

**FOOD SAFETY AND STANDARDS AUTHORITY OF INDIA
FOOD AND DRUG ADMINISTRATION BHAWAN
KOTLA ROAD, NEW DELHI – 110 002**

DRAFT REGULATIONS ON FOOD RECALL PROCEDURE

DRAFT NOTIFICATION

In exercise of powers conferred by section 28 (4) read with section 92 (2) (m) of Food Safety and Standards Act, 2006 (34 of 2006), with the previous of the Central Government and after previous notification, Food Safety and Standards Authority of India hereby makes the following regulations.

CHAPTER-1

Article 1: Short title and commencement: These regulations may be called Food Authority's Food Recall Procedures Regulations, 2009 and shall come into force from date of notification.

Article 2: Definitions- In these regulations, unless the context otherwise requires:

- (i) "Act" means the Food Safety and Standards Act, 2006.
- (ii) "Consignee" means anyone who received, purchased or used the recalled food product.
- (iii) "Depth of recall" means the extent of distribution and the level to which the recalled food product was distributed.
- (iv) "Firm Initiated Recall" means a recall prompted by the company making or distributing a food product, without getting notification or suggestion by the Local Competent Authority.
- (v) "Food Authority Initiated Recall" means a recall initiated at the direction of the Food Authority/Local Competent Authority under specific circumstances.
- (vi) "Food Authority" means the Food Safety and standards Authority of India established under section 4 of the Act.
- (vii) "Food Business Operator (FBO)" in relation to food business means a person by whom the business is carried on or owned and is responsible for ensuring the compliance of the Act, rules and regulations made there under.
- (viii) "Food Business" means any undertaking whether for profit or not and whether public or private, carrying out any of the activities related to any stage of manufacture, processing, packaging, storage, transportation, distribution of food, import and includes food services, catering services, sale of food or food ingredients.
- (ix) "Local Competent Authority (LCA)" means Commissioner of the State Food Authority of the local area appointed under Section 30 of the Act or any other person authorized by him for the purpose.
- (x) "Public warning" means alert to the public by Food Authority or Local Competent Authority or by a firm of its own with approval of Food Authority, that the food product being recalled presents a health hazard.
- (xi) "Recall Plan" means a written set of procedures, practices and actions developed and put in place by firm for food product recall.
- (xii) "Recall" means action taken to remove a marketed food product from distribution, sale and consumption that may pose a safety hazard to consumers.
- (xiii) "Recalling Firm" means the company with primary responsibility for the manufacture and distribution of the recalled food product.
- (xiv) "Seizure" means an action by Food Authority to take possession of food products in order to remove them from the commerce stream.

All other words and abbreviations, which are not defined under these regulations, shall have the same meaning and definition/interpretation as given in the Act or rules & regulations laid there under.

CHAPTER – 2

ARTICLE 3: OBJECTIVES AND SCOPE OF FOOD RECALL

- (i) The objectives of food recall guidelines are:

- To guide FBOs on how to carry out a food recall by facilitating the efficient, rapid identification and removal of unsafe food from the distribution chain and by informing consumers (where necessary) of the presence on the market of potentially hazardous food and ensuring that unsafe food are contained and destroyed or rendered safe;
 - To guide FBOs on how to establish a written recall plan for carrying out food recall in order to ensure the hygiene, safety and quality of food and to protect the health of consumers; and
 - To establish a follow-up action/post recall report in order to ensure the effectiveness of the recall and prevent a repetition.
- (ii) Recall may be carried out voluntarily by manufactures and distributors to remove unsafe food from the market to prevent injury to consumers. Seizure or other court action may be taken when a firm refused to undertake a recall directed by the LCA, or where the LCA/Food Authority has sufficient reasons to believe that a recall would not be effective, determines that a recall is ineffective, or discovers that a violation is continuing. The cost incurred by the LCA/Food Authority for carrying out such actions will be recovered from the firm responsible for such violation. In addition to recovery of cost, such firm will also be liable for penalties or punishments in terms of chapter IX of the Act.
- (iii) Recalls are to be carried out in the shortest time practicable to minimize risk involved.
- (iv) In common interest of the consumer and industry, recall guidelines provide for stopping distribution and sale of the affected food product; informing the LCA (all recalls) and the public (under specific circumstances) of the problem; effectively and efficiently remove the potentially unsafe food product from the marketplace.
- (v) All food businesses engaged in the wholesale supply, manufacture or importation of foods regulated by Food Authority must have a up-to-date recall plan except food retailers, unless they are also engaged in the wholesale supply, manufacture or importation of food. Food businesses within the food service sector such as restaurants and takeaways are exempted to have recall plan unless they are running multi-outlet food business chains having integrated manufacturing and distribution network. However, such food businesses in the food service sector may be part of another business recall i.e. they may need to remove recalled stock from the shelves and return it to the manufacturer, importer or wholesaler. A recall plan must be in written form and should be made available to LCA/Food Authority on request.
- (vi) Recall guidelines outline the procedures which are expected to enhance efficiency and transparency in the recall of food products and are intended to enhance public understanding, improve customer protection and to assure uniform and consistent application of food recall procedures throughout the country.
- (vii) Food Authority will make available a description of each new food recall (bearing a unique identification number) to the public through its portal. The Food Authority may maintain confidentiality of commercially sensitive information as and when necessary upon specific request of recalling firm. The Food Authority may delay public notification of food recalls where ever it determines that public notification may cause unnecessary and harmful panic among consumers.

CHAPTER – 3 **FOOD RECALL PROCEDURE**

ARTICLE 4: INTIATION OF FOOD RECALL:

- I. Firm Initiated Recall:**
- (i) A firm, either of its own or through any other sources viz. Wholesaler, distributor, retailer, exporter, importer, consumer, media etc., coming to know that any of its food product ids unsafe or deficient violating provisions of the Act and rules & regulations made there under, may initiate a recall. In such situations, the firm is required to submit a recall alert notification as per Annexure I to LCA immediately but not later than 24 hours. To ensure speedy communication, such alert

can be sent by fax, e-mail, on-line and/or by post. The LCA will inform of such recall alerts to Food Authority within 24 hours of receipt.

- (ii) Recalling firm will stop any further production and distribution of the food product under recall without waiting for LCA response so as to ensure that consumer safety is not compromised.
- (iii) The LCA will notify the firm (within 48 hours) of its determination and of the need to begin immediately a recall of the food product with a copy of the same to Food Authority. Such notification will be by letter,, e-mail, Fax or telegram to a responsible official of the firm and will specify the violation, the health hazard classification of the violative food product, the recall plan, and other appropriate instructions for conducting the recall.
- (iv) The FBO may initiate a recall at any time to fulfill their responsibility to protect public health from food that is unsafe for the consumer or is not in compliance with the Act and the rules and regulations made there under.
- (v) A recall may be initiated as a result of complaints referred to the FBOs from a variety of sources. The reports may be referred by manufactures, wholesalers, importers, distributors, retailers, consumers, media, government agencies and Food Authority or State Food Authorities. In case the FBO does not respond to the complaint, complainant/consumer may report to the LCA which will take steps to determine the need for recall and instructs the firms involved accordingly.
- (vi) A recall of food manufactured overseas may also be initiated by reports of health authorities, or from information received directly from such authorities or otherwise.

II. Food Authority Initiated Recall

- (i) The LCA / Food Authority may direct a firm to initiate a recall if a food product manufactured and distributed by him poses a health hazard or violation and the firm has not initiates a recall on its own.
- (ii) The LCA will notify the firm of its determination and of the need to begin immediately a recall of the food product with a copy of the same to Food Authority. Such notification will be by letter, e-mail, fax or telegram to a responsible official of the firm and will specify the violation, the health hazard classification of the violate food product, the recall plan, and other appropriate instructions for conducting the recall. A suggested format is at Annexure-II.
- (iii) On such directions, the firm shall execute the recall and will stop any further distribution of the food product under recall so as to ensure that it does not reach the consumer. At the same time the recalling firm will provide a recall alert as per Annexure I to the LCA. The LCA will inform Food Authority of such recall alerts within 24 hours of receipt.

ARTICLE 5: RECALL CLASSIFICATION

The LCA/Food Authority will evaluate the health hazard posed by a food product under recall and categorize the recalls as

- (i) Class I Recalls: for dangerous or defective food products that cause serious health problems or even death.
- (ii) Class II Recalls: for food products that are unlikely to cause any adverse health problems, but that violate the Act and the rules & regulations made there under.

ARTICLE 6: RECALL PLAN

- (i) Within 6 months of this notification coming into effect, each firm should frame its proposed recall plan taking into account; results of health hazard evaluation/classification; ease/challenges in identifying the product degree to which the food product's deficiency is obvious to consumer, degree to which the food product remains unused in the marketplace and submit to the same to LCA.
- (ii) The LCA will review the adequacy of a proposed recall plan developed by a recalling firm and recommend changes as appropriate. The recalling firm should conduct the recall in accordance

with an approved recall plan but need not delay initiation of a recall pending review of its recall plan.

- (iii) A recall plan should invariably outline the depth of recall indicating the level i.e. Wholesale/distributor level; Retail level; Consumer/End user level.
- (iv) Wherever the urgency/gravity of the situation so demands, LCA/Food Authority in consultation with the recalling firm will issue a public warning. The recall plan will specify the need for such public warning and the media likely to be used for effective and speedy dissemination of such information. In all cases, the cost of such public warning will be borne by the recalling firm.
- (v) In case of recalls involving exported food products; Food Authority will specifically monitor the recall strategy. The LCA needs to keep Food Authority fully informed in all such cases of the proposed recall plan. Food Authority may also consider communicating with the regulatory bodies of the importing countries for effective recall of such food products.

ARTICLE 7: RECALL COMMUNICATION

- (i) The recalling firm is responsible for promptly notifying each of its affected consignees about the recall. The format, content, and extent of a recall communication should be commensurate with the hazard of the food product being recalled and the plan developed for recall
- (ii) Such recall communication should be accomplished by e-mail, fax, letter or combination thereof; conspicuously marked "Food Recall" preferably in bold red type. The communication should also be marked "urgent". Telephone calls or other personal contacts should ordinarily be confirmed by one of the above methods and documented in an appropriate manner.
- (iii) A recall communication should be:
 - a) Brief and specific;
 - b) Identify clearly the food product size, lot number(s), code(s) or serial number(s) and any other pertinent descriptive information to enable accurate and immediate identification of the food product.
 - c) Explain concisely the reason for the recall and the hazard involved if any;
 - d) Provide specific instructions on what should be done with respect to the recalled food products;
 - e) Provide a ready means for the recipient of the communication to report to the recalling firm whether it has any of food product in question, e.g. by sending a postage-paid, self addressed postcard or by allowing the recipient to place a collect call to the recalling firm.
 - f) The recall communication should not contain irrelevant qualifications, promotional materials, or any other statement that may detract from the message. Where ever necessary, follow up communications should be sent to those who fail to respond to the initial recall communication.
- (iv) Consignees who receive a recall communications should importantly carry out the instructions set forth by the recalling firm and, wherever necessary, extend the recall to its own consignees in accordance with paragraphs (ii) and (iii) of this article. The suggested format is at Annexure-III
- (v) The FBO shall inform the consumer of the recall at the earliest possible moment which may take the form of a press release, letter to the concerned parties or paid advertisement in the media. Such press release, letter or advertisement shall be in the form of Food Recall Notice and shall contain the following information :
 - a) Name of the FBO recalling the food.
 - b) Name of the food
 - c) The contamination/violation in the food
 - d) The "do not consume message" if the food is unsafe
 - e) Health warning and action
 - f) The places/outlets where the product is found.
 - g) The action to be taken by the consumer.
 - h) A contact number for queries.

ARTICLE 8: FOOD RECOVERY

- (i) The recalling firm is liable to ensure that the food product recovered as a result of recall must be stored in an area which is separated from any other food product
- (ii) The recalling firm is liable to maintain accurate records of the recovered food product and their batch codes. Proper recording system must be available to ensure all food products are retrieved.
- (iii) Recalling firm may correct or reprocess the recovered food product in consultation with LCA before release to the market if it is fit and safe for human consumption. In all other cases, the recalling firm will ensure appropriate destruction of such product.

ARTICLE 9: EFFECTIVENESS CHECK

During the recall, recalling firm is required to carry out effectiveness checks to verify that all consignees at the recall depth specified by the strategy have received notification about the recall and have taken appropriate action. The effectiveness of the recall will be assessed based on the amount of food product returned as a percentage of the amount of food product which left the manufacturer, while taking into account the retail turnover of that food product.

ARTICLE 10: RECALL STATUS REPORTS:

- (i) The recalling firm is required to submit periodic recall status reports to the LCA 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 LCA/Food Authority in each recall case in the notification at Article 2. However, in any case the reporting interval should not be more than 2 weeks.
- (ii) Unless otherwise specified or inappropriate in a given recall case, the recall status report should contain the following information:
 - a) Number of consignees notified of the recall and date and method of notification.
 - b) Number of consignees that did not respond to the recall communication and quantity of food products dispatched at their end. (if needed, the identify of non responding consignees may be requested by the LCA/Food Authority)
 - c) Number of food products returned or corrected by each consignee contacted and the quantity of products accounted for
 - d) Number and results of effectiveness checks that were made
 - e) The proposed method of disposal or otherwise of recalled stock with record of destruction;
 - f) The action proposed to be implemented in future to prevent recurrence of the problem
 - g) Estimated time frames for completion of the recall.

A suggested format is at Annexure-IV
- (iii) Recall status are to be discontinued when the recall is terminated by LCA/Food Authority
- (iv) The FBO shall properly retain complete documentation on food recall for inspection and verification by the LCA/Food Authority.

ARTICLE 10: TERMINATION OF A RECALL:

- (i) A recalling firm may request termination of its recall by submitting a written request to the competent authority along with latest recall status report stating that the recall was effective. A suggested format is at Annexure-V
- (ii) A recall will be terminated when the Food Authority/LCA 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/LCA to the recalling firm.
- (iii) In case of unsatisfactory reports the LCA/Food Authority may consider further action like stepped-up inspection, seizure or any other legal action, against the recalling firm.
- (iv) The completion of either a firm initiated recall of Food Authority initiated recall does not preclude the LCA from taking further regulatory action against a responsible FBO.

ARTICLE 11: ROLE OF LOCAL COMPETENT AUTHORITY

- (i) The LCA shall supervise the recall by the FBO and inspect the FBO's capacity of recall after receiving the recall alert notification. The work of the LCA shall include the following:
 - a) Inspect the violating food after receiving complaint from the consumer, taken action by law and advise the FBO to recall such food.
 - b) In recalls involving consumers, and where warranted liaise with the FBO to prepare a media release for immediate use by the media.
 - c) Conduct audit checks selectively when the FBO is unable to check the effectiveness of its recall due to lack of distribution records and procedure.
 - d) Advise the FBO who has submitted an incomplete recall proposal to make improvements.
 - e) Give instruction on the frequency of reporting the condition of recall, subject to the urgency of the case, and monitor the FBO's recall progress.
 - f) Supervise the FBO in its completion of recall and assess their recall report.
 - g) Offer follow-up guidance to the FBO; conduct periodic inspections to ascertain the extent of recall accomplished; file relevant recall information and issue the necessary press release.
 - h) Monitor the effectiveness of the recall notification, correction or removal, verify appropriate food disposal and terminate the recall.
 - i) Where exported Indian made foods are subject to recall, liaise with the FBO in order to determine
 - The recall plan for the exported foods;
 - The form of advice about the recall to be given to health authorities in the importing countries.
- (ii) The Food Authority shall be kept informed by the LCA in the execution of the above work and will be guided by such instructions as it may give.

FOOD RECALL ALERT NOTIFICATION FORMAT
(To be given on Recalling firm's letterhead)

To
Food Authority/Local Competent Authority

1.	Name and Address of the Recalling Firm	
2.	Name , designation and Contact details of person who should be contacted	
3.	Identity of the Product (brand, code, type etc.)	
4.	Reason for recall	
5.	Date and circumstances under which product deficiency was discovered	
6.	Evaluation of the risk involved with deficiency(if any testing done, results should be indicated)	
7.	Total amount of product produced	
8.	Time span of production	
9.	Total amount of product in distribution channels	
10.	detailed distribution Information(level of distribution, No. of direct accounts, Identity of direct accounts if possible)	
11.	Copy of recall communication(if already issued otherwise proposed communication)	
12.	Action already taken and proposed strategy for recall	
13.	Any other relevant information	

*Please attach extra sheets if space is insufficient

Signature and title

Date

(Recalling Firm)

FOOD RECALL NOTIFICATION FORMAT
(to be given by the local competent authority)

Date: _____

To

<Responsible Official>

Recalling firm

Ref: your food recall alert notification no. _____ dated _____

Dear _____

Based on the information provided in your above referred food recall alert notification, the competent authority has made the following determination and direct you to immediately recall the product from market. The authority may also kept apprised of the status till termination of recall.

Food Authority's Unique Identification No. for recall _____

LCA Contact: _____ Phone: _____ Email: _____

Product Brand: _____ Product code: _____

Violation involved in the product: _____

Health Hazard classification of the product: _____

Suggested recall plan for the product: _____

Public warning (required or not required) _____

(if yes, the content of warning and media to be used for such warning)

Period/Interval for submission of Recall Status Report: _____

If you have further questions, please do feel free to contact us. Thank you for your assistance

Signature and title

date

(The Local Competent Authority)

FOOD RECALL ALERT COMMUNICATION FORMAT
(to be given on Recalling firm's letterhead)

FAX/Letter template

To

All consignees of Recalled Food Product
(Distributors/ Wholesalers/ Retailers/ Restaurants)

URGENT!

FOOD RECALL(should be in bold red type)

Food Authority's unique identification number for recall _____

Date: _____

Our firm is voluntarily recalling _due to (reason for recall) __. it may not meet company quality standards, and/or may represent a small/moderate/serious (CHOOSE one word)health or safety threat to people who use it.

Please follow these instructions to ensure a successful recall:

*Immediately discontinue selling or distributing your existing stock of ____ (brand , name , code of product, package size etc)___.

*Inform us of the quantity of product you have on hand by completing the bottom portion of this form .Sign the form and return it by FAX to (FAX no.) as soon as possible.

*DO NOT dispose off this product! Instead: (Choose one of the two options)

(Wait for further instructions from ____ (their sales rep)___) OR

(Return the recalled product to ____ (name of firm's contact person)___ as soon as possible).

If you have distributed any of the recalled products, please immediately:

- Contact your consignees by telephone and in written to advice them about the recall
- Instruct them to return their unused, undestroyed stock to (recalling firm or supplier).
- Instruct them to also notify any of their consignees, which may have received the recalled product.

Thank you for your cooperation! If you have any questions regarding this recall, please feel free to contact ____ (firm's contact person)___ at ____ (phone)___.

Sincerely,

(Recalling Firm Representative)

CUSTOMERS NAME: _____

QUANTITY ON HAND: _____ cases/cans/packages(Circle one)

Owner's Name-Please Print

Owner's Signature

ANNEXTURE-IV

FOOD RECALL STATUS REPORT FORMAT
(to be given on Recalling firm's letterhead)

Date: _____

Food Authority's Unique Identification No. for recall _____

Product Brand: _____ Product code: _____ Date Code: _____

Food Authority Contact: _____ Phone: _____

Email Address : _____

Dear _____:

(recalling firm) hereby submits the following recall Status report regarding the above-listed product.

1. Notification

- a. total number of Consignees identified: _____
- b. number of Consignees notified: _____
- c. Method of notification (check all that apply):
 1. Letter _____
 2. Phone _____
 3. FAX _____
 4. Email _____
 5. Other ___(specify)_____

2. Consignee Response

- a. total number of consignees responding : _____
- b. total number of consignees not responding : _____
- c. total quantity of products dispatched at Non-responding consignees end: _____
- d. Number/amount pf product returned by each consignee:
 1. Consignee1 _____
 2. Consignee2 _____
 3. Consignee3 _____
 4. Consignee4 _____
 5. Consignee5 _____
- e. quantity of product accounted for: _____

3. Effectiveness Checks

- a. Total number required: _____
- b. Total number completed: _____
- c. Completion date: _____

4. Estimated recall completion date: _____

5. Proposed method of disposal of recovered stock/record of destruction:

6. Actions proposed to avoid recurrence in future

Please let us know if you require additional information.

Sincerely,

Signature and title

Date

(Recalling Firm) _____

FOOD RECALL TERMINATION REQUEST FORMAT
(to be given on Recalling firm's letterhead)

Date: _____

To

The Local Competent Authority/ Food Authority

Food Authority's Unique Identification No. for recall _____

Product Brand: _____ Product code: _____ Date Code: _____

Food Authority Contact: _____ Phone: _____ Email: _____

Ref: Request for Recall Termination

Dear _____

_____(Recalling firm name)__ initiated a Class __ recall of the above-listed product on ____ (date) __ that extended to the ____ level. Proper consignees notification was made by phone , fax, email, mail and personal visits, and records of these notifications have been provided to your office.

An Effectiveness Check Level of ____ was assigned to this product. _____ (Recalling firm) __ therefore contacted a total of ____ consignees, __ of which replied with the requested information.

all requested status reports have been filed within the proper timeframes, and the latest report is being submitted with this request .__(recalling firm) __ believes the above-listed product has been successfully recalled in accordance with the recall strategy(reviewed and approved by LCA)requirements.
<ADD Additional data here if necessary.>

In light of this successful and conscientiously executed recall, __ (recalling firm) __ hereby request that this food product recall be terminated, and that __ (Recalling firm) __ be provided with written confirmation of the termination.

If you have further questions, please do feel free to contact us. Thank you for your assistance.

Signature and title

Date

_____(Recalling Firm)_____