Administrative Enforcement Reporting (AER) System

Objectives

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

1. Describe the purpose of the AER system.

2. Describe the role of the EIAO in the AER process.

3. Describe what an exhibit is and the types of exhibits that may be part of an AER file.

4. Describe the purpose of a decision document and when it should be prepared.

5. Describe the purpose of a memorandum of interview and what it should include.

Introduction

To ensure that all administrative actions are supportable and based on the applicable statute and regulations, FSIS instituted the AER system in April 2003. The system provides for the proper and accurate maintenance of documents produced by the Agency related to various administrative actions. Since implementation there have been numerous effective enforcement actions taken utilizing the AER system. Hundreds of enforcement actions are taken each year utilizing the AER process.

Documenting Administrative Enforcement Actions

FSIS carries out administrative enforcement actions under the Rules of Practice regulations (9 CFR part 500) when a Federal establishment is not meeting provisions of the Federal Meat Inspection Act (FMIA) and Poultry Products Inspection Act (PPIA). When OFO, the Office of Field Operations, decides to pursue an enforcement action under 9 CFR 500.3, withholding action or suspension without prior notification or under 9 CFR 500.4, withholding action or suspension with prior notification (i.e., NOIE), the Case Specialist will begin completing FSIS Form 5400-9, the AER report form, with all supporting documentation attached as exhibits.

An AER report form, including a separate report number, list of exhibits, and accompanying exhibit documents are required <u>for each</u>:

- NOIE.
- Suspension.
- Reinstatement.

At the time a NOIE, suspension, or reinstatement letter is issued, a completed AER must be available. Therefore, as soon as the decision is made to proceed with enforcement, the assembling of the AER report and exhibits should begin immediately.

We must remember our due process obligations. The plant is entitled to know the reasons for proposing or taking enforcement and the evidence upon which these actions are based. The AER must immediately be available:

- If the plant requests a copy of the AER.
- If the plant appeals or requests an administrative hearing.
- If FSIS files a complaint to withdraw.
- If a temporary restraining order (TRO) is filed for by the plant, or there are other District Court filings.

The AER report and accompanying exhibits must demonstrate that FSIS had a sound basis for taking the action. It should provide an outside reader with an understanding of key events that prompted the decision.

FSIS also carries out other administrative activities for which an FSIS Form 5400-9 is started. Such administrative activities include the:

1. Review of the sanitary conditions at custom exempt operations, and, when necessary, the preparation of written recommendations to remove custom exempt privileges, along with supporting evidence to the Office of Program Evaluation, Enforcement, and Review (OPEER).

2. Detention of product as set out in FSIS Directive 8410.1.

3. Recall Effectiveness Checks.

4. Investigations of prohibited activities as set out in the FMIA, section 10, and the PPIA, section 9 and 10, such as adulterated product deliberately distributed into commerce.

5. Investigation of illness outbreaks such as one that is related to a recall (NOTE: Illness outbreak investigations related to the Consumer Complaint Monitoring System are documented under the CCMS system, not the AER system).

6. Non-Routine Incident investigations addressed in FSIS Directive 6500.1, Emergency Management Committee, and FSIS Directive 6500.2, Incident Investigation Teams.

Case Specialist

The Case Specialist in the District Office is the “focal point” for ensuring that the AER case file, including the list of exhibits and accompanying exhibit documents, is properly maintained and complete. They will oversee the District Office system for maintaining hard and electronic copies of the AER case file. The AER must readily be available if requested and one paper copy of the AER and one electronic copy must be maintained at the District Office.

Role of the EIAO

You, as the EIAO, will play a key role in *collecting evidence* to support the action or proposed action that will become part of the AER file. Later, we will discuss the types of exhibits that will be included in the AER for each type of administrative action. Collecting evidence, however, is the easy part. Analyzing the information and describing what it means can be much more difficult.

Analysis is a critical component of the AER process and the word "analysis" is in the EIAO title because it is an expected duty. At every enforcement stage it is important to analyze information and decide what should happen next. All decisions reached concerning enforcement should be well thought out and based on an analysis of all relevant facts. The conclusions and decisions reached must be supported by the facts. Describe what specific facts caused you to reach the decision. You can't simply state, "The Noncompliance records show the plant's HACCP/SSOP plan has failed or is ineffective." You must be able to describe why the conclusion was reached and the public health significance.

Completing the Report

The District Case Specialist will complete the AER form and the List of Exhibits. This information is given to you, as the EIAO, for general background information.

For any type of AER, there needs to be a completed cover sheet (the first page of the FSIS Form 5400-9) and a well described List of Exhibits (the second page).

FSIS Form 5400-9 is available on outlook at: Public Folders\All Public Folders\Agency Issuances\Forms\FSIS 5,000 SERIES. There is an example of the blank form, as well as a completed example, in the back of this module.

The District Case Specialist will assign a report number to the AER. A numbering system has been devised to facilitate using the AER for multiple types of cases. To number the AER:

- The first number is the DO number.
- The second number is the fiscal year.
- The lettering identifies the report type.
- The last numbers enable FSIS to determine how many reports of this nature have been completed in a given District.

For *example*, AER 65-05-N003, the:

- 65 is for the Albany DO.
- 05 is for the fiscal year 2005.
- N indicates an NOIE.
- 003 means the NOIE is the 3rd NOIE issued in Albany in the fiscal year.

This table contains all of the types of reports that may be completed under the AER system and the abbreviations for each type.

AER Report Type	**Report Number Example**
NOIE (**N**)	65-05-**N**003
Suspension (**S**)	65-05-**S**001
Reinstatement (**R**)	65-05-**R**001
Appeal to DM (**A**)	65-05-**A**010
Withholding of Labels (**WL**)	65-05-**WL**001
Custom (**C**)(Request to withdraw the custom exemption)	65-05-**C**001
Recall Effectiveness Check (**REC**) NOTE: When completed for recall effectiveness checks, insert in block 11 of the FSIS 5400-9, the FSIS Recall Number, (e.g., FSIS-REC-XXX-200X).	65-05-**REC**001
Detention (**D**)	65-05-**D**002
Prohibited Act (**PA**)	65-05-**PA**001
Outbreak of Illnesses Investigation (**OI**)	65-05-**OI**001
Non-routine incident report (**NRI**)	65-05-**NR**I001
Withdrawl of Inspection (**W**) NOTE: This would be specified under OTHER in block 11.	65-05-**W**001
Complaint for Suspension (**CS**) NOTE: This would be specified under OTHER in block 11.	65-05-**CS**001
Other (**O**)	65-05-**O**001

Exhibit List

Each AER must have an exhibit list and the accompanying documents and records which support the basis for the NOIE, suspension, or reinstatement of suspension. All supporting documents that formed the basis for taking the enforcement action should be identified and included as exhibits. The AER report is incomplete if supporting documents exist but are not included and identified in the report.

Exhibits typically included in the AER are:

- Noncompliance Records, notes of plant meetings, lab reports.
- HACCP, SSOP, pre-requisite program records, or other plant records.
- Comprehensive assessment reports.
- NOIE, Suspension, or Reinstatement letters.
- Plant responses to the enforcement actions and accompanying documents.
- Memorandums of Interview or Signed Statements.
- Memos to the file documenting discussions held with the plant officials regarding the adequacy of the plant's response.
- Letters issued to the plant requesting clarification concerning issues.
- Memos to the file documenting discussions with the TSC, OPHS, OPPED, or other Agency officials regarding the enforcement action.
- Letters of Deferral or Abeyance.
- Verification Plans.
- Reports/recommendations pertaining to FSIS' verification activities.
- Letters closing the enforcement action.

The supporting documents and evidence should be referenced on and attached to the AER in a manner that makes it clear why a particular action is justified. These documents should address the - who, what, when, where, and how - of the alleged violation. For enforcement actions, the documents are to link the alleged violations to the FMIA or PPIA. The documents are to be written in a manner that someone unfamiliar with the facts will be able to understand what has occurred, and why it violates the statute.

Exhibit Organization

The first exhibit should be the letter to establishment notifying them of the action or intended action. The last exhibit should be the document closing out the action. This format allows the reader to quickly find the basis for the NOIE, Suspension, or Reinstatement and the closing action. A new AER file will be prepared if a subsequent administrative action is taken.

Here are some examples.

NOIE – AER: the first exhibit should be the NOIE letter and the last exhibit should be the document representing the NOIE closing action (e.g., Letter of Warning, Suspension in Effect letter).

Suspension – AER: the first exhibit should be the suspension letter and the last exhibit should be suspension closing action (e.g., Letter of Warning, Reinstatement of suspension letter, Request for complaint to withdraw inspection)

For a Reinstatement – AER: the first exhibit should be the reinstatement of suspension letter and the last exhibit should be the reinstatement closing action (e.g., Letter of Warning, Suspension remaining in effect, Request for complaint to withdraw)

Description of Exhibits

On the List of Exhibits part of the form, describe exhibits in a manner which makes it clear what the exhibit is. Reading the exhibit description should provide an overall summary of events, dates of significant activities and key players.

Multiple records may be included under one exhibit. If multiple records are under one exhibit tab, the description should make clear the total number of records in the exhibit and what they represent. For example,

Exhibit 5 Description: 14 NR's documenting SSOP deficiencies of direct product contamination during operational inspection for the period March 1, 2006 thru April 2, 2006.

Voluminous documents, such as binders of information received from a plant may be kept separately from the tabbed hard copy of the AER. When this occurs a label/note should be affixed to the document which identifies it as an exhibit and which includes the exhibit number. For example:

Exhibit 10 Description: See binder re: plant's Environmental Testing Program provided to the District Manager on 3/23/06.

The exhibit would be listed and described on the exhibit sheet but maintained separately if it is too voluminous to copy.

Use judgment in determining which NR records to include as exhibits, such as when voluminous NR records exist. Key NR's associated with the enforcement action and the plant's responses, if available, should be always be included. PBIS summary reports may also be included.

All proposed corrective/preventive plans provided by the plant in response to a NOIE or suspension, including all submittals received that were not found to be acceptable should be an exhibit. For each corrective/proposed measure that was rejected, there should be an exhibit in the report which addresses why the proposal was not deemed acceptable to ensure food safety.

There is no required order for listing or grouping exhibit documents, except for the first and last exhibit. Exhibits should be listed and grouped in a manner that best "tells the story."

Photographs

In compiling an AER file, it may be necessary for you as EIAO's, who have been trained and supplied a camera, to take photographs that document the existence of insanitary conditions that are causing, or are likely to cause, the adulteration of product or of practices likely to render product injurious to health or otherwise in violation. You may be instructed to take photographs for other purposes; however, at no time are you to take photographs if you have not been trained by FSIS, have not been authorized by supervisory personnel to take photographs, and have not been issued a camera by FSIS. Also, under no circumstances are non-FSIS issued cameras (e.g., cell phone camera, personal cameras) to be used to take photographs in an inspected establishment.

Note: You are encouraged to use digital cameras to photograph observations and to "copy" relevant records but only copy those individual records necessary to support the case. There is no need to copy the entire HACCP plan or SSOP.

The purpose of photographic evidence is to provide:

- Visual documentation of the facts, conditions, or the sequence of events.
- Visual support that there was a problem or violation of the law.

Examples of documents, conditions, or practices effectively documented by photographs include:

- All FSIS forms, decision documents, letters to the establishment, memoranda of interview.
- Evidence of rodents or insect infestation, faulty construction or maintenance, or other failure of Sanitation Performance Standard conditions which contribute to insanitary conditions.
- Routes of, as well as, actual contamination of raw materials or finished Products.
- Condition of raw materials or finished products.
- Employee practices contributing to adulteration of product or to violative conditions.
- Manufacturing processes.
- Labeling.

Documents

Documents include all FSIS Forms (e.g., NRs, and the Food Safety Assessment). Documents also include:

- Letters to an establishment related to enforcement actions such as an NOIE, deferral of an NOIE, institution of a suspension, or holding a suspension in abeyance.

- Letters to an establishment related to other administrative actions such as notification that a recall was ineffective, or notification that the establishment failed to notify all customers of a recall.

- Decision documents that render an FSIS opinion about a matter, memoranda from District Managers (DM) to the Office of Field Operations (OFO) Headquarters management, or memoranda between Assistant Administrator offices.

- Memoranda of interview that report the discussions that Agency personnel have with members of the public such as establishment management, consumers, or custom exempt operators.

We have already discussed letter writing to the establishment (i.e., NOIE, Letter of Suspension) in a previous module. Now let's look at some other types of documents that may be part of the AER file.

Memorandum of Interview

For administrative cases, a memorandum of interview is encouraged to clarify information. A memorandum of interview is:

- Prepared by the person receiving the information (e.g., EIAO).
- Less contentious in nature than formal signed statements.
- A means to get additional information in the AER.

The EIAO should use interviewing as a means to clarify information and ensure the administrative record fully addresses the facts. Interviews are important if the facts are unclear or there is relevant information apart from what is portrayed in the collected documentation or new information is learned that impacts the enforcement decision. The memorandum of interview summarizes key points of information as stated by persons who have direct knowledge of pertinent facts. It should be based on the facts, not speculation or opinion. Such memoranda are to:

- Identify all participants present at the meeting.
- Explain all facts that provide the basis for the meeting.
- Fully describe the meeting.
- Be written in a concise and clear manner.

Signed Statements

Signed statements are a more formal record of an interview in that the person being interviewed is requested to sign. They are normally not needed for administrative type cases. They are routinely prepared by Program Investigators in OPEER for criminal cases and there is a required investigative format for preparing signed statements. If you encounter a situation where you believe a signed statement is needed, consult the Case Specialist or DDM for guidance.

Decision Documents

Decision documents are an important component to the AER process. There are various points in the enforcement process where decisions are reached and documents should be included in the AER to support how such decisions were reached. They serve as evidence to document that the decisions reached regarding enforcement were well thought out and based on an analysis of relevant facts. It is important that they be written in a manner so that they clearly describe what has occurred and the basis for the decision reached.

Decision Documents are part of the plant's due process and the plant is entitled to know the basis for the decision reached. In the event the enforcement action is challenged or appealed, persons who are unfamiliar with the facts will be reviewing the AER and accompanying documents.

It is important that evidence exists in the AER to clearly reflect why a given decision was reached, or, in other words, the "thought process" and relevant factors considered in reaching the decision at each decision point. Decision points commonly encountered in the enforcement process include:

- Before issuing a NOIE.
- After plant response to the NOIE.
- Before deferring when the plant is submitting action plans including corrective and preventive measures.
- Before closing a NOIE.
- Before suspending.
- After plant response to the suspension.
- Before abeyance when the plant is submitting action plans including corrective and preventive measures.
- Before closing a suspension.
- Before recommending withdrawal.

If the thought process used in reaching the decision is not in another document, a decision document should be prepared. However, if the thought process is documented in another document in the AER, there is no need for duplication of effort. For example, if an EIAO prepares a comprehensive assessment recommending an NOIE, there is no need for a decision document because the thought process is in the assessment report. The assessment report would serve as the decision document because it explains the thought process. Another example of unnecessary documentation would be if a decision memo is prepared recommending a suspension based on an insufficient plant response to a NOIE, and the suspension letter contains the same information in the decision memo. If a suspension letter addresses the factors used to reach the suspension

decision, there is no need to prepare another decision document. The suspension letter would be the decision document provided there are adequate support documents in the AER to show how that decision was reached.

Decision Documents may consist of memos to the file:

- Documenting decisions reached after discussions with the TSC, OPHS, OPPD or other subject matter experts regarding the noncompliance and the plant's proposed corrective/preventive actions.
- Documenting decisions reached after discussions with plant officials regarding proposed corrective actions or matters that need further clarification.
- Documenting FSIS' verification activities and recommending next appropriate action.
- Recommending reinstating a suspension.
- Recommending filing a complaint to withdraw inspection.

Points to Consider When Preparing Decision Documents:

- What data and information exists to support the decision?
- What conclusions have been reached regarding an analysis of the data and information?
- What is the significance of the data and information?
- Does the data and information demonstrate that the plant is executing its corrective and preventive measures in a manner that is producing a safe food?
- What is the public health significance of the results of the data and information?
- What directives, policies, or regulations are at issue?
- What sections of the FMIA, PPIA or EPIA are at issue?
- Does the information conclusively support the decision reached?
- What should be the recommended next course of action?

Typical Exhibits for Various Actions

Exhibits include all documents and photographs that are attached to FSIS Form 5400-9 to support the action taken. The following sets out the typical exhibits that may be found as part of the AER file for the action as listed in block 11:

Enforcement Actions

For enforcement actions pursuant to 9 CFR part 500, the exhibits may include:

- FSIS Form 5000-8 and accompanying exhibit list (e.g., all relevant NRs).
- Food Safety Assessment reports that served as the basis for taking enforcement.
- Memoranda of interview.
- Conversation records documenting discussions with the TSC; OPPED, or OPHS.
- Any relevant laboratory results.
- Any relevant photographs of product conditions or plant conditions.
- The NOIE and establishment response.
- Communications regarding deferral actions and establishment response, if applicable.
- Communications regarding withholding or suspension actions and the establishment response.
- Communications regarding abeyance actions and establishment response, if applicable.
- Communications regarding withholding of labels.

Custom Exempt Reviews

For a review of custom exempt operations before referral to OPEER, the exhibits may include:

- Review forms.
- Photographic evidence of the condition of product, as well as conditions under which the product is produced.
- Memoranda of interview with facility management regarding the situation.
- Letters of warning issued by the DO.
- Decision memoranda for various enforcement actions up to recommendation of removal of exemption privilege.

Detentions

For detention actions as described in FSIS Directive 8410.1, Detention and Seizure, the exhibits may include:

- Evidence such as laboratory reports.
- Photographic evidence of the adulterated or misbranded product and the condition under which it was being packaged and held.
- Memoranda of interview with the responsible officials.
- Photograph of the —US Detain Tag“.
- FSIS Form 8080-1, Notice of Detention.
- FSIS Form 8080-4, Voluntary Destruction Notice.

- Evidence that the product was destroyed (e.g., a renderer‘s record).
- Communications regarding approval of extended detention procedures.
- Paperwork surrounding court seizure.
- FSIS Form 8400-1, Notice of Termination or Destruction.

Recalls

For a recall related incident, the exhibits may include:

- Recall worksheets.
- Memoranda of interview with producing establishment management.
- Conversation records with inspection program personnel over critical issues.
- Decision memoranda to request voluntary recall.
- Laboratory reports (internal and external).
- CCMS or consumer documentation.
- Notification by recalling firm of consignees.
- Company press release.
- USDA press release.
- Recall notification report.
- Official notification by establishment of intent to voluntarily recall and the name of the coordinators.
- FSIS Form 8400-4, Report of Recall Effectiveness.

Prohibited Activities

For prohibited activities (e.g., adulterated product deliberately distributed into commerce), the exhibits may include:

- Memoranda of interview with responsible officials;
- Photographic evidence;
- FSIS decision memorandum;
- Information of how the product was shipped or received; and
- Any other information that supports the action.
- Illness Outbreak

Illness Outbreak

For an illness outbreak, the exhibits may include:

- Information supplied by FSIS or by other public health stakeholders.
- Memoranda of interview with affected parties.
- Description of the sample taken.
- Photographic evidence.
- Laboratory results.
- FSIS decision memorandum.

Non-Routine Incidents

For a non-routine incident report completed by the Case Specialist or District Staff in situations related to such activities as disposition of products or verification that contamination concerns have been addressed, the exhibits may include:

Investigative files of non-routine incidents;

- Photographic evidence;
- Memoranda of interview; and
- Memoranda describing incidents of adulteration.

Establishment Appeals

When an establishment appeals an administrative enforcement action or decision, the appeal will be decided on the basis of the establishment's appeal and the AER supporting the action or decision. Once the appeal is decided, the decision and any supporting documentation are to be included as an exhibit in the supporting AER.

Case File Scanning and Document Management

The physical copies of FSIS Form 5400-9 and the supporting documentation are maintained at the appropriate District Office. The Case Specialist or District Staff will also scan the cases into a file two days after receiving the form and supporting documentation for administrative activities or within 24 hours of initiation of an Administrative Enforcement Action by the District Office. The Case Specialist or District Staff will send the scanned (TIFF) file to the Financial Processing Center (FPC) for processing and to create a PDF file that can be put onto a CD. A program called Kofax Ascent Capture is used at the FPC to process the images to create indexes that can be searched through SmeadLink, which is a database program.

FSIS Form 5400-9 Blank Example

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
FIELD OPERATIONS

ADMINISTRATIVE ENFORCEMENT REPORT

1. REPORT NO.

2. EST. NO.

3. EST. ID.

4. NON-COMPLIANCE TYPE *(Check all applicable boxes)*

☐ SPS ☐ SSOP ☐ HACCP ☐ HUMANE TREATMENT ☐ THREAT, INTIMIDATION, ASSAULT ☐ OTHER _____

5(a). NAME OF BUSINESS _____

5(b). ADDRESS OR P.O. BOX _____

5(c). CITY, STATE, ZIP CODE _____

☐ Check if the business type is a non-federally inspected facility.)

6. TYPE OF NON-FEDERALLY INSPECTED BUSINESS

☐ Broker/Distributor
☐ Retail/Restaurant
☐ Other _____ *(Describe)*

7. PLANT SIZE

☐ Large
☐ Small
☐ Very Small

8. HACCP PROCESSING CATEGORIES *(If non-compliance type shown in block 2 is HACCP, check all that apply to the NOIE/Suspension letter issued)*

☐ Slaughter - all species
☐ Raw Product - ground
☐ Raw Product - not ground
☐ Thermally Processed - commercially sterile
☐ Not Heat Treated - shelf stable
☐ Heat Treated - shelf stable
☐ Fully Cooked - not shelf stable
☐ Heat Treated But Not Fully Cooked - not shelf stable
☐ Product With Secondary Inhibitors - not shelf stable

9. PRODUCT TYPE

☐ Meat ☐ Poultry
☐ Meat/Poultry ☐ Eggs

10. LABORATORY FINDINGS (Check if applicable to case)

☐ Listeria monocytogenes ☐ Salmonella ☐ E. coli O157:H7
☐ Other (specify): _____

11. REPORT TYPE AND DATE OF ACTIONS

NOIE _____ DEFERRAL _____ SUSPENSION _____ ABEYANCE _____

REINSTATEMENT_____ WITHHOLDING OF LABELS _____
(Dates the establishment provided written notice of these actions)

CUSTOM (1) _____ CUSTOM (2) _____ CUSTOM (3) _____
(Date LOW) ***(Date LOW)*** ***(Date LOW)***

DETENTION _____ TERMINATION _____
(Date product detained, and if applicable, terminated by FSIS personnel)

RECALL (1) _____ RECALL (2) _____
(Date product was recalled by producing firm) ***(Date of final recall effectiveness report to RMD)***

RECALL (FSIS Recall Number) _____ PROHIBITED ACTIVITY _____
(Date establishment/business provided written notice of this action)

APPEAL (1) _____ APPEAL (2) _____ APPEAL (3) _____
(Date of appeal to DM) ***(Date of appeal to EARO)*** ***(Date of EARO decision)***

ILLNESS OUTBREAK (1)_____ ILLNESS OUTBREAK (2) _____
(Date investigation closed with no enforcement action) ***(Date enforcement action initiated)***

NON ROUTINE INCIDENT _____ OTHER (Specify): _____ _____
(Date incident reported to OFSEP) ***(Date of action)***

12. COMPREHENSIVE ASSESSMENT OF THE EXECUTION AND DESIGN OF AN ESTABLISHMENT'S FOOD SAFETY SYSTEMS

FROM: _____ TO: _____

13. OTHER SPECIAL REVIEW (e.g. IDV, Epidemiological Review, etc.) _____

FROM: _____ TO: _____

14. REFERRED TO OPEER FOR: *(Provide date of referral)*

COMPLAINT _____ *(Date)* SEIZURE _____ *(Date)*

TERMINATE CUSTOM _____ *(Date)* CRIMINAL INVESTIGATION _____ *(Date)*

OTHER (Specify): _____ _____ *(Date)*

15. LIST PAST/RELATED REPORTS

16. COMPLETE WHEN CASE IS CLOSED

LOI DATE _____ LOW DATE _____ OTHER (Specify): _____ DATE _____

17. SIGNATURE OF ENFORCEMENT INVESTIGATION AND ANALYSIS OFFICER	18. SIGNATURE OF CASE SPECIALIST	19. DATE

FSIS FORM 5400-9 (4/14/2005) PREVIOUS EDITIONS ARE OBSOLETE. Designed in FormFlow

PAGE ____ OF ____ PAGES

LIST OF EXHIBITS

NAME/ADDRESS OF ESTABLISHMENT	REPORT NO.

EXHIBIT NUMBER	DESCRIPTION

FSIS FORM 5400-9 (2/17/2005)

Example 5400-9 for Training Purposes Only

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
FIELD OPERATIONS

ADMINISTRATIVE ENFORCEMENT REPORT

1. REPORT NO. 65-06-S003

2. EST. NO. 00038 M

3. EST. ID.

4. NON-COMPLIANCE TYPE *(Check all applicable boxes)*
☐ SPS ☒ SSOP ☒ HACCP ☐ HUMANE TREATMENT ☐ THREAT, INTIMIDATION, ASSAULT ☐ OTHER

5(a). NAME OF BUSINESS: XYZ Company, Inc
5(b). ADDRESS OR P.O. BOX: Avenue A
5(c). CITY, STATE, ZIP CODE: Anywhere, NY 12345
☐ Check if the business type is a non-federally inspected facility.)

6. TYPE OF NON-FEDERALLY INSPECTED BUSINESS
☐ Broker/Distributor
☐ Retail/Restaurant
☐ Other _____ *(Describe)*

7. PLANT SIZE
☐ Large
☒ Small
☐ Very Small

8. HACCP PROCESSING CATEGORIES *(If non-compliance type shown in block 2 is HACCP, check all that apply to the NOIE/Suspension letter issued)*
☐ Slaughter - all species
☐ Raw Product - ground
☐ Raw Product - not ground
☐ Thermally Processed - commercially sterile
☐ Not Heat Treated - shelf stable
☐ Heat Treated - shelf stable
☒ Fully Cooked - not shelf stable
☐ Heat Treated But Not Fully Cooked - not shelf stable
☐ Product With Secondary Inhibitors - not shelf stable

9. PRODUCT TYPE
☒ Meat ☐ Poultry
☐ Meat/Poultry ☐ Eggs

10. LABORATORY FINDINGS (Check if applicable to case)
☒ Listeria monocytogenes ☐ Salmonella ☐ E. coli O157:H7
☐ Other (specify): _____

11. REPORT TYPE AND DATE OF ACTIONS
NOIE _____ DEFERRAL _____ SUSPENSION 3-05-06 ABEYANCE 3-26-06
REINSTATEMENT _____ *(Dates the establishment provided written notice of these actions)*
WITHHOLDING OF LABELS _____
CUSTOM (1) _____ *(Date LOW)* CUSTOM (2) _____ *(Date LOW)* CUSTOM (3) _____ *(Date LOW)*
DETENTION _____ TERMINATION _____ *(Date product detained, and if applicable, terminated by FSIS personnel)*
RECALL (1) _____ *(Date product was recalled by producing firm)*
RECALL (2) _____ *(Date of final recall effectiveness report to RMD)*
RECALL (FSIS Recall Number) _____
PROHIBITED ACTIVITY _____ *(Date establishment/business provided written notice of this action)*
APPEAL (1) _____ *(Date of appeal to DM)* APPEAL (2) _____ *(Date of appeal to EARO)* APPEAL (3) _____ *(Date of EARO decision)*
ILLNESS OUTBREAK (1) _____ *(Date investigation closed with no enforcement action)*
ILLNESS OUTBREAK (2) _____ *(Date enforcement action initiated)*
NON ROUTINE INCIDENT _____ *(Date incident reported to OFSEP)*
OTHER (Specify): _____ *(Date of action)*

12. COMPREHENSIVE ASSESSMENT OF THE EXECUTION AND DESIGN OF AN ESTABLISHMENT'S FOOD SAFETY SYSTEMS
FROM: _____ TO: _____

13. OTHER SPECIAL REVIEW _____ (e.g. IDV, Epidemiological Review, etc.)
FROM: _____ TO: _____

14. REFERRED TO OPEER FOR: *(Provide date of referral)*
COMPLAINT _____ *(Date)* SEIZURE _____ *(Date)*
TERMINATE CUSTOM _____ *(Date)* CRIMINAL INVESTIGATION _____ *(Date)*
OTHER (Specify): _____ *(Date)*

15. LIST PAST/RELATED REPORTS

16. COMPLETE WHEN CASE IS CLOSED
LOI DATE _____ LOW DATE _____ OTHER (Specify): _____ DATE _____

17. SIGNATURE OF ENFORCEMENT INVESTIGATION AND ANALYSIS OFFICER

18. SIGNATURE OF CASE SPECIALIST

19. DATE

FSIS FORM 5400-9 (4/14/2005) PREVIOUS EDITIONS ARE OBSOLETE. Designed in FormFlow

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LIST OF EXHIBITS

NAME/ADDRESS OF ESTABLISHMENT	REPORT NO.
XYZ Company, Inc. Avenue A Anywhere, NY 12345	65-06-S003

EXHIBIT NUMBER	DESCRIPTION
1	Notice of Suspension in Effect dated March 5, 2006 with addendum dated March 6, 2006; Decision Memo to District Manager dated March 5, 2006.
2	Establishment Response to Notice of Suspension dated March 17, 2006. Cover letter document with three enclosures 1) List of contamination source potentials, 2) SSOP modifications, and 3) GMP modifications.
3	Additional establishment response to Notice of Suspension dated March 18, 2006, with four enclosures 1) HACCP modifications, 2) SSOP modifications, 3) Listeria Sampling Program, and 4) Contract Laboratory Analysis Report
4	USDA Technical Service Center analysis of establishment's response to the Notice of Suspension dated March 20, 2006.
5	Signed statement of Joseph K. Labrat, Quality Assurance Manager
6	Letter from District Office to Establishment dated March 21, 2006, requesting further corrective and preventive actions.
7	Establishment response to District Office letter dated March 24, 2006, consisting of three enclosures 1) Cover document, 2) HACCP and SSOP modification and 3) Listeria Monitoring Sampling Program
8	Suspension in Abeyance dated March 26, 2006, and Decision Memo to District Manager
9	FSIS Verification Plan regarding Suspension in Abeyance
10	Noncompliance Record #03-06 dated March 31, 2006, documenting Sanitation Performance Standards (SPS) deficiencies
11	Noncompliance Record #04-06 dated April 1, 2006 documentation Sanitation Standard Operating Procedures (SSOP)
12	April 15, 2006, IIC notes regarding weekly PBIS meeting with plant management

FSIS FORM 5400-9 (2/17/2005)

Designed In FormFlow Software

Workshop

1. Describe the purpose of the AER system.

2. Describe the role of the EIAO in the AER process.

3. Describe what an exhibit is and the types of exhibits that may be part of an AER file for a NOIE issued to a plant as a result of findings during a Food Safety Assessment.

4. Describe the purpose of a decision document and when you would prepare one.

5. Describe the purpose of a memorandum of interview and what it should include.