

Voluntary Report – Voluntary - Public Distribution

Date: June 07, 2023

Report Number: IN2023-0040

Report Name: India's FSSAI Re-Operationalizes its Directive Relating to Revised Limit Specifications for Infant Nutrition Foods

Country: India

Post: New Delhi

Report Category: FAIRS Subject Report

Prepared By: Radha Mani, Agricultural Specialist and Mariano J. Beillard, Senior Regional Agricultural Attaché

Approved By: Mariano Beillard, Senior Regional Agricultural Attaché

Report Highlights:

On May 22, 2023, the Ministry of Health and Family Welfare/Food Safety and Standards Authority of India (FSSAI) notified on its website Direction REG-11027/3/2022-Regulation-FSSAI. The FSSAI direction informs that the draft Food Safety and Standards (Food for Infant Nutrition) Regulations (2022) are being re-operationalized. Limit levels for selenium, manganese, iron, and biotin are being re-operationalized as of April 1, 2023. The FSSAI is issuing this directive assuming that the draft regulation published on April 5, 2023, which invites public comments, may be delayed before it is notified in final form.

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 Microsoft Edge. Indian host sites will geo-block site access on a rolling basis].

GENERAL INFORMATION

On May 22, 2023, the Ministry of Health and Family Welfare/Food Safety and Standards Authority of India (FSSAI) notified on its website **Direction REG-11027/3/2022-Regulation-FSSAI** (see, Appendix I). The FSSAI direction informs that the **draft Food Safety and Standards (Food for Infant Nutrition) Regulations (2022)**, are being re-operationalized.¹ Limit levels for selenium, manganese, iron, and biotin are being re-operationalized as of April 1, 2023. The FSSAI is issuing this directive assuming that the draft regulation published on April 5, 2023, which invites public comments, may be delayed before it is notified in final form.

Background:

Date	Description	GAIN Report Number
December 14, 2020	India: Final Standards for Infant Nutrition Foods Published in Indian Gazette	IN2020-0192
April 5, 2021	India: FSSAI Publishes Corrections to Nutrient Levels in the Final Foods for Infant Nutrition Regulations of 2020	IN2021-0047
June 22, 2021	India: FSSAI Extends Implementation Date for Infant Nutrition Foods Standard	IN2021-0078
September 6, 2021	India: FSSAI Mandates BIS Certification Mark on Infant Nutrition Foods	IN2021-0124
September 22, 2021	India: FSSAI Publishes Draft Amendments for the Infant Nutrition Foods Regulation	IN2021-0125
October 18, 2022	FSSAI Notification relating to operationalization of Food Safety and Standards (Foods for Infant Nutrition) Amendment Regulations, 2022, revising limits of selenium, manganese, iron, and biotin	-----
March 29, 2022	India: FSSAI Extends the Implementation Timeline for Infant Food Nutrition Regulations	IN2022-0039
April 5, 2023	India’s FSSAI Publishes 2023 Draft Amendments to the Foods for Infant Nutrition Regulations	IN2023-0036

¹ As per the Food Safety and Standards Act of (2006), the FSSAI is required to re-operationalize regulations every six-months while these are in draft form.

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

[https://fssai.gov.in/upload/advisories/2023/05/646b51c03cd5cDirection_Reoperationalization_FSS\(Foods%20for%20infant%20Nutrition\)Reg_revised%20limits%20of%20Selenium,%20Manganese,%20Iron%20and%20Biotin.pdf](https://fssai.gov.in/upload/advisories/2023/05/646b51c03cd5cDirection_Reoperationalization_FSS(Foods%20for%20infant%20Nutrition)Reg_revised%20limits%20of%20Selenium,%20Manganese,%20Iron%20and%20Biotin.pdf)

**APPENDIX I: FSSAI DIRECTIVE REG-11027/3/2022-REGULATION-FSSAI
RELATING TO RE-OPERATIONALISATION OF INFANT NUTRITION FOODS
REGULATIONS MODIFYING LIMITS OF SELENIUM, IRON, MANGANESE, AND
IRON**

F. 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-110002

Dated, the 22 May, 2023

Subject: Direction under Section 16 (5) of Food Safety and Standards Act, 2006 regarding re-operationalisation of Food Safety and Standards (Foods for Infant Nutrition) Amendment Regulations, 2022 relating to revised limits of Selenium, Manganese, Iron and Biotin

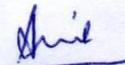
Reference is drawn to direction issued dated 18th October, 2022 under Section 18(2)(d) of Food Safety and Standards Act, 2006 for operationalization of the revised limits of Selenium, Manganese, Iron and Biotin in some foods for infant nutrition specified in the Food Safety and Standards (Foods for Infant Nutrition) Amendment Regulations, 2022.

2. In the above said direction, revised limits of Selenium, Manganese, iron and biotin were operationalised in view of representations received from industry associations regarding difficulty in reformulating & manufacturing infant food products in order to adhere to the previously specified levels of Manganese, Selenium, Biotin and Iron.

3. As the draft FSS (Food for Infant Nutrition) Amendment Regulations, 2022 are under the process of notification for inviting stakeholder comments and finalization of the same may take more time; the revised limits of Selenium, Manganese, Iron and Biotin are required to be re-operationalised under section 18(2)(d) of Food Safety and Standards Act, 2006 from 1st April, 2023.

4. Therefore, it has been decided, to re-operationalise the limits of Selenium, Manganese, Iron and Biotin specified at Annexure-1 [Food Safety and Standards (Foods for Infant Nutrition) Amendment Regulations, 2022] under section 18(2)(d) of Food Safety and Standards Act, 2006 w.e.f. 1st April, 2023.

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.



(Dr. Amit Sharma)
Director
Regulation Division
FSSAI, New Delhi

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 18th 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.

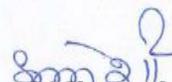
Reference is drawn to direction issued dated 29th March, 2022 under section 16(5) of Food Safety and Standards Act, 2006 wherein revised limits of Selenium, Manganese, Iron and Biotin were specified in foods for infant nutrition, as relevant, and the transition period for the implementation of *Food 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 regulation 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";
------	---------------	------	---------

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";
------	---------------	------	---------

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";
------	----------	--------	-------------

- 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";
------	---------------	------	---------

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";
------	-------------	---------	--------------

- 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".
------	----------------	-------	------------

- 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";
------	--------------	------	---------

Attachments:

No Attachments.