
Introduction to AER

- FSIS Directive 5100.3
 - Administrative Enforcement Action Decision Making and Methodology
- FSIS Form 5400-9
 - Administrative Enforcement Report
 - The electronic 5400-9 is maintained in AssuranceNet



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AER Initiation

- The AER is prepared to include the supporting documentation and evidence that was used to support the action.



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AER Report and Exhibits

- Demonstrates FSIS had sound basis
 - provides an outside reader such as a judge an understanding of the key events associated with the case



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Other Actions that Require an AER

- Recall effectiveness checks
- Prohibited activities as indicated FMIA Sec 610 & PPIA Sec 458-459
- Appeals to the District Manager
- Requests to withdraw custom exemption
- Requests to withdrawal of inspection services

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AssuranceNet

- The case management component of the AssuranceNet is used to:
 - Maintain an “electronic” copy of the AER including:
 - FSIS Form 5400-9
 - A list and description of each exhibit
 - The exhibit documents
 - Search and review of AER information

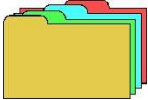


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During All Phases of Enforcement

- Develop and compile supporting documents for decisions reached
 - Examples
 - Noncompliance Records
 - Food Safety Assessments
 - Establishment Records
 - Lab Reports
 - Photographs
 - Letters/MOIs




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Supporting Documents

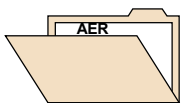
- Described in the AER system in a way that make the facts of the case clear
 - Who
 - What
 - When
 - Where
 - and How of the alleged violation
- For enforcement actions, the documents are to link the alleged violations with FSIS statutory and regulatory requirements



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AER Case File


- For each administrative action:
 - One “hardcopy” is prepared and maintained in the District Office including:
 - Signed copies of Agency enforcement letters
 - Other FSIS letters pertaining to action
 - Any responses from establishment officials
 - Any responses to the establishment



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Appeals

- If an establishment appeals
 - Decision will be made based on the appeal and the AER in support of the action/decision
 - A copy of decision to deny or sustain the appeal along with supporting documentation must be included as an exhibit in the AER



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District Case Specialist

- DCS has primary responsibility to ensure:
 - All AER information is entered in AssuranceNet
 - Official hardcopy of the report is maintained



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Entering the AER in AssuranceNet

- The procedure for entering information into AssuranceNet may vary.
 - If an EIAO has the necessary computer equipment and internet access, they may enter AER information directly into the system.
 - Other times, it may be more efficient for the DCS to enter the information into the system in the District Office .

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Entering the AER in AssuranceNet

- The DCS will discuss with you the method used in your District for entering cases into AssuranceNet.



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Time Frames for Entry

- FSAs that result in enforcement action should be entered into AssuranceNet within 48 hours of the exit conference.
- As new information is gathered; this information should be added to keep the AER up to date



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AER Numbering System

- Numbered by Report Type
- Examples
 - NOIE AER
 - 80-16-N003

District FY NOIE

3rd NOIE that
was created
nationally
during the FY

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AER Report Types

- N NOIE 80-16-N003
- S Suspension 80-16-S001
- R Reinstatement 80-16-R001
- A Appeals to DM
- REC Recall Effectiveness Checks

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AER Report

NOIE

Suspension

Reinstatement

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EIAO Role – Perform FSA

- Performs PHREs, FSAs, investigations, and administrative activities, analyzes and documents findings
- Recommends appropriate enforcement action
- Collects all relevant information and evidence to support the AER

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EIAO Role – Communicate Findings

- Communicates findings to the IPP, FLS, SEIAO, District Case Specialist, DDM/DM, and establishment
- Information used to support enforcement must be documented in one of the following:
 - PHRE
 - FSA Report
 - MOI
 - Other documents

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EIAO Role – Seek Expert Advice


- For clarification of scientific or technical issues prior to recommendation
 - Contact OPPD or OPHS, use “Ask FSIS”
 - Document guidance and include in AER
- For expedited help in any unusual cases contact the District Office



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EIAO Role – Draft Letters

- Draft NOIE and Suspension letters or other documents associated with an AER



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NOTICE OF INTENDED ENFORCEMENT

Mr. Joe,

This serves as official notification by the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) of its intent to withhold the marks of inspection and suspend the assignment of inspection program personnel at Joe’s BBQ, Establishment 12345 M/P, located at 62 Joe’s Industrial Blvd., Joetown, JO 12345.

BACKGROUND/AUTHORITY

The Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.) and Poultry Products Inspection Act (PPA) (21 U.S.C. 451 et. seq.) provides that it is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and poultry, and meat and poultry food products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged.

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EIAO Role – Verification Plan

- Develop a Verification Plan when a deferral or abeyance decision is made
- Discuss the VP with the DCS, FLS, IPP, and establishment

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EIAO Role – Follow-up Visits

- Conduct follow-up visits at 30, 60, and 90 day intervals
 - Evaluate generated data
 - Determine if corrective actions are effective
 - Provide recommendations and decide next steps

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District Case Specialist

- The DCS takes the lead in developing the AER strategy and assuring that the AER has all documents to support enforcement or other action
- The DCS communicates with EIAOs as AER cases are in progress

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District Case Specialist


- Serves as the designed Evidence Officer and maintains AER system
- Ensures the integrity of all documentation
- Reviews PHRE and FSA and ensures recommendations are supportable
- Responsible for the final AER

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District Case Specialist

- Ensures proper distribution of the enforcement letters
- Includes all relevant documents are in AER case file



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District Manager

- Ensures administrative enforcement actions are consistent with policy
- Communicates with the DCS and EIAO about case strategy
- Correlates with the OFO AERO
- Refers the case to ELD/CID for violations that require administrative enforcement action, seizure, or other issues as needed

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Exhibit Examples

- FSIS Form 5400-9 and accompanying exhibit list
- FSA Report
- Copies of HACCP, SSOP, prerequisite records
- Decision documents, MOIs
- Guidance from OPHS, OPPD or AskFSIS
- Lab results
- Relevant photographs
- Establishment responses to agency letters
- Communications regarding actions
- Any document that supports decisions

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Order of Exhibits


- First exhibit should be the letter to establishment notifying them of the action or intended action
- Last exhibit should be the document closing out the action



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Example NOIE AER


- Initial Exhibit - NOIE letter
- Final Exhibit
 - Letter of Warning
 - Notice of Suspension



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Example Suspension AER

- Initial Exhibit – Notice of Suspension
- Final Exhibit
 - Letter of Warning
 - Notice of Reinstatement of Suspension
 - Referral Letter
 - Voluntary Withdrawal of Inspection Letter



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Evidence Procedures

- EIAOs must collect, maintain, and safeguard evidence.
- Follow FSIS Directive 8010.3, Procedures for Evidence Collection, Safeguarding and Disposal, when sending evidence you collect that is associated with an AER to the District Office/ District Case Specialist.

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Workshop – Directive 5100.3

1. List types of enforcement letters EIAOs may draft
2. Describe the exhibits that may close a Reinstatement AER

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Questions



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