

Preparing the NOIE or Enforcement Letter

Objectives

Upon completion of this module, the trainee will be able to:

1. Draft a Notice of Intended Enforcement (NOIE) letter to an establishment based upon the findings of a comprehensive Food Safety Assessment.

Contents of the Letter

Opening Paragraph

The opening paragraph should clearly describe the *purpose of the letter*, either the intent to take enforcement action, or the fact that FSIS has withheld the marks of inspection and suspended the assignment of inspectors.

Background/Authority

The next section should 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. It is important that you read the sections in each Act and understand why the action is being taken. The provisions of the statutes that are described in this paragraph should be well thought out and consistent with the strategy used to develop the enforcement action. It is important that you understand under what authority our inspection personnel acted in the execution of their roles, under what authority you acted in the execution of your role, and what provisions of the Act the establishment violated.

Findings and Basis for Action

In this section, you will describe the findings that serve to *support* the fact that violations of the Act and regulations exist. Remember to cite the title and the specific section of the applicable regulatory requirement for each violation – for example 9 CFR 417.5(a)(1). In addition, be sure to cite the title and the specific section and paragraph of the statute – for example 21 USC 601 (m)(1).

This section should describe:

- Establishment processes that are the source of the violation.
- What is objectionable about the violation(s).
- What the public health significance is.
- Why the plant's actions to address the violation are inadequate.
- Why this inadequacy results in the product being adulterated or other violation.

You should also describe the 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; or 451 U.S.C (g)(1), (g)(3), or (g)(4) of the PPIA, or other applicable provisions.

Be very clear and concise in describing events at the establishment that formed the factual basis for the case. These facts must be supported by documentation of observations, records examinations, interviews of plant officials and employees, or other information gathered by FSIS inspection personnel. Be very thorough in describing the documentation and why it demonstrates that noncompliance exists.

Notification/Appeal/Hearing Rights

The NOIE should notify the plant that it has 72 hours to respond in writing to the NOIE, and that FSIS will determine what further action is necessary based on the establishment's response. There are no appeal or hearing rights provided for under the Rules of Practice when issuing a NOIE because the enforcement action has not yet been taken.

If FSIS takes a withholding action or suspends the assignment of inspectors, the Rules of Practice provide the establishment a right to appeal the matter and to request a hearing (9 CFR 500.5). The suspension or withholding letter should advise the establishment of the right to appeal the matter to the appropriate Executive Associate for Regulatory Operations, Field Operations. The letter should also advise the establishment of the right to request a hearing by contacting, the Director, Evaluation and Enforcement, Office of Program Evaluation, Enforcement and Review.

Determining the Sufficiency of a Plant's Response to a NOIE or Suspension

You, as the EIAO, may be directed by the District Office to review and evaluate the sufficiency of establishment's corrective actions submitted in response to a NOIE, a suspension letter, or to data generated during an abeyance or deferral period. The plant is given 72 hours to respond to a NOIE. For a suspension letter, there is no definite period of time. Once a response is received by the District Office, FSIS must promptly review and evaluate the response. FSIS must sustain communication with the plant during the review period of the plant's response. You will work under the direction of the District Office to review the response. You should engage the IIC at the plant to confirm and obtain additional information necessary to evaluate the plant's proposed corrective actions and maintain communication with the FLS regarding the ongoing evaluation. You should review the issues addressed in the NOIE or Suspension letter and the comprehensive assessment report/decision document that was the basis for the action.

Formulate a list of questions that are critical to your evaluation of the sufficiency of the submission.

- What noncompliance(s) 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 plant has addressed the food safety issues?
- What information do you need to assess what may be missing?

Determine whether the plant's submitted response is complete. Some examples of questions you might want to consider when determining this are given below. Remember that each establishment's response will be different and, depending upon the situation, a response may not need to include any of these.

- Are the hazard analysis and supporting documentation included?
- Are the revised HACCP plan and SSOP included?
- Are the revised prerequisite programs, SOPs or GMPs that are discussed in the hazard analysis included?
- Is other relevant data necessary to do a complete evaluation of the submission included?
- 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?

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?

If necessary, contact the Technical Service Center to obtain the experts' opinions and, if experts from OPHS are needed, work with the TSC staff to arrange for their involvement. You should provide the TSC and OPHS experts with copies of the plant's submission. As needed, you should conduct daily discussions with the experts during the review process and include the IIC by phone in these discussions. You will also want to maintain daily contact with the DDM and the FLS regarding the progress of the review and issues that emerge.

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, explains why the plant's response is not adequate.
- Includes an analysis of the sufficiency of the response and includes a recommendation for acceptance or denial of the plant's corrective actions.

Submit this draft decision document to the DDM and wait for guidance.

If the corrective actions are acceptable this will be the substance of the Deferral or 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.

If the plant's corrective actions are incomplete, you should draft a response to the plant that describes the documents that are needed and assist the District Office in communicating verbally with the plant to inform them of the additional documentation that is needed for the agency's evaluation.

The DM will decide whether to issue a letter to initiate a suspension (from a NOIE), or to sustain the suspension, or to engage in further correspondence with the plant in an attempt to reach a successful resolution to move to a deferral or abeyance.

Workshop

Using the template example of a NOIE on the following page, draft a NOIE based on the provided Food Safety Assessment results.



Food Safety and Inspection Service
United States Department of Agriculture

Lincoln District Office
620 Ohio Avenue
Lincoln, USA 11111

For Training Purposes Only

**TEMPLATE FOR WRITING A NOIE BASED ON THE RESULTS OF A
COMPREHENSIVE ASSESSMENT**

(Date)

(Name of Plant Official and Plant Address)

NOTICE OF INTENDED ENFORCEMENT

This serves as official notification by the Food Safety and Inspection Service (FSIS) of our intent to withhold the marks of inspection and suspend the assignment of inspection program personnel at:

(Name, number, and address of establishment)

Background/Authority

The Federal Meat Inspection Act (FMIA)(21 U.S.C. 601 et seq.) and Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 et seq.) provide that it is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and poultry products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged. These Acts give FSIS the authority, as designated by the Secretary of the Department of Agriculture, to prescribe rules and regulations describing sanitation requirements for inspected establishments. They also provide FSIS program personnel the authority to refuse to allow meat or meat food products to be labeled, marked, stamped, or tagged as "inspected and passed" and to prevent the entry of products into commerce when the sanitary conditions of any such establishment are such that rendered product adulterated and provide definitions for the term "adulterated". Furthermore, the Acts provide FSIS the authority to appoint inspectors from time to time to examine and inspect products, including the sanitary conditions of facilities. They also give FSIS program personnel the right to examine and inspect all carcasses and parts of carcasses that are further treated and prepared and the right to access and examine establishment records. When the sanitary conditions of a facility are not properly maintained, FSIS can refuse to render inspection and indefinitely withdraw inspection from an establishment provided the establishment is afforded the right to an administrative hearing.

Under the authorities, of the Acts, FSIS has prescribed rules and regulations required for establishments producing meat and poultry products, including the requirements pertaining to sanitation and Hazard Analysis and Critical Control Point (HACCP) (9 CFR Parts 416 and Part 417) and other matters. FSIS has also developed Rules of Practice regarding enforcement (9CFR Part 500). The Rules of Practice describe the types of

enforcement action that FSIS may take and include procedures for taking a withholding action and or suspension, with or without prior notification, and for filing a complaint to withdraw a grant of Federal inspection.

Findings/Basis for Action

The following information is provided to support this notification of intended enforcement for your facility:

- **Provide dates of the comprehensive assessment (if applicable), identify who conducted the comprehensive assessment and the reason it was conducted.**
- **Describe the data and information that support there is a basis to withhold the marks of inspection. Extract pertinent information from your assessment report that supports regulatory noncompliance exists and why the plant's previous actions to address the problem are inadequate, if appropriate.**
- **Describe the significance of the data of information, including the public health significance of the data and information. For SSOP, HACCP, and pathogen reduction issues, you should correlate the noncompliance to the applicable statutes (FMIA or PPIA) and cite the specific section and paragraphs of the statute to support the definition of adulterated product.**

Remember, it is important to describe the facts in a manner so that it is clear why the decision to issue a NOIE was reached. Your findings and basis for the action should address the “who, what, when, where, how” associated with the matter and should be described in a manner so that someone unfamiliar with the circumstances can understand the basis for taking the action.

In accordance with FSIS Rules of Practice, 9 CFR Part 500, we are notifying you of our intent to withhold the marks of inspection and suspend the assignment of inspectors at your facility. Please provide this office with a written response concerning this notice of intended enforcement (NOIE) within three (3) working days from the date of your receipt of this letter. We will determine further action, if any, based upon your response.

If you have any questions regarding this matter, please feel free to contact me, the Deputy District Manager, or _____, EIAO at (000)000-0000.

Sincerely,

Dr. Jane Doe
District Manager