

**MINISTRY OF HEALTH AND FAMILY WELFARE
(FOOD SAFETY AND STANDARDS AUTHORITY OF INDIA)**

NOTIFICATION

New Delhi, the 26th October, 2020

F.No. Stds/SC/A-1.34/N-1.—The draft regulations further to amend the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, which the Food Safety and Standards Authority of India proposes to make with previous approval of the Central Government, in exercise of the powers conferred by clause (e) of sub-section (2) of section 92 read with section 16 of the Food Safety and Standards Act, 2006 (34 of 2006) is hereby published as required under sub-section (1) of section 92 of the said Act for the information of all persons likely to be affected thereby, and notice is hereby given that the said draft regulations shall be taken into consideration after the expiry of the period of sixty days from the date on which copies of the Gazette in which this notification is published are made available to the public;

Objections or suggestions, if any, may be addressed to the Chief Executive Officer, Food Safety and Standards Authority of India, FDA Bhawan, Kotla Road, New Delhi- 110002 or may be sent by e-mail at regulation@fssai.gov.in;

Objections or suggestions which may be received with respect to the said draft regulations within the period specified above shall be considered by the Food Safety and Standards Authority of India.

Draft Regulations

1. (1) These regulations may be called the Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations, 2020.
- (2) They shall come into force with effective date for implementation to be either 1st January or 1st July subject to a minimum of 180 days from the date of their final publication in the official Gazette.
2. In the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011,-
 - (1) in regulation 1.2 related to 'Definitions', after clause 26, the following clause shall be inserted, namely-
"27. "Raw edible oils" are obtained by mechanical procedures e.g expelling and pressing, with or without application of heat. They may be purified by washing with water, settling, filtering and centrifuging. Such oils are fit for human consumption. They shall conform to the provisions mentioned under sub-regulation 2.2.1 prescribed for specific vegetable oil except the standards laid down under regulation 2.2.1 (16)"
 - (2) in regulation 2.2 relating to Fats, Oils and Fat Emulsions, in sub-regulation 2.2.1 relating to Oils
 - (i) in clause 1 relating to Coconut oil (naryal ka tel), for the entry against the words and figures 'Refractive Index at 40°C', following figures shall be substituted, namely-
 "1.4480- 1.4500"
 - (ii) in clause 24 for the words 'Blended Vegetable Oil' following shall be substituted, namely-
"Multi-sourced Edible vegetable Oil"
 - (3) in regulation 2.3 relating to Fruit and Vegetable Products
 - (i) in sub-regulation 2.3.3 relating to Thermally Processed Vegetables, in clause 1, item (c) under sub-clause (i) shall be substituted with following, namely-
 "(c) Edible fungi\vegetables including baked beans packed in sauce 25.0 percent of net weight of contents"
 - (ii) in sub-regulation 2.3.31 relating to 'Jam, Fruit Jellies and Marmalades',
 - (a) clause 7 shall be substituted by the following, namely-
 "The total Soluble Solid content, in the case of jams shall not be less than 65 percent, by weight and not less than 60 percent by weight in case of jellies and marmalades. To be called as a reduced sugar product, Jam, Jellies and marmalades must not have TSS more than 45 %."
 - (b) clause 13 shall be substituted with the following, namely:
 "Standards specified in this sub-regulation shall not apply to the products which are clearly intended or labelled as intended for special dietary uses"
 - (iii) the sub-regulation 2.3.36 relating to "Dehydrated Vegetables" shall be substituted with following, namely: -

“2.3.36 Dehydrated Vegetables:

1. Dehydrated Vegetables means the product, prepared from edible portions of suitable variety of sound vegetable, free from insect or fungal infection, free from blemishes, suitably prepared, from which moisture has been removed under suitable conditions of temperature, pressure, humidity & airflow, to the extent that the product is preserved by any suitable method.

2. It may be whole, sliced, quarters, pieces, flakes, kibbled granules or powdered. The finished product shall have uniform colour and shall be free from discolouration due to scorching or enzymatic reaction. It shall be free from stalks, peels, stems and extraneous matter. When in powder form, it shall be free flowing and free from agglomerates.

3. The product may contain food additives permitted in these regulations including Appendix A. The product shall conform to the microbiological requirements given in Appendix B. It shall meet the requirements as given in the Table below

S. No.	Name of Vegetables	Moisture not more than (percent)	Ash insoluble in dilute HCl not more than (percent)	Peroxidase Test
1.	All dehydrated vegetables	8.0	0.5	Negative
2.	Powders of all vegetables	5.0	0.5	Negative”

(4) in regulation 2.4 relating to Cereal and Cereal Products,

(i) in sub-regulation 2.4.1, clause 3 relating to ‘Protein rich (paushtik) atta’, shall be substituted with the following, namely-

“3. Protein rich *atta* (Protein prachur *atta*)**1. Description**

Protein rich *atta* (Protein prachur *atta*) means the product obtained by mixing wheat *atta* with Solvent extracted groundnut flour, Solvent extracted Soya flour and Whey Protein powder; either singly or a combination of these, up to an extent of 15.0 per cent. Soya flour individually shall not be more than 10.0 per cent and Whey Protein powder should not be more than 5.0 per cent. It shall not contain added flavouring and colouring agents. The product shall be free from abnormal flavours, odours, living insects, visible mould, filth (impurities of animal origins, including dead insects).

It shall conform to the following standards:

Parameter	Limit
Moisture % by mass, Not more than	12.0
Ash insoluble in dilute hydrochloric acid, % by mass (on dry basis), Not more than	0.1
Total Protein (N x 6.25), % by mass (on dry basis), Not less than	15.0
Total Dietary Fibre, % by mass (on dry basis), Not less than	7.0
Alcoholic acidity (with 90 percent alcohol) expressed as H ₂ SO ₄ , % Not more than	0.12
Gluten, % by mass (on dry basis), Not less than	6.0
Urease activity, Not more than	0.02
Uric Acid, mg/kg, Not more than	100”

(ii) in sub-regulation 2.4.2, clause 3 relating to ‘Protein rich (paushtik) maida’, shall be substituted with the following, namely-

“3. Protein rich refined wheat flour (Protein prachur maida)**1. Description**

Protein rich refined wheat flour (protein prachur maida) means the product obtained by mixing maida (refined wheat flour) with solvent extracted groundnut flour, ~~or~~ solvent extracted soya flour, Whey Protein flour; either

singly or a combination up to an extent of 15.0 per cent. Soya flour individually shall not be more than 10.0 per cent and Whey Protein powder should not be more than 5.0 per cent. It shall not contain added flavor and colouring agents. The product shall be free from abnormal flavours, odours, living insects, **visible mould**, filth (impurities of animal origins, including dead insects).

It shall conform to the following standards:

Parameter	Limit
Moisture % by mass, Not more than	12.0
Ash insoluble in dilute hydrochloric acid, % by mass (on dry basis), Not more than	0.1
Total Protein (N x 6.25), % by mass (on dry basis), Not less than	15.0
Total Dietary Fibre, % by mass (on dry basis), Not less than	3.0
Alcoholic acidity (with 90 percent alcohol) expressed as H ₂ SO ₄ , % Not more than	0.12
Gluten, %by mass (on dry basis), Not less than	6.0
Urease activity, Not more than	0.02
Uric Acid, mg/kg, Not more than	100”

(iii) after sub-regulation 2.4.34, the following sub-regulations shall be inserted, namely-

“2.4.35 Multigrain *Atta* and Wheat flour (*atta*) with other grain flour

1. Description:

- a) **Multigrain *Atta*:** Multigrain *atta* means the product obtained by milling/grinding blend of clean whole wheat and other permitted ingredients or mixing their flours. The product shall have flour composition obtained from maximum 50% of whole wheat and rest of the flour composition shall be from other permitted ingredients singly or in combination. The product shall be free from abnormal flavours, odours, living insects, visible mould, filth (impurities of animal origins, including dead insects).
- b) **Wheat flour (*atta*) with other grain flour** means the product obtained by milling /grinding blend of clean whole wheat and other permitted ingredients or mixing their flours. The product shall have flour composition obtained from minimum 80% of whole wheat and other permitted ingredients in the range of 10%-20% singly or in combination. The product shall be free from abnormal flavours, odours, living insects, visible mould, filth (impurities of animal origins, including dead insects).

Other Permitted Ingredients – Processed Soybean, Cereals, Pulses, Millets, Psyllium husk, Gluten, wheat bran and fenugreek seeds.

2. It shall conform to the following standards:

S. No.	Parameters	Limit
(i)	Moisture, % by mass, Not more than	12.0
(ii)	Acid Insoluble Ash on dry basis, % by mass, Not more than	0.15
(iii)	Gluten, % by mass (on dry basis), Not less than	Multigrain <i>Atta</i> – 3.5 Whole Wheat flour (<i>atta</i>) with other grains flour – 5.5
(iv)	Protein (N x 6.25), % by mass (on dry basis), Not less than	10.0
(v)	Total Dietary Fiber, % by mass (on dry basis), Not less than	12.0
(vi)	Alcoholic acidity (with 90 percent alcohol) expressed as H ₂ SO ₄ , % on dry mass basis, Not more than	0.15
(vii)	Particle size, Not less than	98% should pass through 40 mesh

(viii)	*Urease activity, Not More Than	0.02
(ix)	Uric acid, mg/kg, Not more than	100

*The test of urease activity is applicable in case soya is used.

3. Percentage of Wheat flour (Atta) in the product shall be declared on the label

2.4.36 Mixed Millet Flour

1. Description:

Mixed millet flour means the product obtained by milling /grinding blend of clean millets/pseudomillets or by blending flour obtained from clean millets. The product shall be free from abnormal flavours, odours, living insects, visible mould, filth (impurities of animal origins, including dead insects).

Note: - Note: - Millets/pseudomillets are Sorghum/ Jowar (Sorghum bicolor), Pearl Millet / Bajra (Pennisetum glaucum) , Finger Millet/ Ragi/Mandua (Eleusine coracana), Foxtail Millet/Kanngani/kakun (Setaria italica), Proso Millet/ Cheena (Panicum milliaceum), Kodo Millet/ Kodo (Paspalum scrobiculatum), Barnyard Millet/ Sawa/Sanwa/Jhangora (Echinochola crus-galli) , Little Millet/ Kutki (Panicum sumatrense) , Brown top millet (Brachiaria ramosa) and pseudo-millets are Buck wheat / Kuttu (Fagopyrum esculentum) , Amaranth/ Chaulai (Amaranthus cruentus).

2. It shall conform to the following standards:

S. No.	Parameters	Limits
(i)	Moisture, % by mass, Not more than	11.0
(ii)	Acid Insoluble Ash on dry basis, % by mass, Not more than	0.15
(iii)	Protein (N x 6.25), % by mass (on dry basis), Not less than	8.0
(iv)	Alcoholic acidity (as H ₂ SO ₄) with 90 percent alcohol) expressed as H ₂ SO ₄ , % by mass (on dry basis), Not more than	0.15
(v)	Dietary fiber, % by mass (on dry basis), Not less than	12.0
(vi)	Particle size, Not less than	98% should pass through 40 mesh
(vii)	Urease activity, Not More Than	0.02
(viii)	Uric acid, mg/kg, Not more than	100"

(5) for the note given under sub-regulation 2.5.2 related to Meat and Meat Products,

(i) the sentence 'All the products listed in regulation 2.5.2 under clause 7, 8, 9, 10, 11, 12 shall comply with following requirements:' shall be substituted with the following namely:

"All the products listed in regulation 2.5.2 shall comply with following requirements:"

(ii) note (c) shall be substituted with the following namely:

"(c) Milk and meat producing animals except poultry, pig and fish shall not be fed with feed containing meat or bone meal including internal organs, blood meal and tissues of bovine or porcine origin materials except milk and milk products. Commercial feeds shall comply with the relevant BIS standards, as may be specified by the Food Authority from time to time, and carry BIS certification mark on the label of the product."

(6) in regulation 2.6, relating to Fish and Fish Products, in sub-regulation 2.6.1, clause 6 relating to the standards of 'Dried shark fins' shall be omitted.

(7) in regulation 2.8 relating to Sweetening agents including Honey, in the sub-regulation 2.8.3 related to Honey and its by products,

(i) under Clause (1) related to Honey, the item (I) shall be substituted with the following, namely-

"(I) Honey is the natural sweet substance produced by honey bees from the nectar of plants or from secretions of living parts of plants or excretions of plant sucking insects on the living parts of plants, which the bees collect, transform by combining with specific substances of their own, deposit, dehydrate, store and leave in the honey comb to ripen and mature.

- a) Blossom Honey or Nectar Honey is the honey which comes from nectars of plants.
- b) Honeydew Honey is the honey which comes mainly from excretions of plant sucking insects (Hemiptera) on the living parts of plants or secretions of living parts of plants.

(ii) table under the item (V) shall be substituted with the following, namely-

* $\Delta\delta^{13}C$ Max. is the maximum difference observed between all possible isotopic ratios measured ($\Delta\delta^{13}C$ fructose-

Sl. No.	Parameters	Limits
1.	Specific gravity at 27° C, Min.	1.35
2.	Moisture, per cent. by mass, Max.	20
3.	Total reducing sugars, per cent. by mass, Min.	
	(a) For the Honey not listed below	65
	(b) Carviacallosa and Honeydew honey	60
	(c) Blends of Honeydew honey with blossom honey	45
4.	Sucrose, per cent. by mass, Max.	
	(a) For the Honey not listed below	5.0
	(b) Carviacallosa and Honeydew honey, Max.	10
5.	Fructose to Glucose ratio (F/G Ratio)	0.95-1.50
6.	Total Ash, per cent. by mass, Max.	0.50
7.	(a) Acidity expressed as formic acid, per cent. by mass, Max.	0.20
	(b) Free Acidity milliequivalents acid/ 1000 g, Max.	50.0
8.	Hydroxymethylfurfural (HMF) mg/kg, Max.	80.0
9.	Diastase activity, Schade units per gram, Min.	3
10.	Water insoluble matters, per cent. by mass, Max.	
	(a) For the Honey not listed below	0.10
	(b) For Pressed honey	0.5
11.	C4 Sugar, per cent. by mass, Max.	7.0
12.	Pollen count and plant element/g, Min.	5000
13.	2-Acetylfuran-3-Glucopyranoside (2-AFGP) as Marker for Rice Syrup	Absent**
14.	Foreign oligosaccharides (Max. Percent Peak)	0.7
15.	Proline, mg/kg, Min.	180
16.	Electrical Conductivity:	
	(a) Honeys not listed under Honeydew, Max.	0.8 S/cm
	(b) Honeys listed under Honeydew, Min.	0.8 mS/cm
17.	(a) $\Delta\delta^{13}C$ Max*. (Maximum difference between all measured $\delta^{13}C$ values); per mil	± 2.1
	(b) $\Delta\delta^{13}C$ Fru – Glu (The difference in $^{13}C/^{12}C$ ratio between fructose and glucose); per mil	± 1.0
	(c) $\Delta\delta^{13}C$ Protein – Honey (The difference in $^{13}C/^{12}C$ between honey and its associated protein extract); per mil	≥ -1.0

disaccharides / $\Delta\delta^{13}C$ fructose-trisaccharides / $\Delta\delta^{13}C$ fructose -protein / $\Delta\delta^{13}C$ glucose-disaccharides / $\Delta\delta^{13}C$ glucose-trisaccharides / $\Delta\delta^{13}C$ glucose-protein / $\Delta\delta^{13}C$ disaccharides-trisaccharides / $\Delta\delta^{13}C$ disaccharides-protein / $\Delta\delta^{13}C$ trisaccharides-protein).

**Minimum Required Performance Level- 1mg/kg

(iii) the item (VII) and (VIII) shall be substituted with the following, namely-

“(VII) In addition to the labelling provisions as given in the Food Safety and Standards (Packaging and Labelling) Regulations, 2011, the following specific provisions shall be applicable for labelling of honey:

(a) Honey shall be labelled as:

- A. **Honeydew Honey** - If the product complies with the definitions given in part I (a) of this standard;
- B. **Blend of Honeydew Honey and Blossom Honey** – If the product is mixture of Blossom or Nectar Honey and Honeydew honey
- C. **Carvia Callosa Honey** - If the honey is derived from flower of *Carviacallosa* plant which is described as thixotropic and is gel like extremely viscous when standing still and turns into liquid when agitated or stirred.
- (b) If the honey is obtained by pressing broodless combs, honey shall be labeled as “Pressed Honey”. If honey belongs to any of the categories mentioned at a) above and also falling into the category of pressed honey, it shall be labeled as “Pressed Honeydew Honey” or “Pressed and Blend of Honeydew Honey and Blossom Honey” or “Pressed Carvia Callosa Honey”.

(VIII) Honey may be labeled as follows, according to floral or plant source, if it comes from any particular source and has the organoleptic, physicochemical and microscopic properties corresponding with that origin. It shall be in addition to the labeling requirements as given at (vii) above:

- A. **Monofloral Honey** - If the minimum pollen content of the plant species concerned is not less than 45 percent of total pollen content;
- B. **Multi Floral Honey** – If the pollen content of any of the plant species does not exceed 45 percent of the total pollen content;”

(iv) after item (VIII), item (IX) shall be inserted, namely:

“(IX) The said standards are applicable to packaged/ processed honey.”

(8) in regulation 2.9, relating to Salt, Spices, Condiments and Related Products, after sub-regulation 2.9.39, the following sub-regulation shall be inserted, namely -

“2.9.40 Dried Sweet Basil Leaves

1. Dried sweet basil leaves are obtained from the species *Ocimum basilicum* L., belonging to the family Lamiaceae. Dried sweet basil leaves shall have characteristic colour, odour and flavour. It shall be free from visible moulds, living/dead insects, insect fragments and rodent contamination. The product shall be free from foreign odours, flavours, any other harmful substances and added colouring matters. It shall conform to the following requirements:

Sr. No.	Requirements	Limit
i.	Moisture content, per cent by mass (<i>Maximum</i>)	12.0
ii.	Total Ash, per cent by mass on dry basis, (<i>Maximum</i>)	16.0
iii.	Acid-insoluble ash, per cent by mass on dry basis, (<i>Maximum</i>)	2.0
iv.	Volatile oil content, ml/100g, on dry basis (<i>Minimum</i>)	0.3
v.	Foreignmatter, per cent m/m, (<i>Maximum</i>)	1.0
vi.	Extraneous vegetable matter, per cent m/m, (<i>Maximum</i>)	3.0
vii.	Yellow or Brown leaves, per cent m/m, (<i>Maximum</i>)	5.0

Explanations:

Foreign matter: Any visible objectionable matter or material not usually associated with the natural components of the spice plant such as sticks, stones, burlap bagging, metal etc.

Extraneous vegetable matter: Vegetative matter associated with the plant from which the product originates - but is not accepted as part of the final product.”

- (9) in regulation 2.10 relating to Beverages (Other than Dairy and Fruits & Vegetables based), in sub-regulation 2.10.6, for the paragraph starting with “Provided that the products” and ending with the words “distributed or sold in returnable containers” under sub-clause (1) of clause (1) following shall be substituted, namely:

“Provided that the products which contain aspartame, acesulfame-K or any other artificial sweetener for which special labeling provisions have been provided under regulations 2.4.5 (24, 25, 26, 28 and 29) of Food Safety and Standards (Packaging and Labeling) Regulations, 2011, may be packed, stored, distributed or sold in returnable containers subject to the compliance of these labelling provisions for artificial sweeteners prominently on the bottle but not on crown.”

- (10) after sub- regulation 2.15 relating to the standards of ‘Food specially processed to reduce gluten content to a level 20 -100mg/kg’, the following sub-regulations shall be inserted, namely-

“2.16. Hemp seeds and seed products:

1. For the purpose of these regulations, hemp seed means the hulled¹, non-viable² seeds³ obtained from of industrial variety of *Cannabis sativa* plants in which the concentration of THC⁴ is 0.3% w/w or less.

2. The hemp seed and its products can be sold as food or used as an ingredient in a food for sale subject to conforming to the following standards:

i) Hemp seed

S. No	Parameters	Requirements
1.	Moisture, per cent m/m, Max.	7.0
2.	Protein (N x 6.25), per cent m/m, Min.	30.0
3.	Fat, per cent m/m, Min.	45.0
4.	Ash, per cent m/m, Max.	6.0
5.	Total THC ⁵ , mg/kg, Max.	5.0

ii) Oil extracted from hemp seeds

S. No	Parameters	Requirements
1.	Free fatty acid, per cent m/m, Max.	0.50
2.	Peroxide value, mEq/kg, Max.	1.0
3.	Total THC ⁵ , mg/kg, Max.	10.0

iii) The total THC shall not exceed 0.2 mg/kg in any beverages made from hemp seeds.

iv) The total THC shall not exceed 5mg/kg in hemp flour.

3. The level of cannabidiol⁶ (CBD) in any food for sale consisting of hemp seed or seed products shall not exceed 75 mg/kg.

4. Cannabinoids⁷ in any food for sale consisting of hemp seed or seed products shall only be present naturally in or on the seeds.

5. The food for sale that consists of hemp seed or seed products shall not be labelled or otherwise presented for sale in a form which expressly or by implication suggests that the product has a psychoactive effect.

6. The label for the food containing hemp seed or seed products for sale shall not include:

- a nutrition content claim about cannabidiol; or
- a health claim about cannabidiol; or
- an image or representation of any part of the *Cannabis sativa* plant (including the leaf of that plant) other than the seed; or
- the words ‘cannabis’, ‘marijuana’ or words of similar meaning.

7. The label for the food containing hemp seed or seed products for sale may include the word ‘Hemp’.

8. The food products containing hemp seed or seed products are intended for the general population (age 2 and above) and are not intended to be added to any foods intended for infants.

9. The cultivation of *Cannabis sativa* for the purpose of hemp seeds in India shall comply with Narcotic Drugs and Psychotropic Substances (NDPS) Act, 1985 and rules made thereunder.

Note:

1. Hulled seeds mean seeds from which the outer coat or hull of seeds has been removed.
2. Non-viable seeds mean seeds that are not able to germinate.
3. Seeds include a part of a seed.
4. THC means delta-9-tetrahydrocannabinol.
5. Total THC means the total amount of delta 9-tetrahydrocannabinol (THC) and delta 9-tetrahydrocannabinolic acid.
6. Cannabidiol (CBD) is the non-psychoactive component of *Cannabis sativa*.
7. Cannabinoids means any of various naturally-occurring, biologically active, chemical constituents such as cannabidiol or cannabinol of *Cannabis sativa* including some that possess psychoactive properties like delta 9-tetrahydrocannabinol (THC).

(11) in Chapter 3, under Appendix A,

(i) under the heading 'I. FOOD CATEGORY SYSTEM' the food category '8.2.3 Frozen processed meat and poultry products in whole pieces or cuts' shall be substituted with the following, namely-

"8.2.3 Frozen raw, flavored/marinated, processed meat and poultry products in whole pieces or cuts"

(ii) under the heading 'II. FOOD CATEGORY DESCRIPTIONS',

a) the description for the food category 4.2.2.4 regarding Canned or bottled (pasteurized) or retort pouch vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds, shall be substituted with the following, namely-

"Fully preserved product in which fresh vegetables are cleaned, blanched, and placed in cans or jars in liquid (e.g. brine, water, oil or sauce), and heat-sterilized or pasteurized such as canned peas, canned baby corn, asparagus packed in glass jars, canned and/or cooked/baked beans, canned tomato paste/ puree and canned tomatoes (pieces, wedges or whole), canned mushrooms, canned chestnuts etc."

b) the food category 8.2.3 and the related description shall be substituted with the following, namely-

"8.2.3 Frozen raw, flavored/marinated, processed meat and poultry products in whole pieces or cuts
-Includes raw, flavoured/marinated raw and cooked meat cuts that have been frozen".

(iii) in Table 14, under the heading 'IV. USE OF FOOD ADDITIVES IN FOOD PRODUCTS',

(a) in the Food Category System 14.1.4, the food additive 'Tatrazine' and the related entries shall be omitted.

(b) in the Food Category Systems 14.1.4.2,

i) below the column for food additive 'L-Tartaric acid' and the related entries, following row shall be inserted, namely-

"No colours permitted in iced tea and iced tea mixes"

ii) the food additive 'Tatrazine' and 'Sunset yellow FCF' and the entries relating thereto, shall be omitted.

(c) in the Food Category Systems 14.1.4.3,

i) in the column for food additives and the related entries, following note shall be inserted, namely-

"No colours permitted in iced tea and iced tea mixes"

ii) the food additive 'Tatrazine' and 'Sunset yellow FCF' and the entries relating thereto, shall be omitted.

(12) in Chapter 3, in Appendix B, after Table related to 'Reference Test Methods' in the Table 8B, related to Microbiological Standards for Egg and Egg Products, the following shall be inserted, namely-

“Table-9 Microbiological Standards of Food Grains and their Products

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

Sr. No.	Product Description	Yeast and Mould Count (cfu/g)				<i>Staphylococcus aureus</i> count (cfu/g)				Enterobacteriaceae count (cfu/g)			
		Sampling plan		Limit		Sampling plan		Limit		Sampling plan		Limit	
		n	c	m	M	n	c	m	M	n	c	m	M
1.	Sprouted grains, sweet corn cob or packed wet grains for direct consumption	NA				NA				5	2	10	10 ²
2.	Batters and doughs (Ready to Cook)	NA				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				NA				5	2	10	10 ²
4.	Test Methods	IS: 5403/ ISO 21527 Part 1 and 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				IS/ISO 7402/ ISO 21528 Part 2			

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

Sr. No.	Product Description	<i>Salmonella</i>			<i>Listeria monocytogenes</i>		
		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/25g	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/25g	5	0	Absent/25 g
4.	Test Methods	IS: 5887 Part3 / ISO:6579			IS: 14988, Part 1 / ISO 11290-1		

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 ($\pm 2^{\circ}\text{C}$) or under refrigerated conditions at $2-5^{\circ}\text{C}$ 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 them selves, 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)
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1. Satisfactory, if all the values observed are $\leq m$	1. Satisfactory, if all the values observed are $\leq m$
2. Unsatisfactory, if one or more of 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.	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
2.	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
3.	<i>Staphylococcus Aureus</i> count	Methods for detection of bacteria responsible for food poisoning: Part 2 Isolation, identification and enumeration of <i>Staphylococcus aureus</i> 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/ (<i>Staphylococcus aureus</i> 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/ (<i>Staphylococcus aureus</i> And Other Species) Section 2 Technique using rabbit plasma fibrinogen agar medium- IS 5887 (Part 8/Sec 2) / ISO 6888-2: 1999)
4.	<i>Salmonella</i>	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.	<i>Listeria monocytogenes</i>	Microbiology of the food chain -- Horizontal method for the detection and enumeration of <i>Listeria monocytogenes</i> and of <i>Listeria</i> spp. -- Part 1: Detection method –ISO 11290-1 Microbiology of Food and Feeding Stuffs - Horizontal method for Detection and Enumeration of <i>Listeria Monocytogenes</i> , Part 1: Detection Method -IS 14988-1

ARUN SINGHAL, Chief Executive Officer

[ADVT.-III/4/Exty./310/2020]

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

- 1) F.No. 4/15015/30/2011, dated 7th June, 2013;

- 2) F.No. P. 15014/1/2011-PFA/FSSAI, dated 27th June, 2013;
- 3) F.No. 5/15015/30/2012, dated 12th July, 2013;
- 4) F.No. P. 15025/262/2013-PA/FSSAI, dated 5th December, 2014;
- 5) F.No. 1-83F/Sci. Pan- Noti/FSSAI-2012, dated 17th February, 2015;
- 6) F.No. 4/15015/30/2011, dated 4th August, 2015;
- 7) F.No. P.15025/264/13-PA/FSSAI, dated 4th November, 2015;
- 8) F.No. P. 15025/263/13-PA/FSSAI, dated 4th November, 2015;
- 9) F.No. P. 15025/261-PA/FSSAI, dated 13th November, 2015;
- 10) F.No. P. 15025/208/2013-PA/FSSAI, Dated 13th November, 2015;
- 11) F.No. 7/15015/30/2012, dated 13th November, 2015;
- 12) F.No. 1-10(1)/Standards/SP(Fish and Fisheries Products)/FSSAI-2013, dated 11th January, 2016;
- 13) F.No. 3-16/Specified Foods/Notification(Food Additives)/FSSAI-2014, dated 3rd May, 2016;
- 14) F.No. 15-03/Enf/FSSAI/2014, Dated 14th June, 2016;
- 15) F.No. 3-14F/Notification (Nutraceuticals)/FSSAI-2013, dated 13th July, 2016;
- 16) F.No. 1-12/Standards/SP (Sweets, Confectionery)/FSSAI-2015, dated 15th July, 2016;
- 17) F.No. 1-120(1)/Standards/Irradiation/FSSAI-2015, dated 23rd August, 2016;
- 18) F. No. 11/09/Reg/Harmoniztn/2014, dated 5th September, 2016;
- 19) F.No. Stds/CPLQ.CP/EM/FSSAI-2015, dated 14th September, 2016;
- 20) F.No. 11/12 Reg/Prop/FSSAI-2016, dated 10th October, 2016;
- 21) F.No. 1-110(2)/SP (Biological Hazards)/FSSAI/2010, dated 10th October, 2016;
- 22) F.No. Stds/SP (Water & Beverages)/Notif (2)/FSSAI-2016, dated 25th October, 2016;
- 23) F.No. 1-11(1)/Standards/SP (Water & Beverages)/FSSAI-2015, Dated 15th November, 2016;
- 24) F.No. P.15025/93/2011-PFA/FSSAI, Dated 2nd December, 2016;
- 25) F.No. P. 15025/6/2004-PFS/FSSAI, dated 29th December, 2016;
- 26) F.No. Stds/O&F/Notification(1)/FSSAI-2016, dated 31st January, 2017;
- 27) F.No. 1-12/Standards/2012-FSSAI, dated 13th February, 2017;
- 28) F.No. 1-10(7)/Standards/SP (Fish & Fisheries Products)/FSSAI-2013, dated 13th February, 2017;
- 29) F. No. Stds /SCSS&H/ Notification (02)/FSSAI-2016, dated 15th May, 2017;
- 30) F. No. Stds/03/Notification (LS)/ FSSAI-2017, dated 19th June, 2017;
- 31) F.No. 1/Additives/Stds/14.2Notification/FSSAI/2016, dated 31st July, 2017;
- 32) F.No. Stds/F&VP/Notification(01)/FSSAI-2016, dated 2nd August, 2017;
- 33) F.No. 1-94(1)/FSSAI/SP(Labelling)/2014, dated 11th September, 2017;
- 34) F.No. Stds/M&MPIP(1)/SP/FSSAI-2015, dated 15th September, 2017;
- 35) F.No. Stds/SP (Water & Beverages)/Noti(1)/FSSAI-2016,dated 15th September,2017;
- 36) F.No.1-10(8)/Standards/SP (Fish and Fisheries Products)/FSSAI-2013, dated 15th September,2017;
- 37) File No. 2/Stds/CPL & CP/Notification/FSSAI-2016, dated 18th September, 2017;
- 38) F. No. A-1 (1)/Standard/MMP/2012, dated 12th October, 2017;
- 39) F. No. Stds/O&F/Notification (3)/FSSAI-2016, dated 12th October, 2017;
- 40) F. No. 2/Stds/CPL & CP/Notification/FSSAI-2016(part), dated the 24th October, 2017;
- 41) F. No. A-1/Standards/Agmark/2012-FSSAI(pt.I), dated 17th November, 2017;
- 42) F.No. 1/Additives/Stds/BIS Notification/FSSAI/2016, dated 17th November, 2017;

- 43) F. No. Stds/O&F/Notification (5)/FSSAI-2016, dated 20th February , 2018;
- 44) F.No. Stds/01-SP(fortified & Enriched Foods)-Reg/FSSAI-2017, dated 13th March, 2018;
- 45) F. No. 1/Infant Nutrition/Stds/Notification/FSSAI/2016, dated 13th March, 2018;
- 46) F. No.1-110(3)/SP (Biological Hazards)/FSSAI/2010, dated the 21st March, 2018;
- 47) File No. Stds/SCSS&H/ Notification (03)/FSSAI-2016, dated the 10th April, 2018;
- 48) F. No. Stds/CPL&CP/Notification/FSSAI-2016, dated 4th May, 2018;
- 49) F.No. Stds/SP(SCSSH)/Ice lollies notification/FSSAI-2018, Dated 20th July,2018;
- 50) F.No. Stds/SP(Water & Beverages)/Notif(3)/FSSAI-2016, Dated 20th July,2018;
- 51) Stds/CPL&CP/ Draft Notification/FSSAI-2017, Dated 31st July, 2018;
- 52) File No.1/Additional Additives/Stds/Notification/FSSAI/2016, Dated 8th November, 2018;
- 53) F.No. Stds/03/Notification (CFOI&YC)/FSSAI-2017, Dated 16th November, 2018.
- 54) F. No. Stds/O&F/Notification (7)/FSSAI-2017, dated 19th November, 2018;
- 55) F.No. Stds/M&MP/Notification (02)/FSSAI-2016, dated 19th November, 2018;
- 56) F. No. Stds/F&VP/Notifications (04)/FSSAI-2016, dated 19th November, 2018;
- 57) F. No. 1-116/Scientific Committee (Noti.)/2010-FSSAI, dated 26thNovember, 2018;
- 58) F. No. 02-01/Enf-1(1)/FSSAI-2012, dated 29th January, 2019;
- 59) F.No. Stds/F&VP/Notification (07)/FSSAI-2018, dated 5th July, 2019;
- 60) F.No.Stds/O&F/Notification(10)/FSSAI-2017, dated 5th July, 2019;
- 61) F.No. Stds/SP (Water & Beverages)/Notification(5) FSSAI-2018, dated 30th October, 2019;
- 62) F.No. M&MP/Misc. Stds/Notification(03)/FSSAI-2018, dated 28th November , 2019;
- 63) F.No.1-110/SP (Biological Hazards)/Amendment-1/FSSAI/2018, dated 23rd June, 2020;
- 64) F. No. Stds/CPL & CP/Notification/01/FSSAI-2018, dated 9th July, 2020;
- 65) F. No. Stds/CPL & CP/Notification/01/FSSAI-2017, dated 9th July, 2020;
- 66) F. No. Stds/ M&MPIP (3)/SP/FSSAI-2018, dated 9th July, 2020;
- 67) F.No.A-1/Standards/Agmark/2012-FSSAI (p+1) , dated 23rd July, 2020;
- 68) F. No. Stds./M&MP/Notification (04)/FSSAI-2019, dated 2nd September, 2020;
- 69) F.No. Stds/Additives-1/Notification/FSSAI/2018, dated 16th September, 2020;
- 70) F.No. 1/Additional Additives-III/Stds/Notification/FSSAI/2017, dated 9th October, 2020 and
- 71) F. No. Stds/Processing aids/Notification/FSSAI/2018 dated 9th October, 2020.