

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"; |
|------|---------------|------|---------|

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"; |
|------|--------------|------|---------|