

Preparing Enforcement Letters and Evaluating Establishment Responses

EIAO Training



Objectives

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

- Describe the purpose of an NOIE letter.
- Identify required contents of an NOIE letter.
- State how long an establishment has to answer an NOIE letter.

Major Sections of Enforcement Letter

- Opening Paragraph
- Background/Authority
- Findings and Basis for Actions
- Notification, Appeal, Hearing Rights

Opening Paragraph

- Clearly describe the letter's purpose
 - Intent to take enforcement action (NOIE)
 - FSIS has withheld the marks of inspection or suspended assignment of inspectors

Background/Authority

- Describe in clear language what sections of the FMIA, PPIA, or EPIA give us the authority to initiate this enforcement action under the Rules of Practice.
- Be sure that you read the sections in each Act and understand why the action is being taken.

Background/Authority

- Statutory provisions cited should be well thought out and consistent with the strategy used to develop the enforcement action.
- You should understand.....
 - Under what authority our inspection personnel acted
 - Under what authority you acted
 - Provisions of the Act the establishment violated

Findings and Basis for Action

- Describe the findings and facts that serve to support that violations of the Act and regulations exist.

Findings and Basis for Action

- Cite the title and the specific section of the applicable regulatory requirement for each violation that is supported by the evidence
 - Example: 9 CFR 417.5(a)(1)

Findings and Basis for Action

- Cite the title or the specific section and paragraph of the statute
 - Example 21 U.S.C. 601(m)(1).

21 U.S.C. 601

Findings and Basis for Action

- This section should describe:
 - Establishment processes that are the source of the violation
 - What is objectionable.
 - What the public health significance is.
 - Why the plant's actions to address the problem are inadequate.
 - Why this inadequacy results in the product being adulterated or other violation.

Findings and Basis for Action

- Describe conditions or evidence that demonstrates adulteration under the provisions of:
 - 21 U.S.C. 601(m)(1), (m)(3), or (m)(4), of the FMIA
 - 21 U.S.C 451 (g)(1), (g)(3), or (g)(4) of the PPIA
 - Other applicable provisions

Findings and Basis for Action

- Describe events which formed the factual basis for the case.
 - These facts must be supported by documentation
 - Describe why documentation demonstrates noncompliance

Notification/Appeal/Hearing Rights

- The NOIE should notify the plant that it has 72 hours or 3 business days to respond in writing
 - FSIS will determine further action based on the establishment's response.

72 Hours

Notification/Appeal/Hearing Rights

- Establishment may contest the basis for the NOIE

NOIE

Notification/Appeal/Hearing Rights

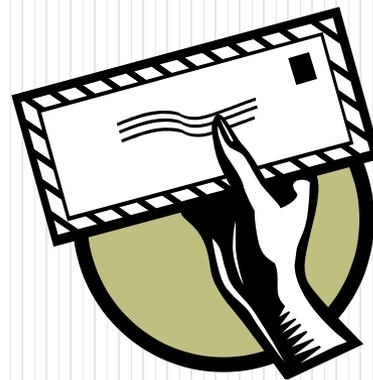
- Withholding or Suspension
- Rules of Practice provide establishments a right to appeal the matter and to request a hearing

Notification/Appeal/Hearing Rights

- Advise the establishment of the right to appeal the matter to EARO, Field Operations
- Advise the establishment of the right to request a hearing by contacting, the Director, Enforcement and Litigation Division, OIEA

Evaluating an Establishment's Response

Determining Sufficiency of an Establishment's
Response to a NOIE or Suspension



Evaluating an Establishment's Response

- EIAOs will review and evaluate the sufficiency of establishment's corrective actions submitted in response to:
 - An enforcement action
 - Data generated during abeyance or deferral

Evaluating an Establishment's Response

- Due Process under the Rules of Practice
 - Establishment has 72 hours to respond to NOIE (Suspension letter indefinite time)
 - Once response is received by District Office, FSIS must promptly review and evaluate the response
 - FSIS must sustain communication with the establishment during the period of review of the plant's response

Evaluating an Establishment's Response

- Work under the direction of the District Office to review the response
- Engage the IIC to confirm and obtain any additional information to evaluate the proposed corrective actions
- Maintain communication with the FLS regarding the ongoing evaluation

Evaluating an Establishment's Response

- Read and review the issues addressed in the NOIE or Suspension letter
- Review the FSA report and decision document that was the basis for the action
- Formulate a list of questions that are critical to evaluate the sufficiency of the response

Evaluating an Establishment's Response

- What noncompliance served as the basis for the action?
- What are the significant issues identified related to the establishment's food safety systems?
- What information do you need to determine whether the establishment has addressed the food safety issues?
- What information do you need to assess what may be missing?

Evaluating an Establishment's Response

- Determine whether the submitted response is complete. For example:
 - Are the hazard analysis and supporting documentation included?
 - Are the revised HACCP plan and SSOP included?
 - Are the revised prerequisite programs, SOPs or GMPs discussed in the hazard analysis included?
 - Is other relevant data necessary to completely evaluate the submitted response?

Evaluating an Establishment's Response

- Has the establishment proffered anything new?
- Has the establishment reassessed their HACCP plan?
- Does the establishment have data to support the decisions they are making?

Evaluating an Establishment's Response

- Continue your review to identify the issues that will need to be discussed with subject matter experts
- Determine the types of expertise you will need to assist in the review
 - Are there microbiological issues?
 - Are there slaughter inspection issues?
 - Are there RTE processing issues – lethality, cooling, stabilization?

Evaluating an Establishment's Response

- If necessary, contact OPPD to obtain the experts' opinions
- If experts from OPHS are needed, work with the OPPD staff to arrange for their involvement
- Provide the OPPD and OPHS experts with copies of the establishment's submission

Evaluating an Establishment's Response

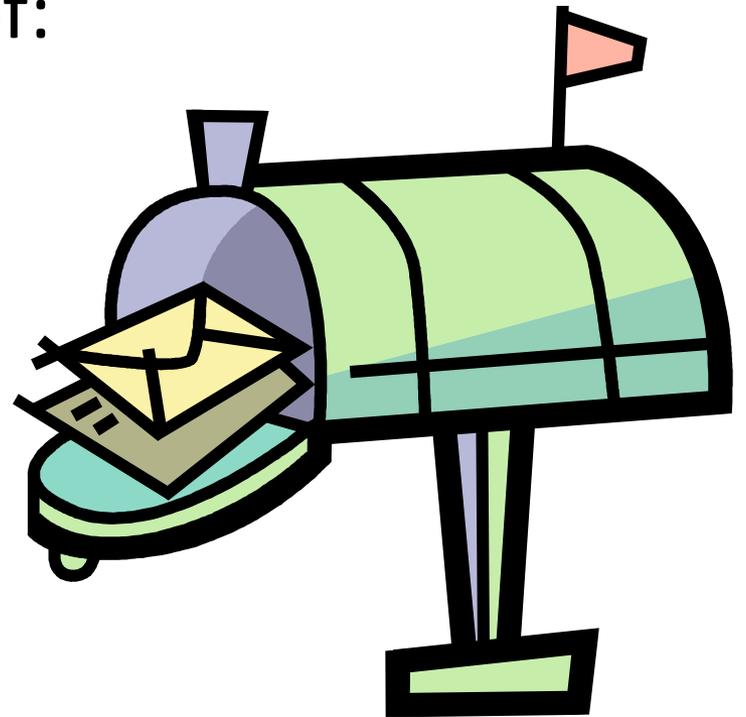
- As needed, conduct daily discussions with the experts during the review process
- Include the IIC by phone in these discussions
- Maintain daily contact with the DDM and the FLS about the progress of the review and issues that emerge

Evaluating an Establishment's Response

- If the corrective actions are deemed insufficient, prepare a decision document that:
 - Describes each issue raised in the NOIE or Suspension letter
 - For each issue, explain why the response is not adequate
 - Includes an analysis of the sufficiency of the response and a recommendation for acceptance or denial of the establishment's corrective actions
 - Submit this draft to the DDM and wait for guidance

Evaluating an Establishment's Response

- If the corrective actions are acceptable this will be the substance of:
 - Deferral Letter
 - Abeyance Letter



Evaluating an Establishment's Response

- If the corrective actions are acceptable, work with the FLS, IIC and in-plant inspection personnel to develop the verification plan that will accompany the deferral or abeyance letter.

Evaluating an Establishment's Response

- If the corrective actions are incomplete, draft a response to the establishment that describes the documents that are needed
- Assist the DO in communicating verbally with the establishment to inform them of the additional documentation that is needed for the agency's evaluation

Evaluating an Establishment's Response

- The DM will decide whether to:
 - issue letter to initiate a suspension (from NOIE)
 - sustain the suspension or
 - engage in further correspondence with the establishment to reach a successful resolution to move to a deferral or abeyance

WORKSHOP

