The People's Republic of Bangladesh Government Bangladesh Food Safety Authority

Draft Notification Dated:

S. R. O. No 87-Act/2021 – The Bangladesh Food Safety Authority, in line with the power entrusted in section 87 and 43 of the Food Safety Act, 2013 (Act No, 43, of the year 2013) and as per prior approval of the government, made the following regulations, as: -

Chapter 1 Preamble

- **1. Title and Commencement.** (1) These regulations may be called as Food Safety (Food Recall) Regulations, 2023.
- (2) It shall be effective immediately.
- 2. Definition (1)— If there is nothing contrary to the subject or context, in these regulations---
 - (a) "Act" means Food Safety Act, 2013 (Act No. 43 year of 2013)
 - (b) "Authority" means the Bangladesh Food Safety Authority as defined in the act
 - (c) "Food Recall" means action taken to remove a marketed food from distribution, sale, and consumption that is unsafe and violates the provisions of the act and the rules and regulations made thereunder or any other law.
 - (d) **Food Withdrawal**" means an action by the food business operator to withdraw the product/package from the market. This may be for non-compliance issues that do not lead to a food safety hazard and/or are not a violation of legal requirements, or the violation is technical in nature and would not be subject to regulatory legal action.
 - (e) "Responsible Officer" means an officer assigned by the authority to perform any specific dutyin relation to the recall of food under these regulations.
 - (f) "Recalled food" means food declared to be recalled by the authority or food business operator which is unsafe, hazardous, substandard or do not comply with the standards set out under the act or any other law, in addition the Batch Number, Lot Number, Barcode / QR code, manufacturing and expiry date, brand etc. of recalled food products or food materials shall also be included.
 - (g) "Supply Chain" means the aggregation of steps or stages involved in transportation,



storing, distribution to distributor, wholesaling and retail sale to reach the consumer after processing or importation.

- (2) All words or expressions used in these regulations but not defined or explained shall have the same meaning as in the act.
- 3. Supplementary of other Law-- The provisions of this regulation shall be deemed to be supplementary to the provisions of other laws, rules and regulations currently in force regarding food make withdrawal.

Chapter-2 Food Recall

- **4. General Conditions of Food Recall.-** (1) The following general conditions shall be followed incase of recalling food products, as: -
 - (a) If the food does not comply with the Bangladesh National Standard, and/or standard or safety limit or risk control set by the authority, recall proceedings shall be initiated as soon as the food business operator is informed or receives the instruction of the authority,
 - Explanation To fulfill the purpose of this clause, "Bangladesh National Standard" shall mean the definition of Bangladesh Standard as mentioned in clause 2 (11) of Bangladesh Standards and Testing Institution Act, 2018 (Act No. 67 of 2018).
 - (b) In the case of recall of food items, the following points shall be considered, namely:
 - i. The presence of toxic substances or unapproved or excessive chemicals or excessive microorganisms or harmful microorganisms or other food hazards in food or substandard foods according to Bangladesh National Standards or international standards which may cause health risk or death.
 - Explanation. To fulfill the purpose of this clause, the expression of "food hazard" means presence of any substance in food or prevailing condition of food created or naturally produced due to any biological, chemical or physical effect that may cause any adverse effect on human health.
 - ii. Providing wrong or false information about food or undisclosed or concealed information about the use of unauthorized, excessive or substances (e.g., antibiotics, allergens, GMOs, etc.) that may cause an individual health risk, and
 - iii. Technical or process deviations that make food unsafe or may become cause of hazard or health risk
 - (c) Food business operator shall preserve all information, documents and reports on food recall; and
 - (d) shall ensure not supplying, marketing, selling or using of recalled food products.

5. Food Withdrawal. A food business operator may withdraw food and in such case the food business operator shall notify the authority when the decision of food withdrawal is taken and a withdrawal report shall be submitted when the withdrawal is completed.

Provided that, if a risk to public health and safety is established, the food must be recalled.

- **6. Classification of food declared to be Recalled.** -(1) The authority shall classify the food declared to be recalled as follows, namely: -
 - (a) Food Category-1: Food declared to be recalled which may cause serious health risks or even death due to exposure to or ingestion
 - (b) Food Category-2: Food declared to be recalled which may cause temporary adverse health effects upon exposure or consumption; and
 - (c) Food Category-3: Food declared to be recalled which does not cause any adverse health effects as a result of contact or consumption, even if it appears that the food does not comply with the standards determined by law or any other law.
- 7. Food Recall Plan. (1) An up-to-date recall plan shall be formulated as part of the food safety management system and maintained by all food business operators involved in the production, importation, or wholesale supply of foods.

Provided that food business operators who do not operate multi-outlet food business chains with unified manufacturing and distribution systems (i.e. restaurants, caterers, takeaway joints etc.) are exempted.

- (2) Within 2 days of the announcement of a food recall, the food business operators shall submit a written plan to the authority and the following matters shall be included in the plan, viz.
 - (a) Procedures for information sharing and communication regarding food recall
 - (b) List of all distribution chains, including distributors, hoarders, suppliers, wholesalers, and retailers of recalled food.
 - (c) Time schedule to ensure speedy and effective recall and instructions to carry out food recall activities at any time outside of it.,
 - (d) Determining the location of storage until transportation, distribution, return, destruction or disposal of recalled food; and
 - (e) Determining the strategy and scope of food withdrawal or recall
- (3) The means of evaluating the progress and performance of product recall shall be described in the recall plan.
- (4) Potential problems with the implementation of food recalls by food business operator shall be identified and the source of contamination.
- (5) Recall progress and assessment report as per the form-2 described in the schedule shall be submitted to the authority within the time limit for execution of food recall.



Chapter 3

Food recall procedures, coordination, supervision etc.

8. Food Recall Procedure. -

(1) Initiation of Recall Procedure.-

- (a) The authority may direct the food business operator to initiate the recall process.
- (b) The food business operator shall initiate a recall process to fulfill his responsibility in accordance with section 43 of the Act. Failure to implement the recall shall render the food business operator liable to action as provided under the Act or the rules or regulations made thereunder.
- (c) The initiation of food recall shall not prevent the authority from taking further regulatory action against the concerned food business operator as may be required under the Act.

(2) Operation of Food Recall System.—

- (a) 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.
- (b) The food business operator shall submit information as specified in form-1 under Schedule to the 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.
- (c) The food business operator shall stop the distribution of food under recall and also stop its production if necessary, without waiting for any instructions from the authority so as to ensure that consumer safety is not compromised shall follow the communication strategy described in regulation 4.

9. Recall Communication.-

- (1) The following matters shall be included by the food business operator in the manner of exchanging informationregarding recall and notification of recall, planning and implementation.
- (2) The following information shall be clearly mentioned in the food recall notification, namely: -
 - (a) Full description of the recalled food (food name, brand batch or lot number, quantity or number of foods, packet or box code, date of manufacture, expiration date and any barcode or QR code capable of identifying the food) or relevant descriptive information,
 - (b) Reasons for recall relevant details and health risk information,
 - (c) Name and address of the withdrawing food business operator,
 - (d) Contact information withdrawing food business operator (telephone, mobile, email, fax for contactwith food supplier, hoarder, wholesaler),
 - (e) Information regarding the instruction on the supply, distribution or already removal or destruction of remaining or recalled foods and instructions on stopping their use or consuming and seizing,
 - (f) A description of the harm that can be caused to the user by using the food and information about the harm remedy.

3 4

- (g) "do not consume" message;
- (3) Food Business Operators shall not include any irrelevant information, statements, or advertisements in food notices and shall not hide necessary information related to the recall.

Food recall information exchange and communication management shall be done in the following ways or in a combination thereof.

- (a) Providing mass notifications through front page of widely circulated two (02) national daily newspaper,
- (b) Sending through telephone, fax, email, text message, telex
- (c) Publishing through social media,
- (d) Publishing through other electronic means,
- (e) Distribution of posters, leaflets; and
- (f) Exchanging information through special carriers or in any other acceptable way.
- (4) 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.
- (5) The withdrawing food business operator shall execute the withdrawal of his produced or imported food by communication and surveillance arrangements at all stages of the food supply chain.
- 10. Recall status report.—(1) The food business operator shall determine whether the recall is progressing effectively and shall submit periodic status reports to the authority to inform the progress of the recall. Unless otherwise specified or not applicable in a given recall case, the recall status report shall contain the information as specified in Form-2 of Schedule. The food business operator shall keep softcopies and hardcopies of all documents on food recall for inspection and verification of the authority.
- 11. Recalled Food recovery.—(1) The recovered food shall be stored in a separate area labeled with "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.
- (3) With the prior approval of the authority, the food business operator may correct or re-process the recovered food.
- (4) In all other cases, the food business operator shall ensure the disposal of such food in consultation with the Authority. A complete record of the disposal of such product shall be maintained and the food business operator shall submit the disposal record to the authority.



- 12. Termination of a recall.—(1) The food business operator may request termination of recall by submitting a written request to the authority along with a recall status report or post-recall report certifying that the recall was effective. The request may be made in the form-3 specified in Schedule.
- (2) A recall shall be terminated when the authority 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 and food business operator can resume normal operations thereafter.
- (3) The authority shall inform the people about the completion of food or recall activities by issuing a public notice; and
- (4) If the concerned food business operator delays or fails to recall food products after the issuance of the recall notice, he is liable to commit the offense as mentioned in column (3) of the Schedule to the Act for stocking, marketing, supplying or selling substandard or hazardous or toxic food items, as the case, shall be punished as described in columns (4) and (5).
- 13. Follow-up action.—(1) The food business operators shall provide the authority 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 a record of destruction and/or correction; and
 - (f) the action proposed to be implemented in the future to prevent a recurrence of the problem.
- 14. Coordinating, supervising and verifying the effectiveness by the authority. In case of food recall, the authority shall check the coordination, supervision and effectiveness of the following, namely: -
- (1) In case of recall of food items, the authority shall check whether the food business operator has properly followed the provisions of these regulations,
- (2) The following points shall be included in the verification of the effectiveness of food recall, namely: -
 - (a) Verifying the effectiveness of the recall, where applicable, on-the-spot inspection of food business operator, distributors or other steps in the supply chain by the assigned officer and verification of the information and documents relating to the withdrawal,
 - (b) Reviewing the supply list of recalling food business operators,



- (c) Informing the evaluation report whether there are any problems or inconsistencies in the recall procedure and plan,
- (d) Ensuring that food production processes or processing methods or causes of food being unsafe or hazardous have been corrected; and
- (e) Ensuring that foods having harmful or adverse effect on public health must not be produced in future.
- (3) The authority shall issue food recall instructions again in that areas of the food supply chain or the area of distributor where withdrawal or recall is ineffective,
- (4) In the case of food recall, the authority shall inform the concerned food business operators, agencies, local governments, city corporations and the concerned ministries and, if necessary, shall take their cooperation,
- (5) The list of food and related information shall be open to the public and preserved in the authority's office, website which shall be provided by the authority subject to compliance with the provisions of Information Right Act, 2009 (Act No. 20 of 2009)

Chapter 4 Miscellaneous

- **15. Repeals.** As soon as these regulations go into effect Bangladesh Pure Food Rules, 1967 shall be repealed as far as it relates to the rules of these regulations.
- **16.** Publish translated English text. After the commencement of these regulations, the Government may, if necessary, by notification in the official Gazette, publish an authentic English text of these regulations:

Provided that in the event of conflict between the Bangla and the English text, the Bangla text shall prevail.



Schedule

Form-1 Food Recall Information

То

Chairman

Bangladesh Food Safety Food Authority

Sr. No.		Particu	llars
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
4.	Reason for Recall	.1	
5.	Date and circumstances under		
	which need for food recall was discovered		
6.	Nature of violation of the		
	provisions related to food		•
	safety risk		
7.	Name, designation and		
	address and telephone		
	number of person reporting the problem		
8.	Has any testing been under		
0.	taken; If yes, results thereof		
9.	Total quantity food		
	produced/manufactured		
10.	Duration of food business for this		



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 planfor recall	
14.	Any other relevant information	

Date: Signature and Title



Form-2 FOOD RECALL STATUS REPORT FORMAT

Date:	****
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- Director (Enforcement), Bangladesh Food Safety Authority I,, the authorised representative of (Name of the Company) her following Recall Status Report regarding the above-listed food:	
1. Quantity related details of the implicated product before recall initiation	<u>1:</u>
(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 involved (as applicable)	
(b)	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 Operator who responded:	Business			
(b)	Total number of food business not responding	s operator			
(c)	Total quantity of food disponents of the contract of the contr				
(d)	Number of packaged units	Sold		Returned	
	and its quantity sold to and returned by each responding	Numbari	Quantity	Number	Quantity
	food business operator/				
	individual (as per traceability):				



	(i)	Food business ope individual	rator/			
	(ii)	Food business ope individual	erator/			
	(iii)	Food business ope individual	erator/			
	(iv)	Food business ope individual	erator/			
	(v)	Food business ope individual	erator/			
		Add more, if required				
		Total				
	l expres	aplicated product accounted as percentage of total veness Checks:				ıt
	(a)	Total number required:				
	(b)	Total number completed:				
	(c)	Completion date:				
5. 6.		ated Recall Completion Da		ecard of destruc	tion:	
	•	•				
7.	Action	s proposed to avoid recurr	rence in ruture, if a	ivailable at this p		
sincere	lv				Yours	
51110010	^,;			S	ignature 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.

Form -3

FOOD RECALL TERMINATION REQUEST FORMAT

Date:

То	·
Chairn	nan
Bangla	adesh Food Safety Food Authority,
Date Date Food Ref:	rence No. for Recall: d Business Operator Name & License No. & Registration No.: d Name: Code: Batch No. Manufacturing Date / Packaging Best before / Expiry date d Authority Contact: Phone: Request for Recall Termination Attention- Director Forcement) Bangladesh Food Safety Authority
1. I (initiate the visits,	, the authorised representative of (Name of the Company) state that the Company has ed a recall of the above-listed product/products on (date) that extended to _level. Proper communications were made by phone, fax, email, mail and personal and records of these communications have been provided to your office which are ed along.
	e-frames), and the latest report is being submitted with this communication
(Foo	believes the above-listed product has been bessfully 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 Authorized Signatory Name of the company *** By order of the Bangladesh Food Safety Authority Md. Abdul Kayowm Sarker

Chairman