

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

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Version #: 2	Effective Date: 12/28/2016
Title: Enforcement Trigger and Assessment SOP	

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1. PURPOSE

The purpose of this procedure is to describe the process used by the MN Department of Agriculture's (MDA) Food and Feed Safety Division Staff to identify, report and process regulated entities for ENFORCEMENT ACTIONS and/or ENFORCEMENT CASE review.

2. SCOPE

This procedure applies to the Food and Feed Safety Division staff for Manufactured and Retail Food firms or other firms that fall under the inspection and licensing authorities in Minnesota Statutes (Minn. Stat.) § 28A, 31 and 34A.

3. BACKGROUND

Enforcement TRIGGER EVENTS are used by the Minnesota Department of Agriculture (MDA) Food Feed Safety Division (FFSD) to ensure accurate and consistent referrals for ENFORCEMENT ACTION and ENFORCEMENT CASE review. TRIGGER EVENTS will be used to identify when regulated entities require assessments for ENFORCEMENT ACTIONS. A progressive enforcement evaluation is used to prioritize and process ENFORCEMENT ACTIONS.

4. RESPONSIBILITY

Division Director – The Division Director will offer guidance as needed and review the *Egregious Violation Threshold Table* when updated.

Food Program Manager - The Retail or Manufactured Food Program Manager will provide information as requested by the Compliance Officer and ensure coordination with inspection staff as needed.

Compliance Supervisor - The Compliance Supervisor will update the *Egregious Violation Threshold Table* and work with the Business and Quality Management Unit Supervisor (BQM) to ensure trigger event reporting from USAFS is occurring; and oversee the work of the Compliance Staff.

Compliance Case Administrator – The Compliance Case Administrator will monitor and track the USAFS Trigger Event reporting and Compliance Inbox; create SharePoint document sets as working files; and create USAFS enforcement IDs for permanent record keeping.

Compliance Officer - The Compliance Officer may add enforcement files to applicable facilities in USAFS and upload/review documentation as needed to the Compliance Case file.

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Food Inspection Program Staff - The Food Inspection Program Staff (Program Managers, Supervisors, and Inspectors) will monitor inspection reports, sample results, investigations, laboratory reports and other information related to regulated entities as applicable to their position and refer items to Compliance for case review. The Food Inspection Program Staff will provide information and feedback as requested by the Compliance Staff.

Business and Quality Management (BQM) Unit Supervisor – The BQM Unit Supervisor will update the USAFS SQL Server based on the current version of the *Egregious Violation Threshold Table*.

5. DEFINITIONS

Acute Violation: An Acute Violation is a violation of significant public health or regulatory impact as identified in the *Appendix A - Acute Violation List*.

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.

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

Critical Violation: A Critical Violation is a Major Violation as defined by Minn. Stat. § 28A.03 Subd.9 or a Critical Item as defined by MR 4626.0030 Subd.2 and includes violations of Minn. Stat. §§ 31.121, 31.123, 31.161, 31.165, 31.02, 34A.04 Subd.1, 34A.05, and 34A.11 Subd.1.

Egregious Violation: An incident of a statistically significant count of total orders or critical orders issued in the inspection report (as determined by the *Egregious Violation Threshold Table*).

Enforcement Action: 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.

Prohibited Act: An act as identified in Minnesota Statute § 31.02 or the causing of such act(s) within Minnesota.

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 a 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 Identify Egregious Violation Thresholds – Compliance Supervisor

6.1.1 Calculate the egregious violation threshold number for total violations and critical violations by using two (2) standard deviations greater than the mean every six (6) months for routine inspection reports stratified by license classification and risk classification.

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6.1.2 Round calculated values to the nearest whole number and update the *Egregious Violation Threshold Table*.

6.1.3 Save the completed table to the Compliance SharePoint site.

6.1.4 Send a notice regarding the updated table to Compliance Officers, Food Inspection Supervisors, Program Managers, and the Division Director.

6.1.5 Send a notice regarding the updated table to the Business and Quality Management Unit Supervisor so the USAFS SQL Server reporting system can be updated accordingly.

6.2 Referral to Compliance – Food Inspection Program Staff

6.2.1 Monitor information from inspections, complaints, response investigations, compliance investigations, and laboratory sampling reporting for regulated entities to identify:

6.2.1.1 Endangerment of public health – for example a severe health risk such as contamination of product with known pathogen, toxins, undeclared major allergens or harmful physical contaminate;

6.2.1.2 Overall lack of compliance of the firm – for example a loss of process control;

6.2.1.3 Facility has multiple inspection reports with violations that need to be reviewed which separately may not be identified on a trigger report (i.e.-a facility that conducts both retail and manufacturing processes and therefore receives two inspection reports);

6.2.1.4 Occurrence of CHRONIC VIOLATION that is based on an inspection report which was not conducted in USAFS (paper inspection report);

6.2.1.5 History of issues at the firm – for example reissuing the same order multiple times across multiple inspections, reinspections or follow up inspections; and/or

6.2.1.6 Specific information from investigations – for example false statements are revealed or deliberately deceptive actions.

6.2.2 When 6.2.1 conditions are identified, notify Compliance Staff of the referral using one of the following methods:

6.2.2.1 Email MDA.FFSDCompliance@state.mn.us with the following information: Legal entity ID, legal entity name and a description of the issue with “Refer to Compliance” in the subject line.

6.2.2.2. Select the “Refer to Compliance” option in the “Further Action” section of an inspection report in USAFS. This option must be selected by the Food Inspection Supervisor as part of the inspection report approval process for Compliance Staff to receive the notification and the Enforcement ID to be created.

6.3 Trigger Event Reporting – Compliance Supervisor

6.3.1 Work with the Business and Quality Management Unit Supervisor to set and/or update TRIGGER EVENT reporting from USAFS.

6.3.1.1 Automatic reporting will be based on the following TRIGGER EVENTS:

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- a. Inspection reports identifying EGREGIOUS VIOLATIONS – total violations and CRITICAL VIOLATIONS
- b. Inspection reports referencing ACUTE VIOLATIONS
- c. Inspection reports identifying CHRONIC VIOLATIONS
- d. Referrals to Compliance

6.3.2 Ensure the Compliance Case Administrator receives the daily USAFS Trigger Event Report.

6.4 Trigger Event Monitoring– Compliance Case Administrator

- 6.4.1 Monitor the USAFS Trigger Event reporting, including USAFS automatic reporting and the Compliance Inbox “Refer to Compliance” emails daily.
- 6.4.2 Identify all regulated entities where the TRIGGER EVENT is limited to CHRONIC VIOLATIONS identified for the first time. Refer to *FOOD.60.04 – Notice of Repeat Violations SOP* for further instructions.
- 6.4.3 For each regulated entity with a TRIGGER EVENT that is not limited to a CHRONIC VIOLATION identified for the first time, create an ENFORCEMENT CASE using the SharePoint document set and create a USAFS Enforcement ID if one has not already been created, in accordance with *FOOD.60.02 - Enforcement Case Review and Monitoring SOP* and *FOOD.WI.60.01 - Compliance Case Processing WI*.

7. RELATED DOCUMENTS (includes References, Attachments)

Appendix A – Acute Violations List

Egregious Violation Threshold Table Template

FOOD.60.02 – Enforcement Case Review and Monitoring SOP

FOOD.WI.60.01 – Compliance Case Processing WI

Progressive Enforcement Continuum

8. EQUIPMENT/MATERIALS NEEDED

N/A

9. SAFETY

N/A

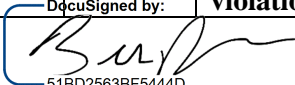
10. CIRCULATION

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

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11. APPROVAL/DOCUMENT HISTORY

Document History		
Version #	Status (I, R)	Change History
1	I	Initial Policy Drafting.
1.1	R	Updates made to the SOP to include specific responsibilities; removal of “continuous” and “reoccurring” verbiage when describing acute and chronic violations; changed “Field” to “Food” Inspector under section 6.2; removed Table 1: Chronic Violations; additional USAFS language regarding use of internal notes for communication about enforcement; and increased timelines for assessment completion.
2	R	Removal of “initial” from procedure name; removed original section 6.2- Compliance Review Recommendation and Notification and original section 6.5- Initial Enforcement Assessment; further defined Referral to Compliance by Food Inspection Staff in section 6.2; removed non-critical violation definition; added definitions for enforcement case, enforcement actions, and egregious violation.
DocuSigned by:  <small>51BD2563BE5444D</small>		12/28/2016
Approved By:		Date
Approved By:		Date

I = Initial document; R = Revised document