

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

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Version #: 3	Effective Date: 12/14/2016
Title: <b>Regulatory Foundation Review and Change</b>	

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## **1. PURPOSE**

This procedure describes the process used to evaluate the legal authority and regulatory provisions to inspect and investigate food plants, gather evidence, collect and analyze samples, and take enforcement actions by the Manufactured Food Program in the Food and Feed safety Division (FFSD) of the Minnesota Department of Agriculture. The procedure also explains the process to adopt and implement changes in state and federal regulations.

## **2. SCOPE**

This procedure applies to all state statutes and rules and federal laws and regulations that apply to the Manufactured Food Program within the Food and Feed Safety Division (FFSD) of the Minnesota Department of Agriculture (MDA). This procedure does not apply to the Retail Food Program or Commercial Feed Programs within FFSD.

## **3. BACKGROUND**

The State of Minnesota adopts U.S. Food and Drug Administration (FDA) 21 CFR Part 0-1299 by reference on continuous basis per *Minnesota State Statute 31.101*. Subd. 8. The Manufactured Food Regulatory Program Standards (MFRPS) requires the evaluation of legal authority and regulatory provisions by each manufactured food program enrolled in the MFRPS to ensure the legal authority and regulatory provisions to protect public health by ensuring the safety and security of the manufactured food supply within its jurisdiction. The State program's evaluation includes a determination of how the State's regulatory foundation corresponds to the U.S. FDA's regulatory foundation. This determination is done through the completion of *Appendix 1-Self-Assessment* Worksheet.

## **4. RESPONSIBILITY**

**Manufactured Food Program Manager:** The Manufactured Food Program Manager will follow all procedures described in this document including review of State and Federal changes in legal language and initiation of updated procedures and training.

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**Manufactured Food Program Supervisors:** The Manufactured Food Program Supervisors will support the Food Program Manager with the update of procedures and training as required.

**MDA Legal Counsel:** MDA Counsel will assist in the review of state and federal regulations, regulatory changes and provide guidance as requested.

**Food Standards Coordinator:** The Food Standards Coordinator will coordinate with the Manufactured Food Program Manager to complete *Appendix 1*, submit *Appendix 1* for review to the Manufactured Food Program Manager on an annual basis, and maintain documents per the procedure.

## 5. DEFINITIONS

**Equivalent:** means that the State law directly references the relevant provision or regulation of the FD&C Act or 21 CFR. The State Program specifies the Federal statute or regulation that is incorporated into the State law, including the revision date of the State statutory provision or regulation, the date the Federal statutory provision or regulation was incorporated into State law, and whether that statutory or regulatory provision is included in whole, in part, or modified from the original.

**Equivalent in Effect:** means that the State law has the same regulatory effect as the relevant FD&C Act provision or CFR regulation. A State law may have the same regulatory effect as the Federal law or regulation if either a single State law or rule has the same regulatory effect as the Federal law or regulation, or when multiple laws of that State are combined and deemed equivalent to a single Federal law or regulation. In conducting such self-assessment, the State program may need to consult with its legal counsel when a provision is determined to be Equivalent in effect.

**Not Equivalent:** means there is no State law equivalent to the relevant Federal law or regulation, there is such a State law but it does not apply to the State's food plant or manufacturing establishment program, or the Federal and State laws address the same matter but are inconsistent and do not have the same regulatory effect.

**Regulatory Foundation:** means laws, regulations, rules, ordinances, or other regulatory requirements that govern the operation of a food plant or manufacturing establishment.

## 6. PROCEDURES

### 6.1. Review of State statute/rule and Federal law/regulation (Evaluate Legal Authority) – Manufactured Food Program Manager

6.1.1. Review all changes to relevant state statutes or rules and federal laws and regulations when needed to ascertain how they will affect FFSD's REGULATORY FOUNDATION.

6.1.2. Complete reviews by using one or more of the following mechanisms:

- a. Federal Changes – Sign-up for Code of Federal Regulation Changes <https://www.federalregister.gov/articles/search?#advanced>. Identify the CFR

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parts relevant to the Food Program. This program will send out a notification whenever the selected CFR parts appear in the Federal Register in a rule or proposed according to the preferences.

- b. State Changes: Receive information regarding changes or updates to State rule or statute through the legislative liaison, MDA Legal Counsel, and review of laws passed related to food inspection on <http://leg.state.mn.us>.
- 6.1.3. Assess the impact of the change to the Manufactured Food Program and identify action item(s) if required.
- a. Notify the Manufactured Food Supervisors, Manufactured Food Inspectors, Food Standards Coordinator, Outreach Coordinator, and Food Compliance Staff of significant changes.
  - b. Assign staff the duty of reviewing and revising procedures as necessary in coordination with the Food Standards Coordinator. The timeline for revisions of the SOP will depend on the size and significance of the change.
  - c. Once procedures have been updated, notify the Training Coordinator regarding the change information and training that will be provided for all staff affected by the change.

**6.2. Assess Regulatory Foundation – Manufactured Food Program Manager**

- 6.2.1. Complete or update MFRPS Standard 1 *Appendix 1-Self-Assessment Worksheet* annually in coordination with the Food Standards Coordinator and MDA Legal Counsel.
- 6.2.2. Determine if the rules and regulations are EQUIVALENT, EQUIVALENT IN EFFECT OR NOT EQUIVALENT.

**6.3. Review Standard 1 Appendix– Manufactured Food Program Manager and MDA Legal Counsel**

- 6.3.1. Review *Appendix 1-Self-Assessment Worksheet* with MDA Legal counsel if there are significant changes.
- 6.3.2. Notify Food Standards Coordinator when the review is complete.

**6.4. Submit Standard 1 Appendix – Food Standards Coordinator**

- 6.4.1. Submit *Appendix 1-Self-Assessment Worksheet* for review on an annual basis to the Food Program Manager and MDA Legal Counsel.
- 6.4.2. Once a review is complete, upload the most current version to SharePoint and move all other versions of the appendix to the historical folder under Standard 1.

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

MFRPS Standard 1

Appendix 1-Self Assessment Worksheet

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Minnesota State Statute 31.101

**8. EQUIPMENT/MATERIALS NEEDED**

N/A

**9. SAFETY**

N/A

**10. CIRCULATION**

This policy will be circulated to the following: Manufactured Food Program Manager, Manufactured Food Program Supervisors, MDA Legal Counsel, Food Standards Coordinator, Outreach Coordinator, Food Compliance Staff, and the Training Coordinator.

**11. APPROVAL/DOCUMENT HISTORY**

Document History		
Version #	Status (I, R)	Change History
2	R	This document supersedes COMP.113. Regulatory Foundation Management Controls. COMP 113 was previously approved but never fully implemented.
3	R	Updates made to reflect division structure change from DFID to FFSD. SOP made specific to the Manufactured Food Program. Added definitions. Section 6.2-Assess Regulatory Foundation added. Changed legal counsel review from annual basis to if there are significant changes in Section 6.3.
DocuSigned by:  54BB2563BF5444D...		12/14/2016
<b>Approved By:</b>		<b>Date</b>
<b>Approved By:</b>		<b>Date</b>

I = Initial document; R = Revised document