Proposal No. 2 7 - 3 0 5

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)
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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