ISSC

Interstate Shellfish Sanitation Conference

Task Force III Proposals for Consideration At the 2027 Biennial Meeting

Newport, Rhode Island
January March 24-29, 2027

ISSC Task Force III
2027 Proposal Inventory

Proposal Number	Proposal Subject	Page
11-310	Internal Authority Self-Assessment Using a National Program Standards Manual	1
13-301	Growing Area Classification Criteria	5
17-204	Add in-field Compliance Criteria for Control of Harvest Element	9
19-30	Evaluation of Shellfish Sanitation Program Elements	13
19-312	Plant and Shipping Element Evaluation Criteria	16
23-301	Guidance Documents	17
23-303	Revision of Standing Committee List	20
23-304	Remove Proposal Review Committee	22
23-305	Biotoxin Management Plan Criteria	24
27-300	ISSC Membership	36
27-301	Constitution, Bylaws and Procedures Update	38
27-302	States Forum	81
27-303	Definition of Shellfish	83
27-304	Definition of Certification Number	84
27-305	New State in the NSSP Process	86
27-306	Changes to the Patrol Evaluation Section	88
27-307	Quantitative risk assessment of individual oyster harvests using real-time observations can expand Vibrio risk management options	91
27-308	Add new Section X, Notes, to the Guide as well as endnote reference numbers within the Guide, referring Guide readers to specific proposal number(s) that created/altered Guide language	93

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. X Administrative

Submitter	Julie Henderson
Affiliation	Virginia Department of Health Division of Shellfish Sanitation
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	N/A
Action by 2011 Task Force III	Recommended referral of Proposal 11-310 to the appropriate committee as determined by the Conference Chairman.
Action by 2011 General Assembly	Adopted the recommendation of Task Force III on Proposal 11-310.
Action by FDA February 26, 2012	Concurred with Conference action on Proposal 11-310.

Action by 2013 NSSP Evaluation Criteria Committee	Recommended referral of Proposal 11-310 to the appropriate committee as determined by the Conference Chairperson with the following instructions. Establish a workgroup to evaluate the Manufactured Food Standards and determine the applicability of and/or use of these Manufactured Standards to the National Shellfish Sanitation Model Ordinance requirements and report their findings and recommendations to the NSSP Evaluation Criteria Committee at the next ISSC Meeting. The Committee further recommended that self-assessments should be voluntary and that the word "shall" should be replaced with the word "may".
Action by 2013 Task Force III	Recommended adoption of the NSSP Evaluation Criteria Committee recommendation on Proposal 11-310.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force III on Proposal 11-310.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 11-310.
Action by 2015 NSSP Evaluation Criteria Committee	Recommended that draft standards be developed for each program element. These draft standards will be developed using the 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
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 General Assembly	Adopted the recommendation of Task Force III on Proposal 11-310.
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. 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	Recommended continued development of the voluntary program standards.
Action by 2023 Task Force III	Recommended adoption of the Standards Committee recommendation on Proposal 11-310.

Action by 2023 General Assembly	Adopted recommendation of Task Force III on Proposal 11-310.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 11-310.

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. X Administrative

Submitter	ISSC Executive Office
Affiliation	ISSC
Email	issc@issc.org
Proposal Subject	Growing Area Classification Criteria
Specific NSSP Guide Reference	To Be Determined
Text of Proposal/ Requested Action	The ISSC has adopted evaluation criteria for several program elements within the NSSP. These include laboratories, plant sanitation, and patrol. The development of these criteria has seemed to provide a better understanding of expectations, improve uniformity in State evaluations and enhance compliance. The ISSC should expand its evaluation criteria efforts to include growing area classification. Most illnesses associated with molluscan shellfish can be traced to problems associated with growing area classification. Although more complex, this element of the program could benefit from the development of evaluation criteria. The purpose of this proposal is to request the Evaluation Criteria Committee be charged with the task of developing evaluation criteria for the growing area element.
Public Health Significance	Growing area classification criteria will enhance State classification efforts and ensure a high level of uniformity and effectiveness in FDA evaluations.
Cost Information	
Action by 2013 Task Force III	The submitter of Proposal 13-301 requested that the following sentence be deleted from the proposal. ~~Most illnesses associated with molluscan shellfish can be traced to problems associated with growing area classification.~~ The Task Force recommended adoption of Proposal 13-301 with the amendment as requested by the submitter.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force III on Proposal 13-301.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-301.
Action by 2015 NSSP Evaluation Criteria Committee	**Recommended:** 1) The following criteria be used in evaluating the State Growing Area classification element 1. Written Sanitary Survey

	(A) Is there a written Sanitary Survey for each growing area that is classified other than prohibited? (B) Is the Sanitary Survey complete? A. Executive Summary B. Description of Growing Area C. Pollution Source Survey D. Hydrographic and Meteorological Characteristics E. Water Quality Studies F. Interpretation of Data in Determining Classification to Be Assigned to Growing Area: A discussion of how actual or potential pollution sources, wind, tide, rainfall, etc. affect or may affect water quality, that will address the following: G. Conclusions (C) Is the Sanitary Survey current? A. Annual B. Triennial C. 12 Year) 2. Shoreline Survey (A) Does Shoreline Survey include identification and evaluation of all actual and potential sources of pollution (B) Does Shoreline Survey include boundaries? (C) Does Shoreline Survey include unique designation? (D) Does Shoreline Survey include required maps? (E) Does Shoreline Survey include a summary of survey findings? 3. Adequate Sampling (A) Are the number and location of sampling stations adequate to effectively evaluate all pollution sources. (B) Were adequate samples collected for each area consistent with the classification and type of sampling approach used (i.e. Remote, Adverse Pollution, Systematic Random Sampling)? (C) Were samples collected under appropriate conditions consistent with the type of sampling approach? 4. Data to support Classification (A) The assigned classifications are based on data/information supporting the classification and performance standards? (B) Is appropriate data/information available to support the classification within each designated growing area? 5. Proper Classification (A) Are all growing areas properly classified? (B) Does SSCA have appropriate MOU(s) with appropriate parties for each area classified as conditional? 2) The subcommittee will develop a scoring system which assigns appropriate significance to the criteria and establishes compliance standards which can be used to assign compliance designations as outlined in the other 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. 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	Recommended referral of Proposal 13-301 to an appropriate committee as determined by the Conference Chairperson.
Action by 2023 Task Force III	Recommended adoption of the Growing Area Evaluation Criteria Committee recommendation on Proposal 13-301.
Action by 2023 General Assembly	Adopted recommendation of Task Force III on Proposal 13-301.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 13-301.

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. X Administrative

Submitter	US Food & Drug Administration (FDA)
Affiliation	FDA
Email	Melissa.Abbott@fda.hhs.gov
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	1. ~~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

v. 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** vi. 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** **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.
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	N/A

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	Recommended referral of Proposal 17-204 to an appropriate committee as determined by the Conference Chairperson.
Action by 2023 Task Force III	Recommended adoption of the Control of Harvest Evaluation Criteria Committee recommendation on Proposal 17-204.
Action by 2023 General Assembly	Adopted recommendation of Task Force III on Proposal 17-204.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 17-204.

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. X Administrative
Submitter	Kristen DeRosia Banick, David Carey, Sue Ritchie
Affiliation	Connecticut Department of Agriculture NYS DEC – Division of Marine Resources
Email	Kristin.DeRosia-Banick@ct.gov
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 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	Recommended 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 Force III	Recommended adoption of the Plant Evaluation Criteria Committee recommendation on proposal 19-305.
Action by 2023 General Assembly	Adopted recommendation of Task Force III on Proposal 19-305.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 19-305.

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. X☐ Administrative

Submitter	US Food & Drug Administration (FDA)
Affiliation	FDA
Email	Melissa.abbott@fda.gov
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 Plant Evaluation Criteria Committee	Recommended referral of Proposal 19-312 to an appropriate committee as determined by the Conference Chairperson.
Action by 2023 General Assembly	Recommended adoption of the Plant Evaluation Criteria Committee recommendation on proposal 19-312
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 19-312

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. X Administrative
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
Email	Eric.hickey@mass.gov
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

~~1.~~ 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	Recommended 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.
Action by 2023 General Assembly	Adopted recommendation of Task Force III on Proposal 23-301.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-301.

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. X Administrative

Submitter	ISSC Executive Office
Email	issc@issc.or
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	N/A
Action by 2023 Task Force III	Recommended referral of Proposal 23-303 to an appropriate Committee or Committees as determined by the Conference Chair.
Action by 2023 General Assembly	Adopted recommendation of Task Force III on Proposal 23-303.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-303.

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. X Administrative
Submitter	ISSC Executive Office
Email	issc@issc.or
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

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;
   - 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.
2. A quorum for…
3. The Nine-member…

~~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 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	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	N/A
Action by 2023 Task Force III	Recommended referral of Proposal 23-304 to an appropriate Committee or Committees as determined by the Conference Chair.
Action by 2023 General Assembly	Adopted recommendation of Task Force III on Proposal 23-304.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-304.

Proposal No. 2 3 - 3 0 5

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. X Administrative

Submitter	ISSC Executive Office
Email	issc@issc.org
Proposal Subject	Biotoxin Management Plan Criteria
Specific NSSP Guide Reference	Section II Model Ordinance; Chapter IV. Shellstock Growing Areas @.04.B
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

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 onitoring: this strategy involves a routine program for sampling and testing shellfish meats for the presence of marine biotoxins. nless 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 BiotoxinPlans. (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.~~
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.
Cost Information	N/A
Action by 2023 Task Force III	Recommended referral of Proposal 23-305 to an appropriate Committee or Committees as determined by the Conference Chair.
Action by 2023 General Assembly	Adopted recommendation of Task Force III on Proposal 23-305.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-305.

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. X Administrative
2. Submitter	ISSC Executive Office
3. Affiliation	Interstate Shellfish Sanitation Conference
4. Address Line 1	4801 Hermitage Road
5. Address Line 2	Suite 102
6. City, State, Zip	Richmond, VA 23227
7. Phone	(804) 330-6380
8. Email	issc@issc.org
9. Proposal Subject	ISSC Membership
10. Specific NSSP Guide Reference	ISSC Constitution, Bylaws & Procedures. Article III, Section 2
11. Text of Proposal/ Requested Action	**ARTICLE III. MEMBERSHIP AND REGISTRATION** 1. The membership and registration fees shall be set by the Executive Board as necessary to defray the costs of the Biennial Meeting and the operating costs of the Conference. 2. Membership Fees a. The fee for each category of membership and the membership period shall be set by the Executive Board. State membership fees will be established as necessary to provide, at a minimum, ten percent (10%) of the operating budget of the Conference. The Executive Board will follow the guidelines of Procedure XIX. in establishing membership fees b. There shall be ~~two (2)~~ five (5) categories of membership: i. State Authority (a) Shellfish producing states (b) Non-producing states ii. Agency membership: Individuals employed by agencies that are responsible for NSSP oversight and law enforcement activities at state, federal or local levels. iii. Industry Membership: Individuals employed by or representing the shellfish industry. iv. Academia membership: Individuals employed by a two- or four- year college or university involved in education or research involving foods, drugs, cosmetics, devices, or product safety. v. Individual Membership: Individuals interested in the objectives of the ISSC, but do not fall under any of the other categories.

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<tr><td></td><td>
c. Group Membership: Organizations interested in having multiple members from their organization may be eligible for group membership at a reduced rate. To be eligible for group membership, a list of all members of the group must be submitted together to issc@issc.org indicating who the group contact will be. The following group membership discounts will apply:
<table>
<tr><th># Memberships</th><th>Discount rate</th></tr>
<tr><td>3 - 5</td><td>5%</td></tr>
<tr><td>6 - 10</td><td>10%</td></tr>
<tr><td>11 - 15</td><td>15%</td></tr>
<tr><td>> 15</td><td>20%</td></tr>
</table>
d. The membership fees may be paid annually or biennially.
e. The State authority membership fees shall include one membership for one Voting Delegate. Persons other than Voting Delegates shall be considered members by payment of the membership fee.
f. The membership period shall coincide with the calendar year. Applications for membership shall be mailed at least thirty (30) days prior to the beginning of the membership period to the two (2) previous years' membership rolls.
</td></tr>
<tr><td>12. Public Health Significance</td><td></td></tr>
<tr><td>13. Cost Information</td><td></td></tr>
<tr><td>14. Changes Needed to Guidance (if proposed change is adopted)</td><td></td></tr>
</table>

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☒ Administrative
2. Submitter	US Food & Drug Administration (FDA)
3. Affiliation	US Food & Drug Administration (FDA)
4. Address Line 1	5001 Campus Drive
5. Address Line 2	CPK1, HFS-325
6. City, State, Zip	College Park, MD 20740
7. Phone	240-402-1401
8. Email	Melissa.Abbott@fda.hhs.gov
9. Proposal Subject	Constitution, Bylaws and Procedures Update
10. Specific NSSP Guide Reference	N/A
11. Text of Proposal/ Requested Action	See attached supplemental documentation
12. Public Health Significance	Updates to the Constitution, Bylaws and Procedure are needed to reflect current organizational structure and processes at the FDA.
13. Cost Information	No cost
14. Changes Needed to Guidance (if proposed change is adopted)	TBD

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. X Administrative
2. Submitter	Andrew Bell
3. Affiliation	State of Delaware, Department of Natural Resources & Environmental Control
4. Address Line 1	285 Beiser Boulevard
5. Address Line 2	Suite 102
6. City, State, Zip	Dover, DE 19904
7. Phone	302-608-5511
8. Email	andrew.bell@delaware.gov
9. Proposal Subject	States Forum
10. Specific NSSP Guide Reference	Constitution of the Interstate Shellfish Sanitation Conference Article VIII. Duties of the Executive Director
11. Text of Proposal/ Requested Action	Article VIII. Duties of the Executive Director 13. The Executive Director shall arrange two virtual forums of ISSC states on a semi-annual basis for the purpose of facilitating communication and resource sharing between states. One semi-annual forum shall be for topics and questions relating to growing area classification, patrol, and laboratory matters. The other semi-annual forum shall be for topics and questions relating to aquaculture and processing and shipping matters. Sixty (60) days prior to the forums, the Executive Director shall send the date and other pertinent details, and solicit questions and topics for discussion, to all ISSC members of producing states for the forum relating to growing area classification, patrol, aquaculture, Vibrio control plan, and laboratory matters, and to all ISSC members of all states for the forum relating to processing and shipping matters. State attendance at these virtual forums is optional.
12. Public Health Significance	Consumer safety is strengthened when public health authorities have the opportunity to have discussions and share resources. It would be beneficial if Authorities met occasionally to discuss emerging topics and ask questions amongst ourselves. The intent is an opportunity for informal dialogue, to provide state representatives with a place to ask questions and obtain resources, so that shellfish sanitation can be improved and standardized at the national level. Examples of questions and topics that a state may wish to bring to these forums might be "At what rainfall level do other states issue an emergency closure?" or "Are any states requiring shading on harvest boats outside Vibrio Control Plan months?" or "Does anyone have a template for a cooler process study that they could share?" There is an observation that Authorities generally don't communicate much outside Biennial Meetings, and this proposal is an attempt to provide them with an optional opportunity for increased communication. This proposal adds to the duties of the Executive Director to hold two semi-annual virtual forums for ISSC state members, one for growing area, patrol, aquaculture, Vibrio control plan, and laboratory topics, and the other for processing and shipping topics (the idea is that the first type of forum would be relevant for producing states, while the second type of forum would be relevant for all states). Both these forums would be held every six months to facilitate state communication.

13. Cost Information	None or minimal
14. Changes Needed to Guidance (if proposed change is adopted)	None

Proposal No. 27-303
~~Date~~

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☒ Administrative
2. Submitter	ISSC Executive Office
3. Affiliation	Interstate Shellfish Sanitation Conference
4. Address Line 1	4801 Hermitage Road
5. Address Line 2	Suite 102
6. City, State, Zip	Richmond, VA 23227
7. Phone	(804) 330-6380
8. Email	issc@issc.org
9. Proposal Subject	Definition of Shellfish
10. Specific NSSP Guide Reference	ISSC Constitution, Bylaws & Procedures. Definitions
11. Text of Proposal/ Requested Action	(10) SHELLFISH – means all species of: (a) Oysters, clams or mussels, whether: ~~(ii)~~(i) Shucked or in the shell; ~~(iii)~~(ii) Raw, including post-harvest processed; ~~(iv)~~(iii) Frozen or unfrozen; ~~(v)~~(iv) Whole or in part; and (b) Scallops in any form, except when the final product form is the adductor muscle only~~.~~, attached or unattached to the shell.
12. Public Health Significance	Proposal 23-101 was adopted at the 2023 Biennial Meeting which amended the definition of shellfish in the NSSP Model Ordinance. The new language aligns the definition in the ISSC Constitution, Bylaws and Procedures with the new definition in the NSSP Model Ordinance.
13. Cost Information	
14. Changes Needed to Guidance (if proposed change is adopted)	

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☒ Administrative
2. Submitter	ISSC Executive Office
3. Affiliation	Interstate Shellfish Sanitation Conference
4. Address Line 1	4801 Hermitage Road
5. Address Line 2	Suite 102
6. City, State, Zip	Richmond, VA 23227
7. Phone	(804) 330-6380
8. Email	issc@issc.org
9. Proposal Subject	Definition of Certification Number
10. Specific NSSP Guide Reference	
11. Text of Proposal/ Requested Action	**(17) Certification Number** means the unique identification number issued by the Authority to each dealer for each location. Each certification number shall consist of a one (1) to five (5) digit Arabic number preceded by the two letter State abbreviation and followed by a two (2) letter abbreviation for the type of activity or activities the dealer is qualified to perform in accordance with Chapter X. .04 B. ~~The certification type will be followed by applicable permit designation as indicated in Chapter I. @.02 E.1.~~
12. Public Health Significance	This language is submitted to address an unintended consequence related to the adoption of proposals 19-201 and 19-204 at the 2019 Biennial Meeting. The two related proposals addressed the information that is required to be submitted to FDA by states when a dealer is certified. Proposal 19-204 amended language to clarify that any permit designations held by the dealer being certified must be submitted along with the certification number so that the information can be included in the ICSSL. Proposal 19-201 amended the definition of "certification number" to add a reference to the appropriate section of Chapter X related to certification types instead of repeating the section. In addition, a phrase was added stating that "the certification type will be followed by the applicable permit designation as indicated in Chapter I. @.02.E.1." Although Chapter I @.02.E.1. refers only to information that is to be listed in the ICSSL, the inclusion of the statement added to the definition by the

	adoption of 19-201 arguably created a new requirement that permit designations must be added anywhere that a dealer certification number is required which includes shellstock tags as well as all packages of shucked shellfish and in-shell product. This issue was discussed by the ISSC Executive Board, many of whom were not aware that the new language may have created a significant new labeling requirement. A motion was adopted that directed the ISSC Executive Office to submit a proposal for discussion of the issue at the next Biennial Meeting.
13. Cost Information	
14. Changes Needed to Guidance (if proposed change is adopted)	

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☒ Administrative
2. Submitter	US Food & Drug Administration (FDA)
3. Affiliation	US Food & Drug Administration (FDA)
4. Address Line 1	5001 Campus Drive
5. Address Line 2	
6. City, State, Zip	College Park, MD 20740
7. Phone	301-436-26-1
8. Email	Melissa.Abbott@fda.hhs.gov
9. Proposal Subject	New State in the NSSP Process
10. Specific NSSP Guide Reference	Guide for the Control of Molluscan Shellfish, 2023 Revision Section IV. Guidance Documents Chapter I. @.01 .02
11. Text of Proposal/ Requested Action	.02 Procedures for Initiating a New State Program Under the National Shellfish Sanitation Program The requirements of the NSSP are contained in its Model Ordinance. Implementation of the Model Ordinance ….. The ISSC provides the formal structure …. To ensure uniformity in the administration and implementation of the requirements of the NSSP Model Ordinance at the State and tribal regulatory agency level, the FDA reviews their programs on an annual basis. New State or tribal regulatory programs under the NSSP are required to have their proposed program reviewed prior to its initiation to assure that any shellstock produced, stored or shipped under the State or tribal program for movement in interstate commerce meets the requirements of the Model Ordinance. *New State or Tribal Program* The Authority must apply to the FDA for evaluation and be found in conformity or compliance with the NSSP before initiating a State or tribal shellfish sanitation program or a new program element within an existing State or tribal program. The application should consist of a letter of intent to participate in the NSSP with a description of the shellfish sanitation program the State or tribal authority will initiate. The letter of intent should be on letterhead of the agency or department that will serve as the Authority. The FDA will ~~act on~~ acknowledge receipt of the ~~any~~ application submitted by the Authority and begin the review and evaluation process of the proposed shellfish sanitation program. ~~If the FDA has not acted within thirty (30) days, the Authority may proceed with the new shellfish sanitation program.~~

	When two (2) or more State or tribal agencies will be involved in the sanitary control of the shellfish industry, a clear statement of each agency's responsibilities should be developed in the form of a memorandum of understanding. This administrative practice eliminates misunderstandings concerning agency responsibility and ensures that all aspects of shared program responsibility are addressed. States and tribes are responsible for maintaining shellfish programs that conform to or comply with the requirements contained in the most current revision of the Model Ordinance. These requirements ~~should~~ shall be mandatory within each State program.
12. Public Health Significance	This guidance section provides instructions for a state or tribal authority to initiate the process of participating in the NSSP. This process does not apply to foreign governments seeking arrangements with the FDA to export bivalve molluscan shellfish to the U.S. Eliminating the statement that states or tribal authorities can initiate their shellfish sanitation program if the FDA fails to act within 30 days takes away the possibility of proceeding with a non-compliant program potentially risking public health. With that statement removed, the timeframe for initiating the process by FDA is not needed. There is no public health significance of these arbitrary timeframes and removing them provides more flexibility in beginning and completing the initial program review and evaluation process.
13. Cost Information	No cost to industry or the Authority
14. Changes Needed to Guidance (if proposed change is adopted)	This proposal is a change to guidance Chapter I. @.1 .02

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☒ Administrative
2. Submitter	US Food & Drug Administration (FDA)
3. Affiliation	US Food & Drug Administration (FDA)
4. Address Line 1	5001 Campus Drive
5. Address Line 2	
6. City, State, Zip	College Park, MD 20740
7. Phone	301-436-2601
8. Email	Melissa.Abbott@fda.hhs.gov
9. Proposal Subject	Changes to the Patrol Evaluation Section
10. Specific NSSP Guide Reference	NSSP Model Ordinance, Chapter I. @.03 3, i.
11. Text of Proposal/ Requested Action	**i.** The following procedures will be implemented when an FDA evaluation identifies deficiencies with the above patrol evaluation criteria. i. The overall Patrol Program element will be assigned one (1) 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) **Nonconformance:** The program has: i. at least one (1) critical deficiency; ii. two (2) or more key deficiencies; or iii. a repeat **[Key]** deficiency from the previous evaluation. (d) **Major Nonconformance:** The program has multiple deficiencies, key or critical, that suggests the program has become ineffective to control harvest in harvest restricted waters. ii. During the closeout meeting for patrol evaluation, the Shellfish Specialists shall ~~identify~~ discuss any observations that may become a ~~patrol~~ deficiency ~~to~~ with the State patrol agency; iii. ~~Within thirty (30) days of~~ After the closeout meeting, the Shellfish Specialist shall provide a draft written Program Element Evaluation Report (PEER), including supporting documentation, to the State patrol agency; ~~iv. Within thirty (30) days of receiving the~~

	~~PEER,~~ The State patrol agency shall have the opportunity to review, comment and provide a written response to the draft PEER. ~~provide a written response that indicates:~~ ~~(a) The item(s) was corrected;~~ ~~(b) A correction plan has been developed with a completion date; or,~~ ~~(c) The reasons why the State disagrees with FDA's finding(s).~~ v. ~~Within fifteen (15) days of receipt FDA shall review the State response, and respond to the State;~~ For any deficiency that cannot be corrected prior to issuance of the final PEER, the State patrol agency will submit a corrective action plan including steps they will take to correct the deficiency and a timeframe for correction. vi. ~~Any CRITICAL item deficiency shall be corrected within thirty (30) days of acceptance by FDA of the correction plan;~~ The FDA will monitor the state's actions to complete the corrective action plan to correct the deficiency. ~~vii. Any KEY item deficiency shall be corrected within one (1) year of acceptance by FDA of the correction plan.~~ ~~viii. FDA shellfish specialists shall be responsible for monitoring the progress of State action plans.~~ ~~ix. Patrol Program recommendations addressing improvements not associated with the criteria included in Section I or recommendations addressing improvements beyond the requirements of the Model Ordinance should be submitted to the Authority in correspondence.~~
12. Public Health Significance	This section contains very specific timeframes for steps in the Program Element Evaluation Report process and for correcting reported deficiencies. Chapter I. @.03 does not have specific process timeframes for the growing area classification, plant processing and shipping and risk assessment and risk management program element evaluations. It places requirements on the FDA that do not belong in a section for requirements of the authority. It is often difficult for the FDA or the state patrol agency to meet the timeframes specified for a variety of reasons and there is no allowance for extensions. The FDA includes timeframes for completing the field portion of evaluations, for providing a draft PEER, for the state to review the PEER, for providing a corrective action plan if needed and for completing the corrective action plan in Compliance Program 7328.004 Molluscan Shellfish as policy, not an MO requirement. This is a public document and provided to the Authority. The timeframes in this section are not aligned with

	timeframes in the compliance program. Removing the specific timeframes allows for more flexibility for the state authority and FDA to effectively conduct the PEER process. Having uniform timeframes across all program area evaluations adds to consistency in expectations. There is no public health significance to the specific timeframes outlined in this section and they are better included in the FDA Compliance Program than in the MO.
13. Cost Information	There is no cost to the industry or Authority.
14. Changes Needed to Guidance (if proposed change is adopted)	TBD

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	ISSC Executive Office
3. Affiliation	ISSC
4. Address Line 1	4801 Hermitage Rd
5. Address Line 2	
6. City, State, Zip	Richmond, VA 23227
7. Phone	(804) 330-6380
8. Email	issc@issc.org
9. Proposal Subject	Quantitative risk assessment of individual oyster harvests using real-time observations can expand Vibrio risk management options
10. Specific NSSP Guide Reference	TBD
11. Text of Proposal/ Requested Action	Develop guidance through the Vibrio Management Committee to assist implementation of existing quantitative risk assessment models by state authorities and industry to manage vibrio risk of individual oyster harvests using real-time observed water and oyster temperatures as an alternative to historical monthly mean maximum water temperatures to achieve an equivalent level of consumer protection.
12. Public Health Significance	Quantitative risk assessment (QRA) for *V. vulnificus (*Vv) in raw oysters was released by the Food and Agriculture Organization/World Health Organization in 2005. Water temperature determined Vv levels in oyster at harvest and post-harvest growth on ambient air temperature and cooldown time to minimum growth temperature (<13°C). The US Food and Drug Administration developed an Excel risk calculator based on this QRA to facilitate scenario analysis by state authorities. The National Shellfish Sanitation Program (NSSP) adopted a Vv Control Plan based on this risk calculator in 2009. State can use average monthly maximum water temperature in the previous five years to implement controls that will minimize risk to: (<3/100,000 when >80°F; <2.5/100,000 when 75-80°F; and <1.75/100,000 when 70-75°F). The NSSP allows states other risk management options: "may implement alternative controls that will reduce the risk to a level comparable to the risk per serving identified above". States have generally adopted plans based on a single scenario analysis with rigid maximum harvest and cooling times. This "one size fits all" policy can result in excessive risk during heat anomalies and also restricts industry risk

	management options that could extent harvest periods by harvesting at cooler times or rapid cooling. A paradigm shift using observed harvest condition instead or relying on average historical temperatures is a more granular alternative control that improves QRA accuracy and expands compliance options. QRA models are available for *V. parahaemolyticus* and are amenable to real-time inputs by stakeholders to improve risk management using scenario analysis for emerging industry practices such as serving oysters during farm tours or to support a variance from re-mergence requirements.
13. Cost Information	N/A
14. Changes Needed to Guidance (if proposed change is adopted)	TBD

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☒ Administrative
2. Submitter	US Food & Drug Administration (FDA)
3. Affiliation	US Food & Drug Administration (FDA)
4. Address Line 1	5001 Campus Drive
5. Address Line 2	CPK1, HFS-325
6. City, State, Zip	College Park, MD 20740
7. Phone	240-402-1401
8. Email	Melissa.Abbott@fda.hhs.gov
9. Proposal Subject	Add new Section X, Notes, to the Guide as well as endnote reference numbers within the Guide, referring Guide readers to specific proposal number(s) that created/altered Guide language
10. Specific NSSP Guide Reference	Create new Section X.
11. Text of Proposal/ Requested Action	Currently, there is no reference mechanism within the Guide to allow readers to easily reference the proposal(s) that created/altered specific Guide language. Creating a reference mechanism linking Guide language to the proposals that created/altered that language would aid the reader in researching specific proposal(s) and the 'intent' of those changes. Currently the only way to research why Guide language was created or altered is to compare current Guide language to previous Guide versions to find the specific Guide version where that language changed, and then research that conference year's Task Force reports to find the specific proposal, a cumbersome process. This proposal would add a new Section X, *Notes*, to the Guide, as well as require that a superscript reference number be added to any new adopted language (or at a minimum any new adopted language of significance). The superscript reference number would refer the reader to the appropriate endnote in the *Notes* section, and that would include a brief description of that language/change, the related proposal number(s), and the conference year(s) adopted. Additionally, as sometimes Guide language is altered outside of the traditional Conference process by ISSC Executive Board action, this proposed referencing system would also capture those Board actions. As an example, in Section II Chapter VI. @.02 Seed Shellstock, subsection A., there is a relatively new 120 day minimum grow-out requirement for shellfish seed grown in Prohibited waters. This proposal would insert a superscript endnote reference number in that subsection as follows, '…a minimum of 120 days[1] of growing… The new Section X, *Notes* (organized in the same manner as the Guide), would read, Section II. Chp. VI. @.02 Seed Shellstock 1. 120 day grow-out requirement – Previously 6 months, See Proposal 13-107, adopted 2017.

12. Public Health Significance	A reference mechanism linking Guide language to the proposal(s) that created that language would increase the understanding of the reader as to why particular Guide language was adopted.
13. Cost Information	No cost to States/Industry. If adopted, this proposal would increase the administrative burden of the ISSC office when publishing a new Guide, going forward.
14. Changes Needed to Guidance (if proposed change is adopted)	TBD