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FSSAI Publishes Final Regulations on Food Recall Procedures

Report Categories:

Sanitary/Phytosanitary/Food Safety

Exporter Guide

Food and Agricultural Import Regulations and Standards - Narrative

Approved By:

Jonn Slette

Prepared By:

Radha Mani

Report Highlights:

The Government of India's (GOI) Food Safety and Standards Authority of India (FSSAI) published the [Food Safety and Standards \(Food Recall Procedure\) Regulations, 2017](#). The updated regulation includes specifics about food recall procedures for manufactures, processors, distributors, sales, importers and exporters.

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 January 25, 2017, FSSAI published its regulation on food recall procedures in the Indian Gazette. The regulations include detailed procedures to recall food from the market at any stage of the food chain, including the food possessed by consumers. The following chapters and schedules are covered under the regulation:

Chapter I: General

Chapter II: Objectives

Chapter III: Scope

Chapter IV: Food Recall Procedure

Schedule I: Food Recall Information

Schedule II: Food Recall Status Report Format

Schedule III: Food Recall Termination Request Format

Interested readers are advised to review the text of the regulation provided below or access it from FSSAI's website: <http://www.fssai.gov.in/>.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Food Safety and Standards Authority of India)

NOTIFICATION

New Delhi, the 18th January, 2017

F. No. 1-59/FSSAI/2009.—Whereas the draft of the Food Safety and Standards (Food Recall Procedure) Regulations, 2015, were published as required by sub-section (1) of Section 92 of the Food Safety and Standards Act, 2006 (34 of 2006), *vide* notification of the Food Safety and Standards Authority of India number F. No. 1-59/FSSAI/2009, dated the 22nd April 2015, in the Gazette of India, Extraordinary, Part III, Section 4, inviting objections and suggestions from the persons likely to be affected thereby, before the expiry of the period of sixty days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas the copies of the said Gazette were made available to the public on the 29th May 2015;

And whereas the objections and suggestions received from the public in respect of the said draft regulations have been considered by the Food Safety and Standards Authority of India;

Now, therefore, in exercise of the powers conferred by clause (m) of sub-section (2) of section 92 read with sub-section (4) of section 28 of the Food Safety and Standards Act, 2006, the Food Safety and Standards Authority of India hereby makes the following Regulations, namely: -

Food Safety and Standards (Food Recall Procedure) Regulations, 2017.

CHAPTER-I

GENERAL

1. **Short title and commencement.**—(1) These regulations may be called as the Food Safety and Standards (Food Recall Procedure) Regulations, 2017.
- (2) They shall come into force on the date of their publication in the Official Gazette.
2. **Definitions.**—(1) In these regulations, unless the context otherwise requires,
 - (a) “**Act**” means the Food Safety and Standards Act, 2006 (34 of 2006);
 - (b) “**food chain**” for the purposes of these regulations includes food involved in manufacture, processing, distribution, sale, import and export;
 - (c) “**food recall**” means the action to remove food from the market at any stage of the food chain, including that possessed by consumers;
 - (d) “**food recall plan**” means the procedures and arrangements that a food business operator shall have in place to retrieve food and food products from the food chain if a problem arises.;
 - (e) “**food under recall**” means the specific lot or batch or code number of food product that has been determined by the Food Authority or the Commissioner of Food Safety of the State or Union territory or the Food Business Operator as not in compliance with the Act or rules or regulations made thereunder;
 - (f) “**recall alert**” means any alert issued to the public by the Chief Executive Officer, Food Safety and Standards Authority of India or the Commissioner of Food Safety of the State or Union territory or the Food Business Operator under intimation to Chief Executive Officer, Food Safety and Standards Authority of India and the concerned Commissioner(s) of Food Safety of the State(s) about the food under recall;
 - (g) “**traceability**” means the ability to follow the movement of a food article through specified stage(s) of its production, processing and distribution;
 - (h) “**unsafe food**” means food as defined under clause (zz) of sub-section (1) of section 3 of the Act.

- (2) All other words and expressions used herein and not defined but defined in the Act, rules or regulations made thereunder shall have the meanings assigned to the same in the Act, rules or regulations respectively.

CHAPTER-II

OBJECTIVES

3. **Objectives of the food recall procedure.**—(1) Ensure removal of food under recall from all stages of the food chain in accordance with section 28 of the Act;
- (2) ensure dissemination of information to concerned consumers and customers; and
- (3) ensure retrieval, destruction or reprocessing of food under recall.

CHAPTER -III

SCOPE

4. **Scope of the Food Recall Procedure.**—These regulations shall apply to the food or food products that are determined or prima facie considered unsafe and/or as may be specified by the Food Authority from time to time.

Explanation: Food articles which require the mandatory mention of statutory warnings related to consumption being “injurious to health” may not be treated as unsafe food as part of any recall plan unless they are specifically determined unsafe and injurious to health.

CHAPTER IV

FOOD RECALL PROCEDURE

5. **Initiation of the food recall process.**—(1) Every food business operator shall follow food recall procedure including complete process of recall, post-recall report, and follow-up action in order to ensure the effectiveness of the recall and prevent recurrence.
- (2) The food business operator shall initiate a recall process to fulfill his responsibility in accordance with section 28 of the Act.
- (3) The Chief Executive Officer, Food Safety and Standards Authority of India or the Commissioner of Food Safety of the State or Union territory or both may direct the food business operator to initiate the recall process.
- (4) The recall process shall also be initiated as a result of reports or complaints referred to the food business operator from any stakeholder and if food business operator determines that there is a need to recall. In case the food business operator does not respond to the complaint, the complainant or the consumer may inform the Chief Executive Officer, Food Safety and Standards Authority of India or Commissioner of Food Safety of the State or Union territory or both who will take steps to determine the need for recall and instruct the concerned food business operator regarding the recall, who shall be bound by such instructions.
- (5) It is the responsibility of all the food business operators in the entire food chain to implement the instructions relating to food recall. Failure to do so shall render the food business operator liable to action as provided under the Act or the rules or regulations made thereunder.
- (6) When a food business operator refuses to undertake a recall directed by the Chief Executive Officer, Food Safety and Standards Authority of India or Commissioner of Food Safety of the State or Union territory or where the Chief Executive Officer, Food Safety and Standards Authority of India or Commissioner of Food Safety of the State or Union territory has sufficient reasons to believe that additional measures would be required to make the recall effective, or determines that a recall is ineffective, or has a reason to believe that unsafe food is continuing to be manufactured by food business operator, the Chief Executive Officer, Food Safety and Standards Authority of India or Commissioner of Food Safety of the State or Union territory will take appropriate action as provided under the Act, rules or regulations made thereunder and the food business operator shall be liable for such action.
- (7) A recall of imported food may also be initiated on the basis of reports of health and food authorities, or from information received from such authorities or if it otherwise comes to the notice of the concerned authority.

- (8) The initiation of food recall shall not preclude the Chief Executive Officer, Food Safety and Standards Authority of India or Commissioner of Food Safety of the State or Union territory from taking further regulatory action against the concerned food business operator as may be required under the Act.
6. **Operation of Food Recall System.**—(1) The food business operator shall maintain the food distribution records which include the names and addresses of suppliers and customers, nature of food, date of purchase, date of delivery, lot number, batch code, pack size, brand name, date of manufacture, date of expiry and best before date, and shall maintain such records for a period of one year from best before date or the expiry date, as applicable.
- (2) In case of alcoholic beverages where declaration of best before date is exempted under food safety regulations, one shall maintain records for a period of two years from date or month of supply from the manufacturer.
- (3) The food business operator shall submit information as specified under **Schedule I** to the concerned Authority immediately but not exceeding twenty-four hours from the time it comes to his notice that such food requires recall in accordance with the provisions of these regulations and initiate the recall exercise, such information alert(s) may be sent by quickest means of communication including fax, e-mail, and speed post. The Commissioner of Food Safety of the State or Union territory shall inform the Chief Executive Officer, Food Safety and Standards Authority of India within twenty-four hours of receipt of such information.
- (4) The food business operator shall stop distribution of food under recall and also stop its production if necessary, without waiting for any instructions from the Chief Executive officer, Food Safety and Standards Authority of India or Commissioner of Food Safety of the State or Union territory so as to ensure that consumer safety is not compromised and he shall contact everyone from the raw material vendor to the final consumer of the affected food by written communication, phone, e-mail, fax, or a combination thereof, notify the suppliers and any other relevant retailer or trade association and immediately identify all required product details along with any additional details which would facilitate speedy identification and recall.
7. **Food Recall plan.**—(1) All food business operators engaged in the manufacture or importation or wholesale supply of food regulated under the Act must have an up-to-date recall plan. The food retailers are not required to have a food recall plan, unless they are also engaged in the manufacture or importation or wholesale supply of food.
- Provided that food businesses in the food service sector such as restaurants, caterers and takeaway joints are exempted from having a recall plan unless they are running multi-outlet food business chains with integrated manufacturing and distribution network.
- (2) The food retailers and food businesses in the food service sector, which do not require to have a recall plan, shall remove the recalled stock from shelves and return it to the manufacturer, importer or wholesaler and must ensure that food under recall is separated and identified from other food until it is disposed of in accordance with the instructions provided under the recall plan.
- (3) The recalling food business operator(s) shall formulate a detailed recall plan as part of their food safety management system as per the guidelines that may be framed by the food authority from time to time.
- (4) At the time of actual recall being carried out, the food business operator shall submit the details of the implementation of the food recall plan to the Chief Executive Officer, Food Safety and Standards Authority of India and the Commissioner of Food Safety of the State or Union territory taking into account the food safety aspects, supervise the recall, assemble data and report on the completion of recall.
- (5) The food business operator(s) shall ensure effective implementation of the recall process as per the formulated recall plan.
8. **Recall communication.**—(1) The food business operator initiating a food recall shall promptly inform food business operator(s) in the food chain including consumers about the recall.
- (2) Such recall communication shall be through written communication, phone, e-mail, fax, print media, electronic media (TV or Radio or Internet or combination) or a combination thereof and in case of written communication it shall be conspicuously marked "Food Recall". The communication shall also be marked "urgent" and telephone

- calls or other personal communication shall be confirmed by one of the above methods and documented in an appropriate manner.
- (3) Every Food business operator in the food chain who receives a recall communication shall immediately carry out the instructions detailed therein by the recall initiating food business operator and extend the recall to all concerned stakeholders in accordance with sub-regulations (1) and (2) .
 - (4) The food business operator shall promptly inform the consumers in the affected area of the food recall through press release, letters to the concerned parties or advertisements in the media and such press release, letter or advertisement shall be in the form of 'Food Recall Notice' and shall contain the following information, namely:-
 - (a) Name of the Food Business Operator recalling the food;
 - (b) Name of the food, brand name, pack size, batch and code number, date of manufacture, used by date or best before date;
 - (c) The contamination or violation in the food or reason for such recall;
 - (d) "do not consume message";
 - (e) Health warning and action;
 - (f) The places or outlets where the food is found;
 - (g) The action to be taken by the consumer;
 - (h) Contact number for queries.
 - (5) The food business operator shall respond to queries if any from the Chief Executive Officer, Food Safety and Standards Authority of India and Commissioner of Food Safety of the State or Union territory within twenty-four hours of the receipt of the query. However detailed data, if required, may be submitted subsequently.
- 9. Recall status report.**—(1) The food business operator shall determine whether the recall is progressing effectively and shall submit periodic status reports to the Chief Executive Officer, Food Safety and Standards Authority of India or Commissioner of Food Safety of the State or Union territory to inform them of the progress of the recall. The frequency of such reports shall be submitted once in a week or as otherwise specified by the Chief Executive Officer, Food Safety and Standards Authority of India or Commissioner of Food Safety of the State or Union territory based on the relative urgency or gravity of the recall.
- (2) Unless otherwise specified or not applicable in a given recall case, the recall status report shall contain the information as specified in **Schedule-II**.
 - (3) Recall status reports are to be discontinued when the recall is terminated by the Chief Executive Officer, Food Safety and Standards Authority of India or Commissioner of Food Safety of the State or Union territory or both, as the case may be.
 - (4) The food business operator shall retain proper and complete documentation on food recall for inspection and verification by the Chief Executive Officer, Food Safety and Standards Authority of India or Commissioner of Food Safety of the State or Union territory or both, as the case may be.
- 10. Food recovery.**—(1) The food business operator shall store the recovered food in an area which is separated from any other food and is identified by a label plate including prominently that "RECALLED PRODUCT NOT FIT FOR HUMAN CONSUMPTION".
- (2) The food business operator shall maintain accurate records of the recovered food including their lot number, batch code, pack size, brand name, date of manufacture, date of expiry, best before date, and all related data. Proper recording system shall be available to ensure that recalled food is retrieved and its details are recorded.
 - (3) The food business operator may correct or re-process the recovered food, if permitted by Chief Executive Officer, Food Safety and Standards Authority of India. In all other cases, the food business operator shall ensure

disposal of such food in consultation with the Chief Executive Officer, Food Safety and Standards Authority of India. A complete record of the disposal of such product shall be maintained.

11. **Post-recall report.**—(1) The food business operator shall submit a post-recall report to the Chief Executive Officer, Food Safety and Standards Authority of India after completion of the recall process so as to enable the assessment of adherence to the recall procedures.
 - (2) In addition, it is necessary for the food business operator to investigate the reasons that led to such recall and taking action to prevent recurrence of the problem.
12. **Termination of a recall.**—(1) The food business operator may request termination of recall by submitting a written request to the Chief Executive Officer, Food Safety and Standards Authority of India along with recall status report or post-recall report certifying that the recall was effective. The request may be made in the form specified in **Schedule-III**.
 - (2) A recall may be terminated when the Chief Executive Officer, Food Safety and Standards Authority of India determines that it is reasonable to believe that the food under recall has been removed and/or disposed of in an appropriate manner and that steps have been taken to ensure that such incidents do not recur and a written communication shall be sent to the food business operator within two weeks of the request submitted by the food business operator and food business operator can resume normal operations thereafter.
 - (3) In case of unsatisfactory reports, the Chief Executive Officer, Food Safety and Standards Authority of India may consider further action like stepped-up inspection, seizure or any other legal action against the food business operator.
13. **Follow-up action.**—The food business operators shall provide the Chief Executive Officer, Food Safety and Standards Authority of India with a report as soon as a recall is completed, in any case not later than thirty days after the completion of a recall, covering the following information, namely: -
 - (a) the circumstances leading to the recall;
 - (b) the action taken by the food business operator including details of any publicity;
 - (c) the extent of distribution of the relevant batch in the country and overseas;
 - (d) the results of the recall (quantity of stock returned, corrected, outstanding, etc.);
 - (e) the proposed method of disposal or otherwise of recalled stock with record of destruction and/or correction; and
 - (f) the action proposed to be implemented in future to prevent a recurrence of the problem.
14. **Responsibility of the food business operator.**—(1) The food business operator shall have procedures and systems in place to identify the food businesses to whom they have supplied their food.
 - (2) The food business operator shall collaborate with the Commissioner of Food Safety of the State or Union territory or the Food Authority on action taken to avoid or reduce risks posed by the specific batch or lot or code of food, which they supply or have supplied.
 - (3) The food business operator shall remove the food from sale or distribution, when requested by the Commissioner of Food Safety of the State or Union territory or the Food Authority, as the case may be.
15. **Responsibility of the Commissioner of Food Safety of the State or Union territory.**—(1) The Commissioner of Food Safety of the State or Union territory shall supervise the recall by the food business operator and inspect the food business operator's capability of recall after receiving the recall alert information and shall also be responsible for the following, namely:-
 - (i) inspect the suspected or determined unsafe food after receiving complaint from the consumer, take action as per the provisions of the Act and advise the food business operator, in consultation with the Food Authority wherever required, to recall such food;

- (ii) to prepare and issue a media release for immediate use by the media in recalls involving consumers, and where required, in consultation with the food business operator;
 - (iii) conduct audit checks when it is determined that the food business operator is unable to ensure the effectiveness of its recall;
 - (iv) give instructions on the frequency of reporting the condition of recall, subject to the urgency of the case, and to monitor the recall progress of the food business operator(s);
 - (v) supervise the food business operator in completion of recall and assess their recall report;
 - (vi) as for the foods imported into India which are recalled products in other markets or where Indian made foods are subject to recall or rejection in country of export and returned to India, the Food Authority or the Commissioner of Food Safety of the State or Union territory shall, in consultation with the concerned food business operator, determine the fate of such products for disposal or reprocessing at port or otherwise and shall review recall plan for the exported foods and advise the health authorities in the importing countries about such recall.
- (2) The Commissioner of Food Safety of the State or Union territory shall inform the Food Authority about the execution of the above process and follow such instructions as the Food Authority may deem appropriate.
- 16. Responsibility of the Food Authority.—**(1) The Food Authority shall guide and supervise the Commissioner of Food Safety of the State or Union Territory in the execution of the Recall Plan and, where necessary, it may assess the relevant reports submitted by the food business operator and give instructions as may be required.
- (2) The Food Authority may establish a web based facility titled 'Food Recall portal' on its website with a unique identification number assigned to each recall for monitoring and to provide information to the consumers about such recall.
- (3) The Food Authority may also publicise about the recall when it considers that the public need to be alerted about the health hazard depending upon seriousness of the situation and it shall keep the concerned food business operator(s) aware of the same.

Schedule – I

[See Regulation 6(3)]

Food Recall Information

To

The CEO of the Food Authority,

The Commissioner of Food Safety of the State or Union territory _____

Sr. No.	Subject	Particulars		
1.	Name and Address of the food business operator			
2.	Name, Designation and Contact details of person who should be contacted			
3.	Identity of the implicated food	(a)	Name of the food	
		(b)	Brand Name	
		(c)	Date of Manufacturing	
		(d)	Quantity of Food affected	
		(e)	Batch/Lot/Code number	
		(f)	FSSAI License / Registration number with a copy	

Sr. No.	Subject	Particulars
4.	Reason for Recall	
5.	Date and circumstances under which need for food recall was discovered	
6.	Nature of violation of the provisions of the Act, Rules or Regulations made thereunder	
7.	Name, designation and address and telephone number of person reporting the problem	
8.	Has any testing been under taken; If yes, results thereof	
9.	Total quantity food produced/manufactured	
10.	Duration of food business for this product	
11.	Quantity of implicated product sold to the food business operator/ individual in the food chain with documentary proof	
12.	Copy of Recall Communication (if already issued) otherwise proposed communication and means/ proposed means of communication	
13.	Action already taken and Proposed plan for recall	
14.	Any other relevant information	

* Please attach extra sheets, if space is insufficient

Signature and title

Date:

Schedule-II

[See Regulation 9 (2)]

FOOD RECALL STATUS REPORT FORMAT

Date: _____

Food Authority's Reference number for recall _____

1.	Name of the food	
2.	Name of the company	
3.	Brand Name:	
4.	Batch/Lot / Code Number:	
5.	Date of Mfg/ Packaging (PKD):	
6.	Phone:	
7.	Email address:	

Attention-CEO, FSSAI/Commissioner of Food Safety of the State or Union territory

I, _____, the authorised representative of(Name of the Company) _____ hereby submit the following Recall Status Report regarding the above-listed food:

1. Quantity related details of the implicated product before recall initiation:

(a)	Total quantity of food manufactured:	
(b)	Total sold to Food Business Operator/individual in distribution channel:	
(c)	Total quantity of food to be recalled:	
(d)	Details in case quantities in row (a) and (c) are different, (reason thereof)	

2. Communication:

(a)	Total number of Food Business Operator /individual identified:	
(b)	Number of Food Business Operator / individual notified:	
(c)	Method of notification (check all that apply):	
(i)	Letter	
(ii)	Phone	
(iii)	Fax	
(iv)	Email	
(v)	Other(s): Please specify	

3. Food business operator response:

(a)	Total number of food business operator / individual responding:				
(b)	Total number of food business operator / individual not responding:				
(c)	Total quantity of food dispatched to Non-responding food business operator/individual end:				
(d)	Number of packaged units and its quantity sold to and returned by each responding food business operator/ individual (as per traceability):	Sold		Returned	
		Number	Quantity	Number	Quantity
(i)	Food business operator/ individual				
(ii)	Food business operator/ individual				
(iii)	Food business operator/ individual				
(iv)	Food business operator/ individual				
(v)	Food business operator/ individual				
	Add more, if required				
	Total				

Quantity of implicated product accounted for (Total amount in custody of firm, including that recalled expressed as percentage of total implicated product):

4. Effectiveness Checks:

(a)	Total number required:	
(b)	Total number completed:	
(c)	Completion date:	

5. Estimated Recall Completion Date: _____

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

7. Actions proposed to avoid recurrence in future, if available at this point

Yours sincerely,

Signature and title

Food Business Operator

Note:

1. Provide cumulative information.
2. The final status report to be attached with the Recall termination request shall provide decided method of disposal / records of destruction in point 6.

Schedule-III

[See Regulation 12 (1)]

FOOD RECALL TERMINATION REQUEST FORMAT

Date: _____

To

The CEO, Food Authority _____

The Commissioner of Food Safety of the State or Union territory _____

Food Authority's Reference No. for Recall: _____

Food Business Operator Name & License No. & Registration No.: _____

Product Brand: _____

Food Name: _____

Date Code: _____ Batch No. _____ Manufacturing Date / Packaging Date _____

Best before / Expiry date _____

Food Authority Contact: _____ Phone: _____ Email: _____

Ref: Request for Recall Termination

Attention-CEO, FSSAI/Commissioner of Food Safety of the State or Union territory

I, _____, the authorised representative of(Name of the Company) state that the Company has initiated a recall of the above-listed product/products on ____ (date)____ that extended to the _____ level. Proper communications were made by phone, fax, email, mail and personal visits, and records of these communications have been provided to your offices which are annexed along.

2. All requested Status Reports have been filed (indicated if or not within the proper time-frames), and the latest report is being submitted with this communication. _____ (Food Business Operator) _____ believes the above-listed product has been successfully recalled.
3. In light of this executed recall, I hereby request that this food product recall be terminated.
4. The following Actions are proposed to avoid recurrence in future:

Signature

Name and designation of Authorised Signatory

Name of the company

PAWAN AGARWAL, Chief Executive Officer

[ADVT.-III/4/Exty./392/16(187O)]