

Program Element Evaluations: Evaluations in the Days of COVID and Beyond

Program Element Evaluations: 2020-2021

- FDA placed on travel restrictions
- Only mission critical work
- ORA initiated RRA
- Completed program element evaluations without the in-field components

Program Element Evaluations

- Evaluations are based on the requirements of the Model Ordinance
- How to conduct the evaluations is described in the Molluscan Shellfish Compliance Program

Molluscan Shellfish CP Workgroup

- Charge from Shellfish Steering Committee
 - Update to reflect organizational changes
 - Update to reflect current procedures

What are Compliance Programs?

...**provide instructions** to FDA personnel for conducting activities to evaluate industry compliance with the Federal Food, Drug, and Cosmetic Act and other laws administered by FDA.

Molluscan Shellfish Program Objective

....to **evaluate** the activities of the participating states using a risk-based approach and to provide **capacity building** for the state program.

Molluscan Shellfish CP

-evaluation of state, tribal, and foreign shellfish programs and related **technical assistance** ...
-intended for use by shellfish specialists and those involved in making admissibility decisions...

Changes to Reporting Requirements

- Clarified PEER, APER, and IPER reporting requirements
 - Use of the PEER, APER and IPER templates
 - Use of cover letter templates
 - Distribution of reports to state partners in electronic format using electronic signatures

Reporting Timeframes

REPORT	DUE DATE	SUBMIT FINAL REPORT TO:
Program Element Evaluation Report (PEER)	60 calendar days after completion of evaluation but no later than January 31	Division of Seafood Safety (DSS)/Shellfish and Aquaculture Policy Branch (SAPB), National Shellfish Standard, and appropriate subject matter expert
Annual Program Evaluation Report (APER)	30 calendar days upon completion of all PEERs but no later than March 1	DSS/SAPB and National Shellfish Standard
International Program Element Evaluation Report (IPER)	120 calendar days after completion of evaluation	DSS/SAPB and National Shellfish Standard
Annual Domestic Evaluation Schedule	January 1	DSS/SAPB and National Shellfish Standard

Program Evaluation Timeframes

- Shellfish specialist will work with states to complete the **in-field** portion of the evaluation within **30 calendar days of initiation**.
- Draft PEER submitted to OSCP Branch Director and CFSAN SMEs for review within **30 calendar days** of completing the evaluation.
- OSCP management and CFSAN SMEs have 10 business days to provide feedback on draft reports.

Program Evaluation Timeframes

- The authority will have **15 business days** to review, comment, and provide the summary of the state's response to the draft PEER.
- If the state does not respond within **15 business days**, OSCP will issue the final report
- The state will have **5 calendar days** to review the APER prior to issuing to upper management.

Language Added for All Program Elements

- The shellfish specialist and the authority will **collaborate** to select (growing areas, plants, patrol areas) for evaluation.
- The selection.... should be risk-based, represent the ... overall inventory, and to the extent possible, consider the efficient use of time and resources to conduct the evaluation.

Growing Area Classification Element

- Frequency of evaluation has not changed
 - Remains based on risk assessment (production, classification complexity, illness outbreaks)
 - High Risk – every year; Low Risk – every two years
 - States High Risk for illness outbreaks are annual
 - If element does not meet MO requirements will be high risk until element meets the requirements

Plant Processing and Shipping Element

- In FY 22 Shellfish Specialists will be utilizing the interim compliance criteria published in the 2019 MO for determining conformance status
- Frequency of evaluation remains the same

Plant Processing and Shipping Element

Shellfish specialists must coordinate with the authority regarding standardization activities and whether the standardization activity is conducted during a plant processing and shipping evaluation.

Control of Harvest Evaluations

- . Change to Frequency of Evaluation
 - All shellfish producing states shall have the shellfish control of harvest element evaluated **every two (2) years**
 - States that are on an action plan or that have outstanding nonconformities shall receive a **follow-up review** during the non-evaluation year.
 - States that have at least one (1) High Risk patrol area, or where >20% of their patrol areas are in the Medium Risk category, shall receive a **follow-up review** in non-evaluation years to ensure those patrol areas are being patrolled at minimum required frequencies.

Vibrio Management Evaluation

- The CP has the old language regarding the Vibrio Management evaluation
- States will have a Chapter II/Risk Assessment Risk Management Evaluation

Observed Deficiencies, Corrections, and Reporting

- If deficiencies can't be corrected during the evaluation or prior to finalizing the PEER, the authority must develop and complete an action plan.

Observed Deficiencies, Corrections, and Reporting

- If corrective action is taken (during evaluation or prior to issuing the final PEER) the correction is documented in the PEER
- Deficiency (ies) and conformance status, though corrected, remains documented in the PEER and the deficiency is reported as corrected.

Observed Deficiencies, Corrections, and Reporting

- If the Authority develops and submits an action plan prior to the issuance of the final PEER, the action plan will be incorporated into the summary of the state's response to the PEER



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