

Voluntary Report – Voluntary - Public Distribution

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Report Name: India's FSSAI Extends Compliance Timeline on Specialty Food Products Imports for Inborn Errors of Metabolism and Hypoallergenic Conditions

Country: India

Post: New Delhi

Report Category: Sanitary/Phytosanitary/Food Safety, Exporter Guide, FAIRS Subject Report, SP1 - Expand International Marketing Opportunities, Policy and Program Announcements, Agriculture in the News, Agriculture in the Economy

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Report Highlights:

On June 30, 2021, the Food Safety and Standards Authority of India (FSSAI) published a new directive extending the compliance timeline for the implementation of regulations governing the import of specialty food products for inborn errors of metabolism (IEM) and hypoallergenic conditions. Specialty food products, listed in Appendix - I, are permitted through March 31, 2022, under certain conditions.

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 June 30, 2021, the Food Safety and Standards Authority of India (FSSAI) notified extension of the compliance timeline for the implementation of regulations governing the import of specialty foods into India (see, Appendix – I). The timeline is extended for inborn errors of metabolism (IEM) and hypoallergenic conditions.

The final standards for specialty food products are now established and covered under the Food Safety and Standards (Foods for Infant Nutrition) Regulations (2020). The current directive gives March 31, 2022, as the final date to import these specialty foods. FAS New Delhi's earlier [GAIN-INDIA IN2021-0021-FSSAI Discloses Final Timeline on Specialty Foods Imports for Inborn Errors of Metabolism and Hypoallergenic Conditions](#) report provides details on this issue, and in particular, the specific conditions for the import of specialty food products.

The full text of the notification is now accessible on the FSSAI website located at:
https://fssai.gov.in/upload/advisories/2021/06/60dc63950f19cDirection_IEM_30_06_2021.pdf

APPENDIX - I: INDIA, FSSAI Direction on Food Safety and Standards (Foods for Infant Nutrition) Regulations (2020)

F. No. Stds/03/Notification (IFR)/FSSAI-2017
Food Safety and Standards Authority of India
(A Statutory Authority established under the Food Safety & Standards Act, 2006)
FDA Bhawan, Kotla Road, New Delhi-110 002

Dated, the 30th June, 2021

Direction

Subject: Direction under 16 (5) of Food Safety and Standards Act, 2006 regarding Inborn Errors of Metabolism (IEM) conditions.

Reference is drawn to direction under Section 16 (5) of Food Safety and Standards Act, 2006 dated 19th January, 2021 regarding import and manufacturing of foods required for management of Inborn Errors of Metabolism (IEM) and Hypoallergenic Conditions, which is applicable upto 30th June, 2021.

2. The standards for *Foods for Infants with IEM and Hypoallergenic infant milk substitutes* are now notified under Food Safety and Standards (Foods for Infant Nutrition) Regulations, 2020 which 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 1st July, 2021. However, the date of compliance of the said regulations is extended upto 1st April, 2022.

3. Since, the date of compliance of Food Safety and Standards (Foods for Infant Nutrition) Regulations, 2020 having standards for IEM has been extended upto 1st April, 2022 and earlier direction is only upto 30th June, 2021, it has been decided to allow the import of foods products for IEM condition, as listed in the Annexure-1, till 31st March, 2022, under the following conditions:

(a) The importing firm would submit to FSSAI well in advance, all the necessary documents related to the composition, label and claims for the product they intend to import. FSSAI after due examination, would allow the import of such foods on a case to case basis. Once a particular composition, label & claims is permitted by FSSAI for import, future consignments strictly adhering to the requirements can be imported on the basis of this onetime permission.

(b) The labels on these foods shall clearly mention the medical conditions for which they have to be used.

(c) The importer/manufacturer of such foods shall ensure that they are consumed only under supervision of health care professionals.

5. The above conditions shall also apply to domestically produced specialty food products for which FSSAI shall grant permission after due examination.

6. This issues with the approval of the Competent Authority in exercise of the power vested under Section 16(5) of the Food Safety and Standards Act, 2006.


(Inoshi Sharma)

Executive Director (Regulatory Compliance)

Inborn Errors of Metabolism (IEM) Conditions		
S. No	Medical condition	Description of food products
1.	Maple syrup urine disease	Isoleucine, Leucine and Valine free diet powder
2.	Glutaric Acidemia Type I	Lysine free and Tryptophan low/free diet powder
3.	Homocystinuria	Methionine free diet powder
4.	Isovaleric Acidemia, 3-Methylcrotonyl-CoA, Carboxylase Deficiency, 3-Methylglutaconyl-CoA, Hydratase Deficiency	Leucine free diet powder
5.	Methylmalonic Acidemias, Propionic Acidemia	Isoleucine, Methionine, Threonine and Valine free diet powder
6.	Amino acid metabolic disorders	Protein and amino acid free diet powder (with and without fat)
7.	Phenylketonuria (PKU)	Phenylalanine free diet powder
8.	Urea Cycle Disorders, Argininemia, Argininosuccinic Aciduria, Carbamoylphosphate Synthetase Deficiency1, Citrullinemia	Non-essential amino acid free diet powder
9.	Tyrosinemia	Phenylalanine and Tyrosine free diet powder
10.	Galactosemia	Galactose free formula
11.	3-Hydroxy Long Chain Acyl-CoA Dehydrogenase Deficiency	LCHAD Deficiency
12.	Defects in the intraluminal hydrolysis of fat; defective mucosal fat absorption; defective lymphatic transport of fat	Milk protein-based powder with medium-chain triglycerides (MCT) for children and adults
13.	Disaccharidase deficiencies; Disorders of carbohydrate metabolism Sucrase/isomaltase deficiency, Fructose intolerance	Protein hydrolysate formula base powder with iron for use with added carbohydrate.
14.	Non-ketotic Hyperglycinemia, Lysinuric protein intolerance	Protein free formula
15.	Glucose transport defect(Glut1 def), Pyruvate dehydrogenase complex deficiency	Low carbohydrate, sucrose, fructose, sugar free formula
Hypoallergenic Conditions		
1	Severe allergy due to multiple food protein intolerance that cannot be effectively managed by extensively hydrolyzed formula	Amino acid based Hypoallergenic formula
2	Cow milk protein (CMP) allergy	i. Amino acid based formula (1 st preference) ii. Extensively hydrolysed formula (2 nd preference) iii. Soy based formula (3 rd preference)

Attachments:

No Attachments.