
FSIS DIRECTIVE

8010.5
Revision 5

12/4/17

CASE REFERRAL AND DISPOSITION

I. PURPOSE

This directive provides the Office of Investigation, Enforcement and Audit (OIEA) Compliance and Investigations Division (CID) Regional Directors (RD) and Office of Field Operations (OFO) District Managers (DM), or their designees, instructions to apply in determining actions for Reports of Investigations (ROI), Administrative Enforcement Reports (AER), and other case documentation. This directive also describes the methodologies to refer enforcement matters, including recommendations for criminal, civil, and administrative actions, to the Enforcement and Litigation Division (ELD), OIEA; the methodologies that the Director of ELD, or designee, is to apply for evaluation and disposition of criminal, civil, or administrative enforcement cases; and the methodologies that authorized CID, ELD, and OFO program employees are to follow for cases referred to ELD. FSIS is reissuing this directive to provide additional information and to make other clarifications.

KEY POINTS:

- *Identifies types of criminal, civil, and administrative enforcement actions*
- *Clarifies procedures for taking action to deny or withdraw voluntary services*
- *Describes how to refer ROI, AER, or other case documentation to ELD*
- *Describes the policies for Notices of Warning (NOW), Letters of Information (LOI), and NOW appeals*
- *Describes responsibilities of authorized OIEA and OFO program employees*
- *Describes the referral of all shell egg and Siluriformes violations to ELD*

II. CANCELLATION

FSIS Directive 8010.5, Revision 4, Case Referral and Disposition, 4/24/14

III. BACKGROUND

The Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA), Egg Products Inspection Act (EPIA), and Humane Methods of Slaughter Act (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, egg products, or shell eggs 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.

IV. CASE REPORTS

OIEA CID Investigators, OFO Enforcement, Investigations, and Analysis Officers (EIAO), and other authorized program employees, in accordance with applicable directives, (e.g., [FSIS Directive 8010.4](#), *Report of Investigation*; [FSIS Directive 5100.3](#), *Administrative Enforcement Reporting (AER) System*; [FSIS PHIS Directive 5220.1](#), *Granting or Refusing Inspection*; *Voluntary Suspending or Withdrawing Inspection*; and *Reinstating Inspection Under PHIS*; [FSIS Directive 5930.1](#), *Custom Exempt Review Process*), are to:

1. Complete ROI, AER, and other case documentation (e.g., Custom Exempt Review Reports); and
2. Submit ROI, AER, and other case documentation through their supervisors to their respective management officials (i.e., CID RD, OFO DM) for review and action.

V. CASE ACTIONS

A. OIEA CID

1. CID RD is to review ROIs and other case documentation, as necessary, to determine the appropriate enforcement action or case referral.
2. CID RD or designee, as appropriate, is to:
 - a. Refer the ROI ([FSIS Directive 8010.4](#)) or other case documentation to ELD when it describes violations that require evaluation for:
 - i. 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; inhumane slaughter; economic fraud; intent to defraud);
 - ii. Civil enforcement action (e.g., threat to public health; unsafe products in commerce; repetitive violations);
 - iii. Administrative enforcement action (e.g., convictions of applicants for or recipients of Federal inspection service);
 - iv. Seizure of adulterated, misbranded, or other illegal product in commerce ([FSIS Directive 8410.1](#), *Detention and Seizure*);
 - v. Enforcement action for shell eggs stored or transported in violation of the EPIA;
 - vi. Violations of administrative consent agreements, civil consent decrees, criminal plea agreements and non-prosecution agreements, and other administrative or Federal court settlements or orders; or
 - vii. Administrative subpoena when program employees are denied access to or examination of facilities, inventory, or records.
 - b. Issue a NOW (Section IX) or a LOI (Section XII);
 - c. Recommend continued verification through in-commerce surveillance or other regulatory activities;
 - d. Close the ROI or other case documentation with no action; or

- e. Refer the ROI or other case documentation to OIG, in accordance with the Memorandum of Agreement (MOA) with OIG ([FSIS Directive 8010.2](#)) or to another Federal or State agency (e.g., State Meat and Poultry Inspection (MPI), Food and Drug Administration, Internal Revenue Service, Environmental Protection Agency, Centers for Disease Control and Prevention).

B. OFO District Office

1. OFO DM is to review AERs and other case documentation, as necessary, to determine the appropriate enforcement action or case referral.
2. OFO DM or designee, as appropriate, is to:
 - a. Refer the AER or other case documentation to ELD when it describes violations of amenable products (e.g., meat, poultry, egg products) that require evaluation for:
 - i. Administrative enforcement action ([FSIS Directive 5100.3](#); [FSIS Directive 5220.1](#); [FSIS Directive 5930.1](#)), including refusal, denial, suspension, or withdrawal of inspection for:
 - 1) Failure to maintain sanitary conditions (9 CFR 500.3(a)(4), 500.4(c));
 - 2) Shipment of adulterated or misbranded products (9 CFR 500.3(a)(1));
 - 3) Hazard Analysis and Critical Control Points (HACCP) violations (9 CFR 500.3(a)(2), 500.4(a));
 - 4) Inhumane slaughter or handling (9 CFR 500.3(b));
 - 5) Intimidation, interference, assault, or threaten inspection personnel (9 CFR 500.3(a)(6));
 - 6) Convictions of applicants for or recipients of Federal inspection service or individuals responsibly connected (9 CFR 500.6(i)); or
 - 7) Termination of exempt status for custom exempt slaughter or processing (Section 623(c)(2) of the FMIA).
 - ii. Seizure of adulterated, misbranded, or other violative product in commerce ([FSIS Directive 8410.1](#)); or
 - iii. Administrative subpoena when program employees are denied access to or examination of facilities, inventory, or records ([FSIS Directive 5100.3](#) and [FSIS Directive 8010.3](#)).
 - b. 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 CFR Part 500 and applicable FSIS Directives; e.g., [FSIS Directive 5100.3](#); [FSIS PHIS Directive 5220.1](#); [FSIS Directive 5930.1](#));
 - c. Refer the AER or other case documentation to ELD when it describes violations of products subject to voluntary inspection that require violations for administrative enforcement action to deny or withdraw voluntary identification, certification or inspection services in accordance with:

- i. 9 CFR 350.6 and 362.4 for denial or withdrawal of voluntary meat or poultry identification or certification service;
 - ii. 9 CFR 352.6 for denial or withdrawal of voluntary inspection for slaughter and processing of exotic animals;
 - iii. 9 CFR 354.21 for suspension or revocation of inspection service for processing or packing products of rabbits and edible products thereof;
 - iv. 9 CFR 351.20 for suspension or withdrawal of certification service of technical animal fats; or
 - v. 9 CFR 355.8 for withdrawal of inspection, certification, or identification service of pet food
 - d. Close case with no action.
3. OFO DM is to refer criminal enforcement matters and allegations to CID as early as possible; OFO personnel are not to conduct investigations into criminal matters.

VI. CASE REFERRAL TO ELD

- A. When referring the ROI, AER, and other documentation to ELD, the CID RD and OFO DM are to:
 1. Prepare a case referral memo to the attention of the Director of ELD stating the recommended action (e.g., criminal prosecution, civil injunction, seizure, refusal or withdrawal of inspection service, termination of custom exemption, administrative subpoena, civil penalties), as applicable:
 - a. CID referrals are to be signed by and routed from the RD, or designee, to ELD.
 - b. OFO referrals are to be signed by and routed from the DM, or designee, to ELD.
- B. Submit the ROI, AER, or other case documentation, case referral memo, and case evidence to ELD electronically through the AssuranceNet/In-Commerce System (ANet/ICS), where possible, or by e-mail.
- C. ELD, OGC, OIG, or the U.S. Attorney's Office may request a hard copy of the ROI and the original evidence. OFO and CID are to follow the procedures in [FSIS Directive 8010.3](#) for any transfer of original evidence.
- D. All reports documenting violations regarding shell eggs and fish of the order of Siluriformes are to be referred to ELD.

VII. ELD CASE REVIEW AND DISPOSITION

- A. ELD Director or designee is to take one or more of the following actions, as appropriate:
 1. Review the ROI, AER, or other case documentation referred to ELD 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; initiate civil penalties; take or initiate refusal or withdrawal of Federal inspection service or other administrative enforcement action; issue an NOW, LOI, or other enforcement correspondence; close case with no action; or take other action);

2. Contact the RD 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 ([FSIS Directive 5930.1](#));
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. Initiate civil penalties for shell eggs stored or transported in violation of the EPIA, including entering stipulation agreements, referral to OGC, or other action. In determining civil penalties, ELD is to consider gravity (e.g., temperature), culpability (e.g., knowledge), and compliance history in accordance with the EPIA;
7. Obtain an administrative subpoena, through OGC;
8. 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. ELD 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);
9. 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. ELD may determine that a SCL is not necessary when in the public interest;

NOTE: Only ELD is to issue PYV letters and SCL.

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

VIII. ENFORCEMENT LIAISON

- A. Once CID refers a case to ELD, the RD and appropriate CID employees, in coordination with ELD,

are to:

1. Participate in conference calls with ELD and others, when requested, to discuss case findings, evidence sufficiency, and related matters, to address any questions or concerns;
2. Participate in developing food safety, enforcement, and legal strategies, when requested;
3. Obtain, when needed, information from ELD 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 ELD 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 ELD, 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 ELD.

B. Once OFO refers a case to ELD, the DM and appropriate OFO program employees, in coordination with ELD, are to:

1. Participate in conference calls with ELD and others, when requested, to discuss case findings, evidence sufficiency, and related matters, to address any questions or concerns;
2. Participate in developing food safety, enforcement, and legal strategies, when requested;
3. Provide supporting documents, such as a chronology, to determine evidence sufficiency and related matters and to address any questions or concerns;
4. Attest to case evidence or serve as a witness in legal proceedings, when requested;
5. 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;
6. Document case updates, verification activities, and related matters in ANet/ICS, or otherwise, as applicable;
7. Inform ELD, 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 ELD.

IX. NOW

A. The RD or ELD Director are to issue an NOW for minor violations, or otherwise as appropriate, as provided by the FMIA 21 U.S.C. 676, PPIA 21 U.S.C. 462, and EPIA 21 U.S.C. 1042. The NOW is to identify the violative conduct, condition, practice, or product; provide the opportunity to achieve voluntary compliance; and is sent to the firm and responsible individuals. Situations where an 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 is to prepare the NOW for issuance, as appropriate, to each subject of the ROI and to responsible individuals.

1. If the case disposition is issuance of an NOW, and the investigation involves two (or more) CID Regions, the RD in the Region where the violation was discovered and initiated in ANet/ICS is to investigate the case as completely as possible.
2. The RD is then to transfer the investigation, through ANet/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.
3. 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 an NOW to each violator in the Region.

C. The ELD Director is to issue an 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.

D. The NOW, issued by CID RD or ELD Director, 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. Explain briefly the requirements of the Acts and regulations and FSIS' enforcement authorities;
5. Use FMIA, PPIA, EPIA, HMSA, U.S. Code citations, 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.

X. CASE CLOSEOUT

A. Once enforcement actions have been completed, the owner of the Enforcement Record (CID/RD or ELD) will take the steps to close the Enforcement Record in ANet/ICS. The RD or appropriate ELD personnel is to follow the steps outlined in the ANet/ICS Enforcement Online User Instructions to properly close out the Enforcement Record.

B. When the Enforcement Record is in ELD workflow and is linked to an Investigation Record, the ELD Specialist will notify the appropriate RD that the Enforcement Record is closed, so the RD can close out the Investigation Record.

C. Once the Enforcement Record, including all Enforcement Records linked to the Investigation Record are closed or placed in monitoring, the Investigation Record can be closed in ANet/ICS. This is completed by the RD that owns the Investigation Record.

XI. NOW APPEALS

A. When the individual or firm receiving an NOW questions (orally or in writing) the issuance of the NOW, the RD is to:

1. Explain orally the violations and reason for issuance and prepare, if necessary, a memorandum summarizing the discussion;
2. Issue a letter to the individual or firm that rescinds the NOW if the RD determines, after review of the information provided by the individual or firm, that the NOW is not supported by the case evidence; or

NOTE: If the NOW is rescinded, the RD is to update the Violator Case Disposition in ANet/ICS with 'NOW Rescind' in the Enforcement Info tab of the Enforcement module.

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 ELD Director. The letter from the RD is to provide contact information for the ELD Director.

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

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, as necessary, to discuss the appeal;
4. Work with OGC or other FSIS program areas, if necessary, 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 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.

XII. LOI

The CID RD or ELD Director is to issue an 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 an LOI is appealed, follow NOW appeal procedures in Section XI above.

XIII. OFO ADMINISTRATIVE ENFORCEMENT LETTERS

The OFO DM is to issue administrative enforcement letters to propose, initiate, defer, put in abeyance, or close an enforcement action ([FSIS Directive 5100.3](#)); to advise custom exempt operators of noncompliance ([FSIS Directive 5930.1](#)); to advise individuals or firms of ineffective recalls ([FSIS Directive 8080.1](#), *Recall of Meat and Poultry Products*); or for other reasons.

XIV. QUESTIONS

Refer questions regarding this directive through supervisory channels.

A handwritten signature in cursive script that reads "Sabrina J. Wagner".

Assistant Administrator
Office of Policy and Program Development