

File No. 1-1715/FSSAI/Imports/2017  
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 20<sup>th</sup> 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.

  
20/04/20  
(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**


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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.

  
(Suneti 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**

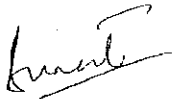
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Dated, the | November, 2018

**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

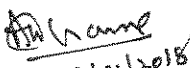
**Enclosure: as above**

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		
S. No	Medical condition	Description
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 Deficiency <sup>1</sup> , 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
<b>Hypoallergenic Conditions</b>		
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 <sup>st</sup> preference) (ii) Extensively hydrolysed formula (2 <sup>nd</sup> preference) (iii) Soy based formula (3 <sup>rd</sup> preference)