

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

Document FOOD.60.02	Page 1 of 8
Version #: 2	Effective Date: 12/28/2016
Title: <b>Enforcement Case Review and Monitoring</b>	

Table of Contents

1. PURPOSE
2. SCOPE
3. BACKGROUND
4. RESPONSIBILITY
5. DEFINITIONS
6. PROCEDURES
7. RELATED DOCUMENTS (includes References, Attachments)
8. EQUIPMENT/MATERIALS NEEDED
9. SAFETY
10. CIRCULATION
11. APPROVAL/DOCUMENT HISTORY

**1. PURPOSE**

The purpose of this procedure is to establish a uniform system for the determination of enforcement actions through case review for the Minnesota Department of Agriculture (MDA) Food and Feed Safety Division (FFSD) Manufactured and Retail Food Programs.

**2. SCOPE**

This procedure applies to Manufactured and Retail Food Program enforcement case review by the Compliance Unit done under the authority in Minn. Stat. 34A. This procedure does not apply to Food Program field inspection compliance actions and Feed Inspection Program enforcement case review.

**3. BACKGROUND**

Enforcement Case Reviews completed by the Compliance Unit staff are done under the authority of Minnesota Statute 34A. An independent assessment of evidence collected to establish violations is needed for fair and informed decision making regarding enforcement actions. Completing timely and consistent enforcement case reviews after trigger events promotes fair and effective communication between the agency and the regulated entities regarding compliance with state and federal regulations.

The determination of enforcement actions will include the assessment for the evidence having met the Burden of Proof. Burden of Proof defines the duty placed upon a party to prove or disprove a disputed fact, or it can define which party bears this burden. In criminal cases, the burden of proof is placed on the prosecution, who must demonstrate that the defendant is guilty before a jury may convict him or her. In civil cases, the plaintiff is normally charged with the burden of proof, but the defendant can be required to establish certain defenses. Burden of proof can also define the burden of persuasion, or the quantum of proof by which the party with the burden of proof must establish or refute a disputed factual issue. In criminal cases, the prosecution must prove the defendant's guilt beyond a reasonable doubt.

**4. RESPONSIBILITY**

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

Document FOOD.60.02	Page 2 of 8
Version #: 2	Effective Date: 12/28/2016
Title: <b>Enforcement Case Review and Monitoring</b>	

**Division Director** – The Food and Feed Safety Division Director, or designee, will provide feedback regarding enforcement recommendations as needed.

**Food Program Manager** – The Retail or Manufactured Food Program Manager will provide information as requested by the Compliance Officer and participate in the meetings or discussions as requested.

**Compliance Unit Supervisor** – The Compliance Unit Supervisor will assist in determining case assignments to compliance unit staff; review and approve enforcement recommendations as needed; and will assist in closing out enforcement cases.

**Compliance Officer** – The Compliance Officer will conduct the initial case review to recommend supported enforcement actions; monitor the case when active; and communicate with other compliance unit staff, inspection staff, and management as needed.

**Compliance Case Administrator** – The Compliance Case Administrator will create the enforcement case file in SharePoint and add all initial documentation. The Compliance Case Administrator will send correspondence and maintain compliance case files. The Compliance Case Administrator will review the final SharePoint Case file and move all necessary documentation to the enforcement ID in USAFS.

**Food Inspector** - The Food Inspector will participate in planning calls and other meetings or discussions as requested and provide information to assist in closing out enforcement cases.

**Food Inspection Supervisor** - The Food Inspection Supervisor will participate in planning calls and other meetings or discussions as requested and provide information to assist in closing out enforcement cases.

## 5. DEFINITIONS

**Burden of Proof:** Burden of Proof is the duty of proving a disputed assertion or charge. Burden of proof can define the duty placed upon a party to prove or disprove a disputed fact, or it can define which party bears this burden. In criminal cases, the burden of proof is placed on the prosecution, who must demonstrate that the defendant is guilty before a jury may convict him or her. But in some jurisdiction, the defendant has the burden of establishing the existence of certain facts that give rise to a defense, such as the insanity plea. In civil cases, the plaintiff is normally charged with the burden of proof, but the defendant can be required to establish certain defenses. Burden of proof can also define the burden of persuasion, or the quantum of proof by which the party with the burden of proof must establish or refute a disputed factual issue. In criminal cases, the prosecution must prove the defendant's guilt Beyond a Reasonable Doubt.

**Chronic Violator:** A chronic violator is a legal entity that has an approved enforcement action equal to or greater than a Warning Letter and that has had a prior enforcement action equal to or greater than a Warning Letter issued in the last three (3) years.

**Chronic Violation (Repeat Violation):** A chronic violation is a specific violation observed and documented during at least two (2) inspections in a row, also known as a repeat violation.

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

Document FOOD.60.02	Page 3 of 8
Version #: 2	Effective Date: 12/28/2016
Title: <b>Enforcement Case Review and Monitoring</b>	

**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.

**Person:** A Person is any individual, firm, partnership, cooperative, society, joint stock association, association, company, or corporation and includes any officer, employee, agent, trustee, receiver, assignee, or other similar business entity or representative of one of those entities.

**Trigger Event:** A Trigger Event is an event that identifies an assessment for progressive enforcement action must be completed and includes: an inspection report with an Acute Violation, an inspection report with a Chronic Violation, an inspection report with an egregious number of critical or total violations, and referral from FFSD staff based on specific information such as endangerment of public health, overall or history of non-compliance, investigation results or laboratory results.

## 6. PROCEDURES

### 6.1 Create Enforcement Case File – Compliance Case Administrator

- 6.1.1** Identify all regulated entities where the TRIGGER EVENT is limited to CHRONIC VIOLATIONS identified for the first time and follow the procedures outlined in *FOOD.60.10 - Enforcement Trigger and Assessment SOP*.
- 6.1.2** For each regulated entity with a TRIGGER EVENT that is not limited to a CHRONIC VIOLATION identified for the first time, complete the following:
- a. Create an Enforcement ID in USA Food Safety (USAFS) for each firm or individual identified on a trigger report if new, or utilize existing ID if an active case was previously referred to compliance.
  - b. Create a working file document set in SharePoint (SP) for each Enforcement ID, firm or individual identified that does not already have an active working document set.
  - c. Add all applicable documentation including inspection reports, photos, laboratory reports, attachments and other pertinent documents from the TRIGGER EVENT to the document set in accordance with *FOOD.WI.60.01 – Compliance Case Processing WI*.
  - d. Perform a license search in LIS and attach documentation of the current license status to the document set.
  - e. Perform a public document search of company information from the Secretary of State's web site and add the information to the document set or include a statement in the notes section that no information was found.

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

Document FOOD.60.02	Page 4 of 8
Version #: 2	Effective Date: 12/28/2016
Title: <b>Enforcement Case Review and Monitoring</b>	

- f. Attach the *Progressive Enforcement Matrix Template* in the SP document set and add the facility details from USAFS in the appropriate sections.
- g. Attach the *Enforcement Case Assessment Summary Template* to the SP document set filling in the trigger event details and the facility and owner details from USAFS.
- h. Assign Compliance Unit staff to the SP enforcement case based on current work volumes or direction from the Compliance Unit Supervisor.

**6.2 Case Review and Progression– Compliance Officer**

- 6.2.1 Conduct an initial case review of case assignment to determine which action should be recommended.
  - a. Complete the *Progressive Enforcement Matrix* based on case details and discussions with inspection staff. Determine if discussion with Compliance Unit Supervisor is required prior to case review based on *Progressive Enforcement Matrix* score from Assessment – see Table 1: Enforcement Recommendation Options. Coordinate discussion when necessary.
  - b. Review all documents in the document set.
  - c. Collect previous paper inspection reports and photos (if available) if missing from the document set.
  - d. Schedule a planning call with the Food Inspector, Food Inspection Supervisor, and Food Program Manager, when applicable.
  - e. Review the enforcement action options based on *Progressive Enforcement Matrix* score as identified in Table 1: Enforcement Recommendation Options.
  - f. Complete applicable sections of the *Enforcement Case Assessment Summary* to record pertinent case details and timeline of events.
- 6.2.2 Prepare either an ENFORCEMENT ACTION and forward to Compliance Unit Supervisor for approval, or for cases requiring approval before completing, prepare and present the case summary to the Compliance Unit Supervisor for ENFORCEMENT ACTION approval. Base the ENFORCEMENT ACTION determination on the strength and detail from the evidence provided. Multiple enforcement actions can be taken concurrently if warranted.
  - a. Identify the burden of proof necessary for the specific enforcement action(s) selected.
  - b. Contact the Food Inspector and/or Food Inspection Supervisor if additional detail or explanation for current evidence is required and/or if further inspections have occurred.

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

Document FOOD.60.02	Page 5 of 8
Version #: 2	Effective Date: 12/28/2016
Title: <b>Enforcement Case Review and Monitoring</b>	

- c. Complete recommended enforcement action using applicable procedures and after any required preapprovals are received from the Compliance Unit Supervisor.
  - d. Update the SP Enforcement Case information to reflect the step in the case.
- 6.2.3** Update SP Enforcement Case status when actions are ready for approval and issuance in accordance with *FOOD.WI.60.01 – Compliance Case Processing WI*.

**Table 1: Enforcement Recommendation Options**

	Level 1	Level 2	Level 3	Level 4
Supervisor discussion prior to full case review	No	No	No	Required
Enforcement Action Options**	No Action	Letter of Information	Warning Letter	Corrective Action Order
	Letter of Information	Notice of Repeat Violation	Corrective Action Order	Civil Penalty
	Notice of Repeat Violation	Warning Letter	Civil Penalty	License limitation or revocation
		Corrective Action Order	License limitation or revocation	Injunction / TRO
			Injunction / TRO	*Administrative Meeting
			*Administrative Meeting	Administrative Penalty
			Criminal Prosecution	
Supervisor approval prior to starting recommended action	No	No	Required	Required
*Requires additional review of enforcement case details and enforcement action recommendation after completed.				
<b>**Additional actions may be utilized as determined by the Division Director. When approved by the Division Director, an issued or contemplated enforcement action may be resolved through the use of a stipulated settlement agreement.</b>				

**6.3 Monitoring of Enforcement Case – Compliance Case Administrator**

- 6.3.1** Send all correspondence via first class and/or certified mail according to *FOOD.WI.60.01 – Compliance Case Processing WI*, and/or other guidance. Include all enclosures identified and copy all parties listed.
- 6.3.2** Attach any responses and/or all other documentation received via mail or email, including monitoring Compliance Unit’s inbox, into SP and/or USAFS in accordance with *FOOD.WI.60.01 – Compliance Case Processing WI*.
- 6.3.3** Maintain compliance records, files and data in accordance with data practices policy, record retention rules, *FOOD.WI.60.01 – Compliance Case Processing WI*, and/or other guidance.

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

Document FOOD.60.02	Page 6 of 8
Version #: 2	Effective Date: 12/28/2016
Title: <b>Enforcement Case Review and Monitoring</b>	

**6.4 Monitoring of Enforcement Case – Compliance Officer**

- 6.4.1** Monitor all correspondence, ongoing inspections actions or investigations relating to the firm/individual.
- 6.4.2** Review cases at each milestone and/or at least monthly until compliance is achieved and the case can be closed out. Update and/or consult with the Compliance Unit Supervisor as necessary to ensure cases continue moving towards completion.
- 6.4.3** Direct all appeals as described in *FOOD.30.14 - Industry Complaint SOP* and update the SP enforcement case status in accordance with *FOOD.WI.60.01 – Compliance Case Processing WI* and/or other guidance.
- 6.4.4** Coordinate and facilitate planning meetings throughout the case as needed for active communication with Compliance Unit Supervisor, Program Management and assigned Food Inspection staff. Review information and recommend additional enforcement actions as situation warrants.
- 6.4.5** Use the Case Summary and/or OneNote Investigations as appropriate to capture the timeline of the enforcement review, specific actions that are completed and pertinent discussions held.
- 6.4.6** Attach all other documentation in SP and/or USAFS and add internal notes as necessary into USAFS in accordance with *FOOD.WI.60.01 – Compliance Case Processing WI* and/or other guidance.

**6.5 Completing the Enforcement Case Review – Compliance Officer**

- 6.5.1** In consultation with the Compliance Unit Supervisor, Food Inspection Supervisor and Food Inspector(s), determine that:
  - a.** Submitted ENFORCEMENT ACTION appeals are resolved, or
  - b.** Appeal timeframes are passed, and
  - c.** No additional inspection or investigation information indicates additional ENFORCEMENT ACTION review and recommendation is needed at this time.
- 6.5.2** Coordinate with all pertinent staff the next steps, if any, which may be necessary to follow-up and ensure continued compliance, e.g. increasing inspection frequency.
- 6.5.3** Delete duplicate records and/or drafts of items which are saved in a finalized format.
- 6.5.4** Finalize the *Enforcement Case Summary*, digitally sign, and save/upload to the SP Enforcement case document set and USAFS Enforcement ID in accordance with *FOOD.WI.60.01 – Compliance Case Processing WI*.
- 6.5.5** Update the SP enforcement case status and identify if the entity meets the definition of CHRONIC VIOLATOR as appropriate per *FOOD.WI.60.01 – Compliance Case Processing WI*.

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

Document FOOD.60.02	Page 7 of 8
Version #: 2	Effective Date: 12/28/2016
Title: <b>Enforcement Case Review and Monitoring</b>	

**6.6 Closing the Enforcement Case and Data Management – Compliance Case Administrator**

- 6.6.1** Review SP Enforcement case file to verify all necessary documentation has been uploaded.
- 6.6.2** Combine all existing documents in the SP file set into one document and upload into USAFS in accordance with *FOOD.WI.60.01 – Compliance Case Processing WI* and/or other guidance.
- 6.6.3** Ensure all case documents loaded to the facility in USAFS are able to be opened and viewed.
- 6.6.4** Delete remaining files from SharePoint which are already maintained in or have been properly uploaded to USAFS.
- 6.6.5** Update the USAFS enforcement case ID and SP document set statuses in accordance with *FOOD.WI.60.01 – Compliance Case Processing WI* and/or other guidance.

**6.7 Maintain Documentation - All**

- 6.7.1** Maintain all compliance records, files, and data related to enforcement case review and enforcement process in the electronic files in accordance with data practices policy, record retention rules, *FOOD.WI.60.01 – Compliance Case Processing WI*, program procedures, and/or other guidance.

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

Minnesota Statutes 34A

Enforcement Case Summary Template

Progressive Enforcement Evaluation Matrix

FOOD.30.14 - Industry Complaint SOP

Data Practices Policy

FOOD.60.10 – Enforcement Trigger and Assessment SOP

FOOD.WI.60.01 - Compliance Case Processing Work Instruction

**8. EQUIPMENT/MATERIALS NEEDED**

N/A

**9. SAFETY**

N/A

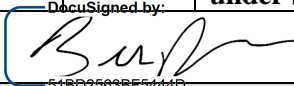
**10. CIRCULATION**

This policy will be circulated to the following groups: Food Program Supervisors, Food Program Management, Food Inspectors, Compliance Supervisor, Compliance Officers, Case Administrator, Division Director, Assistant Division Director, BQM Unit Supervisor, and Food Standards Coordinator. The current version will be stored electronically on the FFSD document control site.

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

Document FOOD.60.02	Page 8 of 8
Version #: 2	Effective Date: 12/28/2016
Title: <b>Enforcement Case Review and Monitoring</b>	

**11. APPROVAL/DOCUMENT HISTORY**

Document History		
Version #	Status (I, R)	Change History
1	I	Initial Policy Drafting.
1.1	R	Updates to SOP based on new responsibility language; addition of 6.1.3; additional language added to 6.2.6; addition of 6.2.9; removal of scoring values from Table 1; addition of 6.3.2; 6.4.3 changed to 6.3.6; addition of 6.5-Data Management of Enforcement Case-Case Administrator; and updates to timeframes.
2	R	Added references to new FOOD.WI.60.01-Compliance Case Processing WI; addition of 6.1.1 and 6.1.2; minor process changes to 6.2; addition of 6.3-Monitoring of Enforcement Case-Case Administrator; addition of Notice of Repeat Violation Letter and Corrective Action Order to Table 1; addition of definition of Chronic Violator and subsequent monitoring; addition of Enforcement Actions definition. Removal of Progressive Enforcement Process Flow from related documents.  Original procedure approved on 12/28/2016. Typographical error was found under Section 6.5.5 and updated per FFSD.POLICY.90.06.
DocuSigned by: 		1/23/2017
<b>Approved By:</b>		<b>Date</b>
<b>Approved By:</b>		<b>Date</b>

I = Initial document; R = Revised document