



Standards setting process in India

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Structure



- About BIS
- Process of development of Indian standards
- Harmonization with International Standards
- Indian Standard on infant formula

Bureau of Indian Standards (BIS)



- National Standards body of India
- Constituted under the Bureau of Indian Standards Act, 1986 as a statutory body and works under the aegis of Ministry of Consumer Affairs, Food and Public Distribution, Govt. of India.

Objectives

Harmonious development of the activities of Standardization, Quality and Certification

Activities of BIS



- ▣ Formulation of National Standards
- ▣ Certification Schemes
 - Product Certification
 - ▣ Voluntary & Mandatory
 - Hall Marking of Gold Jewellery
 - Imported Goods Certification
 - ECO Mark Scheme
- Management System Certification



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Activities of BIS (contd.)



- Laboratory Services
- Training Services
- Information Services
 - ▣ Technical Information Service Centre
 - ▣ Library Services
 - ▣ Small Scale Industry Facilitation & Information Cell
- Complaints and Grievances Redressal System
- Enforcement Activities

Formulation of National Standards



- **Indian Standards are formulated in a transparent manner through a consensus process by the Technical Committees comprising of experts from all concerned areas such as Consumers, Producers/ Manufacturers, R&D Centres, NGOs, Regulatory Bodies etc.**
- **The Bureau has published over 18000 standards so far.**

Is it mandatory for all manufacturers to adopt Indian Standards ?



- ❖ **Adoption of Indian Standards is generally voluntary in nature and their implementation depends on adoption by concerned parties. An Indian Standard becomes binding if it is stipulated in a contract, referred to in a legislation or made mandatory by specific orders by the Central or State Governments.**

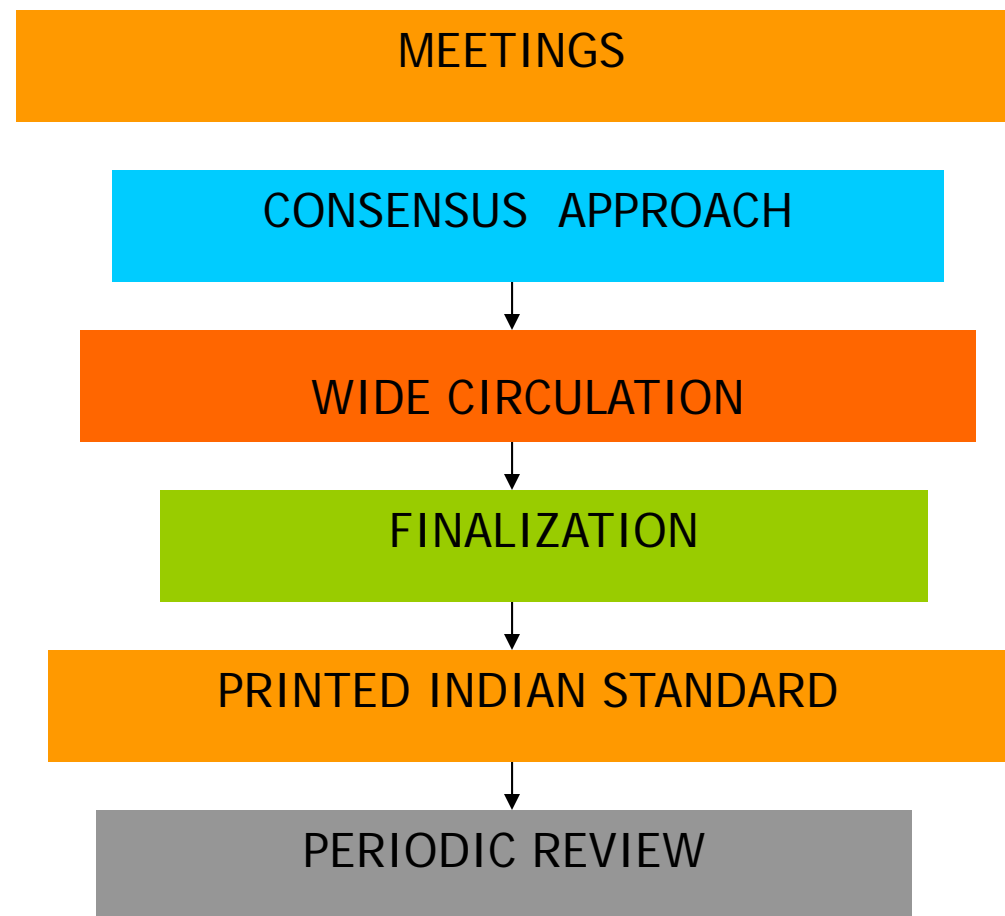
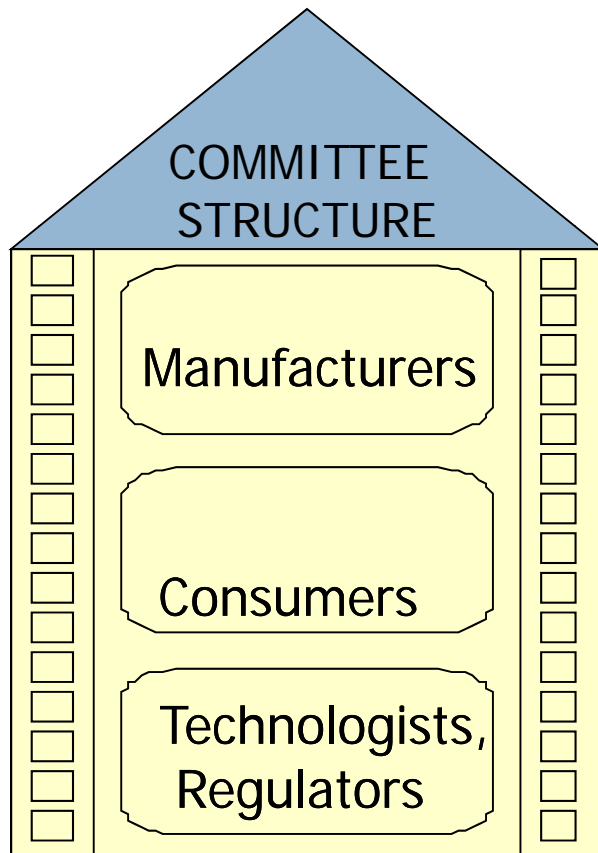


Formulation of National Standards

- In BIS, the Indian Standards are formulated through following 14 Division Councils :
 - Chemical Division Council (CHDC)
 - Civil Engineering Division Council (CEDC)
 - Electro-Technical Division Council (ETDC)
 - Electronics & Telecommunication Division Council (LITDC)
 - **Food and Agriculture Division Council (FADC)**
 - Mechanical Engineering Division Council (MEDC)
 - Management and Systems Division Council (MSDC)
 - Metallurgical Engineering Division Council (MTDC)
 - Petroleum, Coal & Related Products Division Council (PCDC)
 - Production and General Engineering Division Council (PGDC)
 - Transport Engineering Division Council (TEDC)
 - Textile Division Council (TXDC)
 - Water Resources Division Council (WRDC)
 - Medical Equipment & Hospital Planning Division Council (MHPC)



Standards Formulation Process





SECTIONAL COMMITTEE

- **Scope and Terms of Reference**
- **Chairman**
- **Members**
 - **Industry**
 - **Testing Laboratories**
 - **Consumers**
 - **Industry Associations**
 - **Government Organizations**
 - **Regulatory Bodies**
 - **Organized Buyers**
 - **R & D Institutions**
 - **Technical Institutions**
 - **Members Secretary from BIS**



Types of Standards

- ❖ **Terminologies**
- ❖ **Product Specification**
- ❖ **Methods of Tests**
- ❖ **Codes of Practice**
- ❖ **Guides**
- ❖ **Symbols or Dimensional**
- ❖ **Others**



Development of a Standard

- Receipt of Proposal
- Acceptance of Proposal
- Preparation of Proposed Draft
- Development & Acceptance of Proposed Draft
- Approval of Wide Circulation Draft
- Consideration of comments
- Finalization of Draft
- Publication of Standard

Development of Indian Standard – A Project Approach



Sl. No.	Project Stage	Associated Doc	Stages at the ISO Level	Remarks
1.	Proposal	New Work Item Proposal (NWIP)	New Work Item Proposal (NWIP)	Request for new standard constitute a proposal
2.	Preparatory	Working Draft (WD)	-	Proposal usually is accompanied with WD.
3.	Committee	Preliminary Draft (P-Draft)	Committee Draft (CD)	WD modified by the Member Secretary becomes the P-Draft.
4.	Approval	Wide Circulation Draft (WC)	Draft International Standard (DIS)	P-Draft modified by the Committee becomes the WC Doc.
5.	Publication	National Standard	International Standard	WC Doc is finalized by the Committee based on comments received.

Proposal for New Subject for Formulation of Indian Standard



- Requests for new Indian Standards or revisions of or amendments to existing standards may come from any Ministry of Central Government, State-government, Union territory administrations, Consumer Organization, Industrial units, Industry Associations, professional Bodies, Members of Bureau and Members of BIS technical committees.
- Source wishing to submit a proposal to BIS for new standardization work is first requested to furnish information explaining its significance, justification etc. in a prescribed format.

Proposal for new subject for national standardization



The proposal has to be made in a defined format with information on:

- Purpose and Justification
- Likely users of standards and their inputs
- Bearing with Govt. legislation regulation,
- Name and address of manufacturers/ implementing industries/purchasing organization/component supplier/raw material supplier
- Availability of test facilities
- Whether related to variety reduction, export, health, safety consumer protection, mass consumption, energy conservation, technology transfer, technology up gradation, protection of environment & other national priorities, and
- A working draft on the subject



Committee Stage

- The first P-draft is circulated to all members of the Sectional Committee and concerned Sub-committee(s) and Panel(s) for comments, with a clear indication of the latest date for sending comments.
- Comments received are discussed in the meeting of the Committee.



Committee Stage

- ❑ The decision to approve the P-draft as Wide Circulation draft is taken on the basis of the consensus principle.
- ❑ "Consensus: General agreement, characterized by the absence of sustained opposition to substantial issues by any important part of the concerned interests and by a process that involves seeking to take into account the views of all parties concerned and to reconcile any conflicting agreements"
- ❑ Note: Consensus need not imply unanimity.



Committee Stage

- ❑ A proposed Draft Standard when approved by Sectional Committee for wide circulation becomes a draft standard.
- ❑ A draft standard is normally available for public comment irrespective of its national or international origin and is hosted on BIS website besides physical circulation to all stake holders.
- ❑ Amendments affecting the technical content of published Indian Standards are also made available for public comments as draft Amendments.
- ❑ The period of circulation is determined by the committee concerned.



Committee Stage

- The sectional committee or a delegated sub-committee reviews all comments of substance received on the draft standard.
- If the content or structure of document is radically changed as a result of comments received, a second draft for public comment is circulated.
- If Sectional Committee considers that the subject matter of the draft standard is non-controversial in nature or the need for the standard is urgent, it may decide about dispensation with wide circulation. Possible implications of such measures are kept into consideration while arriving at the decision and it should be supported by adequate justification.

FORMULATION PROCESS

(Contd...)



- ❑ Finalization of Draft Standard
- ❑ Processing and approval of finalized document
- ❑ Printed standard
- ❑ Gazette notification of standard
- ❑ Publicity/seminars & conferences
- ❑ Review of standard (every 5 years)
- ❑ Amendment / revision / withdrawal of standard

Principles of Standardization



Transparency

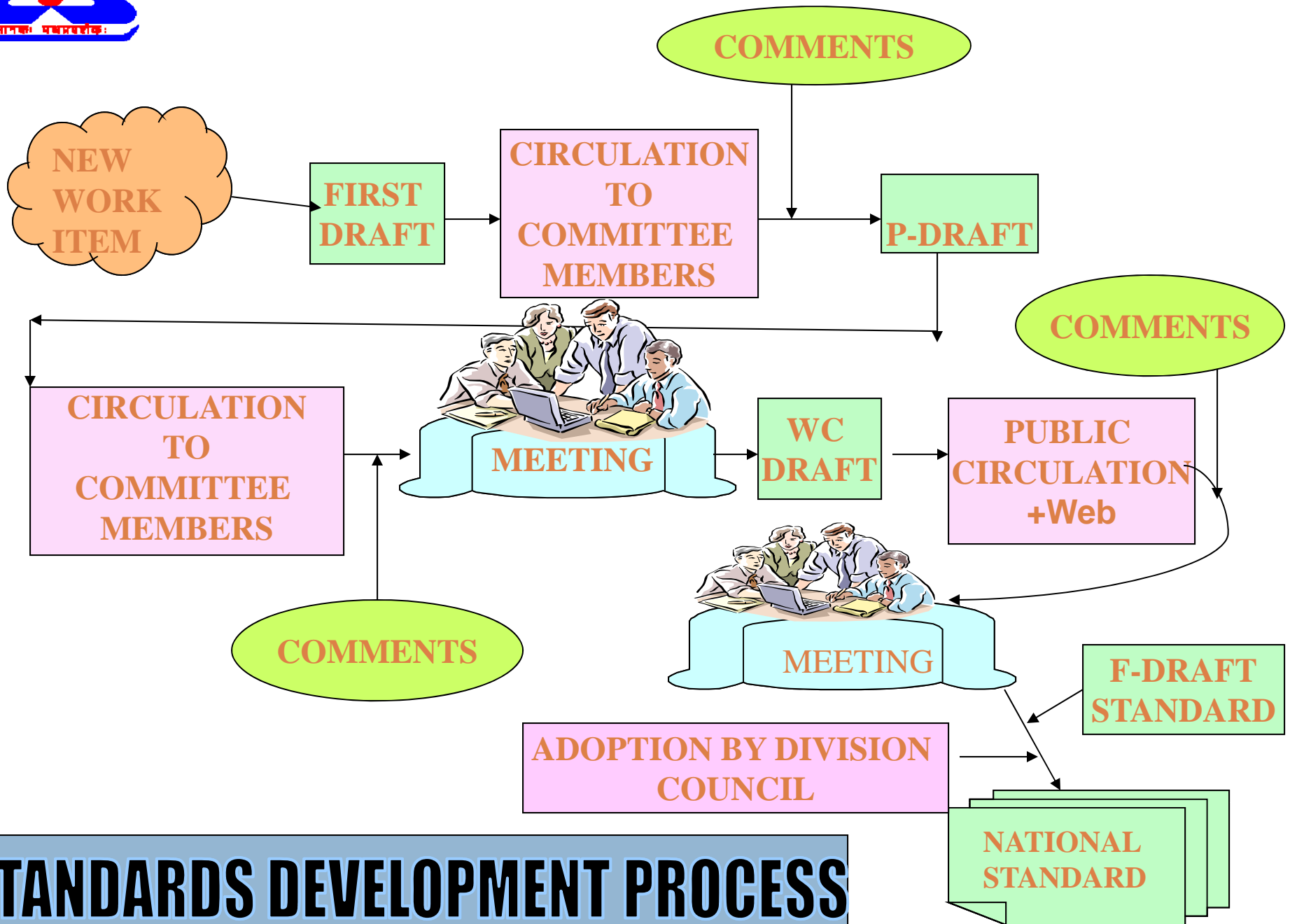
- Access to BIS work programmes & documents in its development stages for Comments by interested parties.

- **Openness**

- Any one can participate by virtue of sending comments

Access

- All Indian Standards are available on e-sale through BIS portal.



STANDARDS DEVELOPMENT PROCESS



Review of Indian Standards

Standards are periodically reviewed by the technical committees to keep pace with technological growth and changes in International Standards

Each standard is subject to review after every five years to:

- **revise, or**
- **amend, or**
- **reaffirm, or**
- **withdraw**

REVISION



- ❖ **Review of a standard may result in the decision for its revision**
- ❖ **Revision is taken up for up-gradation & up-dation of a standard and may incorporate technological developments, improved practices, changed needs of users, regulatory requirements, etc.**
- ❖ **Steps for revision is similar to that of development of a new standard.**

STANDARD – Preliminary Elements



- ✓ Title page
- ✓ Foreword
- ✓ Scope
- ✓ Normative References
- ✓ Definitions
- ✓ Symbols & Abbreviations
- ✓ Requirements



STANDARD – Preliminary Elements (contd.)

- ✓ Sampling
- ✓ Test Methods
- ✓ Marking, Labeling, Packing
- ✓ Normative Annexes
- ✓ Supplementary Elements such as Notes, Foot notes, Figures, Tables etc.
- ✓ Bibliography
- ✓ Annexes for guidance



BIS & ISO

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BIS is founder member of ISO

PARTICIPATING 'P' 302 TC's/SC's

OBSERVER 'O' 308 TC's/SC's

SECRETARIATS 2 TC's

6 SC's



TC/SC Chairs in India

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- ✓ TC 113 Hydrometry
- ✓ TC 113/SC 3 Terminology
- ✓ TC 113/SC 6 Sediment Transport
- ✓ TC 34/SC 7 Spices, Culinary Herbs & Condiments
- ✓ TC 120 Leather



Standardization in Food and Agriculture

- Food and Agriculture Department (FAD) formulates Indian Standards in the field of food and agriculture under the aegis of the Food and Agriculture Division Council (FADC) which oversees and supervises its work.

- Scope of FADC

“Standardization in the field of Food, Feed and Agriculture produce covering Food and Feed chain from primary production to consumption. This also includes Agricultural inputs, Agriculture Machinery, Management, Animal keeping and husbandry, Fisheries and Aquaculture, Food Processing, Food and Feed Safety Management, Biotechnology for Food and Agriculture and Ayurveda.”

Some Statistics for Food & Agriculture Department !!!!!

(as on 1 January 2012)



□ Total Number of Standards in Force	1189
□ Standards with Eco-Requirement	88
□ Total Standards under BIS Certification	174

Some Statistics for Food & Agriculture Department (1 January 2012) (contd.)



Product Standards		– 1189
Tests Methods	–	361
Code of Practices		– 156
Terminology		– 39
Dimension		– 1
Symbols		– 4
Others		– 119
TOTAL		– 1869



Harmonization with international standards

- **220** Indian Standards are totally harmonised with ISO standards
- Also participate actively in various committees of Codex Alimentarius Commission through National Shadow Committees
- **104** Indian Standards are harmonised with codex standards

Implementation of Indian Standards



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- Indian Standards(IS) are generally voluntary.
- IS referred in technical specification, purchase document.
- Referred in Government Regulations/legislation.
- Implemented by Public authorities in procurement.
- Mandatory certification of products.

Food standards under Regulation



- ✓ A total of **83** Indian Standards are under mandatory Certification of BIS through various regulations, i. e, it is mandatory for these products to carry BIS mark, both for domestic production as well for imported products.
- ✓ Out of these **83** Indian standards **12** are on food products.

LIST OF STANDARDS UNDER MANDATORY CERTIFICATION

1. IS 1165 Milk powder
2. IS 1166 Condensed milk, partly skimmed and skimmed condensed milk
3. **IS 1656 Milk-cereal based complementary foods**
4. **IS 11536 Processed cereal based complementary foods**
5. IS 12176 Sweetened ultra high temperature treated condensed milk
6. IS 13334(Part 1) Skimmed milk powder, standard grade
7. IS 13334(Part 2) Skimmed milk powder, extra grade
8. IS 14542 Partly skimmed milk powder
9. **IS 14433 Infant milk substitute**
10. IS 13428 Packaged Natural Mineral Water
11. IS 14543 Packaged Drinking Water (Other than Packaged Natural Mineral Water)
12. **IS 15757 Follow –up formula- Complementary Foods**



Indian standards on Foods for Infants



□ Following Indian Standards on foods for infants formulated

- IS 14433:2007 Infant milk substitutes
- IS 1656:2007 Milk cereal based complementary foods
- IS 11536:2007 Processed cereal-based complementary foods
- IS 15757:2007 Follow-up formula – complementary foods



- Objective : Nutritional requirements for optimal growth of infants are met adequately with minimum physiological stress on the developing organs and enzymatic system of the infant.

IS 14433:2007 Infant milk substitutes



- **SCOPE-** prescribes the types, requirements, methods of test and sampling for Infant milk substitutes
- **Infant Milk Food-** The material as prepared by spray drying of the milk of cow or buffalo or a mixture thereof. The milk may be modified by the partial removal/substitution of different milk solids, carbohydrates such as sucrose, dextrose and dextrans, maltodextrans, maltose and lactose, salts such as phosphates, citrates; vitamins A, D, E, B group, C, and other vitamins, minerals such as iron, copper, zinc, iodine and others.



IS 14433:2007 Infant milk substitutes

- **Infant Formula** — The material as prepared by spray drying of the milk of cow or buffalo or a mixture thereof. The milk may be modified by the partial removal/substitution of milk fat with edible vegetable oils rich in polyunsaturated fatty acids and/or by different milk solids, either singly or in a suitable combination; carbohydrates such as sucrose, dextrose and dextrans/maltodextrans, maltose and lactose; salts such as phosphates, citrates; vitamins A, D, E, B, group C, and other vitamins; minerals such as iron, copper, zinc, iodine and others.
- **NOTE** — Infant formula meant for premature infants (born before 37 weeks) or infants with low birth weight (less than 2500 g) and suitably modified with addition of proteins, whey proteins, minerals so as to achieve the required whey casein ratio; calcium: phosphorus ratio along with other requirements, as given in the standard, shall be termed as Premature/Low birth weight infant milk substitute.



Two types of Infant Milk Substitutes (IS 14433:2007)



Type I — Infant milk food

- ❖ Prepared by spray drying of the milk modified by the partial removal/substitution of different milk solids, carbohydrates such as sucrose, dextrose and dextrans/maltodextrans, maltose and lactose, salts such as phosphates, citrates; vitamins A, D, E, B group, C, and other vitamins, minerals such as iron, copper, zinc, iodine and others.

Type II— Infant formula

- Apart from the above substitutions the milk may be modified by the partial removal/substitution of milk fat with edible vegetable oils rich in polyunsaturated fatty acids.
- Special requirement for premature or low birth weight infant milk substitutes and lactose free infant milk substitute, lactose and sucrose free infant milk substitute and sucrose free infant milk substitute, hypoallergenic infant milk substitute have also been specified



IS 14433:2007 Infant milk substitutes

Types of Infant Milk substitutes:

- Type I — Infant milk food, and
- Type II — Infant formula including:
 - 1) Infant formula for general purpose
 - 2) Pre-mature/Low birth weight infant milk substitute;
 - 3) Lactose free infant milk substitute, lactose and sucrose free infant milk substitute and sucrose free infant milk substitute; and
 - 4) Hypoallergenic infant milk substitute.



Important requirements for infant milk substitute

- Description
- Freedom from extraneous matter, preservatives ,added colours, flavours, etc
- Restriction on addition of only permitted food additives

Important requirements for infant milk substitute



- ✓ Milk protein - 12 % (Min.) in infant milk food
- ✓ 10 % (Min.) in infant formula
- ✓ Milk fat - 18 % (Min.) in infant milk food
- ✓ 12 % (Min.) in infant formula and
- ✓ added vegetable oils shall be rich in PUFA containing a min. linoleate content of 1.398 g in 100g of product.
- ✓ Solubility - 98.5 % (Min.)
- ✓ Minimum requirements for vitamin A, B, C, D, K, E
- ✓ Minimum requirements for important minerals like iron, calcium, phosphorus, iodine, zinc, magnesium, selenium
- ✓ Recommended sources of vitamins and minerals.

Additional requirements for Low Birth Weight Infant Milk Substitute



- ✓ Protein content - 2.25 g/100 kcal/J to 2.75 g/100 kcal/J,
- ✓ Mineral content - not less than 0.5 g/100 kcal.
- ✓ Calcium: Phosphorus ratio - 2:1
- ✓ Sodium, Potassium and Chloride combined together - not less than 40 milliequivalent per litre
- ✓ Whey:Casein ratio - 60:40.
- ✓ Essential amino acids should include taurine, cystine, tyrosine and histidine.

Additional requirements for Lactose free Infant Milk Substitute, Lactose and Sucrose free Infant Milk Substitute and Sucrose free Infant Milk Substitute



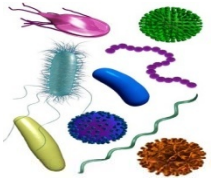
- ❖ Substitution of edible vegetable oil rich in PUFA in place of milk fat and lecithin may be used as emulsifier
- ❖ Soy protein-based, lactose-free formula shall have soy-protein and carbohydrate as glucose, dextrose, dextrin/maltodextrins, maltose and/or sucrose
- ❖ Lactose-free cow's/buffalo's milk-based formulas shall have carbohydrate as glucose, dextrose, dextrin/maltodextrins, maltose and sucrose



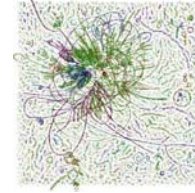
Additional requirements for Hypoallergenic Infant Milk Substitute



- ✓ Protein shall be hydrolyzed casein or whey or,
- ✓ 100% free amino acids as a protein source.



Microbiological requirements



Characteristics	Requirements
Bacterial count per gram, Max	10,000
Coliform count and <i>E. coli</i> per 0.1 gram	Absent
<i>Staphylococcus aureus</i> per 0.1 gram	Absent
<i>Salmonella</i> and <i>Shigella</i> per 25 gram	Absent
Yeast & Mould count per 0.1 gram	Absent



Indian standards for Infant foods



- ❖ **IS 1656:2007** Milk-cereal based complementary foods
Obtained from milk, variety of cereals, pulses, soyabean, millets and edible oil seeds after processing to a low moisture content.

- ❖ **IS 11536:2007** Processed cereal-based complementary foods.

Foods based on cereals and/or legumes (pulses), soyabean, millets, nuts and edible oilseeds, processed to low moisture content and so fragmented as to permit dilution with water, milk or other suitable medium.





Important requirements for infant foods



- Milk protein - 12 % (min.) (10% milk casein) in milk-cereal based
15 % in processed-cereal based complementary foods
- Carbohydrate - 55 % (min.)
- Ash - 5 % (min.)
- Crude fibre - 0.1 % in milk-cereal based
1.0% in processed-cereal based complementary foods
- Minimum requirements for vitamin A, B, C, D, K, E
- Minimum requirements for important minerals like iron, calcium, phosphorus, iodine, zinc, magnesium
- Recommended sources of vitamins and minerals.



Thank You

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