

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

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| Version #: 1 | Effective Date: 06/10/2016 |
| Title: Recall Effectiveness Audit Check SOP | |

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1. PURPOSE

The purpose of this document is to provide guidance to Food and Feed Safety Division (FFSD) staff of the Minnesota Department of Agriculture (MDA) for the performance of Recall Effectiveness Audit Checks.

2. SCOPE

This procedure applies to routine responsibilities of the FFSD Inspection Staff and the Rapid Response Team (RRT), including the Recall Coordinator.

3. BACKGROUND

A recall is initiated to remove product from commerce when there is reason to believe it is adulterated or misbranded. Manufacturers, distributors, and/or retail food establishments (or a “person” representing the firm) may initiate a recall at any time to fulfill their responsibility to protect the public from products that present a risk of illness, injury, or gross deception, or are otherwise defective. Firms may also initiate a recall following notification of a problem by MDA, the Food and Drug Administration (FDA) or the United States Department of Agriculture (USDA); in response to a request by MDA, FDA, or USDA; or as mandated by FDA or USDA. MDA does not have authority to mandate a recall.

A recall involving manufactured, processed, packaged, and/or unpackaged food or food ingredients may have far-reaching effects due to the complexity of the distribution system. The food distribution system can include, but is not limited to: manufacturers, distributors, retail establishments, and the public. To protect the health of the public, it is imperative that all recalled food items and ingredients are promptly removed from commerce. The issuing firm is the responsible party to assure that all recalled food items are removed from sale and that procedures will be implemented to assure the recalled food item will not re-enter commerce. However, in some cases, MDA staff may be asked to verify the effective removal of recalled products from

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commerce by completing Recall Effectiveness Audit Checks. Recall Effectiveness Audit Checks may be issued and assigned my MDA, FDA, USDA, or a combination thereof.

4. RESPONSIBILITY

Inspection Supervisor – The Supervisor will issue assignments to inspection staff per Recall Coordinator instructions. Inspection Supervisors also include supervisors of delegated agency inspection staff.

Inspector – Inspectors will follow the procedures described as applicable to their position and notify their supervisor when the procedures cannot be followed.

Recall Coordinator – The Recall Coordinator will coordinate Recall Effectiveness Audit Check assignments, review audit check results, and maintain records of audit checks in SharePoint.

5. DEFINITIONS

Consignee – Any individual, firm, corporation, company, association, cooperative, or partnership who purchased, distributed, or received the product being recalled.

Distributor – Any individual, firm, corporation, company, association, cooperative, or partnership who sells food to others for resale, stores or handles food for another, including buildings, trucks, trailers, or other portable structures.

Food – Every ingredient used for, entering into the consumption of, or used or intended for use in the preparation of food, drink, confectionery, or condiment for humans or other animals, whether simple, mixed, or compound; and articles used as components of these ingredients (MN Statute 34A.01 Subd. 4).

Food Adulteration – As defined in Minnesota Statute 34A.02.

Manufacturer – Any individual, firm, corporation, company, association, cooperative, or partnership who processes or manufactures raw materials and other food ingredients into food items, or who reprocesses food items or who package food for sale to others for resale. This includes those who extract, ferment, distill, pickle, bake, freeze, dry, smoke, grind, mix, stuff, pack, bottle, recondition, or otherwise treat or preserve food for sale to others for resale and also to salvage food processors.

Person – Any individual, firm, partnership, cooperative, society, joint stock association, association, company, or corporation and includes any officer, employee, agent trustee, receiver, assignee, or other similar business entity or representative of one of those entities (MN Statute 34A.01, Subd. 10).

Place of Business – Every location where food or food items are manufactured, processed, sold, stored, or handled including buildings, locations, permanent or portable structures, carnivals, circuses, fairs or any other permanent or temporary location. Any vehicle or similar mobile unit from which food is sold shall be considered a place of business for purposes of this selection if

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the food therefrom has been manufactured, packaged, or dispensed from bulk or processed in any manner thereon (MN Statute 28A.03 Subd. 4).

Recall – A firm’s removal or correction of a marketed product that the FDA considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g. seizure. Recall does not include a market withdrawal or a stock recovery (21 Code of Federal Regulations, Part 7.3(g)).

Recall Effectiveness – The recalling firm’s responsibility to determine whether its recall is progressing satisfactorily. The firm has an obligation to conduct effectiveness checks as part of its recall strategy. Effectiveness checks assist in the verification that all known affected consignees have received notification about a recall and have taken appropriate action.

Recall Effectiveness Audit Check – A recall audit check is a personal visit, telephone call, letter, e-mail, or a combination thereof, to a consignee of a recalling firm, or a user or consumer in the chain of distribution. It is made to verify all consignees at the recall depth specified by the strategy have received notification about the recall and have taken appropriate action.

Retail Food Establishment – Any individual, firm, corporation, company, association, cooperative, or partnership who sells food directly to a consumer to include the following definition of a “food establishment” (in full) from the proposed 2012 MN Retail Food Code 4626.0020 1-201.10: An operation that (a) stores, prepares, packages, serves, vends food directly to the consumer or otherwise provides food for human consumption such as a restaurant; satellite or catered feeding location; catering operation if the operation provides food directly to a consumer or to a conveyance used to transport people; market; vending location; conveyance used to transport people; institution; or food bank; and (b) relinquishes possession of food to a consumer directly or indirectly through a delivery service such as home delivery of grocery orders or restaurant takeout orders or delivery service that is provided by common carriers. “Retail food establishment” includes: (a) an element of the operation such as transportation vehicle or a central preparation facility that supplies a vending location or satellite feeding location unless the vending or feeding location is permitted by the regulatory authority; and (b) an operation that is conducted in a mobile, stationary, temporary or permanent facility or location; where consumption is on or off the premises; and regardless of whether there is a charge for the food.

Sell; sale – The keeping, offering, or exposing for sale, use, transporting, transferring, negotiating, soliciting, or exchange of food; having in possession with intent to sell, use, transport, negotiate, solicit, or exchange food; storing, manufacturing, producing, processing, packing and holding of food for sale; dispensing or giving food; or supplying or applying food in the conduct of any food operating or carrying food in aid of traffic whether done or permitted in person or through others (MN Statute 34A.01 Subd. 12).

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USDA Recall: A firm's removal of distributed (i.e., the product has left the firm's direct control) meat or poultry products from commerce when there is reason to believe that such products are adulterated or misbranded under the provisions of the Federal Meat Inspection Act (FMIA) or the Poultry Products Inspection Act (PPIA). "Recall" does not include a market withdrawal or a stock recovery.

6. PROCEDURES

6.1. Audits Implemented by Federal Agency – Recall Coordinator

6.1.1. Notify FFSD staff and delegated agencies that the federal agency is conducting the audit if the federal agency does not request assistance from MDA.

6.1.2. If the federal agency requests assistance from MDA FFSD and its delegated agencies, schedule a joint MDA FFSD/Federal planning meeting. Include the federal Recall Coordinator and members from other agencies, as necessary.

6.1.3. Facilitate the identification of consignees during the planning meeting, creation of audit assignments and deadlines, and set the report review frequency. Create an audit intake survey, if necessary.

6.1.4. Assign audits to Inspection Supervisors and affected delegated agency Inspection Supervisors. Send the following information to the Inspection Supervisors and delegated agency Inspection Supervisors:

- a. Description of the recall and audit check assignment;
- b. Firm/consignee list that includes firm name, address, and phone number;
- c. Description of a recall and audit check assignment;
- d. Audit check tool (if the tool is a survey, send survey link and printable PDF);
- e. Date when audit checks shall be completed; and
- f. Point of contact for questions.

6.1.5. Notify the federal agency when assignments have been made.

6.1.6. Review audit reports at a pre-determined frequency and complete the audit report and calculate effectiveness level at the conclusion of the audit.

6.1.7. Share audit findings with relevant federal agencies.

6.2. Audits Implemented by MDA – Recall Coordinator

6.2.1. Determine if a Recall Effectiveness Audit Check is warranted. Take into account factors such as public health risk; number and distribution of known illnesses; and type, distribution, and shelf life of the product.

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6.2.2. Schedule a planning meeting if an audit is warranted. Include relevant MDA staff, and members from other agencies, as necessary. During the planning meeting, facilitate the identification of consignees, creation of audit assignments and deadlines, and set the report review frequency. Create an audit intake survey, if necessary.

6.2.3. Assign audits to Inspection Supervisors and affected delegated agency Inspection Supervisors. Send the following information to the Inspection Supervisors and delegated agency Inspection Supervisors:

- a. Description of the recall and audit check assignment;
- b. Firm/consignee list that includes firm name, address, and phone number;
- c. Description of a recall and audit check assignment;
- d. Audit check tool (if the tool is a survey, send survey link and printable PDF);
- e. Date when audit checks shall be completed; and
- f. Point of contact for questions.

6.2.4. Review audit reports at a pre-determined frequency and complete the audit report and calculate effectiveness level at the conclusion of the audit.

6.2.5. Share audit findings with relevant agencies.

6.3. Audits Implemented by Federal Agency or MDA – Inspection Supervisors

6.3.1. Assign the audit check information to the appropriate inspection staff by sending instructions and information compiled by the Recall Coordinator (see Section 6.1.4 and Section 6.2.3). The inspection staff will be responsible for conducting assigned audits and completing the audit surveys. For a description of action to take at a firm, see *FOOD.30.06 – Inspection Recall Removal SOP*.

6.4. Documentation Maintenance – Recall Coordinator

6.4.1. Retain electronic copies of all records collected during Recall Effectiveness Audit Checks in SharePoint. Store records for each individual firm as attachments within MDA's electronic inspection system (USAFS).

7. RELATED DOCUMENTS

- 7.1. Food Recall Guidance Document
- 7.2. *FOOD.30.06.v.2– Inspection Recall Removal SOP*
- 7.3. Inspection Recall Removal Process Flow
- 7.4. Recall Effectiveness Audit Checks Process Flow
- 7.5. *RESP.50.05 – RRT Communications SOP*
- 7.6. *RESP.50.06 – RRT Communications with the Public SOP*

8. EQUIPMENT/MATERIALS NEEDED

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N/A

9. SAFETY

N/A

10. CIRCULATION

This document is circulated to the following: FFSD Inspection Staff and FFSD Inspection Supervisors, RRT Staff (including Recall Coordinator), FFSD Program Managers, and the FFSD Division Director.

11. APPROVAL/DOCUMENT HISTORY

| Document History | | |
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| Version # | Status (I, R) | Change History |
| 1 | R | SOP Previously named FOOD.30.07 – Recall Effectiveness Audit Check SOP. Main responsibilities moved to the Response Unit (RESP). Updates also made due to division structure changes from DFID to FFSD. |
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| Approved By: | | Date |
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I = Initial document; R = Revised document