



Michigan Department of Agriculture

Food Product Recalls Guidance For Industry

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Introduction

A food recall is a firm's voluntary removal of distributed food products from commerce when there is a reason to believe that such products are adulterated or misbranded under the provisions of applicable state and federal laws.

All food firms should have a recall plan in place, in order to act promptly and effectively in the event of a recall. Being prepared reduces the risk of potentially harmful or hazardous food from reaching consumers and potentially wreaking devastating effects on human health and the economy.

This document is not intended to be an all-inclusive recall guide, however, the Michigan Department of Agriculture is providing helpful information that industry can incorporate into their food recall plans.

Abbreviations

FDA: U.S. Food and Drug Administration

MDA: Michigan Department of Agriculture

USDA: United States Department of Agriculture

HACCP: Hazard Analysis and Critical Control Points

CFSAN: Center for Food Safety and Applied Nutrition (one of six centers within the FDA)

Recall Terminology

Recall – A firm’s voluntary removal of distributed food products from commerce when there is reason to believe that such products are adulterated or misbranded under the provisions of applicable state and federal laws. “Recall” does not include a market withdrawal or a stock recovery.

Market Withdrawal – A firm’s removal or correction by its own volition of a distributed product that involves a minor infraction that would not warrant legal action by MDA, or involves no violation of the state or federal laws, or health hazard.

Stock Recovery – A firm’s removal or correction of product that has not been marketed or has not left the direct control of the firm. For example, product is located on premises owned by or under the control of the firm and no portion of the lot has been released for sale or use.

Recall Classifications – MDA assesses the public health concern or hazard presented by a product being recalled, or considered for recall, whether firm-initiated or requested by MDA, and classifies the concern using criteria developed by the FDA:

Class I – A situation in which there is a strong likelihood that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.

Class II – A situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

Class III – A situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.

Depth of Recall – The level of product distribution to which the recall is to extend:

Consumer level – This includes household consumers as well as all other levels of distribution.

Retail level – This includes all retail sales of the recalled product.

User level – This includes hotels, restaurants, and other food service institutional consignees.

Wholesale level – This is the distribution level between the manufacturer and the retailer. This level may not be encountered in every recall situation (e.g., the recalling firm may sell directly to the retail or consumer level).

Scope – This defines the amount and kind of product in question. For example, all products produced under a single HACCP plan between performance of complete cleaning and sanitation procedures (clean up to clean up).

Disposition – The firm’s action to correct a situation leading to the recall such as relabeling, reworking, or destroying product.

Recall Classifications

Examples of Class I, II, and III Recall Situations

Recall classifications often occur on a case-by-case basis. Certain hazards may be classified as Class I, II, or III depending on circumstances and risk. Each unique situation cannot be captured in list format, therefore the following list is meant as a guide only. When the state is assisting with a recall, the FDA or the USDA is consulted as appropriate to assure proper recall classification.

Note: Currently, CFSAN has not officially classified many allergens. Allergens below are put into categories of most common classification based on recall postings.

Class I

A situation in which there is a strong likelihood that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.

Examples

- *Listeria monocytogenes* in ready-to-eat food
- *Clostridium botulinum* toxin
- *E. coli* O157:H7
- *Salmonella sp.* in ready-to-eat food
- Uneviscerated fish (Kapchunka) greater than 5" in length (FDA Compliance Policy Guide 540.650)
- Excessive/undeclared sulfites

Note: May be Class I, II, or III depending on level of sulfites present in the product. An algorithm is available to help make this determination.

- Undeclared Crustaceans such as:
 - Shrimp
 - Crab
 - Crayfish
 - Lobster
- Undeclared peanuts, includes ingredients such as :
 - Peanut butter
 - Peanut flour

Note: Hydrolyzed peanut protein and peanut oil may or may not present a hazard to an allergic individual, depending on how they were processed.

- Undeclared tree nuts
 - Hazelnuts or filberts
 - Walnuts
 - Pecans
 - Cashews
 - Brazil nuts
 - Almonds
 - Pistachios
 - Chestnuts
 - Macadamia nuts
 - Hickory nuts
 - Pine nuts
- Undeclared eggs
 - Egg white
 - Egg yolk
 - Ingredients such as egg albumen and powdered eggs

- Undeclared dairy- includes any ingredient which contains protein from milk such as:
 - Milk
 - Cream
 - Dry milk
 - Whey
- Undeclared soy
 - Soybeans
 - Soy protein
 - Soy flour

Note: Generally, soy oil, soy lecithin and hydrolyzed soy protein are not included, since these may be processed in a manner that eliminates or denatures the protein.
- Undeclared fish

Class II

A situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote (e.g., yellow #5, filth).

Examples

- Certain coloring agents- See 31 CFR 101.22 (k) (3) for requirements specific to color declaration on butter, cheese and ice cream.
- Norovirus
- Excessive/undeclared sulfites

Note: May be Class I, II, or III depending on level of sulfites present in the product. An algorithm is available to help make this determination.
- Certain unapproved additives or ingredients

Note: Refer to the Federal Food, Drug and Cosmetic Act as amended for specific circumstances. Generally considered as Class II are foods which contain the following: pesticide residues within the meaning of section 408 (a), food additives unsafe within the meaning of section 409, new animal drugs unsafe within the meaning of section 512, and color additives unsafe within the meaning of section 721 (a).
- Undeclared wheat

Class III

A situation in which use of or exposure to a violative product is not likely to cause adverse health consequences (e.g., technically misbranded).

Examples

- Undeclared certified colors. Refer to CFSAN and FDA Federal Food, Drug and Cosmetic Act, section 721 (a).
- Decomposition
- Filth
- Mold contamination (may depend on type of mold involved)
- Excessive/undeclared sulfites

Note: May be Class I, II, or III depending on level of sulfites present in the product. An algorithm is available to help make this determination.
- Minor labeling problems (e.g., format, undeclared ingredients that are not allergens)

Public Notification and the Press Release

Public notification is important, particularly in situations where the recalled product may pose a significant health hazard and may be in the hands of consumers. In such situations, often Class I recalls, prompt issuance of a press release should be high priority. Unique situations will be handled on a case-by-case basis.

When public notification is necessary, MDA Lansing office and regional staff will work with Michigan firms initiating a recall to issue a press release as soon as the recall situations are identified. The firm will be informed if it does not issue a press release within 24 hours, MDA will issue its own.

Press Releases

Essential elements of a press release include the following:

1. **Establishment** – The name and address of the firm with points of contact for recall information as appropriate (e.g., Compliance/Recall Coordinator, Recall Management, Media Inquiries, Consumer Inquiries, website) and phone or fax number(s);
2. **Product Recalled** – Exact and complete description of the specific product(s) recalled;
3. **Production Dates/ID Codes** – Specific identifying codes or marks on the packages; specific dates of production including plant codes, sell-by dates, expiration dates;
4. **Quantity Recalled** – The product quantity recalled (required for USDA regulated products);
5. **Recall Classification** – Class I, II, and III (required for USDA regulated products);
6. **Recall Notification Level** – Wholesale, retail, consumer (required for USDA regulated products);
7. **Problem/Reason for Recall** – The problem with the product or the reason for the recall;
8. **Specific Nature of Potential Hazard** – Examples; allergic reaction, infection;
9. **How and When Discovered** – Details regarding the discovery of the hazard (required for USDA regulated products);
10. **Distribution** – Geographic (nationwide, statewide, specific counties);
11. **Media and Consumer Contacts and Instructions** – Two different contacts are often given. Instructions to the public regarding typical symptoms of illness and what to do with the recalled product if they have it, including the name and telephone number of a company contact for consumers with any questions.
12. **Risk Information** – Succinct information about specific steps consumers can take to reduce their risk of illness. An explanation of the risk involved in consuming the product including typical signs and symptoms of adverse health effects caused by the agent.
13. **Follow-up Activities** – A statement regarding the status of the investigation and agencies involved, as appropriate (e.g., “the firm is cooperating with the investigation by state and federal officials to identify the source of contamination”).

Example Press Releases

Note: The phrase “potentially harmful” is not adequate to express the nature of a hazard for a Class I recall.

Template

<COMPANY NAME>
<COMPANY ADDRESS>
<COMPANY CITY, STATE, ZIP>

FOR IMMEDIATE RELEASE **<TODAY’S DATE>**
<COMPANY OFFICIAL NAME, TITLE, PHONE>

<DESCRIPTIVE TITLE OF RECALL>

<**CITY**> <COMPANY NAME, ADDRESS>, is recalling its <SPECIFIC PRODUCT(S)> because they <SPECIFIC REASON FOR RECALL>.

INSERT PATHOGEN OR OTHER REASON FOR RECALL DESCRIPTION

The recalled <PRODUCT> was distributed <DISTRIBUTION DESCRIPTION>.

<SPECIFIC PRODUCT DESCRIPTION>

Illnesses <HAVE/HAVE NOT> been reported to date in connection with this problem.

The contamination was noted after testing by <STATE/FEDERAL AGENCY NAME> revealed the presence of <PATHOGEN NAME> in some <DESCRIPTION OF PRODUCT>.

Production of the product has been suspended while <THE COMPANY, STATE AND FEDERAL OFFICIALS> continue their investigation as to the source of the problem.

Consumers who have purchased <DESCRIPTION OF PRODUCT> are urged to return them to the place of purchase for a full refund. Consumers with questions may contact <THE COMPANY and COMPANY CONTACT NUMBER>.

Pathogen Example

ABC Produce
43234 Test Drive
Lansing, MI 48912

August 20, 2007

FOR IMMEDIATE RELEASE

John Smith, Communications Director, 517-444-2333

ABC Produce Announces the Recall of Cantaloupe Melons Due to Potential Salmonella Contamination

LANSING— ABC Produce, a wholesale importer of fresh fruit and vegetables, announced the recall of cantaloupes due to potential Salmonella contamination. The recalled product has been linked with a multi-state outbreak of Salmonella.

Healthy persons infected with Salmonella often experience fever, diarrhea (which may be bloody), nausea, vomiting and abdominal pain. In rare circumstance, infection with Salmonella can result in the organism getting into the bloodstream and producing more severe illnesses such as arterial infections (infected aneurysms), endocarditis and arthritis. The very young, the elderly, and persons with compromised immune systems are the most susceptible to foodborne illness. People experiencing these problems should seek immediate medical attention.

Approximately 3,430 cantaloupes were distributed to retail stores in Ohio, Michigan, Indiana, and Wisconsin. The cantaloupes have a light green color skin on the exterior with orange flesh. The cantaloupes were distributed for sale in bulk in cardboard cartons, with 10-12 cantaloupes per carton. The recalled cartons are a natural brown color, with "Tropi-loupes de Costa Rica" printed on the side in green and white lettering. On the bottom of each carton is a 10-digit code; the first three digits are between 099 and 135. Cantaloupes bear a "Tropi-loupe de Costa Rica" sticker, with a code of 09879.

The recalled product has been epidemiologically linked with a multi-state outbreak of Salmonella. Investigation is ongoing.

Consumers who have purchased the recalled cantaloupes are urged to return them to the place of purchase for a full refund. Consumers with questions may contact ABC Produce at 517-444-2333.

Allergen Example

XYZ Company
P.O. Box 123
Lansing, MI 48912

August 20, 2007

FOR IMMEDIATE RELEASE

Mary Smith, Communications, 877-111-2222, ext. 12

XYZ COMPANY ISSUES ALLERGY ALERT ON UNDECLARED MILK AND EGG IN “XYZ CHOCOLATE CHIPPERS, CHOCOLATE CHIP COOKIES”

LANSING – XYZ Company of Lansing, MI is recalling 16-ounce packages of “XYZ Chocolate Chippers, Chocolate Chip Cookies” because they may contain undeclared milk. People who have allergies to milk run the risk of serious or life-threatening reactions if they consume this product.

The recalled “XYZ Chocolate Chippers, Chocolate Chip Cookies” were distributed nationwide through retail stores.

The recalled product comes in a 16-ounce red package with gold writing, UPC code of 33333-49393. All date codes are included in this recall. The codes are located on the back label.

No illnesses have been reported to date in connection with the recalled product.

The recall was initiated after it was discovered that the milk containing product was distributed in packaging that did not reveal the presence of milk. Subsequent investigation indicates a malfunction in the labeling equipment. This has been corrected.

Consumers who have purchased 16-ounce packages of “XYZ Chocolate Chippers, Chocolate Chip Cookies” are urged to return them to the place of purchase for a full refund. Consumers with question may contact the company at 877-111-2222, ext. 12.

Recommended Wording for Specific Contaminants

Common Signs and Symptoms

***E. coli* 0157:H7**

E. coli 0157:H7 infections can cause diarrhea (bloody or nonbloody), dehydration, abdominal cramps, and in severe cases a serious condition involving kidney failure called *hemolytic uremic syndrome* (HUS). The very young, the elderly, and persons with compromised immune systems are the most susceptible to foodborne illness. People experiencing these problems should seek immediate medical attention.

Listeria monocytogenes

Consumption of food contaminated with *Listeria monocytogenes* can cause listeriosis, an uncommon but potentially fatal disease. Listeriosis can cause high fever, severe headache, neck stiffness, and nausea. Listeriosis can also cause miscarriages and stillbirths. The very young, the pregnant, the elderly, and persons with compromised immune systems are the most susceptible to infection. People experiencing these problems should seek immediate medical attention.

Clostridium botulinum

Botulism, a potentially fatal form of food poisoning, can cause the following symptoms: general weakness, dizziness, double vision and trouble with speaking or swallowing. Difficulty in breathing, weakness of muscles, abdominal distension and constipation may also be common symptoms. The very young, the elderly, and persons with compromised immune systems are the most susceptible to foodborne illness. People experiencing these problems should seek immediate medical attention.

Salmonella

Healthy persons infected with *Salmonella* often experience fever, diarrhea (which may be bloody), nausea, vomiting and abdominal pain. In rare circumstance, infection with *Salmonella* can result in the organism getting into the bloodstream and producing more severe illnesses such as arterial infections (infected aneurysms), endocarditis and arthritis. The very young, the elderly, and persons with compromised immune systems are the most susceptible to foodborne illness. People experiencing these problems should seek immediate medical attention.

Allergens

People who have an allergy or severe sensitivity to specific type of allergen (e.g., peanuts, tree nuts {chestnuts, Brazil nuts, walnuts, hazelnuts, pecans, pine nuts, cashews}, eggs, sulfites) run the risk of serious or life-threatening allergic reaction if they consume these products.

Example Customer Notification Letter

Recalling firm: <NAME>
 <ADDRESS>
 <TELEPHONE NUMBER>

 <TODAYS DATE>

<CUSTOMER FIRM NAME & ADDRESS>

Attention: <CONTACT PERSON NAME & TITLE>

Re: Recall of <TYPE OF PRODUCT>

Dear Sir or Madam:

This letter is to confirm that <COMPANY NAME> is recalling the following product(s) because
<SPECIFY REASON FOR RECALL>:

<DESCRIBE THE PRODUCT(S), INCLUDING NAME, BRAND, CODE, PACKAGE SIZE AND TYPE,
ESTABLISHMENT NUMBER, ETC.>

We request that you review your inventory records, and discontinue selling your existing stock of this product. Please segregate the <PRODUCT(S)> and <INDICATE PROPER DISPOSITION> as soon as possible. We will credit your account for product returned.

We are undertaking this action in cooperation with the <REGULATORY AGENCY/AGENCIES>. State and federal officials may contact you to confirm that you have received this notice and are cooperating in this action.

Your prompt action will greatly assist <COMPANY NAME> in this action. If you have any questions, please do not hesitate to contact <COMPANY RECALL COORDINATOR at PHONE NUMBER>.

Thank you for your cooperation.

Sincerely,

<COMPANY OFFICIAL NAME AND TITLE>

Additional Content For Class I Recalls

In order to advise the <REGULATORY AUTHORITY> about the effectiveness of this recall, please inform us of the quantity of the above product on hand immediately after you received this recall letter. Please sign and send or fax to <FAX NUMBER> this letter back to us as soon as possible.

Quantity on Hand: _____ Cases/Cans/Packages (Circle One)

(Store Owners Name)

(Signature)

Example of In-Store Notification

Voluntary Recall Notice

We were notified on <DATE> that traces of <ADULTERANT> were present in <PRODUCT> produced on <DATE(S)> in our store. We believe this to be an isolated occurrence in this one batch. We have had no other reports of <ADULTERANT> to date and are cooperating fully with the Michigan Department of Agriculture's investigation of this incident.

If you have any <PRODUCT> at all with a packed on date of <DATE> and sell by date of <DATE>, please return it for a full refund.

We appreciate your business and if you have any further questions, please feel free to call the store meat manager <NAME> at <PHONE NUMBER> or contact the store director <NAME> at <PHONE NUMBER>.

Thank You,

(Store Owner's Name)

Regulators' Roles and Authority

Federal and state regulatory agencies generally do not have the authority to order a recall. Recalls are typically voluntary actions carried out by the manufacturer or distributors of the food product. In some cases, a company will discover one of its products is defective and conducts a recall entirely on its own. In other cases, the federal or state regulatory agency notifies a company that one of its products is defective and suggests or requests a recall. If the company does not recall the product, the regulatory agency can seek legal action, which may include seizure of available product.

Cooperation between industry and regulatory agencies has proven to be very effective and efficient in removing potentially dangerous products from the market. Both industry and regulatory agencies benefit when a potentially harmful product is prevented from reaching consumers.

During a recall, the company takes full responsibility for product recalls, including follow-up (effectiveness) checks to assure that recalls are successful. Regulatory agencies may assess the adequacy of the recall by conducting audit checks on a portion of the firms that received the recalled product. The need for and number of audit checks conducted depends on the classification of the recall.

Michigan Food Law, Act No. 92 of 2000, §2105

<http://legislature.mi.gov/doc.aspx?mcl-act-92-of-2000>

21 CFR Part 7 , Subpart C - Recalls (7.41-7.59)

www.access.gpo.gov/nara/cfr/waisidx_00/21cfr7_00.html

21 CFR Part 107, Subpart E - Infant Formula Recalls

www.access.gpo.gov/nara/cfr/waisidx_03/21cfr107_03.html

FSIS Directive 8080.1, Recall of Meat and Poultry Products, 5/2004

www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/8080.1Rev4.pdf

Contacts and Additional Resources

MDA: Food and Dairy Division, 517-373-1060

FDA: Detroit District Office, 313-393-8100

USDA: Madison District Office, 608-240-4080

Food and Drug Administration (FDA) Recall Page

<https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts>

United States Department of Agriculture (USDA) Recall Page

www.fsis.usda.gov/Fsis_Recalls/Open_Federal_Cases/index.asp

