



**Voluntary Report** – Voluntary - Public Distribution

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# **Report Highlights:**

On November 15, 2021, the Indian government's Food Safety and Standards Authority of India published amendments to the Food Safety and Standards (Food Product Standards and Food Additives) Regulations (2011) in the Official Gazette of India (notification No. Stds/SC/A- Explorer. Indian host sites will geo-block site access on a rolling basis]. I.34/N-1). The amendments introduce new standards as well as modify existing requirements for a variety of food products including raw edible oils, dehydrated vegetables, jams, Atta flours, honey, animal feed requirements, hemp seed, and food additives, among others.

# **DISCLAIMER:**

The information contained in this report was retrieved from the Food Safety and Standards Authority of India's (FSSAI) website http://www.fssai.gov.in. The U.S. Embassy in New Delhi – Foreign Agricultural Service (FAS) Office of Agricultural Affairs (OAA), USDA and/or the U.S. Government make no claim of accuracy or authenticity. The Government of India has not officially endorsed this report. Import approval for any product is subject to local rules and regulations as interpreted by Indian officials at the time of product entry. [Note: Use Google Chrome to access the links that do not open in Internet.

# **GENERAL INFORMATION:**

On November 15, 2021, the Indian government's Food Safety and Standards Authority of India (FSSAI) published additional amendments to the Food Safety and Standards (Food Product Standards and Food Additives) Regulations (2011) in the Indian Official Gazette. The amendments include new standards and modify existing requirements for a variety of food products and ingredients. These products include raw edible oils, multi-source edible oil, dehydrated vegetables, jams, jellies and marmalades, protein rich *Atta* (finely ground whole meal wheat flour), multigrain *Atta*, mixed millet flour, honey, animal feed requirements, dry sweet basil leaves, hemp seed, food additives used in iced tea, and food grain microbiological standards. The draft amendment for this notification was notified to the World Trade Organization on November 9, 2020 (see GAIN-INDIA (IN2020-0168) India Notifies Draft Amendments for New and Modified Standards on Various Food Products).

The full text of the current FSSAI notification is pasted as Appendix-I below and is also available on FSSAI's website at:

https://fssai.gov.in/upload/notifications/2021/11/619b553646e10Gazette\_Notification\_Oil\_Flour\_22\_11\_2021.pdf.

# APPENDIX-I: FSSAI DRAFT FOOD SAFETY AND STANDARDS (FOOD PRODUCT STANDARDS AND FOOD ADDITIVES) REGULATIONS, 2021

# FOOD SAFETY AND STANDARDS AUTHORITY OF INDIA NOTIFICATION

New Delhi, the 15th November, 2021

**F. No. Stds/SC/A-1.34/N-1.**—Whereas the draft of the Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations, 2020, were published as required by sub-section (1) of section 92 of the Food Safety and Standards Act, 2006 (34 of 2006), *vide* notification of the Food Safety and Standards Authority of India, F. No. Stds/SC/A-1.34/N-1, dated the 26<sup>th</sup> October, 2020, published in the Gazette of India, Extraordinary, Part III, section 4, inviting objections and suggestions from all persons likely to be affected thereby, before the expiry of the period of sixty days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas copies of the said Gazette were made available to the public on the 28th October, 2020;

And whereas the objections and suggestions received from the public in respect of the said draft regulations have been considered by the Food Safety and Standards Authority of India;

Now, therefore, in exercise of the powers conferred by clause (e) of sub-section (2) of section 92 read with section 16 of the said Act, the Food Safety and Standards Authority of India hereby makes the following regulations further to amend the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, namely: -

#### Regulations

- 1. Short title and commencement. (1) These regulations may be called the Food Safety and Standards (Food Products Standards and Food Additives) Fifth Amendment Regulations, 2021.
- (2) They shall come into force on the date of their publication in the Official Gazette and food business operator shall comply with all the provisions of these regulations by 1<sup>st</sup> June, 2022.
- 2. In the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011(hereinafter referred as said regulations), -
- (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. The expelled/pressed oil may be purified by washing with water, settling, filtering and centrifuging. No processing aid shall be used. 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",
  - (a) 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";
  - (b) in clause 24 for the words 'Multi-Sourced Edible Vegetable Oils' following shall be substituted, namely-

"Multi-Source Edible Oil";

(3) in regulation 2.3 relating to "Fruit and Vegetable Products",

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- (a) in sub-regulation 2.3.3 relating to "Thermally Processed Vegetables", in clause 1, in sub-clause (i), for item (c), the following shall be substituted, namely:-
  - "(c) Edible fungi/vegetables including baked beans packed in sauce- 25.0 percent of net weight of contents.";
- (b) in sub-regulation 2.3.31 relating to "Jam, Fruit Jellies and Marmalades" -
  - (i) clause 7 shall be substituted by the following, namely:-
    - "7. The total soluble solid content, in the case of jams shall not be less than 65 Percent by mass content and not less than 60 percent by mass content, in case of jellies and marmalades. To be called as a reduced sugar product, Jam, Jellies and marmalades shall not have TSS more than 45 percent by mass content."
  - (ii) 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"
- (c) 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)	Acid insoluble Ash 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",
  - (a) in sub-regulation 2.4.1, for clause 3 relating to 'Protein rich (paushtik) atta', the following shall be substituted, namely"-

## "3. Protein rich wheat flour (Protein prachur atta)

- 1. Protein rich wheat flour (Protein prachur atta) means the product obtained by mixing wheat flour with Solvent extracted groundnut flour, Solvent extracted Soya flour and Whey Protein powder and other edible standardised flour as mentioned in regulations notified under Food Safety and Standards Act, 2006; either singly or a combination of these, up to an extent of 15.0 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).
- 2. It shall conform to the following standards, namely:-

S. No.	Parameter	Limit
1.	Moisture % by mass, Not more than	13.0
2.	Acid insoluble ash, % by mass (on dry basis), Not more than	0.1
3.	Total Protein (N x 6.25), % by mass (on dry basis), Not less than	15.0
4.	Total Dietary Fibre, % by mass (on dry basis), Not less than	7.0
5.	Alcoholic acidity, % Not more than	0.18
6.	Gluten, % by mass (on dry basis), Not less than	5.0

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	7.	* Urease activity(pH units rise), Not more than	0.02
	8.	Uric Acid, mg/kg, Not more than	100

<sup>\*</sup> Urease activity test shall be applicable if soy flour is used.";

(b) in sub-regulation 2.4.2, for clause 3 relating to 'Protein rich (paushtik) maida', following shall be substituted, namely: -

#### "3. Protein rich refined wheat flour (Protein prachur maida)

- 1. Protein rich refined wheat flour (protein prachur maida) means the product obtained by mixing maida (refined wheat flour) with solvent extracted groundnut flour, 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 shall 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).
- 2. It shall conform to the following standards, namely:-

S. No.	Parameter	Limit
1.	Moisture % by mass, Not more than	12.0
2.	Acid insoluble ash, % by mass (on dry basis), Not more than	0.1
3.	Total Protein (N x 6.25), % by mass (on dry basis), Not less than	15.0
4.	Total Dietary Fibre, % by mass (on dry basis), Not less than	3.0
5.	Alcoholic acidity, % Not more than	0.12
6.	Gluten, %by mass (on dry basis), Not less than	6.0
7.	Urease activity (pH units rise), Not more than	0.02
8.	Uric Acid, mg/kg, Not more than	100";

(c) after sub-regulation 2.4.36 relating to "Yellow Pea Powder", the following sub-regulations shall be inserted, namely: -

# "2.4.37 Multigrain flour (atta)

- Multigrain flour (Atta): Multigrain flour (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 whole wheat ranging from 50-90 % and rest of the flour (10% 50%)
  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).
- Other Permitted Ingredients.— Processed Soybean, Cereals, Pulses, Millets, Psyllium husk, Gluten, wheat bran and fenugreek seeds.
- 3. It shall conform to the following standards:

S. No.	Parameters	Limit
1.	Moisture, % by mass, Not more than	13.0
2.	Acid Insoluble Ash on dry basis, % by mass, Not more than	0.15
3.	Gluten, % by mass (on dry basis), Not less than	3.0
4.	Protein (N x 6.25), % by mass (on dry basis), Not less than	10.0
5.	Total Dietary Fiber, % by mass (on dry basis), Not less than	12.0
6.	Alcoholic acidity, % on dry mass basis, Not more than	0.18
7.	Particle size, Not less than	98% shall pass through 40 mesh
8.	*Urease activity(pH units rise), Not More Than	0.02

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9.	Uric acid, mg/kg, Not more than	100
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<sup>\*</sup>The test of urease activity is applicable in case soya is used.

#### 2.4.38 Mixed Millet Flour

- 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 and filth (impurities of animal origins, including dead insects).
  - Note: Millets/pseudomillets are Sorghum/ Jowar (Sorghum bicolor), Pearl Millet / Bajra (Pennisetumglaucum) , Finger Millet/ Ragi/Mandua (Eleusinecoracana),Foxtail Millet/Kanngani/kakun (Setariaitalica), Proso Millet/ Cheena (Panicummilliaceum), Kodo Millet/ Kodo (Paspalumscrobiculatum), Barnyard Millet/ Sawa/Sanwa/Jhangora (Echinochola crus-galli) , Little Millet/ Kutki (Panicumsumatrense) , Brown top millet (Brachiariaramosa)and pseudo-millets areBuck wheat / Kuttu (Fagopyrumesculentum), Amaranth/ Chaulai (Amaranthuscruentus).
- It shall conform to the following standards, namely: -

S. No.	Parameters	Limits
1.	Moisture, % by mass, Not more than	11.0
2.	Acid Insoluble Ash on dry basis, % by mass, Not more than	0.15
3.	Protein (N x 6.25), % by mass (on dry basis), Not less than	8.0
4.	Alcoholic acidity, % by mass (on dry basis), Not more than	0.18
5.	Total Dietary fiber, % by mass (on dry basis), Not less than	12.0
6.	Particle size, Not less than	98% should pass through 40 mesh
7.	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,
  - (a) 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:"
  - (b) 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 '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 it's by products",
- (a) 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.";
- (b) table under the item (V) shall be substituted with the following, namely-

<sup>4.</sup> Percentage of Wheat flour (Atta) in the product shall be declared on the label.

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	"Sl. No.	Parameters	Limits	

"Sl. No.	Pa	nrameters	Limits
1.	Sp	pecific gravity at 27° C, Min.	1.35
2.	Moisture, per cent. by mass, Max.		20.0
3.	Total reducing sugars, per cent. by mass, Min.		
	(a)	For the Honey not listed below	65.0
	(b)	Carvia callosa and Honeydew honey	60.0
	(c)	Blends of Honeydew honey with blossom honey	45.0
4.	Sucro	ose, per cent. by mass, Max.	
	(a)	For the Honey not listed below	5.0
	(b)	Carvia callosa and Honeydew honey, Max.	10.0
5.	Fruct	ose to Glucose ratio (F/G Ratio)	0.95-1.50
6.	Total	Ash, per cent. by mass, Max.	0.50
7.	(a)Ac Max.	cidity expressed as formic acid, per cent. by mass,	0.20
	(b) F1	ree Acidity milliequivalents acid/ 1000 g, Max.	50.0
8.	Hydr	oxymethylfurfural (HMF) mg/kg, Max.	80.0
9.	Diast	ase activity, Schade units per gram, Min.	3.0
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	4 Sugar, per cent. by mass, Max.	7.0
12.	Po	ollen count and plant element/g, Min.	5000
13.		Acetylfuran-3-Glucopyranoside (2-AFGP) as Marker r Rice Syrup	Absent**
14.	Fo	oreign oligosaccharides (Max. Percent Peak Area)	0.7
15.	Pr	roline, mg/kg, Min.	180.0
16.	El	ectrical Conductivity:	
	(a)	Honeys not listed under Honeydew, Max.	0.8 S/cm
	(b)	Honeys listed under Honeydew, Min.	0.8 mS/cm
17.	(a) m	) $\Delta \delta^{13} C$ Max*. (Maximum difference between all easured $\delta^{13} C$ values); per mil (‰)	± 2.1
	be	) $\Delta\delta^{13}$ CFru – Glu (The difference in $^{13}$ C/ $^{12}$ C ratio etween fructose and glucose); per mil(‰)	± 1.0
	be	) $\Delta\delta^{13}$ C Protein – Honey (The difference in $^{13}$ C/ $^{12}$ C tween honey and its associated protein extract); per il(‰)	≥-1.0

<sup>\*</sup> $\Delta\delta13C$  Max. is the maximum difference observed between all possible isotopic ratios measured ( $\Delta\delta13C$  fructose-disaccharides /  $\Delta\delta13C$  fructose-trisaccharides /  $\Delta\delta13C$  fructose-protein/ $\Delta\delta13C$  glucose-disaccharides /  $\Delta\delta13C$  glucose-trisaccharides /  $\Delta\delta13C$  glucose-protein/ $\Delta\delta13C$  disaccharides-protein/ $\Delta\delta13C$  disaccharides-protein).

<sup>\*\*</sup>Minimum Required Performance Level- 1mg/kg

<sup>(</sup>c) for item (vi), (vii) and (viii), shall be substituted with the following, namely: -

<sup>&</sup>quot;(VI) Honey shall not be heated or processed to such an extent that it's essential composition is changed and/or it's quality is impaired.

(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 1 (i) of this standard:

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- 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 thixotrophic 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 labelled 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 labelled as "Pressed Honeydew Honey" or "Pressed and Blend of Honeydew Honey and Blossom Honey" or "Pressed Carvia Callosa Honey".

(VIII) Honey may be labelled 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 labelling 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.";
- (d) 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 2.9.41, the following sub-regulation shall be inserted, namely: –

#### "2.9.42 Dried Sweet Basil Leaves:

1. Dried sweet basil leaves are obtained from the species *Ocimumbasilicum* 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
1.	Moisture content, per cent by mass (Maximum)	12.0
2.	Total Ash, per cent by mass on dry basis, (Maximum)	16.0
3.	Acid-insoluble ash, per cent by mass on dry basis, (Maximum)	2.0
4.	Volatile oil content, ml/100g, on dry basis (Minimum)	0.3
5.	Foreign matter, per cent m/m, (Maximum)	1.0
6.	Extraneous vegetable matter, per cent m/m, (Maximum)	3.0
7.	Yellow or Brown leaves, per cent m/m, (Maximum)	5.0

- 2. Explanations: for the purpose of this clause: -
  - (1) 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.
  - (2) 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, in clause (1) relating to "Carbonated Water" in sub-clause (1) for the provision, following shall be substituted, namely: -

"Provided that the products which contain aspartame, acesulfame-K or any other non-caloric sweetener(s) for which special labelling provisions have been provided under Schedule II of Food Safety and Standards (Labelling and Display) Regulations, 2020, may be packed, stored, distributed or sold in returnable containers subject to the compliance of these labelling provisions for non-caloric sweeteners prominently on the label of bottle/container but not on crown.":

(10) after regulation 2.15, the following regulations shall be inserted, namely-

#### "2.16. Hemp seeds and seed products:

- (1) For the purpose of these regulations, hemp seed means the hulled 1, non-viable 2 seeds 3 obtained from Cannabis sativa/other indigenous Cannabis species. The cultivation of Cannabis species for the purpose of hemp seeds in India shall comply with Narcotic Drugs and Psychotropic Substances (NDPS) Act, 1985 and rules made thereunder.
- (2) The hemp seed, hemp seed oil and hemp seed flour shall 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, percent m/m, Max.	7.0
2.	Protein (N x 6.25), percent 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 <sup>4</sup> , mg/kg, Max.	5.0

#### (ii) Oil extracted from hemp seeds

S. No	Parameters	Requirements
1.	Free fatty acid (expressed asOleic Acid), per cent m/m, Max.	0.50
2.	Peroxide value, mEq/kg, Max.	10.0
3.	Total THC <sup>4</sup> , mg/kg, Max.	10.0

(iii) **Hemp seed flour** means solid product after seeds are milled to a powder with or without extraction of oil. The flour prepared after hemp seed has been pressed to extract oil shall clearly be labelled as 'Deoiled hemp seed flour'.

S. No.	Parameters	Requirements			
1.	Total THC, mg/kg, Max.	5.0			

- (iv) The total THC shall not exceed 0.2 mg/kg in any beverages made from hemp seeds.
- (v) Any other food for sale that consists of hemp seed or seed products shall not exceed Total THC content of 5 mg/kg.
- (3) The level of cannabidiol<sup>5</sup> (CBD) in any food for sale consisting of hemp seed or seed products shall not exceed 75 mg/kg.
- (4) Cannabinoids<sup>6</sup> 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) a nutrient content claim about cannabidiol; or
  - (b) a health claim about cannabidiol; or
  - (c) an image or representation of any part of the Cannabis plant (including the leaf of that plant) other than the seed; or

- (d) 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) No person shall manufacture, import or sale any food product containing hemp seed or seed products intended for administration to infant upto the age of 24 months.

#### 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. Total THC means the total amount of delta 9-tetrahydrocannabinol (THC) and delta 9-tetrahydrocannabinolic acid.
- 5. Cannabidiol (CBD) is the non-psychoactive component of Cannabis species.
- 6. Cannabinoids means any of various naturally-occurring, biologically active, chemical constituents such as cannabidiol or cannabinol of *Cannabis species* including some that possess psychoactive properties like delta 9-tetrahydrocannabinol (THC).
- (11) in Chapter 3, under Appendix A,
- (a) 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, flavoured/marinated, processed meat and poultry products in whole pieces or cuts"
- (b) under the heading 'II. FOOD CATEGORY DESCRIPTIONS',
  - (i) 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."
  - (ii) 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".
- (c) under the heading 'IV. USE OF FOOD ADDITIVES IN FOOD PRODUCTS',
- (i) in table 8, in column (1), under the heading food category system, against item 8.2.3, in column (2), for the entry "Frozen processed meat and poultry products in whole pieces or cuts", the entry "Frozen raw, flavoured/marinated, processed meat and poultry products in whole pieces or cuts" shall be substituted;
- (ii) in table 14,
  - (A) in the Food Category Systems 14.1.4.2, 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"

(B) in the Food Category Systems 14.1.4.3, 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"

(12) in Chapter 3, in Appendix B, after Table 8, related to Microbiological Standards of Egg and Egg Products-, the following shall be inserted, namely:-

"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 <sup>2</sup>
2.	Batters and doughs (Ready to Cook)	5	2	$10^{2}$	10 <sup>3</sup>	5	2	10 <sup>2</sup>	10 <sup>3</sup>
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		5	2	10	10 <sup>2</sup>			
	Test Methods	part 8	8(Sec 1 87Part	)/ <b>ISO</b>	d IS 5887 6888-1 or (Sec2)/ISO	IS/IS	O 7402/ IS	O 21528	Part 2

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

Sr. No.	Product Description	Salmone	ella		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		Part3 /	ISO:6579	IS: 149	88, Part 1 /	ISO 11290-1	

<sup>\*</sup> 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	1.	Satisfactory, if all the values observed are ≤ 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 $\mathbf{M}$			
		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.	Enterobacteriac eae 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 Aureuscount	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) <b>Section 1 Technique using baird-parker agar medium</b> - 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 <i>Listeria monocytogenes</i> 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

ARUN SINGHAL, Chief Executive Officer [ADVT.-III/4/Exty./429/2021-22]

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

# **Attachments:**

No Attachments.