

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**

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Dated, the 19<sup>th</sup> January, 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 the under Section 16 (5) of Food Safety and Standards Act, 2006 dated 02<sup>nd</sup> November, 2016 for two years or till their standards are notified, whichever is earlier regarding import and manufacturing of foods required for management of Inborn Errors of Metabolism (IEM) and Hypoallergenic Conditions. the compliance was extended till 01.05.2021 or till their standards are notified, whichever is earlier.

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 1<sup>st</sup> July, 2021.

3. Since, the standards for IEM has been notified on 4<sup>th</sup> December, 2020 under Food Safety and Standards (Foods for Infant Nutrition) Regulations, 2020 and earlier direction is superseded by this notification, it has been decided to allow the import of foods products for IEM condition, as listed in the Annexure-1, till 30<sup>th</sup> June, 2021, 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/manufacture of such foods shall ensure that they are consumed only under supervision of health care professionals.

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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.



**(N. Bhaskar)**

**Advisor (Science & Standards)**

To

1. All Food Safety Commissioners,
2. All Authorized Officers, FSSAI,
3. All Designated Officers, FSSAI.

Copy for information to:

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

## Annexure I

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

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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 <sup>st</sup> preference) (ii) Extensively hydrolysed formula (2 <sup>nd</sup> preference) (iii) Soy based formula (3 <sup>rd</sup> preference)

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