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1. **PURPOSE**

The document describes the procedures used by the Rapid Response Team (RRT) staff and Food Program Staff within the Food and Feed Safety Division (FFSD) of the Minnesota Department of Agriculture (MDA) for the performance of recall effectiveness audit checks.

1. **SCOPE**

This procedure applies to routine responsibilities of the FFSD Food Programs and the Rapid Response Team (RRT), including the Recall Coordinator, when conducting recall effectiveness audit checks. While responsibility primarily falls on RRT staff, Food Program Supervisors are responsible for assigning checks to staff and ensuring checks are completed in the predetermined timeframe. This procedure does not outline inspector actions during a recall effectiveness audit check or actions if a recalled product is identified for sale in commerce (reference *FOOD.30.06 – Inspection Recall Removal SOP*). Additionally, this does not apply to recall effectiveness audit checks conducted by the Feed Program within MDA FFSD.

Sharing recall and recall effectiveness audit check information with affected government agencies is necessary for a successful response. Communication procedures between agencies during a response are described in *RESP.50.05 – RRT Communications SOP*.

1. **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, 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, but may recommend a recall be conducted.

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 important that all recalled food items and ingredients are promptly removed from commerce. The issuing firm is the responsible party to ensure that all recalled food items are removed from sale and that procedures are implemented to prevent the recalled food item from re-entering commerce. However, in some cases, MDA may verify the effective removal of recalled products from commerce by completing Recall Effectiveness Audit Checks. Recall Effectiveness Audit Checks may be issued and assigned by MDA, FDA, USDA, or a combination thereof.

1. **RESPONSIBILITY**

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

**Recall Coordinator** – The Recall Coordinator will develop the Recall Effectiveness Audit Check survey, coordinate assignments through the Food Inspection Supervisor, review audit check results, and maintain records of audit checks in SharePoint.

**RRT Investigator/Analyst** – The RRT Investigator/Analyst will assist the Recall Coordinator as requested with the development of the Recall Effectiveness Audit Check survey, coordination of assignments, audit check results review, and the maintenance of audit check records in SharePoint.

**Response and Outreach (RO) Supervisor** – The RO Supervisor will provide expertise and guidance in determining the need to conduct recall effectiveness audit checks. The RO Supervisor may also assist in additional recall effectiveness check duties in the absence of the Recall Coordinator and/or RRT Investigator/Analyst or by request.

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

**Recall (FDA)** – 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 (USDA) -** 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.

**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 (as defined in the MN Food Code).

**Sell; sale** – The keeping, offering, or exposing for sale, use, transporting, transferring, negotiating, soliciting, or exchange of food; having in procession 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).

1. **PROCEDURES**
   1. **Audits Implemented by Federal Agency – Recall Coordinator/RRT Investigator/Analyst**
      1. Notify relevant FFSD staff and delegated agencies that the federal agency is conducting the audit if the federal agency does not request assistance from MDA.
      2. If the federal agency requests assistance from MDA FFSD and/or its delegated agencies, schedule a joint MDA FFSD/Federal planning meeting. Include the federal Recall Coordinator and members from other agencies, as necessary.
      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. Surveys may be created using SurveyMonkey or other similar programs. Surveys created should include all information required to complete the *FDA 3177 Recall Audit Check Report Form*.
      4. Assign audits to Inspection Supervisors and affected delegated agency Inspection Supervisors. Share the following information::
2. Description of the recall and audit check assignment;
3. Firm/consignee list that includes firm name, address, and phone number;
4. Description of a recall and audit check assignment;
5. Audit check tool (if the tool is a survey (e.g. SurveyMonkey), send survey link and printable PDF);
6. Date when audit checks shall be completed; and
7. Point of contact for questions.
   * 1. Notify the federal agency when assignments have been made.
     2. Review audit reports at a pre-determined frequency and complete the audit report and calculate effectiveness level at the conclusion of the audit.
     3. Share audit findings with relevant federal agencies.
   1. **Audits Implemented by MDA – Recall Coordinator/RRT Investigator/Analyst**
      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.
      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.
      3. Assign audits to Inspection Supervisors and affected delegated agency Inspection Supervisors. Send the following information:
8. Description of the recall and audit check assignment;
9. Firm/consignee list that includes firm name, address, and phone number;
10. Description of a recall and audit check assignment;
11. Audit check tool (if the tool is a survey (e.g. SurveyMonkey), send survey link and printable PDF);
12. Date when audit checks shall be completed; and
13. Point of contact for questions.
    * 1. Review audit reports at a pre-determined frequency and complete the audit report and calculate effectiveness level at the conclusion of the audit.
      2. Share audit findings with relevant agencies.
    1. **Audits Implemented by Federal Agency or MDA – Inspection Supervisors**
       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*.
       2. Communicate priority with staff receiving audit check assignments. Inspection staff should consider them high priority and complete them as soon as possible.
    2. **Documentation Maintenance – Recall Coordinator/RRT Investigator/Analyst**
       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 (USA Food Safety).
14. **RELATED DOCUMENTS**

FDA 3177 Recall Audit Check Report Form

FOOD.30.06 – Inspection Recall Removal SOP

RESP.50.05 – RRT Communications SOP

1. **EQUIPMENT/MATERIALS NEEDED**

N/A

1. **SAFETY**

N/A

1. **CIRCULATION**

This document is circulated to the following: FFSD Food Program Managers, FFSD Food Program Inspection Supervisors, RRT Staff (including Recall Coordinator), FFSD Division Director and Assistant Director. The current version will be stored electronically on the FFSD document control site.