Plant & Shipping
Interim In-Field Evaluation Criteria

Keith Skiles, ISSC Executive Director

Plant & Shipping In-Field Evaluation Criteria

2019 ISSC Biennial Meeting Proposals

- 19-305, 19-311, 19-312 ISSC action: Referred to committee
- 19-310 ISSC Action (1) Refer to NSSP Evaluation Committee requesting that the Committee immediately address concerns associated with In-Field Plant Criteria and the development of recommendations for Executive Board interim action at the 2020 Spring Board meeting.
- 19-310 ISSC Action (2) Suspension of In-Field Plant Criteria until the Executive Board provides modified criteria

Plant & Shipping In-Field Evaluation Criteria

- The ISSC Executive Board adopted interim criteria recommended by the Plant Evaluation Committee on July 15, 2020.
- The Committee is expected to consider the Plant Evaluation requirements (Chapter I, @03.B.4) as a whole, and develop a proposal for consideration at the 2021 Biennial Meeting.

Plant & Shipping In-Field Evaluation Criteria
What Didn't Change:

Individual Plants Evaluated Based on (@03.B.4.e.vii):

HACCP Requirements:

- HACCP Plan
- No critical deficiencies
- Not more than 4 (SP/RP), or 3 (SS/RS) key deficiencies

Sanitation & Additional M.O. Requirements:

- No critical deficiencies
- Not more than 4 (SP/RP), or 3 (SS/RS) key deficiencies

Plant & Shipping In-Field Evaluation Criteria *What (almost) Didn't Change*:

Four Conformance Designations:

- Conformance
- ~~Conformance with Deficiencies~~ **Provisional Conformance**
- Nonconformance
- Major Nonconformance

Plant & Shipping Evaluation Criteria
Existing Criteria (in-field portion suspended)

Conformance

- Meets all criteria in @03.B.4.e, including in-field criteria in @03.B.4.e.vii

Conformance with Deficiencies

- Meets all criteria in @03.B.4.e.i through vi
- 25% or less plants with deficiencies associated with @03.B.4.e.vii

Nonconformance

- Meets criteria in @03.B.4.e.vi
- Does not meet all criteria in @03.B.4 e.ii – e.vi, or
- Has 26% - 50% of plants with deficiencies associated with @03.B.4.e.vii

Major Nonconformance

- Does not meet @03.B.4.e.i, or
- Has two or more deficiencies in @03.B.4.e.v.ii – e.vi, or
- Has >50% of plants with deficiencies associated with @03.B.4.e.vii

Plant & Shipping In-Field Evaluation Criteria
New Interim Criteria

Conformance
- Meets all criteria in @03.B.4.e.i through e.vi, and
- Has 25% or fewer plants with deficiencies outlined in @03.B.4.e.vii

Provisional Conformance
- Meets all criteria in @03.B.4.e.i through vi
- 26-42% of plants with deficiencies associated with @03.B.4.e.vii

Nonconformance
- Meets criteria in @03.B.4.e.vi
- Does not meet all criteria in @03.B.4 e.ii through.vi, or
- Has > 42% of plants with deficiencies associated with @03.B.4.e.vii

Major Nonconformance
- Does not meet @03.B.4.e.i, or
- Has two or more deficiencies in @03.B.4.e.v.ii through e.vi, or
- Failure to develop and implement an acceptable and effective action plan

Plant & Shipping In-Field Evaluation Criteria Evaluation Follow-up

- The existing language in the NSSP Model Ordinance does not have guidance for specific action to take in response to an adverse finding in the Plant Element Evaluation

- The issue is addressed in Procedure IX in the ISSC Constitution, Bylaws and Procedures which states *"If corrective action is taken by the state or the FDA or a mutually agreed upon action plan is developed and implemented, no action by the Conference will be necessary."*

Plant & Shipping In-Field Evaluation Criteria Evaluation Follow-up

Interim Criteria

- Conformance: The Authority will work with the individual firms to correct deficiencies or develop deficiency-specific compliance schedules

Plant & Shipping In-Field Evaluation Criteria Evaluation Follow-up

Interim Criteria – Response Actions for Provisional Conformance

- Correct deficiencies in plants audited by FDA within 30 (*45) days
- Conduct one of the following:
  1. Within 30 days, the SSO will conduct an audit of the same # of plants audited by FDA to determine compliance with e.ii; or
  2. Conduct inspections of all certified dealers within 120 days to identify and correct deficiencies. Within 30 days of the completion of the inspections, the SSO will conduct an audit of the same # of plants audited by FDA to determine compliance with e.vii
- Conduct a file review for the purpose of comparing FDA and SSO findings to previous inspections
- Determine if inspector re-standardization or additional training is needed
- Re-standardize and provide additional training as needed.

Plant & Shipping In-Field Evaluation Criteria Evaluation Follow-up

Interim Criteria – Response Actions for Provisional Conformance

Should the Program complete the prescribed actions and the SSO audit determines compliance (25% or fewer plants), the designation will be reassigned to Conformance

If the actions aren't completed or the SSO audit determines that the program is not in compliance (>25% plants), the designation will be reassigned to Nonconformance

*** Exception: If the program is found to meet Provisional Conformance criteria for two consecutive audits, the second will be reassigned immediately to Nonconformance

Plant & Shipping In-Field Evaluation Criteria Evaluation Follow-up

Interim Criteria – Response Actions for Nonconformance

- An Action Plan is required.
- If the finding of Nonconformance was the result of deficiencies associated with v.ii, the Action Plan must include:
  1. Correct deficiencies or develop compliance schedules within 30 (*45) days
  2. Within 10 days, the state must request re-standardization of the SSO
  3. Within 60 days, the SSO will conduct an abbreviated (3 plants) re-standardization of all inspectors
  4. Provide additional inspector training as needed
  5. Conduct compliance inspections of all plants within 120 days or another timeframe mutually agreed upon by the Authority and FDA
  6. Within 30 days, the SSO will conduct an audit of the same # of plants audited by FDA
  7. SSO file review to compare FDA and SSO findings

Plant & Shipping In-Field Evaluation Criteria Evaluation Follow-up

Interim Criteria – Response Actions for Nonconformance

- Failure to complete the action plan will result in a conformance designation of major Nonconformance.
- If the Nonconformance was the result of a Provisional Conformance failure, an action plan would be required consistent with a conformance designation of Nonconformance

Plant & Shipping In-Field Evaluation Criteria Evaluation Follow-up

Interim Criteria – Response Actions for Major Nonconformance

- All determinations of Major Nonconformance and the identification of deficiencies that pose imminent health concerns will be immediately reported to the ISSC Executive Board for consideration for appropriate action.
- Further action to be taken at this point are outlined in Procedure IX of the ISSC Constitution, Bylaws, and Procedures

INTERSTATE SHELLFISH SANITATION CONFERENCE

Thank you

209-1 Dawson Road
Columbia SC 29223
Phone: 803-788-7559
Fax: 803-788-7576
Email: issc@issc.org