

**Minnesota Department of Agriculture
Food and Feed Safety Division**

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Version #: 1.1	Effective Date: 1/5/2017
Title: Enforcement Case Audit SOP	

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1. PURPOSE

This procedure describes the process used by the Minnesota Department of Agriculture (MDA) Food and Feed Safety Division (FFSD) for the periodic review of food enforcement activities taken by the Compliance Unit. The audit is conducted to verify that internal enforcement procedures are followed.

2. SCOPE

This procedure applies to the audit of formal and informal food program enforcement activities to verify conformance with enforcement procedures. The audit pertains to the enforcement case file produced and maintained by the Compliance Unit within FFSD. This procedure does not apply to field compliance activities such as correction on site, embargo, and sanitary notice. Refer to *FOOD.60.11 – Retail Establishment File Audit SOP* for the audit of field compliance procedures for the Retail Food Program and *FOOD.60.13 – Manufactured Foods Field Compliance Actions Audit SOP* for the audit of field compliance procedures for the Manufactured Food Program.

3. BACKGROUND

Standard 6 of the Manufactured Food Regulatory Program Standards (MFRPS) requires that a State agency perform an annual review of its enforcement actions to evaluate the effectiveness of the compliance and enforcement program. Results of the review are used to identify improvements, modify procedures, and develop enforcement strategies. Standard 6 of the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS) also requires demonstration of credible follow-up for each violation noted during an inspection. Proper use, completion, and submission of documentation within an enforcement case file are key components in assuring those purposes are adequately and consistently being met in the Compliance Unit. The audit form was constructed using current enforcement procedures.

4. RESPONSIBILITY

Business and Quality Management (BQM) Unit Supervisor – The Business and Quality Management Unit Supervisor will assist with auditing and provide oversight as necessary.

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Division Director and Assistant Division Director – The Division Director and the Assistant Division Director will assist in determining corrective actions when program-related deficiencies are noted and resolve audit disputes.

Compliance Supervisor - The Compliance Supervisor will assist in determining corrective actions when Compliance Unit deficiencies are noted.

Qualified Enforcement Case Auditor (Auditor) – The Auditor will select enforcement case files for review; complete the *Enforcement Case Audit Worksheet* for each file; complete *Appendix 6.2*; and schedule an audit review meeting with applicable parties.

5. DEFINITIONS

Enforcement Actions Enforcement actions are informal (non-appealable) or formal (appealable) actions taken outside of an inspection to achieve compliance with regulations. These actions include, but are not limited to, Letters of Information, Warning Letters, Corrective Action Orders, Administrative Meetings, issuance of penalties (civil or administrative), Criminal Prosecution, License Limitation or Revocation, Injunction, or other court actions. These actions are initiated by a firm's non-compliance with regulatory requirements as evidenced by an inspection report, violative sample results, or other collected documentation of conditions.

Enforcement Case: An enforcement case is the file (paper and/or electronic) for supporting documentation related to enforcement actions.

Field Compliance Actions: Field compliance actions are actions performed during an inspection to achieve compliance with regulations. These actions include, but are not limited to, reinspections, cease and desist orders, and embargos. These actions are initiated by a firm's non-compliance with regulatory requirements as evidenced by an inspection report, violative sample results, or other collected documentation of conditions.

Qualified Enforcement Case Auditor (Auditor): A qualified enforcement case auditor is someone who has completed the most current training on the following SOPs:

- a) FOOD.60.01 – Assessing Administrative Penalties SOP
- b) FOOD.60.02 – Enforcement Case Review and Monitoring SOP
- c) FOOD.60.03 – Intent for Civil Penalties SOP
- d) FOOD.60.05 – Criminal Prosecution SOP
- e) FOOD.60.06 – Warning Letters SOP
- f) FOOD.60.07 – Letters of Information SOP
- g) FOOD.60.08 – Conducting an Administrative Meeting SOP
- h) FOOD.60.10 – Enforcement Trigger and Initial Assessment SOP

6. PROCEDURES

6.1. Select Enforcement Case Files for Review

Food Standards Coordinator/Auditor

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- 6.1.1.** Select enforcement case files for review based on the following:

Manufactured Food

6.1.1.1. Select all enforcement case files closed by a Compliance Officer for the fiscal year (October 1st-September 30th) to be audited.

Retail Food

6.1.1.2. Select any enforcement case file that corresponds to an establishment file audit as noted in *FOOD.60.11 – Retail Establishment File Audit SOP*, if not already included.

6.2. Complete the *Enforcement Case Audit Worksheet* – Food Standards Coordinator/Auditor

- 6.2.1.** Complete the *Enforcement Case Audit Worksheet* for each file that qualifies for auditing.

a. Refer to all applicable SOPs and *Guidance for Completing the Enforcement Case Audit Worksheet* when completing form.

- 6.2.2.** Upload the completed *Enforcement Case Audit Worksheet* for each audited file to the MFRPS SharePoint site within five (5) business days of completion.

- 6.2.3.** Complete the applicable section of the *Establishment File Worksheet* if the enforcement case file was referred based on *FOOD.60.11 – Retail Establishment File Audit SOP*.

6.3. Complete *Appendix 6.2 – Level of Conformance to Compliance Procedures* – Food Standards Coordinator/Auditor

- 6.3.1.** Enter the information from each *Enforcement Case Audit Worksheet* into *Appendix 6.2 – Level of Conformance to Compliance Procedures* on an on-going basis.

- 6.3.2.** Calculate the conformance rating to procedures and document on the form once all audits have been completed.

- 6.3.3.** Email completed *Appendix 6.2 – Level of Conformance to Compliance Procedures* to the Compliance Supervisor and BQM Unit Supervisor upon completion.

6.4. Review of Audit Findings and Completion of Corrective Action Plans

Food Standards Coordinator

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6.4.1. Schedule a meeting with the Compliance Supervisor, Assistant Division Director, Division Director, Business and Quality Management Unit Supervisor, and other interested parties to review the *Appendix 6.2 – Level of Conformance to Compliance Procedures* within thirty (30) days of completion. Topics of discussion should include:

- a. Effectiveness of the compliance program and current procedures based on performance ratings and potential improvements needed.
- b. Best practices used to achieve quality enforcement activities supported by sound judgment, adequate evidence, and appropriate documentation.
- c. Corrective Action Plan needs if the performance rating is below 80%.
- d. Resolve any audit disputes.

6.4.2. Enter comments into the *Appendix 6.2 – Level of Conformance to Compliance Procedures* regarding improvements needed to follow enforcement procedures at the close of the meeting.

6.5. Documentation – Food Standards Coordinator Role

6.5.1. Retain all Worksheets and documentation related to the enforcement case audits and corrective actions in an electronic file.

7. RELATED DOCUMENTS (includes References, Attachments)

Enforcement Case Audit Worksheet
 Guidance for Completing the Enforcement Case Audit Worksheet
 Appendix 6.2 – Level of Conformance to Compliance Procedures
 Previous DFID Compliance SOPs
 FOOD.60.01 – Assessing Administrative Penalties SOP
 FOOD.60.02 – Enforcement Case Review and Monitoring SOP
 FOOD.60.03 – Intent for Civil Penalties SOP
 FOOD.60.04 – Notice of Repeat Violation Letter SOP
 FOOD.60.05 – Criminal Prosecution SOP
 FOOD.60.06 – Warning Letters SOP
 FOOD.60.07 – Letters of Information SOP
 FOOD.60.08 – Conducting an Administrative Meeting SOP
 FOOD.60.10 – Enforcement Trigger and Assessment SOP
 FOOD.60.11 – Retail Establishment File Audit SOP
 FOOD.60.13 – Manufactured Foods Field Compliance Actions Audit SOP

8. EQUIPMENT/MATERIALS NEEDED

N/A

9. SAFETY

N/A

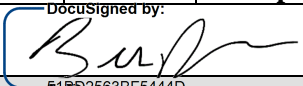
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10. CIRCULATION

This policy will be circulated to the following individuals: Compliance Unit, Business and Quality Management Unit Supervisor, Assistant Division Director, Division Director, Retail and Manufactured Food Program Managers, and the Food Standards Coordinator. The current version will be stored electronically on the FFSD document control site.

11. APPROVAL/DOCUMENT HISTORY

Document History		
Version #	Status (I, R)	Change History
1	I	Initial Policy Drafting.
1.1	R	Added clarification that enforcement cases need to be closed by a Compliance Officer to qualify for auditing in section 6.1.1.1. Addition of FOOD.60.04-Notice of Repeat Violation Letter SOP to the related documents.
DocuSigned by: 		1/5/2017
Approved By:		Date
Approved By:		Date

I = Initial document; R = Revised document