

File No. STD/SP-05/T(Foods for Infant Nutrition)
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 12th March 2024

Subject: Direction under Section 18 (2) (d) read with 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 revise limits of Selenium, Manganese, iron and biotin.

Reference is drawn to directions issued on 18th October, 2022 and 22nd May, 2023 under section 18(2)(d) of the Food Safety and Standards Act, 2006 wherein the revised limits of Selenium, Manganese, iron and biotin were operationalised and re-operationalised respectively.

2. In the above said directions, 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 adhering to the levels of Manganese, Selenium, Biotin and Iron.

3. As the Food Safety and Standards (Food for Infant Nutrition) Amendment Regulations, 2022 is under the process of finalization and same may take some more time, therefore, the revised limits of Selenium, Manganese, iron and biotin are required to be re-operationalized under section 18(2) (d) of the Food Safety and Standards Act, 2006 from 1st October, 2023.

4. Therefore, it has been decided, to re-operationalise the provisions specified in the directions dated 18th October, 2022 and 22nd May 2023 respectively, under section 18(2) (d) of the Food Safety and Standards Act, 2006 with effect from. 1st October, 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.


(Anil Mehta)
Director
Regulation Division
FSSAI, New

Encl: Copy of directions dated 22.05.2023 and 18.10.2022

To

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

Copy for information to:

1. PPS to Chairperson, FSSAI
2. PS to CEO, FSSAI
3. All Divisional Heads, FSSAI
4. CITO, FSSAI- for uploading on the website

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

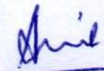
Reference is drawn to direction issued dated 18th October, 2022 under Section 18(2)(d) of Food Safety and Standards Act, 2006 for operationalization of the revised limits of Selenium, Manganese, Iron and Biotin in some foods for infant nutrition specified in the Food Safety and Standards (Foods for Infant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

To:

1. ED(CS)-with a request to communicate to Food Safety Commissioners of all States/UTs and all Regional Directors, FSSAI
2. Director (Import)-with a request to communicate to all Authorized Officers

Copy to:

1. PPS to Chairperson
2. PS to CEO
3. Advisor (S&S)
4. Advisor (QA)
5. CITO - with a request to upload the direction on the FSSAI website

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)

To

1. All Food Safety Commissioner.
2. All Authorized Officer, FSSAI.
3. All Central Designated Offices of FSSAI.

Copy for information to:

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

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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