Proposal No. 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	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.