

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

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Version #: 1	Effective Date: 1/12/2017
Title: <b>Investigation Procedures – Food or Environmental Contamination</b>	

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**1. PURPOSE**

This document and the associated work instructions describe the procedure for Minnesota Department of Agriculture (MDA) Food and Feed Safety Division (FFSD) staff conducting a directed ENVIRONMENTAL ASSESSMENT investigation at a food manufacturing facility in response to a FOOD-RELATED INCIDENT.

**2. SCOPE**

This SOP is applied to directed investigations of FOOD-RELATED INCIDENTS in a facility that manufactures food for wholesale distribution. Investigations may be initiated in response to a foodborne illness outbreak, or to a known or suspected food and/or environmental contamination. This SOP does not apply to routine inspections at food manufacturing facilities or to inspections or investigations in retail food establishments. The SOP applies to response activities from time of initial notification through response and recovery. This SOP does not cover communication with the public in relation to an investigation, which is covered in *RESP.50.06 – Communication with the Public SOP*.

**3. BACKGROUND**

While ICS is not officially “stood up” for every response initiated within FFSD, the MDA Rapid Response Team (RRT) uses the general structure of the system for response, assigning positions as needed based on the scale of the incident. See *RESP.50.04 – ICS SOP* for detailed guidance on the use of the Incident Command System (ICS) during incident response.

The associated Job Action Sheet (JAS) Work Instructions (WI) provide detailed information for each individual position as it associates to the response. Not all of these roles are required to be filled during every incident/investigation. Additionally, taskforces within the Operations Section will only be assigned when there is work in those areas. Based on the size of the incident or availability of resources, personnel may be assigned in more than one taskforce. For example, only one or two field positions may be assigned to an incident, but could fulfill the duties of the Field Inspections, Sampling, and Records Review Taskforces.

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Finally, not all situations described in the JAS WIs will be applicable in every response. For example, not every response will involve a recall of product or issuing a Cease and Desist order for operations. However, the general structure of the response will remain the same each time, as described in the JAS WIs.

In this procedure, an investigation response has been divided into four phases. The general description of the phases of an incident are as follows:

**Phase I – Initial Planning and incident Assessment** – Assess the scope of the issue and relevant events leading to its discovery, hold a briefing and planning meeting, establish the response team, complete an initial ENVIRONMENTAL ASSESSMENT, and determine the need for further actions, which may include include field compliance actions, sampling, record review, other actions to control potentially affected foods.

**Phase II – Post-Assessment Action** – Determine next steps, request facility to provide a corrective action plan, and provide oversight of re-sampling if needed.

**Phase III - Recovery/Restoration** – Confirm contaminated food has been removed from the food supply and and production of adulterated food has been halted, verify proper implementation of corrective action plan, review sampling results, verify the facility is producing food in conditions that will not result in adulteration of product.

**Phase IV - Event Close-Out** – Demobilize the response team and return the firm’s inspection duties back to the area inspector, prepare necessary documentation for further compliance/enforcement action, and conduct an After Action Review (AAR),.

The associated work instructions detail duties of each position for all four phases of an investigational response.

#### **4. RESPONSIBILITY**

**Division Director** - The Director will offer guidance as needed during incident response, serving as agency lead when necessary.

**Response, Training and Outreach (RTO) Supervisor** – The RTO Supervisor will offer guidance as needed during incident response, serving as agency lead when necessary.

**Manufactured Food Program Manager** – The Program Manager will serve as the agency lead when necessary and will ensure all assigned staff in their respective program area receive the appropriate training for their role in the response and follow the procedures described in the relevant JAS work instructions.

**Manufactured Food Supervisors** – FFSD Manufactured Foods Supervisory staff will ensure all assigned staff in their respective program area receive the appropriate training for their role in the response and follow the procedures described in the relevant JAS work instructions.

**Inspector** – The Inspector will follow the procedures described in the Job Action Sheet Work Instruction applicable to their position during the investigation.

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**RRT Coordinator** – The RRT Coordinator will serve as the main contact for coordination of a response involving the RRT. The RRT Coordinator may also be assigned a role within the ICS structure.

**RRT Investigator/Analyst** – The RRT Investigator/Analyst will assist that RRT Coordinator in response coordination and data collection and organization. The RRT Investigator/Analyst may serve as primary response contact as requested or when RRT Coordinator and RTO Supervisor are not available.

## 5. DEFINITIONS

**Agency Lead** – Approves the activation of an ICS structure and serves as the Lead during the initial planning meeting. The Agency Lead may serve as Incident Commander (IC) or recommend another staff member to serve as IC.

**Environmental Assessment** - On-site food product or food processing environment investigation, conducted in conjunction with investigations as needed to assess and rule out the potential that the contaminant of concern was introduced at a particular point in the distribution or production system. This is achieved by identifying contributing factors and environmental antecedents.

**Food** - Human food (raw or ready to eat, ingredient or finished product) or animal feed.

**Food-Related Incident** – An unintentional or deliberate contamination, threatened or actual, of food that may occur at any point in the production system (e.g. pre-harvest production, processing, distribution) and may cause food-related illness, injury, outbreaks, and hazards. Examples of food-related incidents include, but are not limited to, foodborne illness outbreaks and food tampering.

**Rapid Response Team (RRT)** – 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.

## 6. PROCEDURES

### 6.1 Sharing of Confidential Information – All Staff

- 6.1.1. Identify staff who are FDA Commissioned or who are covered under a 20.88 confidentiality agreement so all staff know with whom they can share confidential or trade secret information obtained by FDA. Communicate in a manner that works with the needs and restrictions of all partners involved in the response. Lists of commissioned staff and staff who have signed a confidentiality agreement are maintained on the RRT SharePoint site.
- 6.1.2. Reference *RESP.50.05 – RRT Communications SOP* and *RESP.50.06 – Communication with the Public SOP* for additional information-sharing guidance including notification requirements to relevant agencies

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## 6.2 Initial Planning Meeting

### Agency Lead

6.2.1 Following the initial notification (*see RESP.50.05 – RRT Communications SOP*) about a potential food-related incident, determine whether or not to implement an Incident Command System (ICS) structure. Follow criteria in the *RESP.50.04 – Incident Command System (ICS) SOP*.

### RRT Coordinator

6.2.2 Following the initial notification (*see RESP.50.05 – RRT Communications SOP*) about a potential food-related incident, schedule an initial planning meeting within two (2) business days with all relevant personnel. Include Agency Lead on all communications. Develop the planning meeting agenda and incident summary, including the following topics:

1. Known facts about the incident;
2. Severity of the incident;
3. Determination of a joint response or single agency (e.g. MDA-only) response considering resource availability, nature, and severity of incident;
4. Staff expertise required for response (e.g. identification of appropriate staff trained to conduct a particular inspection, investigation, or sampling assignment);
5. Determination on whether or not official implementation of an ICS structure is needed (*see RESP.50.04 – ICS SOP*);
6. Other agencies to notify or involve in the investigation (FDA, USDA FSIS, law enforcement/FBI, State or Local Health Agencies).

6.2.3 Facilitate (or delegate) the initial planning meeting.

6.2.4 If ICS is being implemented, follow the steps in the *RESP.50.04 – Incident Command System (ICS) SOP* to complete the first Incident Action Plan (IAP).

## 6.3 Probable Intentional Act

### Inspection Staff

6.3.1. Immediately notify direct supervisor, RTO Supervisor, and RRT Coordinator if there is a suspect threat involving biological, chemical, or radiological agents or indications that instances of disease may not be the result of natural causes.

### RRT Coordinator

6.3.2. When notified of a suspected threat involving biological, chemical, or radiological agents or indications that instances of disease may not be the

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result of natural causes, immediately notify the Department of Justice (DOJ) through the Federal Bureau of Investigations (FBI) Weapons of Mass Destruction Operations Unit. The local contact for the FBI can be found in the *RRT Contacts List*. Note that the FBI will then notify the National Operations Center (NOC) and the National Counterterrorism Center.

#### **6.4 Phases of an Investigation – All Staff**

- 6.4.1** A Manufactured Foods investigation response is divided into four phases. Job Action Sheets (JAS) have been created for all relevant ICS positions and must be referenced to understand roles, responsibilities, and duties of each position named in the particular response. The JAS assist personnel in conducting the ENVIRONMENTAL ASSESSMENT as applicable to their role in the investigation.

The general description of the phases and locations where each phase is covered in the JAS Work Instructions are as follows:

##### **Phase I – Initial Planning and Incident Assessment**

- a. Follow instructions covered in Section B of the Job Action Sheet Work Instructions for each position.
- b. Actions taken during this phase may include but are not limited to: initial ENVIRONMENTAL ASSESSMENT, environmental and product sampling, GMP inspection, evidence collection, record review, and field compliance actions.

##### **Phase II – Post-Assessment Action**

- a. Follow instructions covered in Section C of the Job Action Sheet Work Instructions for each position.
- b. Actions taken during this phase may include but are not limited to: evidence evaluation, recall request, consumer advisory or other public notification, corrective action plan (CAP) request and review of submitted CAP, enforcement action, or additional ENVIRONMENTAL ASSESSMENT, inspection, and field compliance actions.

##### **Phase III - Recovery/Restoration**

- a. Follow instructions covered in Section D of the Job Action Sheet Work Instructions for each position.
- b. Actions taken during this phase may include but are not limited to: witnessing disposal or destruction of adulterated product, conducting recall effectiveness checks, assessment of CAP implementation, pre-production re-inspection, and recommending future inspection frequency.

##### **Phase IV - Event Close-Out**

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- a. Follow instructions covered in Section E of the Job Action Sheet Work Instructions for each position.
- b. Actions taken during this phase may include but are not limited to: attend demobilization meeting, prepare necessary documentation for Compliance Unit, compile an investigation summary, share documentation with necessary partners, and prepare for an after action review.

### **6.5 After Action Review**

#### RRT Coordinator

- 6.5.1 Assess the need for conducting an after action review (AAR) within two (2) weeks of the close of the investigation and oversee the completion of an AAR. See *RESP.50.03 – After Action Review SOP* for more details.

#### All Staff

- 6.5.2 Participate in the AAR.

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

Documents and Records Request Form

Job Action Sheet Work Instructions

- RESP.WI.50.01 – Incident Commander (IC) Job Action Sheet (JAS)
- RESP.WI.50.02 – Operations Section Chief (OSC) Job Action Sheet (JAS)
- RESP.WI.50.03 – Planning Section Chief (PSC) Job Action Sheet (JAS)
- RESP.WI.50.04 – Field Inspection Taskforce Job Action Sheet (JAS)
- RESP.WI.50.05 – Record Review Taskforce Job Action Sheet (JAS)
- RESP.WI.50.06 – Sampling Taskforce Job Action Sheet (JAS)
- RESP.WI.50.07 – Safety Officer (SO) Job Action Sheet (JAS)
- RESP.WI.50.08 – Public Information Officer (PIO) Job Action Sheet (JAS)
- RESP.WI.50.09 – Liaison Officer (LO) Job Action Sheet (JAS)

FOOD.30.01 – Inspection Protocol – Manufacturing SOP

FOOD.30.10 – Environmental Sampling-Food Manufacturing SOP

RESP.50.04 – ICS SOP

RESP.50.05 – RRT Communications SOP

RESP.50.06 – Communication with the Public SOP

RESP.50.03 - After-Action Review (AAR) SOP

Food & Feed Emergency Response Plan (FFERP)

## **8. EQUIPMENT/MATERIALS**

N/A

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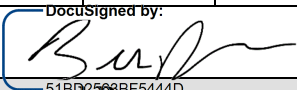
### 9. SAFETY

All MDA employees must follow the personal protective equipment requirements and field safety guidelines outlined in the initial and annual Food Inspector safety training. Food inspection staff must follow the Verbal and Physical Assault of State Agriculture Inspectors Policy. If the inspector has concerns about in-facility safety, please contact supervisor.

### 10. CIRCULATION

This policy will be distributed to the following individuals: Rapid Response Team (RRT) Staff, Manufactured Food Inspection staff, Manufactured Food Inspection Supervisors, Manufactured Food Program Manager, and the Division Director. 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	R	<b>Previous name FOOD.50.01-Investigation Procedures for Food or Environmental Contamination SOP and transferred to RESP.50.01. Updates made due to division structure changes from DFID to FFSD, Background section updated to provide phase information related to an investigation, associated job action sheets converted to work instructions, added definition of food-related incident and environmental assessment; added references to RESP.50.05 and RESP.50.06, deleted ICS procedural information as this information is now found in RESP.50.04, added final AAR procedure step, and updated related documents section.</b>
<small>DocuSigned by:</small> 		1/12/2017
<b>Approved By:</b>		<b>Date</b>
<b>Approved By:</b>		<b>Date</b>

I = Initial document; R = Revised document