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

# FSIS DIRECTIVE	8010.5, Revision 2	6/25/08

CASE REFERRAL AND DISPOSITION

I. PURPOSE

This directive describes the procedures and methodologies that are to be followed by the Food Safety and Inspection Service (FSIS), Office of Program Evaluation, Enforcement and Review (OPEER), Compliance and Investigations Division (CID), and Evaluation and Enforcement Division (EED), for determining actions on Reports of Investigations (ROI), including referral to the Office of the General Counsel (OGC) and the Department of Justice (DOJ) for criminal, civil, and administrative enforcement actions.

Key Points Covered

- Review of the ROI.
- How to refer cases to EED.
- Possible enforcement actions.
- Notices of Warning (NOW).
- Letters of Information (LOI).
- How to refer actions to other agencies.

II. CANCELLATION

FSIS Directive 8010.5, Revision 1, Case Referral and Disposition, dated 9/4/07

III. REASON FOR REISSUANCE

FSIS is reissuing this directive in its entirety to incorporate instructions related to the In-Commerce Surveillance (ICS) system.

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 CFR Sections 320.4, 381.146, 381.178 and 590.200
FSIS Directive 8010.3, Procedures for Evidence Collection, Safeguarding and Disposal
FSIS Directive 5930.1, Custom Exempt Review Process
FSIS Directive 8010.1, Methodology for Conducting In-Commerce Surveillance Activities
FSIS Directive 8010.4, Report of Investigation
FSIS Directive 8410.1, Detention and Seizure

V. BACKGROUND

The Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act (EPIA) (the Acts) provide FSIS with the authority for criminal, civil, and administrative enforcement actions and sanctions against individuals and firms that have violated these statutes. Criminal, civil, and administrative enforcement actions help to prevent adulterated, misbranded, or otherwise unsafe meat, poultry, and egg products from reaching consumers; gain compliance; restrain and deter violations; and, in appropriate cases, sanction violations of the FMIA, PPIA and EPIA. FSIS takes administrative enforcement actions and recommends criminal and civil enforcement actions through OGC, the Office of the Inspector General (OIG), and DOJ.

VI. REVIEW OF THE ROI

A. CID Investigators are to complete the “Report of Investigation” (ROI) and submit it to the CID Supervisory Investigator (SI) and the CID Regional Manager (RM) or designee for review and action in accordance with FSIS Directive 8010.4, “Report of Investigation.”

B. CID Regional Managers (or designees) are to:

1. review the ROI for completeness and make a determination on the appropriate action or referral;

2. using the criteria in the Memorandum of Understanding (MOU) with the OIG, determine whether he or she should provide a copy of the information obtained in the case to OIG;

3. refer the ROI to EED when it describes violations that warrant evaluation for criminal, civil, or administrative enforcement action;

4. issue a NOW (see section XI.) letter for minor violations; and

5. issue an LOI (see section XII.), recommend continued verification through

in-commerce surveillance activities, or close the case with no action.

NOTE: The OPEER LOI is different from an Office of Field Operations (LOI), which is issued regarding Notices of Intended Enforcement Action (NOIE).

VII. CASE REFERRAL TO EED

A. An ROI that describes repeated or serious violations of the FMIA, PPIA, or EPIA that warrant evaluation for criminal, civil, or administrative enforcement action is to be referred to EED. Examples of situations in which an ROI is to be referred to EED for evaluation for enforcement action include, but are not limited to, violations involving product adulteration or misbranding that pose a threat to the health and safety of consumers; distribution of adulterated products; gross negligence in sanitation, handling, or storage that causes or has the effect of causing product adulteration; violations involving economic fraud or intent to defraud; and convictions of applicants for or recipients of Federal inspection.

B. CID Regional Managers (or designees) are to refer the ROI to EED when it describes violations that warrant evaluation for criminal, civil, or administrative enforcement action. They are to do so by:

1. preparing a transmittal memo to the attention of the Director of EED stating the recommended action (e.g., prosecution, injunction, other), when applicable; and

2. sending a copy of the ROI or other documentation to support the recommended action to the Director of EED.

NOTE: The ROI and case evidence may be submitted electronically in the ICS system or by hard copy. EED, OGC, or the U.S. Attorney's Office may require a hard copy of the ROI and the original evidence before proceeding with action.

VIII. ENFORCEMENT ACTIONS

A. OPEER, EED Director (or designee) will:

1. review the case evidence and recommendations to determine whether to take administrative enforcement action; initiate criminal or civil enforcement action through OGC and the U.S. Attorney; issue a NOW; issue a LOI; close the case if the evidence does not support enforcement action; or, take other action;

2. when necessary, contact the RM, SI or Investigator to discuss the case findings and the sufficiency of the evidence upon completion of the case review;

3. issue a "Present Your Views" (PYV) or "Show Cause" letter to the responsible individuals, when applicable. The PYV or "Show Cause" letter affords the responsible individuals and firms the opportunity to present their views and information regarding the allegations in question or to show cause as to why enforcement proceedings should not be initiated;

4. refer criminal, civil, and administrative cases to OGC and the U.S. Attorney, when appropriate;

5. coordinate communication between EED, OGC, and the RM, SI, or Investigator as necessary, to discuss evidence sufficiency or address any concerns;

6. assist OGC in the preparation of a formal referral to the U.S. Attorney or in the preparation of other documents or correspondence;

7. coordinate communication between EED, OGC and the RM, SI, or Investigator to discuss case presentation strategies, desired outcomes, and other issues, before presenting the case to the U.S. Attorney;

8. work with OGC and the U.S. Attorney's office to draft supporting affidavits, complaints, indictments, and other documents or to develop disposition proposals such as plea agreements, pretrial diversions, consent decrees, and other proposed actions;

9. ensure consistency and effectiveness in criminal, civil, and administrative enforcement actions and sanctions; and

10. coordinate follow-up surveillance or other activities with the RM, SI or Investigator, such as to determine compliance with case settlement terms once actions are completed.

B. Regional Managers (or designees) are to:

1. participate in conference calls with EED and OGC to discuss case findings and evidence sufficiency and to address any concerns after completion of the case review;

2. provide direction to the SI and Investigator in the development of case presentation strategies when requested by EED;

3. as necessary, participate with the SI and Investigator in presenting the case to the U.S. Attorney; and

4. monitor and ensure that the Investigator makes periodic (e.g., monthly) contacts with the U.S. Attorney to obtain information on case status.

C. Investigators are to:

1. participate in conference calls with EED and OGC to discuss case findings and evidence sufficiency and to address other questions or concerns;

2. participate in developing case presentation strategies to present case findings to the U.S. Attorney;

3. present or participate in presenting case findings to the U.S. Attorney;

4. obtain information from EED regarding precedent cases involving similar violations that have led to successful outcomes;

5. as necessary, serve legal documents, attest to case evidence, or serve as a witness in legal proceedings;

6. obtain certified copies of court documents and provide copies to EED as soon as practical;

7. verify compliance of settlement terms by firms and individuals once actions are completed; and,

8. fully and timely inform EED about case activities and developments.

IX. SEIZURES

For case actions regarding seizure requests, refer to FSIS Directive 8410.1, "Detention and Seizure."

X. CUSTOM EXEMPT OPERATIONS

For case actions regarding custom exempt operations, refer to FSIS Directive 5930.1, "Custom Exempt Review Process."

XI. NOTICE OF WARNING

A NOW provides notice of violations to firms and responsible individuals. The NOW identifies the violative conduct, condition, practice, or product; provides the opportunity to achieve voluntary compliance; and is sent to the firm and the most responsible official. Situations where a NOW is issued include, but are not limited to, situations involving improperly labeled product with no intent to defraud and no public health risk.

A. Regional Managers (or designees) are to:

1. prepare the NOW for issuance to each subject of the ROI within ten (10) days of the completion of the ROI by the Investigator.

NOTE: A case requiring issuance of a NOW involving two (or more) CID Regions is to be investigated as completely as possible by the Investigator(s) in the Region where the violation was discovered and documented in the ICS system. The RM will transfer the investigation to the Region where the primary violator is located for further investigation and completion of the ROI. Upon request, original evidence is to be transferred in accordance with Directive 8010.3, "Procedures for Evidence Collection, Safeguarding, and Disposal," to the Investigator in the Region where the primary violator is located. The RM in the Region where the violator is located will issue a NOW to each violator in his/her Region. The RM in this Region will notify the RM(s) in the Region(s) that initiated the investigation and provided evidence, who will issue a NOW to each additional violator in his/her Region(s).

2. The NOW is to:

a. include the name of the firm, responsible official and title, and the address of the firm or responsible official;

b. state that there is an ROI that evidences that a violation of one or more of the Acts has occurred;

c. use FMIA, PPIA, EPIA, U.S. Code, and regulatory citations, as appropriate;

d. include a specific description of the alleged violation (i.e., who, what, when, and where) and the date the violation was discussed with the subjects;

e. briefly explain the requirements of the Acts and regulations, as applicable, and FSIS' enforcement authorities; and

f. explain the Agency's expectations of compliance and advise of possible penalties or future sanctions.

3. follow these guidelines when the individual or firm receiving the NOW questions the issuance of the NOW:

a. proceed to explain the violations and reason for issuance;

b. prepare a memorandum of conversation summarizing the discussion; and

c. issue a letter to the individual or firm summarizing the discussion and advising that if the individual or firm wishes to appeal the decision, he or she is to prepare a letter of appeal and submit it to the Director of EED. The letter from the RM should provide contact information for the Director of EED.

B. The EED Director (or designee) is to:

1. issue a NOW when he or she determines that the evidence in an ROI referred by the RM or designee does not support criminal, civil, or administrative enforcement action;

2. issue a NOW when the ROI documents minor violations of the Act;

3. issue a NOW when the U.S. Attorney has declined to initiate legal proceedings in a case;

4. follow these guidelines when the individual or firm receiving the NOW submits an appeal:

a. review the letter and contact the RM or designee, as necessary, to obtain a copy of the ROI and discuss any findings;

b. evaluate and determine whether the evidence in the ROI supports the NOW letter;

c. if necessary, work with USDA's OGC and other program areas to gather additional information or make any legal determinations;

d. deny the appeal if he or she determines that the evidence in the case supports the issuance of the NOW;

e. rescind the NOW if he or she determines that the evidence in the case does not support the issuance of the NOW letter;

f. inform the RM or designee that the NOW appeal is to be denied or that the NOW is to be rescinded; and

g. issue a written response to the individual or firm advising him or her, or the firm, of the Agency's decision to deny the appeal or rescind the NOW, and provide a copy of the written response to the RM or designee.

XII. LETTERS OF INFORMATION

OPEER may issue LOIs when it has determined that an 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. The main purpose of a LOI is to establish awareness of statutory and regulatory requirements. A RM or designee, or EED, may issue a LOI.

XIII. ISSUING ENFORCEMENT LETTERS

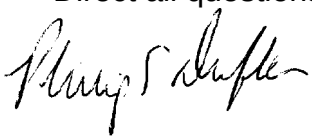
NOW and LOI letters are sent to the recipient by certified or registered mail. When the recipient of the NOW or LOI does not claim the letter, CID Investigators generally will not hand-deliver the letters. Instead, EED or the CID Regional Office may send the letter by regular mail to the last known place of business or mailing address of the firm or to the last know residence of the individual. This practice is consistent with the USDA Rules of Practice (ROP) (7 CFR Part 1, subpart H), which govern formal adjudicatory proceedings under the FMIA, PPIA, EPIA, and other USDA statutes.

XIX. REFERRING ACTIONS TO OTHER AGENCIES

Using the criteria established in the MOU with OIG, CID and EED officials are to determine whether to refer the information obtained in an ROI concerning an alleged violation of the Acts to OIG. The OIG will determine whether to investigate (e.g., open a case memorandum) and, if appropriate, notify other Federal, State, or local law enforcement officials or authorities.

When appropriate, CID and EED officials will coordinate with other Federal or State agencies (e.g., FDA) on possible referrals for investigations or enforcement actions under other Federal and State programs.

Direct all questions on this directive through supervisory channels.



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