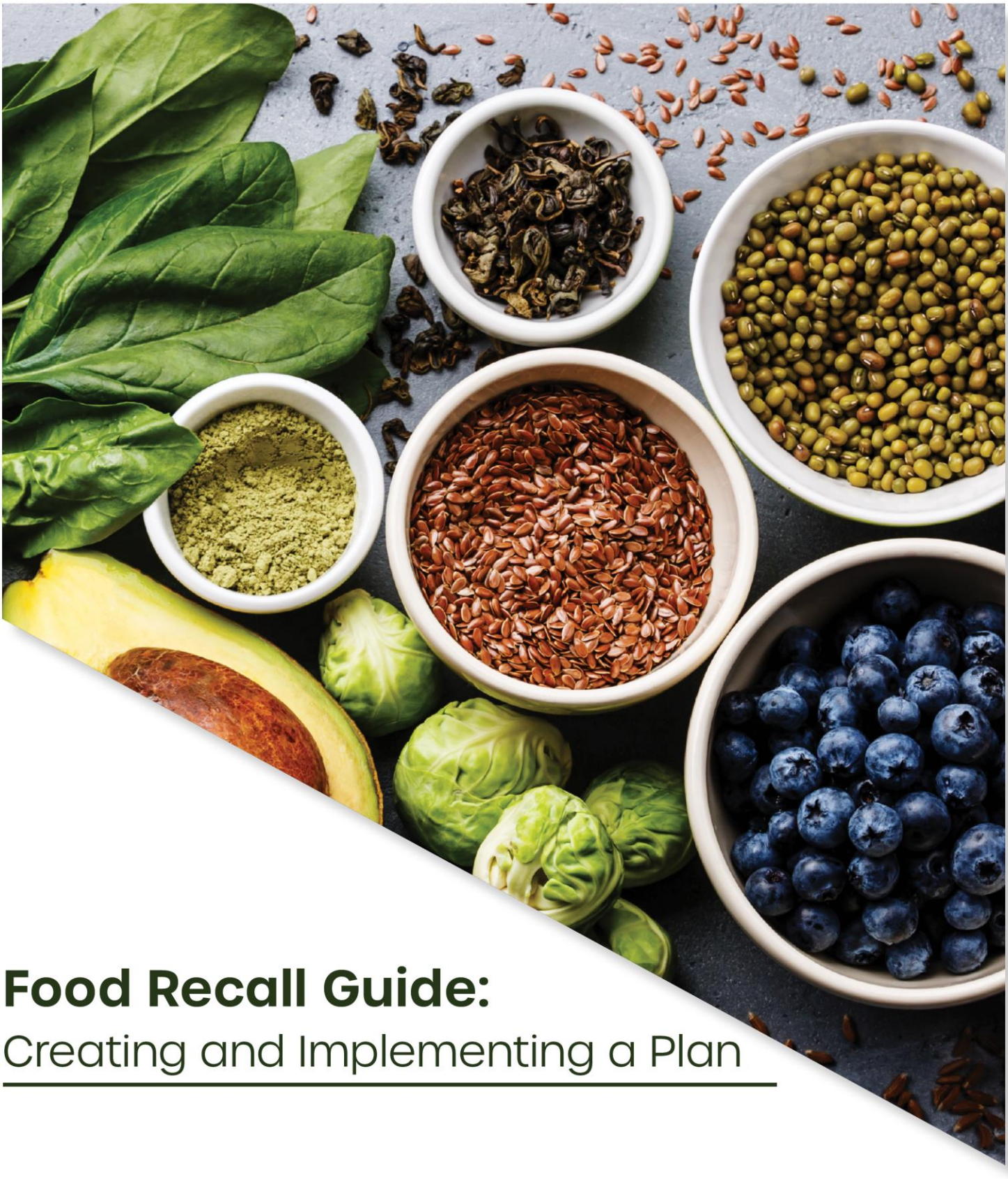

Food Recall Guide:

Creating and Implementing a Plan

The Coyle Group
RISK MANAGEMENT

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INTRODUCTION

Every food manufacturer has its own controls in place to ensure that the food and beverages they produce don't harm consumers. However, even the most discerning and organized companies can mistakenly sell products that cause injury or illness. No food safety system can guarantee zero risk of failure.

At any point in production, food can become contaminated with bacteria, viruses, parasites, chemicals, undeclared allergens, or harmful materials like glass or metal fragments. In the event an unsafe food product leaves the control of the manufacturer or is in violation of safety legislation, the product must be removed from the market in what's referred to as a recall. And these recalls can be costly, with many leading to class-action lawsuits that easily fetch six figures or more.

Each year, about 48 million people get sick, 128,000 are hospitalized and 3,000 people die due to preventable foodborne diseases.

Despite these facts, many food manufacturers are unprepared to mobilize quickly following an incident. This guide is designed to help organizations address these issues by identifying best practices for implementing and executing a food recall plan. In addition, this document provides a general overview of food recall legislation and compliance considerations of which all food manufacturers should be aware.

Please note, this guide is informative in nature and should not be used as a substitute for legal or compliance advice. For additional assistance, seek the help of legal counsel and a qualified insurance professional at The Coyle Group.

FOOD RECALLS AND APPLICABLE LEGISLATION

Put simply, a food recall occurs when a product is believed to be unsafe for consumers and the responsible party—whether it's the original manufacturer or distributor—takes corrective action (e.g., the product is removed from distribution or retail stores). A recall is one of the most effective methods for containing products that are in violation of Food and Drug Administration (FDA) laws. Often, recalls are performed voluntarily, as manufacturers and distributors of food products have a responsibility to ensure the public's well-being.

There are a variety of reasons why a food product may be considered unsafe, including contamination and misbranding. The following are common scenarios where a food product may pose harm to the general public and must be recalled:

- The food product is contaminated with a pathogen like E. coli or salmonella.
- Foreign objects, like plastic, glass or metal, made their way into the food product at some point during the production process.
- The food product includes an allergen (e.g., peanuts, dairy or soy) that was not indicated on any nutrition facts or product packaging.

While you may take every precaution to ensure your products are safe for consumers, recalls can still occur. As such, it's critical that your organization is prepared with a written recall plan. Developing such a document can help businesses remove unsafe or violative products they have purchased or sold. Additionally, taking the appropriate action to protect your customers will not only safeguard your reputation, but it can also aid in your defense should claims be brought against your business.

What's more, businesses that don't take the proper steps to recall potentially harmful food products may face civil and criminal penalties, particularly if they fail to follow compliance considerations detailed in the Federal Food, Drug and Cosmetic (FD&C) Act.

The FD&C Act and Who It Applies To

The FD&C Act, which was passed in 1938, is designed to prevent the adulteration or misbranding of food products in interstate commerce. The FD&C Act is enforced by the FDA and, among other things, sets quality standards for food, drugs, medical devices and cosmetics manufactured and sold in the United States. For the purposes of this guide, we will focus specifically on what the FD&C Act means to organizations that produce or distribute food products.

Effectively, any business—domestic or otherwise—that manufactures, processes, packs or holds food for human or animal consumption in the United States must register with the FDA and is therefore subject to the FD&C Act. It should be noted that the definition of food under the FD&C Act is relatively broad and can be used to describe:

- Foods and drinks designed for humans and animals
- Components of foods and drinks (e.g., additives)
- Chewing gum
- Certain dietary supplements

It should be noted that the FD&C Act is federal legislation, and businesses may have to comply with other state and local laws. While there are seemingly no major differences between federal and state food safety laws, there are some considerations to keep in mind. For instance, states have a number of authorities not granted to them by the FD&C Act, including the ability to stop the sale of food products and revoke the permits of food companies that violate food safety requirements.

For the purposes of this guide, we are focusing on the overarching federal guidance. However, it is critical that you review state and local compliance considerations alongside legal professionals.

When Is a Recall Necessary Under the FD&C Act?

In general, a food recall may be necessary under the FD&C Act when a product is adulterated or misbranded:

When is Food Considered Adulterated?	When is Food Considered Misbranded?
A food may be considered adulterated for a number of reasons, including, but not limited to, the following: • The food contains a poisonous or hazardous substance. • The food is partially or completely rotten, filthy, putrid or otherwise unfit for consumption. • The food is prepared, packed or held under unsanitary conditions. • The food is a dietary supplement that presents a significant or unreasonable risk of illness or injury. • The food is a new dietary ingredient, and there's little information available to determine whether it presents a significant risk of illness or injury.	Under the FD&C Act, a food is misbranded if it contains a food allergen that is not appropriately identified on labels through a "contains" statement or in an ingredient list. Major food allergens highlighted in the FD&C Act include: • Milk • Eggs • Fish • Crustacean shellfish • Tree nuts • Wheat • Peanuts • Soybeans • Any food ingredients that contain a protein derived from the above foods

When a food product poses a potential hazard, the FDA will conduct what is called a health hazard evaluation to determine the severity of the recall. These evaluations are completed by a committee of FDA scientists and take the following factors into account:

- Whether the consumption of a product has already led to disease or injuries
- Whether preexisting conditions play a factor in the product's hazard
- How hazardous the product is to at-risk segments of the population, including children and the elderly
- Long-term and immediate health hazards

Based on these evaluations, the FDA assigns the recall a classification indicating the seriousness of the hazard. For food recalls, there are three classifications to be aware of:

01

Class I recalls—Class I recalls are the most serious and generally occur when the defective food product is reasonably believed to cause serious adverse health effects or death.

02

Class II recalls—Class II recalls are used when a product can cause temporary or reversible adverse health effects. Many food recalls fall under this classification.

03

Class III recalls—Class III recalls are used when the food product is not likely to cause injuries or adverse health effects.

The FDA relies on organizations to initiate recalls themselves when a potentially harmful food product is discovered. However, the FDA can request that a business perform a recall based on legislation passed in 2011.

FDA-requested and Voluntary Recalls

When it comes to food recalls, the FD&C Act was significantly enhanced when the Food Safety Modernization Act (FSMA) was signed into law in 2011. At the time, the FSMA represented some of the most sweeping reforms in food safety laws in more than 70 years.

As previously mentioned, many recalls are voluntary, and, prior to the FSMA, this was almost exclusively the case. However, the FSMA gave the FDA mandatory recall authority for the first time ever. This means that, should a food product (other than infant formula, tobacco products or controlled substances, which all have their own set of standards) have the potential to cause serious adverse health consequences or death, the FDA can order the responsible party to perform a recall.

The table below details the key differences between an FDA-requested recall and a firm-initiated (voluntary) one.

FDA-requested Recall	Voluntary Recall
Under the FD&C Act, the Commissioner of Food and Drugs (the Commissioner) or their designee may request that an organization carry out a recall if: • A distributed product puts consumers at risk of injury or illness. • A distributed product deceives the public in some way (e.g., allergens aren't listed	Organizations may recall a food product at any point if they believe it endangers the public in some way. In these instances, organizations must notify the appropriate FDA district office. It should be noted that the removal or correction of such a food product will only be considered a recall if the FDA believes issues with the food product creates a violation subject to legal action.

or the product doesn't feature the appropriate warnings). • Despite the apparent risk, the organization has not initiated a recall voluntarily. • The organization must act to ensure the public's health and well-being. Should the above criteria for an FDA-requested recall be met: • The Commissioner or their designee will notify the organization in writing that a recall is necessary and needs to begin immediately. An authorized FDA official may also follow up with an on-site visit. The notification will specify the violation, health hazard classification and recall strategy. • The organization responsible for initiating the recall will be asked to provide information regarding the recalled product. This information is similar to what is provided during voluntary recalls (see the Voluntary Recall column of this table).	In such instances, organizations are required to provide the following information: • The types of products involved in the recall. • Reasons for the recall. • When and how the organization determined a recall was necessary. • An overview of the risks or potential risks associated with the product. • Details regarding the number of products produced as well as the time frame in which they were produced. • The number of products estimated to be in distribution channels. • Distribution information, including the number of direct accounts and, where necessary, the identity of those direct accounts. • Copies of recall communications or proposed communications. • The organization's proposed recall strategy. • Contact information for the individual the FDA should contact if they have questions regarding the recall. Should an organization perform a voluntary recall, the FDA will: • Review any information submitted to them. • Advise the organization regarding the recall classification. • Recommend appropriate changes to the organization's recall strategy. • Place the recall in the weekly FDA Enforcement Report.

The Consequences of Failing to Perform a Recall

Whether your firm determines a recall is necessary on its own or the FDA orders you to perform one, food and public safety should always be top of mind. Failing to take the appropriate actions following a

product issue not only jeopardizes the health of your customers and your reputation, but it can also lead to:

Warning letters

Injunctions

Criminal prosecution and up to three years of imprisonment for the responsible party's directors and officers

Criminal fines of up to $500,000 per offense

As such, it's important to understand the recall methodology laid out by the FDA, which can involve preparing for a recall, executing a recall and evaluating a recall.

PREPARING FOR A FOOD RECALL

Before developing a recall strategy based on FD&C Act guidance, it's crucial for organizations to prepare for potential food issues. To ensure FD&C Act compliance and effective recall procedures, every organization subject to FDA regulations must first create a food recall team.

Above all, food recall teams help organizations develop a recall plan that's customized to their business and its needs. What's more, creating a recall team allows organizations to:

Review available information and determine the steps needed to:

- Protect the health and safety of consumers.
- Maintain positive relationships with key stakeholders, including consumers and business partners.
- Safeguard the organization's reputation.
- Meet any applicable regulatory obligations.

Create and manage a food recall plan.

Ensure effective communication with consumers, relevant government and industry authorities and other key stakeholders before, during and after a recall.

Execute recall decisions and actions effectively, ensuring that, if a recall is necessary, it causes limited business disruptions.

When establishing a recall team, organizations must assign clear duties to each person involved. The table below outlines the roles, expertise and responsibilities of a food recall team. Please note that how you divvy up these roles and responsibilities will depend largely on your organization. For instance, smaller organizations may task one person to handle multiple aspects of a recall, whereas larger organizations may be able to spread out jobs more evenly.

Roles/Expertise Required	Activities and Responsibilities
Recall Coordination and Leadership	• Acts as the main point of contact following an incident notification • Has a high-level authority to make key decisions regarding a recall, which can include:

	○ Determining the scope of a recall and making a final determination regarding recall strategies and execution ○ Notifying members of your supply chain of a recall incident ○ Putting food production on hold in order to conduct an investigation ○ Preventing the sale of a food product at any point in the supply chain ○ Notifying applicable regulatory bodies of a food product incident, providing reports and documentation per relevant requirements ○ Assessing the effectiveness of a recall and making recommendations about its progress ○ Ending recall operations as necessary • Assesses and escalates incidents as needed • Ensures that, in the event of an incident, the appropriate parties are informed and decisions are made in a timely manner • Oversees the creation and management of the food recall team • Facilitates meetings and action steps • Ensures that, in the event of an incident, all relevant information is properly collected and reported • Oversees communication following an incident notification, ensuring they are consistent and controlled • Facilitates all relevant follow-up processes
Technical and Engineering	• Leads incident investigations • Reviews internal processes, including recordkeeping procedures, quality control and traceability systems • Leads the risk analysis or risk assessment process • Communicates with laboratories, testing authorities and other experts involved in risk analysis • Acts as the intermediary with suppliers • Participates in the recall decision

Operations	• Gathers distribution records, ensuring their accuracy • Oversees the retrieval, replacement, repair and disposal of adulterated or misbranded products • Keeps accurate records to support the continual improvement of the recall process • Participates in the recall decision
Sales and Marketing	• Establishes communication with affected consumers following an incident • Addresses consumer questions and concerns in a timely manner • Arranges refunds • Participates in the recall decision
Finance and Risk Management	• Establishes a budget and estimates the costs of proposed actions (e.g., recall decisions) • Notifies insurers as needed and keeps records of any claims • Works closely with sales and marketing to arrange refunds and replacement products • Participates in the recall decision
Legal Counsel	• Ensures the organization meets applicable regulatory requirements • Ensures the organization meets contractual requirements • Advises the organization, helping to minimize liability concerns wherever possible • Participates in the recall decision
Communications	• Identifies key audiences and stakeholders, paying close attention to the most vulnerable consumer groups • Assists in the development of the communication strategy • Manages the resources required to handle consumer questions • Recommends changes to communication plans post-recall as needed

It should be noted that recalls can happen outside of regular business hours. As such, organizations should prepare a list of alternates in case key individuals can't be reached at the time of a recall. The list of people who make up your team should be well-documented, reviewed and updated on a regular basis.

EXECUTING A FOOD RECALL

Once you learn a recall is necessary—whether via an FDA recommendation or through an internal determination—you must execute a recall strategy to protect the health of consumers. Thankfully, the FDA works closely with responsible parties to hone this recall strategy based on information gathered during health hazard evaluations.

Elements of a Recall Strategy

Per the FD&C Act, recall strategies are developed either by FDA officials for FDA-requested recalls or by the recalling organization for voluntary recalls. In general, recall strategies should be customized for each individual recall to account for differences in food hazards. Additionally, recall strategies should take the following into consideration:

- The results of health hazard evaluations
- How easy or difficult it will be for members of the supply chain or consumers to identify the affected product
- How obvious the adulteration or misbranding of the product is to the consumer
- The current availability of the affected product on the market
- How the organization will continue to make essential products available to consumers

Again, recall strategies will differ by organization and the specific hazards an adulterated or misbranded food presents. However, the FDA recommends that all recall strategies include the following elements:

01

Depth of recall—The recall strategy should determine the scope of the recall based on the product's degree of hazard and how widely it's been distributed. Per the FDA, the recall strategy should state what consignees the product has reached. Under the FD&C Act, a consignee is any entity or individual that received, purchased or used the product being recalled. This can include wholesalers, retailers, distributors or consumers.

02

Public warning—In some cases, recall strategies will need to include public warnings, which are used to alert consumers of food products that create potential health hazards. This is reserved for urgent situations where other means for preventing the consumption of recalled foods is inadequate. In general, the FDA will consult with the recalling firm to issue public warnings. However, some organizations may issue their own public warnings. When doing so, they must submit proposed communications to the FDA. Above all, the recall strategy should specify whether a public warning is needed and how it will be disseminated (e.g., news outlets, press releases or through trade publications). For more details regarding public warnings, click here.

03

Effectiveness checks—Effectiveness checks are designed to verify that all consignees specified in the depth of recall—whether it be wholesalers, retailers or consumers—have received a recall notification and have taken the appropriate action. Consignees may be contacted via a combination of personal visits, telephone calls or letters. The recalling firm will ordinarily be responsible for conducting effectiveness checks, but the FDA will assist where necessary and appropriate. Specifically, the recall strategy will outline what methods the recalling firm should use to conduct effectiveness checks and to what degree those checks will be performed, broken down as follows:

a. Level A effectiveness checks (100% of consignees are contacted)
b. Level B effectiveness checks (between 10% and 100% of consignees are contacted)
c. Level C effectiveness checks (10% of consignees are contacted)
d. Level D effectiveness checks (2% of consignees to be contacted)
e. Level E effectiveness checks (no consignees are contacted)

Once a firm develops a recall strategy, the FDA will review it and make recommendations as necessary. However, firms should not wait until the FDA approves the strategy to initiate the recall, especially in the face of widespread food issues.

Recall Communications

You need to implement your communication plan once you or the FDA have decided a recall is necessary. Specifically, the sections below outline what your firm needs to communicate to your local FDA district recall coordinator, your direct accounts and the public:

Communication to the FDA

Topic	What to Communicate/Notes

Product Information	• The product's name, including its brand name and generic name.
	• The model, catalog or product order numbers.
	• A description of the product, highlighting the following:
	  ○ Whether the product is a powder, liquid, tablet or capsule.
	  ○ What the intended use of the product is.
	  ○ Whether the product is perishable and its expected shelf life.
	  ○ What packaging the product is stored in.

	○ Information related to the product's labeling. You should provide two complete sets of all labeling to your local FDA district recall coordinator. Such labeling could include: ▪ Private labels ▪ Individual package labels ▪ Case labels ▪ Package inserts ▪ Directions for use ▪ Promotional materials
Codes (Production Identification Numbers)	• The lot and unit numbers of affected products.* • An explanation of your lot number coding system. • Expiration dates, use-by dates or the expected shelf life of affected products. • UPC codes of affected products. *If all lots are involved in the recall or the product is not coded, firms must explain how nonrecalled or reintroduced product can be distinguished from affected foods.
Recalling Firm	• The firm's name, address, city, state and ZIP code. • The type of firm (e.g., manufacturer, importer, broker, repacker or own-label distributor). • The name, title, phone, fax number and email of the recall contact and the public contact.
Manufacturer	• The manufacturer's name, address, city, state and ZIP code. • The manufacturer's FDA registration number, if applicable.
Firm Responsible for the Violation/Problem	• The firm's name, address, city, state and ZIP code.
Reason for the Recall	• Details regarding how the product is defective or violative. • Details regarding how the defect affects the performance and safety of the product: ○ **Foreign objects**—A description of any foreign objects found in the affected product where applicable. Include the

	size, composition, hardness and sharpness of the foreign object. ○ **Contaminants**—If the recall is due to the presence of a contaminant (e.g., cleaning fluid, machine oil or paint vapors), explain the level of contaminant in the product. Provide labeling, a list of ingredients and the material safety data sheet for the contaminant. ○ **Product specifications**—If the recall is due to failure of the product to meet specifications, provide the specifications and report all test results. Provide copies of any sample analysis. ○ **Ingredient issues**—If the recall is due to a label or ingredient issue, provide and identify the correct and incorrect labels, descriptions and formulations. • Details on how the problem occurred, how it was discovered and dates it occurred. • Whether or not the defect impacts all units subject to the recall or just a portion of them. If the problem only affects certain units, explain why. • Information on complaints associated with the product and problem, providing the following information: ○ The dates of the complaint ○ A description of the complaint ○ The lot or serial number involved • Whether or not a state agency is involved in this recall and, if so, who that agency is.
Health Hazard Assessment	• An assessment of the health risk associated with the deficiency.* *A recall decision does not depend solely on the health risk of the product. Defective products and misbranded products where no health hazard exists may still be in violation of the law and subject to a recall.
Volume of Recalled Product	• The total quantity of recalled product produced. • The dates the product was produced. • How much of the product was distributed

	• When the product was distributed. • How much of the affected product is currently on hold by the recalling firm and its distribution centers. • Details on how the product is being quarantined. • An estimate on how much product remains in the marketplace at the distributor, retailer and user levels.

Distribution Pattern	• Information regarding your direct accounts* (e.g., customers you sell directly to) by type. This could include:
	  ○ Wholesalers
	  ○ Distributors
	  ○ Repackers
	  ○ Manufacturers
	  ○ Retail outlets
	  ○ Consumers
	  ○ Federal government consignees
	  ○ Foreign consignees
	• Details regarding geographic areas of distribution, including foreign countries.
	• A list of consignees, including their names, addresses and contact information. Be sure to include any foreign customers and federal government consignees (e.g., USDA agencies). Also, you'll need to clearly state what the consignee list represents (e.g., all customers who were shipped recalled product, all customers who were sold recalled product or all customers who may have been shipped or sold recalled product).
	• Whether or not the product was sold under a government contract. If yes, provide the contract number, contract date and implementation date.
	• Whether or not the product was sold to any federal, state or local agency involved in a school lunch program. If yes, list the consignees and provide information regarding food quantities as well as the sale and shipment date.
	*The FDA recommends that firms notify both "ship to" and "bill to" customers of the recall. That way, ship to customers can retrieve the

	product from their location and bill to customers, if responsible, can initiate a subrecall.
Recall Strategy	• The level in the distribution chain to which you are extending the recall (e.g., wholesalers, retailers or consumers). If your recall only extends to the wholesaler or distributor level, the FDA recommends that you explain your rationale for not recalling to the retail level. • The method of notification (e.g., mail, phone, fax or email). Include a written notification so customers will have a record of the recall and your instructions. If you have a website, you should consider posting the recall notification on the website as an additional method of recall notification. • How letters will be sent to customers (e.g., overnight mail, first-class mail, certified mail or fax). If initial notification is by phone, provide a copy of the phone script to the FDA. • What you instructed customers to do with the recalled product. If you're asking consumers to return the affected product, explain the mechanics of the process. • Whether or not the recall will create a market shortage that will impact on consumers. • Details regarding recall effectiveness checks. Include your actions for nonresponders. • Details on your course of action for out-of-business distributors. • A proposed method for the destruction of affected product, if applicable.* • If the product is to be reconditioned, explain how and where the reconditioning will take place. Provide details of the reconditioning plan to your local FDA district recall coordinator before implementation. Be sure to describe how reconditioned product will be identified so it is not confused with recalled product. *The FDA recommends that firms contact their local FDA district recall coordinator prior to product destruction. The FDA will review your proposed method of destruction and may

	choose to witness the destruction. The recalling firm and customers should keep adequate documentation of product destruction, detailing whether or not destruction was witnessed by an FDA investigator.

Communication to Direct Accounts

Your firm is responsible for notifying each direct account that has received potentially harmful or violative products. The format, content and degree of recall communications should be proportionate to the hazard of the product and align with the strategy you've developed to address that hazard.

In general, your firm needs to communicate:

- What products are subject to the recall
- That further distribution of the affected products should cease immediately
- That, where applicable, direct accounts should notify customers who may have received the affected products
- What stakeholders should do with the affected products

Communications to direct accounts can be completed via telegrams, mailgrams or conspicuously marked first-class letters. Communications should include the following language in bold red type on both the letter and envelope:

- "Food recall" (or correction)
- "Urgent" (for Class I and II recalls and, when appropriate, for Class III recalls)

In terms of best practices, all recall warnings and notifications should be completed in writing and must:

- Be brief and to the point
- Identify affected products clearly and accurately
- Explain the reasons for the recall and the hazards at play
- Provide instructions on what to do with affected products
- Highlight action items (e.g., notify the recalling firm that you received the notification)
- Be void of any superfluous information (e.g., promotional materials)

Above all, consignees that receive a recall communication should immediately carry out the instructions set forth by the recalling firm and, where necessary, extend the recall to its own customers and partners.

Public Warnings

Typically, public warnings and notifications are reserved for urgent situations and are used to alert key stakeholders that a product being recalled presents serious health hazards. Often, public warnings are used where other means of preventing the use of the recalled product are inadequate.

The FDA generally gives businesses the first opportunity to prepare and issue public warnings during recalls as part of the recalling firm's larger recall strategy. The FDA may supplement public warnings with notifications of their own, if necessary. The FDA can also request that recalling firms create a public warning if they feel it is warranted and such a notification wasn't included in the recall strategy.

In situations where affected products pose significant health hazards and are in the hands of consumers, press releases are generally the most appropriate method for public warnings. Firms should consult with the FDA before issuing a press release.

Per the FDA, press releases and other forms of written notifications should include the following information:

Topic	What to Communicate/Notes
Titling	• Include the phrase "URGENT: FOOD RECALL or CORRECTION" in large, bold print on all recall notifications. Envelopes should be formatted similarly.
Product Identification	• Include an accurate and complete description of the product and any codes used to identify the product (e.g., lot/unit numbers, expiration date, serial numbers, catalog numbers, model numbers and UPC codes). • Consider including a copy of the product label with the recall notification. This could be helpful for wholesalers and retailers in identifying and removing the recalled product.
Description of the Problem	• Identify the problem and any potential health hazards associated with it.
Depth of the Recall	• Identify the depth of the recall (e.g., wholesale, retail or user level). • Include instructions for subrecalls if the product could be further distributed by your customers. Subrecall instruction should also include the depth of the recall. If your customers are instructed to conduct subrecalls, provide them with the date range

	that the recalled product was distributed. Wholesalers and distributors may need this information in order to identify customers they sold recalled product to. • Consider providing a subrecall letter with your notification package for your customers.
Instructions to Customers	• Ensure your instructions are clear. Consider the following instructions as part of your recall notifications: o Remove the product from sale o Cease distribution o Subrecall (if appropriate) o Return the product • Include a return response form. This form should include all of the instructions from your recall letter.

EVALUATING A FOOD RECALL

Once a recall is initiated and affected parties are notified as appropriate, recalling firms must continually evaluate their recall. This involves performing effectiveness checks, providing status reports, terminating the recall as necessary and ensuring the proper follow-up actions are completed.

Effectiveness Checks

Recalls are an ever-evolving challenge for organizations. During and after every recall, it's crucial to measure its effectiveness. This can help you identify issues and adjust future recall practices accordingly.

As detailed in the Elements of a Recall Strategy section of this guide, effectiveness checks are assessments recalling firms must use to ensure food recalls run smoothly. Again, effectiveness checks allow recalling firms to confirm that:

01

A recall notification was received by the customer.

02

The customer read and understood the notification.

03

The customer followed the recall instructions.

04

The recall reached the appropriate level in the distribution chain.

There are several different ways to perform effectiveness checks, including distributing questionnaires, mailing letters and scheduling outbound phone calls. Best practices for completing effectiveness checks are detailed by the FDA in a government resource entitled Methods for Conducting Recall Effectiveness Checks. Recalling firms should contact their district recall coordinator to receive this document.

If your effectiveness checks indicate that the recall notification was not received or instructions were not followed, you may need to send out additional, clearer communications. For sample effectiveness check assessments, including letters and questionnaires, click here.

It should be noted that the FDA may perform its own effectiveness checks—sometimes referred to as an audit check—to ensure you are adhering to your recall responsibilities. If the FDA's audit checks determine the recall is ineffective, you may be asked to reissue recall notifications.

Recall Status Reports

Once you have initiated a recall, you will be asked to submit periodic recall status reports to the appropriate FDA district office. This allows the FDA to assess the progress of the recall and take action as necessary.

Firms will need to provide these reports to the FDA every two to four weeks, depending on the severity of the recall. In general, recall status reports should contain the following information:

- The dates customers were notified
- The number of customers notified
- The number of customers responding to the recall notification
- The amount of recalled product that was returned or accounted for
- The details of your firm's effectiveness checks

Terminating the Recall

Once all possible responses to the recall notification have been received and you reasonably believe all affected product has been recovered, corrected, reconditioned or destroyed, you can evaluate the recall for termination. The decision to terminate a recall will be made alongside FDA officials once a recalling firm submits a written request to the appropriate office. When submitting this request, recalling firms must provide the most recent recall status report and an update regarding the nature of the recalled product (e.g., the affected product has been destroyed).

Upon receiving the necessary termination information, your local district recall coordinator will prepare a recall termination document that will need to be approved by relevant FDA officials. Once approval has been received, the local district recall coordinator will notify the recalling firm.

Additional Considerations

Recalls can lead to significant disruptions and potential litigation, and it's important for firms to take every precaution to protect themselves from food product concerns. While it's important to have a plan in place for responding to food safety issues, it's equally critical to prevent future concerns whenever possible. Continual improvement should be a constant goal, and you should review your organization's communication plan, risk assessment procedures, recall strategy and similar activities on a regular basis.

Furthermore, to ensure you're appropriately prepared for future incidents, the FDA recommends that businesses:

- Prepare and maintain a written contingency plan for use in initiating and effecting a recall.
- Use sufficient coding of regulated products to facilitate the effective recall of all violative lots.
- Maintain such product distribution records as necessary to facilitate location of products that are being recalled. Such records should be maintained beyond the shelf life and expected use of the product.

CONTINUED SAFETY

When it comes to ensuring public safety, effective recall plans and management can make all the difference. What's more, with the proper plan in place, your business can survive the financial burden of a full-scale recall.

While recall plans are necessary to all organizations that manufacture, supply or distribute food, proper insurance coverage is just as important. To learn about the different policy options you can use to supplement your risk management program, contact a qualified insurance broker at The Coyle Group today.

Additional Resources

EXHIBIT 7-1

MODEL EFFECTIVENESS CHECK LETTER (INDUSTRY)

[CONSIGNEE]

[NAME AND ADDRESS] [DATE]

[PRESSURE SENSITIVE LABEL]

Dear [NAME]:

On [DATE] you were notified by letter that [RECALLING COMPANY NAME AND ADDRESS], is recalling [PRODUCT NAME, CONTAINER SIZE AND CODE NUMBER]. All products were manufactured by [RECALLING COMPANY] and distributed solely under the manufacturer's label.

Recall of the product was initiated following a change in their formulation, which resulted in products in distribution channels having the same brand name but different ingredients. The old formulation contained [X], and there is concern that consumers may receive the old formula. Use of the old formulation by some consumers represents a potential health hazard.

The recall notice from [RECALLING COMPANY] requested consignees (wholesalers and retailers) to discontinue selling their existing stock of the old formulations and return existing inventories of the recalled formulations to [RECALLING COMPANY].

In order to advise the Food and Drug Administration about the effectiveness of this [RECALLING COMPANY] recall, you are requested to complete and return the enclosed questionnaire promptly using the prepaid self-addressed envelope.

If you have any questions or problems with this request, please call [NAME AND TELEPHONE NUMBER].

Thank you for your cooperation.

Sincerely,

[RECALLING COMPANY]

NOTE: If this letter is sent to distributors who may have further sold the product to other distributors or to retail outlets, the third paragraph should include the fact that the recall notice requested the direct consignees to conduct sub-recalls by notifying their customers of the recall situation.

EXHIBIT 7-2

MODEL EFFECTIVENESS CHECK RESPONSE FORMAT (INDUSTRY)

[CONSIGNEE]

[NAME AND ADDRESS] [DATE]

[PRESSURE SENSITIVE LABEL]

[RECALLING COMPANY] PRODUCT RECALL

PLEASE READ EACH QUESTION AND CHECK THE PROPER ANSWER YOU HAVE CHOSEN. PLEASE CHECK WITH ANYONE WHO MAY HAVE RECEIVED THIS NOTIFICATION BEFORE ANSWERING.

DATE: **NAME:**

1. Did your firm receive notification that [RECALLING COMPANY] is recalling its [PRODUCT NAME] product?

   YES _____ NO _____

2. Did your firm receive shipments of the product being recalled? (If no, please sign and return).
   YES _____ NO _____

3. Do you now have any of the recalled product on hand? (Please check inventories before answering).
   YES _____ NO _____

4. If the answer to question 3 is YES, do you intend to return the product to [RECALLING COMPANY] as requested?
   YES _____ NO _____

5. If the answer to question 4 is NO, please explain your intentions:

6. Have you received any reports of illness or injury related to this product?

   YES _____ NO _____

   If yes, please provide details:

EXHIBIT 7-3

MODEL EFFECTIVENESS CHECK QUESTIONNAIRE FOR TELEPHONE OR PERSONAL VISITS (INDUSTRY)

[CONSIGNEE]

[NAME AND ADDRESS] [DATE]

[PRESSURE SENSITIVE LABEL]

[RECALLING COMPANY] PRODUCT RECALL

This is [NAME OF INTERVIEWER]. I am calling for [RECALLING COMPANY] to check on the effectiveness of the company recall of [PRODUCT NAME, CONTAINER SIZE AND CODE NUMBER]. On [DATE], [RECALLING COMPANY] notified all firms that may have purchased [PRODUCT NAME] via [METHOD OF CONTACT] that all stock should be [RETURNED, DESTROYED, MODIFIED OR RELABELED]. I have the following questions to ask you about this recall:

1. Did your firm receive notification that products manufactured by [RECALLING COMPANY] are being recalled?
   YES _____ NO _____

2. Did your firm receive shipments of the product being recalled? (If no, terminate questioning and go to the closing).
   YES _____ NO _____

3. Do you have any of the recalled product on hand? (Please check inventories before answering).
   YES _____ NO _____

4. If the answer to question three is "YES," do you intend to return the product to [RECALLING COMPANY] as requested?
   YES _____ NO _____

   If the answer to question four is "NO," please explain your intentions:

5. Have you received any reports of illness or injury related to this product?
   YES _____ NO _____

   If yes, please provide details:

CLOSING

Thank you for your cooperation. Could you please provide your name and job title:

Interviewer:

Date:

NOTE: If the respondent has any further questions, ask them to contact the [RECALLING COMPANY] via [PREFERRED METHOD].

EXHIBIT 7-4

MODEL RECALL LETTER (GENERIC, ALL CENTERS)

[COMPANY LETTERHEAD]

URGENT: FOOD RECALL

[CONTACT NAME OR DEPARTMENT] [DATE]
[RECALLING COMPANY]
[ADDRESS]

This is to inform you of a product recall involving:

[PRODUCT NAME, BRAND NAME, DESCRIPTION, UPC CODES, LOT NUMBERS]

See enclosed product label [FOR EASE IN IDENTIFYING THE PRODUCT AT RETAIL/USER LEVEL].

This recall has been initiated due to [PROBLEM]. Consumption of this product may [HAZARD].

We began shipping this product on [DATE]. **(Or)** This product was shipped to you on [DATE].

(**Note:** If possible, provide consignee with shipping dates and quantities shipped).

Immediately examine your inventory and quarantine product subject to recall. In addition, if you may have further distributed this product, please identify your customers and notify them at once of this product recall.

Your notification to your customers may be enhanced by including a copy of this recall notification letter. **(Or)** Enclosed is a letter you should use in notifying your customers.

(**Note:** Your notification must include instructions on what customers should do with the recalled product).

This recall should be carried out to the [WHOLESALE, RETAIL, CONSUMER OR USER] level. Your assistance is appreciated and necessary to prevent consumer illness.

Please complete and return the enclosed response form as soon as possible. If you have any questions, call [TELEPHONE]. This recall is being made with the knowledge of the Food and Drug Administration.

[NAME AND TITLE]

EXHIBIT 7-5

MODEL RECALL RETURN RESPONSE FORM

[COMPANY LETTERHEAD]

[PRODUCT NAME]
[LOT NUMBER]

Please check ALL appropriate boxes:

- □ I have read and understand the recall instructions provided in the [DATE] letter.
- □ I have checked my stock and have quarantined inventory consisting of [UNITS OR CASES].
- □ Indicate disposition of recalled product:
  - □ Returned (specify quantity, date and method)/held for return)
  - □ Destroyed (specify quantity, date and method)
  - □ Relabeled (specify quantity and date)
  - □ Quarantined pending correction (specify quantity)
  - □ Transfused – blood or blood products (specify date and quantity)
  - □ Implanted (specify date and quantity)
- □ I have identified and notified my customers that were shipped or may have been shipped this product by (specify date and method of notification). **(Or)** Attached is a list of customers who received/may have received this product. Please notify my customers.

Any adverse events associated with recalled product?

YES _____ NO _____

If yes, please explain:

Please check the appropriate box(es) to describe your business:

- □ Wholesaler/distributor
- □ Retailer
- □ Grocery corporate headquarters food service/restaurant
- □ Repacker
- □ Manufacturer
- □ Pharmacy – retail
- □ Hospital/medical facility
- □ Hospital pharmacies
- □ Medical laboratory
- □ Other:

Name:

Title:

Telephone number:

Firm name: **Address**:

Please fax/mail completed response form to [CONTACT INFORMATION].

NOTE: This template is intended to serve as guidance for recalling firms. It may not conform to your firm's recall strategy. Please make any appropriate modifications to the response form. IT IS ADVISABLE TO SUBMIT THE PROPOSED RECALL LETTER AND RESPONSE FORM TO YOUR LOCAL FDA RECALL COORDINATOR FOR REVIEW, PRIOR TO ISSUANCE.