

Determining the Reach and Severity of Your Food Recall

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A critical component of responding to a food recall is completely understanding the extent and implications involved. In order to take effective action, be sure to ask these essential questions to uncover the full breadth of the event at hand.

What is the scope or scale of the recall?

Determining the scope of the recalled product will depend heavily on your testing and documentation processes. You must be able to consult accurate production, traceability and sanitation records. In addition, you'll need to assess the depth of the recall, or the level in the distribution chain to which a recall notification must be given, including:

- Consumer/end user level
- Retail level
- Wholesale level

The keys here are automation and transparency.

Food safety touches every department of your company from top to bottom, including plant managers, corporate quality and food safety personnel, the corporate supply chain, operations, maintenance, quality assurance, the laboratory, crisis management and every team member in between. Wide-reaching transparency translates to more successful monitoring and control efforts, enabling you to react more efficiently and effectively to a recall situation.

Automated technology solutions make this kind of transparency a reality, affording invaluable support like quick, easy access to an organized database of policies, workflows and reporting. You'll need this data immediately in order to carry out your recall recovery plan. When there is a food safety incident, the FDA requests information below for a public press release:

- Product Information
- Product Identification Codes
- Recall Firms
 - Contact information
- Manufacturers
- Identify the Firm Responsible for Violation
- Reasons for the recall
- Health Hazard Assessment
- Volume of Recalled Products
- Distribution Patterns
- Recall Strategy

What is the level of severity?

Ascertain what level of risk, if any, there is to consumer health and safety. Recalls are designated into classification based on public health risk. You should understand the classifications and operate under this system as you issue notifications and develop your recall recovery strategy.

RECALL CLASSIFICATIONS

- Class I Recall: a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.
- Class II Recall: a situations in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote
- Class III Recall: a situations in which the use of or exposure to a violative product is not likely to cause adverse health consequences

Source: [FDA Recall](#)

As you assess severity, keep in mind that recalled products specifically geared toward infants, and the elderly are often viewed more risk than the products geared towards regular consumers.

What notifications or statements are being made?

From press releases to government and consumer notification letters, it will be important to ensure your recall is being communicated appropriately. An announcement that scales into a larger statement is helpful to end consumers. For instance, take a look at this General Mills statement provided on the company's website in reference to a 2016 flour recall.

FDA GUIDANCE ON PUBLIC NOTIFICATION

Press Release

In a situation where the product may pose a significant health hazard and recalled product is in the hands of consumers, a press release is usually appropriate. Issuance of a press release should be the highest priority and it should be issued promptly. Unique situations will be handled on a case-by-case basis.

You should consult with your local District Recall Coordinator before issuance of a press release whenever possible. A joint press release may benefit the firm and FDA by alerting the public to a serious health hazard or situations deemed to be in the public interest.

(Note: For those recalls where FDA believes a Press Release is warranted, the Agency will issue a Press Release if the firm has failed to do so, or if the firm-initiated press release is not adequate.)

Recall Notifications should be flagged in large bold print "URGENT: FOOD" Envelopes should be similarly flagged. FDA recommends that you should include the following information notification:

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 hazard(s) associated with it.

DEPTH OF THE RECALL:

- The recall notification should clearly identify the depth to which the recall is to extend (e.g., wholesale, retail or user level). If the recall is to the retail level, a statement should read “This recall is to the retail level.”
- If the product could have been further distributed by your customers, then you should include instructions to sub-recall. Sub-recall instruction should also include the depth of the recall, e.g., “If you have further distributed this product, you should notify your customers to the retail level.”
- If your customers are instructed to conduct sub-recalls, it is advisable to provide them with the date range that the recalled product was distributed. Wholesalers/ distributors may need this information in order to identify customers they shipped/sold recalled product to.
- You should consider providing a sub-recall letter with your notification package for your customers to further notify their sub accounts. You are then assuring that the information to sub accounts is accurate and complete.

INSTRUCTIONS TO CUSTOMERS:

- Your recall INSTRUCTIONS should be clear. For example:
 - Remove product from sale
 - Cease distribution
 - Sub-recall (if appropriate)
 - Return product
 - Explain procedure for product correction
- Include a RETURN RESPONSE card/form. This return response card/form should include all instructions from your recall letter. Your customers should be required to indicate that they followed every instruction.
- Provide examples of ALL recall communications (include letters, attachments, envelope) to your Local District Recall Coordinator.

Source: U.S. Food & Drug Administration

RECALLS NEED TO BE EVALUATED

- Effectiveness of the Recall
 - It is the recalling firm's responsibility to assure that the recall is effective. Therefore, we recommend that you consider effectiveness checks for every recall. The purpose of an effectiveness check is to verify your recall notification letter was received by the customer, that the customer read and understood the letter and followed the recall instructions. The effectiveness check should also verify your recall reached the appropriate level in the distribution chain. This highly associated with your firm's documentations, records, and SOPs of your daily production and testing.
- Recall Status Reports
- The report includes the information below:
 - Dates customers were notified
 - Number of customers notified
 - Number of customers responding
 - Quantity of RECALLED product returned or accounted for
 - Details of your recall effectiveness checks
- Root Cause of the problem that resulted in the recall
- CORRECTIVE ACTIONS TO PREVENT FUTURE OCCURANCES OF THE PROBLEM
- Termination of the recall

Source: **U.S Food & Drug Administration**

How is insurance affected?

Most food companies have recall insurance to protect their assets if a recall takes form. But, are you fully informed on what it means to work through a recall with your underwriter or how a recall affects your premiums? Is there a possibility of losing your insurance? It's crucial to understand how your insurance is affected by a recall and what is contractually covered under your plan.

In fact, a recent Food Safety Magazine article explains how “many insurance claims can result in litigation. To avoid a lengthy coverage dispute with insurers and to ensure maximum coverage for their losses, insureds in the food industry should carefully consider the specific provisions in their policies and the relevant case law and also consult knowledgeable counsel as soon as they become aware of a potential claim.”

What steps can you take to prevent a recall happening the future?

In order to prevent similar circumstances from happening in the future, we need to first evaluate the recall and learn from it. Conducting this through root cause analysis of the problem and assigning corrective actions are the first key steps. Afterwards, a proper prevention plan shall be implemented. Every department should get on board and be empowered to gain a strong understanding of the overall effort. You must prepare employees for the changes going into effect.

It is essential to equip them with the proper food safety knowledge and include them in the development of new preventative plans. There must also be a seamless exchange of information between departments. In terms of contamination prevention efforts, a lack of communication has the potential to cause mistakes that result in devastating product recalls.

Through root cause analysis, implementation of a prevention plan in a good timely manner, and learn from your own organizations records are major factors in achieving success and preventing recalls. It's wise to consider utilizing innovative food safety software that makes true visibility and help you translate your data into practical information.

With easy access to an organized database of policies, workflows and reporting, as well as automatic notifications and facilitated documentation, you give every department the visibility and communication tools they need to meet unfolding regulations and promote the kind of food safety culture that effectively mitigates the risk of food recalls.

Start Documenting & Learning About Your Own Operational Records

Learn how to better manage your food safety program with powerful scheduling, visual monitoring, accurate analysis, automated reporting and more.

[GET STARTED](#)