ISSC 2019

Committee Report

Committee Name: NSSP Evaluation Criteria

Chairperson: Mike Hickey

Approved by: _____

Date of Meeting: October 6, 2019 Mike Hickey

Recorder: Amy M. Fitzpatrick

COMMITTEE MEMBERS PRESENT:

X Mike Hickey (Chairperson)	**X** Shannon Jenkins	Joel Hansel (EPA)
X Kathy Brohawn	Danielle Schools	**X** Quentin Forrest (FDA)
Scott Berbells	Tracy Fay	**X** Raymond Burditt (FDA)
Eric Hickey	**X** Joe Jewell	**X** John Jacobs (NOAA)
	Kirk Wiles	

Charges

- **Charge 1: Proposal 17-204: Control of Harvest In-Field Compliance Criteria**

Findings/Conclusions:

The FDA submitted the proposal to address a gap in the Control of Harvest element evaluation criteria. The current NSSP Control of Harvest element criteria only address administrative criteria and not the in-field component and other requirements in NSSP Model Ordinance Chapter VIII. The percentage criteria suggested in the proposal were randomly set as a conversation starter. It was hoped that the Patrol Committee would review the proposal first and offer suggestions and comments to the NSSP Evaluation Criteria Committee.

The FDA committed to working with the NSSP Evaluation Criteria Committee and the Regulatory Relationships Committee to work on consistency and uniformity of evaluation criteria for all program elements.

Recommendations:

Joe Jewell motioned that the Conference Chair establish a workgroup including members from the NSSP Evaluation Criteria Committee and the Patrol Committee to review and make recommendations to the conference on proposal 17-204 working with FDA to consider consistency and uniformity of evaluation criteria for all program elements. Raymond Burditt 2nd.

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- **Charge 2: Proposal 13-301 Growing Area Classification Criteria**

Findings/Conclusions:

The FDA submitted this proposal to develop Growing Area Classification evaluation criteria. A sub- committee has worked to reduce the original ~80 criteria into 8-9 categories focusing on the bigger picture, high risk items. The committee got bogged down and made little progress when discussing criticality codes and working on percentage criteria. The last sub-committee report was provided to the ISSC Executive Office, the committee has not seen the latest iteration; it was held pending the Cooperative Programs re-set meeting.

The committee discussed the need to consider if criticality codes are appropriate for use during growing area classification evaluations; there is a fear of the criteria being too strict.

The FDA committed to working with the NSSP Evaluation Criteria Committee and the Regulatory Relationships Committee to work on consistency and uniformity of evaluation criteria for all program elements.

Recommendations:

Raymond Burditt moved to recommend referral to an appropriate committee as determined by the Conference Chair to continue the development of the growing area classification evaluation criteria and make recommendations to the conference on proposal 13-301 working with FDA to consider consistency and uniformity of evaluation criteria for all program elements. Joe Jewell 2nd.

The committee requests the Conference Chair to instruct the committee to start deliberation as soon as possible.

- **Charge 3: Proposal 17-305 State Evaluations**

Findings/Conclusions:

Kathy Brohawn stated that the primary reason for submitting the proposal was during evaluations, when a shellfish specialist identified a concern and her agency addressed the concern before the evaluation was over, the correction was not acknowledged in the final program element evaluation report.

The FDA explained that some of the language was not appropriate for the Model Ordinance, but appropriate for FDA's The Molluscan Shellfish Compliance Program. Raymond Burditt stated that the agency would review the proposal requests and compare to what was in the compliance program and that where appropriate, language from the proposal would be considered for addition to the compliance program. Branch

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Director Elizabeth Ormond stated that corrections during evaluations need to be addressed in the program element evaluation reports and that the branch directors would be making sure that shellfish specialists documented corrective actions in the reports during their review process.

Recommendations:

Joe Jewell made a motion to recommend that the FDA conduct a review of proposal 17-305 in conjunction with The Molluscan Shellfish Compliance Program and report back to the Regulatory Relationships Committee and the NSSP Evaluation Criteria Committee what they incorporated from the proposal, and if they did not, the justification for their decision. Shannon Jenkins 2nd.

Joe Jewell motion to adjourn. Shannon Jenkins 2nd.