

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

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Title: Manufactured Foods Field Compliance Actions 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 annual review of Manufactured Food Inspection reports that include field compliance actions. The audit is conducted to verify that appropriate field compliance actions are taken correctly during inspections.

**2. SCOPE**

This procedure applies to the audit of manufactured food inspection reports to ensure compliance with FFSD field inspection, report writing, and field compliance procedures. The audit may pertain to inspection reports completed for routine inspections, reinspections or follow-up inspections for manufactured food facilities inspected under MDA authority. This procedure does not apply to retail food inspection reports. Refer to *FOOD.60.11 – Retail Establishment File Audit SOP* for the audit of retail food establishment files and *FOOD.60.12 – Enforcement Case Audit SOP* for the audit of enforcement procedures.

**3. BACKGROUND**

Standard 6 of the Manufactured Food Regulatory Program Standards (MFRPS) requires an annual review of compliance and enforcement actions. The results of the review are used to identify improvements and modify procedures. Proper use, completion, and submission of inspection reports are key components in assuring those purposes are adequately and consistently being met in the Manufactured Food Program. Auditing inspection reports can help to identify where deficiencies exist within the current system as well assist in the initiation of corrective actions which are necessary when deficiencies are identified.

**4. RESPONSIBILITY**

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

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**Manufactured Food Program Manager** – The Manufactured Food Program Manager will assist in determining corrective actions when program-related deficiencies are noted.

**Electronic Systems Coordinator** – The Electronic Systems Coordinator will produce the list of reports in USA Food Safety (USAFS) where a field compliance action was taken or the purpose of the inspection was a reinspection or follow-up inspection.

**Compliance Supervisor** - The Compliance Supervisor will assist in determining corrective actions when program-related deficiencies are noted.

**Food Inspection Supervisor** - The Supervisor will assist the Manufactured Food Program Manager in determining corrective actions when deficiencies are noted.

**Qualified Inspection Report Auditor (Auditor)/Food Standards Coordinator** – The Auditor will review the list of reports; gather reports for review; audit reports; and record findings on the *Manufactured Foods Field Compliance Actions Audit Worksheets* and the .

## 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.

**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 Inspection Report Auditor (Auditor):** A qualified establishment file auditor is someone who has completed the most current training on the following SOPs:

- a) FOOD.30.02 – Reinspection SOP
- b) FOOD.30.05 - Inspection Report Writing SOP
- c) FOOD.30.01 – Inspection Protocol-Manufactured Food SOP
- d) FOOD.30.27 – Field Compliance Actions SOP
- e) FOOD.60.10 – Enforcement Trigger and Initial Assessment SOP

## 6. PROCEDURES

### 6.1. Select Inspection Reports for Review

**Electronic Systems Coordinator**

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**6.1.1.** Generate list of all GMP Inspection Reports produced for the year between October 1<sup>st</sup>-September 30th and identify those with the following inspection reasons:

- a. Reinspection
- b. Follow-Up Inspection

**6.1.2.** Use a SQL server report to identify reports that contain the following written orders:

- a. Embargo
- b. Cease and Desist
- c. Condemnation
- d. Sanitary Notice

**6.1.3.** Compile list of reports that meet the criteria outlined in sections 6.1.1 and 6.1.2 and email to the Food Standards Coordinator and Business and Quality Management (BQM) Unit Supervisor.

**Food Standards Coordinator/Auditor**

**6.1.4.** Request a list of reports to audit from the Electronic Systems Coordinator by the end of October each year.

**6.1.5.** Save the list of reports to the MFRPS SharePoint site. Enter the year for which the list was pulled in the naming convention.

**6.2. Complete the *Manufactured Foods Field Compliance Actions Audit Form* – Food Standards Coordinator/Auditor**

**6.2.1.** Complete the *Manufactured Foods Field Compliance Actions Audit Worksheet* for each report to be audited.

- a. Refer to all applicable SOPs and other reference documents when completing form.

**6.2.2.** Upload the completed *Manufactured Foods Field Compliance Actions Audit Worksheet* for each audited report to the MFRPS SharePoint site within five (5) business days of completion.

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

**6.3.1.** Enter the information from each *Manufactured Foods Field Compliance Actions Audit Worksheet* into *Appendix 6.2-Level of Conformance to Compliance Procedures* on an on-going basis.

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6.3.2. Review *Appendix 6.2 – Level of Conformance to Compliance Procedures* when all audits are complete (at least an 80% performance rating is required to meet the requirements in MFRPS Standard 6).

6.3.3. Email completed *Appendix 6.2 – Level of Conformance to Compliance Procedures* to the Manufactured Food Program Manager, Compliance Supervisor, and BQM Unit Supervisor upon completion.

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

**Food Standards Coordinator**

6.4.1. Schedule a meeting with the Compliance Supervisor, Manufactured Food Program Manager, BQM 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 inspection and compliance programs and current procedures based on performance ratings.
- b. Best practices used to achieve quality compliance 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 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 inspection report audits and corrective actions in an electronic file.

**7. RELATED DOCUMENTS (includes References, Attachments)**

Manufactured Foods Field Compliance Actions Audit Worksheet  
*Appendix 6.2 – Level of Conformance to Compliance Procedures*  
FOOD.30.05 - Inspection Report Writing  
FOOD.30.02 – Reinspection SOP  
FOOD.30.27 – Field Compliance Actions SOP  
FOOD.60.10 – Enforcement Trigger and Initial Assessment SOP  
USAFS Guidance/Work Instructions

**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: the Manufactured Food Program Manager, Manufactured Food Program Supervisors, Manufactured Food Program Inspectors, Compliance Supervisor, Compliance Officers, Business and Quality Management Unit Supervisor, Food Standards Coordinator, Assistant Division Director, Division Director. A standing version will be stored electronically on the FFSD server.

**11. APPROVAL/DOCUMENT HISTORY**

<b>Document History</b>		
<b>Version #</b>	<b>Status (I, R)</b>	<b>Change History</b>
<b>1</b>	<b>I</b>	<b>Initial Policy Drafting.</b>
<i>Jan Kelly</i>		12/08/2016
<b>Approved By:</b>		<b>Date</b>
<b>Approved By:</b>		<b>Date</b>

I = Initial document; R = Revised document