Proposal No. 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	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.