Notice Calling for suggestions, views, comments etc from WTO- SPS Committee members within a period of 60 days on the draft notification related to amendment so as to include provision for additional additives in various food categories.

File No. 1/Additional Additives-III/Stds/Notification/FSSAI/2017

In the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011 (hereinafter referred to as said regulation),-

(1) in regulation 2.4,-

(a) in sub-regulation 2.4.1, clause 2 relating to "Fortified atta" shall be omitted.

(b) in sub-regulation 2.4.2, clause 2 relating to "Fortified maida" shall be omitted.

(2) in sub-regulation 2.9.30, clause 2 relating to "IODISED SALT" and clause 3 relating to "IRON FORTIFIED COMMON SALT" shall be omitted.

(3) in regulation 2.10, sub-regulation 2.10.5 relating to "Beverage- ALCOHOLIC" shall be omitted.

(4) in Appendix A, under the heading "IV. USE OF FOOD ADDITIVES IN FOOD PRODUCTS", -

(a) in Table 5, -

(i) against the entries relating to Food Category System 5.1.3, in columns (3), after the food additive "L-tartaric acid" and the entries relating thereto, the following shall be inserted, namely:-

Food Additive	**INS Number**	**Recommended Maximum Level**	**Note**
"SORBITAN ESTERS OF FATTY ACIDS		10,000 mg/kg	101"

(ii) against the entries relating to Food Category System 5.2, pertaining to confectionery including hard and soft candy, nougats etc. other than food categories 5.1, 5.3 and 5.4, for the entries in columns (3) to (6)

Paraffin wax or liquid paraffin (Food Grade)		GMP	

The following entries shall be substituted, namely:-

Food Additive	**INS Number**	**Recommended Maximum Level**	**Note**
"Liquid paraffin	905e	GMP"	

(b) In Table 7,-

(i) against the entries relating to Food Category System 7.1.2, in column (3), after the food additive "Tertiary butyl hydroquinone" and the entries relating thereto, the following shall be inserted, namely: -

Food Additive	**INS Number**	**Recommended Maximum Level**	**Note**

"SORBITAN ESTERS OF FATTY ACIDS		10,000 mg/kg	11"

(ii) against the entries relating to Food Category System 7.1.3, in column (3), after the food additive "Tertiary butyl hydroquinone (TBHQ)" and the entries relating thereto, the following shall be inserted, namely: -

Food Additive	**INS Number**	**Recommended Maximum Level**	**Note**
"SORBITAN ESTERS OF FATTY ACIDS		10,000 mg/kg	11"

(iii) against the entries relating to Food Category System 7.1.4, in column (3), after the food additive "Tertiary butyl hydroquinone (TBHQ)" and the entries relating thereto, the following shall be inserted, namely: -

Food Additive	**INS Number**	**Recommended Maximum Level**	**Note**
"SORBITAN ESTERS OF FATTY ACIDS		10,000 mg/kg	11"

(iv) against the entries relating to Food Category System 7.1.5, in column (3), after the food additive "SODIUM ALUMINIUM PHOSPHATES" and the entries relating thereto, the following shall be inserted, namely: -

Food Additive	**INS Number**	**Recommended Maximum Level**	**Note**
"SORBITAN ESTERS OF FATTY ACIDS		10,000 mg/kg	11"

(v) against the entries relating to Food Category System 7.1.6, in column (3), after the food additive "SODIUM ALUMINIUM PHOSPHATES" and the entries relating thereto, the following shall be inserted, namely: -

Food Additive	**INS Number**	**Recommended Maximum Level**	**Note**
"SORBITAN ESTERS OF FATTY ACIDS		10,000 mg/kg	11"

(vi) against the entries relating to Food Category System 7.2, in column (3) to (6), the following food additives and entries shall be inserted, namely: -

Food Additive	**INS Number**	**Recommended Maximum Level**	**Note**
"SORBITAN ESTERS OF FATTY ACIDS		10,000 mg/kg"	

(c) In Table 12,-

(i) against the entries relating to Food Category System 12.8, in columns (3), after the food additive "Butylated hydroxyanisole (BHA)" and the entries relating thereto, the following shall be inserted, namely: -

Food Additive	**INS Number**	**Recommended Maximum Level**	**Note**

"Sorbitan monostearate	491	10,000 mg/kg"	

(d) In table 14,-

(i) against the entries relating to Food Category System 14.1.2.1, in column (3), after the food additive "Carbon dioxide" and the entries relating thereto, the following shall be inserted, namely: -

Food Additive	**INS Number**	**Recommended Maximum Level**	**Note**
"Nisin	234	5,000 IU	FS04b"

(ii) against the entries relating to Food Category System 14.1.4.3, in column (3), for the entry "*The following additives permitted in synthetic syrups for dispensers" and the entries relating thereto, the following shall be substituted, namely: -

"*The following additives permitted in synthetic syrups for dispensers	127"

(ii) against the entries relating to Food Category System 14.1.4.3, in column (3), for the entry "*The following additives are permitted in sharbat (synthetic syrup)" and the entries relating thereto, the following shall be substituted, namely: -

"*The following additives are permitted in sharbat (synthetic syrup)	127"

(e) In table 15, in column (1),-

(i) against the entries relating to Food Category System 15.1, in column (3) after the food additive "Sunset yellow FCF" and the entries relating thereto, the following shall be inserted, namely: -

Food Additive	**INS Number**	**Recommended Maximum Level**	**Note**
"Paprika oleoresin	160c(i)	GMP	
Curcumin	100(i)	GMP	
Turmeric	100(ii)	GMP"	

(f) In the said regulations, in the Notes to the Food Additives mentioned in the Table 1 to 15, after Note No FS0 4a, and the entries relating thereto, the following shall be inserted, namely: -

Note No.	Notes to the Food Additives mentioned in the Table 1 to 15
FS04b	For use in pre-packed coconut water only.

(5). In the said regulations, in Appendix B relating to "Microbiological Requirements"-

(a) in table 2, -

(i) under the heading "Action in case of unsatisfactory result" for second bullet, the following shall be substituted, namely-

- "Ensure that all food safety criteria as specified in Table-2B are complies 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 products at the end of the manufacturing process and the products in the market during their shelf-life.

(ii) under the heading "Sampling Plans and Guidelines" for first paragraph, the following shall be substituted, namely:-

For Regulators: 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 5^0C (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 shall be ensured as per reference test methods given below in reference test methods for regulatory compliance.

(b) for TABLE 3and the entries relating thereto, the following table and the entries shall be substituted, namely:-

Table: 3 Microbiological Standards for Spices and Herbs

Table -3 A 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	$1x10^5$	$1x10^6$	5	2	$1x10^3$	$1x10^4$	5	2	$1x10^2$	$1x10^3$	5	2	$1x10^2$	$1x10^3$
3.	**Ground or Powdered**	5	2	$1x10^5$	$1x10^6$	5	2	$1x10^3$	$1x\ 10^4$	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	$1x10^2$	$1x\ 10^3$	5	2	$1x10^2$	$1x\ 10^3$	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 -3 B Microbiological Requirements for Spices and Herbs – Food Safety Criteria

Sr. No.	Product Category[1]	*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[2]**												
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[3]**	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 without bleaching 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, stigmas and/ or oleo resins etc.

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

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 products 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.

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.

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.

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. 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 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

iii. 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.

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 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.- ISO 6579
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.

(c) in table 5, -

(i) under the heading "Action in case of unsatisfactory result" for second bullet, the following shall be substituted, namely-

- "Ensure that all food safety criteria as specified in Table-5B are complies 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 products at the end of the manufacturing process and the products in the market during their shelf-life.

(ii) under the heading "Sampling Plans and Guidelines" for first paragraph, the following shall be substituted, namely:-

For Regulators: The sampling for different microbiological standards with respect to the products 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 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 5^0C (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-5A & 5B** shall be taken from same batch/lot and shall be submitted to the notified laboratory shall be ensured as per reference test methods given below in reference test methods for regulatory compliance.