# MSA DIRECTIVE	8010.5 Revision 6	10/21/2021

CASE REFERRAL AND DISPOSITION

I. PURPOSE

This directive describes the procedures and methodologies that are to be followed by the Texas Department of State Health Services (DSHS); Meat Safety Assurance (MSA) Section for determining actions on Reports of Investigations (ROI) and some in-plant noncompliances at Granted establishments, including referral to the Compliance Review Committee (CRC) for criminal, civil, and administrative enforcement actions.

II. CANCELLATION

MSA Directive 8010.5, Revision 5.2, Case Referral and Disposition

III. BACKGROUND

The Texas Meat and Poultry Inspection Act (TMPIA), Federal Meat Inspection Act (FMIA), and the Poultry Products Inspection Act (PPIA), (the Acts) provide MSA 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 and poultry products from reaching consumers; gain compliance; restrain and deter violations; and, in appropriate cases, sanction violations of the TMPIA, FMIA, PPIA and Texas Administrative Code. MSA takes administrative enforcement actions and recommends criminal and civil enforcement actions through CRC, or the Texas Attorney General Office (AG).

IV. REVIEW OF THE ROI

A. Compliance Officers (COs) are to complete the ROI and submit it to the MSA Enforcement Coordinator (EC) or designee for review and action in accordance with MSA Directive 8010.4, "Report of Investigation." In egregious cases, COs may make recommendations for escalated enforcement actions based on the compliance history of the violator, severity of the violation, actions that cause or are intended to cause adulteration, and acts of fraud.

B. EC is to review the ROI for completeness and recommend the appropriate action or referral as described below:

1. continued verification through in-commerce surveillance activities, or close the case with no action;

2. issue a Letter of Concern (LOC) (see section IX);

3. issue a Letter of Warning (LOW) (see section X); or

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

V. ROI CASE REFERRAL TO CRC

A. A ROI that describes violations of the TMPIA, TAC, FMIA, or PPIA that warrant evaluation for criminal, civil, or administrative enforcement action is to be referred to CRC. Examples of situations in which an ROI is to be referred to CRC 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; inhumane treatment of animals; violations involving economic fraud or intent to defraud; and convictions of applicants for or recipients of State or Federal inspection.

B. The EC is to refer the ROI to the CRC when it describes violations that warrant evaluation for criminal, civil, or administrative enforcement action. They are to do so by:

1. preparing an CRC Summary Sheet and transmitting the information to the attention of the CRC and

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

3. Present the ROI and recommendations to the CRC

VI. ENFORCEMENT ACTIONS IN UNGRANTED ESTABLISHMENTS

A. The EC will:

1. review the case evidence to determine if sufficient evidence exists to conclude that a regulatory violation has occurred.

2. if the EC determines that a regulatory violation may have occurred, but there is insufficient evidence to conclude that a regulatory violation did occur, the EC will refer the case back to the Compliance Circuit Manager (CCM). If the CCM deems it appropriate, he/she may issue a LOC to the

establishment or individual in question to educate the establishment or individual on regulatory requirements. If the CCM does not agree with the determination made by the EC, the decision made by the EC may be appealed to the MSA Assistant Director (or designee).

3. if the EC determines that there is sufficient evidence to conclude that a regulatory violation has occurred, he/she will determine if the establishment or individual in question has previously received a LOW from the Meat Safety Assurance program due to a regulatory violation.

4. if the EC determines that there is sufficient evidence to conclude that a regulatory violation has occurred and the establishment or individual has not previously received a LOW due to a regulatory violation, the EC will draft a LOW and submit it to the Assistant Director (or designee) for approval. In addition, the EC will update the LOW database to reflect the issuance of the LOW. If the establishment or individual has not previously received a LOW due to a regulatory violation and the EC believes the violation detailed in the case is particularly egregious and warrants immediate enforcement action, the EC may request that the Assistant Director evaluate the case and determine whether to send the establishment or individual a LOW or proceed directly to enforcement action.

5. if the EC determines that there is sufficient evidence to conclude that a regulatory violation has occurred and the establishment or individual has previously received a LOW due to a regulatory violation, the EC will determine the appropriate penalty for the violation(s) based on the MSA penalty matrix and prepare to present the case to the Compliance Regulatory Committee (CRC).

6. prior to presenting the case to the CRC, the EC will present the case, along with their recommendations for charges and penalties (based on the MSA penalty matrix) to the Assistant Director (or designee).

7. upon approval of the case, charges, and penalties by the Assistant Director (or designee), the EC will enter the case into the appropriate system for referral to the CRC. When necessary, the EC may contact the CO to discuss the case findings and the sufficiency of the evidence upon completion of the case review;

8. with the approval of the Assistant Director (or designee) the EC may refer criminal, civil, and administrative cases to CRC and the AG, when appropriate;

9. when appropriate the EC may coordinate communication between CRC and AG to discuss evidence sufficiency or address any concerns;

10. the EC will assist the CRC in the preparation of a formal referral to the AG or in the preparation of other documents or correspondence;

11. the EC will coordinate communication between CRC, AG, MSA, and the CO to discuss case presentation strategies, desired outcomes, and other issues, before presenting the case to the AG;

12. the EC will work with CRC and the AG 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;

13. the EC will ensure consistency and effectiveness in criminal, civil, and administrative enforcement actions and sanctions; and

14. the EC will coordinate follow-up surveillance or other activities with the CO such as to determine compliance with case settlement terms once actions are completed.

B. The EC is to:

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

2. coordinate with the CCM and the CO in the development of case presentation strategies when requested by CRC;

3. as necessary, participate with the CO and/or the CCM in presenting the case to the CRC or AG; and

4. monitor the status of cases referred to the CRC or AG.

C. COs are to:

1. participate in conference calls with CRC and AG 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 AG;

3. present or participate in presenting case findings to the CRC or AG;

4. obtain information from CRC 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 CRC as soon as practical;

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

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

VII. SEIZURES

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

VIII. CUSTOM EXEMPT OPERATIONS

For case actions regarding custom exempt operations, refer to MSA Custom Exempt Review Glossary.

IX. LETTER OF CONCERN (LOC)

The CCM may issue a LOC when it has been determined that a LOW or other enforcement action is not warranted. The main purpose of a LOC is to advise an individual or firm of statutory and regulatory requirements and to urge compliance.

X. LETTER OF WARNING (LOW)

A LOW provides notice of violations to firms and responsible individuals. The LOW 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.

A. Th EC is to prepare the LOW for issuance to each subject of the ROI within ten (10) days of the completion of the ROI by the CO.

B. The LOW 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 with evidence that a violation of one or more of the Acts has occurred;

    3. use TMPIA, TAC, FMIA, PPIA, U.S. Code, and regulatory citations, as appropriate;

4. 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;

5. briefly explain the requirements of the Acts and regulations, as applicable, and MSA enforcement authorities; and

6. explain the Department's expectations of compliance and advise of possible penalties or future sanctions.

C. Follow these guidelines when the individual or firm receiving the LOW questions the issuance of the LOW in writing.

1. explain the violations and reason for issuance;

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

3. 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 Assistant Director of MSA. The letter from the EC should provide contact information for the Assistant Director of MSA.

XI. ENFORCEMENT ACTIONS IN GRANTED ESTABLISHMENTS

A. When COs encounter incidents of in-commerce noncompliance attributable to a MSA Granted establishment, the CO is to contact the CCM. The CO and/or CCM will then contact the applicable Inspection Circuit Manager (ICM) in charge of inspection at the establishment.

1. The ICM and the CO and/or CCM are to confer regarding the in-commerce noncompliance, taking into account other conditions and situations at the establishment, and determine whether to address the in-commerce noncompliance through typical enforcement channels as detailed above in Section VI or to address the noncompliance through normal inspection channels by writing a Noncompliance Record (NR). When it is agreed to that a NR shall be written, the CO shall include the NR number in the ROI and attach a copy of the NR as evidence in the AssuranceNet/InCommerce System (ANet/ICS), before submitting to the EC for review and tracking purposes. If the CO and/or CCM and ICM are unable to agree on the proper course of action, the Assistant Director will determine the action.

2. If warranted based on other establishment conditions and/or situations the ICM may address the in-commerce noncompliance, together with other issues, by writing a LOC, referring the situation to the Assistant Director by requesting a LOW be issued, or referring the

situation to the MSA Director by requesting a Notice of Intended Enforcement (NOIE) be issued.

3. If further investigation into the conditions and/or situations at the establishment is necessary, the ICM may request a For-Cause Food Safety Assessment (FSA) through the Assistant Director.

B. Routine in-plant noncompliances are typically handled through the use of NRs as detailed in MSA Directive 5000.1. If an establishment fails to correct a routine noncompliance within 60 days of issuance, the following actions may be taken.

1. LOC

   a. The applicable ICM may issue a LOC to the establishment and provide the EC with a copy of the letter for tracking purposes.
   b. The LOC should request that the establishment submit their written intended corrective actions (when appropriate) to the ICM within 14 days and should complete acceptable corrective actions no later than 60 days after the issuance of the LOC.
   c. If the establishment corrects the noncompliance(s) within the above timeframes the LOC is considered closed. In this case the ICM is to inform the EC of the LOC closure for tracking purposes.
   d. If the establishment fails to submit their intended corrective actions within 14 days or fails to complete acceptable corrective actions within 60 days of the issuance of the LOC, the ICM may forward the issue to the EC and the Assistant Director for consideration and tracking purposes.
   e. The LOC should also inform the establishment that failure to adequately respond to the LOC may result in the issue being forwarded to the MSA Central Office for enforcement action consideration.
   f. In cases where a Granted establishment fails to respond adequately to a LOC from a ICM, the Assistant Director will evaluate the circumstances surrounding the issue and, if appropriate, issue a LOW to the establishment. In cases where a noncompliance is particularly serious, a ICM may request that the Assistant Director issue the establishment a LOW without issuing a LOC.

2. LOW
   a. The LOW should require the establishment to respond with written intended corrective actions within 14 days and should complete acceptable corrective actions no later than 60 days after the issuance of the LOW.
   b. If the establishment corrects the noncompliance(s) within the above timeframes the LOW is considered closed. In this case the

Assistant Director is to inform the EC of the LOW Closure for tracking purposes.

c. If the establishment fails to submit their intended corrective actions within 14 days or fails to complete acceptable corrective actions within 60 days of the issuance of the LOW, the Assistant Director may forward the issue to the EC and the MSA Director for consideration and tracking purposes.
d. The LOW should also inform the establishment that failure to adequately respond to the LOW may result in the issue being forwarded to the MSA Director for enforcement action consideration, potentially resulting in a penalty of up to $25,000 per infraction per day, suspension action, withdrawal action, or referral for criminal prosecution if warranted.
e. In cases where a Granted establishment fails to respond adequately to a LOW from the Assistant Director, the MSA Director will evaluate the circumstances surrounding the issue and, if appropriate, issue a Notice of Intended Enforcement (NOIE) to the establishment. In cases where a noncompliance is particularly egregious, the Assistant Director may request that the MSA Director issue the establishment a NOIE without issuing a LOW (or LOC if applicable).

3. NOIE
   a. Once the NOIE is issued by the MSA Director, the MSA Director will contact the EC.
   b. The EC will log the NOIE into the Enforcement Database for tracking purposes.
   c. The EC will prepare the case for submission to the CRC including proposing appropriate penalties under the MSA Penalty Matrix.
   d. Prior to presenting the case to the CRC, the EC will present the case, along with their recommendations for charges and penalties (based on the MSA penalty matrix) to the Assistant Director (or designee).
   e. Upon approval of the case, charges, and penalties by the Assistant Director (or designee), the EC will enter the case into the appropriate system for referral to the CRC and facilitate processing the case as directed in Section VI.A.8. of this Directive.

C. MSA may take a withholding action or impose a suspension with or without prior notification as detailed in MSA 5000.1.

XII. ENFORCEMENT ACTIONS RELATED TO FSAs

A. FSAs will be performed on Granted establishments periodically or for-cause, as referenced in Section XI.A.3. As a result of a FSA, the FSA manager may determine that no further action is required. The FSA manager may also issue a LOC, or recommend a LOW or NOIE, using the process described in Section XI above. Additional details of FSAs are in MSA Directives 5100.1, 5100.4, 5100.12 and 5100.13.

XIII. DELIVERING ENFORCEMENT LETTERS

LOWs, and NOVs are delivered directly to the recipient with a signed acknowledgement of receipt or by certified/registered mail. LOCs may be delivered in the same manner as LOWs and NOVs or they may be emailed, hand delivered, or otherwise conveyed to establishment ownership/management by MSA personnel.

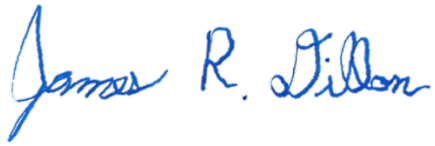
XIV. REFERRING ACTIONS TO OTHER AGENCIES

The EC in conjunction with the Assistant Director (or designee) and CRC are to determine whether to refer the information obtained in an ROI concerning an alleged violation of the Acts to Texas Office of Inspector General. The Office of Inspector General 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, MSA officials will coordinate with other Federal (e.g., FDA) or State agencies on possible referrals for investigations or enforcement actions under other Federal and State programs.

XV. QUESTIONS

Refer questions through supervisory channels.



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