

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

Document FOOD.60.06	Page 1 of 3
Version #: 2	Effective Date: 12/28/2016
Title: Warning Letters	

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 describe the process used to draft and issue WARNING LETTER.

2. SCOPE

This procedure will be used when writing a WARNING LETTER under the authorities in MS 34A.06, and does not apply to Letters of Information or other enforcement action correspondence.

3. BACKGROUND

A WARNING LETTER is an Administrative Action as described in MS 34A.06 and is used as a compliance tool in the Progressive Enforcement Continuum. WARNING LETTER are used when there is a documented issue or violation that is verifiable and may originate from a compliant, investigation or inspection. Additionally, WARNING LETTER can also serve to inform the receiving entity of the regulatory requirements and may be used to establish willfulness for further enforcement actions if non-compliance continues. WARNING LETTERS are not used to issue orders for correction and are not typically used to provide information outside the scope of the violations it addresses.

The purpose of a WARNING LETTER is to notify the receiving entity of MDA's intent to take additional enforcement action based on the applicable evidence available if compliance with written orders is not voluntarily completed. As such, there is no specific burden of proof or evidence required to support the issuance of the WARNING LETTER itself and a WARNING LETTER may be issued to reiterate the need to comply with a previously documented written order or to warn of a potential violation where insufficient evidence exists to support a written order.

4. RESPONSIBILITY

Compliance Officer – The Compliance Officer will draft the WARNING LETTER, upload to the electronic server, and maintain documentation related to issuance of WARNING LETTERS.

Compliance Case Administrator –The Compliance Case Administrator will send completed WARNING LETTERS, email completed WARNING LETTERS to applicable staff, and maintain documentation related to issuance of WARNING LETTERS.

5. DEFINITIONS

Warning Letter: A Warning Letter is a written letter used to notify a regulated entity when MDA intends to take further enforcement action based on evidence obtained and previously written orders if voluntary compliance is not voluntarily completed.

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

Document FOOD.60.06	Page 2 of 3
Version #: 2	Effective Date: 12/28/2016
Title: Warning Letters	

6. PROCEDURES

6.1 Draft Warning Letter - Compliance Officer

- 6.1.1 Draft the WARNING LETTER, using the applicable *Warning Letter Template* when the enforcement case review process supports the issuance of a WARNING LETTER.
- 6.1.2 Identify and include the appropriate mailing address for regulatory correspondence to the firm or individual using public records such as the Secretary of State and public websites. This may not be the mailing address identified in USAFS when that address is directed to accounting departments.
- 6.1.3 Upload the WARNING LETTER to the SharePoint (SP) enforcement file and change the file status as appropriate.

6.2 Finalize and Mail Warning Letter - Compliance Case Administrator

- 6.2.1 Update the date on the WARNING LETTER to the date the letter is being printed and mailed.
- 6.2.2 Print the letter and enclosures to be mailed. Scan the letter and enclosures and attach to the SharePoint enforcement file and the assigned Enforcement ID in USAFS.
- 6.2.3 Send the WARNING LETTER including enclosures of referenced orders to comply via first class mail, and/or email if available.
- 6.2.4 Electronically copy all Department staff indicated on the letter.

6.3 Maintain Documentation – Compliance Officer and Case Administrator

- 6.3.1 Maintain all documentation related to the issuance of the WARNING LETTER in the electronic files per program policy.

7. RELATED DOCUMENTS (includes References, Attachments)

Warning Letter Templates

8. EQUIPMENT/MATERIALS NEEDED

N/A

9. SAFETY

N/A

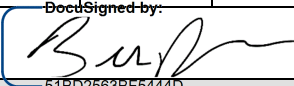
10. CIRCULATION

This policy will be circulated to the following groups: Compliance Officers, Compliance Case Administrator, and the Compliance Supervisor. The current version will be stored electronically on the FFSD document control site.

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

Document FOOD.60.06	Page 3 of 3
Version #: 2	Effective Date: 12/28/2016
Title: Warning Letters	

11. APPROVAL/DOCUMENT HISTORY

Document History		
Version #	Status (I, R)	Change History
1	I	Initial Policy Drafting.
2	R	Divided previous procedure into three sections applicable to Compliance Officer role and Case Administrator roles.
DocuSigned by: 		12/28/2016
Approved By:		Date
Approved By:		Date

I = Initial document; R = Revised document