

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

FSIS DIRECTIVE

8010.5
Rev. 6

5/11/21

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 for taking action on Reports of Investigation (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 Operations Staff (EOS), OIEA; the methodologies that the EOS Director, or designee, is to apply for case evaluation and disposition; and the methodologies that authorized CID, EOS, and OFO program employees are to follow for cases referred to EOS. 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*
- *Describes how to refer ROI, AER, or other case documentation to EOS*
- *Describes the process for EOS case review and enforcement disposition*
- *Describes the policies for Notices of Warning (NOW), Letters of Information (LOI), and NOW and LOI appeals*
- *Describes responsibilities of authorized OIEA and OFO program employees*
- *Includes an attachment detailing the process for the administrative withdrawal of Federal inspection service*

II. CANCELLATION

FSIS Directive 8010.5, Revision 5, *Case Referral and Disposition*, 12/04/17

III. BACKGROUND

The Federal Meat Inspection Act ([FMIA](#)), Poultry Products Inspection Act ([PPIA](#)), Egg Products Inspection Act ([EPIA](#)), Humane Methods of Slaughter Act ([HMSA](#)), and Agricultural Marketing Act ([AMA](#)) 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

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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 Directive 5220.1](#), *Granting or Refusing Inspection; Voluntary Suspending or Withdrawing Inspection; and Reinstating Inspection Under PHIS*; [FSIS Directive 8160.1](#), *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. OIEA CASE ACTIONS

A. CID RD or designee is to review ROIs and other case documentation, as necessary, to determine the appropriate enforcement action or case referral.

B. CID RD or designee, as appropriate, is to refer the ROI ([FSIS Directive 8010.4](#)) or other case documentation to EOS when it describes violations that require evaluation for:

1. 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);
2. Civil enforcement action (e.g., threat to public health, unsafe products in commerce, repetitive violations);
3. Administrative enforcement action (e.g., convictions of applicants for or recipients of Federal inspection service, including convictions of responsibly connected officials);
4. Seizure of adulterated, misbranded, or other illegal product in commerce ([FSIS Directive 8410.1](#), *Detention and Seizure*);
5. Enforcement action for shell eggs stored or transported in violation of the EPIA;
6. Administrative enforcement action for termination of exempt status for custom exempt slaughter or processing ([FSIS Directive 8160.1](#));
7. Violations of administrative consent agreements, civil consent decrees, criminal plea agreements, non-prosecution agreements, and other administrative or Federal court settlements or orders;
8. Administrative subpoena when program employees are denied access to or examination of facilities, inventory, or records; or
9. Any other violations requiring consideration for enforcement action (e.g., retail exempt violations).

- C. CID RD or designee issue a NOW (Section X) or a LOI (Section XII), as appropriate.
- D. CID RD or designee issue a Letter of Warning (LOW) or other administrative correspondence to advise custom exempt operators of regulatory requirements or noncompliance ([FSIS Directive 8160.1](#)).
- E. CID RD or designee recommends continued verification through in-commerce surveillance ([FSIS Directive 8010.1](#), Methodology for Conducting In-Commerce Surveillance Activities), custom exempt review ([FSIS Directive 8160.1](#)), or other regulatory activities.
- F. CID RD or designee closes the ROI or other case documentation with no action, when appropriate.
- G. CID RD or designee refers the ROI or other case documentation to OIG, in accordance with the [Memorandum of Agreement](#) (MOA) with OIG, or to another Federal or State agency (e.g., State Meat and Poultry Inspection (MPI) program, Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC)) ([FSIS Directive 8010.2](#), Investigative Methodology).

VI. OFO CASE ACTIONS

- A. OFO DM or designee is to review AERs and other case documentation, as necessary, to determine the appropriate enforcement action or case referral.
- B. OFO DM or designee, as appropriate, is to issue administrative enforcement letters to propose, initiate, defer, put in abeyance, or close an enforcement action ([FSIS Directive 5100.3](#)); advise custom exempt operators of regulatory requirements or noncompliance ([FSIS Directive 8160.1](#)); advise individuals or firms of prohibited activities ([FSIS Directive 8080.1](#), *Recall of Meat and Poultry Products*); or, for other reasons, as necessary;
- C. OFO DM or designee is to refer the AER or other case documentation to EOS when it describes violations that require evaluation for:
 - 1. Administrative enforcement action ([FSIS Directive 5100.3](#); [FSIS Directive 5220.1](#)), including refusal, denial, indefinite suspension, or withdrawal of inspection for:
 - a. Failure to maintain sanitary conditions (9 CFR [500.3\(a\)\(4\)](#), [500.4\(c\)](#));
 - b. Shipment of adulterated or misbranded products (9 CFR [500.3\(a\)\(1\)](#));
 - c. Hazard Analysis and Critical Control Points (HACCP) violations (9 CFR [500.3\(a\)\(2\)](#), [500.4\(a\)](#));
 - d. Sanitation Standard Operating Procedure (Sanitation SOP) violations (9 CFR [500.3\(a\)\(3\)](#), [500.4\(b\)](#));
 - e. Inhumane slaughter or handling (9 CFR [500.3\(b\)](#));
 - f. Intimidation, interference, assault, or threaten inspection personnel (9 CFR [500.3\(a\)\(6\)](#)); or
 - g. Convictions of applicants for or recipients of Federal inspection service or individuals responsibly connected (9 CFR [500.6\(i\)](#)).

NOTE: The Attachment provides additional guidance to OFO and OIEA-EOS personnel related to the procedures for the administrative withdrawal of Federal inspection service including case referral to EOS, case review and disposition activities performed by EOS, the administrative complaint and hearing processes, and collaboration between OFO and EOS.

2. Administrative enforcement action for termination of exempt status for custom exempt slaughter or processing ([FSIS Directive 8160.1](#));
3. Enforcement action for violations of administrative consent agreements, and other administrative or Federal court settlements or orders;
4. Seizure of adulterated, misbranded, or other violative product in commerce ([FSIS Directive 8410.1](#)); or
5. Administrative subpoena when program employees are denied access to or examination of facilities, inventory, or records ([FSIS Directive 5100.3](#); [FSIS Directive 8010.3](#)).

D. OFO DM or designee is to refer the AER or other case documentation to EOS when it describes violations of products subject to voluntary inspection that require administrative enforcement action to deny or withdraw voluntary identification, certification, or inspection services in accordance with:

1. 9 CFR [350.6](#) and [362.4](#) for denial or withdrawal of voluntary meat or poultry identification or certification service;
2. 9 CFR [352.6](#) for denial or withdrawal of voluntary inspection for slaughter and processing of exotic animals;
3. 9 CFR [354.21](#) for suspension or revocation of inspection service for processing or packing products of rabbits and edible products thereof;
4. 9 CFR [351.20](#) for suspension or withdrawal of certification service of technical animal fats; or
5. 9 CFR [355.38](#) for withdrawal of inspection, certification, or identification service of pet food.

E. OFO DM is to close case with no action, when appropriate.

F. OFO DM or designee is to refer the matter to CID when it involves allegations of a criminal enforcement matter or otherwise requires investigation by CID. OFO DM is to refer these matters to CID as early as possible; OFO personnel are not to conduct investigations into criminal matters.

VII. CASE REFERRAL TO EOS

A. When referring the ROI, AER, and other documentation to EOS, the CID RD and OFO DM or their designee are to:

1. Prepare a case referral memo to the attention of the EOS Director 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 the RD, or designee, to EOS.
 - b. OFO referrals are to be signed by the DM, or designee, to EOS.
2. Submit the ROI, AER, case referral memo, and other case documentation, if any, to EOS electronically through AssuranceNet (ANet). If necessary, the RD, DM, or their designees may submit the information to EOS by e-mail.
3. EOS, OGC, OIG, or the U.S. Attorney's Office may request a hard copy of the ROI or AER and

the original evidence. OFO and CID are to follow the procedures in [FSIS Directive 8010.3](#) for any transfer of original evidence.

VIII. EOB CASE REVIEW AND DISPOSITION

The EOS 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 EOS 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 a NOW, LOI, or other enforcement correspondence; close case with no action; or take other action);
2. Contact the RD or DM, or their designee, 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 8160.1](#));
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 or withdrawal of voluntary reimbursable inspection services);

NOTE: The Attachment provides additional guidance to OFO and OIEA-EOS personnel related to the procedures for the administrative withdrawal of Federal inspection service, including case referral to EOS, case review and disposition activities performed by EOS, the administrative complaint and hearing processes, and collaboration between OFO and EOS.

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, EOS 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 before the initiation of criminal or civil proceedings. EOS 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 before the initiation of administrative proceedings. EOS may determine that a SCL is not necessary when in the public interest;

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

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;
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; or
16. Refer the ROI, AER, or other case documentation, if necessary, to OIG or to another Federal or State agency.

IX. ENFORCEMENT LIAISON

A. Once CID refers a case to EOS, the RD, or designee, and appropriate CID personnel, in coordination with EOS, are to:

1. Participate in conference calls with EOS 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 EOS 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;

NOTE: Only OGC and OIG have authority to refer alleged violations to the Department of Justice (including U.S. Attorney's Offices) (7 CFR [2.31](#), [2.33](#)). Therefore, before presenting any alleged violation, evidence, or case to a U.S. Attorney for any violation of law, including for violations of plea agreements, consent decrees, or other matters, CID personnel are to follow the instructions for submitting the ROI and other information regarding alleged violations to EOS for review and referral in accordance with this Directive.

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 EOS 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, or otherwise, as applicable;

10. Inform EOS, 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 EOS.

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

1. Participate in conference calls with EOS 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, as applicable;
7. Inform EOS, 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 EOS.

X. NOW

A. The RD, or designee, or EOS Director, or designee, is to issue a 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).

B. The RD is to issue a NOW, as appropriate, to each subject of the ROI and to responsible individuals.

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

C. The EOS 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 (FMIA (21 U.S.C. 676), PPIA (21 U.S.C. 462), and EPIA (21 U.S.C. 1042)). 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 EOS Director, or their designee, 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 a 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's enforcement authorities;
5. Cite the FMIA, PPIA, EPIA, HMSA, AMA, U.S. Code, and Code of Federal Regulations (CFR), as appropriate; and
6. Explain the Agency's expectations of compliance and advise of possible penalties, enforcement actions, or sanctions for further violations.

XI. CASE CLOSEOUT

A. Once an enforcement action has been completed, the owner of the Enforcement Record (CID/RD or EOS) is to take the steps to close the Enforcement Record in ANet. The RD, or designee, or EOS is to follow the steps outlined in the ANet Instructions for Enforcement to properly close out the Enforcement Record.

B. When the Enforcement Record is in EOS workflow in ANet and is linked to an Investigation Record, EOS is to notify the appropriate RD, or designee, that the Enforcement Record is closed, so the RD, or designee, can close out the Investigation Record.

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

D. When the Enforcement Record is closed by EOS with a "type of order" as the enforcement disposition, EOS is to open a new Enforcement Record in ANet with the Order Verification Enforcement Case Type for monitoring purposes.

XII. APPEALS

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

1. Review the matter, including the ROI and any other information provided by the individual or firm;
2. If the RD determines that the NOW is supported, issue a letter to the individual or firm that explains the basis of the NOW and provides guidance on how to appeal the matter to the EOS

Director, should they so desire; or

3. If the RD determines that the NOW is not supported, issue a letter to the individual or firm that rescinds the NOW.

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

B. For appeals of NOW issued by the RD, or designee, the EOS Director, or designee, is to follow these instructions when the individual or firm receiving the NOW submits an appeal to EOS:

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.

NOTE: The individual or firm may appeal EOS's decision to the OIEA Assistant Administrator (9 CFR [306.5](#)).

C. For appeals of a NOW issued by the EOS Director, or designee, the EOS Director, or designee, is to follow the instructions in this section.

XIII. LOI

A. The CID RD or EOS Director, or their designee, 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.

B. If a LOI or LOW ([FSIS Directive 8160.1](#)) is appealed, follow the NOW appeal procedures in Section XII above.

XIV. QUESTIONS

Refer questions regarding this directive through supervisory channels.



Assistant Administrator
Office of Policy and Program Development