

**Voluntary Report** – Voluntary - Public Distribution

**Date:** March 10, 2022

**Report Number:** IN2022-0022

**Report Name:** India - FSSAI Publishes Approved List of Specialty Products for Inborn - Congenital - Errors of Metabolism Conditions

**Country:** India

**Post:** New Delhi

**Report Category:** FAIRS Subject Report

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**Report Highlights:**

On February 22, 2022, India's Ministry of Health and Family Welfare/Food Safety and Standards Authority of India (FSSAI) published Stds/SP-05/Orders/FSSAI (E1317). The order includes a list of conditions associated with inborn (congenital) errors of metabolism (IEM) along with the specialty food products that can be manufactured, sold, marketed, or imported to address these imbalances. The FSSAI implementation date for the approved list is April 1, 2022. Until such time, the FSSAI will continue to allow the import of specialty food products listed in its earlier directive of June 30, 2021.

**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 Foreign Agricultural Service (FAS) Office of Agricultural Affairs at the U.S. Embassy in New Delhi, 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 that do not open in Internet Explorer. Indian host sites will geo-block site access on a rolling basis].

## GENERAL INFORMATION

On February 22, 2022, India's Ministry of Health and Family Welfare/Food Safety and Standards Authority of India (FSSAI) published Stds/SP-05/Orders[*sic*]/FSSAI (E1317). The order includes an approved list of inborn (congenital) errors of metabolism (IEM) conditions along with the specialty food products that can be manufactured, sold, marketed, or imported to address these imbalances (see, Appendix I).

The FSSAI implementation date for the approved list is April 1, 2022. Until such time, the FSSAI will continue to allow the import of specialty food products listed in its earlier directive of June 30, 2021.

**Background:** On December 4, 2020, the FSSAI published the Food Safety and Standards (Foods for Infant Nutrition) Regulations, which contain standards for foods for infants affected by inborn (congenital) errors of metabolism. Subsequently on June 30, 2021, the FSSAI issued a new directive permitting the import of food products for IEM under certain conditions through March 31, 2022 (see, [GAIN-INDIA-IN2021-0085-India's FSSAI Extends Compliance Timeline on Specialty Food Products Imports for Inborn Errors of Metabolism and Hypoallergenic Conditions](#)).

The full text of the current FSSAI notification is accessible on the FSSAI website located at: [https://fssai.gov.in/upload/advisories/2022/02/6204fbf56a3aeOrder\\_IEM\\_10\\_02\\_2022.pdf](https://fssai.gov.in/upload/advisories/2022/02/6204fbf56a3aeOrder_IEM_10_02_2022.pdf).

# APPENDIX I – FSSAI, STANDARDS OF FOODS FOR INFANTS WITH INBORN (CONGENITAL) ERRORS OF METABOLISM

F. No. Stds/SP-05/Orders/FSSAI (E1317)  
**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 10<sup>th</sup> February, 2022

## ORDER

**Sub. : Standards of Foods for Infants with Inborn Errors of Metabolism (IEM) specified under Food Safety and Standards (Foods for Infant Nutrition) Regulations, 2020.**

Reference is drawn to the Food Safety and Standards (Foods for Infant Nutrition) Regulations, 2020 published in Gazette of India on 4<sup>th</sup> December, 2020, having standards for foods for infants including IEM and the date of compliance of these regulations was extended up to 01<sup>st</sup> April, 2022. In this regard, a direction dated 30.06.2021 was issued to allow the import of food products for IEM conditions till 31.03.2022.

2. Whereas the regulation 16(1) (e) of the above mentioned Regulations provides that “*the Food Authority shall specify the IEM conditions as approved by it after undertaking proper scientific evaluation. No Food Business Operator (FBO) shall manufacture, sell, market, or import products for IEM conditions except those specified by the Food Authority from time to time.*”
3. In exercise of the power mentioned in the regulation 16(1) (e) as above, the Food Authority has approved the list of IEM conditions as per **Annexure I**. The list will come into effect from 01<sup>st</sup> April, 2022. Till such time, the direction issued on 30.06.2021 will continue to be in force.
4. This issues with the approval of the Competent Authority.



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**Advisor (Science and Standards)**  
**FSSAI, New Delhi**

### To

1. ED (CS) with a request to communicate to Food Safety Commissioners of all States/UTs
2. Advisor (QA)
3. Head (RCD) / Head (Regulations) / Head (Legal)
4. Director (TICD) – with a request to communicate to all Authorized Officers
5. All Regional Directors, FSSAI
6. All Central Licensing Authorities, FSSAI
7. CITO, FSSAI – with a request to upload this direction on FSSAI website

### Copy to:

1. PPS to Chairperson, FSSAI,
2. PS to CEO, FSSAI

### Attachments:

No Attachments.