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### FSSAI Publishes Guidelines on Food Recall

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**Report Highlights:**

The Government of India's Food Safety and Standards Authority of India published [Food Recall Guidelines](#).

## **General Information:**

**DISCLAIMER:** The information contained in this report was retrieved from FSSAI's website <http://www.fssai.gov.in/>. The Office of Agricultural Affairs and/or the U.S. Government make no claim of accuracy or authenticity.

On November 28, 2017 the Food Safety and Standards Authority of India (FSSAI) published food recall guidelines on its website. The guidelines not only explain the role of FSSAI and the industry in food recall but also step by step procedures a food business operator has to be follow to recall a food product. Earlier in January 2017, FSSAI published its Regulation on food recall procedures in the Indian Gazette (GAIN [IN7011](#)).

The full text of the guidelines published by FSSAI is pasted below and is also available on the website <http://www.fssai.gov.in/>.

## **GUIDELINES FOR FOOD RECALL**

### **Introduction**

Food on sale for human consumption must be wholesome, unadulterated, uncontaminated, properly labelled and fit for human consumption. Violation of the provisions in these regards may lead to regulatory action against the concerned FBO under the Act, or rules and regulations made thereunder.

### **food recall**

Food recalls are an appropriate method for removing or correcting marketed food products and their labelling that violate the laws administered by the regulatory authority. Recall can be defined as an action to remove food products from market at any stage of the food chain, including that possessed by consumer, which may pose a threat to the public health or food that violate the Act, or the rules or regulations made thereunder. Recall of food product is in the common interest of the industry, the government and in particular the consumer. Recalls afford equal consumer protection but generally are more efficient and timely than formal administrative or civil actions, especially when the product has been widely distributed.

Manufacturers and/or distributors should initiate a recall at any time to fulfil their responsibility to protect the public health from products that present a risk of injury or gross deception, or are otherwise defective. Firms may also initiate a recall following notification of a problem by Food Authority or a state agency, in response to a formal request by authority, or as ordered by Authority.

### **Purpose of this guideline**

The purpose of this guide is to provide an overview of how to develop a recall plan and how to implement that plan in the event of a recall. It will assist in identifying products which are unsafe that violate the Act, or the rules or regulations made thereunder and enable recall of the product(s) from the market place.

### **Role of the Food Authority**

The Food Authority's main role in a recall is to monitor the progress of the recall and assess the adequacy of the action taken by the FBO in this regard. After a recall is completed, the Food Authority will make sure that the product is destroyed or suitably improved. Where the recall is related to serious defects in the manufacturing process, the concerned authority may review the license of the FBO concerned.

The Food Authority will publicise the recall when it is of the opinion that the public need to be alerted about a health hazard or that clarification of the situation needs to be made to allay public worries.

In cases of public health emergencies, the Food Authority may, depending on the available evidence, alert the public before a decision on recall has been reached.

### **Role of the industry**

Food Business Operators carry the prime responsibility of implementing the recall, and for ensuring compliance with the recall procedure at its various stages including follow-up checks to ensure that recalls are successful and that subsequent batches of the food products are safe for human consumption.

If a food business operator considers or has reason to believe that a food which has processed, manufactured, distributed or imported is not in compliance with the food safety requirements, it shall immediately initiate procedures to recall the food in question from the market where the food has left the immediate control of that initial food business operator and inform the competent authorities thereof. Where the product may have reached the consumer, the operator shall effectively and accurately inform the consumers of the reason for its recall, and if necessary, recall food product from consumer that have already supplied to them.

A food business operator shall immediately inform the competent authorities if it considers or has reason to believe that a food which it has placed on the market may be unsafe for the consumers. FBO shall inform the competent authorities of the action taken to prevent risks to the final consumer and shall not prevent or discourage any person from cooperating, with national law and concerned authorities, where this may prevent, reduce or eliminate a risk arising from a food.

Food business operators shall collaborate with the concerned authorities on action taken to avoid or reduce risks posed by a food which they supply or have supplied.

### **Food recall plan**

All food business operators as prescribed in the regulation 7 of Food Safety and standards (Food Recall Procedure) regulations, 2017 must have an up to date recall plan as provided in Annex (Model recall Plan)- I. At the time of recall being carried out, the FBO shall submit their detailed recall plan to the CEO, FSSAI. A brief step by step procedure and its description are as below.

Assemble the Recall Management Team



Notify the authority



Identify all products to be recalled



Detain and Segregate all products to be recalled which are in your firm's control



Prepare and distribute the information of recall including Press Release



Prepare the Distribution List



Verify the effectiveness of the recall



Control the recalled product(s)



Decide what to do with the recalled product(s)



Fix the cause of the recall if the problem occurred at your facility

## Conducting a recall plan

### Step 1: assemble your recall management team

At the very beginning of the recall the FBO should initiate the formation of recall management team and assign the recall duties to each person and should ensure that all members of the recall management team are informed of the decision to conduct a recall and each member knows their responsibilities during the recall.

The team should include people responsible for:

1. Decision making
2. Quality assurance / technical advisory
3. Media communication
4. Complaint investigation
5. Contacting accounts
6. Food Authority Contact
7. Legal Counsel

The management team document should contain the following:

RECALL MANAGEMENT TEAM				
NAME	ALTERNATE PERSON	BUSINESS PHONE	AFTER HOURS PHONE	RESPONSIBILITIES DURING RECALL

### Step 2: Inform the authority

Inform the concerned regulatory authority at the earliest opportunity, after an incident is identified that may lead to a recall and should be updated throughout the process. The information should include the following:

- a detailed description of the nature of the problem
- the name, brand, size, lot code(s) affected
- details of complaints received and any reported illnesses
- the distribution of the product - local or national
- when was the product distributed (specific dates)
- label(s) of the product(s) which may be recalled
- the total quantity of product manufactured and distributed
- the name of your firm's contact with the authority
- the name and telephone number(s) for your firm's after-hours contact

the detailed information is given under Schedule I of FSS (Recall Procedure) Regulations, 2017

### **Step 3: identify all products to be recalled**

It is the responsibility of FBO to ensure that all products which need to be recalled are identified. In addition to those products directly affected by the problem, the FBO should:

- determine if any other codes, brands or sizes of the same product are affected
- determine if any other products are affected

### **Step 4: detain and segregate products to be recalled which are in your firm's control**

The FBO should ensure that all products to be recalled that are in your firm's control are not distributed and;

- determine the locations of the recalled product(s) e.g. on-site, at the plant, off-site storage
- determine the amounts at each location
- identify and segregate products to prevent distribution

### **Step 5: prepare and distribute the information of recall**

**Informing the Consumer:** - Depending on the extent of the recall, the company concerned should inform the consumer of the recall at the earliest possible moment. Information dissemination may take the form of a press release, letter to the concerned parties or paid advertisement in the media. Sufficient telephone hotline service should be made available to deal with enquiries.

**Information within the Food Chain:** - The FBO shall inform everyone in the food chain from the raw material vendor to the supplier and any other relevant retailer or trade association of the affected food by written communication, phone, e-mail, fax, or a combination of thereof.

The press release, letter or advertisement shall be in the form of 'Food Recall Notice' and shall contain the following information, namely: -

- Name of the Food Business Operator recalling the food;
- Name of the food, brand name, pack size, batch and code number, date of manufacture, used by date or best before date;
- The contamination or violation in the food or reason for such recall;
- "do not consume message";
- Health warning and action;
- The places or outlets where the food is found;
- The action to be taken by the consumer;
- Contact number for queries.

The FBO must:

- complete the press release within two hours after being notified of the recall

- submit a draft of the proposed Press Release, if required, to the concerned Authority for approval
- arrange for translation of the press release for concerned region

**Step 6: prepare the distribution list**

Keeping accurate distribution records allows to limit the recall to the specific accounts that received the product being recalled. Using the distribution record system, produce a **product and lot code specific** distribution list which:

- identifies the accounts that received the recalled product
- lists the accounts names and addresses, contact names and telephone numbers
- identifies the type of account e.g., manufacturer, distributor, retailer

**Step 7: verify the effectiveness of the recall**

The food business operator should determine whether the recall is progressing effectively and submit periodic status reports to the concerned authority to inform the progress of the recall. FBO shall submit the periodic recall status report once in a week or as otherwise specified by the concerned authority

To conduct an effective recall, the FBO should maintain the food distribution records which include Name and address of suppliers and distributors, date of purchase of raw material, batch code, lot number and complete traceability from Raw material to finished good.

The FBO must;

- verify that all accounts have stopped distributing and selling the recalled product(s)
- verify that the recalled product(s) have been returned to the

**Step 8: control of the recalled product(s)**

The product is to be recovered to a central site, or in the case of widely distributed product, to major recovery sites. The recovered product must be stored in an area which is separated from any other food product. Accurate records are to be kept of the amount of recovered product and the batch codes of the product recovered.

It is the responsibility of the FBO to ensure that recalled products do not re-enter the market.

- separate and clearly identify recalled product(s)
- reconcile quantities and monitor returned product(s)
- record the recalled product(s) in Recalled Product Records document

### **Step 9: decide what to do with the returned product**

After recovery, products may be corrected or reprocessed before release to the market if it is fit for human consumption. Otherwise the product is to be destroyed. The action to be taken on the recalled product should be approved by the competent Authority

- decide on the action to be taken on the recalled product e.g., correction, re-export, destruction
- find out if the Authority wants to witness/verify that the action has been taken
- verify that the action has been effective
- record the action taken for each product in your Recalled Product Records document

### **Step 10: fix the cause of the recall**

As the manufacturing firm that produced the unsafe product, it is your responsibility for ensuring that all reasonable steps are taken to prevent similar recalls in the future.

- put controls in place or revise existing controls to prevent similar problems in the future

**(Insert FBO Name) Recall plan**

In the event that if any of our products, that presents a threat to the public health or food that violate the Act and Rules and Regulations made there under \_\_ **(Insert name of FBO)** \_\_ will protect public health by facilitating the efficient, rapid identification and removal of unsafe food from the distribution chain and, by informing consumers of the presence in the market of such food.

There is a documented recall procedure in place and this will be periodically tested to ensure that it is comprehensive and fit for purpose in its ability to remove an unsafe food from consumers and/or the distribution chain.

**Recall Procedure**

**Introduction**

This procedure states the action/s \_\_ **(Insert name of FBO)** \_\_ will take to effectively manage the food recall in case the food does not meet the requirements of the hygiene, safety and quality of food as well as protect the health of consumers

An effective product recall will ensure that the unsafe or food that violate the Act and Rules and Regulations made there under is contained and either destroyed or rendered safe.

We will refer to and follow instructions when required which are laid out in the following documents:

- Food Safety and Standards (Food Recall Procedures) regulation, 2017
- FSSAI Website ([www.fssai.gov.in](http://www.fssai.gov.in))
- Guidelines for food recall plan

**Roles and Responsibilities**

It is our \_\_ **(Insert name of FBO)** \_\_ responsibility to effectively organise and manage the recall of food that presents a threat to the public health or food that violate the Act and Rules and Regulations made there under and to formulate a broad level recall plan as per FSSAI guideline on recall plan.

The recall co-ordinator for the site is \_\_ **(insert name)** \_\_ who has been given authority from management to make recall decisions on behalf of \_\_ **(Insert name of FBO)** \_\_. When a recall is initiated, our actions in recalling the affected food/s need to be co-ordinated with the \_\_ **(insert the name of concerned Authority)** \_\_

We shall notify \_\_ **(insert the name of concerned Authority)** \_\_ as soon as a recall is likely to be initiated. It is our responsibility to manage the recall by clarifying the food safety issue and the exposure (who and where risk exists), and to provide details on distribution and the method of recall.

**The Recall management team**

The recall co-ordinator \_\_ **(insert name)** \_\_ will initiate the formation of a recall management team and will co-ordinate actions with \_\_ **(insert the name of Concerned**

**Authority)**\_\_\_\_ and our marketing and distribution agents. Committee members will include personnel from across our **\_\_(Insert name of FBO)\_\_** Typically the committee would be like

**(Insert name of FBO) RECALL PLAN**

Company name: \_\_\_\_\_

Address: \_\_\_\_\_

Phone No. \_\_\_\_\_

Products produced \_\_\_\_\_

RECALL MANAGEMENT TEAM				
NAME	ALTERNATE PERSON	BUSINESS PHONE	AFTER HOURS PHONE	RESPONSIBILITIES DURING RECALL

The recall management team is responsible for the management of all recall activities and to adhere to this procedure. Duties of the recall management team are to:

- assess the overall problem;
- notify the relevant regulatory authority;
- evaluate the hazard in the food and the extent of contamination;
- determine a strategy to be followed;
- make decisions about product still in manufacture or in storage;
- notify insurers.

**Recall Actions & Documentation**

The recall management team shall reference and follow the actions outlined in the Safety and Standards (Food Recall Procedures) regulation, 2017 when we become aware a product may be unsafe or food that violate the Act and Rules and Regulations made there under. We will ensure that records of all actions and decisions and who was responsible are recorded and retained.

**Decision to Recall**

The decision to recall will be submitted to **\_\_(insert the name of Concerned Authority)\_\_\_\_**

**Notification of a product recall**

If the decision is taken to initiate a recall, we will notify:

- Senior management of **\_\_ (Insert name of FBO) \_\_**, supply chain personnel
- Food Authority.
- Anyone that has received our product, including distributors, wholesalers, retailers and caterers.
- Consumers, via the media contacts included on our contact list.

The contact list must contain the contact details for the following:

- The products recall committee and senior management and key company personnel.
- Suppliers of all ingredients.
- Downstream Food Business Operator and business customers.
- Sources of technical advice and support including laboratory facilities.
- Regulatory Authorities.

### **Regaining control of affected stock**

The recovered product/s will be stored in an area that is separated from any other food products. Accurate records will be kept of the amounts recovered and the codes of the product/s. If the recovered product/s is unfit for human consumption, it may be destroyed or denatured under the supervision of the company management and/or the regulatory authority where legally required.

If the food safety risk can be safely removed from the recovered product/s through relabelling or reprocessing this may be done once it is clear that public health will be protected.

### **Recall Status report**

Periodic status reports will be submitted to the CEO, FSSAI after the notification of the recall for assessing the progress of the recall.

The frequency of such reports will be determined by the relative urgency/gravity of the recall and will be specified by the concerned food authority for each recall. However, in any case the reporting interval shall not be more than 1 week.

The recall status report should contain information specified under Schedule II of Food Safety and Standards (Food Recall Procedure) Regulations, 2017.

### **Post recall report**

Recall management team will submit post recall report to the CEO, FSSAI after the completion of the recall to assess the effectiveness of the recall.

In addition, .....(**insert the name of FBO**) ... will investigate the reasons that led to such recall and will take action to prevent recurrence of the problem.

### **Termination of a recall**

.....(**insert the name of FBO**) ... may request termination of the recall by submitting a written request to the CEO, FSSAI along with the latest recall status report stating that the recall was effective.

The recall will be terminated when the concerned food authority determines that all reasonable efforts have been made in accordance with the recall strategy and it is reasonable to assume that the food product subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled food product. Written notification that a recall is terminated will be issued by the Food authority to the company.

In case of unsatisfactory reports, the concerned food authority may consider further action like stepped-up inspection, seizure or any other legal action, against the .....**(insert the name of FBO)** ....

### **Follow up action**

We..... **(insert the name of FBO)** ... will submit an interim report as soon as recall is completed to the regulatory authorities within an agreed timeframe of the closure of the recall in any case not later than thirty days after the completion of a recall. The final report will include the elements outlined in the FSS (Food Recall Procedure) Regulations, 2017.