
FSIS DIRECTIVE

8010.5
Revision 3

11/5/12

CASE REFERRAL AND DISPOSITION

I. PURPOSE

This directive describes the methodologies that Regional Directors (RD), Compliance and Investigations Division (CID), Office of Program Evaluation, Enforcement and Review (OPEER); Director, Import Inspection Division (IID), Office of International Affairs (OIA); and District Managers (DM), Office of Field Operations (OFO), or their designees, are to apply in determining action on Reports of Investigations (ROI), Administrative Enforcement Reports (AER), and other case documentation. It also describes the methodologies that the Director, Evaluation and Enforcement Division (EED), OPEER, or designee is to apply for evaluation and disposition of ROI, AER, and other case documentation referred to EED for criminal, civil, or administrative enforcement. Finally, it describes the methodologies that authorized OPEER-CID, OPEER-EED, OIA-IID, and OFO program employees are to follow for cases referred to EED for enforcement action.

KEY POINTS

- *Types of criminal, civil, and administrative enforcement actions*
- *How to refer ROI, AER, or other case documentation to EED*
- *Policies for Notices of Warning (NOW) and Letters of Information (LOI)*
- *Procedures for action on appeals of NOW*
- *Responsibilities of authorized OPEER, OIA, and OFO program employees*

II. CANCELLATION

FSIS Directive 8010.5, Revision 2, Case Referral and Disposition, dated 6/25/08

III. REASON FOR REISSUANCE

FSIS is reissuing this directive to update some procedures and to include OIA and OFO employees who will apply the procedures described in this directive.

IV. REFERENCES

Federal Meat Inspection Act (FMIA), (21 U.S.C. 601 et seq.)
Poultry Products Inspection Act (PPIA), (21 U.S.C. 451 et seq.)
Egg Products Inspection Act (EPIA), (21 U.S.C. 1031 et seq.)
Humane Methods of Slaughter Act (HMSA), (7 U.S.C. 1901-1907)
Agricultural Marketing Act of 1946, as amended (7 U.S.C. 1621, et seq.)
21 U.S.C. 458(a)(3)
9 C.F.R Sections 320.4, 381.146, 381.178, 500 and 590.200
FSIS Directive 8010.2, Investigative Methodology
FSIS Directive 8010.3, Procedures for Evidence Collection, Safeguarding and Disposal
FSIS Directive 8010.4, Report of Investigation
FSIS Directive 5930.1, Custom Exempt Review Process
FSIS Directive 5100.3, Administrative Enforcement Reports
FSIS Directive 8080.1, Recall of Meat and Poultry Products
FSIS Directive 5220.1, Granting or Refusing Inspection
FSIS Directive 8410.1, Detention and Seizure

V. BACKGROUND

The FMIA, PPIA, EPIA, and HMSA provide FSIS with the authority for criminal, civil, and administrative enforcement action when firms and individuals violate FSIS statutes and regulations. Criminal, civil, and administrative enforcement actions prevent adulterated, misbranded, or other illegal meat, poultry, and egg products from reaching consumers; stop ongoing violations; deter future violations; improve food safety; and impose, when necessary, sanctions for violations. FSIS takes administrative enforcement actions and recommends criminal and civil prosecution through the USDA Office of the General Counsel (OGC) and the Department of Justice (DOJ). FSIS also collaborates with the USDA Office of Inspector General (OIG) and with other Federal and State agencies on enforcement actions.

VI. CASE REPORTS

A. OPEER CID Investigators, OIA IID Import Surveillance Liaison Officers (ISLO), OFO Enforcement Investigations and Analysis Officers (EIAO), and other authorized program employees are to:

1. Complete ROIs, AERs, and other case documentation (e.g., Custom Exempt Review Reports), in accordance with applicable directives (e.g., FSIS Directive 8010.4, Report of Investigation; Directive 5100.3, Administrative Enforcement Reports; FSIS Directive 5220.1, Granting or Refusing Inspection; FSIS Directive 5930.1, Custom Exempt Review Process);
2. Submit ROI, AER, and other case documentation through their supervisor to their respective management official (i.e., CID RD, OFO DM, IID Director) for review and action, in accordance with the applicable directives (e.g., FSIS Directive 8010.4, Report of Investigation; FSIS Directive 5100.3, Administrative Enforcement Reports; FSIS Directive 5220.1, Granting or Refusing Inspection; FSIS Directive 5930.1, Custom Exempt Review Process).

VII. CASE ACTIONS

A. CID RD, IID Directors, and OFO DM are to review ROI, AER, and other case documentation, as necessary, and make a determination on the appropriate enforcement action or case referral.

B. CID RD, as appropriate, is to:

1. Refer the ROI or other case documentation to EED when it describes violations that require evaluation for:
 - a. Criminal enforcement action (e.g., sale or transport of adulterated products; gross negligence in sanitation, handling, or storage that causes product adulteration; misbranding that poses a threat to public health; illegal slaughter; economic fraud; intent to defraud);
 - b. Civil enforcement action (e.g., threat to public health; unsafe products in commerce; repetitive violations);
 - c. Administrative enforcement action (e.g., convictions of applicants for or recipients of Federal inspection service);
 - d. Seizure of adulterated, misbranded, or other illegal product in commerce (see FSIS Directive 8410.1, Detention and Seizure); or
 - e. Administrative subpoena when program employees are denied access to or examination of facilities, inventory, or records (see FSIS Directive 8010.2, Investigative Methodology; FSIS Directive 8010.3, Procedures for Evidence Collection, Safeguarding and Disposal).
2. Issue a Notice of Warning (NOW) (see section XI) or a Letter of Information (LOI) (see section XIII);
3. Recommend continued verification through in-commerce surveillance or other regulatory activities;
4. Close the ROI or other case documentation with no action; or
5. Refer the ROI or other case documentation to OIG, in accordance with the Memorandum of Agreement (MOA) with OIG (see FSIS Directive 8010.2, Investigative Methodology) or to another Federal or State agency.

C. IID Directors, as appropriate, are to:

1. Refer the ROI or other case documentation to EED when it describes violations that require evaluation for:
 - a. Civil enforcement action (e.g., threat to public health; unsafe products in commerce; repetitive violations);
 - b. Administrative enforcement action (e.g., convictions of applicants for or recipients of Federal inspection service (see FSIS Directive 5220.1, Granting or Refusing Inspection);
 - c. Seizure of adulterated, misbranded, or other illegal product in commerce (see FSIS Directive 8410.1, Detention and Seizure); or

- d. Administrative subpoena when program employees are denied access or examination of facilities, inventory, or records (see FSIS Directive 8010.2, Investigative Methodology; FSIS Directive 8010.3, Procedures for Evidence Collection, Safeguarding and Disposal).
2. Issue a Notice of Warning (NOW) (see section XI) or a Letter of Information (LOI) (see section XIII);
3. Recommend continued verification through in-commerce surveillance or other regulatory activities;
4. Close the ROI or other case documentation with no action; or
5. Refer the ROI or other case documentation to CID when it involves violations that may require referral for criminal or civil prosecution (e.g., sale or transport of adulterated or misbranded product in commerce; fraud; false claims), referral to OIG under the MOA between FSIS and OIG (e.g., alleged criminal acts involving meat, poultry, or egg products; smuggling), or referral to another Federal or State agency for criminal or civil action.

NOTE: The IID Directors are to refer such matters and allegations to CID as early as possible; OIA personnel are not to conduct investigations into criminal matters.

D. OFO DM as appropriate, are to:

1. Refer the AER or other case documentation to EED when it describes violations that require evaluation for:
 - a. Administrative enforcement action (e.g., withdrawal of inspection for failure to maintain sanitary conditions, Hazard Analysis and Critical Control Points (HACCP) violations; inhumane slaughter or handling; intimidation or assault of inspection personnel; repeated or serious violations of custom exempt requirements; or convictions of applicants for or recipients of Federal inspection service (see FSIS Directive 5100.3, Administrative Enforcement Reporting System; FSIS Directive 5930.1, Custom Exempt Review Process; FSIS Directive 5220.1, Granting or Refusing Inspection);
 - b. Seizure of adulterated, misbranded, or other illegal product in commerce (see FSIS Directive 8410.1, Detention and Seizure); or
 - c. Administrative subpoena when program employees are denied access or examination of facilities, inventory, or records (see FSIS Directive 5100.3, Administrative Enforcement Reports; FSIS Directive 8010.3, Procedures for Evidence Collection, Safeguarding and Disposal).
2. Take regulatory enforcement action (e.g., withholding actions, suspensions), issue administrative enforcement letters (e.g., prohibited activity, letter of warning (LOW)), or take other regulatory action (e.g., Notice of Intended Enforcement), in accordance with the Rules of Practice (9 C.F.R Part 500) and applicable FSIS Directives (e.g., Directive 5100.3, Administrative Enforcement Reporting System; FSIS Directive 8080.1, Recall of Meat and Poultry Products; FSIS Directive 5930.1, Custom Exempt Review Process); or
3. Refer the AER or other case documentation to CID when it involves violations that may require investigation of or referral for criminal or civil prosecution (e.g., sale or transport of adulterated or misbranded product in commerce; illegal slaughter; fraud), referral to

OIG under the MOA between FSIS and OIG (e.g., alleged criminal acts involving meat, poultry, or egg products; fraud), or referral to another Federal or State agency for criminal or civil action.

NOTE: The DMs are to refer such matters and allegations to CID as early as possible; OFO personnel are not to conduct investigations into criminal matters.

VIII. CASE REFERRAL TO EED

A. When referring the ROI, AER, or other documentation to EED, the CID RD, IID Directors, and OFO DM are to:

1. Prepare a transmittal memo to the attention of the Director of EED stating the recommended action (e.g., criminal prosecution, civil injunction, seizure, refusal or withdrawal of inspection service, termination of custom exemption, administrative subpoena), as applicable:
 - a. CID referrals are to be routed from the RD to EED.
 - b. OIA referrals are to be routed from the IID Director to EED;
 - c. OFO referrals are to be routed from the DM through the Executive Associate for Regulatory Operations (EARO), to EED.
2. Ensure copies of the ROI, AER, or other case documentation and transmittal memo are available and provided, as necessary, with any recommendation for enforcement action.
3. Submit the ROI, AER, or other case documentation, transmittal memo, and case evidence to EED electronically through the AssuranceNet/In-Commerce System (ANet/ICS), where possible, or by e-mail.

NOTE: EED, OGC, OIG, or the U.S. Attorney's Office may request a hard copy of the ROI and the original evidence. Program employees are to follow the procedures in FSIS Directive 8010.3 for any transfer of original evidence.

IX. EED CASE REVIEW AND DISPOSITION

A. OPEER, EED Director is to take one or more of the following actions, as appropriate:

1. Review the ROI, AER, or other case documentation referred to EED for criminal, civil, or administrative enforcement action and make a determination on the appropriate action (e.g., initiate criminal or civil enforcement action through OGC or DOJ; take or initiate administrative enforcement action; issue a NOW, LOI, or other enforcement correspondence; close case with no action; or take other action);
2. Contact the RD, IID Director, or DM to discuss the case findings, sufficiency of the evidence, or related matters;
3. Take administrative enforcement action to terminate custom exempt eligibility by issuing a "Notice of Ineligibility for Custom Exempt Status" (NOI) to custom exempt operators (see FSIS Directive 5930.1, Custom Exempt Review Process);
4. Refer the ROI, AER, or other case documentation to OGC for initiation of administrative enforcement proceedings (e.g., refusal or withdrawal of inspection service);

5. Refer the ROI, AER, or other case documentation to OGC or DOJ with a recommendation for criminal prosecution, civil injunction, civil seizure, or other enforcement proceedings or legal action;
6. Obtain an administrative subpoena, through OGC;
7. Issue "Present Your Views" (PYV) letters to provide alleged violators the opportunity to present views and information regarding allegations prior to the initiation of criminal or civil proceedings. EED may determine that PYV letters are not necessary in accordance with FSIS statutes and regulations (21 U.S.C. 1042 and 462; 9 CFR 335.40);
8. Issue "Show Cause" letters (SCL) to provide alleged violators the opportunity to present views and information regarding allegations prior to the initiation of administrative proceedings. EED may determine that SCL letters are not necessary when in the public interest;

NOTE: Only EED will issue PYV and SCL letters.

9. Issue NOW, LOI, or other enforcement correspondence (see sections XI, XIII);
10. Close the ROI, AER, or other case documentation with no action or recommend continued verification or other regulatory activities;
11. Assist OGC and DOJ draft complaints, indictments, affidavits, declarations, and other documents; develop consent orders, consent decrees, plea agreements, pretrial diversion agreements, or other case disposition documents; prepare for, testify at, or otherwise participate in administrative hearings, prosecutions, civil hearings, or other legal proceedings;
12. Represent FSIS in negotiations and case disposition decisions with OGC, DOJ, regulated industry, and others;
13. Coordinate communication between and work with OGC, DOJ, OIG, RD, DM, IID Director, and other Agency personnel in case presentations, case dispositions, trial preparation, and related enforcement, case referral, and case disposition activities;
14. Coordinate follow-up surveillance, investigation, or other activities with the RD, DM, IID Director such as to determine compliance with case settlement terms once enforcement or legal actions are completed.

X. ENFORCEMENT LIAISON

A. Once CID refers a case to EED, the RD and CID program employees, are to:

1. Participate in conference calls with EED and others, when requested, to discuss case findings, evidence sufficiency, and related matters, to address any questions or concerns;
2. Participate in development of food safety, enforcement, and legal strategies, when requested;
3. Obtain, when needed, information from EED regarding precedent cases involving similar violations that have led to successful outcomes;
4. Present or participate in presenting case evidence to the U.S. Attorney;

5. Serve legal documents, attest to case evidence, or serve as a witness in legal proceedings, when requested;
6. Obtain certified copies of court sentencing documents, as well as other legal documents, when requested, and provide copies to EED as soon as practical;
7. Maintain periodic contact with the U.S. Attorney on enforcement and legal actions;
8. Participate in monitoring and verification activities to ensure that firms and individuals comply with case disposition and settlement items, once actions are completed;
9. Document case updates, verification activities, and related matters, in ANet/ICS, or otherwise, as applicable;
10. Inform EED, in a timely and complete manner, about case activities, developments, and other issues that may impact enforcement and legal actions; and
11. Conduct other activities to support enforcement or legal action, when requested by EED.

B. Once OIA refers a case to EED, the IID Directors and OIA program employees are to:

1. Participate in conference calls with EED and others, when requested, to discuss case findings, evidence sufficiency and related matters, and to address any questions or concerns;
2. Participate in development of food safety, enforcement, and legal strategies, when requested;
3. Participate with OPEER in presenting case evidence to the U.S. Attorney, when requested;
4. Attest to case evidence or serve as a witness in legal proceedings, when requested;
5. Participate in monitoring and verification activities to ensure that firms and individuals comply with case disposition and settlement items, once actions are completed;
6. Document case updates, verification activities, and related matters in ANet/ICS, or otherwise, as applicable;
7. Inform EED, in a timely and complete manner, about case activities, developments, and other issues that may impact enforcement and legal actions; and
8. Conduct other activities to support enforcement or legal action, when requested by EED.

C. Once OFO refers a case to EED, the DM and OFO program employees are to:

1. Participate in conference calls with EED and others, when requested, to discuss case findings, evidence sufficiency, and related matters and to address any questions or concerns;
2. Participate in development of food safety, enforcement, and legal strategies, when requested;
3. Attest to case evidence or serve as a witness in legal proceedings, when requested;
4. Participate in developing verification and monitoring plans, and conduct monitoring and

verification activities, to ensure that firms and individuals comply with settlement items, once actions are completed;

5. Document case updates, verification activities, and related matters in ANet/ICS, or otherwise, as applicable;
6. Inform EED, in a timely and complete manner, about case activities, developments, and other issues that may impact enforcement and legal actions; and
7. Conduct other activities to support enforcement or legal action, when requested by EED.

XI. NOTICES OF WARNING

A. The RD, IID Directors, or EED Director are to issue a NOW for minor violations, or otherwise as appropriate, as provided by the FMIA Section 406 (21 U.S.C. 676), PPIA Section 13 (21 U.S.C. 462), and EPIA Section 13 (21 U.S.C. 1042). The NOW identifies the violative conduct, condition, practice, or product; provides the opportunity to achieve voluntary compliance; and is sent to the firm and responsible individuals. Situations where a NOW is issued include, but are not limited to, those involving improperly labeled product with no intent to defraud and no public health risk.

B. The RD and IID Directors, as applicable, are to prepare the NOW for issuance, as appropriate, to each subject of the ROI and to responsible individuals.

C. If the case disposition is issuance of a NOW, and the investigation involves two (or more) CID or IID Regions, the RD or IID in the Region where the violation was discovered and initiated in the ICS is to investigate the case as completely as possible. The RD or IID Director is to then transfer the investigation, through ICS, to the Regions where the additional violators are located for further investigation. When all Regions complete their investigative activities, and the ROI is complete, each Region is to communicate (e.g., through e-mail) that investigative activities are complete. At that time, each Region will issue NOW letters to the violators (i.e., firms, responsible individuals) as supported by the ROI. For ROIs prepared by CID, the RD in the Region where the violator is located is to issue a NOW to each violator in the Region. For ROIs prepared by OIA, the IID Director is to issue the NOWs to all violators and notify the appropriate regions.

D. The EED Director is to issue a NOW when he or she determines that the public interest will be adequately served by a written notice of warning. Examples include, but are not limited to, those where:

1. The ROI, AER, or other case documentation does not support referral to OGC or DOJ for criminal, civil, or administrative enforcement actions;
2. The ROI, AER, or other case documentation documents minor violations; or
3. The U.S. Attorney has declined to initiate criminal, civil, or other legal proceedings.

E. The NOW is to:

1. Include the name of the firm, responsible official and title, and the address of the firm or responsible official;
2. State that there is an ROI or other case documentation that supports that a violation has occurred;

3. Include a description of the alleged violation (i.e., who, what, when, and where), and the date the violation was discussed with the subjects;
4. Briefly explain the requirements of the Acts and regulations and FSIS' enforcement authorities;
5. Use FMIA, PPIA, EPIA, HMSA, U.S. Code citation, and regulatory citations, as appropriate; and
6. Explain the Agency's expectations of compliance and advise of possible penalties, enforcement actions, or sanctions for further violations.

XII. NOW APPEALS

A. When the individual or firm receiving a NOW questions (orally or in writing) the issuance of the NOW, the CID RD or IID Director is, as appropriate, to:

1. Explain orally the violations and reason for issuance and prepare a memorandum, if necessary, summarizing the discussion;
2. Issue a letter to the individual or firm that rescinds the NOW if the CID RD or IID Director determines, after review of the information provided by the individual or firm, that the NOW is not supported by the case evidence; or
3. Issue a letter to the individual or firm that explains the basis for the NOW and advises the individual or firm that he or she may appeal the matter to the EED Director. The letter from the RD or IID Director is to provide contact information for the EED Director.

B. The EED Director is to follow these guidelines when the individual or firm receiving the NOW submits an appeal:

1. Review and evaluate the appeal letter, ROI, or other relevant information;
2. Determine whether the ROI, case evidence, or other information supports the NOW;
3. Contact the RD or IID Director, as necessary, to discuss the appeal;
4. If necessary, work with USDA's OGC or other FSIS program areas to gather additional information or to make any legal or policy determinations;
5. Deny the appeal if he or she determines that the evidence in the case supports the issuance of the NOW;
6. Rescind the NOW if he or she determines that the evidence in the case does not support the issuance of the NOW;
7. Inform the RD, IID Director that the NOW appeal is to be denied, or that the NOW is to be rescinded; and
8. Issue a written response to the individual or firm that sets out the decision to deny the appeal or rescind the NOW and provide a copy of the written response to the RD, IID Director.

XIII. LETTERS OF INFORMATION (LOI)

The CID RD, IID Director, or EED Director is to issue a LOI to individuals or firms when he or

she has determined that enforcement action is not warranted, but that it is necessary to advise an individual or firm of the requirements under the statutes or regulations and to urge compliance.

NOTE: If a LOI is appealed, follow NOW appeal procedures in section XII above.

XIV. OFO ADMINISTRATIVE ENFORCEMENT LETTERS

The OFO DMs are to issue administrative enforcement letters, to propose, initiate, defer, put in abeyance, or close an enforcement action (FSIS Directive 5100.3, Administrative Enforcement Reporting System); to advise custom exempt operators of noncompliance (FSIS Directive 5930.1, Custom Exempt Review Process); to advise individuals or firms of ineffective recalls (FSIS Directive 8080.1, Recall of Meat and Poultry Products); or for other reasons.

Direct all questions on this directive through supervisory channels.

A handwritten signature in black ink, appearing to read "Rachel A. Edelstein". The signature is fluid and cursive, with a prominent initial "R".

Assistant Administrator
Office of Policy and Program Development