Proposal No. 2 3 - 3 0 1

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. X Administrative
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Proposal Subject	Guidance Documents
Specific NSSP Guide Reference	ISSC Constitution and Bylaws Section I. Purpose & Definitions Section II Model Ordinance, Chapter I. Shellfish Sanitation Program Requirements for the Authority @03 A. (1) (c) and (3) Section IV. Guidance Documents
Text of Proposal/ Requested Action	**Section I. Purpose & Definitions** (50) **Guidance Document** means a document that provides ISSC current thinking and/or general applicability suggestions on a NSSP provision. Guidance documents do not create or confer any rights or requirements for or on any person that are beyond those outlined in the NSSP Model Ordinance and do not operate to bind FDA, the Authority, or the public. Guidance documents do not preclude the use of alternative approaches for the implementation of NSSP Model Ordinance requirements. ~~(50)~~(51) **HACCP** is an acronym that stands for Hazard Analysis Critical Control Point, a systematic, science-based approach used in food production as a means to assure food safety. The concept is built upon the seven principles identified by the National Advisory Committee on Microbiological Criteria for Foods (1992). ~~(51)~~(52) **HACCP Plan** means a written document that delineates the formal procedures that a dealer follows to implement the HACCP requirements set forth in 21 Code of Federal Regulations (CFR) 123.6 as adopted by the Interstate Shellfish Sanitation Conference. Section II. Model Ordinance **Ch. I @.03 Evaluation of Shellfish Sanitation Program Elements** **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;

c. Evaluate the validity of the elements of the NSSP ~~Guide to the Control of Molluscan Shellfish~~ Model Ordinance.

Ch. I @.03 Evaluation of Shellfish Sanitation Program Elements

A. 3. The focus of data collection shall be on measuring conformity of shellfish program activities with elements of the NSSP ~~Guide to the Control of Molluscan Shellfish~~ Model Ordinance.

ISSC Constitution Bylaws and Procedures Procedure IV Responsibilities of the FDA

~~1.~~ The FDA should prepare an annual evaluation of the shellfish program of each state in accordance with the Procedures of the NSSP Model Ordinance. This evaluation should consider the program as a whole and should also specifically address the legal authority, the classification of shellfish growing waters, the shellfish sanitation control and certification, personnel training, patrol, relaying, depuration and laboratory phases of the program, and the status of state authorities Memorandums of Understanding. The state evaluation prepared by the Regional Shellfish Specialist should be reviewed and discussed with the appropriate state shellfish officials prior to submission to FDA headquarters. A PEER deficiency item can only be found based on the Model Ordinance requirements (not guidance).

INTRODUCTORY STATEMENT TO BE PLACED AT THE BEGINNING OF SECTION IV:

Guidance documents are intended to provide supporting information on how to implement the criteria set forth in the Model Ordinance or the current thinking on topics referenced in the Model Ordinance. Alternative approaches that satisfy requirements of the Model Ordinance may be used. Guidance documents are not intended to be solely used by FDA as a reference to cite NSSP deficiencies in a

	PEER or determine program conformance with the requirements of the NSSP Model Ordinance.
Public Health Significance	The purpose of this proposal is to address concerns of state control authorities and to clarify areas of confusion which include, but are not limited to, guidance concerning marinas and moorings, biotoxin management strategies, and shellfish program element evaluations. Under 21 CFR Part 123 FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidance describes ISSC current thinking on relevant topics and should be viewed only as supporting information, recommendations, and NSSP implementation aids unless specific regulatory or statutory requirements are cited. The use of the word "should" in Agency guidance means that something is suggested or recommended, but not required. Guidance documents represent FDA's current thinking on a topic. They do not create or confer any rights for or on any person and do not operate to bind FDA or the public. The Authority can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. The same definition of guidance and how it is applied should be adopted in the NSSP MO to be consistent with FDA policy and definitions.
Cost Information	N/A
Action by 2023 Task Force III	Recommended referral of Proposal 23-301 to an appropriate Committee or Committees as determined by the Conference Chair. Further recommends that the committee(s) review NSSP Guidance to identify requirements that need to be moved from guidance into the Model Ordinance with completion of the review by the next ISSC Biennial meeting.
Action by 2023 General Assembly	Adopted recommendation of Task Force III on Proposal 23-301.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-301.