

Proposal Subject:	Shellfish Sanitation Plant Element Evaluation Criteria
Specific NSSP Guide Reference:	ISSC Constitution, Bylaws, and Procedures Procedure XV. Procedure for Evaluation of Shellfish Sanitation Elements Section 6. Subdivision b. Subdivision iv. (NEW)
Text of Proposal/ Requested Action	Add new Subdivision iv. as follows: <u>iv. Shellfish sanitation program element compliance will be based on the following criteria:</u> <u>(a) All dealers are required to be certified in accordance with the Guide for the Control of Molluscan Shellfish.</u> <u>(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.</u> <u>(c) Where compliance schedules are required no more than 10% of the certified dealers evaluated will be without such schedules.</u> <u>(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.</u> <u>(e) All critical deficiencies have been addressed by the state inspector in accordance with the Guide for the Control of Molluscan Shellfish.</u>
Public Health Significance:	These criteria will be helpful to both the USFDA and States in the state evaluation process.
Cost Information (if available):	No costs associated with this program addition.
Action by 2005 NSSP Evaluation Criteria Committee	Recommended adoption of Proposal 05-310 as amended by the NSSP Evaluation Criteria Committee, the submitter. <u>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 shellfish sanitation program element compliance will be based on the following criteria:</u> (a) All dealers are required to be certified in accordance with the Guide for the Control of Molluscan Shellfish. (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. (c) Where compliance schedules are required no more than 10% of the certified dealers evaluated will be without such schedules. (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.

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

Action by 2005 Task Force III Recommended adoption of the recommendations in the NSSP Evaluation Criteria Committee report with an effective date of October 1, 2004.

Action by 2005 General Assembly Adopted recommendation of 2005 Task Force III.

Action by USFDA FDA concurs with adoption of the five evaluation criteria for identifying state programs whose plant processing element is seriously out of compliance with the NSSP. FDA Recommended that the ISSC continue with efforts to develop additional criteria that may be used to define when a state program element is sufficiently out of compliance as to pose a public health risk. In particular, criteria are needed that focus on the in-field component of the FDA evaluation process, i.e. criteria to be used during the plant visit component of FDA’s evaluation process. The criteria adopted by the 2005 Conference are more specific to the administrative aspects of a state’s plant sanitation element. These criteria are examined as part of the central file review of a state program evaluation. Criteria that focus on the in-field component of the evaluation are also needed. New criteria should consider the distinction between sporadic plant deficiencies and those of an egregious and chronic nature that are indicative of systemic plant sanitation and safety problem.

Action by 2007 NSSP Evaluation Criteria Committee The NSSP Evaluation Criteria Committee recommended that the following criteria be used by the USFDA in evaluating the state Plant Sanitation Element. FDA should provide a report to the ISSC regarding the effectiveness of the criteria.

ISSC Plant Evaluation Guidance

I. Plant Evaluation Criteria

1. 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]
2. 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.

3. 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.
4. 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.
5. 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.
6. 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.
7. 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
 - (i) HACCP requirements:
 - (a) A HACCP plan accepted by the Authority; and
 - (b) No critical deficiencies; and
 - (c) Not more than 4 key deficiencies; or
 - (d) Not more than 4 other deficiencies.
 - (ii) Sanitation and additional Model Ordinance Requirements
 - (a) No critical deficiencies; and
 - (b) Not more than 4 key deficiencies; or
 - (c) Not more than 6 other deficiencies.
 - b. Shellstock shippers and reshippers
 - (i) HACCP requirements:
 - (a) A HACCP plan accepted by the Authority; and
 - (b) No critical deficiencies; and
 - (c) Not more than 3 key deficiencies; or
 - (d) Not more than 3 other deficiencies.
 - (ii) Sanitation and additional Model Ordinance Requirements
 - (a) No critical deficiencies; and
 - (b) Not more than 3 key deficiencies; or
 - (c) Not more than 5 other deficiencies.

II. The following procedures will be implemented when an FDA evaluation identifies deficiencies with the above plant evaluation criteria.

1. 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 I.1., I.2., I.3., I.4., I.5., I.6 and has less than 25% of plants with deficiencies associated with key or other compliance items in I.7.
 - c. Non-Conformance: The program is in compliance with I.1., but, does not meet the criteria in I.2., or I.3 or I.4 or I.5 or I.6 has greater than 25% (but less than 51%) of plants with deficiencies associated with key or other compliance items in I.7.
 - d. Major Non-Conformance: The program has multiple deficiencies. It is noncompliant with I.1, or 2 or more of I.2 or I.3 or I.4 or I.5 or I.6 or 51% or greater of plants with deficiencies associated with I.7.
2. FDA will follow the current compliance program for communication with the state agencies.

**Action by 2007
Task Force III**

Recommended adoption of the NSSP Evaluation Criteria Committee recommendation on Proposal 05-310. The guidance documents will be incorporated into the NSSP Guide and will be referenced in the ISSC Constitution, By Laws and Procedures. The Task Force recommended these criteria become effective October 1, 2007.

**Action by 2007
General Assembly**

Approved referral of Proposal 05-310 to the NSSP Evaluation Criteria Committee with the following recommendations:

1. That FDA use the criteria in this proposal as a two-year pilot program beginning October 2007; and
2. That FDA provide in-plant compliance rates for the states evaluated for the past two years and report those compliance rates to the first 2008 ISSC Executive Board meeting.

**Action by
USFDA**

December 20, 2007

Concurred with Conference action with the following comments and recommendations for ISSC consideration.

On December 3, 2007, FDA forwarded correspondence to the ISSC Executive Office regarding the plant sanitation evaluation criteria adopted in Proposal 05-310. That correspondence, which asked for clarification regarding the use of the plant evaluation criteria during FDA's 2008 state program evaluation process, is provided below.

At the 2007 ISSC meeting Task Force II recommended adoption of Proposal 05-310 which set forth criteria developed by the NSSP Evaluation Criteria Committee for evaluating a state's Plant Sanitation Element with an effective date for use by FDA of October 1, 2007. However, the Voting Delegates, at the final General Assembly meeting, voted to refer Proposal 05-310 back to the NSSP Evaluation Criteria Committee with the following recommendations.

1. That FDA use the criteria as a two year pilot program beginning October 1, 2007; and
2. That FDA provide in-plant compliance rates for the states evaluated for the past two years and report those compliance rates to the first 2008 ISSC Executive Board meeting.

There is some confusion regarding the intent of the above ISSC action and how FDA should use the evaluation criteria during the recommended pilot. It was FDA's understanding that during the two year pilot the criteria would be used for purposes of determining the level of compliance of a state's Plant Sanitation Element and for recommending appropriate corrective/regulatory action. However, the State of Florida has indicated that this was not the intent of action taken by the 2007 ISSC. Florida suggests that the intent was for FDA to **not** use the evaluation criteria during the pilot for purposes of determining a state's level of compliance, but rather, for FDA to use the criteria to examine the appropriateness of the criteria by measuring the level of compliance. If this was the intended purpose then FDA does not see the need to conduct both a two year pilot and provide in-plant compliance rates for the states evaluated for the past two years and report those compliance rates to the first 2008 ISSC Executive Board meeting. By implementing #1 only, the ISSC can obtain the data necessary to examine the ability of the criteria and the associated levels of compliance (Conformance, Conformance with Deficiencies, etc.) to accurately reflect how well a state's program conforms with NSSP requirements without expending limited FDA and state resources to conduct a two year retrospective review.

The FDA further suggests that the previous plant evaluation criteria be used until the Conference (Voting Delegates or Executive Board) can give approval to use Proposal 05-310 criteria for compliance purposes.

**Action by 2011
NSSP Evaluation
Criteria
Committee**

The NSSP Evaluation Criteria Committee recommended that Section II. (1.)(b.) of the Plant Evaluation Criteria be amended as follows:

- b. Conformance with Deficiencies: The program is in compliance with I.1., I.2., I.3., I.4., I.5., I.6 and has ~~less than~~ 25% or less of plants with deficiencies associated with key or other compliance items in I.7.

The NSSP Evaluation Criteria Committee also recommended that Section I. (7.) of the Plant Evaluation Criteria be amended as follows:

7. In-Field Plant Criteria

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

- a. Shucker/packers and repackers
 - (i) HACCP requirements:
 - (a) A HACCP plan accepted by the Authority; ~~and~~
 - (b) No critical deficiencies; ~~and~~
 - (c) Not more than 4 key deficiencies; ~~or~~
 - (d) Not more than 4 other deficiencies.
 - (ii) Sanitation and additional Model Ordinance Requirements
 - (a) No critical deficiencies; ~~and~~
 - (b) Not more than 4 key deficiencies; ~~or~~
 - (c) Not more than 6 other deficiencies.
- b. Shellstock shippers and reshippers
 - (i) HACCP requirements:
 - (a) A HACCP plan accepted by the Authority; ~~and~~
 - (b) No critical deficiencies; ~~and~~

- (c) Not more than 3 key deficiencies; ~~or~~
- (d) Not more than 3 other deficiencies.
- (ii) Sanitation and additional Model Ordinance Requirements
 - (a) No critical deficiencies; ~~and~~
 - (b) Not more than 3 key deficiencies; ~~or~~
 - (c) Not more than 5 other deficiencies.

Action by 2011 Task Force III Recommended adoption of Proposal 05-310 as amended by the Nssp Evaluation Criteria Committee.

Action by 2011 General Assembly Adopted the recommendation of Task Force III on Proposal 05-310.

Action by FDA February 26, 2012 Concurred with Conference action on Proposal 05-310.