

**Voluntary Report** – Voluntary - Public Distribution

**Date:** December 13, 2022

**Report Number:** IN2022-0109

**Report Name:** India's FSSAI Notifies that the Infant Food Nutrition Regulation is Fully Operational

**Country:** India

**Post:** New Delhi

**Report Category:** FAIRS Subject Report

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**Approved By:** Ronald Verdonk, Agricultural Minister Counselor

**Report Highlights:**

On November 28, 2022, the Ministry of Health and Family Welfare/Food Safety and Standards Authority of India (FSSAI) notified on its website the Direction REG-11027/3/2022-Regulation-FSSAI (October 18, 2022). Through this notification, FSSAI has communicated that the Food Safety and Standards (Food for Infant Nutrition) Regulations (2020), the implementation timeline of which was extended to October 1, 2022, to accommodate industry associations' representations (i.e., written commentary and concerns), is now being operationalized. Previously, on March 29, 2022, the FSSAI had only operationalized the revised limits for selenium, manganese, iron, and biotin included in the regulation.

**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 November 28, 2022, through its website, the Ministry of Health and Family Welfare/Food Safety and Standards Authority of India (FSSAI) communicated **Direction REG-11027/3/2022-Regulation-FSSAI (October 18, 2022)** (see, Appendix I).

The FSSAI direction notifies that the Food Safety and Standards (Food for Infant Nutrition) Regulations (2020) the implementation timeline of which was extended to October 1, 2022, to accommodate industry associations' representations (i.e., written commentary and concerns), is now operationalized. In a March 29, 2022 notification, the FSSAI had only operationalized the revised limits for selenium, manganese, iron, and biotin included in the regulation. The FSSAI Direction advises that the final **Food Safety and Standards (Food for Infant Nutrition) Regulations (2020)**, is fully operationalized as of October 1, 2022.

### Background:

**March 29, 2022:** The Ministry of Health and Family Welfare/FSSAI revised standards' levels for manganese, selenium, biotin, and iron. It also extended the implementation date of the **Food Safety and Standards (Food for Infant Nutrition) Regulations (2020)** to October 1, 2022 (see, [GAIN-INDIA | IN2022-0039 | India's FSSAI Extends the Implementation Timeline for Infant Food Nutrition Regulations](#)). The implementation timeline was extended by the FSSAI to accommodate earlier industry associations' representations requiring additional time to reformulate and manufacture infant food products in line with the revised standards.

The full text of the **Direction REG-11027/3/2022-Regulation-FSSAI (October 18, 2022)** is located on the FSSAI website at:

[https://fssai.gov.in/upload/advisories/2022/11/63849fc9b42f2Direction\\_Infant\\_Nutrition\\_28\\_11\\_2022.pdf](https://fssai.gov.in/upload/advisories/2022/11/63849fc9b42f2Direction_Infant_Nutrition_28_11_2022.pdf)

**APPENDIX I: FSSAI DIRECTIVE DATED OCTOBER 18, 2022 (PUBLISHED ON THE FSSAI WEBSITE ON NOVEMBER 28, 2022)**

**File No. REG-11027/3/2022-Regulation-FSSAI**  
**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.**

The 18<sup>th</sup> October, 2022

**Subject: Direction under Section 18 (2) (d) read with Section 16 (5) of Food Safety and Standards Act, 2006 regarding operationalisation of Food Safety and Standards (Foods for Infant Nutrition) Amendment Regulations, 2022 relating to revise limits of Selenium, Manganese, iron and biotin.**

Reference is drawn to direction issued dated 29<sup>th</sup> March, 2022 under section 16(5) of Food Safety and Standards Act, 2006 wherein revised limits of Selenium, Manganese, Iron and Biotin were specified in foods for infant nutrition, as relevant, and the transition period for the implementation of *Food Safety and Standards (Food for Infant Nutrition) Regulations, 2020* was extended up to 1st October 2022.

2. In earlier above said direction, limits of Selenium, Manganese, Iron and Biotin were revised in view of representations received from industry associations regarding difficulty in reformulating and manufacturing infant food products adhering to the levels of these trace elements.

3. As the *Food Safety and Standards (Food for Infant Nutrition) Regulations, 2020* have been enforced w.e.f. 1st October 2022, the revised limits of Selenium, Manganese, Iron and Biotin are also required to be made operational in accordance with the relevant provisions of the Act.

4. Therefore, it has been decided to operationalise the *Food Safety and Standards (Foods for Infant Nutrition) Amendment Regulations, 2022* (enclosed as Annexure-1) under section 18(2) (d) of Food Safety and Standards Act, 2006 w.e.f. 1st October 2022.

5. This issues with the approval of the Competent Authority in exercise of the power vested under Section 18 (2) (d) and 16 (5) of Food Safety and Standards Act, 2006.

  
(Inoshi Sharma)

**Executive Director (Regulatory Compliance)**

**Notice for operationalisation of Food Safety and Standards (Foods for Infant Nutrition) Amendment Regulations, 2022 relating to revised limits of Selenium, Manganese, iron and biotin.**

The Food Safety and Standards Authority of India, hereby makes the following regulations operational with effect from 1st October 2022.

1. These regulations may be called the Food Safety and Standards (Foods for Infant Nutrition) Amendment Regulations, 2022.
2. In the Food Safety and Standards (Foods for Infant Nutrition) Regulations, 2020,-
  1. in regulation 7, in sub-regulation (1), in clause (g), in the table for serial no 34 and the entries relating thereto the following serial number and entry shall be substituted, namely:-

"34.	Selenium, mcg	5-40	1-8.5";
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2. in regulation 8, in sub-regulation (1), in clause (e), in the table for serial number 11 and the entry relating thereto, the following serial number and entry shall be substituted, namely:-

"11.	Selenium, mcg	5-40	1-8.5";
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3. in regulation 9,-
  - i. in sub-regulation (1), in clause (f), in the table for serial number 15 and the entry relating thereto, the following serial number and entry shall be substituted, namely:-

"15.	Iron, mg	2-5.65	0.42-1.20";
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- ii. in sub-regulation (1), in clause (f), in the table for serial number 23 and the entry relating thereto, the following serial number and entry shall be substituted, namely:-

"23.	Selenium, mcg	5-40	1-8.5";
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4. in regulation 10,-

- i. in sub-regulation (1), in clause (h), in the table for serial number 17 and the entry relating thereto, the following serial number and entry shall be substituted, namely:-

"17.	Biotin, mcg	7.50-50	1.60-10.60";
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- ii. in sub-regulation (1), in clause (h), in the table for serial number 28 and the entry relating thereto, the following serial number and entry shall be substituted, namely:-

"28.	Manganese, mcg	5-500	1-106.40".
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- iii. in sub-regulation (1), in clause (h), in the table for serial number 29 and the entry relating thereto, the following serial number and entry shall be substituted, namely:-

"29.	Selenium, µg	5-40	1-8.5";
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**Attachments:**

No Attachments.