

Voluntary Report – Voluntary - Public Distribution

Date: November 09,2020

Report Number: IN2020-0162

Report Name: INDIA - FSSAI Allows Specialty Food Imports to India for an Additional Six Months

Country: India

Post: New Delhi

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

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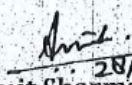
Report Highlights:

On October 28, 2020, the Government of India's Food Safety and Standards Authority of India (FSSAI) published a fourth consecutive timeline extension on specialty food imports for special medical and therapeutic purposes. In its earlier notification dated April 20, 2020, the FSSAI granted a six-month extension from February 2 to November 1, 2020, or until the time the standards were established, whichever was earlier. The current notification extends the timeline by another six months from its previous date to May 1, 2021, or until the FSSAI establishes its corresponding standards, whichever is earlier.

General Information:

DISCLAIMER: The information contained in this report was retrieved from the Government of India website <http://www.fssai.gov.in/>. The U.S. Government makes no claim of accuracy or authenticity.

On October 28, 2020, the Food Safety and Standards Authority of India (FSSAI) granted a six-month timeline extension to allow imports of specialty foods for special medical and therapeutic purposes beyond November 1, 2020. As the standard making process for these foods is still not complete, an additional six-month extension has been provided to allow imports of these specialty foods, or until the time the standards are established, whichever is earlier. As stated in its earlier notifications, these food products are allowed only through the New Delhi and Mumbai ports. All other details remain the same as provided in the previous FSSAI notifications from April 20, 2020, May 2, 2019, and November 1, 2018 (uploaded to the FSSAI's website on November 2). The full text of the current notification, along with the previously issued notifications and Annex are attached below and are available on the [FSSAI](http://www.fssai.gov.in/) website.

<p>File No.1-1715/FSSAI/Imports/2017 (Part 2) Food Safety and Standards Authority of India (A Statutory Authority Established under the Food Safety and Standards Act, 2006) FDA Bhawan, Kotla Road, New Delhi – 110002</p> <hr/> <p style="text-align: right;">Dated: 28th October, 2020</p> <p>Subject: Direction under Section 16(5) of Food Safety and Standards Act, 2006 regarding import of specialty foods for IEM and hypoallergenic conditions- reg.</p> <p>In continuation to the earlier direction dated 20.04.2020 (copy enclosed), it has been further decided to allow the import of Food for Special Medical Purposes (i.e. Food for Inborn errors of metabolism and hypoallergenic conditions) as listed in the Annexure-A for a further period of six months from 02.11.2020 i.e. till 01.05.2021 or till their standards are notified, whichever is earlier.</p> <p>2. Further, for better control, the import of such products shall continue to be permitted through Delhi and Mumbai ports only.</p> <p>3. This issues with the approval of the Competent Authority in exercise of the power vested with Food Authority under Section 16(5) of Food Safety and Standards Act, 2006.</p> <p>Encl: As Above.</p> <p style="text-align: right;"> (Dr. Amit Sharma) Director (Imports) Email- dramit.sharma@fssai.gov.in</p>

File No. 1-1715/FSSAI/Imports/2019
Food Safety and Standards Authority of India
(A Statutory Authority Established under the Food Safety and Standards Act, 2006)
FDA Bhawan, Kotla Road, New Delhi – 110002

Dated, the 20th April, 2020

Subject: Direction under Section 16(5) of Food Safety and Standards Act, 2006 regarding import of specialty foods for IEM and hypoallergenic conditions- reg.

In continuation to the earlier direction dated 02.05.2019 (copy enclosed), it has been further decided to allow the import of Food for Special Medical Purposes (i.e. Food for Inborn errors of metabolism and hypoallergenic conditions) as listed in the annexure-A for a further period of six months from 02.05.2020 i.e. till 01.11.2020 or till their standards are notified, whichever is earlier.

2. Further, for better control, the import of such products shall continue to be permitted through Delhi and Mumbai ports only.
3. This issues with the approval of the Competent Authority in exercise of the power vested with Food Authority under Section 16(5) of Food Safety and Standards Act, 2006.

Encl: As Above.


(Dr. Amit Sharma)
Director (Imports)
Email- dramit.sharma@fssai.gov.in

To,

- All Authorised Officers, FSSAI – for compliance of above order
- Director (Customs) & Commissioner (Single Window Project, CBIC)- with a request to circulate to all officials of Customs Department working as Authorised Officers for compliance.
- All Food Safety Commissioner
- All Central Designated Offices of FSSAI

Copy for information to-

- ED (Compliance), FSSAI-HQ
- Advisor (Standard), FSSAI-HQ
- Head (Regulation/Codex), FSSAI-HQ
- Advisor (QA), FSSAI-HQ
- Director (SBCD), FSSAI-HQ
- Head (RCD), FSSAI-HQ
- Head (Legal), FSSAI-HQ
- Deputy Commissioner, SW, CBIC
- CITO, FSSAI-HQ (for uploading on FSSAI website)

F. No. Stds/Nutra -IEM/FSSAI-2016
Food Safety and Standards Authority of India
(A Statutory Authority established under the Food Safety & Standards Act, 2006)
(Regulation division)
FDA Bhawan, Kotla Road, New Delhi-110 002

Dated, the 02 May, 2019

Subject: Direction under Section 16(5) of Food Safety and Standards Act, 2006 regarding import of specialty foods for IEM and hypoallergenic conditions.

In continuation to the earlier direction dated 01.11.2018 (copy enclosed), it has been further decided to allow the import of Food for Special Medical Purposes (i.e. Food for Inborn errors of metabolism and hypoallergenic conditions) as listed in the Annexure-A for a further period of one year from 02.05.2019 or till their standards are notified, whichever is earlier.

2. Further, for better control, the import of such products shall continue to be permitted through Delhi and Mumbai ports only.

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


(Suneeti Toteja)
Director (Import)

To

1. Sh. Zubair Riaz, Director(Custom), Ministry of Finance
2. All Food Safety Commissioner
3. All Authorised Officer, FSSAI
4. All Central Designated Offices of FSSAI

Copy for information to:

1. PPS to Chairperson, FSSAI
2. PS to CEO, FSSAI
3. All Directors, FSSAI

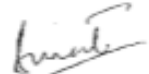
F. No. Stds/Nutra-IEM/FSSAI-2016
Food Safety and Standards Authority of India
(A Statutory Authority under the Ministry of Health and Family Welfare, Govt. of India)
FDA Bhawan, Kotla Road, New Delhi-110 002

Dated, the 1 November, 2018

Subject: Direction under Section 16(5) of Food Safety and Standards Act, 2006 regarding import of specialty foods for IEM and hypoallergenic conditions- Reg.

In continuation to the earlier direction dated 02.11.2016 (copy enclosed), it has been further decided to allow the import of Food for Special Medical Purposes (i.e. Food for 15 Inborn errors of metabolism and two hypoallergenic conditions) as listed in the Annexure-A for a further period of six months from 02.11.2018 or till their standards are notified, whichever is earlier. The Hypoallergenic condition at Sr. No. 2 of Annexure enclosed with direction dated 02.11.2016, may be read as those mentioned in Annexure-A enclosed. Further, for better control, the import shall still be permitted through Delhi and Mumbai ports only.

This issues with the approval of the Competent Authority.


(Suneeti Toteja)
Director (Imports)
FSSAI HQ, New Delhi

Enclosure: as above

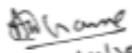
To

1. Sh. Zubair Riaz, Director (Customs), Ministry of Finance
2. All Commissioners of Food Safety
3. All Authorized Officers, FSSAI
4. All Central Licensing Authorities of FSSAI

Copy for information to:

1. PPS to Chairperson, FSSAI
2. PS to CEO, FSSAI
3. All Directors, FSSAI.

4. CITO, FSSAI - for uploading on website of FSSAI.

Shri Kamal
(IT Associate)

02/11/2018

Inborn Errors of Metabolism (IEM) Conditions		
No	Medical condition	Description
	Maple syrup urine disease	Isoleucine, Leucine and Valine free diet powder
	Glutaric Acidemia Type I	Lysine free and Tryptophan low/free diet powder
	Homocystinuria	Methionine free diet powder
	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 Deficiency ¹ , 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)	Low carbohydrate, sucrose, fructose, sugar free

	def),Pyruvate dehydrogenase complex deficiency	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.