Interstate Shellfish Sanitation Conference

2015 Biennial Meeting

Task Force III Report

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Sheraton Hotel

Proposal Subject	Internal Authority Self-Assessment Using a National Program Standards Manual
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter I. Shellfish Sanitation Program Requirements for the Authority
Text of Proposal/ Requested Action	@.01 Administration A. Scope… B. State Law and Regulations… C. Records… D. Shared Responsibilities… E. Administrative Procedures… F. Epidemiologically Implicated Outbreaks of Shellfish-Related Illness… G. Commingling… H. Program Evaluation. The Authority shall conduct a self-assessment using the National Program Standards Manual and report annually to the U.S. Food and Drug Administration the results of the assessment.
Public Health Significance	The purpose of this proposal is to begin discussions on how a self-assessment can be used by Authorities to conduct a comprehensive evaluation of their ability to promote the protection of public health. An assessment conducted by an Authority may encourage continuous improvement and innovation and can assure that individual program activities provide comparability among other domestic and international shellfish programs. The evaluation can be used to assist both the FDA and shellfish Authorities in fulfilling regulatory obligations and ensuring the implementation of the requirements set forth in the NSSP Model Ordinance
Cost Information	
Action by 2011 Task Force III	Recommended referral of Proposal 11-310 to the appropriate committee as determined by the Conference Chairman.
Action by 2011 General Assembly	Adopted the recommendation of Task Force III on Proposal 11-310.
Action by FDA February 26, 2012	Concurred with Conference action on Proposal 11-310.
Action by 2013 NSSP Evaluation Criteria Committee	Recommended referral of Proposal 11-310 to the appropriate committee as determined by the Conference Chairperson with the following instructions. Establish a workgroup to evaluate the Manufactured Food Standards and determine the applicability of and/or use of these Manufactured Standards to the National Shellfish Sanitation Model Ordinance requirements and report their findings and recommendations to the NSSP Evaluation Criteria Committee at the next ISSC Meeting. The Committee further recommended that self-assessments should be voluntary and that the word “shall” should be replaced with the word “may”.
Action by 2013 Task Force III	Recommended adoption of the NSSP Evaluation Criteria Committee recommendation on Proposal 11-310.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force III on Proposal 11-310.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 11-310.
Action by 2015 NSSP Evaluation Criteria Committee	Recommended that draft standards be developed for each program element. These draft standards will be developed using the standards from other programs and the FDA draft. (Available upon request)

	It is further recommended that the ISSC identify volunteer states to pilot the standards once developed. The committee will review results from the pilot and submit a proposal for conference consideration.
Action by 2015 Task Force III	Recommends adoption of the NSSP Evaluation Criteria Committee recommendation on Proposal 11-310.

Proposal Subject	Program Element Evaluation Criteria
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter I. Shellfish Sanitation Program
Text of Proposal/ Requested Action	The ISSC has adopted State Program Evaluation Criteria for several program elements including laboratory, patrol, and processing plants. These evaluation criteria are incorporated into the NSSP as follows: Laboratory: Model Ordinance Chapter II and Guidance Documents Chapter II Growing Areas .12 and Shellfish Laboratory Evaluation Checklists Patrol: Model Ordinance Chapter VIII; Guidance Documents Chapter I General .03; and Guidance Documents Chapter II Growing Areas .09 Shellfish Plant Inspection Program: ISSC Constitution, Bylaws, and Procedures Procedure XV The purpose of this proposal is to move all NSSP evaluation criteria used by the USFDA to evaluate State program elements into a new Model Ordinance Chapter XVII. This proposed change will not involve modification of any criteria. The purpose is to locate all State evaluation criteria into one central location. Presently, the criteria are difficult to locate.
Public Health Significance	The proposed change does not have public health significance.
Cost Information	
Action by 2013 Task Force III	Recommended referral of Proposal 13-300 to an appropriate committee as determined by the Conference Chairman.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force III on Proposal 13-300.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-300.
Action by 2015 NSSP Evaluation Criteria Committee	Recommended creating a new Chapter I @ .03 Procedure For Evaluation of Shellfish Sanitation Program Elements. Existing evaluation criteria language from Chapter III, Chapter VIII, Guidance Document Chapter I .03 and the ISSC Constitution, Bylaws and Procedures will be moved to the new @ .03 section of Model Ordinance Chapter I. This change will not result in any modification to existing criteria. This change will be made for the sole purpose of moving all evaluation criteria to one location. @.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; and (c) Evaluate the validity of the elements of the NSSP Guide for the Control of Molluscan Shellfish. (2) The minimum components of shellfish program evaluation shall include: (a) A description of the program activity;

(b) A comparison of FDA observations with state observations; and
(c) A measurement of conformity of shellfish program activities with elements of the NSSP Guide for the Control of Molluscan Shellfish.

(3) The focus of data collection shall be on measuring conformity of shellfish program activities with elements of the NSSP Guide for the Control of Molluscan Shellfish.

(4) The types of data collected shall include the following:
(a) Program records;
(b) Direct observation made by the evaluator;
(c) Data and information from the Authority or other pertinent sources.

B. Criteria for evaluation of shellfish sanitation program elements shall be as follows:

(1) Laboratory
(a) Laboratory status is determined by the number and types of nonconformities found in the evaluation using NSSP standardized criteria contained in the FDA Shellfish Laboratory Evaluation Checklists found in the Guidance Documents Chapter II. Growing Areas ,12 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists.
(i) Conforms. In order to achieve or maintain conforms status under the NSSP, a laboratory must meet the following laboratory evaluation criteria:
(ii) No critical nonconformities in the microbiological or marine Biotoxin (PSP or NSP) component under evaluation have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist; and
(iii) Not more than twelve (12) key nonconformities in the microbiological component or five (5) in the marine Biotoxin (PSP or NSP) components have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist; and
(iv) Not more than seventeen (17) critical, key, and other nonconformities in total in the microbiological component or nine (9) critical, key and other nonconformities in total for the marine Biotoxin (PSP or NSP) components have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist. This number must not exceed the numerical limits established for either the critical or key criteria; and
(v) No repeat key nonconformities have been identified in the microbiological or marine Biotoxin component under evaluation in consecutive evaluations using the appropriate FDA Shellfish Laboratory Evaluation Checklist.
(b) Provisionally Conforms. In order to be deemed provisionally conforming under the NSSP, a laboratory must meet the following laboratory evaluation criteria:
(i) Not more than three (3) critical nonconformities in the microbiological component or two (2) in the marine Biotoxin (PSP or NSP) component have been identified

using the appropriate FDA Shellfish Laboratory Evaluation Checklist; and

(ii) Not more than twelve (12) key nonconformities in the microbiological component or five (5) in the marine Biotoxin (PSP or NSP) components have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist; and

(iii) Not more than seventeen (17) critical, key and other nonconformities in total in the microbiological component or nine (9) critical, key and other nonconformities in total in the marine Biotoxin (PSP or NSP) components have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist. This number must not exceed the numerical limits established for either the critical or key criteria; and

(iv) Not more than one (1) repeat key nonconformity has been identified in the microbiological or marine Biotoxin component under evaluation in consecutive evaluations using the appropriate FDA Shellfish Laboratory Checklist.

(c) Nonconformance. When a laboratory exceeds the following criteria, it will be determined to be in nonconformance:

(i) More than three (3) critical nonconformities in the microbiological component or two (2) in the marine Biotoxin (PSP or NSP) components have been identified using the appropriate FDA Shellfish Laboratory Checklist; or

(ii) More than twelve (12) key nonconformities in the microbiological component or five (5) in the marine Biotoxin (PSP or NSP) components have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist;

(iii) More than seventeen (17) critical, key, and other nonconformities in total in the microbiological component or more than nine (9) critical, key and other nonconformities in total in the marine Biotoxin (PSP or NSP) components have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist; or

(iv) One (1) or more repeat critical or two (2) or more repeat key nonconformities have been identified in consecutive evaluations in either the microbiological or marine Biotoxin components using the appropriate FDA Shellfish Laboratory Evaluation Checklist.

(d) Time Limit on Laboratory Status.

(i) Conforming Status. A laboratory found to be in conforming status for either the microbiological or marine Biotoxin component or for both components has up to ninety (90) days to successfully correct all nonconformities noted in each component evaluated or has an approved action plan in place to deal with the nonconformities noted. After this period, the

laboratory's status will be downgraded to nonconforming if any key nonconformities remain to be successfully corrected. As a result, data being generated by the laboratory will no longer be acceptable for use in support of the NSSP for the laboratory component in question.

(e) Provisionally Conforms Status. A laboratory found to be in provisionally conforming status for either the microbiological or marine Biotoxin component or for both components has up to sixty (60) days to successfully correct all nonconformities found in each provisionally conforming component evaluated or has an approved action plan in place to deal with the nonconformities noted. After this period, the laboratory will be assigned the following status for the laboratory component(s) in question:

(i) Conforms if all the critical and key nonconformities have been successfully corrected in each provisionally conforming component evaluated; or

(ii) Nonconforming if any critical or key nonconformities remain to be successfully corrected in each provisionally conforming component evaluated. As a result, data being generated by the laboratory will no longer be acceptable for use in support of the NSSP for the laboratory component in question.

(f) Nonconformance.

(i) Upon a determination of nonconforming status in either the microbiological or marine Biotoxin component or in both components, the laboratory has up to thirty (30) days to demonstrate successful correction of all nonconformities found. After this period, if all critical and key nonconformities have been successfully corrected, the status of the laboratory will be upgraded to conforming for the laboratory component(s) in question. However, if any critical or key nonconformities remain to be successfully corrected, the status of the laboratory for the laboratory component(s) in question will continue to be nonconforming; and as a result, data being generated by the laboratory for this/these laboratory components will continue to be unacceptable for use in support of the NSSP.

(ii) When a laboratory is found to be nonconforming in either the microbiological or marine Biotoxin component or in both components for failure to successfully implement the required corrective action, or for having repeated critical or key nonconformities in consecutive evaluations, the Authority will ensure that an action plan is developed to correct the situation in an acceptable and expeditious manner or discontinue use of the laboratory to support the NSSP.

(iii) For each laboratory component evaluated, the laboratory will be reevaluated either on-site or through a thorough desk audit as determined by the FDA Shellfish Laboratory Evaluation Officer and the FDA

certified State Shellfish Laboratory Evaluation Officer if one is utilized by the State. Only a finding of fully conforming in laboratories whose data has ceased to be acceptable to the NSSP will restore its acceptability for use in the NSSP for the laboratory components in question.

NOTE: This section is being moved from Model Ordinance Chapter III. Laboratory @.01 Quality Assurance Sections D. and E.

Delete Model Ordinance Chapter III. Laboratory @.01 Quality Assurance Sections D. and E.

(2) Growing Areas

Requirements for evaluation of the shellfish growing area program element shall include at a minimum:

(a) Records audit of sanitary survey;
(b) Bacteriological standards;
(c) Growing area classification;
(d) Marine Biotoxin control;
(e) Marinas.

(3) Patrol

(a) Legal Penalties – Chapter VIII. @.01 A. (2) (c) Are there penalties in place to address illegal harvest?

Compliance Criteria: The patrol element will be deemed in compliance if laws and regulations exist that provide penalties for controlling harvest from harvest restricted areas. **[Critical]**

(b) Notification of Harvest Restricted Areas – Chapter VIII. @.01 A. (2) (d)

Is the industry notified of the boundaries of Harvest Restricted Areas? – Chapter VIII. @.01 E. (2)

Compliance Criteria: The patrol element will be deemed in compliance with this requirement when the appropriate State Authority demonstrates that the industry has been notified of the boundaries. **[Critical]**

(c) Comprehensive Listing of Harvest Restricted Areas – Chapter VIII. @ .01

Does the Patrol Agency have a comprehensive listing of Harvest Restricted areas?

Compliance Criteria: The patrol element will be deemed in compliance with this requirement when it is determined that the State Authority has a comprehensive listing of all Harvest Restricted areas. **[Critical]**

(d) Patrol Policy Document – Chapter VIII. @.01 B. (7).

(i) Does the Patrol Agency have a patrol policy document?

Compliance Criteria: The patrol element will be deemed in compliance with this requirement when the State Authority provides a patrol policy document. **[Key]**

(ii) Is the patrol policy document complete?

Compliance Criteria: The patrol element will be deemed in compliance with this requirement when it is determined that the patrol policy document includes all

items in Chapter VIII. @.01 B. (7) listed below. **[Key]**

a. Citation of the law providing the legal basis for enforcement authority

b. Citation of the laws and regulations, including penalties, which are directly related to effective control of illegal harvest activities;

(iii) The organizational structure of the unit responsible for patrol activities, including;

a. Patrol unit(s) name, address, and phone number;

b. The roster and chain of command;

c. Area assignments that support the frequencies of patrol delineated in B. (2); and

d. A listing of specific vessels, vehicles, and equipment that support the frequencies of patrol delineated in B. (2);

(iv) Summaries of training in shellfish patrol techniques;

(v) The methods used to inform officers of growing area classifications and status, and of any special activities licensed in the area;

(vi) A listing of growing areas where patrol is required;

(vii) An identification of any patrol problems;

(viii) The type and frequency of reporting by patrol personnel;

(ix) Copy of agreements with other agencies responsible for shellfish control activities; and

(x) Citations/summons for the past year. If available, this information may include:

a. The number of convictions or dismissals;

b. Fines in dollar amount;

c. Equipment or property confiscations and forfeitures;

d. License suspensions or revocations; and

e. Jail sentences; and

f. Written warnings.

(xi) Is the patrol policy document updated annually?

Compliance Criteria: The patrol element will be deemed in compliance with this requirement when the State Authority can determine that the patrol policy document is updated every calendar year. **[Key]**

(e) Officer Training – Chapter VIII. @.01 B. (6)

Has the Patrol Agency met the NSSP patrol training requirements?

Compliance Criteria: The patrol element will be deemed in compliance with this requirement when the Patrol Agency can demonstrate that all officers have met or are scheduled for the training requirements of Chapter VIII. @.01 B. (6) before assuming their patrol duties **[Key]**

(i) Basic law enforcement training, before assuming their patrol duties;

(ii) Training on shellfish control regulations within the jurisdiction of the patrol agency, before assuming independent patrol duties;

(iii) In-service training on the shellfish control regulations within the jurisdiction of the patrol agency, when the regulations change.

(f) Patrol Frequency – Chapter VIII. @.01 B. (2).

(i) Has the agency determined risk categories for all harvest restricted areas? – Chapter VIII. @.01 B. (4)?
Compliance Criteria: The patrol element will be deemed in compliance with this requirement when the State Authority assigns risk categories for each harvest restricted area and provides a listing of those categories. **[Critical]**

(ii) Does a risk management plan exist if required? – Chapter VIII. @.01. B. (3) (c) and (d)
Compliance Criteria: The patrol element will be deemed in compliance with this requirement when the Patrol Authority has conducted a Risk Management Plan for
all areas that are not patrolled at the frequency required in Chapter VIII. @.01 B. (2).
[Critical]

(iii) Has the patrol frequency requirement been met in all areas? – Chapter VIII. @.01 B. (3) (b), (c), and (d)
Compliance Criteria: The patrol element will be deemed in compliance as follows:

a. When the State Authority achieved 95-100 percent of required patrols in all harvest restricted areas the program is considered to be in conformance with NSSP patrol frequency requirements.

b. When the State Authority achieved 80 – 94 percent of required patrols in all harvest restricted areas the program is considered to be in non- conformance with NSSP patrol frequency requirements. **[Key]**

c. When the State Authority achieved <80 percent of required patrols in all harvest restricted areas the program is considered to be in major non- conformance with NSSP patrol frequency requirements. **[Critical]**

(g) Memorandum of Understanding/Agreements Chapter VIII. @.01 B. (5). If enforcement of shellfish regulations is shared with another agency(s), is there a formalized MOU/MOA with the other agency(s)?
Compliance Criteria: The patrol element will be deemed in compliance when the authority has developed a Memorandum of Understanding/Agreement with all Authorities which have delegated patrol responsibilities. **[Key]**

(h) 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 of the following designations: (a) **Conformance:** The program is in compliance with all of the criteria listed above.

a. **Conformance with Deficiencies:** The program only has minor deficiencies

associated with a key compliance item.

b. **Non-Conformance:** 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.

c. **Major Non-Conformance:** 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 any patrol deficiency to the state patrol agency;

(iii) Within thirty (30) days of the closeout meeting, the Shellfish Specialist shall provide a 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 provide a written response that indicates:

(i) The item(s) was corrected;

(ii) A correction plan has been developed with a completion date; or,

(iii) 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;

(vi) Any CRITICAL item deficiency shall be corrected within thirty (30) days of acceptance by FDA of the correction plan;

(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 State Authority in correspondence

NOTE: This section is being moved from Guidance Documents Chapter I. General Section .03 Patrol Evaluation Guidance.

Delete Guidance Document Chapter I. General Section .03 Patrol Evaluation Guidance.

(4) Plants

Requirements for evaluation of the shellfish plant inspection program element shall include at a minimum:

(a) Records audit of past shellfish processing facility inspections;

(b) Direct observation of current shellfish processing facility conditions;

(c) Information collection from the Authority and other pertinent

sources concerning shellfish processing facility inspection program.

(d) Shellfish sanitation program element criteria shall be used to evaluate consecutive full evaluations (not including follow up). If a violation of the same criteria is repeated, the program element is considered out of compliance. This program element compliance will be based on the following criteria:

(i) All dealers are required to be certified in accordance with the Guide for the Control of Molluscan Shellfish.

(ii) 95% of the certified dealers evaluated must have been inspected by the state at the frequency required by the current Guide for the Control of Molluscan Shellfish.

(iii) Where compliance schedules are required no more than 10% of the certified dealers evaluated will be without such schedules.

(iv) States must demonstrate that they have performed proper follow up for compliance schedules for 90% of dealers evaluated, and if the compliance schedules were not met, that proper administrative action was taken by the State.

(v) All critical deficiencies have been addressed by the State inspector in accordance with the Guide for the Control of Molluscan Shellfish.

(e) Plant Evaluation Criteria

(i) Legal Authority – Chapter VIII. @ .01 A. (2) (c).
The plant sanitation element will be deemed in compliance if administrative laws and regulations exist that provide the administrative authority to implement the Dealer Certification requirements listed in Chapter I @ .01 and @ 02. **[Critical]**

(ii) Initial Certification – Chapter I @ 02 B.
The Plant Sanitation Element will be deemed in compliance with this requirement when all plants are certified in accordance with criteria listed below:

a. HACCP requirements:
   i. A HACCP plan accepted by the Authority
   ii. No critical deficiencies;
   iii. Not more than 2 key deficiencies;
   iv. Not more than 2 other deficiencies.

b. Sanitation and additional Model Ordinance Requirements:
   i. No critical deficiencies;
   ii. Not more than 2 key deficiencies;
   iii. Not more than 3 other deficiencies.

(iii) Inspection frequency – Chapter I @ .02 F. and G.
The Plant Sanitation Element will be deemed in compliance with this requirement when no more than one plant inspected doesn't meet the required inspection frequency.

(iv) Compliance schedules.
The Plant Sanitation Element will be deemed in compliance with this requirement when no more than 10% of the certified dealers evaluated are found to be without schedules.

(v) Follow-Up.
The Plant Sanitation Element will be deemed in compliance with this requirement when the state demonstrates that they have performed proper follow-up

for compliance schedules for 90% of dealers evaluated and if the compliance schedules were not met that administrative action was taken.

(vi) Deficiency Follow-up.

The Plant Sanitation Element will be deemed in compliance with this requirement when the state demonstrates that all critical deficiencies have been addressed.

(vii) In-Field Plant Criteria.

The In-Field Plant Sanitation Element will be deemed in compliance with this requirement when the plant meets the following criteria:

a. Shucker/packers and repackers HACCP requirements:

i. A HACCP plan accepted by the Authority;
ii. No critical deficiencies;
iii. Not more than 4 key deficiencies;
iv. Not more than 4 other deficiencies.

b. Shucker/packers and repackers sanitation and additional Model Ordinance requirements:

i. No critical deficiencies;
ii. Not more than 4 key deficiencies;
iii. Not more than 6 other deficiencies.

c. Shellstock shippers and reshippers HACCP requirements:

i. A HACCP plan accepted by the authority;
ii. No critical deficiencies;
iii. Not more than 3 key deficiencies;
iv. Not more than 3 other deficiencies.

d. Shellstock shippers and reshippers sanitation and additional Model Ordinance requirements

i. No critical deficiencies;
ii. Not more than 3 key deficiencies;
iii. Not more than 5 other deficiencies.

(f) The following procedures will be implemented when an FDA evaluation identifies deficiencies with the above plant evaluation criteria:

(i) The overall Plant Sanitation Program element will be assigned one of the following designations:

a. Conformance: The program is in compliance with all of the criteria listed above.

b. Conformance with Deficiencies:

The program is in compliance with Procedure XV. Section F. (2) (e) (i), (ii), (iii), (iv), (v), and (vii) and has 25% or less of plants with deficiencies associated with key or other compliance items in Procedure XV. Section F. (2) (e) (vii).

c. Non-Conformance:

The program is in compliance with Procedure XV. Section F. (2) (e) (i), but, does not meet the criteria in Procedure XV. Section F. (2) (e) (ii) or (iii) or (iv) or (v) or (vi) has greater than 25% (but less than 51%) of plants with deficiencies associated with key or other compliance items Procedure XV. Section F. (2) (e) (vii).

	d. Major Non-Conformance: The program has multiple deficiencies. It is non-compliant with Procedure XV. Section F. (2) (e) (ii) or (iii) or (iv) or (v) or (vi) or 51% or greater of plants with deficiencies associated with Procedure XV. Section F. (2) (e) (vii). (3) Evaluation of shellfish laboratories: (a) Records audit of laboratory operations; (b) Direct observation of current laboratory operating conditions; (c) Information collection from the Authority and other pertinent sources concerning laboratory operations. (4) Evaluation of shellfish growing area patrol: (a) Records audit of past patrol activities; (b) Direct observation of current patrol activities; (c) Information collection from the Authority and other pertinent sources. **C.** FDA will follow the current compliance program for communication with the State agencies.
Action by 2015 Task Force III	Recommends adoption of the NSSP Evaluation Committee recommendations on Proposal 13-300.

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	Recommends adoption of the NSSP Evaluation Criteria Committee recommendations on Proposal 13-301.

Proposal Subject	Changes to Procedure for Evaluation of Shellfish Sanitation Program Elements.
Specific NSSP Guide Reference	ISSC Constitution, Bylaws & Procedures Procedure XV. Procedure for Evaluation of Shellfish Sanitation Program Elements
Text of Proposal/ Requested Action	Section 6. Requirements for evaluation of shellfish sanitation program elements shall include, at a minimum: Subdivision a. Evaluation of growing area classification; Subdivision i. Records audit of sanitary survey; Subdivision ii. Bacteriological standards; Subdivision iii. Growing area classification; Subdivision iv. Marine Biotoxin control; Subdivision v. Marinas. Subdivision b. Evaluation of shellfish plant inspection program; Subdivision i. Records audit of past shellfish processing facility inspections; Subdivision ii. Direct observation of current shellfish processing facility conditions; Subdivision iii. Information collection from the Authority and other pertinent sources concerning shellfish processing facility inspection program. Subdivision iv. Shellfish sanitation program element criteria shall be used to evaluate consecutive full evaluations (not including follow up). If a violation of the same criteria is repeated, the program element is considered out of compliance. This program element compliance will be based on the following criteria: Subdivision (a) All dealers are required to be certified in accordance with the Guide for the Control of Molluscan Shellfish. Subdivision (b) 95% of the certified dealers evaluated must have been inspected by the state at the frequency required by the current Guide for the Control of Molluscan Shellfish. Subdivision (c) Where compliance schedules are required no more than 10% of the certified dealers evaluated will be without such schedules. Subdivision (d) States must demonstrate that they have performed proper follow up for compliance schedules for 90% of dealers evaluated,

			and if the compliance schedules were not met, that proper administrative action was taken by the State.
		Subdivision (e)	All critical deficiencies have been addressed by the State inspector in accordance with the Guide for the Control of Molluscan Shellfish.
	Subdivision v.	Plant Evaluation Criteria	
		Subdivision (a)	Legal Authority – Chapter VIII. @ .01 A. (2) (c). The plant sanitation element will be deemed in compliance if administrative laws and regulations exist that provide the administrative authority to implement the Dealer Certification requirements listed in Chapter I @ .01 and @ .02. [Critical]
		Subdivision (b)	Initial Certification – Chapter I @ .02 B. The Plant Sanitation Element will be deemed in compliance with this requirement when all plants are certified in accordance with criteria listed below: HACCP requirements: (i) A HACCP plan accepted by the Authority (ii) No critical deficiencies; (iii) Not more than 2 key deficiencies; (iv) Not more than 2 other deficiencies. Sanitation and additional Model Ordinance Requirements: (i) No critical deficiencies; (ii) Not more than 2 key deficiencies;

			(iii) Not more than 3 other deficiencies.
		Subdivision (c)	Inspection frequency – Chapter I @ 02 F and G. The Plant Sanitation Element will be deemed in compliance with this requirement when no more than one plant inspected doesn't meet the required inspection frequency.
		Subdivision (d)	Compliance schedules. The Plant Sanitation Element will be deemed in compliance with this requirement when no more than 10% of the certified dealers evaluated are found to be without schedules.
		Subdivision (e)	Follow-Up. The Plant Sanitation Element will be deemed in compliance with this requirement when the state demonstrates that they have performed proper follow-up for compliance schedules for 90% of dealers evaluated and if the compliance schedules were not met that administrative action was taken.
		Subdivision (f)	Deficiency Follow-up. The Plant Sanitation Element will be deemed in compliance with this requirement when the state demonstrates that all critical deficiencies have been addressed.
		Subdivision (g)	In-Field Plant Criteria. The in-field Plant Sanitation Element will be deemed in compliance with this requirement when the plant meets the following criteria: (i) Shucker/packers and repackers HACCP

		requirements: a. A HACCP plan accepted by the Authority; b. No critical deficiencies; c. Not more than 4 key deficiencies; d. Not more than 4 other deficiencies. Sanitation and additional Model Ordinance Requirements a. No critical deficiencies except when the State demonstrates that all critical deficiencies have been addressed prior to the completion of the inspection of that facility; b. Not more than 4 key deficiencies; ~~c. Not more than 4 other deficiencies.~~
	(ii)	Shellstock shippers and reshippers HACCP requirements: a. A HACCP plan accepted by the authority; b. No critical deficiencies; c. Not more than 3 key deficiencies; d. Not more than

	3 other deficiencies. Sanitation and additional Model Ordinance Requirements a. No critical deficiencies except when the State demonstrates that all critical deficiencies have been addressed prior to the completion of the inspection of that facility:; b. Not more than 3 key deficiencies; ~~c. Not more than 5 other deficiencies.~~ Subdivision vi. The following procedures will be implemented when an FDA evaluation identifies deficiencies with the above plant evaluation criteria. Subdivision (a) The overall Plant Sanitation Program element will be assigned one of the following designations: (i) Conformance: The program is in compliance with all of the criteria listed above. (ii) Conformance with Deficiencies: The program is in compliance with Procedure XV. Section 6. Subdivision (b) Subdivision v. (a), (b), (c), (d), (e), and (f) and has 25% or less of plants with

		deficiencies associated with key ~~or other~~ compliance items in Procedure XV. Section 6. Subdivision (b) Subdivision (v) (g). (iii) Non-Conformance: The program is in compliance with Procedure XV. Section 6. Subdivision (b) Subdivision (v) (a), but, does not meet the criteria in Procedure XV. Section 6. Subdivision (b) Subdivision (v) Subdivision (b) or (c) or (d) or (e) or (f) has greater than 25% (but less than 51%) of plants with deficiencies associated with key ~~or other~~ compliance items Procedure XV. Section 6. Subdivision (b) Subdivision (v) (g). (iv) Major Non-Conformance: The program has multiple deficiencies. It is non-compliant with Procedure XV. Section 6. Subdivision (b) Subdivision (v) Subdivision (b) or (c) or (d) or (e) or (f) or 51% or greater of plants with deficiencies associated with Procedure XV. Section 6. Subdivision (b) Subdivision (v) (g).

	FDA will follow the current compliance program for communication with the State agencies. Subdivision c. Evaluation of shellfish laboratories; Subdivision i. Records audit of laboratory operations; Subdivision ii. Direct observation of current laboratory operating conditions; Subdivision iii. Information collection from the Authority and other pertinent sources concerning laboratory operations. Subdivision d. Evaluation of shellfish growing area patrol; Subdivision i. Records audit of past patrol activities; Subdivision ii. Direct observation of current patrol activities; Subdivision iii. Information collection from the Authority and other pertinent sources.
Public Health Significance	Current Infield Plant Criteria automatically "fails" a plant even if the critical deficiency is address and corrected. This puts a plant in non-compliance but still operating which is inconsistent with the evaluation of deficiency follow-up in Subdivision v (f). States are deemed in compliance when evaluating deficiency follow-up when critical deficiencies have been addressed. During a plant inspection, the professional discretion of the inspector is used to determine the severity of the critical deficiency. In some cases a critical deficiency that is addressed and corrected at the time of inspection allows the plant to legally continue to process and sell product. Critical deficiencies that are addressed and corrected at the time of the infield Plant Sanitation Element should be consistent with this. Deficiencies with a criticality code of "Other" vary widely in public health significance and in many cases may be the result of normal wear or use during the operating season. This is especially true with items in Item 17; Plants and Grounds, and Item 21; Equipment Condition, Cleaning, Maintenance and Construction of Non-Food Contact Surfaces. Many of these "other" deficiencies are addressed prior to re-certification for the following season.
Cost Information	No cost to states or industry.
Action by 2013 Task Force III	Recommended referral of Proposal 13-308 to the NSSP Evaluation Criteria Committee
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force III on Proposal 13-308.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-308.
Action by 2015 NSSP Evaluation Criteria Committee	Recommended adoption of Proposal 12-308 as amended. Section 6. Requirements for evaluation of shellfish sanitation program elements shall include, at a minimum: Subdivision a. Evaluation of growing area classification;

		Subdivision i.	Records audit of sanitary survey;	
		Subdivision ii.	Bacteriological standards;	
		Subdivision iii.	Growing area classification;	
		Subdivision iv.	Marine Biotoxin control;	
		Subdivision v.	Marinas.	
	Subdivision b.	Evaluation of shellfish plant inspection program;		
		Subdivision i.	Records audit of past shellfish processing facility inspections;	
		Subdivision ii.	Direct observation of current shellfish processing facility conditions;	
		Subdivision iii.	Information collection from the Authority and other pertinent sources concerning shellfish processing facility inspection program.	
		Subdivision iv.	Shellfish sanitation program element criteria shall be used to evaluate consecutive full evaluations (not including follow up). If a violation of the same criteria is repeated, the program element is considered out of compliance. This program element compliance will be based on the following criteria:	
			Subdivision (a)	All dealers are required to be certified in accordance with the Guide for the Control of Molluscan Shellfish.
			Subdivision (b)	95% of the certified dealers evaluated must have been inspected by the state at the frequency required by the current Guide for the Control of Molluscan Shellfish.
			Subdivision (c)	Where compliance schedules are required no more than 10% of the certified dealers evaluated will be without such schedules.
			Subdivision (d)	States must demonstrate that they have performed proper follow up for compliance schedules for 90% of dealers evaluated, and if the compliance schedules were not met, that proper administrative action was taken by the State.
			Subdivision (e)	All critical deficiencies have been addressed by

			the State inspector in accordance with the Guide for the Control of Molluscan Shellfish.
	Subdivision v.	Plant Evaluation Criteria	
		Subdivision (a)	Legal Authority – Chapter VIII. @ .01 A. (2) (c). The plant sanitation element will be deemed in compliance if administrative laws and regulations exist that provide the administrative authority to implement the Dealer Certification requirements listed in Chapter I @ .01 and @ .02. [Critical]
		Subdivision (b)	Initial Certification – Chapter I @ .02 B. The Plant Sanitation Element will be deemed in compliance with this requirement when all plants are certified in accordance with criteria listed below: HACCP requirements: (i) A HACCP plan accepted by the Authority (ii) No critical deficiencies; (iii) Not more than 2 key deficiencies; (iv) Not more than 2 other deficiencies. Sanitation and additional Model Ordinance Requirements: (i) No critical deficiencies; (ii) Not more than 2 key deficiencies; (iii) Not more than 3 other deficiencies.
		Subdivision (c)	Inspection frequency – Chapter I @ 02 F and G. The Plant Sanitation Element will be deemed in compliance with this

			requirement when no more than one plant inspected doesn't meet the required inspection frequency.
		Subdivision (d)	Compliance schedules. The Plant Sanitation Element will be deemed in compliance with this requirement when no more than 10% of the certified dealers evaluated are found to be without schedules.
		Subdivision (e)	Follow-Up. The Plant Sanitation Element will be deemed in compliance with this requirement when the state demonstrates that they have performed proper follow-up for compliance schedules for 90% of dealers evaluated and if the compliance schedules were not met that administrative action was taken.
		Subdivision (f)	Deficiency Follow-up. The Plant Sanitation Element will be deemed in compliance with this requirement when the state demonstrates that all critical deficiencies have been addressed.
		Subdivision (g)	In-Field Plant Criteria. ~~The in-field Plant Sanitation Element will be deemed in compliance with this requirement when the plant meets the following criteria~~Certified Plants will be evaluated to determine compliance with the criteria listed below.~~:~~ (i) Shucker/packers and repackers HACCP requirements: a. A HACCP

	plan accepted by the Authority; b. No critical deficiencies; c. Not more than 4 key deficiencies; d. ~~Not more than 4 other deficiencies.~~ Sanitation and additional Model Ordinance Requirements a. No critical deficiencies ; b. Not more than 4 key deficiencies; ~~c. Not more than 4 other deficiencies.~~ (ii) Shellstock shippers and reshippers HACCP requirements: a. A HACCP plan accepted by the authority; b. No critical deficiencies; c. Not more than 3 key deficiencies; d. ~~Not more than 3 other deficiencies.~~ Sanitation and additional Model Ordinance Requirements a. No critical deficiencies-; b. Not more than 3 key deficiencies; ~~c. Not more than 5 other deficiencies.~~

	Subdivision vi. ~~The following procedures will be implemented when an FDA evaluation identifies deficiencies with the above plant evaluation criteria~~ ~~Subdivision (a)~~ The overall Plant Sanitation Program element will be assigned one of the following conformance designations~~:~~ based on compliance with the criteria listed in Subdivision v. (i) Conformance: The program is in compliance with all of the criteria listed above and all plants evaluated are in compliance with Procedure XV Section 6 Subdivision (b) Subdivision (v) (g). (ii) Conformance with Deficiencies: The program is in compliance with Procedure XV. Section 6. Subdivision (b) Subdivision v. (a), (b), (c), (d), (e), and (f) and has 25% or less of plants with deficiencies associated with ~~key or other compliance items in~~ Procedure XV. Section 6. Subdivision (b) Subdivision (v) (g). (iii) Non-Conformance: The program is in compliance with Procedure XV. Section 6. Subdivision (b) Subdivision (v) (a), but, does not meet the criteria in Procedure XV. Section 6. Subdivision (b) Subdivision (v) Sub-

	division (b) or (c) or (d) or (e) or (f) has greater than 25% (but less than 51%) of plants with deficiencies associated with ~~key or other compliance items~~ Procedure XV. Section 6. Subdivision (b) Subdivision (v) (g). (iv) Major Non-Conformance: The program has multiple deficiencies. It is non-compliant with Procedure XV. Section 6. Subdivision (b) Subdivision (v) Sub-division (b) or (c) or (d) or (e) or (f) or 51% or greater of plants with deficiencies associated with Procedure XV. Section 6. Subdivision (b) Subdivision (v) (g). Subdivision (vii) FDA will follow the current compliance program for communication with the State agencies. NOTE: All deficiencies observed by FDA while conducting the in-plant inspection portion of the evaluation will be documented and included in the compliance determination outlined in Section 6 Subdivision (b) Subdivision (v) (g).
Action by 2015 Task Force III	Recommends adoption of NSSP Evaluation Criteria Committee recommendations on Proposal 13-308.

Proposal Subject	Name of Organization
Specific NSSP Guide Reference	ISSC Constitution Bylaws and Procedure Article I. Organization
Text of Proposal/ Requested Action	**ARTICLE I. ORGANIZATION** Section 1. The name of the organization shall be the "Interstate Shellfish ~~Sanitation Conference~~Safety Congress", hereinafter referred to as the ~~Conference~~ Congress. Section 2. The ~~Conference~~ Congress shall be directed by and shall be under the control of the various states, federal agencies and shellfish industry that join together to form the ~~Conference~~Congress. The word "Conference" shall be changed to "Congress" throughout the ISSC Constitution Bylaws and Procedures
Public Health Significance	The present name is misleading regarding the primary function of SSC which is to establish guidelines to foster and improve the sanitation of shellfish in the United States. The change would more clearly define the organization as a deliberative body and would encourage more participation by stakeholders.
Cost Information	
Action by 2015 Task Force III	Recommends no action on Proposal 15-300. Rationale: FDA indicated a name change would require the development of a new Memorandum of Understanding which would require a great deal of time and effort for both FDA and ISSC. Additionally, the present Agency requirements for a MOU would most likely result in a very different document.

Proposal Subject	*Vibrio Vulnificus* Illness Review Committee and Laboratory Committee
Specific NSSP Guide Reference	ISSC Constitution, Bylaws, & Procedures Article IV. Executive Board, Officers, Committees
Text of Proposal/ Requested Action	Section 10. The Board may appoint committees from industry, educational institutions, research fields, or any other areas as needed to report to the Board and advise the Conference on proposals under consideration. Committee appointments will be made from the Conference membership by the Executive Board Chairperson. The following committees shall be designated as standing committees and shall convene as needed or as directed by the Executive Board or Chairperson of the Conference: • Education; • Foreign Relations; • Model Ordinance Effectiveness Review; • Patrol; • Proposal Review; • Research Guidance; • Resolutions; • Shellfish Restoration; ~~and~~ • *Vibrio Management*; • *Vibrio Vulnificus* Illness Review; and • Laboratory The Vice-Chairperson of the Conference shall assist the Executive Director in encouraging development of committee work plans and completion of subcommittee assignments prior to convention of the Annual Meeting. Section 16. The Executive Board Chairperson shall appoint a Laboratory Committee. The Committee will review and make recommendations that are presented to the ISSC for approval. Additionally, the Committee will be requested to provide recommendations regarding laboratory related matters. "Laboratory Methods Review Committee" shall be changed to "Laboratory Committee" throughout the ISSC Constitution, Bylaws, and Procedures and the NSSP Guide for the Control of Molluscan Shellfish.
Public Health Significance	These committees have charges that are stated in the ISSC Constitution, Bylaws, and Procedures and should be standing committees.
Cost Information	
Action by 2015 Task Force III	Recommends adoption of Proposal 15-301 as submitted.

Proposal Subject	Study Design Guidance Committee
Specific NSSP Guide Reference	ISSC Constitution, Bylaws, & Procedures
Text of Proposal/ Requested Action	ARTICLE IV. EXECUTIVE BOARD, OFFICERS, COMMITTEES Section 10. The Board may appoint committees from industry, educational institutions, research fields, or any other areas as needed to report to the Board and advise the Conference on proposals under consideration. Committee appointments will be made from the Conference membership by the Executive Board Chairperson. The following committees shall be designated as standing committees and shall convene as needed or as directed by the Executive Board or Chairperson of the Conference: • Education; • Foreign Relations; • Model Ordinance Effectiveness Review; • Patrol; • Proposal Review; • Research Guidance; • Resolutions; • Shellfish Restoration; ~~and~~ • *Vibrio* Management~~.~~; and • Study Design Guidance. The Vice-Chairperson of the Conference shall assist the Executive Director in encouraging development of committee work plans and completion of subcommittee assignments prior to convention of the Annual Meeting. **Section 16.** The Executive Board shall appoint a Study Design Guidance Committee. The Committee will develop guidance to assist States and the industry in establishing target levels and developing protocols for studies to determine the effectiveness of post-harvest processes.
Public Health Significance	Presently the NSSP requires that States conduct studies to (1) demonstrate the effectiveness of post-harvest processes and practices intended to reduce pathogen levels; or (2) to ensure that processes and practices do not result in unintended growth of pathogens. The NSSP offers no guidance for conducting these studies nor does the NSSP provide recommended pathogen target levels. This committee would serve as technical expertise for developing guidance.
Cost Information	
Action by 2015 Task Force III	Recommends adoption of Proposal 15-302 as submitted.

Proposal Subject	Proposal Submission Procedure
Specific NSSP Guide Reference	ISSC Constitution, Bylaws, and Procedures Article XIII. Procedure for the Submission of Proposals
Text of Proposal/ Requested Action	Section 3. Proposals submitted by any Conference participants requiring Conference action are to be referred to the Executive Director for assignment to the appropriate Task Force. Proposals that lack required information will be deemed incomplete and returned to the submitter. The Executive Director will consult with the Proposal Review Committee before declaring any problem or proposal invalid. (Moved from Article XIII. Section 10.) ~~Section 10. The Executive Director will consult with the Proposal Review Committee before declaring any problem or proposal invalid.~~
Public Health Significance	The purpose of this change is to encourage submitters to review and edit proposals for accuracy.
Cost Information	
Action by 2015 Task Force III	Recommends adoption of Proposal 15-303 as amended. Section 3. Proposals submitted by any Conference participants requiring Conference action are to be referred to the Executive Director for assignment to the appropriate Task Force. Proposals that lack required information will be deemed incomplete and returned to the submitter ~~-~~for completion. The Executive Director will consult with the Proposal Review Committee before declaring any problem or proposal invalid. (Moved from Article XIII. Section 10.)

Proposal Subject	Proposal Submission
Specific NSSP Guide Reference	ISSC Constitution, Bylaws, and Procedures Article XIII. Procedure for the Submission of Proposals
Text of Proposal/ Requested Action	Add a new Section 8. To Article XIII. as follows: Section 8. Proposals that are deemed technical in nature may be submitted to a committee for review. The committee will provide a recommendation to the appropriate Task Force(s).
Public Health Significance	Historically, technical, complex, and lengthy proposals have been referred to committee because of the difficulty of fully debating these types of proposals in Task Force. This change would allow a more thorough and meaningful review of the proposal.
Cost Information	
Action by 2015 Task Force III	Recommends adoption of Proposal 15-304 as submitted.

Proposal Subject	Unresolved Issue Procedure
Specific NSSP Guide Reference	ISSC Constitution, Bylaws, and Procedures Procedure IX. Procedures for Handling Complaints and Challenges Regarding the Adequacy of Certification Controls
Text of Proposal/ Requested Action	Section 2. When an FDA field inspection or an overall program evaluation indicates a state program is not meeting the minimum requirements of the NSSP Model Ordinance, the following actions shall be taken: Subdivision a. FDA shall provide written notification to the state shellfish control authority of the item(s) requiring action with supporting documentation and recommendations as appropriate. Subdivision b. The state shall investigate the item(s) and provide a written response within thirty (30) days that it has been corrected, that a corrective action plan has been developed and will be implemented within a specific time frame, or that it disagrees with FDA's finding. The state shall provide supporting documentation regarding any disagreements. FDA shall review the materials submitted by the state and respond to the state within thirty (30) days. Subdivision c. When a state does not disagree with FDA findings, but does disagree with an FDA report, the state shall provide written notification to FDA of the areas of disagreement with supporting documentation and recommendations as appropriate. FDA shall review the information submitted and provide a written response within thirty (30) days that it agrees and the report has been corrected, that it agrees but the report cannot be corrected, or that it disagrees with the state. FDA shall provide supporting documentation regarding any inability to correct a report or any disagreement. The state shall review the materials submitted by FDA and respond to FDA within thirty (30) days. Subdivision d. If corrective action is taken by the state or by the FDA or a mutually agreed upon action plan is developed and implemented, no action by the Conference will be necessary. Subdivision e. If FDA considers the action (or lack of action) taken by the state to be inadequate to resolve the item(s), FDA shall notify the ISSC Executive Director of~~or if the state disagrees with FDA's findings or response, it shall be considered~~ an unresolved issue. If the State disagrees with FDA's findings or response, the State may pursue one of the following actions: Subdivision i. The State may request consultation from the Consultation Subcommittee of the ISSC Unresolved Issues Committee. The purpose of this consultation will allow the State the

	opportunity to seek guidance from the Consultation Subcommittee regarding program requirements and FDA findings; or Subdivision ii. The State shall notify the ISSC Executive Director of an unresolved issue. Subdivision f. Upon notification of an unresolved issue, ~~FDA or the state shall notify~~ the ISSC Executive Director ~~who~~ shall consult with both the state and FDA and prepare recommendations, which will be submitted to the Board with the unresolved issue. The referred unresolved issue shall be handled according to Procedure IX., Section 3. FDA may also take any actions it considers appropriate to deal with any adulterated product.
Public Health Significance	Procedure IX. of the ISSC Constitution, Bylaws, and Procedures does not offer a simple remedy for a State to disagree with an FDA finding in a State evaluation. The proposed language would offer such a remedy.
Cost Information	
Action by 2015 Task Force III	Recommends adoption of Proposal 15-305 as submitted.

Proposal Subject	Critical Deficiencies
Specific NSSP Guide Reference	ISSC Constitution Bylaws & Procedures Procedure XV. Section 6. Subdivision vi.
Text of Proposal/ Requested Action	Subdivision vi. The following procedures will be implemented when an FDA evaluation identifies deficiencies with the above plant evaluation criteria Subdivision (a) The overall Plant Sanitation Program element will be assigned one of the following designations: (i) Conformance: The program is in compliance with all of the criteria listed above. (ii) Conformance with Deficiencies: The program is in compliance with Procedure XV. Section 6. Subdivision (b) Subdivision v. (a), (b), (c), (d), (e), and (f) and has 25% or less of plants with deficiencies associated with critical, key or other compliance items in {Procedure XV. Section 6. Subdivision (b) Subdivision (v) (g)}. (iii) Non-Conformance: The program is in compliance with Procedure XV. Section 6. Subdivision (b) Sub-division (v) (a), but, does not meet the criteria in Procedure XV. Section 6. Subdivision (b) Subdivision (v) Sub-division (b) or (c) or (d) or (e) or (f) has greater than 25% (but less than 51%) of plants with deficiencies associated with critical, key or other compliance items {Procedure XV. Section 6. Subdivision (b) Subdivision (v) (g)}. (iv) Major Non-Conformance: The program has multiple deficiencies. It is non-compliant with Procedure XV. Section 6. Subdivision (b) Subdivision (v) Subdivision (b) or (c) or (d) or (e) or (f) or 51% or greater of plants with ~~deficiencies associated with Procedure XV~~ critical, key or other compliance items {Procedure XV. Section 6. Subdivision (b) Subdivision (v) (g)}. FDA will follow the current compliance program for communication with the State agencies.

Public Health Significance	Presently Procedure XV. is unclear regarding how observed criticals identified during the in-plant evaluation will be used in assigning overall plant sanitation program designations. The in-field plant criteria in Section 6. Subdivision g. includes critical deficiencies; however, Subdivision vi. does not include any reference to critical deficiencies.
Cost Information	
Action by 2015 Task Force III	Recommends no action on Proposal 15-306. Rationale: Proposal is resolved by action on Proposal 13-308.

Proposal Subject	ISSC Annual Meeting
Specific NSSP Guide Reference	ISSC Constitution, Bylaws, and Procedures Article XI. Rules of Annual Conference Meetings
Text of Proposal/ Requested Action	ARTICLE XI. Rules of Biennial ~~Annual~~ Conference Meetings Except for special meetings, as provided for in Article V., Section 5. of this Constitution, the Conference will convene a meeting biennially during odd numbered years ~~annually~~ and will rotate it among the different Regions of the country. If adopted, all other references to Annual in the ISSC Constitution, Bylaws, and Procedures will be changed to Biennial.
Public Health Significance	The Conference has functioned well with biennial meetings since 1999. The costs and time commitment for meeting do not justify meeting annually. Two (2) concerns not addressed during deliberations at the 2013 meeting: 1. FDA may not be able to provide a small conference grant every year; and 2. The new revisions of the NSSP Guide will most likely not be available for proposal submission.
Cost Information	
Action by 2015 Task Force III	Recommended adoption of Proposal 15-307L as submitted.