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Food and Feed Safety Division**

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Title: <b>Response, Complaint, and Enforcement Sampling SOP</b>	

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**1. PURPOSE**

The purpose of this procedure is to describe the rationale and process for identifying and directing the collection of samples as a part of a response, complaint investigation, or enforcement action. Sampling assignments created during these investigations may occur outside the routine inspector-supervisor reporting structure of FFSD and may require unique procedures. This document covers these unique situations.

**2. SCOPE**

This document includes procedures for creating sampling assignments in RRT- or Compliance-led investigations including the following situations: official and unofficial samples associated with a foodborne illness outbreak investigation, official samples collected as part of a known or suspected contamination or allergen control situation at an MDA-regulated facility, official samples collected in response to a potentially valid complaint, and official samples collected as a part of an enforcement action. This document does not include procedures for surveillance sampling-refer to *FOOD.30.26 – Surveillance Sampling SOP*. This document also does not include the specific instructions for collection, transporting and submitting of samples, but these specific instructions may be referenced by this document when necessary.

**3. BACKGROUND**

FFSD routinely responds to foodborne illness clusters or confirmed outbreaks, food contamination events, and complaints related to food offered for sale or objectionable conditions within food facilities. The FFSD Rapid Response Team (RRT) takes the lead or delegates leadership responsibility for all investigations involving confirmed or suspected foodborne illnesses in humans, all responses to food contamination events that exceed the capacity of any one program or require coordinated response, and all complaints of foodborne illness. The FFSD Compliance Program takes the lead on all other complaints. Complaints are evaluated for validity by an assigned Compliance Officer or RRT member. Based on the type of complaint, it may be necessary for food inspection staff to collect a sample as a part of the investigation. Additional compliance activities encompass a variety of actions that can be taken for regulatory enforcement purposes. Collecting samples for

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laboratory analysis is one action that may be necessary to determine whether further enforcement action is necessary or to establish compliance by a firm after other regulatory actions have taken place.

#### 4. RESPONSIBILITY

**Compliance Officer** – The Compliance Officer will evaluate complaints for validity, except for complaints associated with foodborne illness and will determine the need for sampling during enforcement actions.

**Compliance Program Supervisor** – The Compliance Program Supervisor will provide support and recommendations to the Compliance Officer as required.

**Inspector or Sampler** – The Inspector will follow direction of the RRT or Compliance Program regarding collection of response, complaint, or enforcement related samples.

**Inspection Supervisor** – The Inspection Supervisor will provide guidance to the RRT member or Compliance Officer regarding recommendations for sample collection and assign inspectors sampling assignments based on training, availability, and location.

**Program Manager** – The Program Manager will provide guidance to the RRT member or Compliance Officer regarding recommendations for sample collection as well as provide guidance to the Inspection Supervisor as required.

**Response, Training and Outreach (RTO) Supervisor** – The RTO Supervisor will provide support and recommendations to the Rapid Response Team Investigator as needed.

**Rapid Response Team (RRT) Investigator/Analyst** – The RRT Investigator/Analyst will evaluate foodborne illness complaints for validity and determines the need to sample product in response to a complaint or investigation.

#### 5. DEFINITIONS

**Case-patient:** A case-patient is a person who has the food-related disease and is part of an identified foodborne illness outbreak.

**Complaint Sample:** A Complaint Sample is a sample collected as part of a complaint investigation.

**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.

**Compliance Sample:** A Compliance Sample is a sample that is collected to determine compliance with specific food laws. It is collected when following up on a violative sample in a surveillance situation, or when following up on an enforcement action.

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**Foodborne Illness Outbreak:** A foodborne illness outbreak is an incident in which two or more persons experience a similar illness after ingestion of a common food or meal, and a specific food or meal is suspected or has been confirmed through laboratory or epidemiologic methods.

**Foodborne Illness or Injury (FBI/I) Complaint:** A FBI/I Complaint is a report of foodborne illness or injury related to specific products or facilities that are supported by epidemiological data.

**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.

**Rapid Response Team (RRT):** The RRT is a group of individuals within MDA FFSD who are involved in the operational activity of an incident response, including managers, supervisors, field staff, and or subject matter experts.

**Representative sample:** A representative sample is a sample that consists of a number of units that are drawn based on rational criteria such as random sampling and intended to assure that the sample accurately portrays the material being sampled. For example, equal sized subsamples may be taken from multiple sections of the entire lot and combined to form a single sample, such as the four corners and middle of a warehouse bin or randomly selecting several boxes from a large shipment. In the case of convenience and other small sample sizes, care is taken to assure there is no reason to suspect that the sample selected is any different from others of the same type in the same lot.

**Unofficial sample:** An unofficial sample is a sample taken to inform a foodborne illness complaint or outbreak investigation but does not by itself serve as the basis for enforcement and/or legal action. Examples of unofficial samples include those in the possession of a consumer or member of the public.

## 6. PROCEDURES

### 6.1. Samples associated with an Outbreak Investigation-RRT Investigator/Analyst role

When the RRT Investigator and/or RTO Supervisor are notified of a foodborne illness outbreak in Minnesota, an investigation begins and appropriate next steps are determined following the *RESP.50.02 – Outbreak Investigation SOP*.

- 6.1.1. Determine the need to collect a food product or environmental sample using professional judgment with regard to public health and food safety implications.
  - a. Confer with Minnesota Department of Health (MDH) or agency with epidemiologic investigational authority following *RESP.50.02 – Outbreak Investigation SOP* to identify:
    - i. Food(s) that are suspected vehicles or sources for the illnesses.
    - ii. Availability of suspect food(s) that could potentially be collected, including from a case-patient's residence, at a point of service such as a

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restaurant or grocery store, or from a caterer or preparer associated with a foodborne illness.

- b. If food is immediately available, consider whether the sample is an official or unofficial sample and, if unofficial, whether the food is in good enough condition that would not compromise the analysis.
- c. If food is not immediately available, consider whether there are units of the same or similar lot of product available at place of purchase or from elsewhere in the supply chain.
- d. If at any time there is the likelihood that the food was contaminated at a food facility in Minnesota, follow the procedures in Section 6.3 of this document.

6.1.2. Determine the number of samples to be collected using the following guidance:

- a. The purpose of sampling food product associated with illness is to determine whether the food the case-patient consumed was contaminated or adulterated with the agent of interest. Therefore, the food in the case-patient's possession is typically deemed to be a representative sample of the food consumed.
- b. When sampling food of the same or similar lot of product likely to be available at a food facility, plan to take a sample or subsamples that are representative of the lot being sampled. If that is not possible, plan to collect samples in a manner that the sample selected is no different from others of the same type in the same lot.
- c. Refer to the Partnership for Food Protection (PFP) "Food/Feed Testing Laboratories Best Practices Manual" and the ICMSF "Microbiological Testing in Food Safety Management" listed in Section 7 below or similar resource for more information.

6.1.3. Continue with the procedure outlined in section 6.5. Notify the MDA Laboratory when planning to collect foodborne illness outbreak-related samples due to the time-sensitive nature of the investigation.

**6.2. Samples collected as part of a Contamination or Allergen Control Investigation at an MDA-regulated facility - RRT Investigator/Analyst role**

When the RRT Investigator and/or RTO Supervisor are notified of a potential contamination event at an MDA-regulated facility, an investigation begins and appropriate next steps are determined following the *RESP.50.01 – Investigation Procedures for Food or Environmental Contamination SOP*.

- 6.2.1. Determine the need to collect a food product or environmental sample using professional judgment with regard to public health and food safety implications. Refer to *RESP.50.01 – Investigation Procedures for Food or Environmental Contamination SOP* and *FOOD.30.10 – Environmental Sampling – Food Manufacturing SOP* for additional guidelines.

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6.2.2. Identify type(s) of sample(s) to be collected.

- a. Always notify MDA Laboratory when planning to collect facility contamination-related samples due to the time-sensitive nature of the investigation.

6.2.3. Determine the number of samples to be collected using the following guidance:

- a. Environmental samples collected as part of a facility contamination investigation need to be representative of the areas of concern (i.e. the processing, packaging, and/or storage environments). Refer to *FOOD.30.10 – Environmental Sampling – Food Manufacturing SOP* for more information.
- b. Ingredient or finished product samples collected as part of a facility contamination investigation need to be representative of the entire lot being sampled. Refer to representative sampling resources such as PFP “Food/Feed Testing Laboratories Best Practices Manual” and the ICMSF “Microbiological Testing in Food Safety Management” listed in Section 7 below or similar resource for more information.

6.2.4. Continue with the procedure outlined in section 6.5. Always notify the MDA Laboratory when planning to collect foodborne illness facility contamination-related samples due to the time-sensitive nature of the investigation.

**6.3. Samples collected as part of a Complaint Investigation - RRT Investigator/Analyst role**

6.3.1. When a complaint is received, determine if a complaint sample and analysis is required. Use the following criteria below make a determination. Evaluate if the sample will:

- a. Support the conditions identified in the complaint (non-intact or open samples collected from the home, unless supported epidemiological data, will seldom support a complaint),
- b. Assist in determining if the complaint is a valid complaint, or
- c. Help determine if further regulatory actions are necessary.

6.3.2. If sample collection is deemed appropriate, follow procedure section 6.5.

**6.4. Samples collected as part of an Enforcement Action – Compliance Officer role**

6.4.1. When an enforcement action is identified, determine if a compliance sample and analysis is required. Use the following criteria to make a determination, considering whether the sample will:

- a. Support an existing enforcement action,
- b. Assist in determining whether further enforcement actions are necessary, or
- c. Establish a firm’s compliance with prior enforcement actions.

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6.4.2. If sample collection is deemed appropriate, follow procedure section 6.5.

**6.5. All Response- and Compliance-related samples** – RRT Investigator/Analyst or Compliance Officer role (based on sample type)

6.5.1. Identify the appropriate laboratory analysis to be conducted based on the sample type. Consult with Food Program Staff as needed. Refer to *Food Programs Sample Acceptance Criteria* to determine if MDA Laboratory notification is required prior to collection assignment and notify lab if necessary. Notification may be needed for ordering analysis supplies or to assign personnel. Confer with laboratory personnel when there are questions about the type of sample being collected.

6.5.2. Determine collection method using the following guidance:

- a. Samples consisting of environmental sponges/swabs, unpackaged food, or unpackaged water require aseptic collection methods.
- b. Refer to the *Food Programs Sample Acceptance Criteria* for sample type specific direction regarding the following: sampling equipment, sample size, special container needs, special supplies, records collection, and delivery timelines.

6.5.3. Determine if there are documentation needs specific to the sample beyond those described in *FOOD.WI.30.46 – Creating Food Samples in USAFS WI*. This can include, but is not limited to, any of the following:

- a. Traceback Worksheet
- b. Lot and/or distribution records related to the product sampled
- c. Production records related to products produced before and/or after the collected sample
- d. Supplier information for ingredients in the collected product
- e. 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*)
  - iii. A scan or photocopy of a label or print-out of the label from the facility:

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- 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
- f. 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*)
- 6.5.4. Consult by email with the applicable RTO Supervisor, Food Inspection Supervisor(s), Compliance Supervisor, or Food Program Manager to finalize:
  - a. The need for sample collection based on information gathered in previous sections in this SOP,
  - b. Any sample collection details and special considerations,
  - c. Sample collection assignment, and
  - d. Timeline(s) for sample collection.
- 6.5.5. Consult by phone or email with the applicable Food Inspection Supervisor(s) to finalize:
  - a. Sample collection details,
  - b. Assignment of Food Inspector for sample collection, and
  - c. Timeline(s) for sample collection.
- 6.5.6. Upon approval from the sampler's supervisor, complete and email the *Sample Request Form* to the assigned sampler within one working day of the sample decision and attach the *Sample Request Form* to the inspection file in USAFS.
- 6.5.7. If applicable based on *Food Programs Sample Acceptance Criteria*, communicate planned sample delivery timeline to MDA Lab staff.
- 6.5.8. Note that when ICS has been initiated, communication and processes should occur according to *RESP.50.04 – ICS SOP*.

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

"Chapter 7--Sampling Plans." *Micro-organisms in foods 7: microbiological testing in food safety management*. International Commission on Microbiological Specifications for Foods (ICMSF). New York: Kluwer Academic/Plenum Publishers, 2002. 123-144. Print.

FOOD.30.10 - Environmental Sampling – Food Manufacturing SOP

RESP.50.01 - Investigation Procedures for Food or Environmental Contamination SOP

RESP.50.04 – Incident Command System (ICS) SOP

RESP.50.08 – Traceback and Traceforward SOP

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"Food/Feed Testing Laboratories Best Practices Manual." Partnership for Food Protection. Version 11/1/2013. Web. 11 July 2014.

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.30.62 - Documenting Digital Photographs-Video Evidence-Retail Food WI

Food Programs Sample Acceptance Criteria

Sample Request Form

**8. EQUIPMENT/MATERIALS NEEDED**

N/A

**9. SAFETY**

N/A

**10. CIRCULATION**

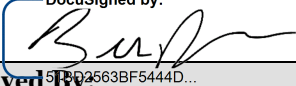
This document is circulated to the following: FFSD Compliance Officers, FFSD Compliance Supervisor, Food Program Inspectors, Food Program Supervisors, Food Program Managers, RRT staff, RTO Supervisor and the Food Standards Coordinator. The current version will be stored electronically on the FFSD document control site.



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**11. APPROVAL/DOCUMENT HISTORY**

Document History		
Version #	Status (I, R)	Change History
1	I	<b>Initial Policy Drafting. Previous sampling SOPs to include FOOD.30.21-Complaint Sampling, FOOD.30.22-Compliance Sampling, and FOOD.30.25-Outbreak &amp; Response Sampling have been combined in this procedure.</b>
DocuSigned by: 		1/3/2017
<b>Approved By:</b>		<b>Date</b>
<b>Approved By:</b>		<b>Date</b>

I = Initial document; R = Revised document