**Table of Contents**

[1. PURPOSE](#_Toc283285790)

[2. SCOPE](#_Toc283285791)

[3. BACKGROUND](#_Toc283285792)

[4. RESPONSIBILITY](#_Toc283285793)

[5. DEFINITIONS](#_Toc283285794)

[6. PROCEDURES](#_Toc283285795)

[7. RELATED DOCUMENTS (includes References, Attachments)](#_Toc283285796)

[8. EQUIPMENT/MATERIALS NEEDED](#_Toc283285797)

[9. SAFETY](#_Toc283285798)

[10. CIRCULATION](#_Toc283285799)

1. **PURPOSE**

The purpose of this procedure is to establish a uniform system for calculating civil penalties and notifying regulated entities of the Minnesota Department of Agriculture (MDA) Food and Feed Safety Division’s (FFSD) Manufactured Food, Retail Food, and Produce Safety Programs intent to take civil action for violations of Minnesota Statutes, Rules, and Federal Laws and Regulations referenced by Minnesota Statute.

1. **SCOPE**

This procedure applies to FFSD Compliance Unit staff for the assessment of Civil Penalties and civil actions under the authority in Minnesota Statute (Minn. Stat.) § 34A.09.

1. **BACKGROUND**

Civil Penalties are a civil action taken against a person(s) in Minn. Stat. § 34A.09. A person(s) who violates the law is subject to a civil penalty of up to $7,500 per day per violation as determined by the court. A Civil Penalty is calculated by using *Table 1-Penalty Assessment Table*. The fine amount is determined by specific violation, occurrence of the violation (1st, 2nd, or 3rd occurrence), and **severity** of violation (critical, non-critical, P1, P2, and P3). The Commissioner may consider; willfulness of the violation, gravity of the violation, person’s history of past violations, number of violations, and the economic benefit from the violation when determining the civil penalty. The Commissioner may also consider; similarity between the violations, time elapsed since the last violation, and the person's response to the most recent violation.

When civil actions are filed with the district court, MDA requests a specific fine to be assessed. The district court will determine the fines to be paid by the person(s). An appeal of court issued fines will result in a court hearing with the district court.

This SOP will have a functional effective date of January 1, 2019 for the purposes of the Compliance Unit’s work to coincide with the release of the revised MN Food Code, Minnesota Rule 4626.

1. **RESPONSIBILITY**

**Division Director** – The Division Director will approve Civil Penalty assessments over $5,000.

**Program Manager** – The Program Manager will provide information and participate in meetings as requested by the Compliance Unit Staff.

**Compliance Supervisor** – The Compliance Supervisor will review all Civil Penalty assessments and submit to Division Director for approval if the total assessment is over $5,000.

**Compliance Officer** – The Compliance Officer will review violations for assessment, prepare the Civil Penalty assessment, draft and issue the Notice of Intent letter.

**Compliance Case Administrator** –The Compliance Case Administrator will send correspondence and maintain compliance case files.

**Inspection Staff** - Inspection Staff, including Inspectors, Supervisors and Program Managers, will provide information and feedback and participate in meetings as requested by the Compliance Unit Staff.

1. **DEFINITIONS**

**Acute Violation:** An Acute Violation is a violation of significant public health or regulatory impact as identified in Appendix A - Acute Violation List, which includes Major Violations as defined by Minn. Stat. § 28A.03 Subd.9 and prohibited act violations.

**Agreement (or Stipulated Settlement Agreement):** An Agreement or Stipulated Settlement Agreement is an agreement between a firm and the MDA which agrees on terms or conditions of enforcement. These agreements may include penalties or consequences if violations are not resolved or continue to occur in the future. They may also include stayed fees or penalties for adherence to the agreement. These agreements may also be used to outline payment plans for penalties and settlements assessed in enforcement actions.

**Chronic Violation (Repeat Violation):** A Chronic Violation is a specific violation observed and documented during at least two (2) inspections in a row, and/or from one (1) routine inspection to the next routine inspection, also known as a repeat violation.

**Civil Penalty:** A monetary penalty sought through a district court against a person due to violations of regulatory requirements. Final penalty is determined by the district court.

**Critical Violation:** A Critical Violation is a Major Violation as defined by Minn. Stat. §

28A.03 Subd.9 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 Sudb.1. For the applicable parts of 21 CFR, critical violations are violations which are directly linked to public health risk, food adulteration, and/or known contributors to foodborne illness and are identified as critical violations in USA Food Safety (USAFS) unless otherwise defined by the Manufactured Food Program.

**Non-Critical or Priority 3 Violation:** A Non-Critical or Priority 3 Violation is a violation of Minnesota Statute or Rule that does not meet the definition of critical violation or Priority 1 or Priority 2 violations.

**Notice of Intent (NOI) Letter**: A letter which communicates to a person FFSD’s intent to file a civil action in court to recover penalties and provides an option for the person to settle out the case before FFSD files the action in court.

**Preponderance of Evidence:** Superiority in weight of an evidence that is more convincing (even if minimally) than the evidence presented by the other party.

**Priority 1 violation:** A Priority 1 violation is defined in MN Food Code 4626 and is designated in USAFS as a P1 Violation and includes Major Violation as defined by Minn. Stat. § 28A.03 Subd.9 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 Sudb.1.

**Priority 2 violation:** A Priority 2 violation is defined in MN Food Code 4626 and is designated in USAFS as a P2 Violation.

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

1. **PROCEDURES**
   1. **Review Violation(s) for Assessment – Compliance Officer**
      1. Select the violation(s) that support civil penalty assessment.
         1. For inclusion in the penalty assessment, the observation must fully and completely support the orders being issued with a preponderance of evidence.
         2. Any observations that are ambiguous, unclear or do not meet the level of preponderance should not be included for penalty assessment.
      2. Identify if a prohibited act has occurred using the following decision guidance:
         1. Assess all the violations noted by orders, observations and supporting evidence for the willfulness of the violation, the person's history of violations, the number of violations, and the nature of the violations.
         2. Determine if any single order(s) with observation and supporting evidence clearly demonstrates that a prohibited act was occurring. Include each single order that independently supports a prohibited act violation and charge separately in the *Civil Penalty Assessment Worksheet* when assessing penalties. For example, if an allergen containing product is produced before a non-allergen containing product on the same production line without sufficient sanitation occurring; this would support a prohibited act violation as adulteration of food. During the same inspection, a leaking roof has allowed water to drip onto a raw ingredient that will not receive a kill-step during processing. This failure to properly protect the ingredient would be charged as a separate prohibited act as adulteration of food. In this example, two (2) separate charges of prohibited act violations (adulteration of food) would be assessed in the *Civil Penalty Assessment Worksheet*.
         3. Determine if multiple orders and observations in combination demonstrate that a prohibited act is occurring. For each instance when a combination of orders will demonstrate a prohibited act has occurred, include that prohibited act in the *Civil Penalty Assessment Worksheet* for penalty assessment. For example, lack of adequate hand washing coupled with direct bare hand contact with ready to eat foods are two separate observations that together support a prohibited act violation (adulteration of food). This example is supported by two (2) observations and would be assessed as one (1) prohibited act violation in the *Civil Penalty Assessment Worksheet*.
      3. For orders or combination of orders that do not demonstrate a prohibited act is occurring, add each chronic violation to the *Civil Penalty Assessment Worksheet* as a critical, priority 1, priority 2, priority 3, or non-critical violation (as identified in USAFS) for penalty assessment.
         1. Additionally, for a chronic violation, the following must also be considered: (1) similarity between the violations; (2) time elapsed since the last violation; and (3) the person's response to the most recent violation.
         2. Further discussion may be required with the Compliance Supervisor to determine if a chronic violation should be included in a penalty.
   2. **Determine Penalty Assessment Occurrence – Compliance Officer**
      1. Review the firm’s enforcement history in USAFS, Compliance Unit records, and other FFSD records and identify the penalty assessment occurrence.
      2. A penalty assessment has occurred if a penalty or settlement fee has been assessed to the person regarding the same violation of Statute or Rule.
         1. If no previous assessments have occurred, consider this the first (1st) assessment.
         2. If one (1) previous assessment has occurred, consider this the second (2nd) assessment.
         3. If two (2) previous assessments have occurred, consider this the third (3rd) assessment.
         4. If three (3) previous assessments have occurred, discuss with supervisor to determine appropriate enforcement action and next steps.
   3. **Complete Penalty Assessment Worksheet – Compliance Officer**
      1. Use *Table 1 - Penalty Assessment Table* and the information from Section 6.1 to identify the penalty for each violation in the *Civil Penalty Assessment Worksheet*.
      2. Add the *Civil Penalty Assessment Worksheet* to the SP enforcement file.
   4. **Draft Notice of Intent Letter – Compliance Officer**
      1. Using the case information and the *Civil Penalty Assessment Worksheet*,prepare the notice of intent letter.
      2. Use the following information to compose content for the notice of intent letter.
         1. Introduce the document.
         2. Describe the factual background which will include specific information to identify the firm and the firm’s operations as well as a history of the firm’s violations and any prior enforcement actions.
         3. Identify the rule, statute, or Code of Federal Regulation (CFR) that was identified as being violated or has been alleged to be violated.
         4. Explain FFSD’s intent to file a civil action.
         5. Describe the settlement opportunity that is being offered to the firm.
         6. Conclude with the effects of the settlement a method for the firm to submit additional information.
   5. **Draft Notice of Intent Cover Letter – Compliance Officer**
      1. Draft a cover letter to send out to the firm with the notice of intent letter to explain the proposed action, settlement options and what method the firm may use to submit additional information regarding the case to FFSD.
      2. Include the *Civil Penalty Assessment Worksheet* as an enclosure in the letter.
      3. Identify FFSD staff to be copied on the letter.
      4. Add drafted letter to SharePoint enforcement file.
      5. Notify the Compliance Unit Supervisor of the completed notice of intent letter, cover letter, and *Civil Penalty Assessment Worksheet*.
   6. **Review and Approval of Notice of Intent Letter and Penalty Assessment Worksheet – Compliance Unit Supervisor**
      1. Review the notice of intent letter and *Civil Penalty Assessment Worksheet*. Send necessary edits to the Compliance Officer.
      2. Present the notice of intent letter and *Civil Penalty Assessment Worksheet* to the Division Director for approval when the amount is greater than $5,000. The Division Director will obtain Commissioner approval for amounts greater than $5,000.
   7. **Issue Notice of Intent Letter – Compliance Case Administrator**
      1. After receiving necessary approvals prepare and send final cover letter including all enclosures: notice of intent letter, *Civil Penalty Assessment Worksheet*, Civil Penalty Statute(s), and copies of inspection report(s).
      2. Print the notice of intent letter and enclosures to be mailed. Scan the notice of intent letter and enclosures and attach to the SharePoint enforcement file and the assigned Enforcement ID in USAFS.
      3. Send correspondence to firm or individual using certified mail and first class mail.
      4. Send electronic copies to individuals identified on the cover letter.
   8. **Maintain Documentation – All Compliance Staff**
      1. Maintain all documentation related to the notice of intent letter in the electronic compliance files.
2. **RELATED DOCUMENTS (includes References, Attachments)**

Appendix A – Acute Violation List

Minnesota Statutes 34A

Civil Penalty Assessment Worksheet

Table 1 - Penalty Assessment Table

NOI Civil Cover Letter templates

Notice of Intent Letter template

1. **EQUIPMENT/MATERIALS NEEDED**

N/A

1. **SAFETY**

N/A

1. **CIRCULATION**

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