Proposal No. 17-305

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting	☐ Growing Area ☐ Harvesting/Handling/Distribution ☒ Administrative

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Proposal Subject	Responsibilities of the FDA for Annual or Bi-Annual Evaluations
Specific NSSP Guide Reference	ISSC Constitution, Bylaws, and Procedures of the ISSC Procedure IV. Responsibilities of the FDA Section 3. and Model Ordinance Chapter I. @.03 (new) E.
Text of Proposal/ Requested Action	Procedures of the Interstate Shellfish Sanitation Conference Procedure IV. Responsibilities of the FDA Section 3. Subdivision a: FDA shall provide a description of all deficiencies/non-compliance or emerging concerns identified during the evaluation. FDA will include the specific NSSP Model Ordinance reference for each deficiency, non-compliance, or emerging concern. This can be accomplished during a close out session with state program officials or at any time during a field inspection or overall program evaluation and shall occur prior to finalizing the Program Element Evaluation Report (PEER) Subdivision b: FDA shall allow state program officials a minimum of 30 days to correct any deficiencies/non-compliance or emerging concerns (that do not pose an imminent health hazard) identified prior to finalizing the PEER. If state program officials correct the identified deficiencies during the 30 day time frame, the final PEER will acknowledge the corrections and reflect compliance with any deficiencies identified or noted during the evaluation

	as in Subdivision a, above. If corrections cannot be accomplished within 30 days an agreed upon timeframe or action plan is required and should be included in the PEER. Subdivision c: All deficiencies, non-compliance, or emerging concerns cited in a PEER will include the specific Model Ordinance references of the requirements. Once a State has corrected any non-compliance FDA shall acknowledge the correction in writing. Model Ordinance Chapter I. @.03 (new) E. E. When notifying the Authority of deficiencies cited as part of a Program Evaluation, the FDA will adhere to the following: (1) FDA shall provide a description of all deficiencies/non-compliance or emerging concerns identified during the evaluation and include the specific NSSP Model Ordinance reference for each. (2) FDA shall allow state program officials a minimum of 30 days to correct any deficiencies/non-compliance or emerging concerns (that do not pose a public health hazard) identified prior to finalizing the Program Element Evaluation Report (PEER). If State program officials correct the identified deficiencies during the 30 day time frame, the PEER will acknowledge and reflect compliance. (3) Once a State has corrected or addressed any non-compliance, deficiencies, or emerging concerns, FDA shall acknowledge the correction in writing.
Public Health Significance	Provides a mechanism to assure consistency and encourages corrections during the evaluation process so that correctin of deficiencies occur in a timely manner. This is consistent with the existing FDA Compliance Program Guidance Manual. This language encourages the cooperative aspect of the NSSP by allowing FDA and State Authorities to work together to address problems sooner rather than later.
Cost Information	Would save time and resources for both FDA and State Regulators.