

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

Document FOOD.30.23	Page 1 of 5
Version #: 2	Effective Date: 1/3/2017
Title: Investigation Sampling – Inspector Initiated SOP	

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 collection of investigation samples in the field by food inspectors within the Minnesota Department of Agriculture's (MDA) Food and Feed Safety Division (FFSD) Manufactured Food and Retail Food Programs. This procedure identifies when samples should be collected to document observations, support inspection-based regulatory actions, or provide further information to be used by supporting units within the division.

2. SCOPE

This document applies to Food Inspectors that initiate and collect samples as part of inspections to support observations and regulatory findings per inspection protocols. All samples collected using this procedure must be official samples and handled accordingly. This document does not include procedures for Surveillance, Outbreak/Response/Illness, Compliance, or Complaint-related sampling. This document also does not include the specific instructions for collecting, transporting, and submitting the samples, but these specific work instructions may be referenced in this document where necessary.

3. BACKGROUND

Food Inspection staff are responsible for inspecting food facilities for compliance with regulatory requirements. Part of the responsibility for food safety inspections is to develop evidence to support findings from inspection observations per *FOOD.30.01 Inspection Protocol – Food Manufacturing SOP* and *FOOD.30.20 Inspection Protocol – Retail Food SOP* along with any other relevant procedures. The collection of physical samples for laboratory analysis is one method available to develop evidence to support findings from an inspection.

4. RESPONSIBILITY

Food Inspector – The Food Inspector will determine when an investigative sample should be taken to support a finding or determine if a violation exists, as well as collect samples following all applicable policies and procedures.

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

Document FOOD.30.23	Page 2 of 5
Version #: 2	Effective Date: 1/3/2017
Title: Investigation Sampling – Inspector Initiated SOP	

Food Inspection Supervisor – The Food Inspection Supervisor will provide guidance for the Food Inspector in making the determination when an investigative sample should be collected.

5. DEFINITIONS

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.

Field Compliance Actions: Field compliance actions are actions performed during an inspection to achieve compliance with regulations. These actions include, but are not limited to, reinspections, cease and desist orders, and embargos. 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.

Investigation Sample: An Investigation Sample is a sample taken during a food safety inspection to document inspection observations, support regulatory actions or provide other information.

Inspection Observation: An Inspection Observation is an observation that occurred within a regulated facility during an inspection. Inspection Observations are recorded in the written inspection report issued to the most responsible person/person in charge at the firm.

Official Sample: An Official Sample is a sample taken in a manner so that it can serve as the basis for enforcement and/or legal action and handled in a manner that preserves integrity as evidence including identity, ownership, traceability, and a clear record of chain of custody.

Violative Condition: A Violative Condition is a condition observed within a regulated facility that is not in compliance or suspected not to be in compliance with current regulatory requirements.

6. PROCEDURES

- 6.1. Determine if sample collection is necessary during any inspection, in consultation with the supervisor as needed, to:
 - a. Substantially support violative conditions noted during inspection by providing physical evidence;
 - b. Assess if a violative condition exists through laboratory analysis; and/or

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

Document FOOD.30.23	Page 3 of 5
Version #: 2	Effective Date: 1/3/2017
Title: Investigation Sampling – Inspector Initiated SOP	

- c. Assist in determining whether potential field compliance action or enforcement action is necessary.
- 6.2. Identify appropriate laboratory analysis required based on the investigation sample type. Refer to *Food Programs Sample Acceptance Criteria* to determine if MDA Lab notification is needed prior to collection and notify the lab if necessary. Notification may be necessary for ordering analysis supplies or to assign personnel.
- 6.3. Determine the collection method using the *Food Programs Sample Acceptance Criteria*.
- 6.4. Collect samples using the appropriate Work Instructions listed below:
 - a. *FOOD.WI.30.02 - Aseptic Food Collection*
 - b. *FOOD.WI.30.03 - Aseptic Water Collection*
 - c. *FOOD.WI.30.04 - Environmental Swabs and Sponges Collection at Retail*
 - d. *FOOD.WI.30.13 – Environmental Sampling at Manufacturing*
 - e. *FOOD.WI.30.05 - Non-Aseptic Collection Methods*
 - f. *FOOD.WI.30.46 – Creating Food Samples in USAFS WI*
 - g. *FOOD.WI.30.61 – Paper Sample Submission WI*
 - h. *FOOD.WI.30.06 - Sample Seal, Storage, and Transfer (required for all samples)*
- 6.5. Collect any documentation specific to the investigation sample collected beyond those described in *FOOD.WI.30.46 – Creating Food Samples in USAFS WI* or other sampling work instructions. This may include any of the following (but is not limited to this listing):
 - a. Lot code and/or distribution records related to the product sampled,
 - b. Production records related to products produced before and/or after the collected sample,
 - c. Supplier information for ingredients in the collected product,
 - d. Labeling related to the product collected if not collecting an in-tact, packaged product. These may include:
 - i. Photographs of the bulk food container label (refer to *FOOD.WI.30.59 - Documenting Digital Photographs-Video Evidence-Manufactured Foods WI* or *FOOD.WI.30.62 - Documenting Digital Photographs-Video Evidence-Retail Food WI as applicable*)
 - ii. Photographs of ALL sides of a packaged food product (refer to *FOOD.WI.30.59 - Documenting Digital Photographs-Video Evidence-Manufactured Foods WI* or *FOOD.WI.30.62 - Documenting Digital Photographs-Video Evidence-Retail Food WI as applicable*)

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

Document FOOD.30.23	Page 4 of 5
Version #: 2	Effective Date: 1/3/2017
Title: Investigation Sampling – Inspector Initiated SOP	

- iii. A scan or photocopy of a label or print-out of the label from the facility:
 - i. attach to the Inspection Maintenance page in USAFS if label is collected to support a written order
 - ii. attach to the Sample Maintenance page in USAFS if label is collected to support a submitted sample
 - e. Photographs of the sample collection location or conditions (refer to *FOOD.WI.30.59 - Documenting Digital Photographs-Video Evidence-Manufactured Foods WI* or *FOOD.WI.30.62 - Documenting Digital Photographs-Video Evidence-Retail Food WI as applicable*)
- 6.6. Consult with Food Inspection Supervisory staff and/or MDA Lab staff as needed if conditions for analysis specified in the *Food Programs Sample Acceptance Criteria* cannot be met or if priority codes other than “Routine” are requested.
- 6.7. Communicate planned sample delivery timeline to MDA Lab staff as applicable based on *Food Programs Sample Acceptance Criteria*.
- 7. RELATED DOCUMENTS** (includes References, Attachments)
 - FOOD.30.01 – Inspection Protocol – Food Manufacturing
 - FOOD.30.20 – Inspection Protocol – Retail Food
 - FOOD.WI.30.02 - Aseptic Food Collection Work Instruction
 - FOOD.WI.30.03 - Aseptic Water Collection Work Instruction
 - FOOD.WI.30.04 - Environmental Sample Collection at Retail Work Instruction
 - FOOD.WI.30.05 - Non-Aseptic Collection Methods Work Instruction
 - FOOD.WI.30.06 - Sample Seal, Storage, and Transfer Work Instruction
 - FOOD.WI.30.13 – Environmental Sampling at Manufacturing Work Instruction
 - FOOD.WI.30.46 – Creating Food Samples in USAFS Work Instruction
 - FOOD.WI.30.59 - Documenting Digital Photographs-Video Evidence-Manufactured Foods WI
 - FOOD.WI.30.61 – Paper Sample Submission WI
 - FOOD.WI.30.62 - Documenting Digital Photographs-Video Evidence-Retail Food WI
 - Food Programs Sample Acceptance Criteria
- 8. EQUIPMENT/MATERIALS NEEDED**
 - N/A
- 9. SAFETY**
 - N/A

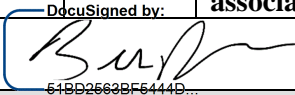
**Minnesota Department of Agriculture
Food and Feed Safety Division**

Document FOOD.30.23	Page 5 of 5
Version #: 2	Effective Date: 1/3/2017
Title: Investigation Sampling – Inspector Initiated SOP	

10. CIRCULATION

This policy will be circulated to the following individuals: Food Inspectors, Food Supervisors, Food Program Managers, and the Food Standards Coordinator. The current version will be stored electronically on the FFSD document control site.

11. APPROVAL/DOCUMENT HISTORY

Document History		
Version #	Status (I, R)	Change History
1	I	Initial Policy Drafting.
2	R	Updated name of procedure to include “inspector initiated”; added enforcement actions and field compliance actions to the definitions; added numbers associated with sampling work instructions.
DocuSigned by:  <small>618D2663BF6444D...</small>		1/3/2017
Approved By:		Date
Approved By:		Date

I = Initial document; R = Revised document