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Guidance for Retailers

Product Recalls

FMI THE FOOD INDUSTRY ASSOCIATION

FMI reviewed and updated this Guide in February 2020

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Contents

Product Removal Checklist

- ☐ Verify recalled product information provided by the recalling firm.
- ☐ Identification of individuals involved – supplier, internal staff and regulatory agency(ies).
- ☐ Implementation of communications plan.
- ☐ Maintain open lines of communication with supplier and regulatory agency or agency(ies) (federal, state and local, as needed).
- ☐ Disseminate information to the stores and distribution centers.
- ☐ Consider blocking UPC and/or GTIN code to prevent scanning and purchasing of recalled product if recall affects all lots and code dates of the product.
- ☐ Collect quantities of product on-hand and disposal information from stores and distribution centers.*
- ☐ Verify stores and distribution centers that submitted effectiveness check data.*
- ☐ Calculate the amount of product received, the amount of product on-hand at the time of the recall, and the amount of product returned by customers.*

**These calculations will be necessary as part of the effectiveness check review conducted by the investigating regulatory agency.*

INTRODUCTION

Food safety is the number one priority of the retail industry. Maintaining food safety for customers requires diligence by the entire supply chain. Prevention of contamination should always be the goal; however, retailers and wholesalers need to be prepared when things go wrong. Product recalls are the last step in the supply chain to effectively and efficiently remove potentially harmful products from commerce, and may include requesting consumers return recalled products to the retail store. There are endless reasons for product recalls but no matter what the reason is, they are always highly stressful situations. The best way to handle recalls is to be prepared with clear and transparent policies and procedures that employees at all levels can use for any recall situation.

The most important goal of product recalls is to remove the product from commerce quickly and effectively. For recalls occurring after the product has been sold to customers, retailers and manufacturers share the responsibility for notifying customers and facilitating product returns.

This guidance document can be modified and personalized for your company. Recall procedures, regulatory requirements, resources, and sample forms are included for your use.

As a member benefit, FMI offers 24-hour crisis support for food safety or other crisis issues. ***See Appendix G*** for the contact information or look on the food safety page of the FMI website.

RECALL POLICY STATEMENT

The Recall Policy Statement can be the opening to the document that may include statements on the company's dedication to quality, the importance of the health of the consumer and its influence on the bottom line, the fact the procedures are operable 24 hours a day and every day of the year, and the procedures are reviewed annually (at a minimum).

{Company's} primary business goal is to distribute safe, wholesome and lawful products to its consumers. However, if a {company}-distributed product is determined to be defective, unsafe or in violation of {U.S. Food and Drug Administration (FDA) / United States Department of Agriculture (USDA) / Consumer Products Safety Commission (CPSC) / U.S. Environmental Protection Agency (EPA) / etc.}, it is necessary to promptly remove the product from the marketplace to protect the consumer.

Recalls are to be implemented in a timely and efficient manner in accordance with the procedures set forth by this document. An effective recall ensures prompt removal of affected product from the marketplace with adequate disposal.

This recall policy should be in effect and capable of being implemented 24 hours a day, seven days a week and every day of the calendar year.

RECALL DEFINITIONS

The definitions of the different classifications are derived from the U.S. Food & Drug Administration definitions. USDA classifications are similar.

Recall: Recalls are actions taken by a company to remove a violative product from the market. A recall does not include a consumer advisory, market withdrawal or a stock recovery.

Consignee: anyone who received, purchased, or used the product being recalled.

Direct account: the first consignee in a recalling firm's distribution chain.

Direct consignee: the first consignee in a recalling firm's distribution chain. 21 CFR 117 uses the term "direct consignee" to have the same meaning as "direct account" in 21 CFR part 7, subpart C.

Depth of Recall: The level in the distribution chain to which a recall is to extend.

> **Wholesale level:** Product removed from a warehouse or distribution center where the product is not under the direct control of the manufacturer.
>
> **Retail level:** Product removed from retail stores.
>
> **User/Consumer level:** Product has been sold to consumers and involves the removal of the product from warehouse and retail sale with possible public notification to the consumer.

Effectiveness Check: A procedure of verification that a recalling establishment and/or an establishment that received or purchased the recalled product (e.g., retail establishment, warehouse, distributor, etc.) takes as part of the recall process to determine whether a recall is progressing adequately. Effectiveness checks verify that affected parties received notification of the recall and have taken the appropriate actions as directed by the recall communications. The recall effectiveness is determined by comparing the amount recalled product recovered to the total amount of recalled product. Effectiveness checks can be completed electronically, by phone, or by physical visits by a regulatory agency, the company or a third party.

Recall Classifications: Removal from distribution channels of a consumer product or ingredient that could present a risk of illness, injury or death and/or which a regulatory agency could otherwise consider to be in violation of a particular act and/or regulation.

> **Class I Recall:** A product which poses a reasonable probability that the use of or exposure to the product could cause serious adverse health consequences or could result in death.
>
> **Class II Recall:** A product in which the use of or exposure to the product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

Class III Recall: A product in which the use of, or exposure to the product is not likely to cause adverse health consequences.

Market Withdrawal: The voluntary removal or correction of a product or ingredient that does not violate regulatory standards, but may not meet the company's quality standards.

Stock Recovery: The company's removal or correction of a product that has not left the direct control of the firm.

RECALL Planning

Planning for a recall can minimize the impact of a recall event. A written recall plan outlines each step in the recall process and describes what needs to be done and who is responsible for carrying out each task. A recall plan ensures that specific actions are taken in a timely and efficient manner.

Although the contents of a recall plan may vary depending on the company, a recall plan should include the following:

- ☐ Defined roles and responsibilities of individuals carrying out recall plan
- ☐ Procedures for determining if a recall is needed
- ☐ Procedures for responding to a recall or executing a recall issued by a manufacturer/supplier
- ☐ Contact list for external notifications (e.g., regulators, customers, public, etc.)
- ☐ Process for identifying lots and how lots are defined
- ☐ Procedures for conducting effectiveness checks
- ☐ Product disposition procedures (may depend on the food and the hazard)
- ☐ Draft notices
- ☐ Templates/forms for collecting information

A retailer or wholesaler operating a manufacturing, processing, packing or holding facility (i.e., registered food facility) that must comply with FDA's Preventive Control for Human or Animal Food rules, are required to have written recall plan (§117.139) if they are producing a food that has a hazard that requires a preventive control. The recall plan must include procedures that describe the steps to be taken and assign responsibility for performing the following actions:

1. Notifying direct customers and consignees of the food being recalled, including how to return or dispose of the affected food (Notification of customers is required for Class 1 recalls and some Class 2 recalls when there is a threat to public health).
2. Notifying the public about any hazard presented by the food, when appropriate, to protect public health.
3. Conducting effectiveness checks to verify that the recall has been carried out.
4. Appropriately disposing of recalled food (e.g., through reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the food).

A critical element of the recall plan is to establish a recall team and identify a single individual responsible for coordinating recall activities. The recall coordinator should be someone who can devote their full attention to the recall and are able to keep things organized throughout the recall process.

Corporate Coordination

The {company} recall team ("recall team") should include staff from areas that may be involved in the recall process, such as:

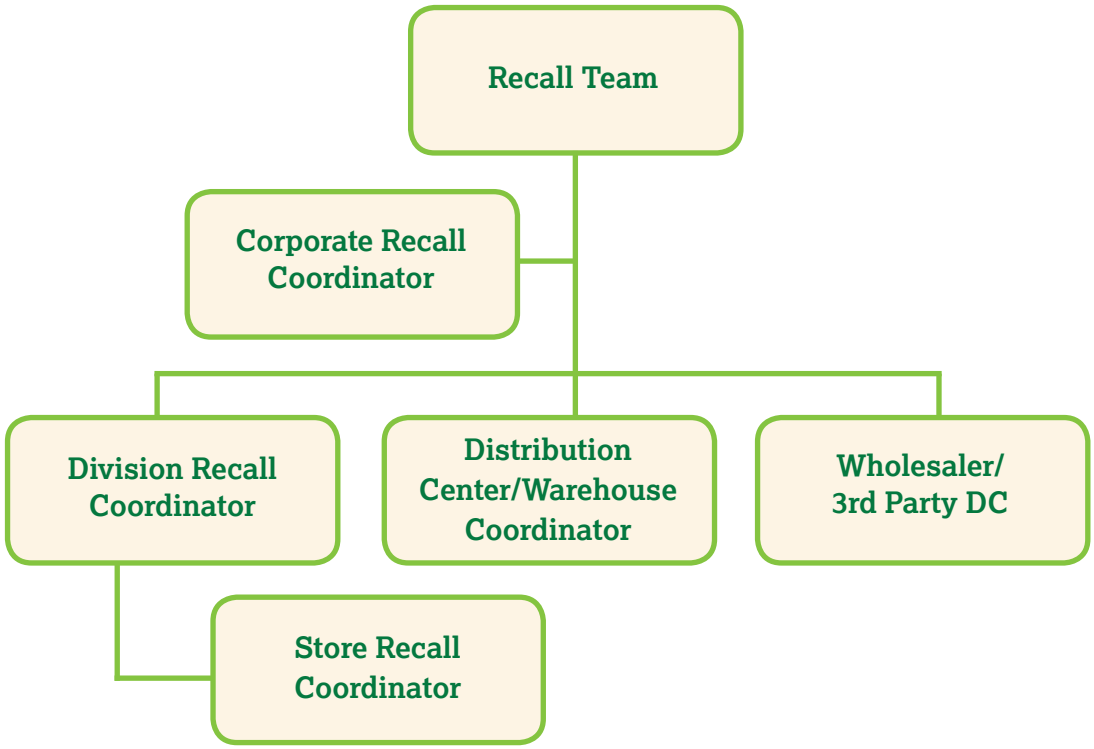
- ☐ food safety/quality assurance
- ☐ operations
- ☐ procurement
- ☐ legal
- ☐ distribution
- ☐ loss prevention
- ☐ risk management
- ☐ media relations

Depending on the size of the {company}, the recall team may include corporate team members. The recall team is responsible for executing recalls under the direction of the company's corporate recall coordinator (or the person responsible for initiating recalls). The corporate recall coordinator should coordinate all recall-related activities including:

- ☐ developing and updating the recall plan;
- ☐ incident investigations;
- ☐ initiating recalls, recall strategy and implementation;

- ☐ ensuring all necessary documentation is collected;
- ☐ communicating with suppliers/manufacturers;
- ☐ communicating with stores, customers, media and other stakeholders;
- ☐ communicating and coordinating activities with regulatory agencies;
- ☐ documenting communications; and
- ☐ tracking and documenting recall effectiveness and closeout of the recall.

Other key staff members may be assembled to assist in the recall process as necessary.



For each member of the recall team an alternate person should be assigned to serve in the absence of the recall team member. The corporate recall coordinator should maintain the list of the recall team members and their alternates, including phone numbers (office, home and/or cell), email addresses and where they can be contacted 24 hours a day ***(see Appendix C)***. This list should be reviewed and updated on a regular basis (annually, at a minimum).

The recall team can assist the corporate recall coordinator in the collection of information and the evaluation of the risks involved in specific situations. When a recall is initiated through the corporate office, it is typically the responsibility of the recall team to determine if a recall is required,

the classification of the recall (if not predetermined by a regulatory agency), (Class I examples may include those products contaminated with a pathogen (e.g., Listeria monocytogenes, E. coli O157:H7, or Salmonella), the depth of the recall and the ensuing recall strategy. One individual on the recall team (typically the corporate recall coordinator) should be responsible for contacting and coordinating communication with the appropriate regulatory agency. All communications with regulatory agencies should be conducted through this individual. The corporate recall coordinator should also communicate with the appropriate manufacturer, distributor and/or warehouse. If a recall is initiated through a supplier, the corporate recall coordinator should coordinate the actions necessary to enact that recall.

The recall team can use the attached Recall Decision Flow Chart to assist in making recall-related decisions ***(see Appendix M)***.

It is the responsibility of the recall team to determine if third-party services are required (e.g., recall services, laboratories, industry experts) ***(see Appendix G)***. In the event of a major recall, consumer questions should be directed to a centralized consumer response center. Any media communication regarding a recall should be directed to a designated corporate media representative. Human Resources or the corporate media representative should be responsible for communicating information to employees.

Division Coordination

If the company has separate division offices, each company division office should designate a division recall coordinator. The corporate recall coordinator should notify the division recall coordinators about recalls and withdrawals via pre-specified electronic and/or written communications (e.g., internal recall systems, emails, text messages) and follow through on collection of effectiveness checks.

Division offices should provide to the corporate recall coordinator an updated list of primary contacts, including alternates, which are to be notified in the event of a recall or withdrawal. These contacts should be available on a 24/7 basis, and the list should include office numbers, home numbers, and/or cell numbers ***(see Appendix D)***.

The division recall coordinator assumes responsibility for coordinating the recall or withdrawal process at the division level. This responsibility may include notification of the recall or withdrawal to division retail stores and/or division warehouses, follow-up to ensure proper notification and facility action to the notice, and/or the collection of effectiveness check reports.

The division recall coordinator should be the point-person for the division office and designated facilities, and should communicate directly with the corporate recall coordinator.

If division staff, such as procurement, media relations, or store personnel, becomes aware of a potential product issue or recall, they should notify their division recall coordinator immediately. The division recall coordinator should contact the corporate recall coordinator as soon as they are aware of

the situation. The corporate and division recall coordinators, as well as the division staff, should work together to collect the appropriate product, code and distribution information and should verify this information with the supplier/manufacturer.

All product recalls and withdrawals should be coordinated directly through the corporate recall coordinator. Any contact from a regulatory agency, including inquiries on recalls or visits to retail facilities, should be communicated to the corporate recall coordinator. The corporate recall coordinator should give guidance in handling the inquiry and should coordinate future communications with that agency.

Retail Store Coordination

The store manager, or manager in charge, may act as the store recall coordinator within their store to ensure the appropriate recall-related actions are taken and product is properly disposed of, as per instructions from the division office or corporate recall coordinator. Store Managers, or managers in charge, should communicate with their division or corporate recall coordinator about recalls and withdrawals and their effectiveness check reports. Retail stores should provide the division and corporate recall coordinators with contact information so recalls and withdrawals can be communicated to the store on a 24/7 basis.

If store personnel become aware of a potential product issue, they are to notify their corporate or division recall coordinator immediately. After discussion with the corporate recall coordinator, the store may want to pull the potentially affected product during the investigation. FMI recommends that all recall decisions be made through a specified process and decision making is consistent with corporate policy.

Warehouse or Distribution Center Coordination

{Company}-owned warehouses and distribution centers should appoint the general manager of the facility as the facility recall coordinator to ensure the appropriate recall-related actions are taken and product is properly disposed of, as per instructions from the division office or corporate recall coordinator. The general manager should communicate with the corporate recall coordinator about recalls and withdrawals and their effectiveness check reports. Retail stores should supply to the corporate recall coordinator contact information so recalls and withdrawals can be communicated to the store on a 24/7 basis ***(see Appendix E)***.

DETERMINING THE NEED FOR A RECALL

Incident Investigation

The company may learn about potential issues from customers, suppliers, regulatory agencies, news media, notification service or other means. All reports of possible product defects or serious/life threatening illnesses believed to be associated with a company-distributed product should be taken seriously and should be promptly forwarded to the corporate recall coordinator for investigation.

Customer Complaints and Regulatory Contacts

All reports of a customer problems or complaints should be recorded and monitored by Consumer Affairs, Customer Service or by the departments involved with customer complaints. If there is an allegation of contamination, illness, injury or death, or if regulatory action is initiated, the information should be forwarded to the corporate recall coordinator, or alternate, immediately for evaluation and investigation. It is critical that as much information as possible is obtained. See the Customer Complaint / Regulatory Contact Handling Form (Appendix K) that can be completed for each reported problem or complaint. Any contact by a regulatory agency regarding a consumer complaint alleging illness or injury should be forwarded to the corporate recall coordinator.

The corporate recall coordinator should coordinate the investigation of potential issues with product. The recall team should evaluate preliminary information and make a determination as to whether a supplier should to be notified. A hazard assessment should be performed and should consider the degree of seriousness of the situation, the impact to the consumer, the likeliness of the occurrence of the event, and the potential consequences of the event. If it is a branded product, consideration should be given to referring the matter to the manufacturer for handling.

Depending on the situation, follow-up with the source of the information or with the affected party (ies) should be conducted immediately. If necessary, the product can be retrieved for inspection. Most companies receive customer complaints regularly and very few end up as a recall.

In the event an illness, injury, death or product tampering (FDA office of criminal investigation or similar regulatory authorities need to be contacted, not just the supplier) is alleged or has occurred, or if there is a suspicion of adulteration or mislabeling, suppliers should be notified and traceability programs initiated immediately. As the supplier is conducting its traceability procedures, the recall team should analyze the facts and determine if product should be removed from sale. If it is determined that the initiation of recall is NOT necessary, the matter may be sent back to Consumer Affairs, Customer Service or the department handling complaints for further follow-up.

STEP 1
INITIATION OF A PRODUCT RECALL

Product recall information can come from a variety of sources. Information should come directly from the manufacturer but may also come from brokers or distributors of a product. A recall may also come from a regulatory agency as a result of an investigation or as a cautionary statement when a product is believed to be a source of an outbreak. Reports of product recalls have also come from current news stories. The retailer may have evidence of product contamination and may initiate a recall.

Supplier-Initiated Recall

If a supplier notifies {company} about a recall they are conducting that directly affects {company}, the following information is to be provided:

- ☐ Product name and description
- ☐ Product identity (UPC/GTIN, NDC, item and case number)**
- ☐ Codes (lot codes, expiration dates, etc.)
- ☐ Package type and size
- ☐ Classification of recall
- ☐ Reason for recall
- ☐ How to identify the product at store level
- ☐ Pictures of the product showing codes
- ☐ Where the product was shipped, when the product was shipped, and how much was shipped to each location (i.e. distribution center, store)
- ☐ Applicable purchase order numbers
- ☐ Disposition of the recalled product (e.g. product return, destruction, retail pick up service)
- ☐ Contacts at recalling firm
    - Media contact
    - Consumer hotline

***Proper identification of recalled product relies on the UPC and/or GTIN number. In order for the recall process to function, the UPC and/or GTIN number must be accurate. In addition to listing the UPC and/or GTIN number, it is a best practice to block barcode to prevent scanning at the registers.*

A Supplier Product Information Request form is attached ***(see Appendix L)*** for collecting the above-listed information from suppliers.

If a retailer is the responsible party (i.e., owner, operator, or agent in charge registered food facility) and becomes aware of a problem with product, in a registered FDA facility, where exposure to or consumption of may result in serious adverse health consequences or possible death, the responsible party must report it to FDA through the Reportable Food Registry portal within 24 hours after discovering the problem ***(see Appendix A)***. The responsible party is also responsible for investigating the cause of the problem and report the findings to FDA when they are known. FDA may also require responsible parties to notify the immediate previous source(s) and/or immediate subsequent recipient(s) of the reportable food.

Retail Store-Prepared Product Recall

If there is a problem with a store-prepared product, such as an allergen or labeling issue, the retailer needs to take immediate action by stopping sale of the product and following the recall procedures outlined in this manual. If the product poses serious adverse health consequences or possible death the firm should issue a notice alerting the public and the regulatory agency.

The company should convene the recall team when determining the classification of a recall. Class I Recalls involve products that could cause serious health problems or death (examples: food containing a pathogen, botulinum toxin, undeclared allergen or dangerous foreign material). Class II Recalls involve products that might cause a temporary health problem or pose a slight threat of a serious nature (examples: undeclared source of allergen or non-sharp foreign material). Class III Recalls involve products that are unlikely to cause any adverse health reaction, but that violate FDA labeling or manufacturing laws (examples: minor container defect or lack of labeling in English).

The recall notification should contain the same information requested of a supplier in the "Supplier-Initiated Recalls" section. In addition, if the product is isolated to one store, the public information should focus the recall on that store location including the retail name, address and timeframe of when the product was offered for sale.

Third-Party Notification

If applicable, the recall team should designate someone to contact their insurance broker and notify them of the situation. In the event of a Class I Recall or other urgent crisis (i.e. product incident), the recall team may contract with a third-party recall services firm or an industry expert to consult on recall strategy or assist with recall-related activities.

Prior to a recall, it is best to establish contacts that can assist the company through the process of a recall or related crisis event. Third-party laboratories, industry experts (e.g., microbiologists, entomologists, pathologists), and recall services firms are excellent resources. FMI can assist in identifying resources, if needed.

Recall Product Disposition

The corporate recall team should decide (possibly in conjunction with a regulatory agency) the product disposition. A written plan of product disposition may be required to be submitted to and approved by the appropriate regulatory agency. If the product is to be returned by consignees, the corporate recall team should designate the consolidation points. Consolidation point should be a separate and segregated area to prevent contamination of food, equipment, utensils, etc.

Product may be retrieved from retailer warehouses and/or retail outlets as appropriate and transported to consolidation points. If necessary, a press release(s) should be issued instructing consumers to return affected products to point-of-purchase.

Supply chain personnel should coordinate product replacement with stores. Other departments affected by the recall can also support the recall activities. (This may include breaking the ordering code so recalled product cannot be ordered and information on what criteria should be in place to verify new product is not the same as recalled item.)

STEP 2
COMMUNICATING THE RECALL TO RETAIL/ DISTRIBUTION

The corporate recall coordinator should complete a Recall Notification form ***(see Appendix H)*** to communicate information on the classification and product disposition. This notification may include recall information provided by suppliers but should be in a consistent format for {company} stores, warehouses and distribution centers.

The corporate recall coordinator should issue the recall or withdrawal notification to divisions, stores, and other company facilities, forwarding copies to the recall team. Store Managers and division offices may be contacted via phone or other mechanisms (such as email alerts and other electronic software systems) regarding the recall to ensure prompt notification. If notified via phone, follow-up information should be sent to stores and/or franchise offices via email and/or fax using the company's standardized form and titled in bold "URGENT: PRODUCT RECALL." Included with the recall notification should be the Effectiveness Check Response Form for stores or other facilities ***(see Appendix I & J)***.

Consideration should be given during a recall to block the barcode so the recalled product(s) cannot be scanned as long as all lots of the product are recalled.

Consumer Notification of Recalls

In the case of a Class I and some Class II recalls, when the recalled product has been sold, customers should be notified. The following useful, practical information should be provided to assist consumers with identifying the recalled product.

1. **Product Description**
   Include one or more descriptors, as appropriate, to help consumers identify the product. Examples include: product name, brand, type, package size.

2. **Identification Code**
   Include one or more, as appropriate, to help consumers identify the product. Examples include: UPC or GTIN, sell by/use by date, expiration date, lot code.

3. **Responsible Party Contact Information**
   Contact name and contact information for manufacturer, distributor or other responsible party

4. **Reason for the Recall**
   Include reason the product is being recalled, such as type of allergen, specific pathogen, chemical or foreign material contaminant, if known.

Current Retail Practices for Consumer Notification

The following include examples of locations and manners currently used by retailers to notify consumer about recalled product. Retailers may utilize multiple manners/methods and locations for different recalls, depending on the circumstances. Information should be posted for at least two weeks.

1. Posting (physical, electronic) at or near register
2. Posting (physical, electronic) at primary point of display
3. Loyalty card/membership notification (email, phone, mail, other) this may include private label or national brands
4. Print out at check-out (example: cash register receipt)
5. Website posting (RSS feeds, links, social media, other)
6. Kiosk in store
7. Posting on a bulletin board or similar information center
8. Service desk sign or notice
9. Press release
10. Other such methods, locations and manners, as deemed appropriate

Consumer questions should be directed to the call center number or customer service department of the recalling firm to ensure accurate information is communicated to the consumer. Media requests must be directed to the appropriate corporate media relations contact.

Questions from retail staff should be forwarded through the corporate recall coordinator or division recall coordinator.

Public Communications

When notification of customers is required for a recalled {company}-branded and/or produced product, such as a Class I or a Class II recall when there is a threat to public health, the recall team should develop a list of talking points including known facts and corrective actions. Press releases, information scripts for the call center/customer service, website postings, social media messages, communications to company employees, shareholders and other stakeholders should be coordinated to ensure consistency and timely release of pertinent details. Media relations should continue to monitor social media channels during and after the recall. The recall team should work closely with FDA to determine whether notification is necessary.

Press releases should include:

- ☐ Company name, contact information, and date of recall
- ☐ Action being taken (e.g. recall)
- ☐ Product information (description, dates of sale)
- ☐ Identification of health hazard
- ☐ Lot number, code date or use by/sell by date
- ☐ Instructions to consumers on how to handle or dispose of the product
- ☐ Refund policy
- ☐ Statement that the company is working with the appropriate regulatory agency in conducting the recall. Explanation of the corrective action that has taken to eliminate the cause of the problem (if known)
- ☐ Pictures of the recalled product to help consumers identify recalled product or specific lot code

Press releases should also include some expression of empathy and apology to the consumer.

Only individuals approved by senior management should talk to the media (ideally one person to maintain consistency). **Company employees should be notified not to speak to any media representative (i.e. reporters) but to immediately refer all calls to the designated {company}**

media relations representative. In the event of a Class I recall, consumer questions should be directed to a centralized corporate response center (i.e. call center).

STEP 3
STORE RECALL ACTIONS

Upon a retail store receiving notification from {company} corporate office or the division office, the store manager, manager in charge or designee should remove the product from sale and follow the disposition instructions provided by the corporate recall coordinator.

The recalled product must be removed from all locations within the store including the customer service counter, special displays, and the back room. If directed to do so, signs are to be placed at the point-of-sale. The exact wording for the signs should be included in the recall notice. A copy of the recall notice should be posted in the back room to assist in stocking procedures.

Store personnel responsible for receiving product as well as the night crew who stocks product should be informed of the recall, and all incoming shipments should be checked as they may have been in transit when the recall was initiated. Stores should have a designated area for accumulating recalled product including customer returns. The recalled product should be marked/labeled in such a way that prevents the product from being returned to the retail shelf.

The store manager, manager in charge, or designee must assume the responsibility of completing Effectiveness Check Forms. These checks should include recording the amount of recalled product removed from sale, on-hand in the back room, and any customer returned recalled product.

The product must be handled per the disposition instructions outlined in the recall notice. If the product is to be held at the store, store management must ensure that the product is adequately isolated and marked as recalled so it does not accidently get returned to the retail shelf.

Any contact from a regulatory agency in regard to a recall, whether in the form of a phone call or a visit, should be communicated to the corporate recall coordinator.

Consumer questions should be directed to the centralized corporate response center, or to the contact number provided by the manufacturer of the recalled product, to ensure current, complete and accurate information is communicated to the consumer. Store employees are not to communicate with media representatives (i.e. reporters) but should immediately refer all communications to the designated media relations representative.

When product recall information is received by a retail company, implementation of the recall should become a top priority. It is a best practice in the retail food store industry to have the recalled product(s) removed from sale in all stores within two hours of notification from the supplier of the recall. If the UPC/GTIN or other identifiers are not given by the supplier, it can take hours

trying to identify whether a retailer even has the product. Most retailers report they can complete implementation of Class II and Class III recalls within 24 hours of receipt of the recall notice from the supplier.

Distribution Center/Warehouse Recall Actions

When a distribution center or other facility receives notification from the corporate recall coordinator, the facility recall coordinator should coordinate the removal of recalled product from distribution. This will include removing the product from the picking slot, segregating it, marking it as recalled product and ultimately arranging for the removal of the product from the facility. Facility personnel should be informed of the recall, and outgoing orders should be rechecked when feasible to ensure recalled product does not ship. Incoming shipments of product from the recalling supplier should be checked for a period of seven days, as the product may have been in transit when the recall was initiated. A copy of the recall notice should be posted visibly within the facility where employees can see it. The sales office should break (or block) the sales code for the recalled item for seven days, or until verification is given by the supplier that all new product is not affected by the recall. Breaking the sales code will ensure no one can order this product until a physical change is made in the ordering system.

Shipments containing recalled product that have already left the facility should be reported to the corporate recall coordinator. Notification of those consignees should be coordinated through the corporate recall coordinator. Inquiries from consignees or sub-consignees are to be forwarded to the corporate recall coordinator. As a reminder, the facility recall coordinator must assume the responsibility of completing Effectiveness Check Forms. Any contact from a regulatory agency, whether in the form of a phone call or a visit, regarding a recall, should be communicated to the corporate recall coordinator.

FDA Reportable Food Registry for Distribution Centers and Warehouses

Food facilities that manufacture, process, pack or hold food for human or animal consumption in the United States register in accordance with the Bioterrorism Act of 2002 under section 415(a) of the FD&C Act (21 U.S.C. 350d), are required to report to the FDA Reportable Food Registry (RFR) as the responsible party whenever they determine that an article of food they manufactured, processed, packed or held is a reportable food. This registration, as specified in section 415, does not apply to retail stores but does include their distribution centers and warehouses that are FDA registered facilities – both domestic and foreign. (This registration does not apply to operations within the exclusive jurisdiction of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act [21 U.SC. 601], the Poultry Products Inspection Act [21 U.S.C. 451], or the Egg Products Inspection Act [21 U.S.C. 1031]).

A reportable food is a food (other than dietary supplements or infant formula) which presents the reasonable probability that the use of, or exposure to, the food will cause serious adverse health consequences or death to humans or animals. Examples of foods that could meet the definition of

reportable are shown in question D.6 of the guidance document provided in the "RFR Resources" section below. A responsible party is not required to submit a reportable food report to FDA when all of the following criteria are met:

- ☐ The adulteration originated with the responsible party; **AND**
- ☐ The responsible party detected the adulteration prior to any transfer to another person of such article of food; **AND**
- ☐ The responsible party
  - corrected such adulteration; or
  - destroyed or caused the destruction of such article of food.

Unless all of the above conditions are met, the firm's facility management or an individual they have authorized has the responsibility to submit a report to the RFR within 24 hours of making the determination that the food is a reportable food. The reporting requirement applies in situations where the product is in or has passed through the warehouse or distribution center. Reporting is not required by any facility that did not receive the food. In instances where multiple facilities, owned by the same company, are in possession of the same reportable food, a report is required to be submitted for the reportable food; however, a single combined report may be submitted for the same reportable food. Instructions for this scenario can be found in **question E.9 of the guidance document** provided in the section, "RFR Resources." Failure to report a reportable food report is a prohibited act under the Federal Food, Drug, and Cosmetic Act. A firm should also notify their supplier and customer(s) that are, or were, in possession of the reportable food, providing them with the unique Individual Case Safety Report (ICSR) number associated with their report. This ICSR number will allow FDA to link any reportable food reports that are related to the initial report and the reportable food.

RFR Resources

- ☐ RFR main page: www.fda.gov/ReportableFoodRegistry
- ☐ Safety Reporting Portal: https://www.safetyreporting.hhs.gov/SRP2/en/Home.aspx?sid=79f57544-4a82-4a65-85e9-17de82969aa8
- ☐ RFR Training Video: http://youtu.be/JF_u9u6qGD0
- ☐ RFR Training Module: https://www.cfsanappsexternal.fda.gov/scripts/FDTraining/course_03/module_03/lesson_01/FD03_03_000.cfm
- ☐ RFR Assistance:
  - RFR Help Center – Answers questions about policy, procedures and interpretations: RFRSupport@fda.hhs.gov

- SRP Service Desk - Answers technical and computer-related questions about the Safety Reporting Portal: SRPSupport@fda.hhs.gov

- ☐ "Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007" at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-questions-and-answers-regarding-reportable-food-registry-established-food
- ☐ RFR Annual Reports: https://www.fda.gov/food/reportable-food-registry-industry/reportable-food-registry-annual-report

Registration of Food Facilities References

Food facilities that manufacture, process, pack or hold food for human or animal consumption in the United States are required to register with the FDA under the Bioterrorism Act of 2002. The Food Safety Modernization Act (FSMA) expanded upon Bioterrorism Act by requiring registered food facilities to submit additional registration information to FDA. In addition, under FSMA food facilities are required to renew their registrations every other year. For more information on Registered Food Facilities visit: http://www.fda.gov/food/guidanceregulation/foodfacilityregistration/default.htm

STEP 4— EFFECTIVENESS CHECKS

Effectiveness checks should be used to verify that the recall was successful in removing product from the distribution system, as well as the retail shelf. It also provides evidence that product disposition instructions were followed.

The corporate recall coordinator should be responsible for coordinating recall effectiveness checks of the affected stores and other facilities in order to verify receipt of the product recall notice and the appropriate actions have been taken. These checks can be conducted electronically, by phone and/or by personal visit, or by a third-party firm. Effectiveness checks should be completed on 100% of stores. If the response is less than 100%, then the recall should be deemed as ineffective and the recall strategy should be reassessed. Effectiveness Check Response Forms should be completed and returned promptly from stores, warehouses and/or distribution centers upon receipt of the recall notification.

All affected stores, warehouses, distribution centers, etc. should be required to complete Effectiveness Check Response Forms ***(see Appendix I & J*** for example hard copy forms) even if no product is

located at that location (quantities of 0 are to be reported). Any warehouse or distribution center that is aware of having shipped product to another location (other than a company-owned retail store), should contact that consignee regarding the recall. Copies of any recall communications should be forwarded along with the completed Effectiveness Check Form to the corporate recall coordinator.

In the event of a Class I Recall, there could be customer returns of product to the store. Returned products should not be returned to sale but disposed of per the instructions on the recall notification. Updates to the Effectiveness Check Response forms are to be completed immediately and forwarded to the appropriate party.

Division offices should coordinate follow up with stores to ensure they submitted their Effectiveness Check Response Forms to {company} corporate office. Records should be maintained indicating the stores contacted and the results.

The corporate recall coordinator should create a recap of the amount of recalled product received, amount of recalled product identified in {company's} distribution system, amount of recalled product returned to supplier/disposed of, amount of any product used in further manufacturing, and/or amount identified at the retail level. All of this information should be communicated to the recalling supplier.

Expect regulatory agencies to visit facilities to audit the recall documentation. Officials will verify effectiveness check documentation, including the number of stores contacted and the amount of product removed, and may check the store or facility to ensure recalled product does not remain in the system. In the event of a discrepancy, the facility should notify the corporate recall coordinator.

PRODUCT DISPOSITION

The recalling firm, the corporate recall team, or governing regulatory agency will determine the appropriate product disposition. The recall coordinator should provide disposition instructions in the initial recall notification.

Ideally, a central location should be established to collect and consolidate all returned stocks of the recalled product. Recalled product should be segregated, properly signed and held in a designated area to prevent product return into distribution channels.

Product disposal must be done in a manner that complies with local, state and federal health and environmental regulations. Any deviations may result in fines and/or legal action against the company. It is recommended that before disposing of any product, companies reference the SDS sheet for disposal of hazardous waste. Many state and local regulatory agencies have unique guidelines and classifications for waste. What may be safe to dispose of in a compactor or dumpster in one state, may be classified as hazardous waste in another. Improper disposition places a company at risk for fines.

Stores, distribution centers, and manufacturing facilities should retain documentation of disposal that includes the date/time of disposal, method of disposal, amount of product disposed of, and witnessing supervisor's signature. If the recalled product was disposed of in a landfill or incinerated, the paperwork must show the facility is licensed with the state EPA and the work was done in compliance with EPA regulations. This documentation should be forwarded to the corporate recall coordinator on a regular basis for inclusion into the master recall file.

Under certain circumstances, the supplier may use a third-party service to visit stores, verify recall effectiveness and remove recalled product from the store if directed by the retailer. In those cases, the third-party service should be responsible for product disposal. If a supplier wants to use a third-party service to visit stores, this must be approved by the corporate recall coordinator prior to this service being allowed in the retail stores.

FMI members should contact FMI for information on companies that specialize in product disposition.

STEP 5
TERMINATION OF THE RECALL

The corporate recall coordinator should be responsible for determining when a recall is to be closed. Once the company believes all affected product has been removed from distribution and/or retail, termination of the recall may be requested from the appropriate regulatory agency, including the results of the root cause analysis and the corrective actions that have been implemented for retailer-initiated recalls. The corporate recall coordinator may be required to submit to the regulatory agency written information demonstrating the effectiveness of the recall efforts, the status of the recovery efforts, and documentation detailing the disposition of the recalled product. In some cases, such as for Class I or high-risk Class II recalls, the FDA may conduct a limited closeout inspection to verify that the recall is completed and to verify product disposition. The recall will not be officially terminated until the governing regulatory agency affirms it is closed. FDA will not terminate a recall until the firm has brought the product into compliance or disposed of it in an acceptable manner. FDA will notify the recalling firm by letter once FDA considers the recall terminated.

POST-RECALL EVALUATION

Whenever necessary, the recall team should complete an analysis to determine the effectiveness of the recall efforts and develop a corrective action plan to prevent reoccurrence.

The recall coordinator, with the assistance of the recall team, should evaluate the strategy employed during the recall. Any deficiencies should be noted, and the official recall procedures updated, where necessary. The corporate recall coordinator should also prepare a final recall report including information such as:

1. The reason for the recall
2. The depth of the recall
3. The amount of recalled product accounted for
4. Disposition of the recalled product
5. Recall effectiveness (# of checks, % compliance)
6. Corrective action to be taken to prevent reoccurrence (if necessary)
7. Number of consumer illnesses or injuries reported
8. The total cost of the recall (for company knowledge only)

If a stock recovery was performed, a brief memo may be written to document the situation and demonstrate completion of the process. The final recall report or stock recovery memo should be distributed to the corporate recall team and other interested parties in management.

If the recalling firm is required to comply with the Preventive Control for Human or Animal Food rules, reanalysis of the Food Safety Plan is required when a recall occurs in order to prevent the problem from reoccurring. In some situations, the Food Safety Plan may need to be revised (e.g., identification of a new hazard).

MOCK RECALLS

Mock recalls should be conducted periodically to test the recall procedures to verify they are effective. Mock recalls should be conducted, at a minimum of once a year, and within three months of any changes to the recall procedures, especially for company-manufactured or store-prepared products. They should be planned ahead of time by the corporate recall coordinator and the applicable division and/or facility recall coordinator(s). The practice scenario should utilize every aspect of the recall process, except contact with outside firms or agencies. Mock recalls should not disrupt product flow, nor be conducted in such a way as to create confusion.

1. The important elements of a mock recall include:
2. Confirming the recall coordinator and team contact information is up-to-date (this includes corporate, divisions, and other facilities)
3. Verifying the public relations/media communications information is up-to-date (this includes contacts at various media channels)
4. Establishing that store and distribution center contact information is up-to-date
5. Identifying the products and codes involved

6. Determining the amount of recalled product in the marketplace
7. Tracking the time taken in completing each step

Documentation of mock recalls should be maintained, noting the date conducted, items tested, and results achieved.

A retail firm with manufacturing facilities or commissaries should include the following information in mock recalls:

1. A list of regulatory agencies that need to be contacted including phone numbers
2. The problem and assessment of the risks to consumers and company
3. Involved ingredients, suppliers, codes, delivery dates and other products in which the ingredients may have been used
4. Quantities produced
5. Current in-house inventory
6. Incidental units (such as lab samples)
7. Consignees who have received product (e.g., sub-consignees, end customers)
8. Consumer communications

RECORD RETENTION

Every company should have a records retention policy for all records, including product distribution and recall information. Currently, there are three different FDA Acts that regulate recordkeeping requirements and, at this time, all three Acts are in effect.

At this time, it is recommended that all product recall information and communications, including related production and shipping records, be retained for two years.

Below is a table with the FDA record retention requirements under the **Bioterrorism Act** which are designed to aid in the tracing of the product one up and one back.

Type of food	Record retention period for nontransporters	Record retention period for transporters or persons keeping records on behalf of nontransporters
Food having significant risk of spoilage, loss of value, or loss of palatability within 60 days after the date food is received or released	6 months	6 months
Food having significant risk of spoilage, loss of value, or loss of palatability occurring after a minimum of 60 days but within 6 months after the date food is received or released	1 year	1 year
Food having significant risk of spoilage, loss of value, or loss of palatability does not occur sooner than 6 months after the date food is received or releasedsooner than 6 months	2 years	1 year
Animal food including pet food	1 year	1 year

The **Food Safety Modernization Act of 2011** has specific requirements for record retention.

- ☐ The owner, operator, or agent in charge of a facility shall maintain, for no less than 2 years from the date of creation, food safety related records as required under the Preventive Controls for Human Food regulation, including documentation related to monitoring of the preventive controls implemented, instances of nonconformance material to food safety, the results of testing and other appropriate means of verification, instances when corrective actions were implemented, and the efficacy of preventive controls and corrective actions.
- ☐ Records of an importer related to a foreign supplier verification programs must be maintained for a period of no less than 2 years from the date they were created or obtained.

The **FDA Reportable Food Registry** (RFR) requires records related to RFR reports (i.e., reports received, notifications made, and reports submitted) to be retained for 2 years (FD&C Act Section 417(g)).

At the end of the record retention timeframe, the {company} should ensure information related to pending or ongoing litigation, or other regulatory action related to the recall, is retained. Recall related documentation outside of the record retention requirements should be destroyed via shredding or electronic erasure.

APPENDIX A—Regulatory Requirements

Regulatory Reporting—FDA Regulated Products

The Bioterrorism Act of 2002 requires food facilities that manufacture, process, pack or hold food for human or animal consumption in the United States under section 415(a) of the FD&C Act (21 U.S.C. 350d) to register with the Federal Food and Drug Administration. (This registration does not apply to USDA inspected establishments or retail food stores.)

FDA-registered food facilities are required to report to the FDA Reportable Food Registry (RFR) portal if they identify a contaminated food product in their possession where there is a reasonable probability that the use of, or exposure to the food, will cause serious adverse health consequences or death to humans or animals.

The FDA requires that registered facilities report food contamination issues (typically those associated with Class I recalls) within 24 hours of being notified of a problem in food that was in a company's possession or if the company identified a potential problem with food in their possession. This applies to foods that have already moved through warehouses or distribution centers and a recall is announced weeks later. It also applies to foods that are currently being held in warehouses and distribution centers. The intention is that FDA receives a report through the RFR portal documenting possession of the contaminated product to help with product tracking. The guidance document from FDA addresses the requirements. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-questions-and-answers-regarding-reportable-food-registry-established-food

If the suspected product is produced by a company-owned facility, the corporate recall coordinator should determine if the potential product defect warrants filing with the FDA Reportable Food Registry (RFR). If so, this must be done within 24 hours of confirmation of the problem.

According to the FDA, information the corporate recall coordinator must be prepared to communicate through the Reportable Food Registry portal includes:

- ☐ Food Facility Registration Number (facility number FDA assigned under the Bioterrorism Act of 2002 – does not apply to retail stores)
- ☐ Date the article of food was determined to be reportable
- ☐ Description of the food, including quantity, amount and location
- ☐ Extent and nature of the adulteration
- ☐ Results of investigation of the cause of the adulteration if it may have originated with the responsible party, when known

- ☐ Disposition of the product, when known
- ☐ Product information typically found on packaging including product codes, sell-by or use-by dates, and names of manufacturers, packers, or distributors sufficient to identify the article of food
- ☐ Contact information for the responsible party
- ☐ The contact information for parties directly linked in the supply chain

Link to the FDA Reportable Food Registry:
http://www.fda.gov/food/complianceenforcement/rfr/default.htm

FDA Recall Coordinators

The Recall Coordinator must also be prepared to communicate the following information directly to the local FDA District Recall Coordinator prior to initiating a recall. For a list of FDA Recall Coordinators, see: http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129334.htm

1. Product information
    a. Product name (include brand name and generic name)
    b. Catalogue or product order number(s), if applicable
    c. Description of the product (i.e. physical description, packaging, copies of the product labeling, any package inserts, directions for use)
    d. Photograph of the product
2. Codes or other product identification numbers
    a. Lot/unit numbers
    b. Expiration, Use by or Best by dates or expected shelf life of the product
    c. UPC codes (consumer and case) or NDC numbers
    d. If OTC, indicate strength and route of administration
3. Recalling firm
    a. Firm name, address, city, state, zip code
    b. Identify firm type (i.e. manufacturer, distributor)

c. Contacts for recalling firm

   i. Name/title/phone/fax/email address for RECALL contact

   ii. Name/title/phone/fax/email address of most responsible individual for the recalling firm (CEO and/or president)

   iii. Name/title/phone/fax/email address for public contact

4. Manufacturing firm

   a. Firm name, address, city, state, zip code

   b. FDA registration number, if applicable

5. Identify firm responsible for the violation/problem

   a. Firm name, address, city, state, zip code

6. Reason for the recall

   a. Explain how the product is potentially defective and/or violative

   b. Explain how the defect affects the performance and safety of the product

   c. If due to the presence of a foreign object, describe the foreign object's size, composition, hardness, and sharpness

   d. If due to the presence of a contaminant, explain level of contaminant in the product. Provide labeling, a list of ingredients and the Material Safety Data Sheet, if available, for the contaminant.

   e. If due to failure of the product to meet product specifications, provide the specifications and report all test results. Provide copies of any sample analysis.

   f. If due to a label/ingredient issue, provide and identify the correct and incorrect labels, descriptions, and formulations.

   g. Explain how the problem occurred and the date(s) it occurred.

   h. Explain how the problem was discovered and the date discovered.

   i. Explain if the problem/defect affects ALL units subject to recall, or just a portion of the units in the lots subject to recall.

   j. Explain why this problem affects only those products/lots subject to recall.

k. Provide detailed information on complaints associated with the product/problem:

   i. Date of complaint

   ii. Description of complaint

   iii. Lot number/serial number involved

l. If a State agency is involved, the agency must be identified and contacted.

7. Health hazard assessment

   a. Provide your assessment of the health risk associated with the deficiency.

      i. A recall decision does not depend solely on the health risk of the product. Defective products and misbranded products where no health hazard exists are still in violation of the law and should be recalled.

8. Volume of recalled product and scope of recall

   a. Total quantity produced

   b. Date(s) produced

   c. Quantity distributed

   d. Date(s) distributed

   e. Quantity on hold by recalling firm and its distribution centers

   f. Indicate how the product is being quarantined

   g. Estimate amount remaining in marketplace and at what level (i.e. distributor, customer)

   h. Provide the status/disposition of the marketed product, if known (i.e. used, used in further manufacturing, destroyed)

9. Distribution pattern

   a. Number of direct accounts by type

   b. Geographic areas of distribution, including foreign countries

   c. Provide a consignee list (names/address/city/state/contact name/phone number) to the local FDA District Recall Coordinator.

   d. Distinguish which consignees were shipped recalled product, sold recalled product, or who may have been shipped recalled product.

   e. Indicate if the product was sold under a government contract. If yes, provide contract number, contract date and implementation date.

10. Recall strategy

    a. Indicate depth and scope of recall.

    b. Indicate method of notification and how letters should be sent to customers (e.g. email, direct phone contact, overnight mail, fax).

    c. If initial notification is by phone, provide a copy of the phone script to FDA.

    d. Explain product disposition instructions to customers. If product is to be returned to the manufacturer, explain how the process should work.

    e. Propose a method of product destruction, if applicable. FDA should review your proposed method of destruction and may choose to witness the destruction.

    f. If the product is to be corrected, explain how and where the field correction should take place and how the corrected product should be identified so it is not confused with recalled product.

    g. Explain effectiveness check strategy. Include actions for non-responders.

In the instance the recalled product was distributed within other countries, the recall coordinator should notify the FDA and provide the appropriate information. The recall coordinator should also contact the appropriate consignee within those countries and be prepared to provide, at a minimum, the same information as above.

Regulatory Reporting—USDA/FSIS Regulated Products

If the product is regulated by USDA/FSIS (contains 2% or more cooked meat or more than 3% raw meat), the recall coordinator for the official establishment(s) should notify their local FSIS District Office personnel within 24 hours ***(see Appendix F)***. According to the USDA, information the recall coordinator must be prepared to communicate includes:

- ☐ Manufacturing establishment number, name, and address
- ☐ Recall Coordinator (name, title, and telephone number)
- ☐ Customer contact (name, title, and telephone number)
- ☐ Media contact (name, title, and telephone number)
- ☐ Reason for recall
- ☐ Product and brand name(s)
- ☐ Packaging (type and size (pounds))
- ☐ Package codes (Use by/Sell by)

- ☐ Case codes
- ☐ Case count (units per case)
- ☐ Packaging dates
- ☐ Photos of label or package
- ☐ Distribution areas
- ☐ School lunch (yes/no)
- ☐ Department of Defense (yes/no)
- ☐ Internet or catalog sales (yes/no)
- ☐ Export countries
- ☐ Production dates
- ☐ Amount produced
- ☐ Amount held at establishment(s)
- ☐ Amount distributed (pounds/cases)
- ☐ Distribution level (depth of the recall, if known)

The corporate recall coordinator will be required to submit status reports of the recall progress to the appropriate regulatory agency at frequency agreed between FSIS and the recalling firm until termination of the recall. More frequent reporting will be required for recalls involving hazards with greater public health threat.

Regulatory Reporting—Consumer Product Safety Commission Regulated Products

The U.S. Consumer Products Safety Commission (CPSC) is a regulatory agency responsible for protecting the public from unreasonable risks of injury and death associated with consumer products other than food. The agency has reporting requirements for retailers when they have knowledge of hazards associated with a non-food consumer product. The reporting requirements are outlined in Section 15(b) of the Consumer Product Safety Act. The following information is an excerpt from the CPSC Recall Handbook.

> "Section 15(b) of the Consumer Product Safety Act establishes reporting requirements for manufacturers, importers, distributors and retailers of consumer products, or other product or substances distributed in commerce over which the Commission has

jurisdiction. Each must notify the Commission immediately if it obtains information which reasonably supports the conclusion that a product distributed in commerce (1) fails to comply with an applicable consumer product safety rule or with a voluntary consumer product safety standard upon which the Commission has relied under section 9, (2) fails to comply with any other rule, regulation, standard or ban under the CPSA or any other Act enforced by the Commission, including the Flammable Fabrics Act, 15 U.S.C. §1193-1204; the Federal Hazardous Substances Act, 15 U.S.C. § 1261-1278; the Children's Gasoline Burn Prevention Act, 110 Public Law 278 (July 17, 2008), the Virginia Graeme Baker Pool and Spa Safety Act, 110 Public Law 140 (with amendments), the Poison Prevention Packaging Act, 15 U.S.C. § 1471-1476, and the Refrigerator Safety Act; 15 U.S.C. § 1211-1214; (3) contains a defect which could create a substantial product hazard, or (4) creates an unreasonable risk of serious injury or death. The Commission has issued an interpretive regulation, 16 C.F.R. Part 1115 that further explains a reporting company's obligations.

What and Where to Report

A company should file its report with the Office of Compliance and Field Operations. The report should be filed electronically through the CPSC website (SaferProducts.gov). Alternatively, a firm can file its request by mail or telephone (800-638-2772). A company should assign the responsibility of reporting to someone with knowledge of the product and of the reporting requirements of section 15. That individual should have the authority to report to CPSC or to quickly raise the reporting issue to someone who does.

Reporting firms should be prepared to provide the information described below. However, no company should delay a report because some of this information is not yet available. The following information should be transmitted:

- ☐ Identification and description of the product;
- ☐ Name and address of the manufacturer and/or importer of the product if known, if not known, then the names and addresses of all known distributors and retailers of the product;
- ☐ Nature and extent of the possible defect, the failure to comply, or the risk;
- ☐ Nature and extent of injury or risk of injury associated with the product;
- ☐ Name and address of the person informing the Commission;
- ☐ If reasonably available, the other information specified in Section 1115.13(d) of the Commission's regulations; and
- ☐ A timetable for providing information not immediately available.

Retailers and distributors may satisfy their reporting obligations in the manner described above. Alternatively, a retailer or distributor may send a letter to the manufacturer or importer of a product describing the noncompliance with an applicable regulation, defect, or risk of injury or death associated with the product. In addition, a copy of the letter should be forwarded to the Office of Compliance and Field Operations. A distributor or retailer may also satisfy their reporting obligations by forwarding to the Office of Compliance and Field Operations reportable information received from another firm. Section 15(b) requires that a manufacturer, retailer, or distributor must immediately inform the CPSC of a failure to comply, a defect, or such a risk unless it has actual knowledge that the Commission has been adequately informed of such failure to comply, defect or risk.

When to Report

Section 15 requires firms to report "immediately." This means that a firm should notify the Commission within 24 hours of obtaining information described in section A.1 ("What and Where to Report") above. Guidelines for determining whether a product defect exists, whether a product creates an unreasonable risk of serious injury or death, and whether a report is necessary or appropriate, are provided in 16 C.F.R. § 1115.12. Section II of this handbook does the same.

A company must report to the Commission within 24 hours of obtaining reportable information. The Commission encourages companies to report potential substantial product hazards even while their own investigations are continuing. However, if a company is uncertain whether information is reportable, the firm may spend a reasonable time investigating the matter. That investigation should not exceed 10 working days unless the firm can demonstrate that a longer time is reasonable in the circumstances. Absent such circumstances, the Commission will presume that, at the end of 10 working days, the firm has received and considered all information that would have been available to it had a reasonable, expeditious, and diligent investigation been undertaken.

The Commission considers a company to have obtained knowledge of product- safety-related information when that information is received by an employee or official of the firm who may reasonably be expected to be capable of appreciating the significance of that information. Once that occurs, under ordinary circumstances, five working days is the maximum reasonable time for that information to reach the chief executive officer or the official assigned responsibility for complying with the reporting requirements.

The Commission evaluates whether/when a firm should have reported. This evaluation will be based, in part, on what the company actually knew about the hazard posed by the product or **what a reasonable person, acting under the circumstances, should have known about the hazard while exercising due care including knowledge obtainable upon the exercise of due care to ascertain the truth of representations.** Thus, a firm is deemed to know what it would have known had it exercised due care in analyzing reports of injury or consumer complaints, or in evaluating warranty returns, reports of experts, in-house engineering analyses, or any other information."

For more information visit: http://www.cpsc.gov

APPENDIX B—Other Facility Coordination

Other Company-Owned Food Facilities

Other facilities (e.g., dairies, bakeries, central kitchens, commissaries, salvage operations, etc.) should designate a facility recall coordinator. All product recalls and withdrawals at the facility level should be coordinated through the facility recall coordinator and the corporate recall coordinator.

In the case of central kitchens or manufacturing facilities, the facility recall coordinator should be assisted by a facility recall team consisting of the facility manager, quality assurance, production, shipping/receiving, accounting or other appropriate managers with interest in recalls. Like the corporate recall team, each member of the Facility Recall Team should assign an alternate person to serve in his or her absence. The facility manager is responsible for establishing the facility recall team and making certain to keep Corporate updated on current contacts and their phone numbers.

The facility recall coordinator should assume responsibility for coordinating the recall or withdrawal process at the facility level and should carry out the recall procedures contained herein at the direction of the corporate recall coordinator. This responsibility may include notification of the recall or withdrawal to consignees, follow-up to ensure proper consignee action to the notice, and/or the collection of effectiveness check reports.

The facility recall coordinator should assist the corporate recall coordinator in gathering accurate information for the development of the recall strategy. The facility recall coordinator should assist in verifying affected products, lot codes, quantity produced, amount of product on-hand, and amounts of product shipped to consignees. The corporate recall coordinator should be supplied by affiliated facilities with **prompt and accurate** product, production and distribution information. The facility recall coordinator should be in charge of isolating and quarantining the product. Proper signage or other indicator (i.e. yellow warning tape), should be affixed to the product to ensure it is not put back in distribution. The corporate recall coordinator may also direct the facility to contact consignees to put the product on hold.

All recalls, withdrawals, and stock recoveries should be coordinated through the corporate recall coordinator.

Any contact from a regulatory agency, including inquiries on recalls or visits to facilities, should be communicated to the corporate recall coordinator. The corporate recall coordinator should give guidance in handling the inquiry and should coordinate communications with that agency.

It is suggested that the corporate recall coordinator identify the local regulatory recall coordinator(s) in advance so when there is a need each party should have an established contact.

APPENDIX C—Corporate Recall Team

Name *(Remember to list alternates)*	**Title**	**Office Phone**	**Cell Phone**	**Home Phone**	**Email**

Updated: _____
DATE

Superseded: _____
DATE

APPENDIX D—Division Office Recall Contacts

Division	Contact

Updated: _____
DATE

Superseded: _____
DATE

APPENDIX E—Store/Warehouse/Distribution Center Recall Contacts

Store	Contact

Updated: _____
DATE

Superseded: _____
DATE

APPENDIX F—Regulatory Contacts

FDA District Recall Coordinators
An updated list can be found at: http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129334.htm

USDA Recall Coordinators
An updated list can be found at: http://www.fsis.usda.gov/wps/portal/informational/districtoffices

Consumer Product Safety Commission
Contact information can be found at: http://www.cpsc.gov/en/About-CPSC/Contact-Information/

FDA Reportable Food Registry:
http://www.fda.gov/Food/ComplianceEnforcement/RFR/default.htm

APPENDIX G—Contact List—FMI and Third Party Contacts

Company	Contact
FMI THE FOOD INDUSTRY ASSOCIATION	2345 Crystal Drive, Suite 800 Arlington, VA 22202 **Tel:** 202-452-8444 **Fax:** 202-429-4519 **24-hour recall support:** **Tel:** 202-494-9016 http://www.fmi.org/food-safety/recalls
Recall Services Provider	
Recall Insurance Provider	
Industry Expert	

Updated: _____
DATE

Superseded: _____
DATE

APPENDIX H—Recall Notification

URGENT: Class (#) Recall / Withdrawal

Date: _____

(Contact)
(Store #)
(Address)
(Phone / Fax / Email)

IMMEDIATELY EXAMINE YOUR INVENTORY AND REMOVE FROM SALE THE FOLLOWING PRODUCT(S):

Product Name
Size/Case Pack
UPC # (Consumer and case) Code(s)
(Consumer and case)
Shipping Date(s)
P.O. #(s)
Quantity Shipped

(Repeat for multiple products)

Attach images of product label, codes, etc.

This product is (These products are) being recalled/withdrawn due to …

If any of this recalled product is in your facility, please remove it from sale and segregate the product.

Product Disposition: (return / destroy / hold)

Please immediately complete the attached Effectiveness Check Response Form. The form may be scanned and emailed or faxed to (Contact, #).

Thank you for your cooperation.

(recall coordinator) Phone
Email

APPENDIX I—Store Effectiveness Check Response Form

Date/Time Notification Received: _____
(Contact)
(Store #)
(Address)
(Phone / Fax / Email)

Inventory On Hand

Item	Codes	Amount On Hand	Disposition

I have removed the product(s) listed above from sale and followed the disposition instructions as outlined in the recall notification.

Signature: _____ Printed Name: _____

Date: _____ Contact Phone: _____

Email: _____

Please scan and email to (Contact email) or fax to (Contact name and fax #).

FMI THE FOOD INDUSTRY ASSOCIATION

APPENDIX J—Warehouse/Distribution Center Effectiveness Check Response Form

Date/Time Notification Received: _____

(Contact)
(Store #)
(Address)
(Phone / Fax / Email)

Inventory On Hand

Item	Codes	Amount On Hand	Disposition

Were sub-consignees notified? ☐ Yes ☐ No

If yes, please attach copies of recall notifications sent to sub-consignees with date/time of release.

I have removed the product(s) listed above from sale and followed the disposition instructions as outlined in the recall notification.

Signature: _____ Printed Name: _____

Date: _____ Contact Phone: _____

Email: _____

Please scan and email to (Contact email) or fax to (Contact name and fax #).

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APPENDIX K—Customer Complaint / Regulatory Contact Handling Form

Date/Time:	
Complainant Name:	Address:
City:	State/Zip:
Email:	Complaint Rec'd Via:
Item #:	Product:
UPC #:	Code:
Nature of complaint:	
When/Where product purchased:	
Was there anything unusual about the product?	
Was there an illness or injury related to the product? Describe the food consumption history, time since consumption and symptoms.	
What is the status of the individual?	
If a foreign object, what is it / where is it?	
If a regulatory contact, was the product tested? For what? What were the results?	
Discovery Notes:	
Form completed by:	Date:
Manager Approval:	Date:

APPENDIX L—Supplier Product Information Request for Recall/Withdrawal

Date:	Time:
Product Name/Identity:	
Size:	Case Pack:
UPC#/PLN (if applicable-product and case):	NDC # (if applicable):
Product Codes/Lot #/Date (product and case):	
Location of Codes (on case and individual package):	
Reason for Recall:	
Distribution:	
Classification of Recall:	I II III Withdrawal
Regulatory Agency Involved:	FDA USDA CPSC EPA
Supplier Information	
Manufacturer:	
Labeler:	
Supplier (if different from labeler):	
Supplier Contact Information:	
Supplier Media Contact Information:	
Consumer Hot-Line:	
Disposition Instructions:	

Request pictures of recalled product package, including block UPC#.

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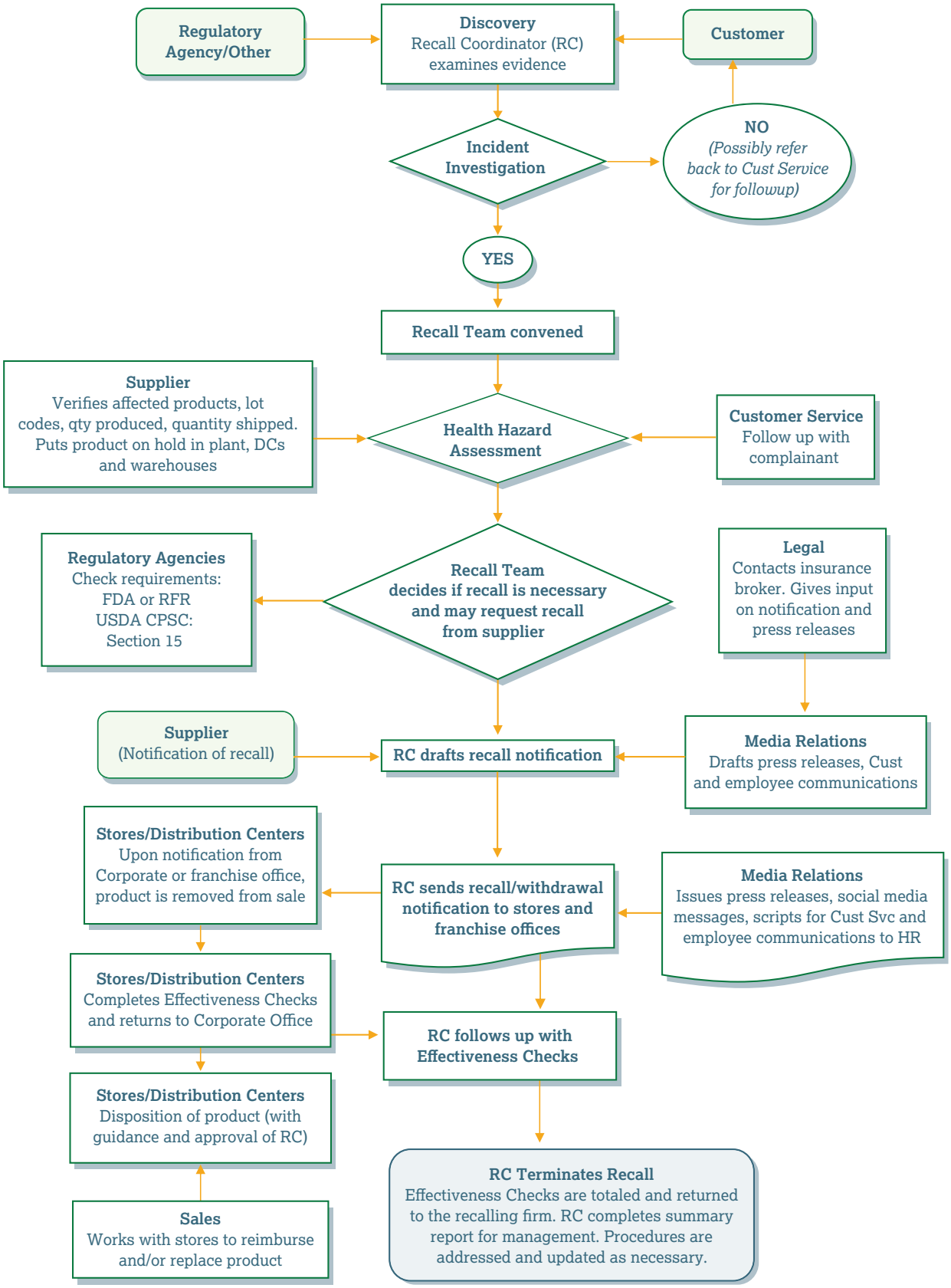
APPENDIX M—Recall Decision Flow Chart



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