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)
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 is has 72 hours or 3 business days to respond in writing
  • FSIS will determine further action based on the establishment’s response

72 Hours

Establishment may contest the basis for the NOIE

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 Operations Staff, OIEA

Evaluating an Establishment’s Response

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

EIAO Training

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

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

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?

22

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?

23

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?

24
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 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

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

• 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