

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**

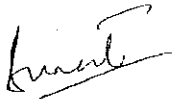
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Dated, the | November, 2018

**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**

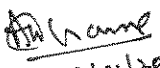
**Enclosure: as above**

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

<b>Inborn Errors of Metabolism (IEM) Conditions</b>		
<b>S. No</b>	<b>Medical condition</b>	<b>Description</b>
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)	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)

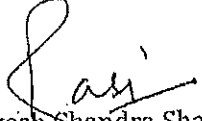
F. No. Stds/Nutra-IEM/FSSAI-2016 (Pt. F1)  
**Food Safety and Standards Authority of India**  
(A Statutory Authority under the Ministry of Health and Family Welfare, Govt. of India)  
FDA Bhawan, Kotla Road, New Delhi-110 002

Dated, the 02<sup>nd</sup> Nov. 2016  
~~October~~, 2016

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

1. Inborn Errors of Metabolism (IEM) and Hypoallergenic conditions are special medical conditions which requires specialty foods. Such specialty foods are not readily available in the country. The hospitals need these specialty foods for the management of infants and children suffering from such conditions.
2. These specialty foods are globally available. However, in the absence of Standards for such foods, it is difficult to import them into India. FSSAI has been receiving representations from various organizations for allowing these foods in the country.
3. And whereas, taking these issues into consideration, the Scientific Panel of FSSAI on "Functional Foods, Nutraceuticals, Dietetic Products and Other Similar Products" has initiated work on for setting the Standards for these products. However, it is likely to take long time to finalize these Standards in view of the complexity of this subject. Taking note of the seriousness of the issue, the Scientific Panel has, therefore, recommended that import of these products may be permitted by FSSAI for two years or till their Standards are developed and notified, whichever is earlier. The Panel, after careful consideration, recommended for allowing the import of foods for fifteen "Inborn Errors of Metabolism" and two Hypoallergenic conditions as per the Annexure.
4. It has been decided to allow the import of foods for special medical purposes, as listed in the Annexure to this Order, for a period of two years or till their Standards are developed and notified, whichever is earlier, 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 for a period of two years from the date of this Order or till their Standards are developed and notified, whichever is earlier. 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 one time 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.

  
Rakesh Chandra Sharma  
Director (Imports)

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.

## ANNEXURE

**Inborn Errors of Metabolism (IEM) and Hypoallergenic conditions**

S. No	Medical condition	Description
<b>A. IEM Conditions</b>		
1.	Maple syrup urine disease	Isoleucine, Leucine and Valine free diet powder
2.	Glutaric Acidemia Type I	Lysine and Tryptophan 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
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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
<b>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	Severe allergy due to intact milk protein & soya protein	For Cow's milk allergy Hypoallergenic Formula