

Voluntary Report – Voluntary - Public Distribution

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Report Name: India's FSSAI Notifies Draft Amendments for Specialty Foods Regulations

Country: India

Post: New Delhi

Report Category: Agriculture in the Economy, Policy and Program Announcements, Agriculture in the News, Exporter Guide, FAIRS Subject Report, Agricultural Situation, SP1 - Expand International Marketing Opportunities, SP2 - Prevent or Resolve Barriers to Trade that Hinder U.S. Food and Agricultural Exports, Sanitary/Phytosanitary/Food Safety, MISC-Commodity

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Report Highlights:

The Ministry of Health and Family Welfare/Food Safety and Standards Authority of India (FSSAI) issued on September 6, 2021, Notification No. Stds/SP-05/T(Nutraceuticals-02). The authority is amending the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations (2016). It is introducing new standards, while seeking to modify existing requirements for specialty products covered under the regulation. World Trade Organization (WTO) members are invited to comment on the proposed draft amendment and the timeline to provide comments is 60 days from the date of notification on the WTO website.

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 if they do not open in Internet Explorer].

GENERAL INFORMATION

On September 6, 2021, the Ministry of Health and Family Welfare/Food Safety and Standards Authority of India (FSSAI) issued Notification No. Stds/SP-05/T(Nutraceuticals-02) (see, Appendix I). The authority is amending the [Food Safety and Standards \(Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food\) Regulations \(2016\)](#). It is introducing new standards, while seeking to modify existing requirements for specialty products covered under the regulation.

FAS New Delhi recommends that interested stakeholders thoroughly read the draft regulations before providing comments on them. World Trade Organization (WTO) members are invited to comment on the proposed draft amendment; the timeline to provide comments is 60 days from the date of notification on the WTO website.

The full text of the proposed draft amendment is accessible on the FSSAI's website located at: https://fssai.gov.in/upload/uploadfiles/files/Draft_Notification_Nutra_08_09_2021.pdf.

Send comments to:

The Chief Executive Officer
Food Safety and Standards Authority of India
3rd Floor, Food and Drug Administration Bhawan, Kotla Road
New Delhi – 110002
Email: spstbt.enqpt@fssai.gov.in

Details of Draft Regulation

Publication Date on the FSSAI Website: September 8, 2021

Date of Implementation: Date of final publication in the Official Gazette of India

Final Date for Comments: 60 days from the date of notification on the WTO website

APPENDIX I: DRAFT AMENDMENTS ON FOOD SAFETY AND STANDARDS (HEALTH SUPPLEMENTS, NUTRACEUTICALS, FOOD FOR SPECIAL DIETARY USE, FOOD FOR SPECIAL MEDICAL PURPOSE, FUNCTIONAL FOODS, AND NOVEL FOODS) AMENDMENT REGULATIONS (2016)

FOOD SAFETY AND STANDARDS AUTHORITY OF INDIA

NOTIFICATION

New Delhi, the 6th September, 2021

F. No. Stds/SP-05/T(Nutraceuticals-02).—The draft regulations further to amend the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Foods and Novel Foods) Regulations, 2016, 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 (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 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 Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Foods and Novel Foods) Amendment Regulations, 2021.
(2) They shall come into force on the date of their final publication in the Official Gazette.
2. In the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Foods and Novel Foods) Regulations, 2016,
 - (a) in regulation 9, for clause (i) of the sub-regulation 1, following shall be substituted, namely,-
“Food for special medical purpose shall include food specially prepared for weight reduction and intended as total replacement of normal diet. Food for special medical purpose may also include Foods intended for Special Diagnostic Purpose with the prior approval of the Authority. Food Business Operator seeking such approval shall take approval of the Authority in accordance with Food Safety and Standards (Approval of non-specified food and food ingredients) Regulations, 2017.”
 - (b) in Schedule I,-

- (i) against serial number A(14) related to 'Folic acid', below the existing entries at column (3) and (4), following shall be inserted, namely:-

“(ii)	(6S)-5-methyltetrahydrofolic acid, glucosamine salt”
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- (ii) against serial number B(1) related to 'Calcium', for the entry 'Calcium from algal source (*Algalcalarius*)' in column (4), following shall be substituted, namely:-

“Calcium from algae including red seaweed”

- (c) for Schedule II, following schedule shall be substituted, namely,-

Schedule – II

[See regulations 3.(13), 4.(2), 6.(2)(i), 7.(2)(i), 8.(2)(i) and 9.(2)(i)]

List of amino acids and other nutrients

A.	Amino Acids	
i.	L-Histidine	ii. L-Aspartic acid
iii.	L-Histidine hydrochloride	iv. L-Arginine L-aspartate
v.	L-Isoleucine	vi. L-Threonine
vii.	L-Isoleucine hydrochloride	viii. L- Alanine
ix.	L-Leucine	x. L-Phenylalanine
xi.	L-Leucine hydrochloride	xii. L-Cystine
xiii.	L-Lysine	xiv. L-Cystinedihydrochloride
xv.	L-Lysine hydrochloride	xvi. L-Tyrosine
xvii.	L-Methionine	xviii. L-Arginine
xix.	L-Cysteine	xx. L-Tryptophan
xxi.	L-Cysteine hydrochloride	xxii. L-Valine
xxiii.	L-Carnitine	xxiv. L-Arginine hydrochloride
xxv.	L-Carnitine hydrochloride	xxvi. L- Proline
xxvii.	L-Glutamic acid	xxviii. L-LysineL- glutamate dihydrate
xxix.	L-Glutamine	xxx. Magnesium L- aspartate
xxxi.	Glycine	xxxii. Calcium L- glutamate
xxxiii.	L-Lysine acetate	xxxiv. Potassium L- glutamate
xxxv.	N-Acetyl L-cysteine	xxxvi. L-Carnitine tartrate
xxxvii.	N-Acetyl L-methionine	xxxviii. Taurine
xxxix.	L- Ornithine	xl. Choline
xli.	L-Ornithine monohydrochloride	xlii. Choline chloride
xlili.	L-Lysine L-Aspartate	xliv. Choline citrate
xlvi.	L-Citrulline	xlvi. L-Serine
xlvi.	Choline hydrogen tartrate	xlvi. Myo-Inositol (=meso-Inositol)
xlvi.	Choline bitartrate	

B. Nucleotides			
i.	Adenosine 5-monophosphate (AMP)	ii.	Disodium Uridine 5-monophosphate salt
iii.	Cytidine 5-monophosphate (CMP)	iv.	Disodium Guanosine 5-mono phosphate salt
v.	Guanosine 5-monophosphate (GMP)	vi.	Disodium Inosine 5-monophosphate salt
vii.	Inosine 5-monophosphate (IMP)		

Note.- Suitable hydrated and anhydrous forms of amino acids, and the hydrochloride, sodium, and potassium salts of amino acids may be used. In such cases, Food Business Operators shall notify in writing to the Authority. Food Business Operators shall be required to submit additional safety data/information when requested by the Authority.

(d) in Schedule VF,

(i) against the serial number 63 for the entry “Sorbitanoleate esters (Tweens)”, in column (2), following entry shall be substituted, namely,-

“Polysorbates (Tweens)”

(ii) after the serial number 86 and the entries relating thereto, the following serial number and entry shall be inserted, namely,-

“87	Magnesium alumina metasilicate	-	1 %
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(e) in Schedule VII, after the serial number 30 and the entries relating thereto, the following shall be inserted, namely,-

“31.	Bacillus indicus”
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(f) in Schedule VIII, after the serial number 13 and the entries relating thereto, the following shall be inserted, namely,-

“14.	Guar gum derivative (partially hydrolysed guar gum)”
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ARUN SINGHAL, Chief Executive Officer

[ADVT.-III/4/Exty./234/2021]

Note : The principal regulations were published in the Gazette of India, Extraordinary, Part III, Section 4, *vide* notification number F. No. 1-4/Nutraceutical/FSSAI-2013, dated the 23rd December, 2016.

Attachments:

No Attachments.