Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. X Administrative

Submitter	ISSC Executive Office
Affiliation	ISSC
Email	issc@issc.org
Proposal Subject	Growing Area Classification Criteria
Specific NSSP Guide Reference	To Be Determined
Text of Proposal/ Requested Action	The ISSC has adopted evaluation criteria for several program elements within the NSSP. These include laboratories, plant sanitation, and patrol. The development of these criteria has seemed to provide a better understanding of expectations, improve uniformity in State evaluations and enhance compliance. The ISSC should expand its evaluation criteria efforts to include growing area classification. Most illnesses associated with molluscan shellfish can be traced to problems associated with growing area classification. Although more complex, this element of the program could benefit from the development of evaluation criteria. The purpose of this proposal is to request the Evaluation Criteria Committee be charged with the task of developing evaluation criteria for the growing area element.
Public Health Significance	Growing area classification criteria will enhance State classification efforts and ensure a high level of uniformity and effectiveness in FDA evaluations.
Cost Information	
Action by 2013 Task Force III	The submitter of Proposal 13-301 requested that the following sentence be deleted from the proposal. ~~Most illnesses associated with molluscan shellfish can be traced to problems associated with growing area classification.~~ The Task Force recommended adoption of Proposal 13-301 with the amendment as requested by the submitter.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force III on Proposal 13-301.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-301.
Action by 2015 NSSP Evaluation Criteria Committee	**Recommended:** 1) The following criteria be used in evaluating the State Growing Area classification element 1. Written Sanitary Survey

(A) Is there a written Sanitary Survey for each growing area that is classified other than prohibited?

(B) Is the Sanitary Survey complete?

A. Executive Summary
B. Description of Growing Area
C. Pollution Source Survey
D. Hydrographic and Meteorological Characteristics
E. Water Quality Studies
F. Interpretation of Data in Determining Classification to Be Assigned to Growing Area: A discussion of how actual or potential pollution sources, wind, tide, rainfall, etc. affect or may affect water quality, that will address the following:
G. Conclusions

(C) Is the Sanitary Survey current?

A. Annual
B. Triennial
C. 12 Year)

2. Shoreline Survey

(A) Does Shoreline Survey include identification and evaluation of all actual and potential sources of pollution
(B) Does Shoreline Survey include boundaries?
(C) Does Shoreline Survey include unique designation?
(D) Does Shoreline Survey include required maps?
(E) Does Shoreline Survey include a summary of survey findings?

3. Adequate Sampling

(A) Are the number and location of sampling stations adequate to effectively evaluate all pollution sources.
(B) Were adequate samples collected for each area consistent with the classification and type of sampling approach used (i.e. Remote, Adverse Pollution, Systematic Random Sampling)?
(C) Were samples collected under appropriate conditions consistent with the type of sampling approach?

4. Data to support Classification

(A) The assigned classifications are based on data/information supporting the classification and performance standards?
(B) Is appropriate data/information available to support the classification within each designated growing area?

5. Proper Classification

(A) Are all growing areas properly classified?
(B) Does SSCA have appropriate MOU(s) with appropriate parties for each area classified as conditional?

2) The subcommittee will develop a scoring system which assigns appropriate significance to the criteria and establishes compliance standards which can be used to assign compliance designations as outlined in the other NSS elements.
3) Field testing of the complete evaluation criteria including compliance designation will be field tested in one state in each ISSC region. The results

	will be reviewed by the NSSP Evaluation Committee, modified as appropriate and presented to the ISSC as a proposal.
Action by 2015 Task Force III	Recommended adoption of the NSSP Evaluation Criteria Committee recommendations on Proposal 13-301.
Action by 2015 General Assembly	Adopted recommendation of Task Force III on Proposal 13-301.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 13-301.
Action by 2017 NSSP Evaluation Criteria Committee	Recommended: 1. The full committee is allowed to review the FDA proposed growing area evaluation criteria immediately. Concurrence with FDA not to initiate a full pilot until the committee completes a review of the FDA proposed criteria.
Action by 2017 Task Force III	Recommended adoption of NSSP Evaluation Criteria Committee recommendation to refer Proposal 13-301 back to the NSSP Evaluation Criteria Committee with the following charge: Review the evaluation criteria provided to the NSSP Evaluation Criteria Committee and provide recommendation for interim approval by the ISSC Executive Board at the Spring Board meeting. The Executive Board is requested to coordinate the piloting of the criteria with FDA as soon as possible.
Action by 2017 General Assembly	Adopted the recommendation of Task Force III on Proposal 13-301.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 13-301.
Action by 2019 NSSP Evaluation Criteria Committee	Recommended Proposal 13-301 be referred to an appropriate committee as determined by the Conference Chairperson to continue the development of the growing area classification evaluation criteria and make recommendations to the conference on proposal 13-301. The committee will work with FDA to assure consistency and uniformity of evaluation criteria for all program elements. The committee requests the Conference Chairperson to instruct the committee to start deliberation as soon as possible.
Action by 2019 Task Force III	Recommended adoption of NSSP Evaluation Criteria Committee recommendation to refer Proposal 13-301 to the NSSP Evaluation Criteria Committee.
Action by 2019 General Assembly	Adopted recommendation of Task Force III on Proposal 13-301.

Action by FDA February 21, 2020	Concurred with Conference action on Proposal 13-301.
Action by Growing Area Evaluation Criteria Committee	Recommended referral of Proposal 13-301 to an appropriate committee as determined by the Conference Chairperson.
Action by 2023 Task Force III	Recommended adoption of the Growing Area Evaluation Criteria Committee recommendation on Proposal 13-301.
Action by 2023 General Assembly	Adopted recommendation of Task Force III on Proposal 13-301.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 13-301.