FDA MAHARASHTRA
FOOD AND DRUG ADMINISTRATION

COMMISSIONER
FOOD AND DRUG ADMINISTRATION, MAHARASHTRA STATE

Survey No. 341, Bandra Kurla Complex, Bandra (East), Mumbai - 400 051

No.: COMM/COMPORDER/INFANT-FOOD/1459/2026 **Date: 29 September, 2026**

ORDER

Subject	**Comprehensive Compliance Order – Manufacture, Import, Storage, Distribution, Sale, Labelling and Promotion of Foods for Infant Nutrition – Directions for strict compliance with the Food Safety and Standards Act, 2006; the Food Safety and Standards (Foods for Infant Nutrition) Regulations, 2020; allied Regulations; and the Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act, 1992, as amended – Applicable to Manufacturers, Brand Owners / Marketers, Repackers, Re-labellers, Importers, Wholesalers / Distributors, Retailers, Pharmacies, Hospital Suppliers and E-commerce Entities in the State of Maharashtra.**

WHEREAS Article 21 of the Constitution of India guarantees to every person the right to life with dignity – a right which the Hon'ble Supreme Court has authoritatively held to encompass the right to safe, wholesome and unadulterated food, and the right to be protected from food that is injurious to health – and this right is at its most acute in the case of infants and young children, who cannot choose, judge or protect themselves;

AND WHEREAS Article 47 of the Constitution casts upon the State a primary and non-derogable duty to raise the level of nutrition and the standard of living of its people and to improve public health – the nutrition received in the first two years of life being determinative of survival, growth and lifelong health;

AND WHEREAS infants and young children constitute a highly vulnerable class, and any nutritional inadequacy, microbial contamination, chemical contaminant, misleading feeding direction or inappropriate commercial promotion may cause serious and irreversible harm;

AND WHEREAS the Food Safety and Standards Act, 2006 ("the Act") – particularly Sections 16, 18, 22, 23, 24, 26 to 28, 31 to 32, 36 to 42, 46, 48 to 53, 55 to 59, 61, 63 and 65 to 67 – and the Regulations framed thereunder, including

1. The FSS (Foods for Infant Nutrition) Regulations, 2020, as corrected by the Corrigenda dated 31 March 2021 and amended by the FSS (Foods for Infant Nutrition) First Amendment Regulations, 2022 (in force from 1 October 2022), together with the directions in force;

2. The FSS (Licensing and Registration of Food Businesses) Regulations, 2011;
3. The FSS (Food Products Standards and Food Additives) Regulations, 2011;
4. The FSS (Contaminants, Toxins and Residues) Regulations, 2011;
5. The FSS (Prohibition and Restrictions on Sales) Regulations, 2011;
6. The FSS (Labelling and Display) Regulations, 2020;
7. The FSS (Packaging) Regulations, 2018;
8. The FSS (Advertising and Claims) Regulations, 2018;
9. The FSS (Import) Regulations, 2017; and
10. The FSS (Food Recall Procedure) Regulations, 2017

lay down comprehensive, science-based and binding standards for the identity, composition, safety, packaging, labelling, import, sale and recall of foods for infant nutrition applicable to every Food Business Operator in the supply chain, and place primary responsibility upon every Food Business Operator to ensure that food satisfies the Act and the Regulations at every stage under its control;

AND WHEREAS the Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act, 1992, as amended in 2003 ("the IMS Act"), and the Rules framed thereunder, independently prohibit the advertisement and promotion of infant milk substitutes, feeding bottles and infant foods (Section 3), samples, gifts, inducements and contact with pregnant women and mothers (Section 4), donations (Section 5), the use of the health care system for promotion (Section 8) and inducements to health workers (Section 9), prescribe mandatory label declarations (Section 6) and the BIS Standard Mark (Section 11), vest powers of entry, search and seizure in the Food Safety Officer (Sections 12 and 13), provide for confiscation and prosecution (Sections 14 to 23), and are by Section 25 in addition to and not in derogation of the Act; and compliance with the compositional and safety standards under the Act does not dilute these independent prohibitions;

AND WHEREAS the Legal Metrology Act, 2009 and the Legal Metrology (Packaged Commodities) Rules, 2011 apply to the net-quantity and price declarations on every covered package;

AND WHEREAS inspections and surveillance by the Food and Drug Administration, Maharashtra State have revealed continuing non-compliance across the infant-nutrition supply chain – including

1. Operation without valid licence, or with a Kind of Business or product endorsement in FoSCoS not matching the actual activity,
2. Sale of products described as "baby cereal", "health mix", "stage food", "nutrition powder" or "traditional mix" which are in substance infant foods, so named to avoid the prescribed standard,
3. Product not conforming to the prescribed compositional ranges through its declared shelf life,

4. Introduction of unapproved novel ingredients, botanicals, probiotic strains, sweeteners, colours and bioactive substances under the guise of proprietary food,
5. Labels lacking the prescribed breastfeeding statement, age of introduction, feeding table, preparation instructions and safety warning, or bearing pictures of infants or mothers and idealising text,
6. Advertisement and promotion through television, print, websites, marketplaces, social media, influencers and parenting platforms in contravention of the IMS Act,
7. Free samples, gifts, coupons and cashback, and sponsorship, hospitality and branded material to hospitals and health workers,
8. Cross-promotion of covered products through the colour, logo, mascot or name of another product,
9. Re-labelling and stickering that conceals mandatory information or alters batch and date particulars,
10. Sale of expired, damaged, bulged, rusted or tampered packs, and of imported product without conformity to Indian standards,
11. Absence of batch-wise traceability, complaint handling and recall capability, and
12. Online listing without seller-licence verification or mandatory pre-sale label information, and
13. Solicitation, collection, processing and sale of human milk and its products by private entities, including online, contrary to the advisory of the Food Authority dated 24 May 2024.

All of which pose grave and unacceptable risk to the life and health of the infants of Maharashtra;

AND WHEREAS the Food Safety and Standards Authority of India, by its Advisory on unauthorised commercialisation of human milk and its products dated 24 May 2024, has clarified that the processing and/or selling of human milk is not permitted under the Act and the Regulations, has directed that all activities relating to the commercialisation of human milk and its products be stopped immediately, and has directed the State and Central Licensing Authorities to ensure that no licence or registration is granted to any Food Business Operator involved in the processing or selling of human milk; and the National Guidelines on Lactation Management Centres in Public Health Facilities of the Ministry of Health and Family Welfare provide that donor human milk shall be collected, processed and provided only through such non-commercial centres, without any monetary benefit to the donor;

AND WHEREAS the Hon'ble Supreme Court of India, in Swami Achyutanand Tirth & Ors. v. Union of India & Ors. [Writ Petition (Civil) No. 159 of 2012, decided on 5th August 2016], taking note of the grave menace of food adulteration, directed the Union of India and the State Governments to implement the Food Safety and Standards Act, 2006 in a more effective manner, to strengthen food-testing infrastructure and the enforcement machinery, to identify high-risk areas for intensified sampling, to ensure analysis through NABL-accredited laboratories, and held it desirable that the punishment for adulteration be made more deterrent

where the adulterant can adversely affect health; and this Order is issued, inter alia, in furtherance of those directions;

AND WHEREAS Section 30 of the Act, read with Sections 18 and 29 thereof, vests in the Commissioner of Food Safety, Maharashtra, the authority to ensure, through the officers under his charge, compliance with the Act and the Regulations made thereunder;

NOW, THEREFORE, I, Tukaram Mundhe, I.A.S., Food Safety Commissioner, Food and Drug Administration, Maharashtra State, in exercise of the powers conferred by sub-section (1) and clauses (a), (b), (d), (e) and (f) of sub-section (2) of Section 30, read with sub-section (6) of Section 29 and Section 18 of the Food Safety and Standards Act, 2006, and all other powers enabling me in this behalf, hereby issue this Comprehensive Compliance Order, which shall have immediate effect in relation to all Food Business Operators engaged in the manufacture, processing, repacking, re-labelling, import, storage, distribution, transport, marketing and sale of foods for infant nutrition throughout the State of Maharashtra.

These directions shall be implemented by all officers and authorities under the Food Safety Commissioner in accordance with the powers respectively vested in them under the Act, Rules and Regulations. Nothing contained herein shall be construed as creating any substantive prohibition, offence, penalty or obligation beyond that provided under the Act, Rules, Regulations, the IMS Act or legally binding directions of the Food Authority.

1. EXTENT, APPLICABILITY AND COMMENCEMENT

1.1 This Order shall extend to the whole State of Maharashtra and apply to every manufacturer, relabeller, repacker, importer, brand owner, marketer, e-commerce entity, distributor, wholesaler, retailer, pharmacy, hospital supplier, warehouse, transporter and other person dealing with covered products.

1.2 It shall come into force immediately.

1.3 Without prejudice to the generality of sub-clause 1.1, this Order applies to ALL Food Business Operators in the infant-nutrition sector operating within the territorial limits of the State of Maharashtra – including manufacturers of infant formula, infant milk food, follow-up formula, milk-cereal-based and processed-cereal-based complementary foods, traditional-ingredient-based infant foods and foods for special medical purpose intended for infants; brand owners and marketers, including those procuring under contract manufacture; repackers and re-labellers; importers; wholesalers, distributors, super-stockists, warehouses and transporters; retailers of every description (kirana stores, supermarkets, departmental stores, baby-product stores and pharmacies); hospital and nursing-home suppliers; and e-commerce entities and online sellers – regardless of size, turnover, handling capacity or nature of ownership.

2. DEFINITIONS AND PRODUCT CLASSIFICATION

2.1 Words and expressions shall have the meanings assigned in the FSS Act, the Foods for Infant Nutrition Regulations, the IMS Act and allied regulations. Where two provisions operate concurrently, the more specific and more protective requirement

shall be applied, subject to law. The detailed classification, headline compositional parameters and category-specific label declarations for every category are set out, for guidance, in Annexure A.

Category	Regulatory position	Core age/use
Infant formula	Standardised product; may function as breast-milk substitute	Infants, as prescribed
Infant milk food	Infant formula in powder form manufactured without vegetable oil, linoleate, vitamin E, starch, specified food additives or optional ingredients (Reg. 7(3), 2022 amendment); FSS and IMS controls apply	First six months, as prescribed
Follow-up formula	Not a breast-milk substitute for first six months	After six months, as part of diversified diet
Milk cereal-based complementary food	Standardised complementary food	Not before six months
Processed cereal-based complementary food	Standardised complementary food	Not before six months
Traditional ingredient-based infant food	Packaged traditional formulation (Reg. 11); must bear "Traditional Food for Infants" on the front of pack	Generally 6–24 months
Infant FSMP	For medically determined needs; medical supervision and special label	As medically indicated

2.2 Product identity shall be determined from composition, intended use, age statement, feeding directions, presentation and marketing—not merely the brand or fanciful name. Expressions such as 'baby cereal', 'health mix', 'stage food', 'nutrition powder' or 'traditional mix' shall not be used to avoid a prescribed standard.

3. LICENSING, PRODUCT ENDORSEMENT AND BIS

3.1 No person shall manufacture, process, repack, relabel, store, distribute, sell or import a covered product except under a valid FSSAI licence/registration appropriate to the activity and premises. The exact product category shall appear in the FoSCoS licence/product list before commencement.

3.2 The requirement of the BIS Certification Mark for foods for infant nutrition under clause (4) of sub-regulation 2.3.14 of the Prohibition and Restrictions on Sales Regulations was omitted by the FSS (Prohibition and Restrictions on Sales) First Amendment Regulations, 2024 notified on 17 October 2024. Notwithstanding that omission, the BIS Standard Mark continues to be mandatory for every infant milk substitute, infant food and feeding bottle by virtue of Section 11 of the IMS Act (sub-clause 3.5), and the FSSAI licence and the BIS licence remain separate and cumulative obligations.

3.3 Every brand owner and marketer shall verify the manufacturer's licence, approved product list, BIS coverage wherever applicable, contractual traceability and batch

release records. Contract manufacture does not transfer or extinguish statutory responsibility.

3.4 Every licensed Food Business Operator shall comply, at all times, with the Conditions of Licence set out in Annexure 3 of Form B in Schedule 2 of the FSS (Licensing and Registration of Food Businesses) Regulations, 2011, as mandated under Regulation 2.1.2(5), and every registered (petty) Food Business Operator shall comply with the Conditions of Registration and the self-attested declaration in Annexure 1 of Schedule 2 under Regulation 2.1.1. The Conditions of Licence and of Registration shall be deemed to form an integral part of this Order. The node-wise requirements applicable to each category of operator are set out in Clause 11.

3.5 Independently of sub-clause 3.2, Section 11(1) of the IMS Act prohibits the sale or distribution of any infant milk substitute or infant food unless it conforms to the standards specified under the Act and the container thereof bears the relevant Standard Mark of the Bureau of Indian Standards; and Section 11(2) similarly requires the BIS Standard Mark on the container of every feeding bottle. Contravention of Section 11(1) is punishable under Section 20(2) of the IMS Act with a minimum of six months' imprisonment. Every manufacturer, importer, brand owner and seller shall accordingly hold a valid BIS licence for each such product and ensure that the Standard Mark appears on every container.

3.6 Manufacture of foods for infant nutrition is a high-risk activity. Every application for licence to manufacture a covered product shall be preceded by inspection of the premises and verification of in-house testing capability, and Licensing and Registering Authorities shall act in accordance with the directions of the Food Authority restricting the grant or renewal of Registration (as distinct from Licence) for the manufacture of infant formula, follow-up formula and complementary foods for infants and young children, as and when notified.

4. FORMULATION AND COMPOSITION

4.1 Each product shall conform throughout its declared shelf life to the applicable energy, protein, amino-acid quality, carbohydrate, fat, essential fatty acid, vitamin, mineral and other compositional ranges prescribed for its exact category, on the per 100 g or per 100 kcal basis specified (Regulation 3(14)). A variation of minus 10 per cent from the declared value of a nutrient is allowed, but no nutrient shall exceed the maximum limit specified in the composition tables (Regulation 3(3)); and the product shall be free from lumps and coarse particles, rancid taste and musty odour (Regulation 3(7)).

4.2 Only ingredients, nutrient sources and food additives expressly listed under the Regulations for the category shall be used, within the prescribed limits and conditions. Under Regulation 5(1), foods for infant nutrition shall be free from preservatives, added colours and flavours; carry-over additives are permitted only in accordance with sub-regulation 3.1.1(10) of the Food Products Standards and Food Additives Regulations. Source compounds for minerals, vitamins and other nutrients shall be those listed in Schedule I(a), I(b) and I(c) to the Regulations (Regulation 3(4)); and DHA and ARA, where added, shall be from the sources and within the limits of

Regulation 3(5) – DHA not exceeding 0.5 per cent of total fatty acids, ARA:DHA not less than 1:1, and DHA not less than 0.2 per cent of total fatty acids where a DHA claim is made.

4.3 No unapproved novel ingredient, botanical, probiotic strain, oligosaccharide, sweetener, colour, preservative, flavour or bioactive substance shall be introduced by treating the product as proprietary food. Under Regulation 3(1), an infant milk substitute, infant food or food for special medical purpose intended for infants whose standard is not specified under the Regulations shall be manufactured, exhibited or stored for sale only after approval of the article and its label by the Food Authority.

4.4 Carbohydrate sources and added sugars. In terms of Regulation 3(6) of the Foods for Infant Nutrition Regulations, lactose and glucose polymers shall be the preferred carbohydrates in every food for infant nutrition. Sucrose and/or fructose shall not be added unless needed as a carbohydrate source, and, where so added, the sum of sucrose and fructose shall not exceed twenty per cent of total carbohydrate (or such lower limit as may be prescribed by amendment from time to time). The need for sucrose or fructose as a carbohydrate source shall be recorded and justified in the product formulation record and produced on demand; honey, glucose syrup, high-fructose syrup, jaggery or any other sweetening ingredient shall not be used except where expressly permitted for the category; and no claim such as “no added sugar”, “sugar-free” or “low sugar” shall be made unless true and permitted under the Advertising and Claims Regulations-2018.

4.5 Raw materials and nutrient premixes shall have approved specifications, supplier qualification, identity and contaminant testing, receipt records, lot traceability and controlled storage. Overages, where technologically necessary, shall be scientifically justified and shall not cause the finished product to exceed a maximum limit.

4.6 Food for special medical purpose intended for infants shall be formulated for a medically determined condition, be nutritionally adequate for its intended use, carry prescribed medical-supervision declarations and shall not be promoted for general infant feeding.

4A. STANDARDS OF QUALITY AND SAFETY

Every food for infant nutrition shall conform to the standards of identity, composition, quality and safety prescribed for that product under the FSS (Foods for Infant Nutrition) Regulations, 2020, read with the FSS (Food Products Standards and Food Additives) Regulations, 2011 and the FSS (Contaminants, Toxins and Residues) Regulations, 2011. Product failing any prescribed parameter is sub-standard, and product containing a pathogen, a toxic or non-permitted substance, or otherwise injurious to health, is unsafe. The principal requirements of general application are as follows:

Parameter	Limit / Requirement	Basis
Compositional ranges (energy, protein, fat, carbohydrate, vitamins, minerals)	Within the range prescribed for the exact category, throughout declared shelf life	Infant Nutrition Regs. 2020
Cronobacter sakazakii (infant formula / infant milk food)	Absent, as prescribed	Appendix B, FPS & FA Regs. 2011 read with Reg. 3(12)
Salmonella	Absent in 25 g, as prescribed	Appendix B, FPS & FA Regs. 2011 read with Reg. 3(12)
Other microbiological parameters (Enterobacteriaceae, B. cereus, S. aureus, yeast & mould, TPC)	Within prescribed limits	Appendix B, FPS & FA Regs. 2011 read with Reg. 3(12)
Melamine	Within prescribed limit for infant formula / infant food	Contaminants Regs. 2011
Lead, arsenic and other heavy metals	Within prescribed limits for infant food	Contaminants Regs. 2011
Aflatoxin M1 / B1 and other mycotoxins	Within prescribed limits	Contaminants Regs. 2011
Pesticide residues	Within limits prescribed for foods for infants	Contaminants Regs. 2011
Trans fatty acids / hydrogenated fat	Not to be used; within prescribed limit	Infant Nutrition Regs. 2020
Preservatives, added colours and flavours	Not permitted; other additives only as listed for the category; carry-over per Reg. 3.1.1(10)	Infant Nutrition Regs. 2020, Reg. 5
Nutrient variation	Minus 10% from declared value allowed; maxima never to be exceeded	Infant Nutrition Regs. 2020, Reg. 3(3)
Moisture (powdered products)	Within prescribed limit	Infant Nutrition Regs. 2020
Bisphenol A in packaging	Free from BPA as prescribed	Packaging Regs. 2018

5. MANUFACTURING, HYGIENE AND QUALITY ASSURANCE

5.1 Manufacturing shall be conducted under documented GMP, GHP and HACCP-based controls appropriate to low-moisture and ready-to-feed infant foods, in addition to the requirements of Schedule IV of the Licensing and Registration Regulations and the Codex Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (CAC/RCP 66-2008), as required by Regulation 6.

5.2 The FBO shall maintain validated controls for water quality, environmental hygiene, dry-zone segregation, personnel movement, air handling, cleaning, pest control, foreign bodies, allergens, rework and post-process contamination.

5.3 A written environmental monitoring programme shall be maintained for relevant organisms and hygienic indicators, with defined sites, frequency, alert/action limits, investigation and corrective action.

5.4 Each batch shall be released by an authorised competent person only after review of manufacturing records, in-process controls, packaging integrity and compliant test results. Positive release shall be mandatory for critical microbiological and compositional parameters.

5.5 Retained samples, batch records, certificates of analysis, distribution records and complaint files shall be preserved for at least the declared shelf life plus one year or the longer statutory period, whichever is greater.

5.6 The FBO shall undertake stability studies under recommended and reasonably foreseeable storage conditions to substantiate nutrient levels, microbiological safety, sensory acceptability and package integrity until expiry.

5.7 Every food handler shall possess a valid Medical Fitness Certificate issued by a Registered Medical Practitioner before commencement of employment and renewed at least once a year, including such tests – typhoid, tuberculosis and other communicable conditions – as may be indicated; persons suffering from infectious or communicable disease shall not handle product until certified fit; and a Fitness Certificate Register shall be maintained and produced on demand. All handlers shall wear clean protective clothing, head-cover, mask and footwear, observe hand hygiene, and refrain from eating, smoking, chewing tobacco / gutka / pan masala and spitting in processing areas. The establishment shall deploy at least one FoSTaC-certified Food Safety Supervisor for every 25 handlers, or part thereof, and maintain training records.

5.8 Every licensed Food Business Operator shall maintain a documented Food Safety Management System based on HACCP principles, commensurate with the nature and scale of the business, as mandated under Schedule 4 of the FSS (Licensing and Registration of Food Businesses) Regulations, 2011, reviewed annually and on any significant change. Operators in categories notified under the FSS (Food Safety Auditing) Regulations, 2018 shall undergo periodic third-party audit and maintain the audit certificate on premises.

6. PACKAGING AND STORAGE

6.1 Foods for infant nutrition shall be packed in hermetically sealed, clean and sound containers or permitted flexible packs that protect against deterioration. Packaging shall comply with the Packaging Regulations 2018, including applicable migration limits, and shall be free from Bisphenol A as prescribed.

6.2 Every food for infant nutrition shall be packed under inert atmosphere (Regulation 3(2)). Container closure, seal integrity and oxygen/moisture barrier performance shall be validated and routinely verified.

6.3 Products shall be stored and transported under declared conditions, protected from moisture, heat, sunlight, infestation, chemicals and cross-contamination, with FEFO stock rotation and full lot traceability.

6.4 All packaging, filling, wrapping, storage and transport materials which come into contact with the product, or are likely to come into contact with it, shall be of food-grade quality conforming to the FSS (Packaging) Regulations, 2018 (Regulation 3(2)); every package shall be clean, hygienic and tamper-proof (Regulation 3(5)); the printed surface shall not come into direct contact with the product (Regulation 3(10)); printing inks shall conform to IS 15495 (Regulation 3(9)); and packaging materials shall conform to the Indian Standards specified in Schedules I, II and III to the said Regulations as applicable to the material used. Newspaper, recycled or reclaimed paper or board, and recycled plastic from any source other than FCM-rPET produced by a recycler holding prior authorisation of the Food Authority, shall not be used in contact with a covered product (Regulation 3(11) and Regulation 4(4)(e)); tin containers once used shall not be re-used for the packaging of any article of food (Regulation 3(7)); and no container previously used for any non-food, chemical or hazardous substance shall be used in any circumstance whatsoever.

6.5 All packaging materials of plastic origin shall pass the overall migration limit of 60 mg/kg or 10 mg/dm² when tested as per IS 9845, with no visible colour migration (Regulation 4(4)(b)), and shall not release substances exceeding the specific migration limits prescribed in Table 1 to Regulation 4(4)(c); pigments and colorants used in plastics shall conform to IS 9833 (Regulation 4(4)(d)).

6.6 Every Food Business Operator shall obtain and hold a certificate of conformity issued by a NABL-accredited laboratory, against the FSS (Packaging) Regulations, 2018, in respect of every packaging material which comes into direct contact with the product or is likely to come into contact with it (Regulation 3(14)). The certificate shall be material-wise and supplier-wise, shall be kept current, and shall be produced to the Food Safety Officer on demand; failure to hold it shall attract an Improvement Notice under Section 32 of the Act.

7. LABELLING AND FEEDING INFORMATION

7.1 Every retail and non-retail package shall comply with the Labelling and Display Regulations and the additional declarations prescribed for its product category under the Foods for Infant Nutrition Regulations and the IMS Act. Product-specific text, placement, type size and conspicuousness shall be reproduced exactly as legally prescribed.

Mandatory verification point	Required control
Identity and age	True statutory name; clear intended age; complementary feeding not before six months where applicable
Breastfeeding statement	Prescribed prominent statement including ‘MOTHER’S MILK IS BEST FOR YOUR BABY’ and corresponding statutory wording

Mandatory verification point	Required control
Preparation	Exact powder-water ratio, potable water instructions, feeding table, use immediately, discard leftovers
Safety warning	Incorrect preparation and storage may make the baby ill; medical supervision where prescribed
Composition	Ingredients in descending order; allergen/source declaration; nutrition per prescribed basis; nutrient names and units
Traceability	Manufacturer/marketer/importer details, FSSAI licence, batch/lot, manufacture and expiry/use-by, country of origin
Storage	Before and after opening; closure; time within which opened pack must be consumed
Prohibited presentation	No infant/mother picture, feeding bottle or idealising text/device where prohibited; no equivalence/superiority to breast milk

7.2 Labels shall be clear, prominent, indelible and legible. Translations shall not contradict the mandatory English or Hindi declaration. A sticker shall not be used to conceal mandatory information, cure a substantive misrepresentation, alter batch/date particulars or regularise a product that is otherwise non-compliant.

7.3 Nutrition and ingredient information displayed on an e-commerce platform shall match the physical label. The product shall not be offered for sale online unless mandatory pre-sale information is available to the consumer.

7.4 In particular, under Section 6(1) of the IMS Act, no person shall produce, supply or distribute any infant milk substitute or infant food unless every container or label bears, in a clear, conspicuous, easily readable and understandable manner, the words "IMPORTANT NOTICE" in capital letters in the language prescribed under the Rules, and thereunder in the same language –

(a) the statement "MOTHER'S MILK IS BEST FOR YOUR BABY" in capital letters;

(b) a statement that the product should be used only on the advice of a health worker as to the need for its use and the proper method of its use;

(c) a warning that the product is not the sole source of nourishment of an infant;

(d) the instructions for its appropriate preparation and a warning against the health hazards of inappropriate preparation;

(e) the ingredients used;

(f) the composition or analysis;

(g) the storage conditions required;

(h) the batch number, date of manufacture and the date before which it is to be consumed; and

(i) such other particulars as are prescribed.

Under Section 6(2), no such container or label shall have pictures of an infant or a woman or both, or pictures, graphic material or phrases designed to increase saleability, or the word "humanised" or "maternalised" or any similar word, or such other particulars as are prescribed. Contravention of Section 6 is punishable under Section 20(2) of the IMS Act.

7.5 In addition, under Regulation 4 of the Foods for Infant Nutrition Regulations, every container or label shall carry –

(a) the words "IMPORTANT NOTICE" in capital letters and, thereunder, the statement "MOTHER'S MILK IS BEST FOR YOUR BABY" in capital letters not less than five millimetres in height, on the front of the pack, in a colour contrasting with the background; and, for infant food, the statement "Infant food shall be introduced only after the age of six months and up to the age of two years" (Regulation 4(1)(a)); the breast-milk statement alone being dispensed with only for a food for special medical purpose where breast-feeding is contra-indicated for the condition concerned;

(b) the statements required by Regulation 4(1)(b) to (d), including the prescribed warning – "Warning/Caution – Careful and hygienic preparation of infant foods or infant milk substitute is most essential for health. Do not use fewer scoops than directed since diluted feeding will not provide adequate nutrients needed by your infant. Do not use more scoops than directed since concentrated feed will not provide the water needed by your infant.";

(c) the approximate composition per 100 g or 100 ml with energy value; the storage condition "Store in a cool and dry place in an air tight container" or the like, with the period within which the opened contents must be used; the feeding chart, directions for use and instruction to discard leftover feed; instructions for use of the measuring scoop (level or heaped) and the quantity per scoop, the scoop being supplied with the pack; the batch number, month and year of manufacture and use-by / expiry date; the protein efficiency ratio (minimum 2.5) where a higher-quality-protein claim is made; and the specific names and class titles of any permitted food additives (Regulation 4(1)(e) to (k));

(d) the allergen warning where ingredients of known allergenicity are present (Regulation 4(5)), and the warning "Warning: Boiled and cooled water shall be used to prepare this product and any leftover product must be discarded to reduce the risk of infection" (Regulation 4(6)); and the statement "Contains no milk or milk products or milk derivatives" where applicable (Regulation 4(3));

(e) no picture of an infant or a woman; no picture, graphic or phrase designed to increase saleability; and none of the expressions "Humanised", "Maternalised", "Full Protein Food", "Energy Food", "Complete Food", "Health Food" or any similar expression (Regulation 4(2)); and

(f) the product-specific declarations – "FOR THE PRETERM BABY (BORN BEFORE 37 WEEKS)" with the product name and "RECOMMENDED TO BE TAKEN UNDER MEDICAL ADVICE ONLY" for preterm infant milk substitutes (Regulation 13); "LACTOSE-FREE" and "RECOMMENDED TO BE USED

UNDER MEDICAL ADVICE ONLY" with the prescribed statements for lactose-free infant milk substitutes (Regulation 14); the corresponding advisory for hypoallergenic infant milk substitutes (Regulation 15); "FOOD FOR SPECIAL MEDICAL PURPOSE" in the immediate proximity of the name, the statement of the condition for which it is intended, "RECOMMENDED TO BE USED UNDER MEDICAL ADVICE ONLY", the sole-source statement and the warning that the product is not for parenteral use, for foods for special medical purpose (Regulation 12(3)); "Traditional Food for Infants" on the front of pack (Regulation 11(3)); and the statement "mono grain based complementary foods for use in specific conditions under medical guidance only" where so required (Regulation 9).

8. ADVERTISING, CLAIMS AND IMS ACT RESTRICTIONS

8.1 No person shall advertise, promote, distribute, supply or market a covered product in a manner prohibited by the IMS Act. This applies across television, print, outdoor media, websites, search advertisements, marketplaces, social media, influencers, messaging applications, parenting platforms, hospitals, pharmacies, conferences and point-of-sale displays.

Prohibited/high-risk conduct	**Direction**
Equivalence or superiority claim	No claim such as 'closest to mother's milk', 'humanised', 'better immunity/IQ' or similar idealisation unless specifically lawful; IMS prohibition prevails
Free samples and gifts	No samples, gifts, coupons, cashback, loyalty inducement or bundled benefit prohibited by law
Health-system promotion	No prohibited display, donation, low-price supply, branded educational material or direct promotion through hospitals and health workers
Consumer contact	No prohibited direct or indirect contact with pregnant women or mothers for promotion
Sponsorship	No sponsorship, funding, contribution, hospitality, travel, registration or speaker fee, grant or other benefit to a health worker, institution or association – including for conferences, scientific meetings, seminars, workshops, CME/CPD programmes, courses or fellowships (see 8.5)
Cross-promotion	Do not use colour, logo, mascot, name or layout of a covered product to indirectly promote it through another product

8.2 Scientific substantiation under the Advertising and Claims Regulations is necessary but not sufficient: where the IMS Act prohibits promotion, a scientifically supportable statement cannot be used as promotional communication.

8.3 Every FBO and e-commerce entity shall preserve for inspection all creatives, media plans, influencer arrangements, discount campaigns, sponsorships, donations and healthcare-institution communications for the preceding three years or the longer statutory period.

8.4 For the removal of doubt, the following are prohibited by the IMS Act in relation to infant milk substitutes, feeding bottles and infant foods, and every Food Business Operator shall ensure compliance –

(a) Section 3: advertising, or taking part in the publication of any advertisement for their distribution, sale or supply; giving an impression or creating a belief in any manner that they are equivalent to or better than mother's milk; or taking part in their promotion

(b) Section 4: supplying or distributing samples, or gifts of utensils or other articles; contacting any pregnant woman or mother of an infant; or offering inducement of any other kind, for the purpose of promoting their use or sale

(c) Section 5: donating or distributing them to any person except an orphanage, or donating or distributing informational or educational equipment or material relating to them save through the health care system under the prescribed conditions

(d) Section 7: issuing educational or other material dealing with infant feeding intended to reach pregnant women or mothers without the prescribed information on breast-feeding, and using any such material to promote their use or sale

(e) Section 8: using any health care system for the display of placards or posters or distribution of promotional material; making any payment to any person working in the health care system for promotion; demonstrating feeding with them by any person other than a health worker; and distributing them to mothers otherwise than through an institution engaged in maternal or infant health care

(f) Section 9: offering or giving financial inducements or gifts to a health worker or his family, or any contribution or pecuniary benefit to a health worker or association of health workers including funding of seminars, meetings, conferences, educational courses, contests, fellowships, research work or sponsorship; and

(g) Section 10: fixing employees' remuneration or commission on the basis of sales volume, and employing such employees to educate pregnant women or mothers on pre-natal or post-natal care.

8.5 Sponsorship of professional and medical education – For the avoidance of doubt, and in terms of Sections 8(2) and 9 of the IMS Act, no producer, supplier, distributor or seller of infant milk substitutes, feeding bottles or infant foods, and no person acting on its behalf, shall offer or give – directly or indirectly, including through an event organiser, professional conference organiser, medical association, society, trust, foundation, agency or intermediary – any sponsorship, funding, financial contribution, hospitality, travel or accommodation support, registration fee, speaker or chairperson fee, honorarium, educational grant, research grant, award, prize or other pecuniary benefit to a health worker, a health care system (including a hospital, nursing home, maternity home, pharmacy or drug store) or an association of health workers, in relation to any medical conference, scientific meeting, seminar, workshop, symposium, Continuing Medical Education (CME) programme, Continuing Professional Development (CPD) programme, educational course, contest, fellowship,

research work or similar professional event. Stalls, banners, branded stationery, product displays, satellite sessions or "scientific" presentations at such events relating to covered products, and the funding of such events by such persons, are within the prohibition. Every hospital, medical college, association of health workers and organiser of such an event in the State is requested, and every Food Business Operator is directed, to ensure compliance; and every such sponsorship, funding or benefit, whether described as educational, scientific, unrestricted or otherwise, shall be recorded and reported by the Food Safety Officer in the manner directed in Clause 13.

9. IMPORT, DISTRIBUTION, RETAIL AND E-COMMERCE

9.1 Importers shall ensure prior conformity with the Import Regulations, product standards, label requirements, shelf-life norms, licensing and applicable BIS requirements. Post-import relabelling shall be limited to what is legally permissible and authorised.

9.2 Distributors and retailers shall procure only against valid invoices from licensed sources, verify product identity, FSSAI/BIS particulars, batch, intact seal, expiry and storage condition, and maintain one-step-back/one-step-forward traceability.

9.3 Expired, damaged, recalled, temperature-abused, insect-infested, leaking, bulged, rusted or tampered packs shall be immediately segregated, marked 'NOT FOR SALE' and disposed of/returned under documented control.

9.4 E-commerce entities shall verify seller licences, prevent listing of prohibited advertisements or promotions, display mandatory label information before sale, preserve seller and transaction records and promptly delist/recall non-compliant products.

10. TRACEABILITY, COMPLAINTS AND RECALL

10.1 Every FBO shall maintain batch-wise traceability from each critical raw material and premix to every consignee. Trace-back and trace-forward information shall be capable of production to the competent authority without delay and ordinarily within four hours of demand.

10.2 A documented complaint and adverse-event system shall classify, investigate and trend complaints relating to illness, preparation, foreign matter, microbiology, allergy, nutrient deficiency/excess, package failure and misleading representation.

10.3 Where an FBO has reason to believe that a product is unsafe or non-compliant in a manner requiring withdrawal, it shall immediately initiate recall, inform the competent authority, stop sale across physical and digital channels, identify affected batches and submit effectiveness checks and disposal records.

10.4 Reporting of suspected adverse events by hospitals and clinicians – Hospitals, neonatal and paediatric units, paediatricians, other registered medical practitioners and health-care institutions shall report, expeditiously suspected adverse events associated with foods for infant nutrition, including suspected food-borne illness, sepsis or meningitis in neonates and infants where a powdered formula has been fed,

microbiological contamination, allergic reactions, foreign matter, preparation-related injury or illness, suspected nutrient deficiency or excess, and any other serious or unusual event potentially associated with a product. Every such report shall be forwarded within twenty-four hours to the Designated Officer of the area in which the product was purchased or the manufacturer is located, who shall obtain the product details, batch number, retention sample where available and the clinical particulars, initiate trace-back under sub-clause 10.1 and sampling under sub-clause 12.3, and share the report with the State and District Surveillance Officers of the Integrated Disease Surveillance Programme.

10.5 **Consumer reporting –** The Administration shall maintain, and publicise on every label-verification and awareness communication, an accessible mechanism – through its toll-free helpline, its online complaint portal and the Food Safety Connect application of the Food Authority – for consumers to report suspected safety, quality, labelling or promotional violations concerning foods for infant nutrition. Reports shall, wherever available, capture the product and brand name, the name of the manufacturer / marketer, the batch or lot number, the date of manufacture and best-before / use-by date, the place or online platform of purchase and the invoice, the nature of the complaint or adverse event, and supporting photographs of the pack, label and product. Every report shall be registered, acknowledged, assigned to the jurisdictional Designated Officer within two working days, and disposed of with a reasoned reply to the complainant; and the number of reports received and acted upon shall be included in the quarterly report to the Commissioner.

10.6 **Reporting by Food Business Operators –** Every manufacturer, importer and brand owner shall, on receipt of any complaint or information of a serious adverse event of the kind described in sub-clause 10.4 in respect of its product, inform the Designated Officer of the area in which its principal place of business in the State is situated within forty-eight hours, together with the batch particulars and the action taken, and shall thereafter act in accordance with the FSS (Food Recall Procedure) Regulations, 2017 wherever the facts so warrant.

11. NODE-WISE COMPLIANCE REQUIREMENTS

In addition to the general duties in Clauses 3 to 10, every Food Business Operator shall comply with the requirements applicable to its node of operation set out below. These requirements are indicative and shall be read with Schedule 4, the FSS (Foods for Infant Nutrition) Regulations, 2020 and the IMS Act; in case of any variance, the Act, the Regulations and the IMS Act shall prevail.

11.1 Manufacturer

11.1.1 Valid licence with the exact product category endorsed in FoSCoS; BIS licence and Standard Mark where mandatory; approved formula, specifications and qualified suppliers for every product.

11.1.2 Conformity of every batch to the compositional and microbiological standard for its category throughout declared shelf life; no unapproved ingredient, additive, strain or substance; nutrient overages scientifically justified and within maximum limits.

11.1.3 GMP / GHP / HACCP-based manufacture with dry-zone segregation, environmental monitoring for Cronobacter and Salmonella, and positive release of every batch by an authorised competent person.

11.1.4 In-house quality control, with batch-wise testing for identity, composition, micronutrients, microbiology and contaminants through an in-house or NABL-accredited / FSSAI-notified laboratory; retention samples and analytical records preserved for shelf life plus one year.

11.1.5 Hermetically sealed, tamper-evident, BPA-free packaging validated for seal integrity and barrier performance, with certificate of conformity for every food-contact material; complete labelling at source including the IMS Act declarations.

11.1.6 Stability studies, complaint and adverse-event system, mock recall at least annually, and traceability and recall capability under the FSS (Food Recall Procedure) Regulations, 2017.

11.1.7 No advertisement, sample, gift, sponsorship, health-worker inducement or cross-promotion in contravention of the IMS Act; preservation of all promotional records for three years.

11.2 Brand Owner / Marketer (including Contract Manufacture)

11.2.1 Verification and retention of the contract manufacturer's licence, product endorsement, BIS coverage, batch-release records and certificates of analysis; contractual traceability to every batch.

11.2.2 Full statutory responsibility for the label, claims, advertisement, promotion, recall and IMS Act compliance of every product marketed under its brand; private contractual allocation shall not defeat statutory liability.

11.3 Repacker and Re-labeller

11.3.1 Valid licence endorsed for "Repacking" / "Re-labelling"; repacking or re-labelling only of product received from a licensed manufacturer / importer, supported by invoices and certificates of analysis establishing full traceability to the original source and batch.

11.3.2 No repacking of expired, near-expiry, sub-standard or unsafe product; no extension or alteration of the original best-before date; no blending, topping-up or alteration of identity; hermetic re-sealing under inert atmosphere where prescribed; fresh repacker batch code linkable to the original batch; declaration of both the original manufacturer and the repacker on the label.

11.3.3 Re-labelling shall never be used to misrepresent the source, identity, grade, batch, date of manufacture or best-before of the product, nor to conceal or obliterate the original manufacturer's particulars or the mandatory IMS Act declarations; re-labelling of expired or unsafe product shall be prosecuted as misbranding / unsafe food.

11.4 Importer

11.4.1 Central Licence; clearance through the FSSAI import clearance system; conformity to Indian standards, shelf-life norms, labelling requirements, the IMS Act

declarations and BIS requirements before release for sale; post-import re-labelling only as legally permissible and authorised.

11.5 Wholesaler / Distributor / Transporter

11.5.1 Stocking only of properly licensed, packed, labelled and (where applicable) BIS-marked product; verification on receipt of the supplier's licence number, batch, best-before and seal integrity; rejection of open, unsealed, damaged or tampered consignments and intimation of the supplier to the Food Safety Officer.

11.5.2 Storage away from moisture, heat, sunlight, infestation, chemicals and odour-bearing or hazardous substances; FEFO observed; clean, dry, pest-controlled godowns; purchase and sale invoices establishing back-to-source and onward traceability retained for not less than shelf life plus one year.

11.5.3 Transport only in clean, dry, covered, dedicated food-grade vehicles, never together with hazardous, chemical or non-food cargo; no distribution of samples or gifts and no participation in any prohibited promotion; liability under Section 27 for the product stored and distributed.

11.6 Retailer / Pharmacy / Hospital Supplier

11.6.1 Sale only of pre-packed, hermetically sealed, properly labelled (and, where applicable, BIS-marked) product; no open or loose sale; no sale of expired, sub-standard, unsafe or damaged / bulged / leaking packs.

11.6.2 No display of placards, posters, branded material or promotional offers for infant milk substitutes or infant foods; no free samples, gifts, coupons or inducements; no supply to any hospital or health-care institution save as permitted by the IMS Act.

11.6.3 Storage away from heat, sunlight and moisture; display of the FSSAI Registration / Licence; issue of a bill; retention of purchase invoices for traceability; and verification on receipt of seal integrity, batch and best-before.

11.7 E-commerce Entity / Online Seller

11.7.1 An e-commerce or online seller of a covered product shall hold the appropriate FSSAI Licence and shall not be listed on any platform without a valid licence; the platform shall verify and display the seller's FSSAI licence number, and only pre-packed, sealed and labelled product shall be sold online.

11.7.2 The platform shall display the mandatory label information, including the IMS Act declarations, before sale; shall not host or serve any advertisement, sponsored listing, influencer content, discount, cashback, sample or bundled offer prohibited by the IMS Act; shall preserve seller and transaction records; and shall promptly delist and recall non-compliant products on intimation.

12. DIRECTIONS TO ENFORCEMENT OFFICERS

12.1 Joint Commissioners and Designated Officers shall map all manufacturers, repackers, importers, warehouses, distributors, major retailers, pharmacies, hospital suppliers and e-commerce sellers within their jurisdiction and adopt risk-based inspection.

12.2 Inspection shall separately record: product identity; licence and BIS status; formulation and records; hygiene; packaging; label; online/offline promotion; traceability; complaints; and recall readiness. A minimum inspection checklist for the purpose may be prescribed by the Commissioner of Food Safety.

12.3 Sampling shall be product-specific and legally representative. The sampling documents and memorandum to the laboratory shall state the exact product category and age band as classified in Annexure A, the stage/age, batch, storage condition and parameters requiring analysis. Statutory sampling procedure and chain of custody shall be strictly followed.

12.4 Label panels, point-of-sale material and digital advertisements shall be preserved by dated photographs, screenshots, URL, account identity, transaction test-purchase where required, invoice and an officer's contemporaneous record. Electronic evidence shall be preserved in accordance with applicable evidence law.

12.5 Officers shall not mechanically label every deviation as unsafe. Classification shall follow the statutory definitions, nature of risk, analyst's report and evidence. Misbranding, substandard food, misleading advertisement, prohibited sale, unlicensed business and unsafe food shall be recorded as distinct contraventions where their ingredients are made out.

12.6 Where facts disclose an IMS Act violation, the case shall be separately examined under that Act and Rules by the officer/authority legally empowered thereunder. FSS Act procedure shall not be assumed to substitute the cognizance, authorisation or complaint requirements of the IMS Act.

12.7 Any immediate prohibition, seizure, recall, suspension, cancellation or prosecution shall be based on the competent authority's satisfaction, recorded reasons, statutory power, proportionality and observance of applicable procedure and natural justice, except where law authorises urgent action in the interest of public health.

13. ENFORCEMENT OF THE IMS ACT – RESPONSIBILITY, POWERS AND DUTIES OF OFFICERS

13.1 Statutory scheme – The IMS Act is, by Section 25 thereof, in addition to and not in derogation of the Act. The enforcement machinery of the IMS Act is, by Sections 12, 13 and 21 thereof as amended by Section 100 of the Act, the machinery of this Administration: the Food Safety Officer appointed under the Act is the officer empowered to enter, search and seize, and the Designated Officer or the Food Safety Officer, on the direction of the Commissioner of Food Safety under Section 42 of the Act, is the complainant on whose complaint the Court takes cognizance. Every Food Safety Officer, Designated Officer and Joint Commissioner (Food) shall accordingly treat enforcement of the IMS Act as an integral part of his duties in relation to foods for infant nutrition.

13.2 Entry and search (Section 12) – Any Food Safety Officer, or any officer not below the rank of a Class I officer authorised in this behalf by the State Government, who has reason to believe that Section 6 (information on containers and labels) or Section 11

(standards and BIS Standard Mark) of the IMS Act has been or is being contravened, may enter and search at any reasonable time any factory, building, business premises or other place where any trade or commerce in infant milk substitutes, feeding bottles or infant foods is carried on or where such products are produced, supplied or distributed. The provisions of the Code of Criminal Procedure relating to searches and seizures apply to every search and seizure under the IMS Act, and the officer shall record his reasons to believe before entry and prepare a search memorandum in the presence of witnesses.

13.3 Seizure (Section 13) – Where the Food Safety Officer or authorised officer has reason to believe that, in respect of any infant milk substitute, feeding bottle or infant food or container thereof, any provision of the IMS Act – including Sections 3, 4, 5, 7, 8, 9 and 10 – has been or is being contravened, he may seize such substitute, bottle, food or container, together with the labels, wrappers, inserts, placards, posters, promotional material, samples, gifts and records evidencing the contravention. A seizure memorandum shall be prepared and a copy given to the person from whom the seizure is made. No seized article shall be retained for more than ninety days from the date of seizure unless the approval of the District Judge within whose jurisdiction the seizure was made has been obtained for such retention; the Designated Officer shall move the District Judge for such approval well before the expiry of ninety days wherever the article is required as evidence.

13.4 Confiscation (Sections 14 to 19) – Every seized article is liable to confiscation. Within ninety days of seizure the Designated Officer shall cause a notice in writing to be given to the owner under Section 18, stating the grounds on which confiscation is proposed and affording a reasonable opportunity of written representation and hearing; failing such notice within ninety days the article must be returned. Confiscation is adjudged by the principal civil court of original jurisdiction within whose local limits the seizure was made (or such other court as the Central Government may notify under Section 17), which may give the owner an option under Section 15 to pay, in lieu of confiscation, such amount as the court thinks fit, subject to the owner first bringing the article into conformity with the IMS Act. An appeal lies under Section 19. Confiscation does not bar prosecution (Section 16).

13.5 Prosecution and cognizance (Sections 20 to 23) – Contravention of Sections 3, 4, 5, 7, 8, 9 or 10, of sub-section (2) of Section 11, or of the Rules made under Section 26 of the IMS Act is punishable under Section 20(1) with imprisonment which may extend to three years, or with fine which may extend to five thousand rupees, or with both; and contravention of Section 6 or of sub-section (1) of Section 11 is punishable under Section 20(2) with imprisonment which shall not be less than six months but which may extend to three years and with fine which shall not be less than two thousand rupees. Offences under the IMS Act are cognizable and bailable (Section 23). Under Section 21, no Court shall take cognizance of any offence under the IMS Act except upon a complaint in writing made by (a) the Designated Officer or the Food Safety Officer directed under Section 42 of the Act, or (b) an officer not below the rank of a Class I officer authorised by general or special order by the Government, or (c) a

representative of a voluntary organisation engaged in child welfare, development and nutrition notified by the Government in the Official Gazette. Accordingly, on detection of an offence under the IMS Act the Food Safety Officer shall submit his report and evidence to the Designated Officer within three days; the Designated Officer shall forward the same, with his recommendation and a draft complaint, to the Commissioner of Food Safety through the Joint Commissioner (Food) within seven days; and, on the direction of the Commissioner under Section 42 of the Act, the Designated Officer or the Food Safety Officer shall file the complaint before the competent Judicial Magistrate. Where an offence under the Act (in particular Sections 24 read with 53, 52 or 59) is disclosed on the same facts, proceedings under the Act shall be taken independently and in addition, in the manner directed in sub-clauses 12.5 and 12.6.

13.6 Offences by companies (Section 22) – Where an offence under the IMS Act is committed by a company, every person who at the time was in charge of and responsible to the company for the conduct of its business, as well as the company, is deemed guilty; and where the offence is committed with the consent or connivance of, or is attributable to neglect on the part of, any director, manager, secretary or other officer, such person is also deemed guilty. The complaint shall accordingly arraign the company and such persons, and the report of the Food Safety Officer shall identify them with supporting documents.

13.7 Scope of the prohibitions to be enforced – Officers shall bear in mind that, under the IMS Act, "advertisement" includes any label, wrapper, document, visible representation or announcement made by electronic, audio or visual transmission; "promotion" means employing directly or indirectly any method of encouraging any person to purchase or use an infant milk substitute, feeding bottle or infant food; "infant milk substitute" means any food marketed or represented as a partial or total replacement for mother's milk for an infant up to two years; "infant food" means any food, by whatever name called, marketed or represented as a complement to mother's milk after six months and up to two years; and "health care system" includes a pharmacy, a drug store, a health worker in private practice and any association of health workers. The prohibitions in Section 3 (advertisement, equivalence or superiority to mother's milk, and promotion), Section 4 (samples, gifts, contact with pregnant women and mothers, and inducements), Section 5 (donation or distribution except to an orphanage), Section 7 (content of educational material), Section 8 (use of the health care system for display, distribution, payments and demonstration), Section 9 (financial inducements, gifts, contributions, funding of seminars, conferences, fellowships, research or sponsorship to health workers or their associations) and Section 10 (sales-volume-linked remuneration and employees educating mothers) shall each be examined and recorded separately.

13.8 Coordination with the health care system – The Joint Commissioners (Food) shall coordinate with the Deputy Director of Health Services, District Health Officer, Civil Surgeon, Deans of Medical Colleges, the District Programme Officer (ICDS) and the managements of private hospitals, nursing homes, maternity homes and pharmacies in

the Division for the observance of Sections 5, 8 and 9 of the IMS Act within health-care institutions and in relation to conferences, CME/CPD programmes and professional events organised or hosted by them (sub-clause 8.5), and shall request the Commissioner, Health Services to issue corresponding instructions to health workers under his control. The Joint Commissioners (Food) shall maintain a register of every IMS Act matter detected, the seizure and confiscation proceedings, the complaint filed and its outcome, and shall report the same quarterly to the Commissioner of Food Safety.

13.9 Nothing in this Order enlarges the powers conferred by the IMS Act or dispenses with any requirement of Sections 12, 13, 18 or 21 thereof; every action shall be taken strictly within the four corners of that Act and the Rules made thereunder.

14. ENFORCEMENT RESPONSE MATRIX

Observation	Prima facie legal response	Evidence focus
Nutrient outside prescribed range	Substandard; assess unsafe classification only on statutory risk evidence	Category table, method, uncertainty, shelf-life point
Pathogen or harmful contaminant	Unsafe food; recall/seizure and prosecution as facts warrant	Accredited method, chain of custody, risk and injury
Missing/incorrect mandatory declaration	Misbranded food; improvement/adjudication as legally appropriate	All label panels and applicable exact text
Prohibited promotional claim/sample	Separate IMS Act action; FSS sections 24/53 where ingredients exist	Creative, reach, sponsor, recipient, transaction
No valid FSSAI licence	Section 63 and regulatory action	Premises, activity, turnover/category, person in charge
BIS Standard Mark absent/invalid on infant milk substitute, infant food or feeding bottle	Contravention of Section 11 of the IMS Act (Section 20(2)); seizure under Section 13 and complaint under Section 21	BIS licence, container/label, exact product
Human milk or its products collected, processed, sold or advertised	Not a permitted food business; stop-sale, seizure, delisting, Section 63 and further action as facts warrant (Clause 4B)	Advisory dated 24.05.2024, listing/URL, invoices, source of milk, storage
Traceability failure	Direction/improvement and substantive action as facts warrant	Invoices, batch and distribution records
Expired/damaged/tampered stock	Stop sale, segregate, sample/seize where warranted	Quantity, condition, expiry, storage, sale evidence

Note: This matrix is guidance for uniform scrutiny and does not replace the statutory satisfaction required in an individual case.

15. PUNISHMENTS, PROSECUTION AND PENALTIES

Non-compliance with the Act, the Regulations, the IMS Act and this Order shall render the Food Business Operator liable to prosecution and to the punishments and penalties under Chapter IX of the Food Safety and Standards Act, 2006 and under the IMS Act.

15.1 Punishments under the Act (offences carrying imprisonment, triable by Court)

(a) Unsafe food, including infant formula or infant food containing a pathogen, melamine or a non-permitted substance (Section 59) –

i) where death results, imprisonment not less than seven years extending to imprisonment for life and fine not less than ₹10,00,000;

ii) where grievous injury results, imprisonment up to six years and fine up to ₹5,00,000;

iii) where non-grievous injury results, imprisonment up to one year and fine up to ₹3,00,000;

iv) and where no injury results, imprisonment up to three months and fine up to ₹3,00,000.

(b) Subsequent and repeat offences (Section 64) – twice the punishment which might have been imposed on a first conviction, a further fine up to ₹1,00,000 per day for a continuing contravention, and suspension or cancellation of the Licence or Registration.

(c) Interfering with, or removing or tampering with, any article seized or detained by the Food Safety Officer (Section 60) – imprisonment up to six months and fine up to ₹2,00,000.

(d) Offences by companies (Section 66) – every director, partner, manager or other person in charge of and responsible for the conduct of the business shall be personally liable to be proceeded against and punished alongside the entity; and the Court or Adjudicating Officer may direct compensation in case of injury or death of a consumer (Section 65 – not less than ₹5,00,000 in case of death; up to ₹3,00,000 for grievous injury; up to ₹1,00,000 for other injury).

15.2 Penalties under the Act (imposed by the Adjudicating Officer)

(a) Carrying on business without a valid Licence or Registration – penalty up to ₹10,00,000.

(b) Misleading advertisement or false claim, including any equivalence, immunity, growth or IQ claim – penalty up to ₹10,00,000.

(c) Giving false information – penalty up to ₹10,00,000.

(d) Possessing an adulterant – penalty up to ₹10,00,000 where the adulterant is injurious to health.

(e) Selling product not of the nature, substance or quality demanded – penalty up to ₹5,00,000.

(f) Sub-standard product, including product not conforming to the prescribed compositional range – penalty up to ₹5,00,000.

(g) Misbranded product, including product lacking the prescribed breastfeeding statement, age, preparation or warning declarations, or bearing a prohibited picture or idealising text – penalty up to ₹3,00,000.

(h) Failure to comply with the directions of the Food Safety Officer – penalty up to ₹2,00,000; and

(i) contraventions for which no specific penalty is provided – penalty up to ₹2,00,000.

(j) Unhygienic or unsanitary processing or manufacturing – penalty up to ₹1,00,000;

(k) and food containing extraneous matter – penalty up to ₹1,00,000.

15.3 Offences under the IMS Act

(a) Contravention of Section 3, 4, 5, 7, 8, 9 or 10, of sub-section (2) of Section 11, or of the Rules made under the IMS Act (Section 20(1)) – imprisonment which may extend to three years, or fine which may extend to ₹5,000, or both.

(b) Contravention of Section 6 (information on containers and labels) or of sub-section (1) of Section 11 (standards and BIS Standard Mark) (Section 20(2)) – imprisonment not less than six months and up to three years, and fine not less than ₹2,000; the Court may, for adequate and special reasons recorded in the judgment, impose imprisonment not less than three months and up to two years and fine not less than ₹1,000.

(c) Confiscation of the infant milk substitute, feeding bottle, infant food or container in respect of which the IMS Act is contravened (Section 14), without prejudice to punishment (Section 16).

(d) Offences by companies (Section 22) – every person in charge of and responsible for the conduct of the business, and every director, manager, secretary or other officer with whose consent or connivance or through whose neglect the offence was committed, is liable to be proceeded against and punished alongside the company.

(e) Offences under the IMS Act are cognizable and bailable (Section 23); cognizance is taken by the Court only on a complaint in writing by the persons specified in Section 21, in the manner directed in Clause 13.

15A. ACTION ON LICENCE / REGISTRATION

Where the Designated Officer has reasonable ground for believing that a Food Business Operator has failed to comply with the Regulations applicable to the food business, appropriate action may be initiated under Section 32 of the Act in accordance with the procedure prescribed therein.

Where the circumstances attract Section 33 or Section 34 of the Act, the Designated Officer shall initiate appropriate proceedings and make the requisite application before the competent court for a Prohibition Order or Emergency Prohibition Order, as the case may be.

Suspension or cancellation of a licence or registration shall be undertaken only by the competent Licensing or Registering Authority and strictly in accordance with the Act, the FSS (Licensing and Registration of Food Businesses) Regulations, 2011 and the principles of natural justice, subject to such exceptional statutory provisions as expressly permit immediate action in the interest of public health.

16. COMPLIANCE TIMELINES AND REPORTING

Action	Responsible entity	Timeline
Self-audit of licences, product list, BIS, formulations, labels and promotions	Manufacturers, importers and brand owners	Within 30 days
Stop prohibited advertisement/promotion and unsafe/non-compliant sale	All FBOs and platforms	Immediately
Submit compliance declaration with enclosures (licence, product list, BIS proof, label artwork, COA, self-audit report)	Manufacturers, importers and brand owners	Within 30 days
Jurisdictional mapping and risk plan	Designated Officers	Within 45 days
First consolidated enforcement report	Joint Commissioners to Commissioner	Within 60 days
Notify the contact channels (e-mail, telephone, portal) for clinician and consumer reports (Clauses 10.4 and 10.5)	Commissioner of Food Safety	Within 30 days
Continuing report	Divisions	Quarterly, by 10th of succeeding month

16.1 Nothing in these timelines permits continuation of an unsafe product, prohibited sale, prohibited advertisement or other continuing offence. Immediate statutory action shall be taken wherever warranted.

16.2 Without prejudice to the table above, all requirements under this Order shall be complied with immediately and forthwith from the date of issue, including –

(a) display of the Licence or Registration with the correct Kind of Business and product endorsement;

(b) cessation of all advertisement, promotion, sampling, gifts, inducements, sponsorship and cross-promotion prohibited by the IMS Act, across offline and online channels;

(c) cessation of sale of any product not conforming to its prescribed standard, any unsafe product, any infant milk substitute, infant food or feeding bottle without the BIS Standard Mark required by Section 11 of the IMS Act, and any expired, damaged or tampered pack;

(d) cessation of any re-labelling or stickering that conceals mandatory information or misrepresents the source, batch or date of the product;

(e) withdrawal and recall of any product found unsafe or requiring withdrawal, with intimation to the Commissioner of Food Safety;

(f) use of hermetically sealed, BPA-free, food-grade packaging only, and of dedicated food-grade storage and transport;

(g) arrangements for batch-wise compositional and microbiological testing and positive release;

(h) maintenance of traceability registers, invoices, complaint records and recall plan; and

(i) cessation of any collection, processing, sale, distribution or advertisement of human milk or its products (Clause 4B).

17. NON-COMPLIANCE

17.1 Failure to comply shall invite action under the applicable provisions of the FSS Act, regulations, IMS Act and other laws, including improvement notice, suspension or cancellation of licence, prohibition/stop-sale direction, seizure, recall, adjudication or prosecution, according to the facts and legal competence.

17.2 The manufacturer, importer, brand owner, marketer, distributor, seller, e-commerce entity and persons in charge may each incur liability to the extent of their statutory duties and acts or omissions. Private contractual allocation shall not defeat statutory liability.

18. INDICATIVE NATURE OF THIS ORDER

This Order is indicative in nature and does not purport to be an exhaustive statement of the obligations of Food Business Operators. Every operator shall, at all times, comply with every standard, regulation, guideline, circular and direction issued by FSSAI, by the authorities under the IMS Act and by the Food Safety Commissioner, Maharashtra State from time to time, to the extent legally applicable, whether or not specifically enumerated herein. The non-mention of any requirement shall not be construed as a waiver of the obligation to comply with it.

19. IMPLEMENTATION, ENFORCEMENT AND PRIORITY ADJUDICATION

All officers of the Food and Drug Administration, Maharashtra State shall ensure effective, uniform and risk-based implementation of the Act, Rules and Regulations in relation to foods for infant nutrition, in the manner directed in Clauses 12 and 13 and within the timelines in Clause 16.

Cases involving unsafe food, contamination, non-conforming composition, misbranding or prohibited promotion of foods for infant nutrition shall be processed expeditiously in accordance with law. In adjudication proceedings, the enforcement authority shall place all relevant facts and material before the Adjudicating Officer and seek an appropriate penalty commensurate with the contravention, having due regard to the factors specified in Section 49 of the Act and to the vulnerability of the consumer class concerned. Nothing contained in this Order shall interfere with the

independent exercise of statutory or quasi-judicial discretion by the Adjudicating Officer or any Court.

20. INTERPRETATION, SAVINGS AND SUPPLEMENTARY EFFECT

20.1 This Order shall be read with the Acts, rules, regulations, standards, notifications, directions and court orders in force. In case of conflict, the parent statute and the latest legally operative provision shall prevail.

20.2 Illustrations and checklists are facilitative and shall not narrow any statutory obligation. Officers shall verify the latest consolidated regulation and applicable amendment on the date of inspection and action.

20.3 If any clause is held invalid, the remaining clauses shall continue to operate to the extent permitted by law.

20.4 This Order is intended to facilitate uniform and effective implementation of the Food Safety and Standards Act, 2006 and the Rules and Regulations made thereunder, and of the IMS Act within the competence of the officers of this Administration, and shall be read harmoniously with them. Nothing contained in this Order shall be construed as creating an offence, prohibition, penalty or substantive obligation inconsistent with or beyond the Act, Rules, Regulations, the IMS Act or legally binding directions issued by the Food Safety and Standards Authority of India. In the event of any inconsistency, the provisions of the Act, Rules, Regulations, the IMS Act and such legally binding directions, as applicable, shall prevail; and nothing contained herein shall affect the operation of any other law for the time being in force to the extent that such law continues to apply to the concerned food business or activity.

Digitally signed by
TUKARAM H MUNDHE
Date: 29-09-2026
13:44:04

(Tukaram Mundhe, I.A.S.)
Food Safety Commissioner
Maharashtra State, Mumbai.

Copy to:

Additional Chief Secretary, Food and Drug Administration, Government of Maharashtra.

Copy forwarded for necessary action:

1. All District Collectors.
2. Commissioner, Health Services and Mission Director, National Health Mission, Maharashtra – with a request to sensitise all Government and private hospitals, nursing homes and health workers to the prohibitions of the IMS Act and to coordinate action thereunder.
3. All Joint Commissioners (Food), Food and Drug Administration, Maharashtra.
4. All Assistant Commissioners (Food) / Designated Officers, Food and Drug Administration, Maharashtra.

5. All Food Safety Officers, Food and Drug Administration, Maharashtra.
6. Director, Food Laboratories, Food and Drug Administration, Maharashtra.
7. Director of Medical Education and Research, Maharashtra; Registrar, Maharashtra Medical Council; and President, Indian Academy of Pediatrics (Maharashtra State Branch) – with reference to Clauses 8.5 and 10.4, for circulation to medical colleges, registered medical practitioners and organisers of conferences and CME/CPD programmes.
8. Concerned associations of manufacturers, importers and distributors of foods for infant nutrition, chemists' and druggists' associations, retailers' associations and e-commerce entities – for compliance and onward communication to members.

ANNEXURE A

CLASSIFICATION AND COMPLIANCE CHART OF FOODS FOR INFANT NUTRITION

(Facilitative – see Clause 20.2. Under the FSS (Foods for Infant Nutrition) Regulations, 2020, Version-II of 04.01.2024 incorporating the Corrigenda of 31.03.2021 and the First Amendment Regulations, 2022, read with the IMS Act, 1992)

Sr.	Category	Regulation	Definition / scope	Age	Base / form – key composition points	Category-specific label declarations (in addition to Reg. 4 and IMS Act s. 6)	IMS Act status	BIS Standard Mark (IMS Act s. 11)	Sale / promotion
1	Infant formula	Reg. 7	Breast-milk substitute based on milk of cow, buffalo or other milch animals or mixture, with other proven-suitable ingredients, to meet the nutritional requirements of infants during the first six months; liquid or powder	0–6 months	Milk-based; protein 10–16 g/100 g (2.1–3.4 g/100 kcal); fat 18–25 g/100 g; carbohydrate 45–70 g/100 g; moisture ≤ 4.5%; lactose/glucose polymers preferred; sucrose+fructose ≤ 20% of carbohydrate; DHA ≤ 0.5% of fatty acids, ARA:DHA ≥ 1:1; no preservatives, added colours or flavours	Reg. 4(1)–(6) in full: IMPORTANT NOTICE; MOTHER'S MILK IS BEST FOR YOUR BABY (≥ 5 mm, front of pack); health-worker advice; not sole source; scoop warning; boiled-water warning; feeding chart; scoop supplied	Infant milk substitute – ss. 3–11 apply in full	Mandatory – s. 11(1)	No advertisement, samples, gifts or health-system promotion; sale only in sealed, labelled container
2	Infant milk food	Reg. 7(3) (First Amendment 2022)	Infant formula in powder form manufactured without any vegetable oil, linoleate, vitamin E, starch, specified food additives or optional ingredients	0–6 months	As for infant formula, minus the excluded ingredients	As for infant formula	Infant milk substitute	Mandatory – s. 11(1)	As for infant formula
3	Preterm infant milk substitute	Reg. 13	Infant milk substitute for babies born before 37 weeks, till they attain 40 weeks or as prescribed by physician	Preterm, until 40 weeks / as prescribed	Nutrient requirements per 100 kcal and per kg/day as in the Reg. 13 table (proviso to Reg. 3(5))	"FOR THE PRETERM BABY (BORN BEFORE 37 WEEKS)" with product name on central panel; "RECOMMENDED TO BE TAKEN UNDER MEDICAL ADVICE ONLY"	Infant milk substitute	Mandatory – s. 11(1)	As above; medical advice only
4	Lactose-free infant milk substitute	Reg. 14	Infant formula / follow-up formula for lactose-intolerant infants; soy-protein based or lactose-free cow/buffalo-milk based	As for base formula	Infant formula / follow-up formula nutrients (except milk fat); carbohydrate as glucose, dextrose, dextrin/maltodextrin, maltose, sucrose	"LACTOSE-FREE"; "RECOMMENDED TO BE USED UNDER MEDICAL ADVICE ONLY"; statements that it is to be used only in diarrhoea due to lactose intolerance and withdrawn if no improvement; "CONTAINS NO MILK OR MILK PRODUCTS" where applicable	Infant milk substitute	Mandatory – s. 11(1)	As above; medical advice only
5	Hypoallergenic infant milk substitute	Reg. 15	Infant milk substitute for infants allergic to cow/buffalo/other milch-animal milk protein	As for base formula	Infant formula / follow-up formula nutrients (except milk fat and milk protein); protein extensively hydrolysed whey or casein, or free amino acids only	"HYPOALLERGENIC FORMULA"; "RECOMMENDED TO BE TAKEN UNDER MEDICAL ADVICE ONLY", "CONTAINS NO MILK OR MILK PRODUCTS" where applicable	Infant milk substitute	Mandatory – s. 11(1)	As above; medical advice only
6	Follow-up formula	Reg. 10	Food for infants after six months up to 24 months, intended as the liquid part of the complementary diet when prepared per instructions; powder or liquid	6–24 months	Milk-based; protein ≥ 3 g/100 kcal; nutritionally adequate to contribute to normal growth; powder requires water	Reg. 4 general declarations; not to be represented as a breast-milk substitute for the first six months	Infant milk substitute (partial replacement up to 2 years)	Mandatory – s. 11(1)	As above

Sr.	Category	Regulation	Definition / scope	Age	Base / form – key composition points	Category-specific label declarations (in addition to Reg. 4 and IMS Act s. 6)	IMS Act status	BIS Standard Mark (IMS Act s. 11)	Sale / promotion
7	Milk-cereal-based complementary food	Reg. 8	Food based on milk, cereals and/or legumes, millets, nuts, protein concentrates/isolates, defatted oilseed extracts, prepared for dilution with water/milk; powder, granules or flakes	6–24 months	Total protein ≥ 15 g/100 g (≥ 3.2 g/100 kcal), milk protein ≥ 5 g/100 g; moisture ≤ 5%; no hydrogenated vegetable fats/oils	Reg. 4 declarations incl. "Infant food shall be introduced only after the age of six months and up to the age of two years"	Infant food (complement to mother's milk, 6 months–2 years) – ss. 3–11 apply	Mandatory – s. 11(1)	No advertisement, samples or promotion; sealed and labelled only
8	Processed-cereal-based complementary food	Reg. 9	Product based on cereals, pulses incl. soybean, millets, nuts and edible oilseeds; milled cereals and legumes ≥ 75%; powder, granules or flakes	6–24 months	Sodium ≤ 100 mg/100 kcal of ready-to-eat product; protein ≥ 15% by weight; mono-grain (rice/ragi) variant with 6–9% protein for restricted-protein conditions	Reg. 4 declarations incl. six-month statement; mono-grain product: "mono grain based complementary foods for use in specific conditions under medical guidance only"	Infant food	Mandatory – s. 11(1)	As above
9	Food for infants based on traditional food ingredients	Reg. 11	Foods known to be prepared traditionally at home for infants (rice, wheat flour, semolina, pulses, cereals, spices, fruits, dry fruits, vegetables, milk, ghee, egg), processed and packaged; ready-to-use or for reconstitution	6–24 months	Ingredients safe and compliant; additives as for milk-cereal-based food if required; technologies that retain nutritional and sensory attributes	"Traditional Food for Infants" prominently on front of pack; clear instructions for use; Reg. 4 declarations	Infant food	Mandatory – s. 11(1)	As above
10	Food for special medical purpose intended for infants (Infant FSMP)	Reg. 12	Substitute for human milk or formula specially manufactured for the special nutritional requirements of infants with specific disorders, diseases or medical conditions; liquid or powder	Birth–24 months	Composition based on infant formula / follow-up formula as modified for the condition; sound medical and nutritional principles; scientifically demonstrated adequacy; Legal Metrology standard-pack-size exemption	"FOOD FOR SPECIAL MEDICAL PURPOSE" next to name; "For the nutrition management of …"; "RECOMMENDED TO BE USED UNDER MEDICAL ADVICE ONLY"; sole-source statement; modified nutrients and rationale; precautions/contra-indications; "not for parenteral use"; breast-milk statement dispensed with only where breast-feeding is contra-indicated	Infant milk substitute	Mandatory – s. 11(1)	Medical supervision only; no general promotion
11	Foods for infants with Inborn Errors of Metabolism (IEM)	Reg. 16	Food formulated for oral or enteral (tube) use for the specific dietary management of infants with an inborn error of metabolism; given under medical supervision	Infants, under medical supervision	Nutrients may exceed RDA on scientific/medical need; Schedule I(d) additives	As for FSMP (Reg. 12(3)) with the IEM condition named	Infant milk substitute / infant food as represented	Mandatory – s. 11(1)	Medical supervision only
12	Feeding bottles	IMS Act only (BIS standard)	Any bottle or receptacle used for feeding an infant milk substitute (IMS Act s. 2(d))	—	—	IMS Act s. 7 – container/label particulars as prescribed	Feeding bottle – ss. 3, 4, 8, 9, 11(2)	Mandatory – s. 11(2)	No advertisement or promotion; no depiction on IMS/infant-food labels