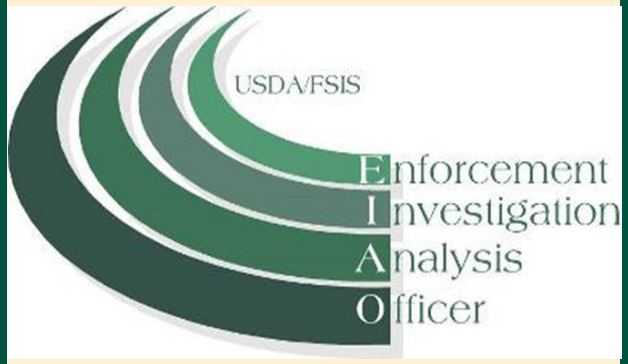
Food Safety and Inspection Service
U.S. DEPARTMENT OF AGRICULTURE

Verification Plans
EIAO Training



Objectives

Upon completion of this module, you will be able to:

- Describe what a verification plan is, the purpose, and when a plan is developed.
- Describe the role of the EIAO in developing the verification plan.

FSIS Responsibility

- Verifying an establishment's corrective measures following an NOIE or suspension is one of FSIS' most important public health responsibilities.

Verification Plan

- Provides a systematic means for FSIS to ensure that an establishment is effectively carrying out its corrective actions regarding a NOIE or suspension.

Verification Plan

- Failure to carry out plan activities may:
  - Jeopardize public health because the establishment may be producing unsafe product
  - Negatively impact our ability to take further enforcement.
  - Impact the establishment's "due process" in that FSIS may be keeping the enforcement action open for a prolonged period without justification.

Verification Plan

- Designed to verify that an establishment has fully implemented revisions and is effective in assuring regulatory compliance
- Assists the establishment to understand the importance of FSIS' verification activities.

Contents

- The background that led to an enforcement action and deferral or abeyance of that action
- The organized list of the establishment's proposed corrective actions and preventive measures
- The documents, processes, products, or programs that are to be verified
- The directed PHIS task associated with each verification activity, the frequency the task is to be performed, and the regulations associated with the verification activity.

Contents

- Free text space to record additional information as needed
- A statement to inform the establishment that the DO is to be informed of any changes to corrective actions and preventive measures during the verification period. The verification plan is to be revised before the establishment implements the changes.

Contents

- The EIAO also determines corrective actions proffered by the establishment that cannot be verified through regular PHIS procedures and lists them in the verification plan.
    - Example: plant improvement plans

Example Verification Plan

FSIS Verification Plan **Good Meats Inc. (M0001 / P0001)** *Verification Point 13*	
Background that led to enforcement action	The establishment utilizes option 3 from the 2017 FSIS Stabilization Guidelines - Appendix B to support CCP 2B, cooling for the stabilization which requires that cured products contain at least 100 ppm ingoing sodium nitrite and 250 ppm sodium erythrobate or ascorbate. However, establishment recipes for the fully cooked, cured ham and summer sausage products do not contain any sodium erythrobate or sodium ascorbate in the formula.
Related Regs	9 CFR 417.5(a)(2)
Establishment Action Plan	New formulations developed for fully cooked, cured hams and summer sausage that contain proper amounts of in-going ppm of sodium nitrite and sodium erythrobate to support the use of Option 3 for stabilization/cooling. Formula batch sheets developed to document use of proper formula when producing the fully cooked, cured hams and summer sausage.
Related Est. Records	Ham Formulation, Summer Sausage Formulation, Ham Batch Sheet, Summer Sausage Batch Sheet
FSIS Verification Activity	Verify that the establishment is utilizing the new formulations for the fully cooked, cured ham and summer sausage products and is recording the formula utilized on the formula batch sheet for each product.
Frequency	Each time Ham or Summer Sausage is produced
Related PHIS Task	Fully Cooked Not Shelf Stable HACCP Verification Task
Wk Date	**Findings / Comments / NR# / MOI#**

When to Develop

- Verification plan should be developed whenever a decision is made to:
  - Defer enforcement after an NOIE has been issued
  - Hold a suspension in abeyance after the assignment of inspectors has been suspended
  - Consent agreement/verify provisions

Verification Plan

- The verification plan must be:
  - referenced in the deferral or abeyance letter
  - provided to the establishment as an enclosure to the deferral or abeyance letter

Preparing the Plan

- EIAO has primary responsibility
  - Include input from the FLS and the IPP team
  - Team approach ensures key issues are covered and proper work methods will be used to conduct verification activities
  - Additional time may be needed to prepare the plan

Verification Activities

- Procedures identified in the verification plan are performed as regularly scheduled PHIS procedures

- In-plant inspection team will verify the corrective actions as a part of the inspection procedure

Flexibility

- In-plant inspection team has the flexibility to increase the frequency of verification based on their findings
    - Inspector generated procedures can also be performed if the establishment increases food safety monitoring and verification activities.

EIAO Follow-up

- The EIAO will:
  - Conduct follow-up at establishments at 30-, 60-, and 90-day intervals
  - Determine establishment compliance
    - For example, at the end of the deferral or abeyance period to determine if the action should be closed out

Establishments in Deferral or Abeyance

- Verification activities could reveal:
  - sufficient basis exists to close a deferral decision or suspension being held in abeyance
  - corrective measures are inadequate, and FSIS should suspend inspection, reinstate a suspension, or initiate proceedings to withdraw inspection
- EIAOs document this in a decision document to the DM or in letter to establishment

Workshop