Notice calling for suggestions, views, comments etc from stakeholders within a period of 30 days on the draft notification related to Table 4 in Appendix B in Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011.

F. No.1-110(3)/SP (Biological Hazards)/FSSAI/2010.- In the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, in APPENDIX B, for TABLE 4, the following table shall be substituted namely:,-

Microbiological Standards of Fruits and Vegetables and their Products

Table 4A- Microbiological Standards for Fruits and Vegetables and their Products –Process Hygiene Criteria

Sr. No.	Product Description [1]	Aerobic Plate Count				Yeast and Mold Count				*Enterobacteriaceae*			
		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.	Fresh[2]							NA					
2.	Cut or minimally processed and packed, including juices	5	2	$1x10^6$/g	$1x10^7$/g	5	1	$1x10^2$/g	$1x10^4$/g	5	2	$1x10^2$/g	$1x10^4$/g
3.	Fermented or pickled or acidified or with preservatives[3]	NA				5	1	$1x10^2$/g	$1x10^3$/g	5	2	$1x10^2$/g	$1x10^3$/g
4.	Pasteurized Juices[4]	5	2	$1x10^2$/ml	$1x10^4$/ml	5	1	$1x10^2$/ml	$1x10^3$/ml	5	0	Absent/ml	
	Carbonated Fruit beverages[4]	5	1	50/ml	$5x10^2$/ml	5	0	2/ml		5	0	Absent/ml	
5.	Frozen	5	2	$1x10^4$/g	$5x10^5$/g	5	1	$1x10^2$/g	$1x10^3$/g	5	2	$1x10^2$/g	$3x10^2$/g

Sr. No.	Product Description [1]	Aerobic Plate Count				Yeast and Mold Count				*Enterobacteriaceae*			
		Sampling Plan		Limit (cfu)		Sampling Plan		Limit (cfu)		Sampling Plan		Limit (cfu)	
		n	c	m	M	n	c	m	M	n	c	m	M
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
7.	Thermally processed (other than pasteurization and less than 100°C)	5	1	50/g	$1x10^2$/g	5	1	50/g	$1x10^2$/g	5	0	Absent/g	
8.	Retort processed[5]	5	0	50/g		NA				5	0	Absent/g	
	Test Methods[6]	**IS: 5402/ISO:4833**				**IS: 5403**				**IS/ISO: 7402**			

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

Sr. No.	Product Description[1]	*Salmonella*			*Listeria monocytogenes*			Sulphite Reducing Clostridia (SRC)				*Staphylococcus aureus* (Coagulase +ve)				*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)	Sampling Plan		Limit (cfu)
		n	c	m M	n	c	m M	n	c	m	M	n	c	m	M	n	c	m M	n	c	m M
1.	Fresh[2]	NA			NA			NA				NA				NA			NA		
2.	Cut or minimally processed and packaged, including juices	5	0	Absent/25 g	5	0	Absent/25 g	NA	NA	NA	NA	5	1	$1x10^2$ /g	$1x10^3$ /g	5	0	Absent/25 g	5	0	Absent/25g
3.	Fermented or pickled or acidified or with preservatives[3]	5	0	Absent/25 g	5	0	Absent/25 g	NA	NA	NA	NA	5	1	10/g	$1x10^2$ /g	5	0	Absent/25 g	5	0	Absent/25g
4.	Pasteurized Juices[4]	5	0	Absent/25 ml	5	0	Absent/25 ml	NA	NA	NA	NA	5	0	Absent/ml		5	0	Absent/25 g	5	0	Absent/25g

	Carbonated fruit beverages[4]	5	0	Absent/25 ml	5	0	Absent/25 ml	NA	NA	NA	NA	5	0	Absent/ml		5	0	Absent/25 g	5	0	Absent/25g
5.	Frozen	5	0	Absent/25 g	5	0	Absent/25 g	NA	NA	NA	NA	5	1	20/g	$1x10^2$ /g	5	0	Absent/25 g	5	0	Absent/25g
6.	Dehydrated or dried	5	0	Absent/25 g	5	0	Absent/25 g	NA	NA	NA	NA	5	1	10/g	$1x10^2$ /g	5	0	Absent/25 g	5	0	Absent/25g
7.	Thermally processed (other than pasteurization and less than 100°C	5	0	Absent/25 g	5	0	Absent/25 g	NA	NA	NA	NA	5	0	Absent/g		5	0	Absent/25 g	5	0	Absent/25g
8.	Retort processed[5]	5	0	Absent/25 g	5	0	Absent/25 g	5	0	Absent/g		5	0	Absent/g		5	0	Absent/25 g	5	0	Absent/25g
	Test Methods[6]	**IS: 5887 Part3 / ISO:6579**			**IS: 14988, Part 1 / ISO 11290-1**			**ISO 15213**				**887, Part 2 and IS 5887 part 8 (Sec 1)/ ISO 6888-1 or IS:5887 Part 8 (Sec2)/ISO 6888-2**				**IS: 14397**			**IS:5887, (Part V)**		

NA-Not Applicable

[1]Definition

1. **Fresh** means the whole fruits and vegetables that are sold fresh.
2. **Cut or minimally processed and packaged including juices**meansfruits, vegetables including their products which are washed or sanitized or peeled or cut up and packed.
3. **Fermented or pickled or acidified or with preservatives**means fruits, vegetables and 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).
4. **Pasteurized Juices** means fruit and Vegetable *J*uices that are subjected to standard process of pasteuization to destroy or inactivate harmful organisms.
5. **Carbonated fruit beverages** means 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.
6. **Frozen** means fruits and vegetables including their products, subjected to a freezing process and maintained at temperature of -18^0C.
7. **Dehydrated or dried** means fruits, vegetables including their products which are preserved by removing most of their water content following an appropriate dehydrating process.
8. **Thermally processed (other than pasteurization and less than 100°C)** means fruits, vegetables and including their products processed by heat in an appropriate manner before or after being sealed in a container so as to prevent spoilage.
9. **Retort processed** means fruits and vegetables including their products that are canned or flexible packaged, processed by retorting at pressureof 1.1 kg/Cm^2(121^0C) for a minimum of 15 minutes.

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

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

[3]In case of fermentation process involving yeast/mold the respective standard for yeast and mould 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 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.

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** are complied with before releasing the product batch/lot in the market.

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 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 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 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-4A & 4B** 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. 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-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 limitthat 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

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.

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.
2.	Yeast and Mold	Method for Yeast and Mold Count of food stuffs and animal feed- IS 5403.
3.	Enterobacteriaceae	Microbiology - General guidance for the enumeration of Enterobacteriaceae without resuscitation - MPN Technique and Colony-Count Technique- IS/ISO 7402.

Sl. No.	Parameter	Reference Test methods
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:
5.	*E. Coli 0157* and Vero or Shiga toxin producing *E*	Methods for detection, isolation and identification of pathogen i.e.*E.coli* in foods- IS :14397.
6.	*Salmonella*	• Methods for detection of bacteria responsible for food poisoning - Part 3: General guidance on methods for the detection of S*almonella*- IS 5887: Part 3. • Microbiology of food and animal feeding stuffs -- Horizontal method for the detection of *Salmonella* spp.- ISO6579.
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).