

# Food Recall In India

A COMPREHENSIVE GUIDANCE DOCUMENT:  
BY FOOD SAFETY WORKS



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## **Introduction**

A food recall is a crucial measure to protect public health by removing unsafe or non-compliant food products from the market. In India, food recalls are governed by the Food Safety and Standards Authority of India (FSSAI) under the Food Safety and Standards (Recall Procedure) Regulations, 2017. This manual serves as a comprehensive guide for Food Business Operators (FBOs) to effectively plan, initiate, and execute food recalls in compliance with regulatory requirements.

The objective of this manual is to outline the procedures, responsibilities, and best practices involved in recalling food products to minimize risks to consumers. It provides clear guidelines on recall classifications, communication protocols, reporting requirements, and post-recall assessments. By adhering to these procedures, FBOs can ensure swift and efficient recall actions while maintaining transparency with regulatory authorities and the public.

This manual is intended for all stakeholders in the food industry, including manufacturers, distributors, retailers, and regulators, to ensure a standardized approach to food safety and consumer protection in India.

# **PART 1- FOOD RECALL**

## **1.1 What is a Food Recall?**

A food recall involves removing food products from the market at any stage of the food chain, including consumer-held products, when those products threaten public health and violate applicable laws, rules, or regulations.

## **1.2 What is the need for a Food Recall?**

Safeguarding consumer health and public safety is a fundamental priority. To ensure this, the Food Safety and Standards (Food Recall Procedure) Regulations, 2017, established essential guidelines for handling food recalls in India. Under Section 28 of the Food Safety and Standards Act, 2016, these regulations outline clear procedures for swiftly removing unsafe food products from the market.

## **1.3 What is the benefit of conducting a Food Recall?**

Recalls offer a more efficient and timely means of consumer protection than formal administrative or civil actions, especially when products have been widely distributed, making them beneficial for the industry, government, and consumers alike.

## **1.4 What is the FSS Act, 2006?**

The Food Safety and Standards Act, 2006 (FSSA, 2006) is a comprehensive law enacted in India to regulate food safety and standards. It was introduced to consolidate various food-related laws and establish a single regulatory authority—the Food Safety and Standards Authority of India (FSSAI)—to oversee food safety and compliance.

## **1.5 What is the role of FSSAI in food recall?**

The **Food Safety and Standards Authority of India (FSSAI)** is an autonomous body established under the Food Safety and Standards Act, 2006. It operates under the Ministry of Health & Family Welfare, Government of India. FSSAI is responsible for regulating and supervising food safety to protect public health. FSSAI plays a crucial role in ensuring the effectiveness of food recalls by providing guidelines, monitoring compliance, and coordinating with stakeholders. It monitors the recall process and ensures that affected food items are effectively removed and disposed of safely. It also verifies that corrective actions are taken to prevent future incidents. They also communicate food recalls to the public through its website, press releases, and social media, ensuring consumers are informed about potentially unsafe products.

## **1.6 Who has the authority to start a food recall?**

Manufacturers and distributors should recall products whenever necessary to protect public health from potential injury, deception, or defects. They may also act upon a problem flagged by the Food Authority or a state agency, respond to an official request, or comply with an Authority order.

## **1.7 What are the various situations that lead to a food recall?**

- a) A food recall may be initiated at any stage of the food supply chain if the Food Business Operator (FBO) determines that the food is unsafe or violates provisions of the FSS Act and its related rules and regulations.
- b) The recall process can also be triggered based on reports or complaints from stakeholders. If the FBO assesses the need for a recall based on such inputs, they must take action accordingly.

c) A recall may also be mandated following the analysis of surveillance or regulatory samples collected by enforcement authorities. If the food is found unsafe or non-compliant with the Act and its regulations, posing a serious risk to public health, the concerned authority can instruct the FBO to recall the product, and compliance with this directive is mandatory.

## **1.8 What is a food Recall Plan?**

A "Food Recall Plan" refers to the set of procedures and measures a food business operator must have in place to remove food products from any point in the supply chain if an issue arises. All food business operators involved in manufacturing, importing, or wholesaling food regulated under the Act are required to maintain an up-to-date recall plan.

### **Note- Exemption:**

- i. Food service businesses like restaurants, caterers, and takeaway joints are not required to have a recall plan unless they operate as multi-outlet chains with integrated manufacturing and distribution.
- ii. Likewise, food retailers are exempt unless they are also engaged in manufacturing, importing, or wholesaling food.

## **PART 2- Food Recall Procedure**

### **2.1 Initiation of the food recall process**

- i. A recall can be started by the FBO voluntarily or under orders from the Chief Executive Officer (CEO) of FSSAI or the Commissioner of Food Safety of a state or Union territory. If the FBO does not take action, regulatory authorities can step in and enforce the recall.
- ii. Under the Food Safety and Standards (Food Recall Procedure) Regulations, 2017, FBOs must initiate a recall when food safety risks arise. The process must align with Section 28 of the Food Safety and Standards Act, 2006, which requires removing unsafe food and obligates FBOs to inform authorities and consumers about the recall.
- iii. The recall process can also be initiated based on reports or complaints received by the food business operator from any stakeholder. If the operator finds a recall necessary, they must take action. If they fail to address the complaint, the complainant or consumer may escalate the issue to the Chief Executive Officer of the Food Safety and Standards Authority of India, the Commissioner of Food Safety of the relevant State or Union Territory, or both. These authorities will evaluate the need for a recall and direct the food business operator accordingly, who must comply with their instructions.
- iv. All food business operators within the food chain must adhere to food recall instructions. Failure to comply may lead to action under the applicable Act, rules, or regulations.



- v. Imported food may be subject to recall based on reports or information from health and food authorities or if the relevant authority becomes aware of the issue through any other source.
- vi. The initiation of a food recall does not prevent the Chief Executive Officer of the Food Safety and Standards Authority of India or the Commissioner of Food Safety of a State or Union Territory from taking additional regulatory action against the food business operator as per the provisions of the Act.

## 2.2 Operation of Food Recall

The food business operator must keep records of food distribution, including supplier and customer details, product information (such as nature of food, purchase and delivery dates, lot number, batch code, pack size, brand name, manufacture date, expiry date, and best-before date). These records must be maintained for one year beyond the expiry or best-before date, as applicable.

For alcoholic beverages, where best-before labelling is exempt, records must be kept for two years from the supply date or month.

If a food recall is necessary, the operator must notify the relevant authority as specified under **Schedule I** within 24 hours of becoming aware of the issue and initiate the recall process. Notifications should be sent via the fastest available means, such as fax, email, or speed post. Additionally, the State or Union Territory's Food Safety Commissioner must inform the Chief Executive Officer of the Food Safety and Standards Authority of India within 24 hours of receiving such information.

The food business operator must immediately halt the distribution of recalled food and, if necessary, stop production without waiting for directives from the Chief Executive Officer of the Food Safety and Standards Authority of India or the State/UT Commissioner of Food Safety to protect consumer safety. They must promptly inform all

stakeholders, from raw material suppliers to end consumers, using written communication, phone, email, fax, or a combination of these. Additionally, they must notify suppliers, relevant retailers, and trade associations while quickly identifying all necessary product details to facilitate an efficient recall.

## **2.3 Food Recall Plan**

All food business operators involved in manufacturing, importing, or wholesaling food must maintain an up-to-date recall plan. However, food retailers are exempt unless they also engage in these activities.

Businesses in the food service sector, such as restaurants, caterers, and takeaway joints, do not need a recall plan unless they operate multi-outlet chains with integrated manufacturing and distribution networks.

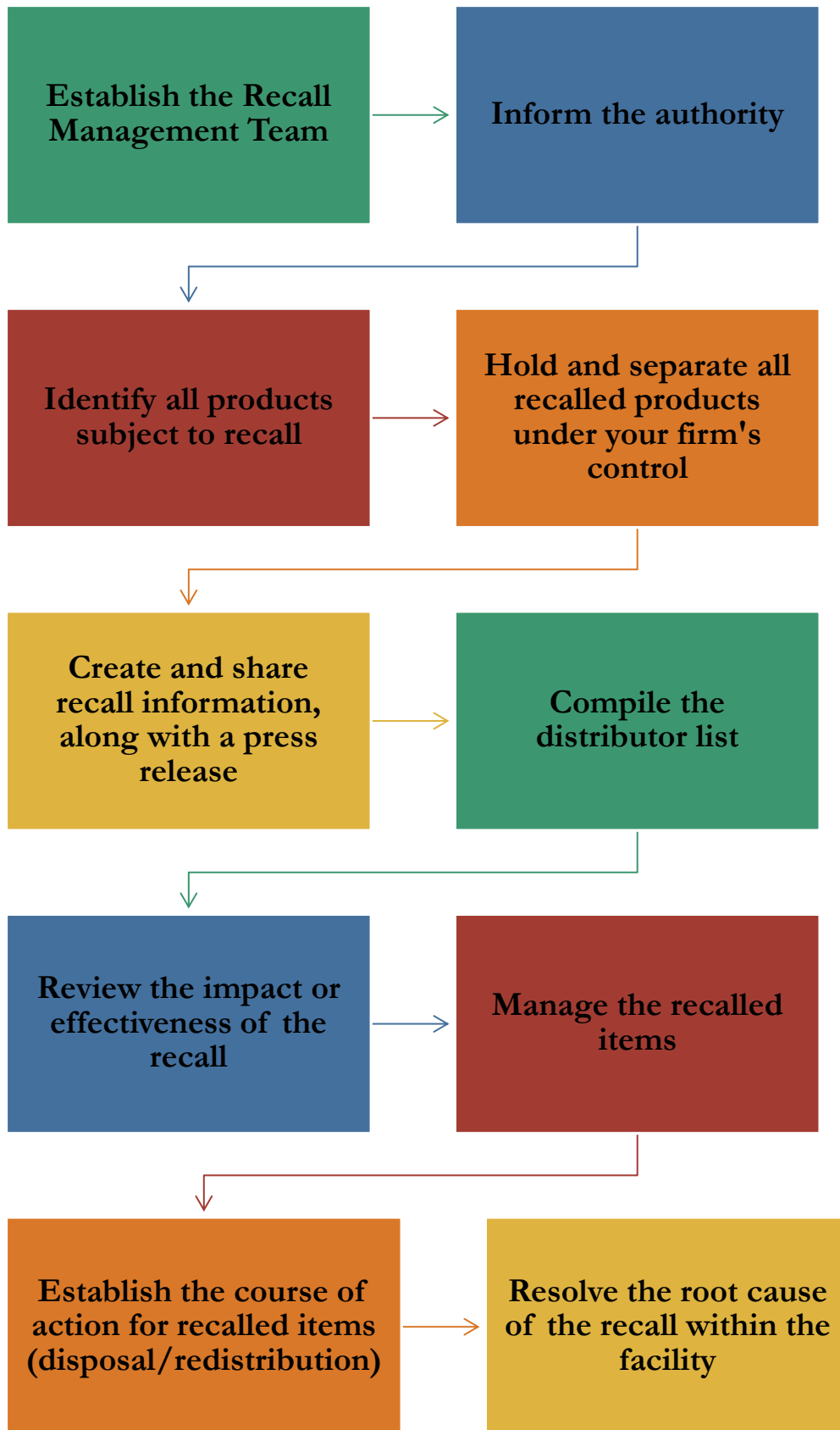
Retailers and exempt food service businesses must remove recalled products from shelves, return them to the manufacturer, importer, or wholesaler, and ensure the recalled food is properly separated and identified until it is disposed of as per the recall plan's instructions.

The food business operator responsible for a recall must develop a detailed recall plan as part of their food safety management system, following guidelines issued by the food authority.

During an actual recall, they must submit details of the recall plan's implementation to the Chief Executive Officer of the Food Safety and Standards Authority of India and the State/UT Commissioner of Food Safety. They must oversee the recall process, ensure food safety, gather necessary data, and report on its completion.

The operator must also ensure the recall is effectively carried out in accordance with the established plan.

**Here is a brief outline of the procedure that FBO shall follow:**



## **1) Establish the Recall Management Team:**

At the start of a recall, the FBO should establish a recall management team, assign specific duties to each member, and ensure everyone is informed of the recall decision and their individual responsibilities.

The team should consist of individuals responsible for:

- a. Decision-making
- b. Quality assurance / technical advisory
- c. Media communication
- d. Complaint investigation
- e. Contacting accounts
- f. Food Authority Contact
- g. Legal Counsel

The document of this management team should contain the following:

- a. Name
- b. Alternate Person
- c. Business Phone
- d. After Hours Phone
- e. Responsibilities During Recall

## **2) Inform the authority:**

The relevant regulatory authority should be informed as soon as possible after identifying an incident that may lead to a recall. Updates should be provided throughout the process. The information shared should include:

- A detailed description of the issue
- Product details (name, brand, size, and affected lot codes)
- Complaints received and any reported illnesses
- Distribution scope (local or national)
- Distribution timeline (specific dates)
- Product labels for potential recall

- Total quantity manufactured and distributed
- Firm's primary contact with the authority
- After-hours contact name and phone number(s)

### **3) Identify all products subject to recall:**

The FBO is responsible for identifying all products that need to be recalled. Beyond the directly affected products, the FBO should also:

- Assess whether other codes, brands, or sizes of the same product are impacted.
- Determine if any additional products are affected.

### **4) Hold and separate all recalled products under your firm's control:**

The FBO must ensure that all recalled products under the firm's control are not distributed. Additionally, the FBO should:

- Locate recalled products (e.g., on-site, at the plant, or in off-site storage).
- Determine the quantity at each location.
- Identify and segregate products to prevent distribution.

### **5) Create and share recall information, along with a press release:**

#### **Consumer Notification:**

The company should promptly inform consumers about the recall based on its scope. This can be done through a press release, direct letters, or paid media advertisements. A dedicated hotline should be available to manage inquiries.

## Communication Within the Food Chain:

The FBO must notify all relevant stakeholders, including raw material vendors, suppliers, retailers, and trade associations, via written communication, phone, email, fax, or a combination of these methods.

The press release, letter, or advertisement should be issued as a "Food Recall Notice" and must include the following details:

Any press release, letter, or advertisement must be titled "**Food Recall Notice**" and include the following details:

- **Name of the Food Business Operator** issuing the recall.
- **Product details:** food name, brand, pack size, batch/code number, manufacturing date, and expiry/best-before date.
- **Reason for recall**, such as contamination or regulatory violations.
- A clear "**Do Not Consume**" warning.
- Any **health risks** and recommended actions.
- **Locations** where the recalled product was sold.
- **Instructions for consumers** on what to do next.
- **Contact details** for further inquiries.

The Food Business Operator (FBO) must issue the press release within two hours of being notified of the recall. If required, a draft must be submitted to the relevant Authority for approval. The FBO must also arrange for translation of the press release to suit the affected region.

## 6) Compile the distributor list:

Maintaining precise distribution records helps confine the recall to only those accounts that received the affected product. Using the distribution record system, generate a product- and lot-code-specific distribution list that:

- Identifies the accounts that received the recalled product.
- Includes account names, addresses, contact persons, and phone numbers.

- Specifies the type of account, such as manufacturer, distributor, or retailer.

## **7) Review the impact or effectiveness of the recall:**

The Food Business Operator (FBO) must monitor the recall's effectiveness and provide regular status reports to the relevant authority. These reports should be submitted weekly or as directed by the authority.

For a successful recall, the FBO should maintain detailed food distribution records, including:

- Supplier and distributor names and addresses.
- Raw material purchase dates.
- Batch codes, lot numbers, and full traceability from raw materials to finished products.

Additionally, the FBO must:

- Confirm that all accounts have stopped distributing and selling the recalled product(s).
- Ensure that the recalled product(s) have been returned.

## **8) Manage the recalled items:**

Recalled products should be collected at a central location or, for widely distributed items, at major recovery sites. The recovered products must be stored separately from other food items.

The FBO is responsible for ensuring that recalled products do not re-enter the market by:

- Separating and clearly labeling recalled products.
- Tracking quantities and monitoring returned items.
- Documenting recalled products in the Recalled Product Records.
- Maintaining accurate records of recovered quantities and batch codes.

## 9) Establish the course of action for recalled items (disposal/redistribution):

Once recovered, products may be corrected or reprocessed if deemed safe for human consumption. If unfit, they must be destroyed. The appropriate action must be approved by the competent Authority.

The FBO must:

- Determine the necessary action (e.g., correction, re-export, destruction).
- Confirm if the Authority requires verification or witnessing of the process.
- Ensure the action taken is effective and properly executed.
- Document all actions in the Recalled Product Records for accountability.

## 10) Resolve the root cause of the recall within the facility:

As the manufacturer of the unsafe product, you are responsible for taking all necessary steps to prevent future recalls. This includes implementing new controls or updating existing ones to avoid similar issues.

### 3.4 Recall Notification

Recall notification involves the process of notifying all relevant parties—such as customers, suppliers, retailers, and regulatory bodies—about a product recall. The goal is to ensure everyone is informed about the recall, understands the potential risks, and knows the appropriate actions to take.

(i) The recalling company must quickly inform each affected consignee about the recall. The **format**, **content**, and **extent** of the communication should match the risk level of the recalled product and align with the recall plan.

(ii) The recall notification should be sent via **email**, **fax**, **letter**, or a combination of these, clearly marked as "**Food Recall**" in bold red



text, and labeled "**urgent**". Any phone calls or personal contacts should be confirmed with written communication through one of these methods, and documented accordingly.

(iii) A recall notification should:

a) Be **concise** and **clear**.

b) **Clearly state** the product details, including size, lot numbers, codes, or serial numbers, along with any other necessary information to ensure correct identification of the recalled product.

c) Provide a **brief explanation** of the recall cause and any associated hazards.

d) Offer **specific instructions** on what steps should be taken regarding the recalled product.

e) Include an easy way for the recipient to confirm whether they possess the recalled product, such as using a **prepaid, self-addressed postcard** or by providing the option to make a **collect call** to the recalling company.

f) The recall notification should exclude any **irrelevant details**, promotional material, or any content that may distract from the main message. If needed, follow-up messages should be sent to those who haven't responded to the initial recall notification.

(iv) Consignees who receive a recall notification must ensure they follow the instructions provided by the recalling company and, if necessary, pass the recall information along to their own consignees, as outlined in paragraphs (ii) and (iii) of this article. The suggested format can be found in Annexure-III.

(v) The Food Business Operator (FBO) must notify consumers of the recall as quickly as possible, which can be done through a press release, letter to relevant parties, or a paid media advertisement. This notification should be labeled as a **Food Recall Notice** and must contain the following information:

a) The **name** of the FBO issuing the recall.

b) The **name** of the food product.

c) Details of the **contamination** or **violation** with the product.

- d) A "**do not consume**" warning if the food is unsafe.
- e) **Health warnings** and actions to take.
- f) The **locations** or **outlets** where the product is sold.
- g) Instructions for the consumer on the **necessary actions** to take.
- h) A **contact number** for any further inquiries.

## **2.5 Food Recovery:**

The recalling firm is responsible for ensuring that any recovered food products are stored in an area that is separate from other food items. Additionally, the firm must maintain accurate records of the recovered products, including their batch codes, and ensure that a proper recording system is in place to track all retrieved food products. If the recovered product is deemed safe for human consumption, the firm may correct or reprocess it in consultation with the relevant authorities (LCA) before it is re-released to the market. In cases where the product is not safe, the recalling firm must ensure its proper destruction.

## **2.6 Effectiveness Review:**

Throughout the recall, the recalling firm must perform effectiveness checks to ensure that all consignees at the designated recall level have been notified and have taken the necessary actions. The effectiveness will be evaluated based on the proportion of returned products compared to the total products shipped by the manufacturer, while also considering the product's retail sales.

## **2.7 Recall Status Reports:**

The recalling firm must submit periodic recall status reports to the Local Competent Authority (LCA) after the recall notification to assess its progress, with the frequency determined by the urgency and severity of the recall, as specified by the LCA/Food Authority in the notification (Article 2), but no less than every two weeks.

Unless otherwise stated, the recall status report should include the number of consignees notified, the date and method of notification, the number of consignees who did not respond and the quantity of food dispatched to them (with the LCA/Food Authority able to request non-

responding consignees' identities if needed), the number of products returned or corrected and the quantity accounted for, the number and results of effectiveness checks, the proposed method of disposal or destruction with records, the actions planned to prevent similar issues in the future, and the estimated timeframes for completing the recall.

A suggested format is provided in Annexure-IV. Recall status reporting will cease once the LCA/Food Authority terminates the recall, and the FBO is required to retain complete documentation on the recall for inspection and verification by the LCA/Food Authority.

## **PART 3- Responsibilities of Different Parties**

### **3.1 Responsibility of the FBO:**

The food business operator must have procedures and systems in place to track the businesses to whom they have supplied their food products. They are also required to collaborate with the Commissioner of Food Safety of the State or Union Territory, or the Food Authority, to take appropriate actions aimed at minimizing risks related to a specific batch, lot, or code of food they supply or have previously supplied. Additionally, the operator must remove the food from sale or distribution when directed by the Commissioner of Food Safety or the Food Authority, as applicable.

### **3.2 Responsibility of the Food Authority/LCA:**

The Food Authority and Local Competent Authority (LCA) play crucial roles in overseeing the execution of the recall plan. The Food Authority provides guidance and supervision to the Commissioner of Food Safety in the State or Union Territory, ensuring the effective implementation of the recall process. It may also assess reports from food business operators (FBOs) and issue necessary instructions.

The Food Authority can establish a ‘Food Recall portal’ on its website for monitoring recalls, assigning a unique identification number to each recall, and providing consumers with relevant information. Additionally, the Food Authority may publicize the recall if it deems necessary to alert the public about health hazards, depending on the severity of the situation, while keeping the concerned FBOs informed.

Meanwhile, the LCA supervises the FBO’s recall activities by inspecting the food products, advising the operator on necessary actions, and ensuring effective communication, including media releases for consumer awareness. The LCA also conducts audits if the FBO lacks proper recall procedures, monitors the recall progress, and provides follow-up guidance, including periodic inspections to verify

the recall's effectiveness. In cases involving exported Indian foods, the LCA liaises with the FBO to establish a recall plan and advises health authorities in the importing countries.

The Food Authority is kept informed of these processes and provides further instructions when necessary, ensuring coordinated and efficient recall management.

### **3.3 Responsibility of the Commissioner of Food Safety of the State or Union territory:**

The Commissioner of Food Safety of the State or Union Territory is responsible for supervising the recall process initiated by the food business operator, ensuring the operator's capability to conduct an effective recall after receiving the alert. This includes inspecting unsafe food after consumer complaints, taking appropriate actions as per the Act, and advising the operator to initiate a recall, in consultation with the Food Authority when necessary.

The Commissioner also prepares and issues media releases for recalls involving consumer safety, conducts audit checks if the operator cannot ensure recall effectiveness, and monitors the recall's progress, including the frequency of reporting. They oversee the operator's completion of the recall and assess the recall report, offering guidance for improvement where needed.

Additionally, the Commissioner handles the disposal or reprocessing of recalled food for imported products or Indian foods subject to recall in export markets and provides advice to health authorities in importing countries. Throughout the process, the Commissioner keeps the Food Authority informed and follows its instructions.

The LCA, similarly, supervises the recall, ensures the operator's effectiveness, conducts audit if required, and offers follow-up guidance, including verifying the disposal of recalled food. The LCA also monitors the recall's progress, advises on reporting frequency, and ensures that recalls are completed properly.

In the case of exported foods, the LCA works with the operator on the recall plan and provides necessary advice to health authorities in the importing countries. The LCA reports to the Food Authority, following its directions in all recall-related actions.

## **PART 4- The Legal Mandates**

### **4.1 How can an FBO issue a 'Food Recall Notice' or alert?**

A Food Business Operator (FBO) must swiftly inform consumers in the affected area about a food recall through a press release, letters to relevant parties, or media advertisements. This 'Food Recall Notice' must include:

- The name of the FBO initiating the recall
- Product details: name, brand, pack size, batch/code number, manufacturing date, and expiry/best-before date
- The reason for the recall, such as contamination or regulatory non-compliance
- A clear "Do Not Consume" warning
- Health risks and recommended actions
- Locations where the product is sold
- Instructions for consumers on the next steps
- Contact information for queries

Additional Requirements:

The press release must be issued within two hours of the recall notice. If required, a draft should be submitted to the relevant authority for approval before publication. Additionally, translations into regional languages must be arranged as needed to ensure clear communication with all affected consumers.

### **4.2 Is it required to update the Food Authority (CEO, FSSAI) on the progress and status of the recall?**

Yes, the Food Business Operator (FBO) must assess whether the recall is progressing effectively and submit periodic status reports to the concerned Commissioner of Food Safety (State/UT), the Designated Officer of the relevant district, and the CEO of FSSAI. These reports

should provide updates on the recall's progress. The FBO must ensure that all distribution and sales of the recalled product have ceased and that the recalled items have been returned to the responsible FBO. Additionally, the recall status report must include the details specified in Schedule-II of the FSS (Recall Procedure) Regulations, 2017, for submission to the appropriate authority.

### **4.3 Penalty**

Non-compliance with recall procedures can lead to serious penalties for food business operators (FBOs). The FSSAI and the Commissioner of Food Safety have the power to enforce regulatory measures if an FBO fails to initiate a recall or if the recall process is ineffective. These measures may include financial penalties or more severe actions such as suspension or revocation of licenses.

Additionally, imported food products are also subject to these regulations. Recalls may be initiated based on reports from international health and food authorities, ensuring that safety standards are upheld for all food products, whether domestic or imported.



## **Part 5 - Why Food Safety Works?**

Food Safety Works specializes in food safety consulting, regulatory compliance, and recall management support for food businesses. We help Food Business Operators (FBOs) develop and implement effective food recall plans, ensuring compliance with FSSAI's various Regulations. Our services include food safety audits, hygiene assessments, product testing, recall management support, and customized training programs to uphold the highest standards of food quality and consumer safety. By partnering with us, businesses can safeguard public health, minimize regulatory risks, and maintain consumer trust in their products.