Proposal No. 2 7 - 3 0 6

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
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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