

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

<h1 style="margin:0">FSIS DIRECTIVE</h1>	5100.3 Revision 1	3/7/06
--	----------------------	--------

ADMINISTRATIVE ENFORCEMENT REPORTING (AER) SYSTEM

I. PURPOSE

The purpose of this directive is to issue FSIS Form 5400-9, Administrative Enforcement Report, explain when and how the form is used, and set out the exhibits that Enforcement Investigative Analysis Officers (EIAOs) are to compile to support the different actions covered by the AER.

II. CANCELLATIONS

FSIS Directive 5100.3, dated 10/26/05

III. REASON FOR REISSUANCE

FSIS is reissuing this directive to provide clarification regarding the use of photographs for the purpose of exhibits in an AER report.

IV. REFERENCES

9 CFR part 313, 416, 417, and 500
FSIS Directive 8410.1, 8080.1, Revision 4, 5000.1, Revision 1, 5100.2, 5420.1, Revision 2, 6500.1, and 6500.2

V. BACKGROUND

A. To ensure that all administrative actions are fully supported and based on the relevant facts, the Acts, and the applicable regulations, FSIS instituted the AER system and the AER form, FSIS Form 5400-9. The system provides for the proper and accurate maintenance of documents produced by the Agency related to various administrative actions.

B. OFO personnel carry 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 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., Notice of Intended Enforcement Action (NOIE), the Case Specialist or designee begins FSIS Form 5000-9, and all supporting documentation will be attached exhibits to the AER form.

DISTRIBUTION: Inspection Offices; T/A Inspectors; Plant Mgt; T/A Plant Mgt; TRA; ABB; TSC; Import Offices **OPI: OPPEd**

C. OFO personnel also carry out other administrative activities for which an FSIS Form 5000-9 is started, and all supporting documentation will be attached exhibits. Such administrative activities include:

1. Reviews of the sanitary conditions at custom exempt operations, and, when necessary, the preparation of written recommendations along with 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 as set out in FSIS Directive 8080.1, Revision 4, Recall of Meat and Poultry Products, and FSIS Directive 5100.2, Enforcement, Investigations, and Analysis Officers (EIAO) Responsibilities Related to Recalls and Consumer Complaints,
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. Investigating illness outbreaks such as an illness outbreak related to a recall, and

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.

D. Under the AER system, OFO personnel at all phases of an administrative enforcement action are to develop and compile supporting documents for the decision reached. Supporting documents include Noncompliance Records (NRs) (FSIS Form 5400-5), EIAO assessment reports, District Veterinary Medical Specialist (DVMS) reports, laboratory findings, agency letters, corrective and preventive measures provided by an establishment that have been determined to be unacceptable, photographs, and memoranda of interview. 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 what has occurred violates the Acts.

E. 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.

VI. FSIS FORM 5400-9 AND AER NUMBERING SYSTEM

A. FSIS Form 5400-9 is available on outlook at: Public Folders\All Public Folders\Agency Issuances\Forms\FSIS 5,000 SERIES.

B. To number the AER, the first number is the DO number and 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 N indicates the issuance of an NOIE in Albany (65) in fiscal year 2005 (05). The last numbers, 003, mean the NOIE is the 3rd NOIE issued in Albany in the fiscal year.

<u>AER Report Type</u>	<u>Report Number</u>
1) NOIE (N)	65-05- N 003
2) Suspension (S)	65-05- S 001
3) Reinstatement (R)	65-05- R 001
4) Appeal to DM (A)	65-05- A 010
5) Withholding of Labels (WL)	65-05- WL 001
6) Custom (C) (Request to withdraw the custom exemption)	65-05- C 001
7) Recall Effectiveness Check (REC)	65-05- REC 001
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). The FSIS recall numbering system is based on calendar years, while the AER numbering system is by fiscal years.	
8) Detention (D)	65-05- D 002
9) Prohibited Act (PA)	65-05- PA 001
10) Outbreak of Illnesses Investigation (OI)	65-05- OI 001
11) Non-routine incident report (NRI)	65-05- NRI 001

12) Withdraw of Inspection (**W**) 65-05-**W001**

NOTE: This would be specified under **OTHER** in block 11.

13) Complaint for Suspension (**CS**) 65-05-**CS001**

NOTE: This would be specified under **OTHER** in block 11.

14) Other 65-05-**O001**

C. For incidents involving assistance from multiple Districts, there would be one District assigned overall responsibility for completing the AER. For example, for recalls involving multiple Districts, the District Recall Officer would be responsible for ensuring that the AER includes recall effectiveness check information collected by the assisting Districts and there would be only one AER.

D. For incidents that have individual AERs and that are related (e.g., a situation where in the course of a recall there has been a prohibited act), Block 15 for each FSIS Form 5400-9 should list the related AER report number (e.g., the AER form for the recall would list AER number under which the prohibited act was recorded and AER for the prohibited act would list the AER number under which the recall was recorded).

VII. PHOTOGRAPHS AND DOCUMENTS

A. Photographic Evidence

1. In compiling an AER file, it may be necessary for OFO personnel (e.g., EIAOs) who have been trained and supplied a camera issued by FSIS 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 violative. OFO personnel may be instructed to take photographs for other purposes; however, at no time are OFO personnel to take photographs if they 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.

2. The purpose of photographic evidence is to:

a. provide a visual documentation of the facts, conditions, or the sequence of events; and to

b. provide visual support that there was a problem or violation of the law.

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

- a. whenever possible, any document list in paragraph VII. B.
- b. evidence of rodents or insect infestation, faulty construction or maintenance, or other failure of Sanitation Performance Standard conditions which contribute to insanitary conditions;
- c. routes of, as well as, actual contamination of raw materials or finished products;
- d. condition of raw materials or finished products;
- e. employee practices contributing to adulteration of product or to violative conditions;
- f. manufacturing processes;
- g. effluent contamination of water systems; and
- h. labeling.

B. Documents

1. Documents include all FSIS Forms (e.g., NRs, and the Food Safety Assessment). Documents also include:
 - a. 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,
 - b. 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.
 - c. decision documents that render an FSIS opinion about a matter, memoranda from District Managers (DM) to Office of Field Operations (OFO) Headquarters management, or memoranda between Assistant Administrator offices.
 - d. 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. Such memoranda are to:
 - i. identify all participants present at the meeting;
 - ii. explain all facts that provide the basis for the meeting;
 - iii. fully describe the meeting; and

- iv. be written in a concise and clear manner.

VIII. EXHIBITS

The following sets out the typical exhibits that are to be a part of the AER file for the action as listed in block 11:

A. Enforcement Actions

For enforcement actions pursuant to 9 CFR part 500, the exhibits would be:

- a. FSIS Form 5000-8 and accompanying exhibit list (e.g., all relevant NRs);
- b. Food Safety Assessment reports that served as the basis for taking enforcement;
- c. Memoranda of interview;
- d. Conversation records documenting discussions with the Technical Service Center; other parts of the Office of Policy, Program, and Employee Development; or Office of Public Health Science;
- e. Any relevant laboratory results;
- f. Any relevant photographs of product conditions or plant conditions;
- g. The NOIE and establishment response;
- h. Communications regarding deferral actions and establishment response, if applicable;
- i. Communications regarding withholding or suspension actions and establishment response;
- j. Communications regarding abeyance actions and establishment response, if applicable; and
- k. Communications regarding the withholding of labels.

B. Custom Exempt Reviews

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

- a. Review forms;
- b. Photographic evidence of the condition of product, as well as conditions under which the product is produced;

- c. Memoranda of interview with facility management regarding the situation;
- d. Letters of warning issued by the DO; and
- e. Decision memoranda for various enforcement actions up to recommendation of removal of exemption privilege.

C. Detentions

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

- a. Evidence such as laboratory reports;
- b. Photographic evidence of the adulterated or misbranded product and the condition under which it was being packaged and held;
- c. Memoranda of interview with the responsible officials;
- d. Photograph of the "US Detain Tag";
- e. FSIS Form 8080-1, Notice of Detention;
- f. FSIS Form 8080-4, Voluntary Destruction Notice;
- g. Evidence that the product was destroyed (e.g., a renderer's record);
- h. Communications regarding approval of extended detention procedures;
- i. Paperwork surrounding court seizure; and
- j. FSIS Form 8400-1, Notice of Termination or Destruction.

D. Recalls

For a recall as set out in FSIS Directive 8080.1, Revision 4, Recall of Meat and Poultry Products, and effectiveness checks as set out in FSIS Directive 5100.2, Enforcement, Investigations, and Analysis Officer (EIAO) Responsibilities Related to Recalls, and Consumer Complaints, the exhibits may include:

- a. Recall worksheets;
- b. Memoranda of interview with producing establishment management;

- c. Conversation records with inspection program personnel over critical issues;
- d. Decision memoranda to request voluntary recall;
- e. Laboratory reports (internal and external);
- f. CCMS or consumer documentation;
- g. Notification by recalling firm of consignees;
- h. Company press release;
- i. USDA press release;
- j. Recall notification report;
- k. Official notification by establishment of intent to voluntarily recall and the name of the coordinators; and
- l. FSIS Form 8400-4, Report of Recall Effectiveness

E. Prohibited Activities

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

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

F. Illness Outbreak

For an illness outbreak, the exhibits may include:

- a. Information supplied by FSIS or by other public health stakeholders;
- b. Memoranda of interview with effected parties;
- c. Description of the sample taken;

- d. Photographic evidence;
- e. Laboratory results; and
- f. FSIS decision memorandum.

G. 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:

- a. Investigative files of non-routine incidents;
- b. Photographic evidence;
- c. Memoranda of interview; and
- d. Memoranda describing incidents of adulteration.

H. OTHER

For any letters sent by FSIS that are not addressed in the above categories such as concerns related to recordkeeping requirements.

X. CASE FILE SCAN AND DOCUMENT MANAGEMENT PROCESS

A. The physical copies of FSIS Form 5400-9 and the supporting documentation are maintained at the appropriate District Office. Additionally, cases will be added to SmeadLink Express via processing images through a software called Kofax Ascent Capture. The Case Specialist or District Staff will 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 need to send the TIFF file to the Financial Processing Center (FPC) for processing and create a PDF file that can be put onto a CD. Kofax Ascent Capture is used at the FPC to process the images to create indexes that can be searched through SmeadLink. The following are the general procedures for the electronic case files.

B. Two days from receipt, the Case Specialist or District Staff will scan the FSIS Form 5400-9 so that Kofax can read data (all fields on form) for importing into Smead to provide search capabilities. The image files will be located on an FPC server so that the FPC IT Staff can retrieve the images for processing through Kofax and into Smead.

C. A record will be established within Smead for each AER and will be considered the main record linking each related exhibit by case number. The Case Specialist or District Staff will scan an exhibit cover sheet for each exhibit. The cover sheets provide a record within Smead for each exhibit.

D. If the exhibit contents are in paper format, the paper will follow the exhibit cover sheet during the physical scanning. If the exhibit is physically scanned, the images will be displayed in Smead as pages; each page will be displayed as a thumbnail.

E. If the exhibit contents are in electronic file format, the electronic files will be attached to the exhibit record within Smead. This process will be manually completed by the Case Specialist or District Staff and will occur after the FPC IT Staff processes the physically scanned TIFF images through Kofax and into Smead.

F. If the exhibit is created by attaching electronic files, the images will be displayed as icons rather than thumbnails of the actual pages. To view the electronically attached files, the user must click on the icon to open the file. The user must also have the software of the attached file on the computer he or she is using to view the file in its format. Example: If a file is attached as a Word document, the user must have Word or the Word viewer installed on the computer to view the document.

G. The process to attach electronic files to records in Smead is briefly described below:

1. Exhibit record must be established in Smead as explained above,
2. Select and then right click on exhibit record that will house attached files,
3. Select "Attach PC File",
4. Look in: Navigate to the path,
5. File name: Select file, and
6. Click on Open

H. The above steps must be completed for each electronic file attachment. Multiple files cannot be selected at one time.

I. If additional exhibits are created after the original case file is scanned and created in Smead, the FSIS Form 5400-9 will be modified by the Case Specialist or District Staff to add the additional exhibit to the "List of Exhibits" and the FSIS Form 5400-9 will be physically scanned along with the additional exhibit coversheet.

J. For recall effectiveness checks, the District Office for the establishment conducting the recall will input all information for recall effectiveness check information received from other Districts into Smead. District Offices that supply recall effectiveness

information are to scan the information and may dispose of paper copies.

Key fields identified by OFO to be indexed in Smead for search capabilities (these are on the FSIS Form 5400-9):

- ✓ Report Number
- ✓ Establishment Number
- ✓ Non-Compliance type
- ✓ Name of establishment
- ✓ Non-federally inspected business type
- ✓ Plant size
- ✓ HACCP processing categories
- ✓ Product type
- ✓ Laboratory findings
- ✓ Report type and date of actions
- ✓ Comprehensive assessment of the execution and design of an establishment's food safety systems
- ✓ Other special review
- ✓ Additional information
- ✓ Completed dates

The Smeadlink Express District Office User Training Guide can be found at:
Public Folders\All Public Folders\OM\FMD\FPC\USDA DO User Trng Guide.pdf.



Assistant Administrator
Office of Policy, Program, and Employee Development