APPENDIX B: Microbiological Requirements:

[28][Table 1A

Microbiological Requirements for Fish and Fishery products -Hygiene Indicator Organisms

Sl. No.	**Product Category***	**Aerobic Plate Count**				**Coagulase positive Staphylococci**				**Yeast &mold count**				**Stage where criterion applies**	**Action in case of unsatisfactory results**
		Sampling Plan		Limits (cfu/g)		Sampling Plan		Limits (cfu/g)		Sampling Plan		Limits (cfu/g)			
		n	c	m	M	n	c	m	M	n	c	m	M		
1.	Chilled/Frozen Finfish	5	3	$5x10^5$	$1x10^7$	-	-	-	-	-	-	-	-	After Chilling/Freezing.	Improvement in hygiene; Time-Temperature Control along value chain
2.	Chilled/Frozen Crustaceans	5	3	$1x10^6$	$1x10^7$	-	-	-	-	-	-	-	-	After Chilling/Freezing	Improvement in hygiene; Time-Temperature Control along value chain
3.	Chilled/Frozen Cephalopods	5	2	$1x10^5$	$1x10^6$	-	-	-	-	-	-	-	-	After Chilling/Freezing	Improvement in hygiene; Time-Temperature Control along value chain
4.	Live Bivalve Molluscs#	-	-	-	-	-	-	-	-	-	-	-	-	-	-

5.	Chilled/Frozen Bivalves	5	2	$1x10^5$	$1x10^6$	-		-	-	-	-	-	-	After Chilling/Freezing	Improvement in hygiene; Time-Temperature Control along value chain
6.	Frozen Cooked Crustaceans/Frozen Heat Shucked Mollusc	5	2	$1x10^5$	$1x10^6$	5	2	$1x10^2$	$1x10^3$	-	-	-	-	End of Manufacturing process	Improvement in hygiene; Selection of raw material; Time-Temperature Control along value chain; process control
7.	Dried/Salted and Dried Fishery Products	5	0	$1x10^5$		-	-	-	-	5	2	100	500	End of Manufacturing process	Improvement in hygiene; Selection of raw material; Adequate drying (water activity ≤ 0.78)
8.	Thermally Processed Fishery Products	Commercially Sterile**				-	-	-	-	-	-	-	-	End of Manufacturing process	Revalidation of thermal process
9.	Fermented Fishery Products	-	-	-	-	5	1	$1x10^2$	$1x10^3$	5	0	100		End of Manufacturing process	Improvement in hygiene; Selection of raw material
10.	Smoked Fishery Products	5	0	$1x10^5$		5	2	$1x10^2$	$1x10^3$	-	-	-	-	End of Manufacturing process	Improvement in hygiene; Time-

														Temperature Control along value chain
11.	Accelerated Freeze Dried Fishery Products	5	0	$1x10^4$		5	0	100		-	-	-	-	End of Manufacturing process	Selection of raw material: Improvement in hygiene; along value chain
12.	Fish Mince/Surimi and Analogues	5	2	$1x10^5$	$1x10^6$	5	2	$1x10^2$	$1x10^3$	-	-	-	-	End of Manufacturing process	Selection of raw material: Improvement in hygiene
13.	Fish Pickle	5	0	$1x10^3$		5	1	$1x10^2$	$1x10^3$	5	0	100		End of manufacturing process (before packing)	Improvement in hygiene; Control of pH/acidity, selection of ingredients
14.	Battered and Breaded Fishery Products	5	2	$1x10^5$	$1x10^7$	5	1	$1x10^2$	$1x10^3$	5	0	100		End of Manufacturing process	Improvement in hygiene; Time-Temperature Control
15.	Convenience Fishery Products	5	2	$1x10^3$	$1x10^4$	5	2	$1x10^2$	$1x10^3$	-	-	-		End of Manufacturing process	Improvement in hygiene; Time-Temperature control of batter mix
16.	Powdered Fish Based Products	5	2	$1x10^4$	$1x10^5$	5	2	1x10	$1x10^2$	5	0	100		End of Manufacturing process	Improvement in hygiene; Selection of raw material

	Test method	IS: 5402/ISO 4833	IS 5887 : Part 2 or IS 5887 Part 8 (Sec 1)/ ISO: 6888-1 or IS 5887 Part 8 (Sec 2)/ISO 6888-2	IS:5403/ISO 21527		

**Commercial sterility should be established as per APHA (2015). Canned Foods—Tests for Commercial Sterility. Compendium of Methods for the Microbiological Examination of Food.

#No hygienic indicators are currently prescribed for the Live Bivalve Molluscs

Table 1B

Microbiological Requirements for Fish and Fishery products –Safety Indicator Organisms

Sl. No.	Product Category*	*Escherichia coli*				*Salmonella*				*Vibriocholerae* (O1 and O139)				*Listeria monocytogenes*				*Clostridium botulinum*			
		Sampling Plan		Limits (MPN/g)		Sampling Plan		Limits		Sampling Plan		Limits		Sampling Plan		Limits		Sampling Plan		Limits(MPN /g)	
		n	c	m	M	n	c	m	M	n	c	m	M	n	c	m	M	n	c	m	M
1.	Chilled/Frozen Finfish	5	3	11	500	5	0	Absent/25g		5	0	Absent/25g		-	-	-	-	-	-	-	-
2.	Chilled/Frozen Crustaceans	5	3	11	500	5	0	Absent/25g		5	0	Absent/25g		-	-	-	-	-	-	-	-
3.	Chilled/frozen Cephalopods	5	0	20		5	0	Absent/25g		5	0	Absent/25g		-	-	-	-	-	-	-	-
4.	Live Bivalve Molluscs	5	1	230 /100g	700 /100g	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5.	Chilled/Frozen Bivalves	5	0	46		10	0	Absent/25g		5	0	Absent/25g		-	-	-	-	-	-	-	-
6.	Frozen cooked crustaceans/Frozen heat shucked mollusca	5	2	1	10	5	0	Absent/25g		5	0	Absent/25g		5	0	Absent/25g		-	-	-	-
7.	Dried/ Salted and dried fishery products	5	0	20		5	0	Absent/25g		-	-	-	-	-	-	-	-	-	-	-	-

8.	Thermally processed fishery products	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	Absence of viable spores or vegetative cells of *Clostridium botulinum* and absence of botulinum toxin.			
9.	Fermented Fishery Products	5	2	4	40	10	0	Absent/25g		-	-	-	-	-	-	-	-	Absence of viable spores or vegetative cells of *Clostridium botulinum* and absence of botulinum toxin.			
10	Smoked fishery products	5	3	11	500	5	0	Absent/25g		5	0	Absent/25g		5	0	Absent/25g		-	-	-	-
11	Accelerated Freeze Dried Fishery Products	5	0	20		5	0	Absent/25g		5	0	Absent/25g		5	0	Absent/25g		-	-	-	-
12	Fish Mince/Surimi and analouges	5	0	20		5	0	Absent/25g		5	0	Absent/25g		5	0	Absent/25g		-	-	-	-
13.	Fish Pickle	5	0	20		5	0	Absent/25g		-	-	-	-	-	-	-	-	-	-	-	-

14.	Battered and Breaded fishery products	5	2	11	500	5	0	Absent/25 g	5	0	Absent/25g		5	5	Absent/25g		-	-	-	-
15.	Convenience fishery products	5	2	1	10	5	0	Absent/25 g	5	0	Absent/25g		5	0	Absent/25g		-	-	-	-
16.	Powered fish based products	-	-	-	-	5	0	Absent/25g	-	-	-	-	-	-	-	-	-	-	-	-
	Test Methods	IS: 5887 Part 1 or ISO 16649-2				IS: 5887 Part 3/ ISO 6579			*Vibrio*, Bacteriological Analytical Manual, Chapter 9. USFDA BAM Online, May, 2004				IS: 14988, Part 1&2/ISO 11290-1 &2				IS: 5887, Part 4 or ISO 17919			

Sampling Plan:

The terms n, c, m and M used in this standard have the following meaning:

n = Number of units comprising a sample.

c = Maximum allowable number of units having microbiological counts above m.

m = Microbiological limit that may be exceeded number of units c.

M = Microbiological limit that no sample unit may exceed.

Product Definitions:

(1) Chilled/Frozen Finfish includes clean and wholesome finfish, which are either in raw, chilled or frozen condition and handled in accordance with good manufacturing practices. Chilling is the process of cooling fish or fish products to a temperature approaching that of melting ice. Chilling can be achieved either by using ice, chilled water, ice slurries of both seawater and freshwater or refrigerated seawater. Similarly, freezing is the process which is sufficient enough to reduce the temperature of the whole product to a level low enough to preserve the inherent quality of the fish and that have been maintained at this low temperature during transportation, storage and distribution up to and including the time of final sale. Freezing process that is carried out in appropriate equipment in such a way that the range of temperature of maximum crystallization is passed quickly. The quick freezing process shall not be regarded as complete unless and until the product temperature reached –18°C (0°F) or lower at the thermal centre after thermal stabilization.

(2) Chilled/Frozen Crustaceans includes clean, whole or peeled crustaceans (shrimp/prawn, crabs and lobster) which are either in raw, chilled or frozen condition and handled in accordance with good manufacturing practices.

(3) Chilled/Frozen Cephalopods includes cleaned, whole or de-skinned cephalopods (squid, cuttlefish and octopus) which are either in raw, chilled or frozen condition and handled in accordance with good manufacturing practices.

(4) Live Bivalve Molluscs includes Oyster, Clam, Mussel, Scallop, Abalone which are alive immediately prior to consumption. Presentation includes the shell. Live bivalve molluscs are harvested alive from a harvesting area either approved for direct human consumption or classified to permit harvesting for an approved method of purification, like relaying or depuration, prior to human consumption. Both relaying and depuration must be subject to appropriate controls implemented by the official agency having jurisdiction.

(5) Chilled/Frozen Bivalves includes clean, whole or shucked bivalves, which are live either in chilled or frozen condition and handled in accordance with good manufacturing practices. This product category includes filter feeding aquatic animals such as oysters, mussels, clams, cockles and scallops.

(6) Frozen cooked Crustaceans or Frozen heat shucked Mollusca means clean, whole or peeled crustaceans, which are cooked at a defined temperature and time and subsequently frozen. Cooking of crustaceans must be designed to eliminate six log reduction of most heat resistant vegetative bacteria i.e. *Listeria monocytogenes*. Frozen heat shucked mollusca includes bivalves where meat is removed from the shell by subjecting the animals to mild heat before shucking to relax the adductor muscle and subsequently frozen.

(7) Dried or Salted and Dried fishery Products means the product prepared from fresh or wholesome finfish or shellfish after drying with or without addition of salt. The fish shall be bled, gutted, beheaded, split or filleted and washed prior to salting and drying. Salt used to produce salted fish shall be clean, free from foreign matter, and has no visible signs of contamination with dirt, oil, bilge or other extraneous materials.

(8) Thermally Processed Fishery Products means the product obtained by application of heat or temperature for sufficient time to achieve commercial sterility in hermetically sealed containers.

(9) Fermented Fishery Products includes any fish product that has undergone degradative changes through enzymatic or microbiological activity either in presence or absence of salt. Non-traditional products manufactured by accelerated fermentation, acid ensilage and chemical hydrolysis also belong to this category.

(10) Smoked Fishery Products means fish or fishery product subjected to a process of treatment with smoke generated from smouldering wood or plant materials. Here the product category refers to hot smoked fish where fish is smoked at an appropriate combination of temperature and time sufficient to cause the complete coagulation of the proteins in the fish flesh.

(11) Accelerated Freeze dried Fishery Products means fish, shrimp or any fishery product subjected to rapid freezing, followed by drying under high vacuum so as to remove the water by sublimation to a final moisture content of less than two percent.

(12) Fish Mince/Surimi and analogues means comminuted, mechanically removed meat which have been separated from and are essentially free from bones, viscera and skin. Surimi is the stabilized myofibrillar proteins obtained from mechanically deboned fish flesh that is washed with water and blended with cryoprotectants. Surimi analogues are variety of imitation products produced from surimi with addition of ingredients and flavor.

(13) Fish Pickle means an oily, semi-solid product with spices and acidic taste obtained from maturation of partially fried fish with vinegar. It is produced by frying edible portions of fish, shrimp or mollusc, followed by partial cooking with spices, salt and oil and maturing for 1-3 days with added organic acids. The product is intended for direct human consumption as a seasoning, or condiment for food.

(14) Battered and Breaded Fishery Products include fish portions, fillets or mince coated with batter and/or breading. Batter means liquid preparation from ground cereals, spices, salt, sugar and other ingredients and/or additives for coating. Typical batter types are non-leavened batter and leavened batter. Breading means dry breadcrumbs or other dry preparations mainly from cereals with colourants and other ingredients used for the final coating of fishery products.

(15) Convenience Fishery Products are tertiary food products made of fish, which are in ready to eat form and also includes snack based items prepared from fish and fishery products meant for direct human consumption such as extruded fishery products, fried items namely fish wafers, crackers, fish cutlets, fish burgers and other such products. These products can be consumed directly after minimal handling and processing. This category includes Sous-vide cooked products, surimi-based products cooked (in-pack), pasteurized crab meat, pasteurized molluscs which are distributed as refrigerated, but meant for direct human consumption with minimal or no cooking.

(16) Powdered Fish based Products include the products which are prepared from finfish/shellfish or parts thereof, with or without other edible ingredients in powdered form, suitable for human consumption. These may be consumed directly or as supplements and also after hydration and this category includes powdered and dried fish products generally used as ingredients in food preparations such as fish soup powder, fish chutney powder, ready to use fish-mix, and such other food.]

[21][Table 2
Microbiological Standards for Milk and Milk Products

Table-2A Microbiological Standards for Milk and Milk Products – Process Hygiene Criteria

Sr. No.	Product Description[1]	Aerobic Plate Count				Coliform Count[4]				*Staphylococcus aureus* (Coagulase positive)				Yeast and Mold Count				*Escherichia coli*			
		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/boiled Milk/ Flavored Milk	5	3	$3x10^4$/ml	$5x 10^4$/ml	5	0	<10/ml	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
2	Pasteurized Cream	5	3	$5x10^4$/g	$7.5x10^4$/g	5	0	<10/g	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
3	Sterilized milk /UHT milk / Evaporated Milk	NA																			
4	Sterilized / UHT Cream	NA																			
5	Sweetened Condensed Milk	5	3	$5x10^2$/g	$1x10^3$/g	5	0	<10/g	NA	5	0	<10/g	NA	5	0	<10/g	NA	NA	NA	NA	NA
6	Pasteurized Butter[2]	5	3	$2.5x10^4$/g	$5x10^4$/g	5	2	10/g	20/g	5	2	10/g	50/g	5	3	20/g	50/g	5	0	Absent/g	NA

Sr. No.	Product Description[1]	Aerobic Plate Count				Coliform Count[4]				*Staphylococcus aureus* (Coagulase positive)				Yeast and Mold Count				*Escherichia coli*			
		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
7	Milk Powder ; SMP, Partly SMP ; Dairy Whitener ; Cream Powder ; Ice Cream Mix Powder ; Lactose ; Whey based Powder ;Butter Milk Powder ; Casein Powder[3]	5	2	$3x10^4$/g	$5x10^4$/g	5	2	10/g	50/g	5	2	10/g	$1x10^2$/g	5	0	50/g	NA	NA	NA	NA	NA
8	[2][Infant Milk Substitute, Infant Formula, Food for special medical purpose intended for infants[4]]	5	2	$5x10^2$/g	$5x10^3$/g	NA	NA	NA	NA	5	0	<10/g	NA	5	0	<10/g	NA	NA	NA	NA	NA

Sr. No.	Product Description[1]	Aerobic Plate Count				Coliform Count[4]				*Staphylococcus aureus* (Coagulase positive)				Yeast and Mold Count				*Escherichia coli*			
		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
	Follow Up Formula [82][Cereal Based Complimentary food, Food for infants based on traditional food ingredients]	5	2	$1x10^3$/g	$1x10^4$/g	10	0	<10/g	NA	5	0	<10/g	NA	5	0	<10/g	NA	10	0	Absent/g	NA
9	Ice Cream, Frozen Dessert, Milk Lolly, Ice Candy	5	3	$1x10^5$/g	$2x10^5$/g	5	3	10/g	$1x10^2$/g	5	2	10/g	$1x10^2$/g	NA	NA	NA	NA	5	0	Absent/g	NA
10	Processed Cheese/ Cheese Spread	5	2	$2.5x10^4$/g	$5x10^4$/g	5	0	<10/g	NA	5	0	<10/g	NA	NA	NA	NA	NA	NA	NA	NA	NA
11	All other cheeses categories including fresh cheeses / Cheddar / Cottage /Soft /Semi Soft[5]	NA	NA	NA	NA	5	3	$1x10^2$/g	$5x10^2$/g	5	3	10/g	$1x10^2$/g	5	3	$1x10^2$/g	$5x10^2$/g	5	0	<10 /g	NA
12	Fermented Milk Products	NA	NA	NA	NA	5	2	10/g	$1x10^2$/g	5	2	10/g	$1x10^2$/g	5	3	50/g	$1x10^2$/g	5	0	Absent/g	NA
13	Paneer/ Chhana/ chhana based sweets	5	3	$1.5x10^5$/g	$3.5x10^5$/g	5	3	10/g	$1x10^2$/g	5	3	10/g	$1x10^2$/g	5	3	50/g	$1.5x10^2$/g	5	0	<10/g	NA

Sr. No.	Product Description[1]	Aerobic Plate Count				Coliform Count[4]				*Staphylococcus aureus* (Coagulase positive)				Yeast and Mold Count				*Escherichia coli*			
		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
14	Khoa/ Khoa based sweets	5	3	$2.5x10^4$/g	$7.5x10^4$/g	5	2	50/g	$1x10^2$/g	5	3	10/g	$1x10^2$/g	5	3	10/g	50/g	5	0	<10/g	NA
	Test Methods[7]	**IS 5402/ ISO: 4833**				**S 5401 Part 1/ISO : 4832**				**IS 5887: Part 2 or IS 5887 Part 8 (Sec 1)/ ISO: 6888-1 or IS 5887 Part 8 (Sec 2)/ ISO 6888-2**				**IS:5403 or ISO : 6611**				**IS 5887: Part 1 or ISO : 16649-2**			

Table-2B: Microbiological Standards for Milk and Milk Products – Food Safety Criteria

Sr. No	Product Description[1]	Salmonella sp.				*Listeria monocytogenes*				*Bacillus cereus*				Sulphite Reducing Clostridia (SRC)				*Enterobacter sakazakii* (*Cronobacter sp.*			
		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/boiled milk/ Flavored Milk	5	0	Absent/ 25 ml	NA	5	0	Absent/ 25ml	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
2	Pasteurized Cream	5	0	Absent/ 25g	NA	5	0	Absent/ 25g	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
3	Sterilized milk /UHT milk / Evaporated Milk	Sterilized /UHT milk products shall comply with a test for commercial sterility as per IS: 4238 (Appendix C or Appendix D)																			
4	Sterilized/ UHT Cream	Sterilized/UHT cream product shall comply with a test for commercial sterility as per IS : 4884																			
5	Sweetened Condensed Milk[6]	5	0	Absent/ 25g	NA	5	0	Absent/ g	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
6	Pasteurized Butter[2]	5	0	Absent/ 25g	NA	5	0	Absent/ g	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

Sr. No	Product Description[1]	Salmonella sp.				*Listeria monocytogenes*				*Bacillus cereus*				Sulphite Reducing Clostridia (SRC)				*Enterobacter sakazakii* (*Cronobacter sp.*			
		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
7	Milk Powder; SMP, PSMP; Dairy Whitener; Cream Powder ; Ice Cream Mix Powder; Lactose; Whey based Powder; Butter Milk Powder; Casein Powder	5	0	Absent/ 25g	NA	5	0	Absent/ g	NA	5	3	$5x10^2$/ g	$1x10^3$/ g	5	3	50/g	$1x10^2$ /g	NA	NA	NA	NA
8	[82][Infant Milk Substitute, Infant Formula, Food for special medical purpose intended for infants]	60	0	Absent/ 25g	NA	10	0	Absent/ 25g	NA	5	2	$1x10^2$/ g	$5x10^2$/ g	5	2	10/g	$1x10^2$ /g	30	0	Absent /10g	NA

Sr. No	Product Description[1]	Salmonella sp.				*Listeria monocytogenes*				*Bacillus cereus*				Sulphite Reducing Clostridia (SRC)				*Enterobacter sakazakii (Cronobacter sp.*			
		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
	Follow Up Formula	15	0	Absent/ 25g	NA	10	0	Absent/ 25g	NA	5	2	$1x10^2$/ g	$5x10^2$/ g	5	2	10/g	$1x10^2$ /g	NA	NA	NA	NA
	[82][Cereal Based Complimentary food, Food for infants based on traditional food ingredients]	15	0	Absent/ 25g	NA	10	0	Absent/ 25g	NA	5	2	$1x10^2$/ g	$5x10^2$/ g	5	2	10/g	$1x10^2$ /g	NA	NA	NA	NA
9	Ice Cream, Frozen Dessert, Milk Lolly, Ice Candy	5	0	Absent/ 25g	NA	5	0	Absent/ g	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
10	Processed Cheese/ Cheese Spread	5	0	Absent/ 25g	NA	5	0	Absent / 25g	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

Sr. No	Product Description[1]	Salmonella sp.				*Listeria monocytogenes*				*Bacillus cereus*				Sulphite Reducing Clostridia (SRC)				*Enterobacter sakazakii* (*Cronobacter sp.*			
		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
11	All other cheeses categories including fresh cheeses / Cheddar / Cottage /Soft /Semi Soft etc	5	0	Absent/ 25g	NA	5	0	Absent/ 25 g	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
12	Fermented Milk Products-	5	0	Absent/ 25g	NA	5	0	Absent/ g	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
13	Paneer/ Chhana/ chhana based sweets	5	0	Absent/ 25g	NA	5	0	Absent/ g	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
14	Khoa/ Khoa based sweets	5	0	Absent/ 25g	NA	5	0	Absent/ g	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
	Test Methods[7]	**IS 5887 : Part 3/ ISO : 6579**				**IS 14988: Part 1/ ISO: 11290-1**				**IS 5887 (Part 6) /ISO: 7932**				**ISO : 15213**				**ISO/TS 22964**			

NA- Not Applicable

[1]Microbiological standards shall also be applicable for proprietary dairy foods depending on their analogy as determined by FSSAI with the product categories specified in **Table 2A and 2 B**

[2]The microbiological specifications for ripened butter are the same as for pasteurized butter excluding the requirements of Aerobic Plate Count.

[3]The yeast and mold count of 50/g as specified in dried product categories shall be applicable only to casein powder

[4]For products in this category (Infant Milk Food, Infant Formulae, Infant Milk Substitute), the *enterobacteriaceae* shall be tested. The microbiological criteria applicable is n=10; c=2; m=Absent/10g; M=Not Applicable. Method of analysis is ISO 21528-1 and 21528-2, as appropriate.

[5]The yeast and mold counts is not applicable in mold ripened cheeses

[6]The Sweetened condensed milk product shall comply accelerated storage test as per IS: 1166 (latest version)

Stage where the Microbiological Standards shall apply:

The Microbiological Standards in **Table-2A** (Process Hygiene Criteria) indicate the acceptable functioning of the production process. These are not to be used as requirements for releasing the products in the market. These are indicative contamination values above which corrective actions are required in order to maintain the hygiene of the process in compliance with food law. These shall be applicable at the end of the manufacturing process.

[63[]The Microbiological Standards in **Table-2B** (Food Safety Criteria) define the acceptability of a batch or lot and shall be met in respect of the product at the end of the manufacturing process and the products in the market during their shelf- life.]

Action in case of unsatisfactory result:

In case of non-compliance in respect of process hygiene criteria specified in **Table- 2A,** the FBO shall:

- check and improve process hygiene by implementation of guidelines in Schedule 4 (Part III) of FSS (Licensing and Registration of Food Businesses) Regulations; and,
- [63[]Ensure that all food safety criteria as specified in Table-2B are complied with.]

The Microbiological Standards in **Table-2B** (Food Safety Criteria) define the acceptability of a batch/lot and shall be met in respect of the product for releasing it in the market. These shall be applicable to the products at the end of the manufacturing process and the products in the market during their shelf- life.

Sampling Plans and Guidelines;

For Regulator: The sampling for different microbiological standards with respect to the products specified in **Table-2A and 2B** shall be ensured aseptically at manufacturing units and/or at retail points, as applicable, by a trained person with specialized knowledge in the field of microbiology following guidelines in the Food Safety and Standards (Food Products and Food Additives) Regulations, 2011 and ISO: 707 **(Latest version)**. The samples

shall be stored and transported at a temperature below 5°C (but not frozen), except the products that are recommended to be stored at room temperature by the manufacturer, to enable initiation of analysis within 24 hours of sampling. Preservatives shall not be added to sample units intended for microbiological examination. The desired number of sample units as per sampling plan given in **Table-2A & 2B** shall be taken from same batch/lot and shall be submitted to the notified laboratory. The testing in laboratory shall be ensured as per reference test methods given below in reference test methods for regulatory compliance. [63][A set (n) of five samples shall be tested from three different accredited laboratories and the final decision shall be drawn based on three test results. There will be no provision for retesting or re-sampling for microbiological testing]. The final decision shall be drawn based on results with no provision for retesting for microbiological parameters.

For FBO: Food Business Operator (FBO) shall perform testing as appropriate as per the microbiological standards with respect to the products specified in **Table-2A & 2B** to ensure validation and verification of compliance with the microbiological requirements. FBO shall decide themselves the necessary sampling and testing frequencies to ensure compliance with the specified microbiological requirements. FBO may use analytical methods other than those described in reference test methods given below for in-house testing only. However, these methods shall not be applicable for regulatory compliance purpose.

Sampling Plan:

The terms n,c,m and M used in this standard have the following meaning:
n = Number of units comprising a sample.
c = Maximum allowable number of units h
aving microbiological counts above m for 2- class sampling plan and between m and M for 3- class sampling plan.
m = Microbiological limit that separates unsatisfactory from satisfactory in a 2- class sampling plan or acceptable from satisfactory in a 3-class sampling plan.
M = Microbiological limit that separates unsatisfactor y from satisfactory in a 3-class sampling plan.

Interpretation of Results:

2-Class Sampling Plan (where n, c and m are specified)	3-Class Sampling Plan (where n, c, m and M are specified)
1. Satisfactory, if all the values observed are ≤ m 2. Unsatisfactory, if one or more of the values observed are >m or more than c values are > m	1. Satisfactory, if all the values observed are ≤ m 2. Acceptable, if a maximum of c values are between m and M and the rest of the values are observed as ≤ m 3. Unsatisfactory, if one or more of the values observed are >M or more than c values are >m

Reference test methods: The following test methods shall be applied as reference methods.

Reference test methods- latest version shall apply. In case where an ISO method adopted by the BIS is specified (e.g IS XXXX / ISO YYYY), latest version of the ISO method (or its BIS equivalent, if available) shall apply. [63][Test methods prescribed in FSSAI Manual of Methods of Analysis of Foods (Microbiological Testing) may also be referred along with the IS/ISO methods specified for Process Hygiene Criteria and Food Safety Criteria].

Sr. no.	Parameter	Reference Test Methods
1.	Aerobic Plate Count	Microbiology of the food chain -- Horizontal method for the enumeration of microorganisms -- Part 1: Colony count at 30 degrees C by the pour plate technique- IS 5402/ ISO:4833
2.	Coliforms	Microbiology of food and animal feeding stuffs -- Horizontal method for the Detection and Enumeration of Coliforms – Part-1 Colony-Count Technique- IS: 5401 Part 1 Microbiology of food and animal feeding stuffs -- Horizontal method for the enumeration of Coliforms - Colony-count technique- ISO 4832
3.	Enterobacteriaceae	Microbiology of food and animal feeding stuffs -- Horizontal methods for the detection and enumeration of Enterobacteriaceae -- Part 1: Detection and enumeration by MPN technique with pre-enrichment- ISO 21528 Part 1 Microbiology of food and animal feeding stuffs -- Horizontal methods for the detection and enumeration of Enterobacteriaceae -- Part 2: Colony-count method- ISO 21528 Part 2
4.	*Staphylococcus aureus*	Methods for detection of bacteria responsible for food poisoning: Part 2 Isolation, identification and enumeration of *Staphylococcus aureus* and *Faecal streptococci*- IS 5887: Part 2 Methods for Detection of Bacteria Responsible for Food Poisoning Part 8 Horizontal Method for Enumeration of *Coagulase-Positive Staphylococci*/ (*Staphylococcus aureus* and other species) **Section 1 Technique using baird-parker agar medium-** IS 5887 (Part 8/Sec 1: / ISO 6888-1: 1999 Methods For Detection Of Bacteria Responsible For Food Poisoning Part 8 Horizontal Method For Enumeration Of *Coagulase-Positive Staphylococci*/ (*Staphylococcus aureus* And Other Species) **Section 2 Technique using rabbit plasma fibrinogen agar medium-** IS 5887 (Part 8/Sec 2) / ISO 6888-2: 1999
5.	*Enterobacter sakazakii*	Milk and milk products -- Detection of *Enterobacter sakazakii*- ISO/TS 22964

6.	Yeast and Mould Count	Method for Yeast and Mould Count of Food Stuffs and Animal feed- IS 5403 Milk and milk products -- Enumeration of colony-forming units of Yeasts and/or Moulds -- Colony-count technique at 25 degrees C- ISO 6611
7.	*Escherichia coli*	Methods for Detection of Bacteria Responsible for Food Poisoning - Part I : Isolation, Identification and Enumeration of *Escherichia coli*- IS 5887 : Part 1 Microbiology of food and animal feeding stuffs -- Horizontal method for the enumeration of beta-glucuronidase-positive *Escherichia coli* -- Part 2: Colony-count technique at 44 degrees C using 5-bromo-4-chloro-3-indolyl beta-D-glucuronide- ISO: 16649-2
8.	*Salmonella*	Methods for Detection of Bacteria Responsible for Food Poisoning - Part 3: General Guidance on Methods for the Detection of *Salmonella*- IS 5887: Part 3 Microbiology of food and animal feeding stuffs -- Horizontal method for the detection of *Salmonella* spp.- ISO 6579
9.	*Listeria monocytogenes*	Microbiology of the food chain -- Horizontal method for the detection and enumeration of *Listeria monocytogenes* and other Listeria spp. -- Part 1: Detection method- ISO: 11290-1 Microbiology of food and animal feeding stuffs -- Horizontal method for the detection and enumeration of *Listeria monocytogenes* -- Part 2: Enumeration Method- ISO: 11290-2 Microbiology of Food and Feeding Stuffs - Horizontal method for Detection and Enumeration of *Listeria Monocytogenes*: Part 1 Detection Method- IS 14988: Part 1 Microbiology of Food and Animal Feeding Stuffs - Horizontal Method for the Detection and Enumeration of *Listeria monocytogenes* - Part 2: Enumeration Method- IS 14988: Part 2
10.	*Bacillus cereus*	Microbiology of food and animal feeding stuffs -- Horizontal method for the enumeration of presumptive *Bacillus cereus* -- Colony-count technique at 30 degrees C- IS 5887 (Part 6) /ISO:7932

11.	Sulfite-reducing bacteria	Microbiology of food and animal feeding stuffs -- Horizontal method for the enumeration of sulfite-reducing bacteria growing under anaerobic conditions- ISO 15213
12.		Milk and milk products - Guidance on sampling- ISO:707
13.		Indian Standard Specification for sterilized milk- IS: 4238
14.		Specification for sterilized cream- IS: 4884
15.		Specification for condensed milk, partly skimmed and skimmed condensed milk - IS :1166.".]

[70][Table: 3 Microbiological Standards for Spices and Herbs
Table -3A Microbiological Requirements for Spices and Herbs – Process Hygiene Criteria

Sr. No.	Product Category[i]	Aerobic Colony Count				Yeast and Mold Count				Enterobacteriaceae				*Staphylococcus aureus*			
		Sampling Plan		Limits (cfu/g)		Sampling Plan		Limits (cfu/g)		Sampling Plan		Limits (cfu/g)		Sampling Plan		Limits (cfu/g)	
		n	C	m	M	n	c	m	M	n	c	m	M	n	c	m	M
1.	**Fresh[ii]**																
2.	**Dried or Dehydrated**	5	2	$1x10^6$	$1x10^7$	5	2	$1x10^4$	$1x10^5$	5	2	$1x10^2$	$1x10^3$	5	2	$1x10^2$	$1x10^3$
3.	**Ground or Powdered**	5	2	$1x10^6$	$1x10^7$	5	2	$1x\ 10^4$	$1x\ 10^5$	5	2	$1x10^2$	$1x10^3$	5	2	$1x10^2$	$1x10^3$
4.	**Extracted**	5	2	$1x10^3$	$1x\ 10^4$	5	2	$1x10^2$	$1x\ 10^3$	5	1	$1x10^1$	$1x\ 10^2$	5	1	$1x10^1$	$1x10^2$
5.	**Wet ground (Paste)/ preserved or pickled**	5	2	$1x\ 10^3$	$1x\ 10^4$	5	2	$1x\ 10^3$	$1x\ 10^4$	5	2	$1x10^2$	$1x\ 10^3$	5	2	$1x10^1$	$1x10^2$
	Method of analysis[iii]	IS: 5402/ ISO 4833				IS: 5403/ ISO 21527 Part 1 and Part 2				IS/ISO:7402/ ISO 21528 Part 2				IS:5887, Part 2 and IS 5887 part 8 (Sec 1)/ ISO 6888-1 or IS:5887 Part 8 (Sec2)/ISO 6888-2			

Table -3B Microbiological Requirements for Spices and Herbs – Food Safety Criteria

Sr. No.	Product Category[i]	*Salmonella*				Sulphite Reducing Clostridia				*Bacillus cereus*			
		Sampling Plan		Limits (cfu/g)		Sampling Plan		Limits (cfu/g)		Sampling Plan		Limits (cfu/g)	
		N	c	m	M	n	c	m	M	N	c	m	M
1.	**Fresh[ii]**												
2.	**Dried or Dehydrated**	5	0	Absent/25 g	NA	5	2	$1x10^2$	$1x10^3$	5	2	$1x10^3$	$1x10^4$
3.	**Ground or Powdered**	5	0	Absent/25 g	NA	5	2	$1x10^2$	$1x\ 10^3$	5	2	$1x10^3$	$1x10^4$
4.	**Extracted**	5	0	Absent/25 g	NA	5	1	$1x10^1$	$1x\ 10^2$	5	1	$1x10^1$	$1x\ 10^2$
5.	**Wet ground (Paste)/ preserved or pickled**	5	0	Absent/25 g	NA	5	2	$1x10^1$	$1x\ 10^2$	5	2	$1x10^1$	$1x\ 10^2$
6.	**Method of analysis[iii]**	IS: 5887 Part 3/ISO:6579				ISO 15213				IS:5887,Part 6 ISO 7932			

NA-Not applicable

[i]-Definitions:

a. **Fresh**: The spices and herbs that are consumed fresh.

b. **Dried or dehydrated**: The product obtained by drying/ removal of most of the moisture by any suitable method which ensures characteristics of fresh spices on rehydration or pre-cooking.

c. **Ground or powdered**: Ground or powdered product obtained by grinding or crushing of clean dried/dehydrated fruits, capsules, buds, seeds, rhizomes, aril, kernel, berries and stigmas etc.

d. **Extracted:** Products of the spices and herbs which are produced by extracting in a concentrated form including oleoresins.

e. Wet ground (paste)/preserved or pickled: Semi solid, preserved product using brine, vinegar and other permitted preservatives or physical methods.

For detailed product definition, refer to Food Safety & Standards (Food Product Standards & Food Additives) Regulations, 2011.

[ii]. The category "Fresh" shall be regulated in accordance with the Good Manufacturing Practices and Code of Good Hygiene Practices notified under Schedule 4 of FSS (Licensing and Registration of Food Businesses) Regulations, 2011.

Stage where the Microbiological Standards shall apply:

The microbiological standards with respect to the product categories specified in **Table-3A** (Process Hygiene Criteria) indicate the acceptable functioning of the production process. These are not to be used as requirements for releasing the products in the market. These are indicative values above which corrective actions are required in order to maintain the hygiene of the process in compliance with food law. These shall be applicable at the end of the manufacturing process. The Microbiological Standards in **Table-3B** (Food Safety Criteria) define the acceptability of a batch/lot and shall be met in respect of the products at the end of manufacturing process and the products in the market during their shelf- life.

Action in case of unsatisfactory result:

In case of non-compliance in respect of Process Hygiene Criteria specified in **Table- 3A,** the FBO shall:

- check and improve process hygiene by implementation of guidelines in Schedule 4 of FSS (Licensing and Registration of Food Businesses) Regulations; and,
- Ensure that all food safety criteria as specified in **Table -3B** are complied with.

Sampling Plans and Guidelines;

For Regulator: The sampling for different microbiological standards specified in **Table-3A and 3B** shall be ensured aseptically at manufacturing units and/or at retail points, as applicable, by a trained person with specialized knowledge in the field of microbiology following guidelines in the Food Safety and Standards (Food Products and Food Additives) Regulations, 2011 and ISO: 707 **(Latest version)**. The samples shall be stored and transported in frozen condition at -18°C(±2°C) or under refrigerated conditions at 2-5°C as applicable except the products that are recommended to be stored at room temperature by the manufacturer to enable initiation of analysis within 24 hours of sampling. Preservatives shall not be added to sample units intended for microbiological examination. The desired number of sample units as per sampling plan given in **Table-3A & 3B** shall be taken from same batch/lot and shall be submitted to the notified laboratory. Three sets, each containing 'n' number of samples (n as defined in the sampling planeg if n=5, then total no. of samples to be drawn is 15) shall be drawn. Each of these three sets shall be tested in three different accredited laboratories. The final decision shall be based on the results of three accredited laboratories. In the case of food safety criteria (Table 8B), results from all the three laboratories should indicate compliance with specified criteria. There will be no provision for retesting or resampling for microbiological testing. The testing in laboratory shall be ensured as per reference test methods given below in reference test methods for regulatory compliance.

For FBO: Food Business Operator (FBO) shall perform testing as appropriate as per the microbiological standards in **Table-3A & 3B** to ensure validation and verification of compliance with the microbiological requirements. FBO shall decide themselves subject to minimum prescribed under FSSR (Licensing and Registration of Food Businesses), the necessary sampling and testing frequencies to ensure compliance with the specified microbiological requirements. FBO may use analytical methods other than those described in reference test methods given below for in-house testing only. However, these methods shall not be applicable for regulatory compliance purpose.

Sampling Plan:

The terms n, c, m and M used in this standard have the following meaning:

n = Number of units comprising a sample.
c = Maximum allowable number of units having microbiological counts above m for 2- class sampling plan and between m and M for 3- class sampling plan.
m = Microbiological limit that separates unsatisfactory from satisfactory in a 2- class sampling plan or acceptable from satisfactory in a 3-class sampling plan.
M = Microbiological limit that separates unsatisfactory from satisfactory in a 3-class sampling plan.

Interpretation of Results:

2-Class Sampling Plan (where n,c and m are specified)	3-Class Sampling Plan (where n,c,m and M are specified)

1. Satisfactory, if all the values observed are ≤ m **2.** Unsatisfactory, if one or more of the values observed are >m.	1. Satisfactory, if all the values observed are ≤ m 2. Acceptable, if a maximum of c values are between m and M. 3. Unsatisfactory, if one or more of the values observed are > M or more than prescribed c values are >m

[iii] **Reference test methods:** The following test methods shall be applied as reference methods. Test methods prescribed in FSSAI Manual of Method of Analysis of Foods (Microbiological Testing) may also be referred along with the IS/ISO methods specified for Process Hygiene Criteria and Food Safety Criteria**.** Latest version of test methods shall apply. In case where an ISO method adopted by the BIS is specified (e.g IS XXXX / ISO YYYY), latest version of the ISO method (or its BIS equivalent, if available) shall apply.

Sr. No.	**Parameter**	**Reference Test methods**
1.	Aerobic Plate Count	Microbiology of the food chain -- Horizontal method for the enumeration of microorganisms -- Part 1: Colony count at 30 °C by the pour plate technique- IS 5402/ ISO:4833
2.	Yeast and Mold Count	Method for Yeast and Mold Count of Food Stuffs and Animal feed- IS 5403 Microbiology of food and animal feeding stuff- Horizontal method for the enumeration of yeasts and moulds-Part1: Colony count technique in products with water activity greater than 0.95-ISO 21527-1 Microbiology of food and animal feeding stuff-Horizontal method for the enumeration of yeasts and moulds-Part2: Colony count technique in products with water activity less than 0.95-ISO 21527-2
3.	Enterobacteriaceae	Microbiology - General Guidance for the Enumeration of Enterobacteriaceae without Resuscitation - MPN Technique and Colony-count Technique- IS/ISO 7402 Microbiology of Food and Animal feeding stuff –Horizontal methods for the detection and enumeration of Enterobacteriaceae- Part 2:Colony- count method-ISO 21528-2

4.	*Staphylococcus aureus*	Methods for detection of bacteria responsible for food poisoning: Part 2 Isolation, identification and enumeration of *Staphylococcus aureus* and faecal streptococci- IS 5887: Part 2 Methods for Detection of Bacteria Responsible for Food Poisoning Part 8 Horizontal Method for Enumeration of Coagulase-Positive Staphylococci/ (*Staphylococcus aureus* and other species) **Section 1 Technique using baird-parker agar medium -** IS 5887 (Part 8/Sec 1: / ISO 6888-1: 1999 Methods for Detection of Bacteria Responsible for Food Poisoning Part 8 Horizontal Method for Enumeration of Coagulase-Positive Staphylococci/ (*Staphylococcus aureus* and Other Species) **Section 2 Technique using rabbit plasma fibrinogen agar medium-** IS 5887 (Part 8/Sec 2) / ISO 6888-2: 1999
5.	*Salmonella*	Methods for Detection of Bacteria Responsible for Food Poisoning - Part 3: General Guidance on Methods for the Detection of Salmonella- IS 5887: Part 3 Microbiology of food and animal feeding stuffs -- Horizontal method for the detection of Salmonella spp.- ISO6579
6.	Sulfite-Reducing Bacteria	Microbiology of food and animal feeding stuffs -- Horizontal method for the enumeration of sulfite-reducing bacteria growing under anaerobic conditions- ISO 15213
7.	*Bacillus cereus*	Microbiology of Food and Animal Feeding Stuffs-Horizontal Method for the Enumeration of Preservative Bacillus Cereus, Part 6 Colony –count Technique at 30°C- IS 5887-6 Microbiology of food and animal feeding stuffs- Horizontal method for the enumeration of presumptive Bacillus cereus- Colony- count technique at 30degrees C.-ISO 7932.]

[46][Table 4A: Microbiological Standards for Fruits and Vegetables and their Products – Process Hygiene Criteria

Sl. No.	Product description [1]	Aerobic Plate Count				Yeast and Mold Count				*Enterobacteriaceae*				*Staphylococcus aureus* (Coagulase +ve)			
		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
1.	Fresh[2]							NA									
2.	Cut or minimally processed and packed, including juices (Non-thermally processed)	5	2	$1x10^6$/g	$1x10^7$/g	5	1	$1x10^2$/g	$1x10^4$/g	5	2	$1x10^2$/g	$1x10^4$/g	5	1	$1x10^2$/g	$1x10^3$/g
3.	Fermented[3] or pickled or acidified or with preservatives			NA		5	1	$1x10^2$/g	$1x10^3$/g	5	2	$1x10^2$/g	$1x10^3$/g	5	1	10/g	$1x10^2$/g
4.	Pasteurized Juices[4]	5	2	$1x10^2$/ml	$1x10^4$/ml	5	1	$1x10^2$/ml	$1x10^3$/ml	5	0	Not detectable as per prescribed method		5	0	Absent/25ml	
	Carbonated Fruit beverages[4]	5	1	50/ml	$5x10^2$/ml	5	0	<10/ml		5	0			5	0	Absent/25ml	

5.	Frozen	5	2	$4x10^4$/g	$5x10^5$/g	5	1	$1x10^2$/g	$1x10^3$/g	5	2	$1x10^2$/g	$3x10^2$/g	5	1	20/g	$1x10^2$/g
6.	Dehydrated or dried	5	1	$4x10^4$/g	$1x10^5$/g	5	1	$1x10^2$/g	$1x10^4$/g	5	1	$1x10^2$/g	$1x10^3$/g	5	1	10/g	$1x10^2$/g
7.	Thermally processed (other than pasteurization at less than 100°C)	5	1	$1x10^2$/g	$1x10^3$/g	5	1	50/g	$1x10^2$/g	5	0	Not detectable as per prescribed method		5	0	Absent/25g	
8.	Retort processed[5]	5	0	50/g		NA				5	0			5	0	Absent/25g	
	Test Methods[6]	IS: 5402/ISO:4833				IS: 5403/ ISO 21527 Part 1 and Part 2				IS/ISO 7402/ ISO 21528 Part 2				IS:5887, Part 2 and IS 5887 part 8 (Sec 1)/ ISO 6888-1 or IS:5887 Part 8 (Sec2)/ISO 6888-2			

Table 4B: Microbiological Standards for Fruits and Vegetables and their Products-Food Safety Criteria

Sl. N.	Product description[1]	*Salmonella*			*Listeria monocytogenes*			Sulphite Reducing Clostridia (SRC)				*E. Coli 0157* and Vero or Shiga toxin producing *E coli*			*Vibrio cholerae*		
		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.	Fresh[2]	NA			NA			NA				NA			NA		
2.	Cut or minimally processed and packaged, including juices (Non-thermally processed)	5	0	Absent/ 25 g	5	0	Absent/25 g	NA	NA	NA	NA	5	0	Absent/25 g	5	0	Absent/25 g
3.	Fermented[3] or pickled or acidified or with preservatives	5	0	Absent/ 25 g	5	0	Absent/25 g	NA	NA	NA	NA	5	0	Absent/25 g	5	0	Absent/25 g
4.	Pasteurized Juices[4]	5	0	Absent/ 25 ml	5	0	Absent/25 ml	NA	NA	NA	NA	5	0	Absent/25 ml	5	0	Absent/25 ml

Sl. N.	Product description[1]	*Salmonella*			*Listeria monocytogenes*			Sulphite Reducing Clostridia (SRC)				*E. Coli 0157* and Vero or Shiga toxin producing *E coli*			*Vibrio cholerae*		
		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
	Carbonated fruit beverages[4]	5	0	Absent/ 25 ml	5	0	Absent/25 ml	NA	NA	NA	NA	5	0	Absent/25 ml	5	0	Absent/25 ml
5.	Frozen	5	0	Absent/ 25 g	5	0	Absent/25 g	NA	NA	NA	NA	5	0	Absent/25 g	5	0	Absent/25 g
6.	Dehydrated or dried	5	0	Absent/ 25 g	5	0	Absent/25 g	NA	NA	NA	NA	5	0	Absent/25 g	5	0	Absent/25 g
7.	Thermally processed (other than pasteurization at less than 100°C	5	0	Absent/ 25 g	5	0	Absent/25 g	NA	NA	NA	NA	5	0	Absent/25 g	5	0	Absent/25 g
8.	Retort processed[5]	5	0	Absent/25 g	5	0	Absent/25 g	5	0	Absent/25 g		5	0	Absent/25 g	5	0	Absent/25 g

Sl. N.	Product description[1]	*Salmonella*				*Listeria monocytogenes*				Sulphite Reducing Clostridia (SRC)				*E. Coli 0157* and Vero or Shiga toxin producing *E coli*				*Vibrio cholerae*			
		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
	Test Methods[6]	IS: 5887 Part3 / ISO:6579				IS: 14988, Part 1 / ISO 11290-1				ISO 15213				IS: 14397				IS:5887, (Part V)/ ISO 21872 Part 1			

Note- 'ml' will be applicable in place of 'g' in case of liquid product.

NA-Not applicable

[1] **Definitions of fruits and vegetables and their products**

(a) **Fresh**: The whole fruits and vegetables that are sold fresh.

(b) **Cut or minimally processed and packaged including juices**: Fruits and vegetables which are washed or sanitized or peeled or cut up and made in to juice and packed.

(c) **Fermented or pickled or acidified or with preservatives**: Fruits and vegetables including their products which are preserved using living ferments like yeast, bacterium, mold, enzyme or in brine to produce lactic acid or marinating and storing it in an acid solution, usually vinegar (acetic acid), salt and sugar.

(d) **Pasteurized Juices**: Fruit and vegetable j*uices that are subjected to pasteurization* to destroy or inactivate harmful microorganisms.

(e) **Carbonated fruit beverages (and fruit drinks):** Any beverage or drink which is prepared from fruit juice and water or carbonated water and containing sugar, dextrose, invert sugar or liquid glucose either in single or in combination which may contain peel oil and fruit essences. It may also contain any other ingredients appropriate to the products.

(f) **Frozen**: Fruits and vegetables including their products which are subjected to a freezing process and maintained at temperature of -18^{0}C.

(g) **Dehydrated or dried**: Fruits and vegetables including their products which are preserved by removing most of their water content following an appropriate dehydrating process.

(h) **Thermally processed (other than pasteurization at less than 100°C)**: Fruits and vegetables including their products which are processed by heat in an appropriate manner before or after being sealed in a container so as to prevent spoilage.

(i) **Retort processed**: Fruits and vegetables including their products which are canned or flexible packaged, processed by retorting.

For detailed product description, refer to regulation 2.3 related to Fruit & Vegetable Products of these regulations.

[2]The category "Fresh" shall be regulated in accordance with the Good Manufacturing Practices and Good Hygiene Practices specified under Schedule 4 of Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011.

[3]In case of fermentation process involving yeast/ mold the respective standard for yeast and mold count does not apply.

[4]Carbonated fruit beverages and pasteurized fruit juices can be excluded for testing of *Listeria*, where the pH is below 4.4.

[5]The retort processed foods shall be tested after incubation at 37°C for 10 days and at 55°C for 7 days.

Stage where the Microbiological Standards shall apply:

The microbiological standards with respect to the products categories specified in Table-4A (Process Hygiene Criteria) indicate the acceptable functioning of the production process. These are not to be used as requirements for releasing the products in the market. These are indicative values above which corrective actions are required in order to maintain the hygiene of the process in compliance with food law. These shall be applicable at the end of the manufacturing process.

[63][The Microbiological Standards in Table-4B (Food Safety Criteria) define the acceptability of a batch/lot and shall be met in respect of the product at the end of the manufacturing process and the products in the market during their shelf- life.]

Action in case of unsatisfactory result:

In case of non-compliance in respect of process hygiene criteria specified in Table- 4A, the FBO shall:

- check and improve process hygiene by implementation of guidelines in Schedule 4 of FSS (Licensing and Registration of Food Businesses) Regulations; and,
- Ensure that all food safety criteria as specified in Table -4B (Food Safety Criteria) are complied with.

[63][Omitted]

Sampling Plans and Guidelines;

For Regulator: The sampling for different microbiological standards specified in Table-4A and 4B shall be ensured aseptically at manufacturing units and/or at retail points, as applicable, by a trained person with specialized knowledge in the field of microbiology following guidelines in the Food Safety and Standards (Food Products and Food Additives) Regulations, 2011 and ISO: 707 (Latest version). The samples shall be stored and transported in frozen condition at -18°C (±2°C) or under refrigerated conditions at 2-5°C as applicable except the products that are recommended to be stored at room temperature by the manufacturer to enable initiation of analysis within 24 hours of sampling. Preservatives shall not be added to sample units intended for microbiological examination. The desired number of sample units as per sampling plan given in Table-4A & 4B shall be taken from same batch/lot and shall be submitted to the notified laboratory. [63][A set (n) of five samples shall be tested from three different accredited laboratories and the final decision shall be drawn based on three test results. There will be no provision for retesting or re-sampling for microbiological testing.] The testing in laboratory shall be ensured as per reference test methods given below in reference test methods for regulatory compliance.

For FBO: Food Business Operator (FBO) shall perform testing as appropriate as per the microbiological standards in Table-4A & 4B to ensure validation and verification of compliance with the microbiological requirements. FBO shall decide themselves the necessary sampling and testing frequencies to ensure compliance with the specified microbiological requirements. FBO may use analytical methods other than those described in reference test methods given below for in-house testing only. However, these methods shall not be applicable for regulatory compliance purpose.

Sampling Plan:

The terms n, c, m and M used in this standard have the following meaning:

n = Number of units comprising a sample.

c = Maximum allowable number of units having microbiological counts above m for 2- class sampling plan and between m and M for 3- class sampling plan.
m = Microbiological limit that separates unsatisfactory from satisfactory in a 2- class sampling plan or acceptable from satisfactory in a 3-class sampling plan.
M = Microbiological limit that separates unsatisfactory from satisfactory in a 3-class sampling plan.

Interpretation of Results:

2-Class Sampling Plan (where n, c and m are specified)	**3-Class Sampling Plan (where n, c, m and M are specified)**
3. Satisfactory, if all the values observed are ≤ m 4. Unsatisfactory, if one or more of the values observed are >m or more than c values are >m	4. Satisfactory, if all the values observed are ≤ m 5. Acceptable, if a maximum of c values are between m and M and the rest of the values are observed as ≤m 6. Unsatisfactory, if one or more of the values observed are > M or more than c values are >m

Reference test methods: The following test methods shall be applied as reference methods.

[6]**Reference test methods-** latest version shall apply. In case where an ISO method adopted by the BIS is specified (e.g IS XXXX / ISO YYYY), latest version of the ISO method (or its BIS equivalent, if available) shall apply. [63][Test methods prescribed in FSSAI Manual of Methods of Analysis of Foods (Microbiological Testing) may also be referred along with the IS/ISO methods specified for Process Hygiene Criteria and Food Safety Criteria.]

Sl. No	**Parameter**	**Reference Test Methods**
1.	Aerobic Plate Count	Microbiology of the food chain - Horizontal method for the enumeration of microorganisms - Part 1: Colony count at 30°C by the pour plate technique- IS 5402/ ISO:4833

Sl. No	Parameter	Reference Test Methods
2.	Yeast and Mold Count	Method for Yeast and Mold Count of Food Stuffs and Animal feed- IS 5403 Microbiology of food and animal feeding stuff-Horizontal method for the enumeration of yeasts and moulds-Part1: Colony count technique in products with water activity greater than 0.95-ISO 21527-1 Microbiology of food and animal feeding stuff-Horizontal method for the enumeration of yeasts and moulds-Part2: Colony count technique in products with water activity less than 0.95-ISO 21527-2
3	Enterobacteriaceae	Microbiology - General Guidance for the Enumeration of Enterobacteriaceae without Resuscitation - MPN Technique and Colony-count Technique- IS/ISO 7402 Microbiology of Food and Animal feeding stuff –Horizontal methods for the detection and enumeration of Enterobacteriaceae- Part 2: Colony- count method-ISO 21528-2
4	*Staphylococcus aureus*	Methods for detection of bacteria responsible for food poisoning: Part 2 Isolation, identification and enumeration of *Staphylococcus aureus* and faecal streptococci- IS 5887: Part 2 Methods for detection of bacteria responsible for food poisoning: Part 8 Horizontal Method for enumeration of Coagulase-Positive Staphylococci/ (*Staphylococcus aureus* and other species) Section 1 Technique using baird-parker agar medium - IS 5887 (Part 8/Sec 1: / ISO 6888-1: 1999) Methods for detection of bacteria responsible for food poisoning: Part 8 Horizontal Method for enumeration of Coagulase-Positive Staphylococci/ (*Staphylococcus aureus* And Other Species) Section 2 Technique using rabbit plasma fibrinogen agar medium- IS 5887 (Part 8/Sec 2) / ISO 6888-2: 1999)
5	*E. Coli 0157* and Vero or Shiga toxin producing *E Coli*	Methods for detection, isolation and identification of pathogen i.e. E.coli in foods- IS :14397

Sl. No	Parameter	Reference Test Methods
6	*Salmonella*	Methods for detection of bacteria responsible for food poisoning - Part 3: General Guidance on Methods for the Detection of Salmonella- IS 5887: Part 3 Microbiology of food and animal feeding stuffs - Horizontal method for the detection of Salmonella spp.- ISO 6579
7	*Listeria monocytogenes*	Microbiology of the food chain - Horizontal method for the detection and enumeration of *Listeria monocytogenes* and other Listeria spp. - Part 1: Detection method – IS: 14988, Part 1 / ISO 11290-1
8	Sulfite-Reducing Bacteria	Microbiology of food and animal feeding stuffs - Horizontal method for the enumeration of sulfite-reducing bacteria growing under anaerobic conditions- ISO 15213
9	*Vibrio cholerae*	Isolation, identification and enumeration of *Vibrio cholerae* and *Vibrio parahaemolyticus* - IS:5887, (Part V) Microbiology of food and animal feeding stuff-Horizontal method for the detection of potentially enteropathogenic Vibrio spp.-Part 1: Detection of Vibrio parahaemolyticus and Vibrio cholerae-ISO/TS 21872-1]

[21][Table 5
Microbial Standards for Meat and Meat Products

Table 5A: Microbiological Standards for Meat and Meat Products- Process Hygiene Criteria

S. No.	Product Category[1]	Aerobic Plate Count				Yeast and Mold Count				*Escherichia coli*				*Staphylococcus aureus* (Coagulase +ve)			
		Sampling Plan		Limits (cfu/g)		Sampling Plan		Limits (cfu/g)		Sampling Plan		Limits (cfu/g)		Sampling Plan		Limits (cfu/g)	
		n	c	m	M	n	c	m	M	n	c	m	M	n	c	m	M
1.	Fresh meat/ Chilled meat[2]	5	3	$1x10^6$	$5x10^6$	5	2	$1x10^4$	$5x10^4$	5	2	$1x10^2$	$1x10^3$	5	2	$1x10^2$	$1x10^3$
2.	Frozen meat[2]	5	2	$1x10^5$	$5x10^6$	5	2	$1x10^3$	$1x10^4$	5	2	1x10	$1x10^2$	5	2	10	$1x10^2$
3.	Raw marinated/minced /comminuted meat[2]	5	2	$5x10^5$	$5x10^6$	5	2	[57][$1x10^4$]	[57][$5x10^4$]	5	2	$1x10^2$	$1x10^3$	5	2	$1x10^2$	$1x10^3$
4.	Semi-cooked /Smoked Meat/ meat food Product[2]	5	2	$1x10^4$	$1x10^5$	5	2	10	$1x10^2$	5	2	10	$1x10^2$	5	2	10	$1x10^2$
5.	Cured/Pickled meat	5	2	$5x10^2$	$5x10^3$	5	2	$1x10^2$	$1x10^3$	5	2	10	$1x10^2$	5	1	$1x10^2$	$1x10^3$
6.	Fermented meat products	NA	NA	NA	NA	NA	NA	NA	NA	5	2	10	$1x10^2$	5	1	$1x10^2$	$1x10^3$
7.	Dried/dehydrated meat products	5	2	$1x10^3$	$1x10^4$	5	2	$1x10^2$	$1x10^3$	5	2	10	$1x10^2$	5	1	10	$1x10^2$

8.	Cooked Meat Products	5	2	$1x10^3$	$1x10^4$	5	1	10	$1x10^2$	5	2	10	$1x10^2$	5	1	10	$1x10^2$
9.	Canned/Retort pouch Meat Products	NA	NA	NA	NA	NA	NA	NA	NA	5	0	Absent	NA	5	0	Absent	NA
	Test Methods[3]	**IS: 5402/ISO 4833**				**IS: 5403/ISO 21527**				**IS: 5887 Part1 or ISO 16649-2**				**IS 5887 : Part 2 or IS 5887 Part 8 (Sec 1)/ ISO : 6888-1 or IS 5887 Part 8 (Sec 2)/ISO 6888-2**			

Table 5B: Microbiological Standards for Meat & Meat Products- Food Safety Criteria

Sr. No.	**Product Category[1]**	***[63][Salmonella$]***				***Listeria monocytogenes***				**Sulphite Reducing Clostridia**				***Clostridium Botulinum***				***Campylobacter* Spp***			
		Sampling Plan		Limits (cfu/25g)		Sampling Plan		Limits (cfu/25g)		Sampling Plan		Limits (cfu/g)		Sampling Plan		Limits (cfu/g)		Sampling Plan		Limits (cfu/g)	
		n	c	m	M	n	C	m	M	n	c	m	M	n	c	m	M	n	c	m	M
1.	Fresh meat / Chilled meat[2]	5	0	Absent		NA	NA	NA		NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
2.	Frozen meat[2]	5	0	Absent		NA	NA	NA		NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
3.	Raw marinated/minced/comminuted meat[2]	5	0	Absent		NA	NA	NA		NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
4.	Semi-cooked /Smoked Meat/meat food Product[2]	5	0	Absent		NA	NA	NA		NA	NA	NA	NA	NA	NA	NA	NA	5	0	Absent	

5.	Cured/Pickled meat	5	0	Absent	5	0	Absent	5	2	$5x10^2$	$5x10^3$	NA	NA	NA	NA	NA	NA	NA	NA
6.	Fermented meat products	5	0	Absent	5	0	Absent	5	2	$5x10^2$	$5x10^3$	NA	NA	NA	NA	NA	NA	NA	NA
7.	Dried/dehydrated meat product	5	0	Absent	5	0	Absent	5	2	$5x10^2$	$5x10^3$	NA	NA	NA	NA	NA	NA	NA	
8.	Cooked Meat Products	5	0	Absent	5	0	Absent	5	1	$1x10^2$	$1x10^3$	NA	NA	NA	NA	5	0	Absent	
9.	Canned/ Retort pouch Meat Products	5	0	Absent	5	0	Absent	5	0	Absent		5	0	Absent		5	0	Absent	
	Test Methods[3]	**IS: 5887 Part 3/ ISO 6579**			**IS: 14988, Part 1 &2/ISO 11290-1 & 2**			**ISO 15213**				**IS:5887, Part 4 or ISO 17919**				**ISO 10272-1&2**			

NA- Not Applicable

[63][$For poultry meat the requirement shall be applicable for *Salmonella enterica* serovars Typhi, Typhimurium and Entritidis.]

[1] Definition of meat and meat products:

Definition of animal, carcass, meat food product and slaughter house are the same as provided in FSS (Food Products Standards and Food Additives) Regulations 2011. Additionally, the following definitions apply for the purpose of this regulation.

- **Canned/Retorted meat product:** Meat product packed in hermetically sealed containers which have been heat treated after sealing to such an extent that the product is shelf stable.
- **Chilled meat**: Fresh meat which has been washed with potable water and kept between 0-7^{0}C.
- **Cooked Meat/meat product**: Meat/meat product that is subjected to heat treatment, wherein minimum thermal core temperature of 75 ^{0}C is achieved.
- **Cured/pickled meat products:** Product prepared after curing/pickling meat in solution containing salt, nitrate/nitrite and adjuncts for the purpose of preservation and obtaining desirable colour, flavour and shelf life.
- **Dried/Dehydrated meat/meat products**: Meat/meat products in which part of free water has been removed by evaporation or sublimation.

- **Fermented meat product:** Chopped or ground meat products that have under gone ageing process and developed characteristics low pH, unique flavour, taste, texture and long shelf life through action of desirable microorganisms.
- **Fresh meat**: Meat that has not been treated in any way to ensure its preservation.
- **Frozen meat**: Fresh meat which has been washed with potable water, chilled and subjected to freezing in an appropriate equipment in such a way that product attains a temperature of -18^{0}C or colder at the thermal centre after thermal stabilization.
- **Raw marinated/minced/comminuted meat**: meat with or without bones which has been reduced to fragments by cutting/grinding/dicing/chopping/milling and/or marinated and with or without additives.
- **Semi-cooked /Smoked Meat/meat food Product:** Partially heat treated and/ or smoked meat and meat product, that will require additional heat treatment before consumption.
- **Slaughter:** Means killing of an animal for food employing a human method not inconsistent with the provisions of the prevention of cruelty to Animal act, 1960 (54 of 1960) in an authorized slaughter house or abattoir where the animal is subjected to through ante- mortem and post-mortem examination".
- **Raw processed whole, cut pieces or comminuted meat Products:** Raw processed, whole, cut pieces bone/ boneless and comminuted meat products with or without addition of other ingredients and additives as per specified in FSSAI standards.

[2] **Products under categories 1-5 to be cooked to make safe before consumption.**

Stage where the Microbiological Standards shall apply:

The Microbiological Standards with respect to the product categories specified in **Table-5A** (Process Hygiene Criteria) indicate the acceptable functioning of the production process. These are not to be used as requirements for releasing the products in the market. These are indicative contamination values above which corrective actions are required in order to maintain the hygiene of the process in compliance with food law. These shall be applicable at the end of the manufacturing process.

[63][The Microbiological Standards in Table-5B (Food Safety Criteria) define the acceptability of a batch/lot and shall be met in respect of the product at the end of the manufacturing process and the products in the market during their shelf- life.]

Action in case of unsatisfactory result:

In case of non-compliance in respect of process hygiene criteria specified in **Table- 5A**, the FBO shall:

- check and improve process hygiene by implementation of guidelines in Schedule 4 (Part IV) of FSS (Licensing and Registration of Food Businesses) Regulations; and,
- [63][Ensure that all food safety criteria's as specified in **Table -5B** are complied with.]

The Microbiological Standards in **Table-5B** (Food Safety Criteria) define the acceptability of a batch/lot and shall be met in respect of the product for releasing it in the market. These shall be applicable to the products at the end of the manufacturing process and the products in the market during their shelf- life.

Sampling Plans and Guidelines;

For Regulator: The sampling for different microbiological standards with respect to the product categories specified in **Table-5A and 5B** shall be ensured aseptically at manufacturing units and/or at retail points, as applicable, by a trained person with specialized knowledge in the field of microbiology following guidelines in Food Safety and Standards (Food Products and Food Additives) Regulations, 2011 and ISO: 707 **(Latest version)**. The samples shall be stored and transported at a temperature below 5°C (but not frozen), except the products that are recommended to be stored at room temperature by the manufacturer, to enable initiation of analysis within 24 hours of sampling. Preservatives shall not be added to sample units intended for microbiological examination. The desired number of samples as per sampling plan given in **Table-5A & 5B** shall be taken from same batch/lot and shall be submitted to the notified laboratory. The testing in laboratory shall be ensured as per reference test methods given below in reference test methods for regulatory compliance. [63][A set (n) of five samples shall be tested from three different accredited laboratories and the final decision shall be drawn based on three test results. There will be no provision for retesting or re-sampling for microbiological testing.] The final decision shall be drawn based on results with no provision for retesting for microbiological parameters.

For FBO: Food Business Operator (FBO) shall perform testing as appropriate as per the microbiological standards in **Table-5A & 5B** to ensure validation and verification of compliance with the microbiological requirements. FBO shall decide themselves the necessary sampling and testing frequencies to ensure compliance with the specified microbiological requirements. FBO may use analytical methods other than those described in reference test methods given below for in-house testing only. However, these methods shall not be applicable for regulatory compliance purpose.

Sampling Plan:

The terms n,c,m and M used in this standard have the following meaning:

n = Number of units comprising a sample.

c = Maximum allowable number of units having microbiological counts above m for 2- class sampling plan and between m and M for 3- class sampling plan.

m = Microbiological limit that separates unsatisfactory from satisfactory in a 2- class sampling plan or acceptable from satisfactory in a 3-class sampling plan.

M = Microbiological limit that separates unsatisfactory from satisfactory in a 3-class sampling plan.

Interpretation of Results:

2-Class Sampling Plan (where n, c and m are specified)	**3-Class Sampling Plan (where n, c, m and M are specified)**
1. Satisfactory, if all the values observed are ≤ m 2. Unsatisfactory, if one or more of the values observed are >m or more than c values are > m	1. Satisfactory, if all the values observed are ≤ m 2. Acceptable, if a maximum of c values are between m and M and the rest of the values are observed as ≤ m 3. Unsatisfactory, if one or more of the values observed are >M or more than c values are > m

[3]**Reference test methods:** The following test methods shall be applied as reference methods

Reference test methods- latest version shall apply. In case where an ISO method adopted by the BIS is specified (e.g IS XXXX / ISO YYYY), latest version of the ISO method (or its BIS equivalent, if available) shall apply. [63][Test methods prescribed in FSSAI Manual of Methods of Analysis of Foods (Microbiological Testing) may also be referred along with the IS/ISO methods specified for Process Hygiene Criteria and Food Safety Criteria.]

S.No	**Parameter**	**Reference Test Method**
1.	Aerobic Plate Count	Microbiology of the food chain -- Horizontal method for the enumeration of microorganisms -- Part 1: Colony count at 30 degrees C by the pour plate technique- IS 5402 /ISO 4833
2.	Yeast and Mould Count	Method for Yeast and Mould Count of Foodstuffs and animal feeds- IS:5403 Microbiology of food and animal feeding stuff-Horizontal method for enumeration of Yeasts and Moulds-part 1: Colony count technique in products with water activity greater than 0.95.- IS0 21527-1: Microbiology of food and animal feeding stuffs -- Horizontal method for the enumeration of Yeasts and Moulds -- Part 2: Colony count technique in products with water activity less than or equal to 0,95- **IS0 21527-2**

3.	*Staphylococcus aureus* and *Faecal streptococci*	Methods for detection of bacteria responsible for food poisoning: Part 2 Isolation, identification and enumeration of *Staphylococcus aureus* and *faecal streptococci*- IS 5887: Part 2 Methods for Detection of Bacteria Responsible for Food Poisoning Part 8 Horizontal Method for Enumeration of Coagulase-Positive Staphylococci/ (*Staphylococcus Aureus* and other species) **Section 1 Technique using baird-parker agar medium-** IS 5887 (Part 8/Sec 1: / ISO 6888-1: 1999 Methods for Detection of Bacteria Responsible for Food Poisoning Part 8 Horizontal Method for Enumeration of Coagulase-Positive *Staphylococci*/ (*Staphylococcus Aureus* and Other Species) **Section 2 Technique using rabbit plasma fibrinogen agar medium-** IS 5887 (Part 8/Sec 2) / ISO 6888-2: 1999
4.	*Escherichia coli*	Methods for Detection of Bacteria Responsible for Food Poisoning - Part I: Isolation, Identification and Enumeration of *Escherichia coli*- IS 5887: Part 1 Microbiology of food and animal feeding stuffs -- Horizontal method for the enumeration of beta-glucuronidase-positive *Escherichia coli* -- Part 2: Colony-count technique at 44 degrees C using 5-bromo-4-chloro-3-indolyl beta-D-glucuronide- ISO: 16649-2
5.	*Salmonella spp.*	Methods for Detection of Bacteria Responsible for Food Poisoning - Part 3: General Guidance on Methods for the Detection of *Salmonell*- IS 5887: Part 3 Microbiology of food and animal feeding stuffs -- Horizontal method for the detection of *Salmonella spp.*- ISO 6579
6.	*Listeria monocytogenes*	Microbiology of Food and Feeding Stuffs - Horizontal method for Detection and Enumeration of *Listeria Monocytogenes*-Part 1: Detection Method- IS 14988: Part 1/ ISO: 11290-1 Microbiology of Food and Animal Feeding Stuffs - Horizontal Method for the Detection and Enumeration of *Listeria monocytogenes* - Part 2: Enumeration Method. IS 14988: Part 2/ ISO: 11290-2

7.	*Campylobacter spp*	Microbiology of Food and Animal Feeding Stuffs - Horizontal Method for the Detection and Enumeration of *Campylobacter spp*- Part 1: Detection Method- ISO 10272-1 Microbiology of food and animal feeding stuffs -- Horizontal method for detection and enumeration of *Campylobacter spp.* -- Part 2: Colony-count technique- **ISO 10272-2**
8.	*Sulphite-Reducing Bacteria*	Microbiology of food and animal feeding stuffs -- Horizontal method for the enumeration of *Sulphite-Reducing Bacteria* growing under anaerobic conditions- ISO 15213
9.	[63][*Clostridium botulinum*]	Methods for Detection of Bacteria Responsible for Food Poisoning: Part 4 Isolation and Identification of *Clostridium perfringens (Clostridium welchii)* and *Costridium botulinum* and enumeration of *Clostridium perfringens*- IS:5887 Part 4 Microbiology of the food chain Polymerase Chain Reaction (PCR) for the detection of food borne pathogens –Detection of botulinum type A, B, E & F- neurotoxin Producing clostridia.- ISO-TS 17919.".]

[27]**[TABLE 6**

MICROBIOLOGICAL REQUIREMENTS OF OTHER PRODUCTS

Food Products	**Parameters**	**Limits**
Baker's Yeast		
Baker's Yeast (Compressed)	Total bacterial count, CFU/g (on dry basis), Max	$7.5X10^5$
	E. coli, CFU	Absent in 1g
	Salmonella, Shigella species	Absent in 25 g
	Coliform count, CFU/g, Max	10
	Rope spore count, CFU/g, Max	10
Baker's Yeast (Dried)	Total bacterial count, CFU/g (on dry basis), Max	$8 X10^6$
	E. coli, CFU	Absent in 1g
	Salmonella, Shigella species	Absent in 25g
	Coliform count, CFU/g, Max	50
	Rope spore count, CFU/g, Max	100.]

Amendment for substitution of highlighted provision

[83][Table 6A: Microbiological Standards for Baker's Yeast- Process Hygiene Criteria

S. No.	Product description	*Escherichia coli*			
		Sampling plan		Limit (cfu)	
		n	c	m	M
1	Baker's Yeast (Compressed and Dried)	5	0	Absent/25g	
	Test Methods	IS: 5887 Part 1 or ISO 16649-3			

Table 6B: Microbiological Standards for Baker's Yeast- Food Safety Criteria

S. No.	Product description	*Salmonella*				*Listeria monocytogenes*			
		Sampling plan		Limit (cfu)		Sampling plan		Limit (cfu)	
		n	c	m	M	n	c	m	M
1	Baker's Yeast (Compressed and Dried)	5	0	Absent/25g		5	0	Absent/25g	
	Test Methods	IS: 5887 Part 3 / ISO:6579				IS: 14988 Part 1 / ISO 11290-1			

Note: In high value low volume (less than 100 g) and large retail pack (pack more than 1 kg) sizes, the sample plan may be modified (e.g. Absence of Salmonella in 10g or 5g in the case of former or 'n' number of samples to be taken from different sites of one large pack) accordingly on case to case basis with the prior approval of Food Safety and Standards Authority of India.

Definition: Definition of Baker's Yeast (Compressed and Dried) are the same as provided in these regulations.

Stage where the Microbiological Standards shall apply: The microbiological standards (food safety criteria) specified above define the acceptability of a batch or lot and shall be met in respect of the products at the end of the manufacturing process and the products in the market during their shelf- life.

Food Business Operator shall ensure that all food safety criteria as specified above are complied with.

Sampling Plan and Guidelines

For Regulator: The sampling for different microbiological standards specified above shall be ensured aseptically at manufacturing units and/or at retail points, as applicable, by a trained person with specialised knowledge in the field of microbiology following guidelines in the Food Safety and Standards (Food Products and Food Additives) Regulations, 2011 and ISO: 17728:2015 (Confirmed in 2019). The samples shall be stored and transported in frozen condition at -18°C (±2°C) or under refrigerated conditions at 2-5°C as applicable except for the products that are recommended to be stored at room temperature by the manufacturer to enable initiation of analysis within 24 hours of sampling. Preservatives shall not be added to sample units intended for microbiological examination. The desired number of sample units as per sampling plan given in the table above shall be taken from same batch or lot and shall be submitted to the notified laboratories. Three sets, each containing 'n' number of samples (n as defined in the sampling plan e.g. if n=5, then total number of samples to be drawn is 15) shall be drawn. Each of these three sets shall be tested in three different accredited laboratories. The final decision shall be based on the results of three accredited laboratories. In the case of Food Safety Criteria, the results from all the three laboratories should indicate compliance with the specified criteria. There will be no provision for retesting or re-sampling for microbiological testing. The testing in laboratory shall be ensured as per the methods given in the table "reference test methods".

For Food Business Operator: Food Business Operator shall perform testing as appropriate as per the microbiological standards in Table above to ensure verification of compliance with the microbiological requirements. Food Business Operator shall decide themselves subject to minimum prescribed under Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011, the necessary sampling and testing frequencies to ensure compliance with the specified microbiological requirements. Food Business Operator may use analytical methods other than those described in "reference test methods" given below for in-house testing only. However, these methods shall not be applicable for regulatory compliance purpose.

Sampling Plan:
The terms n, c, m and M used in this standard have the following meaning, namely:-

n = number of units comprising a sample.
c = Maximum allowable number of units having microbiological counts above m for 2- class sampling plan and between m and M for 3- class sampling plan.
m = Microbiological limit that separates unsatisfactory from satisfactory in a 2- class sampling plan or acceptable from satisfactory in a 3-class sampling plan.
M = Microbiological limit that separates unsatisfactory from satisfactory in a 3-class sampling plan.

Interpretation of Results:

2-Class Sampling Plan (where n,c and m are specified)	3-Class Sampling Plan (where n,c,m and M are specified)
1. Satisfactory, if all the values observed are ≤ m 2. Unsatisfactory, if one or more of the values observed are >m	1. Satisfactory, if all the values observed are ≤ m 2. Acceptable, if a maximum of c values are between m and M. 3. Unsatisfactory, if one or more of the values observed are > M or more than prescribed c values are >m

Reference test methods: The following test methods shall be applied as reference methods. Test methods prescribed in Food Safety and Standards Authority of India Manual of Method of Analysis of Foods (Microbiological Testing) may also be referred along with the IS/ISO methods specified for Food Safety Criteria. Latest version of test methods shall apply. In case where an ISO method adopted by the BIS is specified (e.g. IS XXXX / ISO YYYY), latest version of the ISO method (or its BIS equivalent, if available) shall apply.

S. No.	Parameter	Reference Test methods
1	*Escherichia coli*	Methods for detection of bacteria responsible for food poisoning - Part I: Isolation, Identification and Enumeration of *Escherichia coli*- IS 5887: Part 1 Microbiology of food and animal feeding stuffs -- Horizontal method for the enumeration of betaglucuronidase- positive *Escherichia coli* -- Part 2: Colony-count technique at 44 degrees C using 5-bromo-4-chloro-3-indolyl beta-D-glucuronide- ISO: 16649-3
2	*Salmonella*	Methods for detection of bacteria responsible for food poisoning - Part 3: General Guidance on Methods for the Detection of Salmonella- IS 5887: Part 3 Microbiology of food and animal feeding stuffs -- Horizontal method for the detection of Salmonella spp.- ISO 6579
3	*Listeria monocytogenes*	Microbiology of the food chain -- Horizontal method for the detection and enumeration of *Listeria monocytogenes* and of Listeria spp. -- Part 1: Detection method –ISO 11290-1 Microbiology of Food and Feeding Stuffs - Horizontal method for Detection and Enumeration of *Listeria Monocytogenes*, Part 1: Detection Method -IS 14988-1]

[This amendment shall come into force on 1st May, 2025]

[35][Table 7

Microbiological Requirements for Non-Carbonated Water Based Beverages (Non Alcoholic)

S.No.	Parameters	Limits
1.	Total Plate count per ml.	Not more than 50 CFU per ml.
2.	Yeast and mould count per ml	Not more than 2 cfu per ml.
3.	Coliform count	Absent in 100 ml.

Note: - Non-carbonated beverages shall be free from pathogens]

[73][Table-8 Microbiological Standards of Eggs and Egg Products

Table 8A: Microbiological Standards of Eggs and Egg Products – Process Hygiene Criteria

Sr. No.	Product Description	Aerobic Plate Count (cfu/g)				Enterobacteriacae (cfu/g)			
		Sampling Plan		Limit (cfu)		Sampling Plan		Limit (cfu)	
		n	c	m	M	n	c	m	M
1.	Table Egg	NA							
2.	Pasteurized Liquid egg products (whole, yolk or albumin liquid)	5	2	10^4	10^5	5	2	10^1	10^2
3.	Frozen /dried/ egg products	5	2	10^4	10^5	5	2	10^1	10^2
4.	Cooked/ready-to-eat egg products including mayonnaises	5	2	10^4	10^5	5	2	10^1	10^2
	Test Methods	**IS: 5402/ISO:4833**				**IS/ISO 7402/ISO 21528 Part 2**			

Table 8B

"Table 8B: Microbiological Standards of Eggs and Egg Products – Food Safety Criteria

Sr. No.	Product Description	*Salmonella*			*Listeria monocytogenes* (cfu/g)		
		Sampling Plan		Limit (cfu)	Sampling Plan		Limit (cfu)
		n	c	m M	n	c	m M
1.	Table Egg	NA					
2.	Pasteurized Liquid egg products (whole, yolk or albumin liquid)	5	0	Absent/25 g	5	0	Absent/25 g
3.	Frozen /dried/ egg products	5	0	Absent/25 g	5	0	10^2/g
4.	Cooked/ready-to-eat egg products including mayonnaises	5	0	Absent/25 g	5	0	Absent/25 g
	Test Methods	**IS: 5887 Part3 / ISO:6579**			**IS: 14988, Part 1 & Part 2 / ISO 11290-1& 2**		

Definition.- Definition related to egg and egg products are the same as provided in Food Safety and Standards (Food Products Standards and Food Additives) Regulations 2011. The category "Table egg" shall be regulated in accordance with the good manufacturing practices and code of good hygiene practices notified under Schedule 4 of Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011.

Stage where the Microbiological Standards shall apply.- The microbiological standards with respect to the products categories specified in **Table-8A** (Process Hygiene Criteria) indicate the acceptable functioning of the production process. These are not to be used as requirements for releasing the products in the market. These are indicative values above which corrective actions are required in order to maintain the hygiene of the process in compliance with food law. These shall be applicable at the end of the manufacturing process. The microbiological standards in Table-8B (Food Safety Criteria) define the acceptability of a batch/lot and shall be met in respect of the products at the end of the manufacturing process and the products in the market during their shelf- life.

Action in case of unsatisfactory result:

In case of non-compliance in respect of process hygiene criteria specified in **Table- 8A,** the FBO shall:

- check and improve process hygiene by implementation of guidelines in Schedule 4 of Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations; and,
- Ensure that all food safety criteria as specified in **Table -8B** (Food Safety Criteria) are complied with.

Sampling Plans and Guidelines

For Regulator.- The sampling for different microbiological standards specified in **Table-8A and 8B** shall be ensured aseptically at manufacturing units and/or at retail points, as applicable, by a trained person with specialized knowledge in the field of microbiology following guidelines in the Food Safety and Standards (Food Products and Food Additives) Regulations, 2011 and ISO:707 **(Latest version)**. The samples shall be stored and transported in frozen condition at -18°C(±2°C) or under refrigerated conditions at 2-5°C as applicable except the products that are recommended to be stored at room temperature by the manufacturer to enable initiation of analysis within 24 hours of sampling. Preservatives shall not be added to sample units intended for microbiological examination. The desired number of sample units as per sampling plan given in **Table-8A and 8B** shall be taken from same batch/lot and shall be submitted to the notified laboratory. **Three sets, each containing 'n' number of samples (n as defined in the sampling plan eg if n=5, then total number of samples to be drawn is 15) shall be drawn**. Each of these three sets shall be tested in three different accredited laboratories. The final decision shall be based on the results of three accredited laboratories. In the case of food safety criteria (Table 8B), results from all the three laboratories should indicate compliance with specified criteria. There will be no provision for retesting or resampling for microbiological testing. The testing in laboratory shall be ensured as per reference test methods given below in reference test methods for regulatory compliance.

For FBO.- Food Business Operator (FBO) shall perform testing as appropriate as per the microbiological standards in **Table-8A and 8B** to ensure validation and verification of compliance with the microbiological requirements. FBO shall decide themselvessubject to minimum prescribed under FSSR (Licensing and Registration of Food Businesses), the necessary sampling and testing frequencies to ensure compliance with the specified microbiological requirements. FBO may use analytical methods other than those described in reference test methods given below for in-house testing only. However, these methods shall not be applicable for regulatory compliance purpose.

Sampling Plan.-

The terms n, c, m and M used in this standard have the following meaning:

n = Number of units comprising a sample.

c = Maximum allowable number of units having microbiological counts above m for 2- class sampling plan and between m and M for 3- class sampling plan.

m = Microbiological limit that separates unsatisfactory from satisfactory in a 2- class sampling plan or acceptable from satisfactory in a 3-class sampling plan.

M = Microbiological limit that separates unsatisfactory from satisfactory in a 3-class sampling plan.

Interpretation of Results:

2-Class Sampling Plan (where n,c and m are specified)	3-Class Sampling Plan (where n,c,m and M are specified)
1. Satisfactory, if all the values observed are ≤ m 2. Unsatisfactory, if one or more of the values observed are >m	1. Satisfactory, if all the values observed are ≤ m 2. Acceptable, if a maximum of c values are between m and M and the rest of the values are observed as ≤m 3. Unsatisfactory, if one or more of the values observed are > M or more than prescribed c values are >m

Reference test methods: The following test methods shall be applied as reference methods. Test methods prescribed in FSSAI Manual of Method of Analysis of Foods (Microbiological Testing) may also be referred along with the IS/ISO methods specified for Process Hygiene Criteria and Food Safety Criteria. Latest version of test methods shall apply. In case where an ISO method adopted by the BIS is specified (e.g. IS XXXX / ISO YYYY), latest version of the ISO method (or its BIS equivalent, if available) shall apply.

S.No.	Parameter	Reference Test methods
1.	Aerobic Plate Count	Microbiology of the food chain -- Horizontal method for the enumeration of microorganisms -- Part 1: Colony count at 30 °C by the pour plate technique- IS 5402/ ISO:4833
2.	Enterobacteriaceae	Microbiology - General Guidance for the Enumeration of Enterobacteriaceae without Resuscitation - MPN Technique and Colony-count Technique- IS/ISO 7402 Microbiology of Food and Animal feeding stuff –Horizontal methods for the detection and
3.	*Salmonella*	Methods for Detection of Bacteria Responsible for Food Poisoning - Part 3: General Guidance on Methods for the Detection of Salmonella- IS 5887: Part 3 Microbiology of food and animal feeding stuffs -- Horizontal method for the detection of Salmonella spp.- ISO6579

4.	*Listeria monocytogenes*	Microbiology of the food chain -- Horizontal method for the detection and enumeration of *Listeria monocytogenes* and of Listeria spp. -- Part 1: Detection method – ISO 11290-1 Microbiology of the food chain -- Horizontal method for the detection and enumeration of *Listeria monocytogenes* and of Listeria spp. -- Part 2: enumeration method – ISO 11290-2 Microbiology of Food and Feeding Stuffs - Horizontal method for Detection and Enumeration of *Listeria Monocytogenes*, Part 1: Detection Method -IS 14988-1 Microbiology of Food and Animal Feeding Stuffs - Horizontal Method for the Detection and Enumeration of *Listeria monocytogenes,* Part 2: Enumeration Method- IS 14988-2]

[77] **[Table-9 Microbiological Standards of Food Grain Products**

Table 9A: Microbiological Standards of Food Grain Products – Process Hygiene Criteria

Sr. No.	**Product Description**	***Staphylococcus aureus* count (cfu/g)**				***Enterobacteriaceae* count(cfu/g)**			
		Sampling plan		**Limit**		**Sampling plan**		**Limit**	
		n	**c**	**m**	**M**	**n**	**c**	**m**	**M**
1.	Sprouted grains, sweet corn cob or packed wet grains for direct consumption	NA				5	2	10	10^2
2.	Batters and doughs (Ready to Cook)	5	2	10^2	10^3	5	2	10^2	10^3
3.	Fermented products other than batters and doughs (ready to cook) including bread, cakes and doughnuts, other ready to eat grain products, malted milk food, instant noodles, and pasta products	NA				5	2	10	10^2
	Test Methods	**IS: 5887, Part 2 and IS 5887 part 8(Sec 1)/ ISO 6888-1 or IS: 5887Part 8 (Sec2)/ISO 6888-2**				**IS/ISO 7402/ ISO 21528 Part 2**			

Table 9B: Microbiological Standards of Food Grain Products – Food Safety Criteria

Sr. No.	Product Description	*Salmonella*			*Listeria monocytogenes*		
		Sampling plan		Limit	Sampling plan		Limit
		n	c	m	n	c	m
1.	Sprouted grains, sweet corn cob or packed wet grains for direct consumption	5	0	Absent/25 g	5	0	Absent/25 g
2.	Batters and Doughs (Ready to Cook)	NA			NA		
3.	Fermented products other than batters and doughs (ready to cook) including bread, cakes, doughnuts, other ready to eat grain products, malted milk food, instant noodles* and pasta products*	5	0	Absent/25 g	5	0	Absent/25 g
	Test Methods	IS: 5887 Part3 / ISO:6579			IS: 14988, Part 1 / ISO 11290-1		

* Instant noodles and pasta products shall be tested for Salmonella but not for *Listeria monocytogenes.*

Definitions

Definitions related to Cereal and Cereal Products are as provided in FSS (Food Products Standards and Food Additives) Regulations 2011.

Stage where the Microbiological Standards shall apply:

The microbiological standards with respect to the product categories specified in **Table-9A** (Process Hygiene Criteria) indicate the acceptable functioning of the production process. These are not to be used as requirements for releasing the products in the market. These are indicative values above which corrective actions are required in order to maintain the hygiene of the process in compliance with the food law. These shall be applicable at the end of the manufacturing process. The Microbiological Standards in **Table-9B** (Food Safety Criteria) define the acceptability of a batch/lot and shall be met in respect of the products at the end of the manufacturing process and the products in the market during their shelf- life.

Action in case of unsatisfactory result:
In case of non-compliance in respect of process hygiene criteria specified in **Table- 9A,** the FBO shall:

- check and improve process hygiene by implementation of guidelines in Schedule 4 of FSS (Licensing and Registration of Food Businesses) Regulations; and,

- ensure that all food safety criteria as specified in **Table -9B** (Food Safety Criteria) are complied with

Sampling Plan and Guidelines:

For Regulator: The sampling for different microbiological standards specified in **Table-9A and 9B** shall be ensured aseptically at manufacturing units and/or at retail points, as applicable, by a trained person with specialized knowledge in the field of microbiology following guidelines in the Food Safety and Standards (Food Products and Food Additives) Regulations, 2011 and ISO: 707 **(Latest version)**. The samples shall be stored and transported in frozen condition at -18°C (±2°C) or under refrigerated conditions at 2-5°C as applicable except the products that are recommended to be stored at room temperature by the manufacturer to enable initiation of analysis within 24 hours of sampling. Preservatives shall not be added to sample units intended for microbiological examination. The desired number of sample units as per sampling plan given in **Table-9A & 9B** shall be taken from same batch/lot and shall be submitted to the notified laboratory. Three sets, each containing 'n' number of samples (n as defined in the sampling plan eg if n=5, then total no. of samples is 15) shall be drawn. Each of these three sets shall be tested in three different accredited laboratories. The final decision shall be based on the results of three accredited laboratories. In the case of food safety criteria (Table 9B), results from all the three laboratories should indicate compliance with specified criteria. There will be no provision for retesting or resampling for microbiological testing. The testing in laboratory shall be done as per the methods given in the Table "Reference Test Methods"

For FBO: Food Business Operator (FBO) shall perform testing as appropriate as per the microbiological standards in **Table-9A & 9B** to ensure verification of compliance with the microbiological requirements. FBO shall decide themselves, subject to the minimum prescribed under FSSR (Licensing and Registration of Food Businesses), the necessary sampling and testing frequencies, to ensure compliance with the specified microbiological requirements. FBO may use analytical methods other than those described in reference test methods for in-house testing only. However, these methods shall not be applicable for regulatory compliance purpose.

Sampling Plan:

The terms n, c, m and M used in this standard have the following meaning:

n = Number of units comprising a sample.

c = Maximum allowable number of units having microbiological counts above m for 2- class sampling plan and between m and M for 3- class sampling plan.

m = Microbiological limit that separates unsatisfactory from satisfactory in a 2- class sampling plan or acceptable from satisfactory in a 3-class sampling plan.

M = Microbiological limit that separates unsatisfactory from satisfactory in a 3-class sampling plan.

Interpretation of Results:

2-Class Sampling Plan (where n,c and m are specified)	**3-Class Sampling Plan (where n,c,m and M are specified)**
1. Satisfactory, if all the values observed are ≤ m 2. Unsatisfactory, if one or more of the values observed are >m	1. Satisfactory, if all the values observed are ≤ m 2. Acceptable, if a maximum of c values are between m and M 3. Unsatisfactory, if one or more of the values observed are > M or more than prescribed c values are >m

Reference Test Methods: The following test methods shall be applied as Reference Test Methods. Test methods prescribed in FSSAI Manual of Method of Analysis of Foods (Microbiological Testing) may also be referred along with the IS/ISO methods specified for Process Hygiene Criteria and Food Safety Criteria.

Reference test methods- latest version shall apply. In case where an ISO method adopted by the BIS is specified (e.g IS XXXX / ISO YYYY), latest version of the ISO method (or its BIS equivalent, if available) shall apply.

S.No	**Parameter**	**Reference Test methods**
1.	Enterobacteriaceae count	Microbiology - General Guidance for the Enumeration of Enterobacteriaceae without Resuscitation - MPN Technique and Colony-count Technique- IS/ISO 7402 Microbiology of Food and Animal feeding stuff –Horizontal methods for the detection and enumeration of Enterobacteriaceae- Part 2:Colony- count method-ISO 21528-2

2.	*Staphylococcus Aureus*count	Methods for detection of bacteria responsible for food poisoning: Part 2 Isolation, identification and enumeration of *Staphylococcus aureus* and faecal streptococci- IS 5887: Part 2 Methods for Detection of Bacteria Responsible for Food Poisoning Part 8 Horizontal Method for Enumeration of Coagulase-Positive Staphylococci/ (*Staphylococcus aureus* and other species) **Section 1 Technique using baird-parker agar medium -** IS 5887 (Part 8/Sec 1: / ISO 6888-1: 1999) Methods For Detection Of Bacteria Responsible For Food Poisoning Part 8 Horizontal Method For Enumeration Of Coagulase-Positive Staphylococci/ (*Staphylococcus aureus* And Other Species) **Section 2 Technique using rabbit plasma fibrinogen agar medium-** IS 5887 (Part 8/Sec 2) / ISO 6888-2: 1999)
3.	*Salmonella*	Methods for Detection of Bacteria Responsible for Food Poisoning - Part 3: General Guidance on Methods for the Detection of Salmonella- IS 5887: Part 3 Microbiology of food and animal feeding stuffs -- Horizontal method for the detection of Salmonella spp.- ISO 6579
4.	*Listeria monocytogenes*	Microbiology of the food chain -- Horizontal method for the detection and enumeration of *Listeria monocytogenes* and of Listeria spp. -- Part 1: Detection method –ISO 11290-1 Microbiology of Food and Feeding Stuffs - Horizontal method for Detection and Enumeration of Listeria Monocytogenes, Part 1: Detection Method -IS 14988-1]

[82][Table-10 Microbiological Standards for Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food

Table 10A: Microbiological Standards for Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food – Process Hygiene Criteria

S. No.	Product description	Aerobic Plate Count				Yeast and Mold Count				*Enterobacteriaceae* count			
		Sampling plan		Limit (cfu/g or ml)		Sampling plan		Limit (cfu/g or ml)		Sampling plan		Limit (cfu/g or ml)	
		n	c	m	M	n	c	m	M	n	c	m	M
1.	Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose and Novel Food for consumption after processing	5	3	$1x10^6$	$1x10^7$	5	3	$1x10^4$	$1x10^5$	5	3	$1x10^3$	$1x10^4$
2.	Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose and Novel Food for direct consumption	5	2	$1x10^4$	$1x10^5$	5	2	$1x10^2$	$1x10^3$	5	2	$1x10^2$	$1x10^3$
3.	Probiotics and products containing specified live microorganisms*	NA				NA				NA			
	Test Methods	**IS 5402/ISO 4833**				**IS 5403/ ISO 21527 Part 1 and Part 2**				**ISO 21528 Part 2**			

Note:- *Should contain only the specified microorganism(s) at the level claimed on the label. The counts have to be determined using methodology appropriate for the organisms. e.g. For Lactic acid bacteria ISO 15214/IS 16068, for Bifidobacteria ISO 29981

Table 10B: Microbiological Standards for Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food – Food Safety Criteria

S. No.	Product description	*Salmonella*				*Listeria monocytogenes*			
		Sampling plan		Limit (cfu)		Sampling plan		Limit (cfu)	
		n	c	m	M	n	c	m	M
1.	Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, functional food and Novel Food and not for direct consumption	NA				NA			
2.	Health Supplements, Nutraceuticals , Food for Special Dietary Use, Food for Special Medical Purpose, functional food and Novel Food for direct consumption	5	0	Absent/25g		5	0	Absent/25g	
3.	Probiotics and products containing specified live micro organisms	5	0	Absent/25g		5	0	Absent/25g	
	Test Methods	**IS 5887 Part3 / ISO 6579**				**IS 14988 Part 1 / ISO 11290-1**			

Note: In high value low volume (less than 100 g) and large retail pack (pack more than 1 kg) sizes, the sample plan may be modified (e.g. absence of Salmonella in 10 g or 5 g in the case of former or n number of samples to be taken from different sites of one large pack) accordingly on case to case basis with the prior approval of Food Safety and Standards Authority of India (FSSAI).

Definition

Definition related to Nutraceutical Products are the same as provided in Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016.

Stage where the Microbiological Standards shall apply:

The microbiological standards with respect to the products categories specified in **Table-10A** (Process Hygiene Criteria) indicate the acceptable functioning of the production process. These are not to be used as requirements for releasing the products in the market. These are indicative values above which corrective actions are required in order to maintain the hygiene of the process in compliance with food law. These shall be applicable at the end of the manufacturing process. The Microbiological Standards in **Table-10B** (Food Safety Criteria) define the acceptability of a batch or lot and shall be met in respect of the products at the end of the manufacturing process and the products in the market during their shelf- life.

Action in case of unsatisfactory result:

In case of non-compliance in respect of process hygiene criteria specified in **Table- 10A,** the Food Business Operator (FBO) shall-

- check and improve process hygiene by implementation of guidelines in Schedule 4 of Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011; and
- ensure that all food safety criteria as specified in **Table -10B** (Food Safety Criteria) are complied with.

Sampling Plan and Guidelines

For Regulator: The sampling for different microbiological standards specified in **Table-10A and 10B** shall be ensured aseptically at manufacturing units and/or at retail points, as applicable, by a trained person with specialised knowledge in the field of microbiology following guidelines in the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011 and ISO: 17728:2015 (confirmed in 2019). The samples shall be stored and transported in frozen condition at -18°C (±2°C) or under refrigerated conditions at 2-5°C as applicable

except for the products that are recommended to be stored at room temperature by the manufacturer to enable initiation of analysis within 24 hours of sampling. Preservatives shall not be added to sample units intended for microbiological examination. The desired number of sample units as per sampling plan given in **Table-10A and 10B** shall be taken from same batch or lot and shall be submitted to the notified laboratories. Three sets, each containing 'n' number of samples (n as defined in the sampling plan e.g. if n=5, then total no. of samples to be drawn is 15) shall be drawn. Each of these three sets shall be tested in three different accredited laboratories. The final decision shall be based on the results of three accredited laboratories. In the case of Food Safety Criteria (Table 10B), the results from all the three laboratories should indicate compliance with the specified criteria. There will be no provision for retesting or resampling for microbiological testing. The testing in laboratory shall be ensured as per the methods given in the table "reference test methods".

For FBO: Food Business Operator (FBO) shall perform testing as appropriate as per the microbiological standards in **Table-10A & 10B** to ensure verification of compliance with the microbiological requirements. FBO shall decide themselves subject to minimum prescribed under Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011, the necessary sampling and testing frequencies to ensure compliance with the specified microbiological requirements. FBO may use analytical methods other than those described in "reference test methods" given below for in-house testing only. However, these methods shall not be applicable for regulatory compliance purpose.

Sampling Plan:

The terms n, c, m and M used in this standard have the following meaning:

n = Number of units comprising a sample.

c = Maximum allowable number of units having microbiological counts above m for 2- class sampling plan and between m and M for 3- class sampling plan.

m = Microbiological limit that separates unsatisfactory from satisfactory in a 2- class sampling plan or acceptable from satisfactory in a 3-class sampling plan.

M = Microbiological limit that separates unsatisfactory from satisfactory in a 3-class sampling plan.

Interpretation of Results:

2-Class Sampling Plan (where n, c and m are specified)	3-Class Sampling Plan (where n, c, m and M are specified)
1. Satisfactory, if all the values observed are ≤ m 2. Unsatisfactory, if one or more of the values observed are >m	7. Satisfactory, if all the values observed are ≤ m 8. Acceptable, if a maximum of c values are between m and M. 9. Unsatisfactory, if one or more of the values observed are > M or more than prescribed c values are >m

Reference Test Methods: The following test methods shall be applied as reference methods. Test methods prescribed in FSSAI Manual of Methods of Analysis of Foods (Microbiological Testing) may also be referred along with the IS/ISO methods specified for Process Hygiene Criteria and Food Safety Criteria. Latest version of test methods shall apply. In case where an ISO method adopted by the BIS is specified (e.g IS XXXX / ISO YYYY), latest version of the ISO method (or its BIS equivalent, if available) shall apply.

S. No	Parameter	Reference Test Methods
1.	Aerobic Plate Count	Microbiology of the food chain - Horizontal method for the enumeration of microorganisms - Part 1: Colony count at 30 °C by the pour plate technique- IS 5402/ ISO 4833
2.	Yeast and Mold Count	Method for Yeast and Mould Count of Food Stuffs and Animal feed- IS 5403 Microbiology of food and animal feeding Stuff-Horizontal method for the enumeration of yeasts and moulds-Part1: Colony count technique in products with water activity greater than 0.95-ISO 21527-1 Microbiology of food and animal feeding Stuff-Horizontal method for the enumeration of yeasts and moulds-Part2: Colony count technique in products with water activity less than 0.95-ISO 21527-2

3.	*Enterobacteriaceae* count	Microbiology of Food and Animal feeding stuff –Horizontal methods for the detection and enumeration of *Enterobacteriaceae*- Part 2: Colony- count method - ISO 21528-2
4.	*Salmonella*	Methods for Detection of Bacteria Responsible for Food Poisoning - Part 3: General Guidance on Methods for the Detection of Salmonella- IS 5887 Part 3 Microbiology of food and animal feeding stuffs -- Horizontal method for the detection of Salmonella spp.- ISO 6579
5.	*Listeria monocytogenes*	Microbiology of Food and Feeding Stuffs - Horizontal method for Detection and Enumeration of *Listeria monocytogenes*, Part 1: Detection Method -IS 14988-1 Microbiology of the food chain - Horizontal method for the detection and enumeration of *Listeria monocytogenes* and of Listeria spp. - Part 1: Detection method –ISO 11290-1.**]**

Insertion of Provision

[83][Table 11A: Microbiological Standards for Neera – Process Hygiene Criteria

S. No.	Product description	Aerobic Plate Count				*Escherichia coli*				*Staphylococcus aureus* (Coagulase +ve)			
		Sampling Plan		Limit (cfu)		Sampling Plan		Limit (cfu)		Sampling Plan		Limit (cfu)	
		n	c	m	M	n	c	m	M	n	c	m	M
1	Neera (Pasteurized)	5	2	$1x10^2$/ml	$1x10^4$/ml	5	0	Absent/25ml		5	0	Absent/25ml	
	Test Methods	IS: 5402/ISO:4833				IS: 5887 Part 1 or ISO 16649-3				IS:5887 Part 2 and IS 5887 Part 8 (Sec 1)/ ISO 6888-3 or IS:5887 Part 8 (Sec 2)/ ISO 6888-3			

Table 11B: Microbiological Standards for Neera- Food Safety Criteria

S. No.	Product description	Salmonella				Listeria monocytogenes			
		Sampling Plan		Limit (cfu)		Sampling Plan		Limit (cfu)	
		n	c	m	M	n	c	m	M
1	Neera (Pasteurized)	5	0	Absent/25 ml		5	0	Absent/25 ml	
	Test Methods	IS: 5887 Part 3 / ISO:6579				IS: 14988 Part 1 / ISO 11290-1			

Definitions of Neera: Definition of 'Processed Neera' is the same as provided in these regulations.

Stage where the Microbiological Standards shall apply:

The microbiological standards with respect to the products categories specified in Table-11A (Process Hygiene Criteria) indicate the acceptable functioning of the production process. These are not to be used as requirements for releasing the products in the market. These are indicative values above which corrective actions are required in order to maintain the hygiene of the process in compliance with food law. These shall be applicable at the end of the manufacturing process. The Microbiological Standards in Table-11B (Food Safety Criteria) define the acceptability of a batch or lot and shall be met in respect of the product at the end of the manufacturing process and the products in the market during their shelf- life.

Action in case of unsatisfactory result:

In case of non-compliance in respect of process hygiene criteria specified in Table - 11A, the Food Business Operator shall:

- check and improve process hygiene by implementation of guidelines in Schedule 4 of Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011; and,
- Ensure that all food safety criteria as specified in Table -11B (Food Safety Criteria) are complied with.

Sampling Plans and Guidelines

For Regulator: The sampling for different microbiological standards specified in Table-11A and 11B shall be ensured aseptically at manufacturing units and/or at retail points, as applicable, by a trained person with specialized knowledge in the field of microbiology following guidelines in the Food Safety and Standards (Food Products and Food Additives) Regulations, 2011 and ISO: 17728:2015 (Confirmed in 2019). The samples shall be stored and transported in frozen condition at -18°C (±2°C) or under refrigerated conditions at 2-5°C as applicable except the products that are recommended to be stored at room temperature by the manufacturer to enable initiation of analysis within twenty four hours of sampling. Preservatives shall not be added to sample units intended for microbiological examination. The desired number of sample units as per sampling plan given in Table-11A and 11B shall be taken from same batch/lot and shall be submitted to the notified laboratory. A set (n) of five samples shall be tested from three different accredited laboratories and the final decision shall be drawn based on three test results. There will be no provision for retesting or re-sampling for microbiological testing. The testing in laboratory shall be ensured as per reference test methods given below in reference test methods for regulatory compliance.

For Food Business Operator: Food Business Operator shall perform testing as appropriate as per the microbiological standards in Table-11A and 11B to ensure validation and verification of compliance with the microbiological requirements. Food Business Operator shall decide themselves the necessary sampling and testing frequencies to ensure compliance with the specified microbiological requirements. Food Business Operator may use analytical methods other than those described in reference test methods given below for in-house testing only. However, these methods shall not be applicable for regulatory compliance purpose.

Sampling Plan:
The terms n, c, m and M used in this standard have the following meaning:

n = Number of units comprising a sample.
c = Maximum allowable number of units having microbiological counts above m for 2- class sampling plan and between m and M for 3- class sampling plan.
m = Microbiological limit that separates unsatisfactory from satisfactory in a 2- class sampling plan or acceptable from satisfactory in a 3-class sampling plan.
M = Microbiological limit that separates unsatisfactory from satisfactory in a 3-class sampling plan.

Interpretation of Results:

2-Class Sampling Plan (where n, c and m are specified)	3-Class Sampling Plan (where n, c, m and M are specified)
Satisfactory, if all the values observed are ≤ m Unsatisfactory, if one or more of the values observed are >m or more than c values are >m	Satisfactory, if all the values observed are ≤ m Acceptable, if a maximum of c values are between m and M and the rest of the values are observed as ≤m Unsatisfactory, if one or more of the values observed are > M or more than c values are >m

Reference test methods: The following test methods shall be applied as reference methods.

Reference test methods- latest version shall apply. In case where an ISO method adopted by the BIS is specified (e.g. IS XXXX / ISO YYYY), latest version of the ISO method (or its BIS equivalent, if available) shall apply. Test methods prescribed in Food Safety and Standards Authority of India Manual of Methods of Analysis of Foods (Microbiological Testing) may also be referred along with the IS/ISO methods specified for Process Hygiene Criteria and Food Safety Criteria.

S. No.	Parameter	Reference Test Methods
1	Aerobic Plate Count	Microbiology of the food chain - Horizontal method for the enumeration of microorganisms - Part 1: Colony count at 30°C by the pour plate technique- IS 5402/ ISO:4833
2	*Escherichia coli*	Methods for detection of bacteria responsible for food poisoning - Part I : Isolation, Identification and Enumeration of *Escherichia coli*- IS 5887 : Part 1 Microbiology of food and animal feeding stuffs -- Horizontal method for the enumeration of betaglucuronidase -positive *Escherichia coli* -- Part 2: Colony-count technique at 44 degrees C using 5-bromo-4-chloro-3-indolyl beta-D-glucuronide- ISO: 16649-3
3	*Staphylococcus aureus*	Methods for detection of bacteria responsible for food poisoning: Part 2 Isolation, identification and enumeration of *Staphylococcus aureus* and faecal streptococci- IS 5887: Part 2 Methods for detection of bacteria responsible for food poisoning: Part 8 Horizontal Method for enumeration of Coagulase-Positive *Staphylococci*/ (*Staphylococcus aureus* and other species) section 1 Technique using baird-parker agar medium - IS 5887 (Part 8/Sec 1: / ISO 6888-3) Methods for detection of bacteria responsible for food poisoning: Part 8 Horizontal Method for enumeration of Coagulase-Positive Staphylococci/ (*Staphylococcus aureus* And Other Species) section 2 Technique using rabbit plasma fibrinogen agar medium- IS 5887 (Part 8/Sec 2) / ISO 6888-3
4	*Salmonella*	Methods for detection of bacteria responsible for food poisoning - Part 3: General Guidance on Methods for the detection of Salmonella- IS 5887: Part 3 Microbiology of food and animal feeding stuffs - Horizontal method for the detection of Salmonella spp.- ISO6579
5	*Listeria monocytogenes*	Microbiology of the food chain - Horizontal method for the detection and enumeration of *Listeria monocytogenes* and other Listeria spp. - Part 1: Detection method – IS: 14988, Part 1 / ISO 11290-1]

[This amendment shall come into force on 1st May, 2025]