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Minnesota Department of Agriculture
Food and Feed Safety Division

Document FOOD.30.06	Page **1** of **6**
Version #: **2**	Effective Date: 06/13/2016
Title: **Inspection Recall Removal**	

Table of Contents

1. PURPOSE

The purpose of this document is to provide the process for uniformly identifying and removing recalled food from the marketplace during routine inspections within the State of Minnesota.

2. SCOPE

This procedure applies to the routine responsibilities of the Food Inspection Staff of the Minnesota Department of Agriculture, Food and Feed Safety Division (MDA-FFSD). For Recall Effectiveness Audit Check procedures, refer to RESPONSE.50.15 - Recall Initiation, Notification, and Effectiveness Audit Check SOP.

3. BACKGROUND

A recall is initiated to remove food 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 injury or gross deception, or are otherwise defective. Firms may also initiate a recall following notification of a problem by the 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 the 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 food distribution system. The food distribution system can include, but is not limited to: food manufacturers, food distributors, retail food establishments, vending machines, and the public. To protect the public's health, 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.

The MDA-FFSD Recall Coordinator provides pertinent information regarding recalls affecting food products originating in or distributed to Minnesota firms. The Recall Coordinator communicates recall information to the Minnesota Agencies involved via an electronic mail system mailing list. This recall notification information is shared with all staff of the MDA-

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FFSD, others within the MDA, local public health agencies with MDA-FFSD delegated authority, and the Minnesota Department of Health and local public health agencies with MDH delegated authority. This provides appropriate notification to state and/or local officials of recall actions that may be pertinent to them.

4. 4. RESPONSIBILITY

Supervisor - The Supervisor will assist in determining actions if an inspector finds recalled products have been further distributed and if an inspector encounters refusals related to removal of recalled products during inspections.

Inspector – The Inspector will review recall information received from the Recall Coordinator; identify recalled products during inspections; take appropriate actions to contain or remove recalled products; and maintain documentation of actions taken regarding recalled products.

Recall Coordinator – The Recall Coordinator will monitor recall information from FDA and USDA-FSIS; email recall information to FFSD staff, delegated agencies, and other regulatory personnel (MDH, FDA/MIN-DO); and maintain records of recalls in the SharePoint tracking system.

5. DEFINITIONS

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).

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 reprocess 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).

FDA Recall: A firm's removal or correction of a marketed product that the Food and Drug Administration (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))

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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 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).

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 Maintain and Distribute Information Regarding Current Recalls – Recall Coordinator

6.1.1 Monitor FDA and USDA-FSIS recall updates. Post and send Class I Recalls with known Minnesota or nationwide distribution within 1 business day of notification. Class II and Class III recalls may be batched and distributed on a weekly basis. The products to be reviewed are "food" as defined in Section 5 and dietary or health supplements not included under the FDA category of "drugs."

6.1.2 Email out recall notices to all MDA-FFSD staff, Delegated Agencies, and other regulatory persons (MDH, FDA/MIN-DO) as appropriate.

6.1.3 Maintain records of all "MDA Recall Notifications" sent to MDA-FFSD State Inspectors and Delegated Agencies in the SharePoint tracking system.

6.2 Identify Recalled Products during Routine Inspections – Inspector Role

DocuSign Envelope ID: BAFA8E63-4E39-43B3-B1DB-1DA51991E4E1

6.2.1 Review recalled products in commerce within Minnesota to facilitate timely and effective monitoring in the marketplace during routine inspections.

6.2.2 Identify recalled products during routine inspections.

6.2.3 Focus recall identification on recalled product that would likely be used in the facility. Example: An inspector should not review a sprout recall with a firm that only produces spray-dried dairy products.

6.2.4 If evidence of the recalled product is found during a routine inspection, assess the facility for the presence of the recalled product and the firm's knowledge of the recall.

6.2.5 Verbally review recently-recalled product(s) distributed in Minnesota with the Most Responsible Person (MRP)/Person in Charge (PIC). The verbal review will determine if the firm received notice of the recall(s) and if any subsequent action was taken regarding the recalled product within the firm.

6.2.6 After the verbal review, assess all potential locations within the firm where recalled product(s) may be held. The assessment should include: sales display areas, storage areas, processing areas, and segregated/hold product areas.

6.3 Remove Recalled Foods from Commerce – Inspector Role

6.3.1 Remove from commerce all recalled product(s) identified within the firm during a routine inspection by issuing orders to the firm.

a. If the recalled item is a raw material being used in the facility, determine if any products produced with the recalled materials have been further distributed. If adulterated products have been further distributed, immediately report this information to a Supervisor for further actions.

b. If the product falls under FDA jurisdiction, inform the firm of their obligation to file a report in the Reportable Food Registry (RFR) at www.safetyreporting.hhs.gov.

c. Reference the recall notification to determine if the product should be destroyed on site or segregated for return to the manufacturer/distributor.

6.3.2 If a product has been or will be placed within a segregated/hold area of the facility, review the area and facility operations to determine if controls are in place to prevent recalled products from re-entering commerce. This may include but is not limited to: identification of the area as a segregated/hold area, marking or signage directly on the recalled product, control of the area with locked caging, and/or distance separating the segregated/hold area from products still in commerce.

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6.3.3 If deficiencies are identified in the firm's ability to retain recalled products within the segregated/hold area, issue orders for correction.

6.3.4 If the recall notification indicates the product should be destroyed on site, observe and photograph all product destruction and document in the inspection report. Verify actions are taken to denature the product and prevent potential re-entrance into commerce or human consumption. Methods may include: trash compaction, physical damage to or removal from packaging combined with chemical overlay (odiferous or visible), or diversion to animal feed supplies (this option is only available with approval from a Supervisor).

6.3.5 Report any instances of refusal by the firm to remove recalled products from commerce to a Supervisor for further actions.

6.4 Recall Recordkeeping – Inspector Role

6.4.1 Document recalled foods identified within the firm which are not retained within a segregated/hold area and the removal and/or destruction actions taken on those products in the inspection report using the "Product Disposition" section.

6.4.2 Maintain all recall-related reports and documentation per FFSD retention record policy.

7. RELATED DOCUMENTS (includes References, Attachments)

Inspection Recall Removal Process Flow

8. EQUIPMENT/MATERIALS NEEDED

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

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Document FOOD.30.06	Page **6** of **6**
Version #: **2**	Effective Date: 06/13/2016
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Document History		
Version #	**Status (I, R)**	**Change History**
2	**R**	**Biennial SOP review.**
1	**I**	**Initial policy drafting.**

DocuSigned by:	
Approved By:	**Date**
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Approved By:	**Date**

I = Initial document; R = Revised document