in assigning proposals to Task Forces.~~

	ARTICLE XIII. PROCEDURE FOR THE SUBMISSION OF PROPOSALS 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. Proposals that lack required information will be deemed incomplete and returned to the submitter for completion. ~~The Executive Director will consult with the Proposal Review Committee before declaring any problem or proposal invalid.~~
Public Health Significance	None. The Proposal Review Committee is not necessary as the charge of linking proposals has not proved to be effective. There has also been no need to ask the committee for consultation with Task Force Assignment or invalidating a proposal during the last decade of Biennial Meeting cycles.
Cost Information	None
Action by 2023 Task Force III	Recommends referral of Proposal 23-304 to an appropriate committee as determined by the Conference Chair.

Proposal No. 23-305

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10. Proposal Subject	Biotoxin Management Plan Criteria
11. Specific NSSP Guide Reference	Section II Model Ordinance; Chapter IV. Shellstock Growing Areas @.04.B
12. Text of Proposal/ Requested Action	**Section II Model Ordinance; Chapter IV. Shellstock Growing Areas @.04.B.** B. Marine Biotoxin Management Plan. In those areas that have been implicated in an illness outbreak or where toxin-producing phytoplankton have been documented to occur, the toxins are prone to accumulate in shellfish and during times when marine biotoxins are likely to occur, representative samples of water and/or shellfish shall be collected during harvest periods in accordance with one (1) or a combination of the marine biotoxin management strategies listed below in (4). and in accordance with Section IV. Guidance Documents Chapter II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans. (1) The Authority shall develop and adopt a marine biotoxin management plan for all marine and estuarine shellfish growing areas if there is a history of biotoxin closures related to PSP, ASP, NSP, DSP and/or AZP; if toxin-producing phytoplankton have been documented to occur in the growing area; or a reasonable likelihood that biotoxin closures could occur. (2) The plan shall define the administrative procedures and resources necessary to accomplish the following: (a) Maintain a toxin-producing phytoplankton and/or shellfish sampling program as described below in (4). It is necessary to recognize that different marine biotoxin management strategies are essential to address specific risks as well as geographic and logistical conditions. Marine biotoxin management strategies must include an appropriate number of samples to adequately address the specific risks. Specific criteria are cited in ~~Section IV. Guidance Documents Chapter II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans~~Section 4 Marine Biotoxin Management Strategies. (b) Close growing areas and embargo shellfish; (c) Prevent harvesting of contaminated species; (d) Provide for product recall; (e) Disseminate information on the occurrences of toxic algal blooms and/or toxicity in shellfish meats to adjacent States, shellfish industry, and local health agencies; (f) Coordinate control actions taken by Authorities and Federal agencies; (g) Establish reopening criteria; and

(h) Ensure that all shellfish harvested from growing areas or portion(s) of growing areas placed in the controlled access status meets all conditions of harvest restrictions prior to being placed in distribution. This would include all sampling, testing or product holds.

(3) The Authority may use precautionary closures based on shellfish toxicity screening or phytoplankton sample results as defined in their marine biotoxin management plan. Precautionary closures may be lifted immediately:

(a) if confirmatory testing using an approved method shows the level of biotoxin present in shellfish meats is not equal to or above established criteria as described below in C; or

(b) when shellfish toxicity screening or phytoplankton sample results indicate that the precautionary closure was not necessary.

(4) Marine biotoxin management strategies are as follows:

(a) Phytoplankton monitoring: this strategy involves a routine program for sampling growing area waters for the presence of phytoplankton species known or suspected to produce marine biotoxins. This is a complementary management strategy that enhances predictive capabilities of anticipating toxicity in shellfish and must be used in combination with other management strategies. ~~Specific criteria are cited in Section IV. Guidance Documents Chapter II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans.~~

The marine biotoxin management plan that incorporates this strategy must establish:

- appropriate screening levels,
- appropriate methods,
- appropriate laboratory(s)/analyst(s),
- an appropriate sampling plan,
- appropriate sample locations (stations),
- appropriate sampling frequency; and
- a sufficient dataset to support management decisions.

The phytoplankton monitoring strategy shall be used together with one (1) or more of the other biotoxin management strategies. If it were used as the sole management strategy, phytoplankton monitoring would likely misrepresent the actual risk of marine biotoxins. Cell counts, as measured per liter of water, are often used to trigger additional testing of shellfish in biotoxin monitoring programs. These cell count criteria can only be established with a robust dataset; therefore, new monitoring programs should employ low cell count criteria to trigger shellfish toxicity samples to establish or refine the cell concentrations responsible for toxins accumulating in shellfish.

(b) Routine shellfish toxicity monitoring: this strategy involves a routine program for sampling and testing shellfish meats for the presence of marine biotoxins. Unless species specific shellfish testing is conducted, the highest risk species shall be used. This strategy may be used in combination with other management strategies. ~~Specific criteria are cited in Section IV. Guidance Documents Chapter II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans.~~

The level of monitoring required will vary based on the historical database available to inform the sampling strategy (i.e., growing areas with a long history of defined temporal and spatial patterns of shellfish toxicity may have a more targeted approach to sampling, requiring less monitoring than for growing areas where temporal and spatial patterns have not been determined). A dataset with at least 36 samples per growing area or hydrographically linked waterbodies across representative environmental conditions for a span of at least three (3) years shall be developed before the biotoxin monitoring plan may be modified. Until the Authority is confident they understand the risk posed by marine biotoxins in the growing area, sampling should be as robust as possible, and managers should consider that harmful algal blooms can change dramatically from year to year.

The marine biotoxin management plan that incorporates this strategy must establish:

- appropriate screening levels,
- appropriate methods,
- appropriate laboratory(s)/analyst(s),
- an appropriate sampling plan,
- appropriate sample locations (stations),
- appropriate sampling frequency; and
- a sufficient dataset to support management decisions.

Analytical methods used in this strategy shall be in accordance with Section IV. Guidance Documents Chapter II Growing Areas .14 or Section II. Chapter III.@02C.

(c) Pre-harvest shellfish toxicity testing: this strategy involves sampling and testing shellfish meats for the presence of marine biotoxins in the intended harvest area specifically in advance of harvest. This strategy, if used independent of any other strategy, shall permit harvest for a short period of time following testing. This strategy may be used in combination with other management strategies. ~~Specific criteria are cited in Section IV. Guidance Documents Chapter II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans.~~

This strategy requires representative samples that cover the spatial distribution of the area to be harvested. The duration of permitted harvest following sampling will vary based on the species being tested and the historical database available to inform the sampling strategy. A dataset with at least 36 samples per harvest area shall be developed before the biotoxin monitoring plan may be modified. Without at least 36 samples per harvest area over the span of at least three (3) years, the short duration of permitted harvest shall not exceed three (3) days from the time of shellfish collection for toxicity testing to harvest. The dataset could then be used to modify the duration of permitted harvest.

This management strategy can be applied to harvest areas where collecting, transporting and processing shellfish samples is feasible. This management strategy can be applied to aquaculture or wild harvest. Appropriate venues for this management strategy include but are not limited to; easily accessible and remote wild harvest areas and aquaculture sites in state and federal waters. If toxicity in excess of the established threshold in Section II. Chapter IV. @.04 C. is detected, the

growing area must be either be placed in the closed or controlled access status.
The marine biotoxin management plan that incorporates this strategy must establish:

- appropriate screening levels,
- appropriate methods,
- appropriate laboratory(s)/analyst(s),
- an appropriate sampling plan,
- appropriate sampling frequency,
- a defined harvest area, and;
- appropriate duration for permitted harvesting subsequent to sampling.

This strategy is specifically for permitting harvest following shellfish testing. The duration of permitted harvesting will depend on the species being tested, the risk of increasing toxicity and the timing of additional sampling. Samples must be representative of the harvest area.
Methods shall be used in accordance with Section IV. Guidance Documents Chapter II Growing Areas .14 or Section II. Chapter III. @.02 C.

(d) Shellfish lot testing: this strategy involves sampling and testing shellfish meats for the presence of marine biotoxins on a lot basis after harvest. This strategy may be combined with a pre-harvest shellfish toxicity testing strategy, the results of which permit harvest. ~~Specific criteria are cited in Section IV. Guidance Documents Chapter II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans.~~ Lot testing may also be used on a case by case basis to clear product harvested immediately prior to a biotoxin closure if the Authority determines it is necessary.
This strategy requires representative samples for each lot of harvested shellstock. Lot testing shall be permitted in growing areas in the Controlled Access Status and require Restricted Shellstock tags. The conditions for the area in Controlled Access Status shall be defined in the harvest permit and may include holding shellstock until lot tests are available. A dataset with at least 36 samples per harvest area over the span of at least three (3) years shall be developed before the biotoxin monitoring plan may be modified.
The marine biotoxin management plan that incorporates this strategy must establish:

- appropriate screening levels,
- appropriate methods,
- appropriate laboratory(s)/analyst(s),
- an appropriate sampling plan,
- appropriate sampling frequency, and;
- representative number of samples per lot.

Methods shall be used in accordance with Section IV. Guidance Documents Chapter II Growing Areas.14 or Section II. Chapter III. @.02 C.

(e) Pre-harvest shellfish toxicity screening and lot testing: this strategy requires pre-harvest shellfish toxicity screening of the intended harvest area coupled with shellfish lot testing upon landing or receipt at the initial dealer. ~~Specific criteria are cited in Section IV. Guidance Documents Chapter II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans. (5)~~ The marine biotoxin management plan shall include agreements or memoranda of understanding, between the Authority and individual shellfish harvesters, individual growers or individual shellfish dealers, to allow harvesting in a growing area that is placed in the controlled access status. Such harvesting shall be conducted with strict assurances of safety and in accordance with the marine biotoxin management strategies listed in (4).
This strategy shall permit harvest from intended harvest areas in the Controlled Access Status and require Restricted Shellstock tags. The conditions for the area in Controlled Access Status shall be defined in the harvest permit and may include holding shellstock until lot tests results are available. A dataset with at least 36 samples taken monthly per harvest area spanning at least three (3) years shall be developed before the biotoxin monitoring plan may be modified. In the absence of an adequate dataset, the initial number and frequency of pre-harvest and lot samples must be sufficient to conduct an evaluation of risk in the intended harvest area. The initial number of samples must be adequate to address the size of the intended harvest area and the amount of shellfish harvested. Single samples are not adequate for evaluation of risk. Should initial samples indicate minimal toxin levels or the absence of toxins, sampling can be reduced but must be conducted at least monthly or as often as necessary to monitor risk.

The marine biotoxin management plan that incorporates this strategy must establish:

- appropriate screening levels,
- appropriate methods,
- appropriate laboratory(s)/analyst(s),
- an appropriate sampling plan,
- appropriate sampling frequency,
- a defined harvest area, and;
- representative number of samples.

Methods shall be used in accordance with Section IV. Guidance Documents Chapter II Growing Areas.14 or Section II. Chapter III. @.02 C.

Section IV Guidance Documents; Chapter II Growing Areas .02

Marine Biotoxin Management Strategies

It is necessary to recognize that different marine biotoxin management strategies are essential to address specific risks as well as geographic and logistical conditions. Marine biotoxin management strategies must include an appropriate number of samples to adequately address the specific risks. The Authority initiating biotoxin management plans should employ sampling in accordance with the strategies below until a baseline dataset of at least 36 samples per

growing area or hydrographically linked waterbodies is developed. These samples should cover representative environmental conditions and a time span of at least three (3) years. Once this dataset is developed, the Authority may consider modifying sample numbers and frequency in the marine biotoxin management plan in accordance with the strategies below.

A. Phytoplankton monitoring: this strategy involves a routine program for sampling growing area waters for the presence of phytoplankton species documented or suspected to produce marine biotoxins. This complementary management strategy that enhances predictive capabilities of anticipating toxicity in shellfish must be used in combination with other management strategies. The level of monitoring required will vary based on the historical database available to inform the sampling strategy (i.e., growing areas with a long history of defined temporal and spatial patterns of toxin-producing phytoplankton may have a more targeted approach to sampling, requiring less monitoring than for growing areas where temporal and spatial patterns have not been determined). A dataset with at least 36 samples per growing area or hydrographically linked waterbodies for a time span of at least three (3) years of phytoplankton counts, comparing with the onset of shellfish toxicity when toxic phytoplankton are present, should be developed before the biotoxin monitoring plan may be modified.

Phytoplankton monitoring can be applied to all growing areas where collecting, transporting and processing water samples is logistically feasible, taking into consideration effects of zooplankton grazing and durability of various cell types to temperature and transport. This management strategy may be applied to aquaculture or wild harvest. Appropriate venues for this management strategy include but are not limited to; easily accessible wild harvest areas and aquaculture sites in state waters or aquaculture sites in federal waters.

~~The marine biotoxin management plan that incorporates this strategy must establish:~~

- ~~appropriate screening levels,~~
- ~~appropriate methods,~~
- ~~appropriate laboratory(s)/analyst(s),~~
- ~~an appropriate sampling plan,~~
- ~~appropriate sample locations (stations),~~
- ~~appropriate sampling frequency; and~~
- ~~a sufficient dataset to support management decisions.~~
-

~~The phytoplankton monitoring strategy shall be used together with one (1) or more of the other biotoxin management strategies. If it were used as the sole management strategy, phytoplankton monitoring would likely misrepresent the actual risk of marine biotoxins. Cell counts, as measured per liter of water, are often used to trigger additional testing of shellfish in biotoxin monitoring programs. These cell count criteria can only be established with a robust dataset; therefore, new monitoring programs should employ low cell count criteria to trigger shellfish toxicity samples to establish or refine the cell concentrations responsible for toxins accumulating in shellfish.~~

	When an early warning system such as phytoplankton monitoring detects increased toxicity/cell counts or other information suggests that toxin levels are increasing, it is important that the Authority have procedures to promptly expand sampling to additional stations and/or increase the frequency of sampling for marine biotoxins. The procedures should include plans for obtaining the additional resources necessary to implement the expanded sampling and laboratory analysis program. If a plan consists of water sampling for phytoplankton cell counts as surveillance, the Authority should identify its plan to be able to initiate shellfish sampling. Considerations should be made for how sampling is conducted such as phytoplankton net tows, filtered surface water, or whole water samples. The depth of water sampled should also be considered and evaluated for all species of phytoplankton being targeted. Some species of phytoplankton are known to display diurnal, vertical migration patterns within the water column, while other species are known to occur in dense patches. Laboratory and field methods may include, but are not limited to light microscopy, flowcytometry, DNA fingerprinting, rapid toxin detection tests, and PCR assays. Analysts should be trained in each method employed and consideration should be given to complimentary methods of analysis such as light microscopy with phytoplankton identification confirmed by a rapid test at least in the initial phases of the monitoring program. An appropriate sampling plan, station location, and sampling frequency should all factor in the location and type of the resource being monitored, the species of phytoplankton anticipated or observed, and the environmental conditions that might result in a rapid bloom or trigger the production of toxicity in an existing population. Primary sampling stations (also referred to as indicator or sentinel stations) should be located at sites where toxic phytoplankton are most likely to first appear, based either on experience or knowledge of site conditions. The geographic distribution for collection of samples should take into consideration the randomness of toxic algal blooms. Establishing the frequency and period for collection of samples to identify an event as early as possible is an important consideration. Historical occurrences and fluctuations in coastal phytoplankton populations due to the influence of meteorological and hydrographic events are also significant. For example, a large rain storm may cause nutrient loading in coastal waters and trigger a toxic phytoplankton bloom, or a hurricane may drive an offshore phytoplankton bloom onshore. To facilitate knowledge transfer, it is advisable that the authority describe its rationale in selecting sampling sites. B. Routine shellfish toxicity monitoring: this strategy involves a routine program for sampling and testing shellfish meats for the presence of marine biotoxins. Unless species-specific shellfish testing is conducted, the highest risk species (e.g. species that metabolizes toxin most quickly) occurring in the growing area shall be used. Many biotoxin monitoring

programs have found mussels to be the best sentinel species. This strategy may be used alone or in combination with other management strategies.

~~The level of monitoring required will vary based on the historical database available to inform the sampling strategy (i.e., growing areas with a long history of defined temporal and spatial patterns of shellfish toxicity may have a more targeted approach to sampling, requiring less monitoring than for growing areas where temporal and spatial patterns have not been determined). A dataset with at least 36 samples per growing area or hydrographically linked waterbodies across representative environmental conditions for a span of at least three (3) years shall be developed before the biotoxin monitoring plan may be modified. Until the Authority is confident they understand the risk posed by marine biotoxins in the growing area, sampling should be as robust as possible, and managers should consider that harmful algal blooms can change dramatically from year to year.~~

This management strategy can be applied to all growing areas where collecting, transporting and processing shellfish samples is feasible. This management strategy can be applied to aquaculture or wild harvest. Appropriate venues for this management strategy include but are not limited to, easily accessible wild harvest areas and aquaculture sites in state waters or wild harvest areas and aquaculture sites in federal waters.

~~The marine biotoxin management plan that incorporates this strategy must establish:~~

- ~~appropriate screening levels,~~
- ~~appropriate methods,~~
- ~~appropriate laboratory(s)/analyst(s),~~
- ~~an appropriate sampling plan,~~
- ~~appropriate sample locations (stations),~~
- ~~appropriate sampling frequency; and~~
- ~~a sufficient dataset to support management decisions.~~
- ~~—~~

The routine shellfish toxicity monitoring strategy may be used independently or together with one (1) or more of the other biotoxin management strategies. If used as the sole management strategy, predicting future toxicity levels in shellfish and the appropriate sampling frequency can be difficult. Long-term databases can provide valuable historic information on the timing of toxicity occurring in shellfish as well as toxicity elimination from shellfish. Shellfish toxin levels that are below the regulatory levels may trigger emergency or expanded testing, or precautionary closures. Growing areas should be placed in the closed status at a level that provides an adequate margin of safety, since in many instances, toxicity levels will change rapidly and the time between sampling and results should be considered. Precautionary closures can be made to prevent the harvest of potentially toxic shellfish while sample results are being collected and processed.

	Consideration should be given to the different species of shellfish present in a growing area, the intensity and duration of harmful algal blooms and the uptake and elimination rates of specific toxins from all species of shellfish harvested from the growing areas (e.g., sea scallops). Methods shall be used in accordance with Section IV. Guidance Documents Chapter II Growing Areas.14 or Section II. Chapter III. @.02 C. Additionally, the Authority should identify laboratories that can perform approved methods for marine biotoxins and identify laboratory capacity. An appropriate sampling plan, station location and sampling frequency should factor in the location and type of the resource being monitored, the species of shellfish harvested in the growing area and environmental conditions that might affect toxin uptake, such as water temperatures. Primary sampling stations (also referred to as indicator or sentinel stations) should be located at sites where toxin is most likely to first appear, based either on past experience or knowledge of site conditions. The geographic distribution for collection of samples should take into consideration the randomness of toxic algal blooms. Establishing the frequency and period for collection of samples to identify an event as early as possible is an important consideration. Sample collection, sample transportation, and sample analysis procedures should be developed, and predictable timeframes established between collection and results. The Authority should ensure that in an emergency, such as a suspected biotoxin illness, the normal timeframe can be compressed, and sample results known as quickly as possible. It is important to consider emergency coverage schedules for staff and lab availability outside of normal office hours during harmful algal bloom events. When an early warning system detects increased toxicity/cell counts or other information suggests that toxin levels are increasing, it is important that the Authority have procedures to promptly expand sampling to additional stations and/or increase the frequency of sampling for marine biotoxins. The procedures should include plans for obtaining the additional resources necessary to implement the expanded sampling and laboratory analysis program. C. Pre-harvest shellfish toxicity testing: this strategy involves sampling and testing shellfish meats for the presence of marine biotoxins in the intended harvest area specifically in advance of harvesting. This strategy, if used independent of any other strategy, shall permit harvest in specific geographic locations and for short durations. This strategy may also be used in combination with other management strategies and should be considered as a complementary strategy while developing datasets for alternative management strategies (e.g. pre-harvest shellfish toxicity testing in combination with phytoplankton monitoring which can evolve into a robust shellfish toxicity monitoring strategy). ~~This strategy requires representative samples that cover the spatial distribution of the area to be harvested. The duration of permitted~~

~~harvest following sampling will vary based on the species being tested and the historical database available to inform the sampling strategy. A dataset with at least 36 samples per harvest area shall be developed before the biotoxin monitoring plan may be modified. Without at least 36 samples per harvest area over the span of at least three (3) years, the short duration of permitted harvest shall not exceed three (3) days from the time of shellfish collection for toxicity testing to harvest. The dataset could then be used to modify the duration of permitted harvest.~~

~~This management strategy can be applied to harvest areas where collecting, transporting and processing shellfish samples is feasible. This management strategy can be applied to aquaculture or wild harvest. Appropriate venues for this management strategy include but are not limited to; easily accessible and remote wild harvest areas and aquaculture sites in state and federal waters. If toxicity in excess of the established threshold in Section II. Chapter IV. @.04 C. is detected, the growing area must be either be placed in the closed or controlled access status.~~

~~The marine biotoxin management plan that incorporates this strategy must establish:~~

- ~~appropriate screening levels,~~
- ~~appropriate methods,~~
- ~~appropriate laboratory(s)/analyst(s),~~
- ~~an appropriate sampling plan,~~
- ~~appropriate sampling frequency,~~
- ~~a defined harvest area, and;~~
- ~~appropriate duration for permitted harvesting subsequent to sampling.~~
-

~~This strategy is specifically for permitting harvest following shellfish testing. The duration of permitted harvesting will depend on the species being tested, the risk of increasing toxicity and the timing of additional sampling. Samples must be representative of the harvest area.~~

~~Methods shall be used in accordance with Section IV. Guidance Documents Chapter II Growing Areas .14 or Section II. Chapter III. @.02 C.~~

D. Shellfish lot testing: this strategy involves sampling and testing shellfish meats for the presence of marine biotoxins on a lot basis after harvest. This strategy may be combined with a pre-harvest shellfish toxicity testing strategy, the results of which permit harvest. Lot testing may also be used on a case by case basis to clear product harvested immediately prior to a biotoxin closure if the Authority determines it is necessary.

~~This strategy requires representative samples for each lot of harvested shellstock. Lot testing shall be permitted in growing areas in the Controlled Access Status and require Restricted Shellstock tags. The conditions for the area in Controlled Access Status shall be defined in~~

~~the harvest permit and may include holding shellstock until lot tests are available. A dataset with at least 36 samples per harvest area over the span of at least three (3) years shall be developed before the biotoxin monitoring plan may be modified.~~

This management strategy can be applied to all growing areas where harvest occurs. This management strategy can be applied to aquaculture or wild harvest. Appropriate venues for this management strategy include but are not limited to; easily accessible and remote wild harvest areas and aquaculture sites in state and federal waters.

~~The marine biotoxin management plan that incorporates this strategy must establish:~~

- ~~appropriate screening levels,~~
- ~~appropriate methods,~~
- ~~appropriate laboratory(s)/analyst(s),~~
- ~~an appropriate sampling plan,~~
- ~~appropriate sampling frequency, and;~~
- ~~representative number of samples per lot.~~
- ~~—~~

~~Methods shall be used in accordance with Section IV. Guidance Documents Chapter II Growing Areas.14 or Section II. Chapter III. @.02 C.~~

E. Pre-harvest shellfish toxicity screening and lot testing: this strategy requires pre-harvest shellfish toxicity screening of the intended harvest area coupled with shellfish lot testing upon landing or receipt at the initial certified dealer.

~~This strategy shall permit harvest from intended harvest areas in the Controlled Access Status and require Restricted Shellstock tags. The conditions for the area in Controlled Access Status shall be defined in the harvest permit and may include holding shellstock until lot tests results are available. A dataset with at least 36 samples taken monthly per harvest area spanning at least three (3) years shall be developed before the biotoxin monitoring plan may be modified. In the absence of an adequate dataset, the initial number and frequency of pre-harvest and lot samples must be sufficient to conduct an evaluation of risk in the intended harvest area. The initial number of samples must be adequate to address the size of the intended harvest area and the amount of shellfish harvested. Single samples are not adequate for evaluation of risk. Should initial samples indicate minimal toxin levels or the absence of toxins, sampling can be reduced but must be conducted at least monthly or as often as necessary to monitor risk.~~

This management strategy can be applied to all growing areas where harvest occurs. This management strategy can be applied to aquaculture or wild harvest. Appropriate venues for this management strategy include but are not limited to; easily accessible and remote wild harvest areas and aquaculture sites in state and federal waters.

	~~The marine biotoxin management plan that incorporates this strategy must establish:~~ ~~• appropriate screening levels,~~ ~~• appropriate methods,~~ ~~• appropriate laboratory(s)/analyst(s),~~ ~~• an appropriate sampling plan,~~ ~~• appropriate sampling frequency,~~ ~~• a defined harvest area, and;~~ ~~• representative number of samples.~~ ~~•~~ ~~Methods shall be used in accordance with Section IV. Guidance Documents Chapter II Growing Areas.14 or Section II. Chapter III. @.02 C.~~
13. Public Health Significance	Several sections of Chapter IV of the Model Ordinance refer to language in Section IV Guidance Documents that indicate that the guidance is mandatory. This proposal moves these criteria and strategies for Biotoxin Management from Guidance to Chapter IV of the Model Ordinance to clarify what are minimum requirements for NSSP compliance versus suggested options.
14. Cost Information	No cost
Action by 2023 Task Force III	Recommends referral of Proposal 23-305 to an appropriate committee as determined by the Conference Chair.

Proposal No. 23-306

2. Submitter	ISSC Executive Office
3. Affiliation	
4. Address Line 1	4801 Hermitage Road, Ste 102
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9. Email	issc@issc.org
10. Proposal Subject	Unresolved Issue process clarification
11. Specific NSSP Guide Reference	ISSC Constitution, Bylaws & Procedures, Procedure IX
12. Text of Proposal/ Requested Action	**PROCEDURE IX. PROCEDURES FOR HANDLING COMPLAINTS AND CHALLENGES REGARDING THE ADEQUACY OF CERTIFICATION CONTROLS** 1. Complaints from any state or non-state party regarding possible non-conformities in a producing and/or shipping state shall be handled as follows: a. Only complaints regarding the sanitary quality and effectiveness of public health controls shall be covered under this procedure. b. Complaints shall be made in writing to the Authority as listed in the ICSSL, with a copy to the appropriate FDA Regional Office. c. The complaint shall provide specific and complete factual information concerning all items not in conformity and shall specifically verify that all sampling and testing has been conducted in accordance with the NSSP. d. The Authority shall make an investigation of the complaint within twenty (20) working days of receipt, promptly notify the complainant in writing of the findings and any actions being taken, and provide a copy to the appropriate FDA Regional Office. e. Upon receipt of the response or upon the failure to receive a response within thirty (30) days, the complainant may request in writing to the ISSC Board Chairperson that further investigation by FDA be conducted. FDA may also undertake further investigation at their own initiative. f. FDA shall provide a written report of its findings or the status of the complainant within thirty (30) days to the parties involved and the ISSC Board Chairperson. g. If FDA's investigation does not lead to a satisfactory resolution of the problem, the problem shall be handled as an unresolved issue according to Procedure IX. Section 3. 2. When an FDA field inspection or an overall program evaluation indicates a state program is not meeting the minimum requirements of the NSSP Model Ordinance, the following actions shall be taken:

a. FDA shall provide written notification to the Authority of the item(s) requiring action with supporting documentation and recommendations as appropriate.

b. The state shall investigate the item(s) and provide a written response within thirty (30) days that it has been corrected, that a corrective action plan has been developed and will be implemented within a specific time frame, or that it disagrees with FDA's finding. The state shall provide supporting documentation regarding any disagreements. FDA shall review the materials submitted by the state and respond to the state within thirty (30) days.

c. When a state does not disagree with FDA ~~findings~~observations, but ~~does disagree~~disagrees with an FDA report or FDA's findings in the report regarding the state's NSSP compliance status, the state shall provide written notification to FDA of the areas of disagreement with supporting documentation and recommendations as appropriate. FDA shall review the information submitted and provide a written response within thirty (30) days that it agrees and the report has been corrected, that it agrees but the report cannot be corrected, or that it disagrees with the state. FDA shall provide supporting documentation regarding any inability to correct a report or any disagreement. The state shall review the materials submitted by FDA and respond to FDA within thirty (30) days.

d. If corrective action is taken by the state or by the FDA or a mutually agreed upon action plan is developed and implemented, no action by the Conference will be necessary.

e. If the state and FDA are unable to find a mutually agreeable resolution to the disagreement, or FDA considers the action (or lack of action) taken by the state to be inadequate to resolve the item(s), FDA shall notify the state and the ISSC Executive Director of an unresolved issue. ~~If the State disagrees with FDA's findings or response,~~In response to the FDA notice, the State may pursue one of the following actions:

   i. The State may request consultation from the Consultation Subcommittee of the ISSC Unresolved Issues Committee. The purpose of this consultation will allow the State the opportunity to seek guidance from the Consultation Subcommittee regarding program requirements and FDA findings; or

   ii. The State shall notify the ISSC Executive Director of an unresolved issued.

f. Upon notification from both FDA and the state of an unresolved issue, the ISSC Executive Director shall consult

with both the state and FDA and prepare recommendations, which will be submitted to the Board with the unresolved issue. The referred unresolved issue shall be handled according to Procedure IX., Section 3. FDA may also take any actions it considers appropriate to deal with any adulterated product.

3. After receipt of an unresolved issue, the Executive Director shall immediately send the unresolved issue to the Executive Board. Within thirty (30) days of receipt of the unresolved issue by the Executive Director, the Executive Board shall take one (1) of the following actions:
   a. Resolve the issue on their own initiative.
   b. Refer the matter to the Unresolved Issues Committee.

4. When an issue has been referred, the Unresolved Issues Committee shall convene a meeting, giving all involved parties an opportunity to participate. The Committee shall review the issue, and considering input from involved parties, submit its recommendations to the Executive Board.

5. The following list of deficiencies and sanctions shall serve as a guide for actions should the Executive Board confirm the findings of the FDA evaluation.
   a. State program deficiencies, which may result in ISSC sanctions, are as follows:
      i. Administrative - Inadequate State Laws/ Regulations to Enforce the Program
      ii. Growing Areas
         a. Failure to properly classify.
         b. Failure to close in an emergency situation.
         c. Repeated failure to comply with conditional management plans.
         d. Lack of sanitary survey and supporting documentation justifying classifications.
         e. Lack of Biotoxin contingency plan.
         f. Failure to comply with contingency plans.
      iii. Plant Sanitation
         a. Failure to have a standardization officer.
         b. Certification of plants by non-standardized inspector.
         c. Failure to take action on critical deficiencies.
         d. Significant differences between state vs. state/FDA inspections.
         e. Repeated Critical and Key items at significant number of firms.
         f. Inadequate state laws/ regulations to enforce program.

	iv. Other Program Areas a. Inadequate tagging and records by shellfish dealers. b. Refusal to participate/provide cooperation in FDA program evaluations. c. Failure to control relaying. b. The following actions shall be taken by the Executive Board as appropriate: i. Meeting(s) with responsible state officials to express ISSC concern about the unresolved issue and to develop an acceptable action plan. ii. A letter to top state program administrators, including the governor, expressing ISSC concern regarding state program deficiencies. iii. Notification to ISSC members of the unresolved issue for their information. iv. Recommendation to FDA to include a notice in the ICSSL regarding the unresolved issue. v. Recommendation to the Authority to remove affected dealers from the ICSSL. vi. Recommendation to FDA to remove all certified dealers from future ICSSL publications. vii. Notification to all states and other appropriate authorities describing the unresolved issue and that action against products from a state with significant control problems may be appropriate for their consideration. A letter to FDA expressing ISSC concern regarding the position of FDA.
13. Public Health Significance	The proposal is intended to clarify some of the steps involved in FDA/state disagreements and the unresolved issue process.
14. Cost Information	No cost
Action by 2023 Task Force III	Recommends adoption of proposal 23-300 as submitted.

Proposal No. 23-307

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9. Email	issc@issc.org
10. Proposal Subject	Emergency Procedures
11. Specific NSSP Guide Reference	Section II. Model Ordinance; Chapter I Shellfish Sanitation program Requirements for the Authority; Section @.01 Administration
12. Text of Proposal/ Requested Action	**@.01 Administration** A. Scope… B. State Laws and Regulations… C. Records… D. Shared Responsibilities… E. Administrative Procedures… F. Epidemiolotically Implicated Outbreaks of Shellfish-Related Illness… G. Commingling… H. Personnel training requirements… I. Request for Emergency Consideration In the event of a declared public health emergency or natural or man-made disaster, including the activation of the State Emergency Response Plan, if the Authority is not in a position to operate the program in full compliance with NSSP program requirements, the Authority shall immediately notify the ISSC and the FDA. The FDA shall immediately conduct discussions with the authority to reach a mutually acceptable resolution.
13. Public Health Significance	The COVID-19 pandemic had significant impacts on state and federal shellfish programs. Recognizing that special considerations regarding NSSP program compliance were necessary, the ISSC Executive Board responded with a plan to address the issue that was specific to the COVID-19 pandemic. This language recognizes that similar situations may arise in the future and provides guidance for initiating the process for emergency consideration.
14. Cost Information	No cost.
Action by 2023 Task Force III	Recommends adoption of proposal 23-307 as amended: A. Request for Emergency Consideration In the event of a an official declared ~~public health~~ emergency ~~or~~, natural or man-made disaster, including the activation of the State Emergency Response Plan, if the Authority is not in a position to operate the program in full compliance with NSSP program requirements, the Authority shall immediately notify the ISSC and the FDA. The FDA shall immediately conduct discussions with the ~~a~~Authority to reach a mutually acceptable resolution.

Proposal No. **23-308**

Submitter	U.S. Food and Drug Administration (FDA)
Affiliation	US Food & Drug Administration (FDA)
Address Line 1	5001 Campus Drive
Address Line 2	CPK1, HFS-325
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Email	Melissa.Abbott@fda.hhs.gov
Proposal Subject	Removed the words "hand sanitizing" from item 11 and add Model Ordinance references to items 2, 4, 5, 6 and 7
Specific NSSP Guide Reference	**NSSP Standardized Shellfish Processing Plant Inspection Form**
Text of Proposal/ Requested Action	16. Sanitation Monitoring and Records X. 02 A, B S(K/O)

Agency Name: | Date

Type of Inspection ☐ Certification ☐ Pre-operational ☐ Routine ☐ Follow-up ☐ Standardization

Dealer Name: | Certification Number

Dealer Address:

Hazard Analysis Critical Control Point (HACCP)

1. **HACCP Plan** Yes ☐ No ☐ Required for Certification

2.

Plan Elements Identified and Adequate	Citation	✓/✗ NA	Code	Citation	✓/✗ NA	Code
(a) Hazards	X.01.C.(1)		O	(e) Critical Control Points	X.01.C.(2)		K
(b) Records	X.01.C.(6)		O	(f) Monitoring	X.01.C.(4)		K
(c) Critical Limits	X.01.C.(3)		K	(g)Verification Procedures	X.01.C.(7)		O
(d) Name, Address, Signed and Dated	X.01.H.(1) X.01.D.		O	(h) Corrective Action if identified	X.01.C.(5)		K

3. **HACCP Training** Yes ☐ No ☐ Code O

4. **Plan Implementation**

	Activities	Records
Corrective Actions Recorded (K)	X.01.F.(1)	X.01.F.(4)
Verification Procedures (K) (Signature)	X.01.G.(1)	X.01.G.(1)(c)
Monitoring Procedures (K)	X.01.C.(4)	X.01.C.(6)
Records: Accurate/ Maintained (K) Format (O)	X.01.H	
Initialed/Dated (O)	X.01.H	
Firm's Name on record (O)	X.01.H	

		✓/✗ NA	Code
(a)	Receiving		
(b)	Shellstock Storage		
(c)	Processing		
(d)	Shucked Meat Storage		
(e)	Other Critical Limits		

5.	Approved Source Control Failure	.01 A		C
6.	Time/Temperature Control Failure	.01 A,B,C,D		C
7.	Other Critical Control Failure	.01 A,B,C,D,E,F		C

	Sanitation Items	Citation	✓/✗	Code
8.	Safety of water for processing and ice production	.02A		
9.	Condition and cleanliness of food contact surfaces	.02B		
10.	Prevention of cross-contamination	.02C		
11.	Maintenance of hand-washing, ~~hand sanitizing~~ and toilet facilities	.02D		
12.	Protection from adulterants	.02E		
13.	Proper labeling, storage, and use of toxic compounds	.02F		
14.	Control of employees with adverse health conditions	.02G		
15.	Exclusion of pests	.02H		
16.	Sanitation Monitoring and Records			S(K/O)
	Additional Model Ordinance Requirements	**Citation**	**✓/✗**	**Code**
17.	Plants and Grounds	.03A		
18.	Plumbing and related facilities	.03B		
19.	Utilities	.03C		
20.	Disposal of other waste	.03D		
21.	Equipment condition and cleaning, maintenance, and construction of non-food contact surfaces	.03E		
22.	Shellfish storage and handling	.03F		
23.	Heat shock	.03G		
24.	Supervision	.03H		
25.	Transportation (To include only the person shipping)	IX.05		K
26.	Labeling and Tagging	X.05,.06,.07		S (K/O)
27.	Shipping Documents and Records / Written Recall Procedures	X.08, .03		K

Dealer's Signature | **Inspector's Signature**

[Code: Critical -C; Key-K; Swing-S; Other-O] ISSC Form 93-01(A) revised ISSC 2020 Page 1 of ___
Effective Date: 11/2020

Proposal No. **23-308**

Public Health Significance	The Model Ordinance requires that deficiencies are marked with the proper citation from the MO. Currently, Line 16 is missing its citation. This proposal would correct this oversight.
Cost Information	N/A
Action by 2020 Executive Board	Granted Interim Approval in effect until the Conference convenes at the 2023 ISSC Biennial Meeting.
Action by 2023 Task Force III	Recommend adoption of proposal 23-308 as submitted.

Proposal No. **23-309**

Submitter	Blake Millett
Affiliation	Utah Department of Agriculture and Food
Address Line 1	4315 S 2700 W
Address Line 2	
City, State, Zip	Taylorsville, UT 84129
Phone	801-706-9202
Fax	
Email	Bmillett@utah.gov
Proposal Subject	Addition of Citation to ISSC Form 93-01(A)
Specific NSSP Guide Reference	ISSC Form 93-01(A) revised ISSC 2020 NSSP Standardized Shellfish~~Shelfish~~ Processing Plant Inspection Form Line 16 Citation
Text of Proposal/ Requested Action	16. Sanitation Monitoring and Records X. 02 A, B S(K/O)
Public Health Significance	The Model Ordinance requires that deficiencies are marked with the proper citation from the MO. Currently, Line 16 is missing its citation. This proposal would correct this oversight.
Cost Information	N/A
Action by 2023 Task Fore III	Recommend no action on proposal 23-309. The issue is addressed by proposal 23-308