



भारत का राजपत्र The Gazette of India

सी.जी.-डी.एल.-अ.-01072021-228046
CG-DL-E-01072021-228046

असाधारण
EXTRAORDINARY

भाग III—खण्ड 4
PART III—Section 4

प्राधिकार से प्रकाशित
PUBLISHED BY AUTHORITY

सं. 264]
No. 264]

नई दिल्ली, बृहस्पतिवार, जुलाई 1, 2021/आषाढ 10, 1943
NEW DELHI, THURSDAY, JULY 1, 2021/ASHADHA 10, 1943

भारतीय खाद्य सुरक्षा और मानक प्राधिकरण

अधिसूचना

नई दिल्ली, 30 जून, 2021

फा. सं0. स्टैंडर्ड्स/एसपी-05/ए-1.वाई(01).-खाद्य सुरक्षा और मानक (आयुर्वेद आहार) विनियम, 2021, जो भारतीय खाद्य सुरक्षा और मानक प्राधिकरण, केंद्र सरकार के पूर्वानुमोदन से, खाद्य सुरक्षा और मानक अधिनियम, 2006 (2006 का संख्यांक 34) की धारा 92 की उप-धारा (2) के खंड (फ) द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए बनाना चाहती है, बनाने के लिए इन विनियमों का प्रारूप इससे प्रभावित हो सकने वाले सभी व्यक्तियों की सूचना के लिए उक्त अधिनियम की धारा 22 की उप-धारा (1) के साथ पठित धारा 92 की उप-धारा (1) की अपेक्षा के अनुसार एतद्वारा प्रकाशित करती है और एतद्वारा नोटिस दिया जाता है कि उक्त प्रारूप विनियमों पर उस तिथि से साठ दिनों की अवधि समाप्त होने के बाद विचार किया जाएगा, जिस तिथि को इस अधिसूचना को प्रकाशित करने वाले राजपत्र की प्रतियाँ जनता को उपलब्ध कराई जाएँगी।

यदि कोई आपत्ति या सुझाव हो तो उसे मुख्य कार्यकारी अधिकारी, भारतीय खाद्य सुरक्षा और मानक प्राधिकरण, एफडीए भवन, कोटला रोड, नई दिल्ली-110002 को अथवा regulation@fssai.gov.in पर ई-मेल से भेजा जा सकता है।

उक्त मसौदा विनियमों के संबंध में किसी व्यक्ति से इस प्रकार निर्धारित तिथि तक प्राप्त आपत्तियों और सुझावों पर भारतीय खाद्य सुरक्षा और मानक प्राधिकरण द्वारा विचार किया जाएगा।

FOOD SAFETY AND STANDARDS AUTHORITY OF INDIA**NOTIFICATION**

New Delhi, the 30th June, 2021

F.No. Stds/SP-05/A-1.Y(01).-The following draft Food Safety and Standards (Ayurveda Aahar) Regulations, 2021, which the Food Safety and Standards Authority of India proposes to make, in exercise of the powers conferred by clause (v) of sub-section (2) of section 92 read with sub-section (1) of section 22 of the Food Safety and Standards Act, 2006 (34 of 2006), is hereby published 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 a period of sixty days from the date on which copies of the Gazette of India 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 Bhavan, Kotla Road, New Delhi-110002 or may be mailed at regulation@fssai.gov.in.

Any objections or suggestions, which may be received from any person with respect to the said draft regulations before the expiry of the period specified, shall be considered by the Food Authority.

Draft Regulations

1. These regulations may be called as the Food Safety and Standards (Ayurveda Aahar) Regulations, 2021.

2. Definitions:

- (1) "Act" means the Food Safety and Standards Act, 2006 (34 of 2006);
- (2) "Food Authority" means the Food Safety and Standards Authority of India (FSSAI) established under section 4 of the Act;
- (3) Ayurveda Aahar means a food prepared in accordance with the recipes or ingredients and/or processes as per methods described in the authoritative books of Ayurveda listed under 'Schedule A' of these regulations. It also includes products which have other botanical ingredients in accordance with the concept of Ayurvedic Aahar but does not include Ayurvedic drugs or proprietary Ayurvedic medicines and medicinal products, cosmetics, narcotic or psychotropic substances, herbs listed under Schedule E of Drug and Cosmetic Act, 1940 and Rules 1945 thereunder, metals based Ayurvedic drugs or medicines, bhasma or pishti and any other ingredients notified by the Authority from time to time.

Explanatory note 1: Food is defined under Food Safety and Standards Act, 2006 and regulations made thereunder. Recipes and ingredients specified in the Schedule A authoritative books for promoting health and including those foods specified for consumption during or post specified diseases, disorders referred as pathya in Ayurveda.

Explanatory note 2: Adoption of processes for cooking or preparation of Ayurveda Aahar specified or described in the Schedule A authoritative books for industrial scale manufacture and packing are permitted. Such adoptions shall be aimed to produce Ayurveda Aahar with quality and characteristics closely similar as specified in the books mentioned under Schedule A of these regulations.

Explanatory note 3: Any packed food item used in day to day life for dietary purpose such as pulses, rice, flour, vegetable without addition of Ayurveda Aahar ingredient(s) shall not be covered under these regulations. Minimally processed food items involving cleaning, dedusting, polishing, dehusking, grading shall not fall under these regulations.

- (4) "Schedules" mean the schedules to these regulations.

3. General requirements:

- (1) No person shall manufacture or sale Ayurveda Aahar intended for administration to infants up to the age of 24 months.
- (2) The manufacture of Ayurveda Aahar shall be established by Food Business Operators in accordance with the Schedule 4 of Food Safety and Standards (Licensing and Registration of Food Businesses) Regulation, 2011
- (3) FBOs may add or alter the recipes of Ayurveda Aahar by addition of one or more botanicals listed in 'schedule IV' of Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016 subject to the following:
 - (i) Such addition shall be based on adequate scientific rationale and as per Ayurvedic principles including for their levels of usage.

- (ii) Such addition shall be demonstrable for its presence in the final formulation by suitable analytical techniques
- (4) Addition of vitamins, minerals and amino acids to Ayurveda Aahar shall not be permitted. However, natural vitamins and minerals if present in the Ayurveda Aahar may be declared on the label.
- (5) Food Business Operators shall formulate Ayurveda Aahar in accordance with the categories and requirements specified in Schedule B of these regulations.
- 4. Additives:** The products covered under these regulations shall contain only natural food additives as specified under schedule C of these regulations.
- 5. Contaminants:** The products covered under these regulations shall conform to the safety requirements specified in Schedule D of these regulations. The raw materials used for manufacture of Ayurveda Aahar shall also meet the requirements specified in Schedule D of these regulations.
- 6. Packaging:** Ayurveda Aahar shall conform to the Food Safety and Standards (Packaging) Regulation, 2018.
- 7.** No person shall manufacture, pack, sell, offer for sale, market or otherwise distribute or import Ayurveda Aahar unless the product comply with the requirements laid down in these regulations.
- 8.** The labelling, presentation and advertisement shall not claim that the Ayurveda Aahar has the property of preventing, treating or curing a human disease or refer to such properties.
- 9.** Food Business Operator shall make claims in accordance with the Food Safety and Standards (Advertising and Claims) Regulation, 2018. Food Business Operators shall make claims as per description or indications specified for the recipe or ingredient in the authoritative books listed in Schedule A. Such claim statements should be factual, not misleading or exaggerated and be of a documented history of usage. Disease risk reduction and/or health benefits claims shall be pre-approved by the Food Authority.
- 10.** Ayurveda Aahar whose standards are not specified under these regulations shall be manufactured for sale, exhibited for sale or stored for sale only after obtaining approval of such article of food from the Food Authority in accordance with the Food Safety and Standards (Approval for Non-Specific Food and Food Ingredients) Regulation, 2017.
- 11.** Ministry of AYUSH shall establish a Expert Committee for providing recommendation to Food Authority on approval of claims and products as specified in sub-regulation 09 and 10 above. Such Committee shall also empower to address concerns regarding registration/licensing/certification/laboratory accreditation/testing/quality issues related to Ayurveda aahar.
- 12.** The labelling of Ayurveda Aahar shall be in accordance with the Food Safety and Standards (Labelling and Display) Regulations, 2020, and the specific labelling requirements provided in these regulations.
- 13.** Every label of Ayurveda Aahar shall clearly specify the intended purpose, the target consumer group, recommended duration of use and other specific labelling requirements, namely:
- The words “**AYURVEDA AAHAR**” printed in the immediate proximity of the name or brand name of the product; and the logo as specified below in the front of the pack of the label:



- An advisory warning ‘**ONLY FOR DIETARY USE**’ prominently written;
 - A statement that the Ayurveda Aahar is not to be used as a substitute for a varied diet;
 - A warning or any other precautions to be taken while consuming, known side effects, if any, contraindications, and published product or drug interactions, as applicable; and
 - A statement that the product is required to be stored out of reach of children.
 - A warning that the product is for oral consumption only and not for parenteral use
- 14.** FBOs shall inform the licensing authorities in writing, if any of their existing food products duly licensed to be assigned as an Ayurveda Aahar and the licensing authority shall permit the same with applicable modifications including labelling as specified in these regulations. The Food Authority may specify the validity period of such applications.

Schedule A
List of authoritative books for Ayurveda Aahar

Sl. No.	Books
1.	Abhinava Chintamani
2.	Arka Prakasha
3.	Arogya Kalpadruma
4.	Arya Bishak
5.	Ashtanga Hridaya
6.	Ashtanga Samgraha
7.	Ayurveda Chintamani
8.	Ayurveda Kalpadruma
9.	Ayurveda Prakasha
10.	Ayurveda Ratnakara
11.	Ayurveda Samgraha
12.	Bangasena A. Ayurvedic Formulary of India (Part-1) B. Ayurveda Sara Samgraha C. Volumes of API
13.	Bhaishajya Ratnavali
14.	Bhava Prakash
15.	Bhela Samhita
16.	Bhojana Kutuhalam
17.	Brihat Bhaishajya Ratnakar
18.	Brihat Nighantu Ratnakar
19.	Chakra Datta
20.	Charak Samhita
21.	Dravyaguna Nighantu
22.	Gada Nigraha
23.	Haramekhala
24.	Kaideva Nighantu
25.	Kashyapa Samhita
26.	Ksemakutuhalam
27.	Kupi Pakva Rasayana
28.	MadanpalaNighantu
29.	Manasollasa / AbhilashitarahChintamani
30.	Nighantu Ratnakar
31.	Paka Darpana of Nala
32.	Pathya Apathya Vinishchaya
33.	Raja Nighantu
34.	Rasa Chandanshu
35.	Rasa Pradipika
36.	Rasa Raja Sundara
37.	Rasa Ratna Samuchchaya
38.	Rasa Tantra Sara va Siddha Prayaoga Sangraha - Part 1
39.	Rasa Tarangini
40.	Rasa Yoga Ratnakar
41.	Rasa Yoga Sagara
42.	Rasa Yoga Samgraha
43.	Rasamanjiri
44.	Rasamrita
45.	Rasendra Sara Samgraha
46.	Ruchivadhu Gala Ratnamala
47.	Sahasrayoga
48.	Sarvaroga Chikitsa Ratnam
49.	Sarvayoga Chikitsa Ratnam
50.	Sharangdhara Samhita
51.	Shodhala Nighantu
52.	Siddha Bhaishajya Manimala
53.	Siddha Yoga Samgraha

54.	Siva Tatva Ratnakara II
55.	Soopa Shastra of Mangarasa III
56.	Susena Nighantu/Ayurveda Mahodadhi
57.	Sushruta Samhita
58.	Vaidya Chintamani
59.	Vaidyaka Chikitsa Sara
60.	Vaidyaka Shabda Sindhu
61.	Vasava Rajeeyam
62.	Vidya Jiwan
63.	Vishwanathchikitsa
64.	Vrindachikitsa
65.	Yoga Chintamani
66.	Yoga Ratnakara
67.	Yoga Tarangini
68.	Yogaratra Samgraha

**Explanatory Note: Ingredients and recipes listed in the above original editions of authoritative books and those authoritative texts written and published before 1940 shall be considered for approval as Ayurveda aahar. Ingredients and recipes listed in appendix or annexure to the above authoritative texts in schedule A shall not be considered for approval as Ayurveda aahar.*

Schedule B

Categories of Ayurveda Aahar and Regulatory requirements:

Sl	Category	Ingredients	Health benefits	Safety study	Experience/evidence of claim	
					Published literature	Disease risk reduction or health benefit claims
1	2	3	4	5	6	
A	Ayurveda Aahar prepared in accordance to Schedule A of FSSA/FSSR.	As per text of authoritative books for Ayurveda Aahar of Schedule A	As per text of authoritative books for Ayurveda Aahar of Schedule A	Not required	Classical reference Required	Pre-approval as per FSSR required.
B	Ayurveda Aahar as New recipe / ingredients from schedule A, including other botanicals based on Ayurveda dietetic principles (viz.ras, gun, virya & vipak, karma etc.)	Textual reference of authoritative books for Ayurveda Aahar of Schedule A required	Text rational	Adequate data on safety of the new recipe or ingredient including Ame's test, carcinogenicity, teratogenicity as applicable	Of ingredients / recipe as described in ayurvedic authoritative texts and published scientific literature	Pre-approval as per FSSR required.
B1	Ayurveda Aahar presented in a modified format or a new format for consumption, different from the format specified in authoritative texts of Schedule A (see explanatory note below)	As per text of authoritative books for Ayurveda Aahar of Schedule A	As per text of authoritative books for Ayurveda Aahar of Schedule A	Not required	Required	Pre-approval as per FSSR required.
B2	Ayurveda Aahar intended for a health benefit or as an adjuvant to provide support to specific	As per text of authoritative books for Ayurveda Aahar of	the specific medical purpose shall be clearly specified	Additional safety study data require to support the specific medical	Required	Pre-approval as per FSSR required.

	disease, disorder not specified in the authoritative texts in Schedule A. such Ayurveda aahar shall be food for specific medical purposes	Schedule A	including the target population	purpose specified in the target population		
B3	Ayurveda Aahar fortified or with added botanicals specified in Schedule 4 of Nutraceutical regulations	Ayurveda aahar as per recipes in Schedule A books, approved food ingredients in FSSR.	Required	Additional safety data to support the fortification or additions Required	Required of Ayurvedic item	Pre-approval as per FSSR required.

Explanatory note 1: Mere adoption of the Ayurveda aahar format for suitability to offer it in pre-packaged condition including format conversion for reconstitution prior to use does not constitute change in format.

Schedule C
List of additives

S.No.	Food Additive or Group	Maximum permitted Level	Functional class
1.	Acacia gum	2%	Thickener stabilizer
2.	Tragacanth gum	2%	Thickener stabilizer
3.	Guar gum and its derivatives	2%	Thickener stabilizer
4.	Distilled oils of spices	2%	Preservatives, flavouring agent
5.	Rose oil	1%	Flavouring agent
6.	Keora oil	0.5%	Flavouring agent
7.	Powders of cardamom and other spices	1%	Flavouring agent, colouring agent
8.	Honey	GMP*	Sweetening agent
9.	Jaggery	GMP*	Sweetening agent
10.	Date syrup	GMP*	Sweetening agent
11.	Mollasses	5%	Sweetening agent
12.	Starch and starch derivatives permitted in FSSR	GMP*	Emulsifier, stabilizer, thickener
13.	Nibu satva (citric acid)	GMP*	Acidulant and flavour enhancer
14.	Rosemary oil	1%	Antioxidant

*Level basis scientific rationale

Schedule D
Microbiological Standards for Ayurveda Aahar

Table 1A. Process Hygiene Criteria

*Should contain only the specified microorganism(s) at the level claimed on the label. The counts have to be determined using methodology appropriate for the organisms. e.g. For Lactic acid bacteria ISO 15214/IS 16068, for Bifidobacteria ISO29981

Table 1B. Food Safety Criteria

Sr. No.	Product description	Aerobic Plate Count (cfu/g or ml)				Yeast and Mould Count (cfu/g or ml)				Enterobacteriaceae count (cfu/g or ml)			
		Sampling plan		Limit		Sampling plan		Limit		Sampling plan		Limit	
		n	c	m	M	n	c	m	M	n	c	m	M
1.	Ayurveda aahar unprocessed and not for direct consumption	5	3	10 ⁶	10 ⁷	5	3	10 ⁴	10 ⁵	5	3	10 ³	10 ⁴
2.	Ayurveda aahar for direct consumption	5	2	10 ⁴	10 ⁵	5	2	10 ²	10 ³	5	2	10 ²	10 ³
3.	Ayurveda aahar fermented products*	NA					NA				NA		
4.	Test Methods	IS: 5402/ISO:4833				IS: 5403/ ISO 21527 Part 1 and Part 2				IS/ISO 7402/ ISO 21528 Part 2			

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

Sr. No.	Product description	<i>Salmonella</i>				<i>Listeria monocytogenes</i>			
		Sampling plan		Limit		Sampling plan		Limit	
		n	c	m	M	n	c	m	M
1.	Ayurveda aahar unprocessed and not for direct consumption	NA				NA			
2.	Ayurveda aahar for direct consumption	5	0	Absent/25g		5	0	Absent/25g	
3.	Ayurveda aahar fermented products*	5	0	Absent/25g		5	0	Absent/25g	
4.	Test Methods	IS: 5887 Part3 / ISO:6579				IS: 14988, Part 1 / ISO 11290-1			

Definition

Definition related to Ayurveda Aahar is as provided in Food Safety and Standards (Ayurveda Aahar) Regulations, 2020.

Stage where the Microbiological Standards shall apply:

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

Sampling Plan and Guidelines

For Regulator: The sampling for different microbiological standards specified above shall be ensured aseptically at manufacturing units and/or at retail points, as applicable, by a trained person with 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 $-18^{\circ}\text{C}(\pm 2^{\circ}\text{C})$ or under refrigerated conditions at $2-5^{\circ}\text{C}$ as applicable except for the products that are recommended to be stored at room temperature by the manufacturer to enable initiation of analysis within 24 hours of sampling. Preservatives shall not be added to sample units intended for microbiological examination. The desired number of sample units as per sampling plan given in **Tables above** shall be taken from same batch/lot and shall be submitted to the notified laboratories. Three sets, each containing 'n' number of samples (n as defined in the sampling plan eg if $n=5$, then total no. of samples to be drawn is 15) shall be drawn. Each of these three sets shall be tested in three different accredited laboratories. The final decision shall be based on the results of three accredited laboratories. In the case of Food Safety Criteria, the results from all the three laboratories should indicate compliance with the specified criteria. There will be no provision for retesting or resampling for microbiological testing. The testing in laboratory shall be ensured as per the methods given in the table "reference test methods"

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

Sampling Plan:

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

n = Number of units comprising a sample.

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

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

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

Interpretation of Results:

2-Class Sampling Plan (where n,c and m are specified)	3-Class Sampling Plan (where n,c,m and M are specified)
1. Satisfactory, if all the values observed are $\leq m$	3. Satisfactory, if all the values observed are $\leq m$
2. Unsatisfactory, if one or more of the values observed are $> m$	4. Acceptable, if a maximum of c values are between m and M .
	5. Unsatisfactory, if one or more of the values observed are $> M$ or more than prescribed c values are $> m$

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

S.No	Parameter	Reference Test methods
1.	Aerobic Plate Count	Microbiology of the food chain -- Horizontal method for the enumeration of microorganisms -- Part 1: Colony count at 30 °C by the pour plate technique- IS 5402/ ISO:4833
2.	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.	<i>Enterobacteriaceae</i> 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
4.	Salmonella	Methods for Detection of Bacteria Responsible for Food Poisoning - Part 3: General Guidance on Methods for the Detection of Salmonella- IS 5887 : Part 3 Microbiology of food and animal feeding stuffs -- Horizontal method for the detection of Salmonella spp.- ISO 6579
5.	<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

Table 2: Permissible levels of Contaminants

Name of contaminant	Limits (Maximum)
Lead, mg per kg or mg per L	2.5
Copper, mg per kg or mg per L	30
Arsenic, mg per kg or mg per L	1.1
Tin, mg per kg or mg per L	250
Cadmium, mg per kg or mg per L	1.5
Mercury, mg per kg or mg per L	1.0
Methyl Mercury (Calculated as the element), mg per kg or mg per L	0.25
Total Aflatoxins*, µg per kg	20
Aflatoxin B1*, µg per kg	10
Melamine, mg per kg	2.5

(*Food products containing Arecanut or Betelnut, cereal and cereal products, dried figs, nuts (for further processing and ready to eat), oilseeds or oil (for further processing and ready to eat), pulses and spices/spice mix)

ARUN SINGHAL, Chief Executive Officer

[ADVT.-III/4/Exty./128/2021-22]