

**TO BE PUBLISHED IN THE GAZETTE OF INDIA, EXTRAORDINARY
PART III, SECTION 4]
GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
(Food Safety and Standards Authority of India)
NOTIFICATION**

New Delhi, Dated _____, 2015

F. No.1-110(2)/SP (Biological Hazards)/FSSAI/2010. The following draft of certain regulations further to amend the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, which the Food Safety and Standards Authority of India, proposes to make, with previous approval of the Central Government, in exercise of the powers conferred by clause (e) of sub-section (2) of section 92 read with section 16 of the Food Safety and Standards Act, 2006 (34 of 2006), is hereby published as required by the said sub-section (1) of the said Act, for information of all persons likely to be affected thereby, and notice is hereby given that the said draft shall be taken into consideration after the expiry of the period of sixty days from the date on which the copies of the official Gazette in which this notification is published, are made available to the public;

The Objections or suggestions, if any, duly supported by scientific evidence may be addressed to the Chief Executive Officer, Food Safety and Standards Authority of India, Food and Drug Administration Bhawan, Kotla Road, New Delhi-110002;

The objections and suggestions, which may be received from any person with respect to the said draft regulations before the expiry of the period so specified, will be considered by the Food Authority.

Draft regulations

1. Short title and commencement.- (1) These regulations may be called the Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations, 2015.
- (2) They shall come into force with effect from the ensuing 1st January or 1st July of the year, as the case may be, subject to minimum of 180 days from the date of final notification of these regulations in the official Gazette.
2. In the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, in APPENDIX B relating to "Microbiological Requirements", for TABLE 2 and the entries relating thereto, the following TABLE and the entries shall be substituted, namely:-

“TABLE-2- Microbiological Requirements for Milk and Milk Products

Table-2A Microbiological Requirements for Milk and Milk Products -Hygiene Indicator Organisms

Sr. No.	Product Description	Aerobic Plate Count				Coliform Count				Staph. aureus (Coagulase positive)				Yeast and mold count				Faecal streptococci				
		Sampling plan		Limit (cfu)		Sampling plan		Limit (cfu)		Sampling plan		Limit (cfu)		Sampling plan		Limit (cfu)		Sampling plan		Limit (cfu)		
		n	c	m	M	n	c	m	M	n	c	m	M	n	c	m	M	n	c	m	M	
1	Pasteurized Milk/Flavored Milk ¹	5(3)	3	30 x10 ³ /ml	50x 10 ³ /ml	5(3)	0	Absent/0.1ml		5	0	Methylene blue reduction test (MBRT) applicable at Manufacturing unit shall not decolorized in 5 hrs. when tested in accordance with the IS 1479 (Part III-1977-1992)										
2	Pasteurized Cream	5(3)	3	50x10 ³ /g	75x10 ³ /g	5(3)	0	10/g														
3	Sterilized/UHT/Flavored Milk / Evaporated Milk																					
4	Sterilized/ UHT Cream																					
5	Sweetened Condensed Milk	5(3)	3	5x10 ² /g	1x10 ³ /g	5(3)	0	Absent/0.1g		5(3)	0	10/g		5(3)	0	10/g						
6	Pasteurized Butter ²	5(3)	3	25x10 ³ /g	50x10 ³ /g	5(3)	2	Absent/0.1g	20/g	5(3)	2	10/g	50/g	5(3)	3	20/g	50/g					
7	Milk powder ; SMP, PSMP ; Dairy Whitener ; Cream powder ; Ice Cream Mix powder ; Lactose ; Whey based powder ; Butter Milk powder ; Casein powder ³	5(3)	2	30x10 ³ /g	50x10 ³ /g	5(3)	2	Absent/ 0.1g	50/g	5(3)	2	10/g	1x10 ² /g	5(3)	0	5/0.1g						
8	Infant Milk Food, Infant Formulae, Infant Milk Substitute	5(3)	2	5x10 ² /g	5x10 ³ /g	10 (10)	0	Absent/0.1g		5(3)	0	Absent/0.1g		5(3)	0	Absent/0.1g		5	0	Absent/0.1g		
	Food ,Follow Up Formula			5x10 ² /g	5x10 ³ /g																	
	Cereal Based Complimentary			1x10 ³ /g	10x10 ³ /g																	
9	Ice Cream, Frozen Dessert, Milk Lolly, Ice Candy etc	5(3)	3	1x10 ³ /g	2x10 ⁵ /g	5(3)	3	10/g	1x10 ² /g	5(3)	2	10/g	1x10 ² /g									
10	Processed Cheese/ Cheese Spread (Ready To Eat Products)	5(3)	2	25x10 ³ /g	50x10 ³ /g	5(3)	0	10/g		5(3)	0	10/g										
11	All Other Cheeses Categories Including Fresh Cheeses / Cheddar /Cottage /Soft /Semi Soft ⁴ etc (Not Ready To Eat Products)					5(3)	3	1x10 ³ /g	5x10 ³ /g	5(3)	3	10/g	1x10 ³ /g	5(3)	3	50/g	250/g					
12	Fermented milk products : Yoghurt, Dahi, Chakka, Shrikhand ⁵ etc					5(3)	2	10/g	1x10 ² /g	5(3)	2	10/g	1x10 ² /g	5(3)	3	50/g	1x10 ² /g					
13	Paneer/ Chhana/ chhana based sweets	5(3)	3	15x10 ⁴ /g	35x10 ⁴ /g	5(3)	3	10/g	1x10 ² /g	5(3)	3	10/g	1x10 ² /g	5(3)	3	50/g	150/g					
14	Khoa/ khoa based sweets	5(3)	3	25x10 ³ /g	75x10 ³ /g	5(3)	2	50/g	1x10 ² /g	5(3)	3	10/g	1x10 ² /g	5(3)	3	10/g	50/g					
	Method of Analysis	IS 5402				IS 5401, Part 1				IS 5887, Part 8/Sec 1				IS 5403				IS 5887 (Part-2): 1976				

¹. Pasteurized milk shall be stored at manufacturing unit and at retail points in such a way that temperature of milk shall not exceed 8°C as recommended in IS I3688: 1999

². The microbial specifications for ripened butter are the same as for pasteurized butter excluding the requirements of total plate count.

³.The yeast and mold count of 5/0.1g as specified in dried product categories shall be applicable only to casein powder

⁴.The yeast and mold counts in all other cheese category will be applicable except mold ripened cheeses.

⁵.The standard requirements of lactic counts of one million c.f.u./g min as specified by BIS (IS:12898:1989) in such products/ or such products containing probiotic organisms shall be applicable

() figures in parenthesis indicate no. of samples required for testing at retail points.

Table-2B: Microbiological Requirements For Milk and Milk Products -Safety Indicator Organisms

		<i>E.coli</i>				Salmonella / Shigella				<i>L. monocytogenes</i>				<i>B. cereus</i>				Sulphite Reducing Clostridia (SRC)				<i>Enterobacter sakazakii</i>			
		Sampling plan		Limit (cfu)		Sampling plan		Limit (cfu)		Sampling plan		Limit (cfu)		Sampling plan		Limit (cfu)		Sampling plan		Limit (cfu)		Sampling plan		Limit (cfu)	
		n	c	m	M	n	c	m	M	n	c	m	M	n	c	m	M	n	c	m	M	n	c	m	M
1	Pasteurized Milk/Flavored Milk	5(3)	0	Absent/ 0.1ml		5(3)	0	Absent/25 ml		5(3)	0	Absent/25ml		5	0	Phosphatase test shall be negative as per IS 8479 (Parts I -1977) before release of product in the market									
2	Pasteurized Cream	5(3)	0	Absent/0.1g		5(3)	0	Absent/25g		5(3)	0	Absent/25g													
3	Sterilized/UHT/Flavored Milk / Evaporated Milk	5(3)	0	Sterilized milk products shall comply with a test for commercial sterility as per BIS (IS: 4238-1967)																					
4	Sterilized/ UHT Cream	5(3)	0	Sterilized cream product shall comply with a test for commercial sterility as per BIS (IS : 4884:1968)																					
5	Sweetened Condensed Milk ⁶	5(3)	0	Absent/0.1g		5(3)	0	Absent/25g		5(3)	0	Absent/g		5 (3)	0	Product shall comply accelerated storage test as per IS :1166-1986									
6	Pasteurized Butter	5(3)	0	Absent/0.1g		5(3)	0	Absent/25g		5(3)	0	Absent/g													
7	Milk powder; SMP, PSMP; Dairy Whitener; Cream powder ; Ice Cream Mix powder; Lactose; Whey based powder; Butter Milk powder; Casein powder	5(3)	0	Absent/0.1g		5(3)	0	Absent/25g		5(3)	0	Absent/25g		5 (3)	3	1x10 ² /g	1x10 ³ /g	5 (3)	3	10/g	1x10 ² /g				
8	Infant Milk Food, Infant Formulae, Infant Milk Substitute Follow Up Formula Cereal Based Complimentary Food	10 (5)	0	Absent/0.1g		15 (5)	0	Absent/25g		10 (5)	0	Absent/25g		5 (3)	2	1x10 ² /g	5x10 ² /g	5 (3)	0	10/g	1x10 ² /g	30 (10)	0	Absent/10g	
9	Ice Cream, Frozen Dessert, Milk Lolly, Ice Candy etc	5(3)	0	Absent/g		5(3)	0	Absent/25g		5(3)	0	Absent/g													
10	Processed Cheese/ Cheese Spread ⁷ (Ready To Eat Products)	5(3)	0	Absent/g		5(3)	0	Absent/25g		5(3)	0	Absent / 25g		5 (3)	0	Canned product shall comply accelerated storage test as per IS :2785:1964									
11	All Other Cheeses Categories including Fresh Cheeses / Cheddar / Cottage /Soft /Semi Soft etc (Not Ready To Eat Products)	5(3)	0	Absent/0.1g		5(3)	0	Absent/g		5(3)	0	Absent/25g													
12	Fermented milk products : Yoghurt, Dahi, Chakka, Shrikhand etc	5(3)	0	Absent/g		5(3)	0	Absent/25g		5(3)	0	Absent/g													
13	Paneer/ Chhana/ chhana based sweets	5(3)	0	Absent/0.1g		5(3)	0	Absent/g		5(3)	0	Absent/g													
14	Khoa/ khoa based sweets	5(3)	0	Absent/0.1g		5(3)	0	Absent/g		5(3)	0	Absent/g													
	Method of analysis	IS 5887, Part 1				IS 5887, Part 3& 7				IS 14988-Part 1				IS 5887, Part 6				ISO 15213:2003				ISO / TS 22964:2006			

⁶The Sweetened Condensed milk product shall comply accelerated storage test as per IS: 1166-1986 where sample shall be stored at 37± 1°C for 14 days.

⁷ Processed cheese packed in canned shall comply accelerated storage test when incubated at 30°C for 14 days as per IS: 2785:1964 and should give no bulging.

() figures in parenthesis indicate no of samples required at retail points.

Sampling Guidelines: The sampling for different microbiological parameters specified in **Table-2A and B** shall be ensured aseptically at manufacturing units as well as at retail points as per the sampling plan given in **Table-2C** by a trained person with specialised knowledge in the field of microbiology following guidelines given in IS 11546:1999 /ISO 707:1985 (Reaffirmed 2010). The samples shall be stored and transported under appropriate temperature conditions and insulations within 24 hrs of sampling to accredited laboratories for analysis as per the approved sampling plan ⁸ and test methods ⁹. A large sample size may be drawn (if desired) according to the tests required and the type of product. Preservatives shall not be added to samples intended for microbiological examination. The desired number of samples as per sampling plan given in Table-2A & B shall be taken from full production batches and will be submitted to accredited laboratory in original unopened packaging, sealed at the time of sampling maintained in their original physical state. The final decision shall be drawn based on results with no provision for retesting for microbiological parameters.

Sampling plan ⁸: The following terms, as used by the International Commission on Microbiological Specifications of Foods (ICMSF) are defined and used in this standard:

n= the number of sample units which must be examined from the batch or lot of food to satisfy the requirements of a particular sampling plan.

m= Represents an acceptable level and values above it are marginally acceptable in terms of the sampling plan.

c= the maximum allowable number of defective sample units in 3-class sampling plan applicable at manufacturing units only.

M= A microbiological criterion which indicate unsatisfactory or potentially hazardous quality. Values above M are unacceptable in terms of the sampling plan and detection of one or more samples exceeding this level would be cause for rejection of the lot and will attract prosecution by the concerned food safety authorities.

Table-2C Sampling plan for compliance of microbiological parameters at manufacturing units and at retail points

Sampling area	Sampling Plan						
	2-Class			3-Class			
	n	c	m	n	c	m	M
Manufacturing unit	n=5-30	c=0	Values of m specified for all testing parameters for different products as specified Table-2A & B will be applicable	5-30	c= 2,3	Values of m specified for all testing parameters for different products as specified Table- 2A&B will be applicable	Values of M specified for all testing parameters for different products as specified Table- 2A & B will be applicable
Retail point	n=3-10	c=0	Values of m specified for all testing parameters for different products as specified Table-2 A&B will be applicable	3-10	c=0	Not applicable	Values of M specified for all testing parameters for different products as specified in Table- 2A & B will be applicable

Microbiological criteria and their interpretation: Following three categories of microbiological quality have been assigned in standard based on hygiene and safety indicator organisms. These are satisfactory, unsatisfactory and potentially hazardous.

- Satisfactory:** if the test values of m or M or both applicable within the sampling plan are conforming the specified limits, the microbiological quality of product is considered satisfactory and no action is required.
- Unsatisfactory:** if the test values of m or M or both applicable within the sampling plan are not conforming the specified limits of hygiene indicators i.e. aerobic count, coliform count, coagulase positive *S. aureus*, faecal streptococci and yeast and mold count etc which indicates poor hygiene or poor handling practices, the microbiological quality of product will be considered unsatisfactory. Under these conditions the premises producing such unsatisfactory product(s) shall be investigated for nonconformity or non-compliance and legal action on defected products will be notified by the food safety authority. The subsequent release of such product shall be subject to HACCP / GMP audit clearance of the premises / finished products by the food safety authority.
- Potentially hazardous:** if the test values of m / or M or both applicable within the sampling plan are not conforming the specified limits of safety indicators i.e., *E. coli*, *Salmonella / Shigella*, *B. cereus*, Sulphite Reducing Clostridia (SRC), *Enterobacter sakazakii*, *L. monocytogenes* and sterility tests etc. which indicates serious food safety concern, the microbiological quality of product will be considered as potentially hazardous. Under these conditions the premises producing such unsatisfactory product(s) shall be stopped and legal actions on potentially hazardous products will be notified by the food safety authority. The recall action on withdrawal of any of such food still available for sale or distribution shall be initiated and release of subsequent batches of such hazardous products will be under hold by the food manufacturers. Failure by an owner to either cease manufacture of product or withdraw/recall product from sale when requested to do so shall result in seizure of that product where the officer has reason to believe that it is contaminated with pathogenic bacteria. A detail risk assessment will be carried out to determine by the food safety authority to investigate the source or cause of the problem so that remedial action can commence and the approval for restart of such products under non-conformity will be allowed only after compliance of manufacturing unit for food safety standards requirements or guidelines set by the Authority.

Reference test methods ⁹

Sr. no.	Test reference	References
1	Microbiology - general guidance for the enumeration of micro-organisms- colony count technique at 30°C (first revision)	IS 5402:2002/ ISO:4833:1991 reaffirmed 2007
2	Microbiology - general guidance for the enumeration of coliforms: Part 1 colony count technique (first revision)	IS 5401(Part 1): 2002/ISO 4832:1991 reaffirmed 2007
3	Methods for detection of bacteria responsible for food poisoning: Part 8 Horizontal method for enumeration of coagulase-positive staphylococci (<i>Staphylococcus aureus</i> and other species) Section 1 Technique using Baird-Parker Agar Medium	IS 5887(Part 8/Sec 1):2002 / ISO 6888-1 :1999 reaffirmed 2007
4	Isolation, identification and enumeration of <i>Staphylococcus aureus</i> and faecal streptococci (first revision)	5887 (Part 2) : 1976
5	Milk and milk products — detection of <i>Enterobacter sakazakii</i> (First Edition)	ISO/TS 22964: 2006
6	Method for yeast and mould count of food stuffs and animal feeds(first revision)	IS 5403:1999 reaffirmed 2005/ ISO 7954:1987 reaffirmed 2009
7	Methods for detection of bacteria responsible for food poisoning: isolation, identification and enumeration of <i>Escherichia coli</i> (first revision)	IS 5887(Part 1):1976 reaffirmed 2009 Part 1
8	Methods for detection of bacteria responsible for food poisoning: Part 3:general guidance on methods for detection of <i>Salmonella/Shigella</i> (second revision) Methods for detection	IS 5887(Part 3):1999/ ISO 6579:1993 reaffirmed 2009
9	Methods for detection of bacteria responsible for food poisoning-Part 7: general guidance on methods for isolation and identification of <i>Shigella</i>	IS 5887(Part 7):1999/ ISO 6579 : 1993 reaffirmed 2009
10	Microbiology of food and animal feeding stuffs – horizontal method for detection and enumeration of <i>Listeria monocytogenes</i> : Part 1 Detection method	IS 14988(Part 1):2001/ ISO 11290-1 :1996 reaffirmed 2007
11	Methods for detection of bacteria responsible for food poisoning: Part 6 identification, enumeration and confirmation of <i>B.cereus</i>	IS 5887(Part 6):1999 / ISO 7932:1993 reaffirmed 2007
12	Microbiology of food and animal feeding stuffs- Horizontal method for the enumeration of sulfite reducing bacteria growing under anaerobic conditions	ISO 15213: 2003 -05-01
13	Methods of test for dairy industry part III bacteriological analysis of milk (first revision)	IS 1479 (Part III-1977- reaffirmed 1992
14	Indian Standard Specification for sterilised milk	IS: 4238-1967 reaffirmed 2010
15	Specification for sterilized cream	BIS (IS : 4884:1968) reaffirmed 1999
16	Packaged pasteurized milk – specification (first revision)	IS I3688: 1999
17	Method for determination of phosphatase activity in milk and milk products:	IS 8479 (Parts I):1977 reaffirmed 1997
18	Specification for condensed milk, partly skimmed and skimmed condensed milk (second revision)	IS :1166-1986 reaffirmed 1997
19	Hard cheese, processed cheese and processed cheese spread	IS :2785:1964
20	Methods of sampling for milk and milk products	IS 11546:1999/ ISO 707:1997 reaffirmed 2010
21	Dairy products-Yoghurt specification	IS: 12898:1989 reaffirmed 1994

For IS Standards recent version shall apply.

F. No.1-110(2)/SP (Biological Hazards)/FSSAI/2010

**(Yudhvir Singh Malik)
Chief Executive Officer**

Note. – The principal regulations were published in the Gazette of India, Extraordinary vide notification number F. No. 2-15015/30/2010, dated the 1st August, 2011 subsequently amended vide notification numbers:

- (1) F. No. 4/15015/30/2011, dated the 7th June, 2013;
- (2) F. No. P.15014/1/2011-PFA/FSSAI, dated the 27th June, 2013;
- (3) F. No. 5/15015/30/2012, dated the 12th July, 2013 and
- (4) F. No. P.15025/262/13-PA/FSSAI dated the 5th, December, 2014.

