

F.No. A-1(1)/Standards/MMP/ 2012 (Part-I)
Food Safety and Standards Authority of India
(A Statutory Authority established under the Food Safety & Standards Act, 2006)
(Regulatory Compliance Division)
FDA Bhawan, Kotla Road, New Delhi-110 002

Dated, the 2nd August, 2017

Subject: Directions under Section 16(5) of the Food Safety and Standards Act, 2006 regarding operationalisation of amendment regulations regarding revised standards for milk and milk products and certain restriction on sale of cream.

In exercise of the power conferred under Section 92 of the Food Safety and Standards Act, 2006 (34 of 2006), FSSAI had notified the draft amendment regulations regarding revision of standards for milk and milk products in Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011 and certain restriction on sale of cream in Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011 *vide* F. No. A-1(1)/Standards/MMP/2012, dated 6th December, 2016 for inviting comments of the stakeholders. These regulations have since been finalized and are expected to be notified shortly as final regulations.

2. Finalization of these standards took a long time, as the process included:
 - (i) revision of all existing milk and milk product standards in order to harmonise these with the Codex Standards and various practices prevalent in the domestic dairy sector;
 - (ii) formulation of new standards for some other dairy products; and
 - (iii) consideration of a huge volume of stakeholders comments which were received in response to the said draft notification.
3. Now, as these regulations are eagerly awaited by multiple stakeholders including consumers, dairy industry and dairy producers, the FSSAI has operationalised these standards (as enclosed) with immediate effect (i.e. from 2nd August, 2017).
4. In exercise of the power vested under Sections 16(5) Food Safety and Standards Act, 2006, the Food Authority hereby directs the Food Safety Commissioners of States/ UTs to implement the above mentioned standards.
5. This issues with the approval of the Competent Authority.



S. K. Yadav
Director (Regulatory Compliance)

To

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

Copy for information to

1. PPS to Chairperson, FSSAI,
2. PS to CEO, FSSAI,
3. All Directors, FSSAI.

Dated, the 2nd August, 2017

Notice for operationalisation of amendment regulations regarding revised standards for milk and milk products and certain restriction on sale of cream.

1. The Food Safety and Standards Authority of India, hereby makes the following regulations operational from 2nd August, 2017. The food business operators shall follow the regulations related to revised standards for milk and milk products and certain restriction for sale of cream as specified below. The enforcement of these regulations shall commence only after the final regulations are notified in the Gazette of India.

2. In the Food Safety and Standards (Prohibition and Restrictions on sales) Regulations, 2011, in chapter 2, in regulation 2.1, in sub-regulation 2.1.1, item (1) shall be omitted.

3. In the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, -

(a) in chapter 1, for regulation 1.2 relating to “Definitions”, items 1, 3, 5, 6, 10, 11, 12, 15, 16, 19, 20, 21 and 24 shall be omitted;

(b) in chapter 2, for regulation 2.1 relating to “DAIRY PRODUCTS AND ANALOGUES”, the following shall be substituted, namely:-

“2.1 DAIRY PRODUCTS AND ANALOGUES

2.1.1 General Standards for Milk and Milk Products

The general standard provides over-arching definitions for milk and milk products and guidance on the use of dairy terms in relation to foods to be offered to the consumer or for further processing.

1. Definitions.-

(a) **“Boiling, boiled and similar terms”** when used in association with milk, shall be taken to refer to the process of heating milk continuously to bring it to boil at atmospheric pressure;

(b) **“Composite milk product”** means a product of which the milk, milk products or milk constituents shall be an essential part in terms of quantity in the final product, as consumed:

Provided that the constituents not derived from milk shall not take the place in part or in whole of any milk constituent. Examples of composite milk products are:

(i) *Shrikhand* with fruits etc.;

(ii) ice cream containing fruits etc.;

- (iii) flavoured fermented milks;
- (iv) Drinks based on fermented milks

- (c) **“Dairy terms”** means names, designations, symbols, pictorial or other devices which refer to or are suggestive, directly or indirectly, of milk or milk products;
- (d) **“Heat treatment”** means pasteurization, ultra-pasteurization, sterilisation, ultra-high temperature treatment or boiling;
- (e) **“Milk”** means the normal mammary secretion derived from complete milking of healthy milch animal, without either addition thereto or extraction therefrom, unless otherwise provided in these regulations and it shall be free from colostrum;
- (f) **“Milk Product”** means a product obtained by processing of milk, which may contain food additives and other ingredients functionally necessary for the milk product as permitted in these regulations and shall include the following, namely:-
 - (i) cheese;
 - (ii) *chhana*, skimmed-milk *chhana*, *paneer*;
 - (iii) condensed milk-sweetened and unsweetened;
 - (iv) condensed skimmed milk-sweetened and unsweetened;
 - (v) cream;
 - (vi) curd, skimmed milk curd, *dahi*;
 - (vii) *ghee*, butter oil;
 - (viii) ice-cream;
 - (ix) infant milk food;
 - (x) *khoa*;
 - (xi) *malai*;
 - (xii) milk derivatives such as whey proteins, casein, lactose etc.;
 - (xiii) milk ices, milk lollies, *kulfi*;
 - (xiv) milk powder, skimmed milk powder, partly skimmed milk powder;
 - (xv) processed cheese;
 - (xvi) table butter and white butter;
 - (xvii) yoghurt;
 - (xviii) any other product as may be specified in these regulations;

Provided that milk products shall not contain any substance not found in milk unless specified in these regulations;

- (g) **“Pasteurization, Pasteurized and similar terms”** means a microbicidal heat treatment aimed at reducing the number of any pathogenic micro-organisms in milk and liquid milk products, if present, to a level at which they do not constitute a significant health hazard. Pasteurization conditions shall be designed to effectively destroy the organisms *Mycobacterium tuberculosis* and *Coxiella burnettii*.

Pasteurization, when used in association with milk, shall be taken to refer to the typical process of heating every particle of milk to at least 63°C and holding at such temperature continuously for at least thirty minutes or heating it to at least 72°C and holding at such temperature continuously for at least fifteen seconds, or any other temperature-time combination, sufficient to give a microbicidal effect equivalent to the above defined temperature-time combination and serve to give a negative Phosphatase Test that is applicable to milk immediately after pasteurization only, and cooling it immediately to a temperature of 4°C, or less;

- (h) **“Recombined milk or milk product”** means a product resulting from the combination of milk fat and milk-solids-non-fat in their preserved forms with or without the addition of potable water to achieve similar end product characteristics and appropriate milk product composition as per the Standard for that product and in the case of recombined milk, the source of milk-solids-non-fat shall be dried or concentrated milks only;
 - (i) **“Reconstituted milk or milk product”** means a product resulting from the addition of potable water to the dried or concentrated form of milk or milk products in the amount necessary to re-establish the appropriate water-to-solids ratio to achieve similar end product characteristics and appropriate milk product composition as per the standards for that product;
 - (j) **“Sterilisation, sterilised and similar terms”** means application of heat at high temperatures for a time sufficient to render milk or milk products commercially sterile, thus resulting in products that are safe and microbiologically stable at room temperatures.
 - (i) **“Sterilisation”** when used in association with milk or milk products, shall be taken to refer to the typical process of heating milk or milk product in sealed containers continuously to at least 115°C for fifteen minutes to ensure preservation at room temperature for a period not less than thirty days from the date of manufacture;
 - (ii) **“Ultra High Temperature (UHT) sterilisation/treatment”** when used in association with milk or milk products, shall be taken to refer to the typical process of heating milk or milk product to at least 135°C for one second or more in a continuous flow and then packing under aseptic condition in hermetically sealed containers to ensure preservation at room temperature for a period of not less than fifteen days from the date of manufacture.
2. **General Principles.-** Foods shall be described or presented in such a manner as to ensure the correct use of dairy terms intended for milk and milk products, to protect consumers from being confused or misled and to ensure fair practices in the food trade.
3. **Application of Dairy Terms.-**
- (a) **General requirements.-**

The name of the food shall be declared in accordance with these regulations.

(b) Use of the term “milk”.-

- (i)** Only a food complying with the requirement as specified in sub-item (e) of item 1 of this sub-regulation may be named “milk”;
- (ii)** Milk which is adjusted for milk fat or milk solid-not-fat content or both, may also be named “milk” provided that the minimum and maximum limits of milk fat and milk solid-not-fat content (as the case may be) of the adjusted milk as specified in sub-regulation 2.1.2 (Standard for Milk).

(c) Use of the names of milk products in food standards. -

- (i)** a product complying with the standards of a milk product as specified in these regulations may be named accordingly;
- (ii)** notwithstanding the provisions of entry (i) above, the relevant milk product when manufactured from milk, the fat or protein content, or both, of which have been adjusted, provided that the compositional criteria in the relevant standard are met, may be named as specified in these regulations;
- (iii)** products that are modified through addition or withdrawal of milk constituents may be named with the name of the relevant milk product in association with a clear description of the modification to which the milk product has been subjected:

Provided that the essential product characteristics are maintained and that the limits of such compositional modifications have been provided for in the standards concerned as appropriate (for example ‘lactose reduced’ milk or milk products, ‘cholesterol free’ ghee, etc.).

(d) Use of terms for reconstituted and recombined milk and milk products. -Milk and milk products may be named as specified in these regulations for the relevant milk products when made from recombined or reconstituted milk or from recombination or reconstitution of milk products.

(e) Use of dairy terms for composite milk products. -A product complying with the description given in sub-item(b) of item 1 of sub-regulation 2.1.1 may be named with the term “milk” or the name specified for a milk product as appropriate, provided that a clear description of the other characterising ingredient(s) (such as flavouring foods, spices, herbs and flavours) is given in close proximity to the name.

(f) Use of dairy terms for other foods.-

- (i)** the names referred to in sub-items (b), (c), (d) and (e) of item 3 of sub-regulation 2.1.1 may be used as names or in the labelling of milk, milk

products or composite milk products;

- (ii) in respect of a product which is not milk, a milk product or a composite milk product, no label, commercial document, publicity material or any form of point of sale presentation shall be used which claims, implies or suggests that the product is milk, a milk product or a composite milk product, or which refers to one or more of these products:

Provided that products which contain milk or milk products, or milk constituents, which are an essential part for characterisation of the product, the term "milk", or the name of a milk product may be used in the description of the true nature of the product.

Provided further that the constituents not derived from milk are not intended to take the place, in part or in whole, of any milk constituent:

Provided also that if the final product is intended to substitute milk, a milk product or composite milk product, dairy terms shall not be used:

Provided also that the products which contain milk, or a milk product, or milk constituents, which are not an essential part in terms of characterisation of the product, dairy terms shall only be used in the list of ingredients. For these products, dairy terms shall not be used for other purposes.

4. **Addition of Essential Nutrients.-** Milk and milk products may be enriched/fortified with essential nutrients such as vitamins, minerals, etc., as specified in these regulations including labelling requirements.
5. **Labelling of pre-packaged foods.-** Pre-packaged milk, milk products and composite milk products shall be labeled in accordance with these regulations, except to the extent otherwise expressly provided in item 3 of this sub-regulation.
6. **Use of probiotics and prebiotics.-** For the use of probiotics and prebiotics in dairy products, the provisions specified in the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel food) Regulations, 2016 shall apply.
7. **Use of enzymes.-** Safe and suitable enzymes may be used as processing aids in milk and milk products as specified in individual standards for milk and milk products under these regulations.

2.1.2 Standard for Milk.-This Standard applies to milk as defined in item 1 of this sub-regulation.

1. **Description.-**

- (a) **“Species identified milk”** means milk as defined under the General Standard for Milk and Milk Products. The fat and SNF content of species identified milk specified under this regulation (namely buffalo milk, cow milk, goat milk, sheep milk and camel milk) shall conform to the respective composition given in sub-item (b) of item 2 and product may be subjected to pasteurization, boiling, sterilisation or Ultra High Temperature sterilisation/treatment.
- (b) **“Mixed Milk”** means any combination of species identified milk specified under these regulations. The fat and SNF content of mixed milk shall conform to the standards given in the table under sub- item (b) of item 2 below. The product may be subjected to pasteurization, boiling, sterilisation or Ultra High Temperature sterilisation/treatment.
- (c) **“Full Cream Milk, Standardised Milk, Toned Milk, Double Toned Milk, or Skimmed Milk”** means the product prepared from cow milk, buffalo milk or milk of any other species as defined under this regulation, reconstituted milk, recombined milk, or any combination of these milks, with or without dried or concentrated milks or milk fat that has been standardised to the respective fat and solids-not-fat percentage given in sub-item (b) of item 2. It shall remain homogeneous and no deposition of solids shall take place on standing. The product shall be subjected to pasteurization, sterilisation, Ultra High Temperature sterilisation/treatment or boiling.

2. Essential Composition and Quality Factors.-

(a) Raw Material.-

Raw material used shall be as per the respective definitions in item 1 of this sub-regulation.

(b) Composition.-

The milk of different classes shall conform to the requirements for milk fat and milk solids-not-fat, independently, as specified in columns (4) and (5) of the table given below:

Table

Sl. No	Class of Milk.	Locality or State or Area.	Minimum Milk Fat (per cent, m/m).	Minimum Milk Solids-not-Fat (SNF) (per cent, m/m).
(1)	(2)	(3)	(4)	(5)
1.	Buffalo Milk	Assam Bihar Chandigarh Delhi Gujarat Haryana Jharkhand Maharashtra Meghalaya	6.0	9.0

Sl. No	Class of Milk.	Locality or State or Area.	Minimum Milk Fat (per cent, m/m).	Minimum Milk Solids-not-Fat (SNF) (per cent, m/m).
		Punjab Sikkim Uttar Pradesh Uttarakhand West Bengal		
		Andaman and Nicobar Islands Andhra Pradesh Arunachal Pradesh Chhatisgarh Dadra and Nagar Haveli Goa Daman and Diu Himachal Pradesh Jammu and Kashmir Karnataka Kerala Lakshadweep Madhya Pradesh Manipur Mizoram Nagaland Odisha Puducherry Rajasthan Tamil Nadu Telangana Tripura	5.0	9.0
2.	Cow Milk	All India	3.2	8.3
3.	Goat or Sheep Milk	Chandigarh Haryana Kerala Madhya Pradesh Maharashtra Punjab Uttar Pradesh Uttarakhand	3.5	9.0
		Andaman and Nicobar Islands Andhra Pradesh Arunachal Pradesh Assam Bihar Chhattisgarh Dadra and Nagar Haveli	3.0	9.0

Sl. No	Class of Milk.	Locality or State or Area.	Minimum Milk Fat (per cent, m/m).	Minimum Milk Solids-not-Fat (SNF) (per cent, m/m).
		Delhi Goa Daman and Diu Gujarat Himachal Pradesh Jammu and Kashmir Jharkhand Karnataka Lakshadweep Manipur Meghalaya Mizoram Nagaland Odisha Puducherry Rajasthan Sikkim Tamil Nadu Telangana Tripura West Bengal		
4.	Camel Milk	All India	2.0	6.0
5.	Mixed Milk	All India	4.5	8.5
6.	Standardized Milk	All India	4.5	8.5
7.	Toned Milk	All India	3.0	8.5
8.	Double Toned Milk	All India	1.5	9.0
9.	Skimmed Milk	All India	Not more than 0.5	8.7
10.	Full Cream Milk	All India	6.0	9.0

Note(s):

- (i) When any class of milk is offered for sale in contravention of the requirements specified under this sub-item, the standards prescribed for mixed milk shall apply.
- (ii) These standards would only be applicable at the points of sale.

3. Food Additives. -

Milk shall not contain any food additives:

Provided that the products specified in sub-item (c) of item 1 of this sub-regulation may contain carry over food additives specified in the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011:

Provided further that in sterilised milk, the specific food additives permitted in Appendix 'A' of these regulations may be used and only within the limits specified.

4. Contaminants, Toxins and Residues. -

- (a) The products shall comply with the Food Safety and Standards (Contaminants, toxins and Residues) Regulations, 2011.
- (b) The total urea content in milk shall not be more than 700 ppm.

5. Hygiene. -

- (a) The products shall be prepared and handled in accordance with the requirements specified in Schedule 4, as applicable, of the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011 and such other guidelines as specified from time to time under the provisions of the Food Safety and Standard Act, 2006;
- (b) The products shall conform to the microbiological requirements given in Appendix 'B' of these regulations.

6. Labelling. -

- (a) The following details shall be declared on the label of pre-packaged milk or otherwise if the milk is not pre-packaged and is offered for sale to the consumer, such declaration shall be given on the container from which milk is offered for sale to the consumer:
 - (i) the class of milk as per column 2 of table under sub-item (b) of item 2 of sub-regulation 2.1.2;
 - (ii) the heat treatment, as per the item (1) of sub-regulation 2.1.2, to which product has been subjected to.
- (b) If the milk from any milch animal, mixed milk or skimmed milk is offered for sale to the consumer without any heat treatment, the name of the milk shall be declared on the label of pre-packaged milk; or otherwise if the milk is not pre-packaged, the name of the milk shall be declared and mentioned on the container from which milk shall be offered for sale to the consumer and shall be preceded with the term 'Raw'.
- (c) In addition to the labelling requirements mentioned above, the provisions of the Food Safety and Standards (Packaging and Labelling) Regulations, 2011, shall apply to pre-packaged milk:

Provided that the list of ingredients may not be declared in descending order of usage since the proportion of ingredients used may require change on a daily basis:

Provided further that where 'reconstituted' or 'recombined' milk is declared in the list of ingredients, their components need not be declared separately.

7. Method of Sampling and Analysis. -

The methods of sampling and analysis mentioned in the manuals as specified by the Food Safety and Standards Authority of India from time to time shall be applicable.

2.1.3 Standard for Flavoured Milk

This Standard applies to Flavoured Milk as defined in item 1 of this sub-regulation. *

1. Description. -

“**Flavoured Milk**” means the product prepared from milk or other products derived from milk, or both, and edible flavourings with or without addition of sugar, nutritive sweeteners, other non-dairy ingredients including, stabilisers and food colours. Flavoured milk shall be subjected to heat treatment as provided in sub-regulation 2.1.1 (General Standards for Milk and Milk Products).

Where flavoured milk is dried or concentrated, the dried or concentrated product on addition of prescribed amount of water shall give a product conforming to the requirements of flavoured milk.

2. Essential Composition and Quality Factors.-

(a) Raw Material. -

- (i) Milk
- (ii) Concentrated and dried milk
- (iii) Milk fat, cream, butter and butter oil
- (iv) Potable water for use in reconstitution or recombination

(b) Permitted ingredients. -

- (i) Sugar or other nutritive sweeteners or both;
- (ii) Other non-dairy ingredients like nuts (whole, fragmented or ground), cocoa solids, chocolate, coffee, fruits and vegetables and products thereof including juices, purees, pulps, preparations and preserves derived therefrom, cereals, and cereal products and cereal based extracts, honey, spices, condiments, salt, and other natural flavouring foods and flavours;
- (iii) Potable water.

(c) Composition. -

Flavoured Milk shall have the same minimum percentage of milk fat and milk solids-not-fat as that of the milk, as provided for in the Standard for Milk, from which it is prepared.

3. Food Additives. -

*This standard should be read along with sub-regulation 2.1.1 relating to General Standard for Milk and Milk Products with reference to the generic provisions pertaining to definitions of milk or milk products and heat treatments, guidelines for use of dairy terms, addition of micronutrients, etc.

For products covered under this standard, specific food additives specified in Appendix 'A' of these regulations may be used and only within the limits specified.

4. Contaminants, Toxins and Residues. -

The products shall comply with the Food Safety and Standards (Contaminants, toxins and Residues) Regulations, 2011.

5. Hygiene. -

(a) The products shall be prepared and handled in accordance with the requirements specified in Schedule 4, as applicable, of the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011 and such other guidelines as specified from time to time under the provisions of the Food Safety and Standard Act, 2006.

(b) The products shall conform to the microbiological requirements specified in Appendix 'B' of these regulations.

6. Labelling. -

(a) The name of the product shall be 'Flavoured Milk'.

(b) The following details shall be always declared on the label of pre-packaged product or otherwise if the product is not pre-packaged, in respect of the product offered for sale: -

(i) the class of milk as per General Standard for Milk and Milk Products from which it is prepared;

(ii) the heat treatment, as per the General Standard for Milk and Milk Products, to which product has been subjected to;

(c) In addition to the labelling requirements mentioned above, the provisions of the Food Safety and Standards (Packaging and Labelling) Regulations, 2011, shall apply to pre-packaged products.

7. Method of Sampling and Analysis. -

The methods of sampling and analysis mentioned in the manuals as specified by the Food Safety and Standards Authority of India from time to time shall be applicable.

2.1.4 Standard for Evaporated or Concentrated Milk

This Standard applies to Evaporated Milk as defined in item 1 of this sub-regulation*.

*This standard should be read along with the sub-regulation 2.1.1 relating to General Standard for Milk and Milk Products with reference to the generic provisions pertaining to definitions of milk or milk products and heat treatments, guidelines for use of dairy terms, addition of micronutrients, etc.

1. Description.-

Evaporated Milk means the product obtained by partial removal of water from milk by heat or any other process which leads to a product of the same composition and characteristics. The fat and protein content of the milk may be adjusted, only to comply with the compositional requirements in sub-item (c) of item 2 of this Standard, by addition or withdrawal of milk constituents in such a way as not to alter the whey protein to casein ratio of the milk being adjusted.

2. Essential Composition and Quality Factors.-

(a) Raw materials.-

i) Milk and milk powders, cream and cream powders, milk fat products;

ii) The following milk products are allowed for protein adjustment purposes, only in product covered by item 1 of this sub-regulation.

- “**Milk retentate**” means the product obtained by concentrating milk protein by ultrafiltration of milk, partly skimmed milk, or skimmed milk;

(b) Permitted ingredients.-

- Potable water; and
- Sodium chloride.

(c) Composition.-

The product shall conform to the compositional specifications provided in the table below:

Parameter	Evaporated milk	Evaporated partly skimmed milk	Evaporated skimmed milk	Evaporated high fat milk
Milk fat, %, (m/m)	7.5 (minimum)	More than 1 and Less than 7.5	1.0 (maximum)	15.0 (minimum)
Milk solids, minimum, %, (m/m)	25.0	20.0	20.0	26.5
Milk protein* in milk solids-not fat, minimum, %, (m/m)	34.0	34.0	34.0	34.0

* Protein content is 6.38 multiplied by the total nitrogen determined

3. Food Additives.-

For products covered under this standard, specific food additives specified in Appendix 'A' of these regulations may be used and only within the limits specified.

4. Contaminants, Toxins and Residues.-

The products shall comply with the limits stipulated under the Food Safety and Standards (Contaminants, toxins and Residues) Regulations, 2011.

5. Hygiene.-

- (a) The products shall be prepared and handled in accordance with the requirements specified in Schedule 4, as applicable, of the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011 and such other guidelines as specified from time to time under the provisions of the Food Safety and Standard Act, 2006.
- (b) The products shall conform to the microbiological requirements specified in Appendix 'B' of these regulations.

6. Labelling.-

- (a) According to the definitions in item 1 and composition in sub-item (c) of item 2, the name of the food shall be:

- (i) evaporated milk, or
- (ii) evaporated partly skimmed milk, or
- (iii) evaporated skimmed milk, or
- (iv) evaporated high fat milk, and as appropriate:

Provided that the "evaporated partly skimmed milk" may be designated "evaporated semi-skimmed milk" when the content of milk fat is between 4.0 - 4.5 % (m/m) and minimum milk solids is 24% (m/m).

- (b) In addition to the labelling requirements mentioned above, the provisions of the Food Safety and Standards (Packaging and Labelling) Regulations, 2011, shall apply to pre-packaged products.

7. Method of Sampling and Analysis.-

The methods of sampling and analysis mentioned in the manuals as specified by the Food Safety and Standards Authority of India from time to time shall be applicable.

2.1.5 Standard for Sweetened Condensed Milk

This Standard applies to sweetened condensed milk as defined in item 1 of this sub-regulation.*

1. Description.-

Sweetened Condensed Milk is the product obtained by partial removal of water from milk with the addition of sugar or a combination of sucrose with other sugars, or by any other process which leads to a product of the same composition and characteristics. The fat or protein content or both of the milk may be adjusted, only to comply with the compositional requirements in sub-item (c) of item 2 of this Standard, by addition or withdrawal of milk constituents in such a way as not to alter the whey protein to casein ratio of the milk being adjusted.

2. Essential Composition and Quality Factors.-

(a) Raw materials.-

i) Milk and milk powders, cream and cream powders, milk fat products;

ii) Lactose (for seeding purposes);

iii) The following milk products are allowed for protein adjustment purposes.-

- **Milk retentate:** Milk retentate is the product obtained by concentrating milk protein by processes like ultrafiltration of milk, partly skimmed milk, or skimmed milk.

(b) Permitted ingredients.-

- potable water;
- sugar (In this product, sugar is generally considered to be sucrose, but a combination of sucrose with other sugars, consistent with Good Manufacturing Practice, may be used); and
- Sodium chloride.

(c) Composition.-

The product shall conform to the compositional specifications provided in the table below:

Parameter	Sweetened condensed milk	Sweetened condensed partly skimmed milk	Sweetened condensed skimmed milk	Sweetened condensed high fat milk
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*This standard should be read along with sub-regulation 2.1.1 relating to General Standard for Milk and Milk Products with reference to the generic provisions pertaining to definitions of milk or milk products and heat treatments, guidelines for use of dairy terms, addition of micronutrients, etc.

Milk fat, %, (m/m)	8.0 (minimum)	More than 1.0 and less than 8.0	1.0 (maximum)	16.0 (minimum)
Milk solids, minimum, %, (m/m)	28.0	24.0	24.0	--
Milk solid not fat, minimum, %, (m/m)	--	20.0	--	14.0
Milk protein* in milk solids-not-fat, minimum, %, (m/m)	34.0	34.0	34.0	34.0

* Protein content is 6.38 multiplied by the total nitrogen determined

3. Food Additives.-

For products covered under this standard, specific food additives specified in Appendix 'A' of these regulations may be used and only within the limits specified.

4. Contaminants, Toxins and Residues.-

The products shall comply with the Food Safety and Standards (Contaminants, toxins and Residues) Regulations, 2011.

5. Hygiene.-

- (a) The products shall be prepared and handled in accordance with the requirements specified in Schedule 4, as applicable, of the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011 and such other guidelines as specified from time to time under the provisions of the Food Safety and Standard Act, 2006.
- (b) The products shall conform to the microbiological requirements specified in Appendix 'B' of these regulations.

6. Labelling.-

- (a) According to the definitions in item 1 and composition in sub-item (c) of item 2, the name of the food shall be:-
- (i) Sweetened condensed milk, or
 - (ii) Sweetened condensed partly skimmed milk, or
 - (iii) Sweetened condensed skimmed milk, or
 - (iv) Sweetened condensed high fat milk, as appropriate:

Provided that the "Sweetened condensed partly skimmed milk" may be designated "Sweetened condensed semi-skimmed milk", if the content of milk fat is between 4.0 - 4.5 % (m/m) and minimum milk solids is 28 % (m/m);

- (b) Sweetened condensed milks which are not suitable for infant feeding shall not contain any instruction of modifying them for infant feeding;

- (c) In addition to the labelling requirements mentioned above, the provisions of the Food Safety and Standards (Packaging and Labelling), Regulations, 2011, shall apply to pre-packaged product.

7. Method of Sampling and Analysis.-

The methods of sampling and analysis mentioned in the manuals as specified by the Food Safety and Standards Authority of India from time to time shall be applicable.

2.1.6 Standard for *Khoa*.–

This Standard applies to *Khoa* as defined in item 1 of this sub-regulation. *

1. Description. -

Khoa by whatever name it is sold such as *Khoa* or *Mawa* or any other region specific popular name means the product obtained by partial removal of water from any variant of milk with or without added milk solids by heating under controlled conditions.

2. Essential Composition and Quality Factors. -

(a) Raw materials. -

Milk and milk powders, cream and cream powder and milk fat products.

(b) Composition. -

The product shall conform to the compositional specifications provided in the table below:

Parameter	<i>Khoa</i>
Total solids, minimum, %, (m/m)	55.0
Milk fat, minimum, %, (m/m), dry matter basis	30.0
Total ash, maximum, %, (m/m)	6.0
Titrateable acidity (as % lactic acid), maximum, %	0.9

It shall be free from added starch and added sugar.

The extracted fat from *Khoa* shall meet the standards for Reichert Meissl value, Polenske value and Butyro-refractometer reading as prescribed for ghee.

3. Food Additives. -

*This standard should be read along with sub-regulation 2.1.1 relating to General Standard for Milk and Milk Products with reference to the generic provisions pertaining to definitions of milk or milk products and heat treatments, guidelines for use of dairy terms, addition of micronutrients, etc.

For products covered under this standard, specific food additives specified in Appendix 'A' of these regulations may be used and only within the limits specified.

4. Contaminants. -

The products shall comply with the limits stipulated under the Food Safety and Standards (Contaminants, toxins and Residues) Regulations, 2011.

5. Hygiene.-

- (a) The products shall be prepared and handled in accordance with the requirements specified in Schedule 4, as applicable, of the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011 and such other guidelines specified from time to time under the provisions of the Food Safety and Standard Act, 2006.
- (b) The products shall conform to the microbiological requirements specified in Appendix 'B' of these regulations.

6. Labelling. -

- (a) The name of the food shall be '*Khoa*' or '*Mawa*' or any other region specific popular name.
- (b) In addition to the labelling requirements mentioned above, the provisions of the Food Safety and Standards (Packaging and Labelling) Regulations, 2011, shall apply to pre-packaged product.

7. Method of Sampling and Analysis. -

The methods of sampling and analysis mentioned in the manuals as specified by the Food Safety and Standards Authority of India from time to time shall be applicable.

2.1.7 Standard for Cream and *Malai*. -

This Standard applies to Cream and *Malai* as defined in item 1 of this sub-regulation*.

1. Description. -

- (a) "**Cream**" means the fluid product comparatively rich in fat, in the form of an emulsion of fat-in-skimmed milk, obtained by physical separation from cow milk, buffalo milk or milk of any other species as defined under this regulation or a mixture thereof.
- (b) "**Reconstituted cream**" means cream obtained by reconstituting milk products with or without the addition of potable water and with the same end product characteristics as the product described in sub-item (a) of item 1 of this sub-regulation.

- (c) **“Recombined cream”** means cream obtained by recombining milk products with or without the addition of potable water and with the same end product characteristics as the product described in sub-item (a) of item 1 of this sub-regulation.
- (d) **“Prepared creams”** means the milk products obtained by subjecting cream, reconstituted cream or recombined cream or any combination of these, to suitable treatments and processes to obtain the characteristic properties as specified below:-
- (i) **“pre-packaged liquid cream”** means the fluid milk product obtained by preparing and packaging cream, reconstituted cream or recombined cream, or any combination of these for direct consumption or for direct use as such;
- (ii) **“whipping cream”** means the fluid cream, reconstituted cream and recombined cream or any combination of these, that is intended for whipping. When cream is intended for use by the final consumer the cream should have been prepared in a way that facilitates the whipping process;
- (iii) **“cream packed under pressure”** means the fluid cream, reconstituted cream and recombined cream or any combination of these that is packed with a propellant gas in a pressure-propulsion container and which becomes Whipped Cream when removed from that container;
- (iv) **“whipped cream”** means the fluid cream, reconstituted cream or recombined cream in to which air or inert gas has been incorporated without reversing the fat-in-skimmed milk emulsion;
- (v) **“fermented/cultured/sour cream”** means the milk product obtained by fermentation of cream, reconstituted cream or recombined cream, by the action of suitable micro-organisms that results in reduction of pH with or without coagulation. Where the content of (a) specific microorganism(s) is(are) indicated, directly or indirectly, in the labeling or otherwise indicated by content claims in connection with sale, these shall be present, viable, active and abundant in the product to the date of minimum durability. If the product is heat treated after fermentation the requirement for viable micro-organisms shall not apply;
- (vi) **“acidified cream”** means the milk product obtained by acidifying cream, reconstituted cream or recombined cream, or any combination of these, by the action of acids or acidity regulators, or both to achieve a reduction of pH with or without coagulation.
- (e) **“Malai”** means the product rich in milk fat prepared by boiling and cooling of cow milk, buffalo milk or milk of any other species as defined under this regulation or a mixture thereof. It is characterized by presence of insoluble mass, principally fat and denatured protein, formed on heating and cooling of milk.

2. Essential Composition and Quality Factors.-

(a) Raw Material.-

All creams, prepared creams and *malai*.-

- Milk, which may have been subjected to mechanical and physical treatments prior to cream processing;
- Additionally, for creams made by reconstitution or recombination.-
Butter, milk fat products, milk powders, cream powders, and potable water. The milk product should conform to the relevant Food Safety Standards or Regulations;
- Additionally, for prepared creams described in entries (ii) to (vi) of sub-item (d) of item 1;

The product that remains after the removal of milk fat by churning milk and cream to manufacture butter and milk fat products (often referred to as buttermilk) and that may have been concentrated or dried.

(b) Permitted ingredients.-

Only those ingredients listed below may be used for the purposes and product categories specified, and only within the limitations specified. The product shall be free from any ingredient foreign to milk except otherwise provided in this standard.

For use in products only for which stabilizers or thickeners, or both, are justified (see item 3):

- Products derived exclusively from milk or whey and containing 35.0% (m/m) or more of milk protein of any type (including casein and whey protein products and concentrates and any combinations thereof) and milk powders; these products can be used in the same function as thickeners and stabilizers, provided they are added only in amounts functionally necessary not exceeding 20.0 g/kg, taking into account any use of the stabilizers and thickeners permitted as per the Food Safety and Standards (Food Products Standards and Food Additives) Regulation, 2011;

Additionally, for use in fermented cream, only.-

- Starter cultures of harmless micro-organisms;

Additionally, for use in fermented cream and acidified cream, only.-

- Non-animal rennet and other safe and suitable coagulating enzymes to improve texture without achieving enzymatic coagulation;
- Sodium chloride.

(c) Composition.-

The product shall contain minimum 10.0 per cent. (m/m) milk fat. Acidity of the finished products, other than fermented and acidified creams, should not be more than 0.15 % (as lactic acid).

3. Food Additives.-

For products covered under this standard, specific food additives permitted in Appendix 'A' of these regulations may be used and only within the limits specified:

Provided that stabilizers, acidity regulators, thickeners and emulsifiers may be used when needed to ensure product stability and integrity of the emulsion, taking into consideration the fat content and durability of the product. With regard to the durability, special consideration should be given to the level of heat treatment applied since some minimally pasteurized products do not require the use of certain additives.

4. Contaminants, Toxins and Residues. -

The products shall comply with Food Safety and Standards (Contaminants, toxins and Residues) Regulations, 2011.

5. Hygiene. -

- (a) The products shall be prepared and handled in accordance with the requirements specified in Schedule 4, as applicable, of the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011 and such other guidelines as specified from time to time under the provisions of the Food Safety and Standard Act, 2006.
- (b) The products shall conform to the microbiological requirements specified in Appendix 'B' of these regulations.

6. Labelling. -

- (a) The name of the food shall be as specified in item 1 of this Standard, as appropriate.

However, "pre-packaged liquid cream" may be designated as "cream" and "cream packed under pressure" may be designated by another descriptive term that refers to its nature or intended use or as "Whipped Cream". The term "prepared cream" should not apply as a designation. The type of cream and the fat content in cream shall be always indicated on the label or in case of non-pre-packaged product; such declaration to be given on the container from which product will be offered for sale to the consumer. Creams which have been manufactured by the recombination or reconstitution of dairy ingredients shall be qualified with the term "Recombined" or "Reconstituted" as appropriate.

If the product conforms to the description in sub-item (e) of item 1, the name of the product shall be '*Malai*'.

- (b) Cream may be labelled according to milk fat content (m/m) along with product name as specified in item 1 of this Standard, as follows,-
 - (i) Low fat cream: Minimum 10 per cent. and less than 40 per cent.;
 - (ii) Medium fat cream: Minimum 40 per cent. and less than 60 per cent.;
 - (iii) High fat cream: Minimum 60 per cent.
- (c) Labels on packages of fermented creams may include reference to the starter culture used for fermentation.

- (d) The heat treatment, as per the sub-regulation 2.1.1 relating to General Standards for Milk and Milk Products, to which the product has been subjected to, shall be declared on the label.
- (e) In addition to the above-mentioned labelling requirements, the provisions of the Food Safety and Standards (Packaging and Labelling) Regulations, 2011, shall apply to pre-packaged product.

7. Method of Sampling and Analysis.-

The methods of sampling and analysis mentioned in the manuals as specified by the Food Safety and Standards Authority of India from time to time shall be applicable.

2.1.8 Standard for Milk Fat Products.-

This Standard applies to milk fats including anhydrous milk fat, anhydrous butter oil, butter oil and ghee as defined in item 1 of this sub-regulation*.

1. Description. -

Milk fat, *ghee*, butter oil, anhydrous milk fat and anhydrous butter oil are fatty products derived exclusively from milk or products obtained from milk, or both, by means of processes which result in almost total removal of water and milk solids-not-fat.

Ghee has especially developed flavour and physical structure as a result of its method of manufacturing.

2. Essential Composition and Quality Factors.-

(a) Raw Material.-

Milk and products obtained from milk. The raw material used shall be free from added flavour, colour or preservative.

(b) Composition.-

The standards of quality of milk fat, butter oil, anhydrous milk fat, anhydrous butter oil and ghee shall conform to the following requirements:—

Parameter	Milk Fat, Butter Oil	Anhydrous Milk Fat, Anhydrous Butter Oil	Ghee
Moisture, maximum, %, (m/m)	0.4	0.1	0.5
Milk fat, minimum, %, (m/m)	99.6	99.8	99.5
Butyro-refractometer Reading at 40 °C	40.0 to 44.0	40.0 to 44.0	As per table for

*This standard should be read along with sub-regulation 2.1.1 relating to General Standard for Milk and Milk Products with reference to the generic provisions pertaining to definitions of milk or milk products and heat treatments, guidelines for use of dairy terms, addition of micronutrients, etc.

Parameter	Milk Fat, Butter Oil	Anhydrous Milk Fat, Anhydrous Butter Oil	Ghee
Reichert Meissl Value, minimum	28.0	28.0	<i>Ghee</i> below
Polenske Value	1.0-2.0	1.0-2.0	-
FFA as Oleic Acid, maximum, %	0.4	0.3	3.0
Peroxide Value (Milli-equivalent of Oxygen/Kg fat), maximum	0.6	0.3	-
Baudouin Test	Negative	Negative	Negative

Additionally, the Butyro- refractometer reading and Reichert Meissl value of *ghee* produced in a State or Union territory specified in column (1) of the table below shall be as specified against the said State or Union Territory in the corresponding columns (2) and (3) of the said table.

Name of State or Union Territory	Butyro- refractometer reading at 40 °C	Minimum Reichert Meissl value	Polenske Value
(1)	(2)	(3)	(4)
Andhra Pradesh/ Telangana	40.0 to 43.0	24.0	-
Andaman and Nicobar Islands	41.0 to 44.0	24.0	-
Arunachal Pradesh	40.0 to 43.0	26.0	-
Assam	40.0 to 43.0	26.0	-
Bihar	40.0 to 43.0	28.0	-
Chandigarh	40.0 to 43.0	28.0	-
Chhattisgarh	40.0 to 44.0	26.0	-
Dadra and Nagar Haveli	40.0 to 43.0	24.0	-
Delhi	40.0 to 43.0	28.0	-
Goa	40.0 to 43.0	26.0	-
Daman and Diu	40.0 to 43.5	24.0	-
Gujarat			-

Name of State or Union Territory	Butyro- refractometer reading at 40 °C	Minimum Reichert Meissl value	Polenske Value
(a) Areas other than cotton tract areas	40 to 43.5	24.0	
(b) Cotton tract areas	41.5 to 45	21.0	
Haryana			-
(a) Areas other than cotton tract areas	40.0 to 43.0	28.0	
(b) Cotton tract areas	40.0 to 43.0	26.0	
Himachal Pradesh	40.0 to 43.0	26.0	-
Jammu and Kashmir	40.0 to 43.0	26.0	-
Jharkhand	40.0 to 43.0	28.0	-
Karnataka-			-
(a) Areas other than Belgaum district	40.0 to 43.0	24.0	
(b) Belgaum district	40.0 to 44.0	26.0	
Kerala	40.0 to 43.0	26.0	-
Lakshadweep	40.0 to 43.0	26.0	-
Madhya Pradesh-			-
(a) Areas other than cotton tract areas	40.0 to 44.0	26.0	
(b) Cotton tract areas	41.5 to 45.0	21.0	
Maharashtra-			-
(a) Areas other than cotton tract areas	40.0 to 43.0	26.0	
(b) Cotton tract areas	41.5 to 45.0	21.0	
Manipur	40.0 to 43.0	26.0	-
Meghalaya	40.0 to 43.0	26.0	-
Mizoram	40.0 to 43.0	26.0	-
Nagaland	40.0 to 43.0	26.0	-

Name of State or Union Territory	Butyro- refractometer reading at 40 °C	Minimum Reichert Meissl value	Polenske Value
Odisha	40.0 to 43.0	26.0	-
Pudducherry	40.0 to 44.0	26.0	-
Punjab	40.0 to 43.0	28.0	-
Rajasthan-			
a) Areas other than Jodhpur District	40.0 to 43.0	26.0	-
b) Jodhpur District	41.5 to 45.0	21.0	
Tamil Nadu	41.0 to 44.0	24.0	-
Tripura	40.0 to 43.0	26.0	-
Uttar Pradesh	40.0 to 43.0	26.0	-
Uttarakhand	40.0 to 43.0	26.0	-
West Bengal-			
a) Areas other than Bishnupur Sub-Division	40.0 to 43.0	28.0	-
b) Bishnupur Sub-Division	41.5 to 45.0	21.0	
Sikkim	40.0 to 43.0	28.0	-

Explanation: By cotton tract is meant the areas in the States where cotton seed is extensively fed to the cattle and so notified by the State Government concerned.

3. Food Additives. -

For products covered under this standard, specific food additives permitted in Appendix 'A' of these regulations may be used and only within the limits specified.

4. Contaminants, Toxins and Residues. -

The product shall comply with the limits stipulated under the Food Safety and Standards (Contaminants, toxins and Residues) Regulations, 2011.

5. Hygiene. -

The product shall be prepared and handled in accordance with the requirements specified in Schedule 4, as applicable, of the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011

and such other guidelines as specified from time to time under the provisions of the Food Safety and Standard Act, 2006.

6. Labelling. -

(a) According to the definitions in item 1 and composition in sub-item (b) of item 2, the name of the food shall be:

- (i) Milk fat or Butter Oil
- (ii) Anhydrous Milk fat or Anhydrous Butter Oil
- (iii) *Ghee*

(b) In addition to the above-mentioned labelling requirements, the provisions of the Food Safety and Standards (Packaging and Labelling) Regulations, 2011, shall apply to pre-packaged product.

7. Method of Sampling and Analysis. -

The methods of sampling and analysis mentioned in the manuals as specified by the Food Safety and Standards Authority of India from time to time shall be applicable.

2.1.9 Standard for Butter.-

This Standard applies to butter as defined in item 1 of this sub-regulation. *

1. Definition. -

“Butter” means the fatty product principally in the form of an emulsion of the type water-in-oil derived exclusively from milk or milk products, or both,

Butter may be of following types:

- (i) Table butter
- (ii) White butter/ Cooking butter

Table butter shall be made from pasteurised cream.

2. Essential composition and quality factors. -

(a) Raw materials. -

Milk and/or milk fat based products obtained from milk.

(b) Permitted ingredients. -

- Sodium chloride and food grade salt (*only in table butter*)

*This standard should be read along with sub-regulation 2.1.1 relating to General Standard for Milk and Milk Products with reference to the generic provisions pertaining to definitions of milk or milk products and heat treatments, guidelines for use of dairy terms, addition of micronutrients, etc.

- Starter cultures of harmless lactic acid and flavour producing bacteria
- Potable water

(c) Composition. -

The product shall conform to the compositional specifications provided in the table below:

Parameter	Table butter	White butter/ Cooking butter
Moisture, maximum, %, (m/m)	16.0	--
Milk fat, minimum, %, (m/m)	80.0	76.0
Milk solids-not-fat, maximum, %, (m/m)	2.0	--
Common salt, maximum, %, (m/m)	3.0	--

Note: Where butter is sold or offered for sale without any indication as to whether it is table butter or white butter, the Standards of table butter shall apply.

The extracted fat from butter shall meet the standards for Reichert Meissl value and Butyro-refractometer reading as prescribed for ghee.

3. Food Additives. -

For products covered under this standard, specific food additives specified in Appendix 'A' of these regulations may be used and only within the limits specified.

4. Contaminants, Toxins and Residues. -

The products shall comply with the limits for contaminants, toxins and residues stipulated under the Food Safety and Standards (Contaminants, toxins and Residues) Regulations, 2011.

5. Hygiene. -

(a) The product shall be prepared and handled in accordance with the requirements specified in Schedule 4, as applicable, of the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011 and such other guidelines as specified from time to time under the provisions of the Food Safety and Standard Act, 2006.

(b) The products covered under this standard shall conform to the microbiological requirements specified in Appendix 'B' of these regulations.

6. Labelling. -

(a) The name of the product shall be "Pasteurized Table butter" or "White butter/ Cooking Butter", as appropriate, in conformance to the composition specified in sub-item (c) of item 2. Additionally, in case of white/cooking butter, the name

should be preceded by the term 'Pasteurised' if the product has been prepared from pasteurised cream.

- (b) In addition to the labelling requirements mentioned above, the provisions of the Food Safety and Standards (Packaging and Labelling) Regulations, 2011 shall apply to pre-packaged products.

7. Method of Sampling and Analysis. -

The methods of sampling and analysis mentioned in the manuals as specified by the Food Safety and Standards Authority of India from time to time shall be applicable.

2.1.10 Standard for Milk Powders and Cream Powder. -

This Standard applies to cream powder and milk powders as defined in item 1 of this sub-regulation. *

1. Description. -

Milk powders and cream powder are milk products which can be obtained by partial removal of water from milk or cream. The fat or protein content, or both of the milk or cream may be adjusted, only to comply with the compositional requirements in sub-item (b) of item 2 of this sub-regulation, by addition or withdrawal of milk constituents in such a way as not to alter the whey protein to casein ratio of the milk or cream being adjusted. Product shall be free from added whey and whey preparations.

2. Essential Composition and Quality Factors. -

(a) Raw materials-

i) Milk and cream

ii) The following milk products are allowed for protein adjustment purposes:

- Milk retentate: Milk retentate is the product obtained by concentrating milk protein by ultrafiltration of milk, partly skimmed milk, or skimmed milk;

(b) Composition. -

The product shall conform to the compositional specifications provided in the table below:-

Parameter	Whole Milk Powder	Partly Skimmed Milk Powder	Skimmed Milk Powder	Cream Powder
Moisture*, maximum, %, (m/m)	5.0	5.0	5.0	5.0

*This standard should be read along with sub-regulation 2.1.1 relating to General Standard for Milk and Milk Products with reference to the generic provisions pertaining to definitions of milk or milk products and heat treatments, guidelines for use of dairy terms, addition of micronutrients, etc.

Parameter	Whole Milk Powder	Partly Skimmed Milk Powder	Skimmed Milk Powder	Cream Powder
Milk fat, %, (m/m)	Minimum 26.0 and less than 42.0	More than 1.5 and less than 26.0	1.5 (maximum)	42.0 (minimum)
Milk protein** in milk solids-not-fat, minimum, %, (m/m)	34.0	34.0	34.0	34.0
Titration acidity, maximum (ml 0.1 NaOH for 10 g - solids-not-fat)	18.0	18.0	18.0	--
Insolubility Index, maximum, ml	2.0	2.0	2.0	--
Total ash, maximum, % (m/m), on moisture and fat free basis	9.3	9.3	9.3	--
Scorched particles, maximum	Disc B	Disc B	Disc B	Disc B

* The moisture content does not include water of crystallization of the lactose; the milk solids-not-fat content includes water of crystallization of the lactose.

** Protein content is 6.38 multiplied by the total nitrogen determined.

3. **Food Additives. -**

For products covered under this standard, specific food additives specified in Appendix 'A' of these regulations may be used and only within the limits specified.

4. **Contaminants, Toxins and Residues. -**

The products shall comply with the limits stipulated under the Food Safety and Standards (Contaminants, toxins and Residues) Regulations, 2011.

5. **Hygiene. -**

- (a) The products shall be prepared and handled in accordance with the requirements specified in Schedule 4, as applicable, of the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011 and such other guidelines provided from time to time under the provisions of the Food Safety and Standard Act, 2006.
- (b) The products shall conform to the microbiological requirements specified in Appendix 'B' of these regulations.

6. **Labelling. -**

- (a) According to the composition in sub-item (b) of item 2, the name of the food shall be:

- (i) whole milk powder, or
- (ii) partly skimmed milk powder, or
- (iii) skimmed milk powder, or
- (iv) cream powder, as appropriate:

Provided that the “partly skimmed milk powder” may be designated “semi-skimmed milk powder” if the content of milk fat does not exceed 16% (m/m) and is not less than 14% (m/m).

- (b) Wherever the word “milk” appears on the label of a package of skimmed milk powder as the description or part of the description of the contents, it shall be immediately preceded or followed by the word “skimmed or partly skimmed”, as the case may be.
- (c) There shall not be placed on any package containing the product covered under this Standard any comment on, explanation of, or reference to either the statement of equivalence, contained in the prescribed declaration or on the word “skimmed” [or “unsuitable for babies”] except instructions as to dilution as follows:

“To make a fluid not below the composition of (here insert type of milk - toned milk or skimmed milk as the case may be) with the contents of this package, add (here insert the number of parts) of water by volume to one part by volume of this product”.
- (d) In addition to the labelling requirements mentioned above, the provisions of the Food Safety and Standards (Packaging and Labelling) Regulations, 2011 shall apply to pre-packaged product.

7. Method of Sampling and Analysis.-

The methods of sampling and analysis mentioned in the manuals as specified by the Food Safety and Standards Authority of India from time to time shall be applicable.

2.1.11 Standard for Dairy Whitener.-

This Standard applies to Dairy Whitener as defined in item 1 of this sub-regulation. *

1. Description.-

Dairy Whitener is a milk product prepared through an appropriate processing of cow milk, buffalo milk or milk of any other species as defined under this regulation or a mixture thereof, and contains added carbohydrates such as sucrose, dextrose and maltodextrin, singly or in combination. The fat or protein content, or both, of

*This standard should be read along with sub-regulation 2.1.1 relating to General Standard for Milk and Milk Products with reference to the generic provisions pertaining to definitions of milk or milk products and heat treatments, guidelines for use of dairy terms, addition of micronutrients, etc.

the milk may be adjusted by addition or withdrawal of milk constituents in such a way as not to alter the whey protein to casein ratio of milk.

2. Essential Composition and Quality Factors.-

The product shall be white or light cream in colour, uniform in composition and free from lumps except those that break up readily under slight pressure. The product shall be free from extraneous matters and added colours.

The flavour of the product before or after reconstitution shall be pleasant and sweet. It shall be free from off flavours. It is recommended that the flavour and taste may be judged on the basis of their sensory characteristics.

The product shall conform to the compositional specifications provided in the table below:–

Sr. No.	Characteristics	Requirement			
		Skimmed Milk Dairy Whitener	Low Fat Dairy Whitener	Medium Fat Dairy Whitener	High Fat Dairy Whitener
1.	Moisture, maximum, %, (m/m)	4.0	4.0	4.0	4.0
2.	Milk Fat, %, (m/m)	1.5 (maximum)	More than 1.5 and less than 10.0	Minimum 10.0 and less than 20.0	20.0 (minimum)
3.	Milk protein** (in solids-not-fat), minimum, %, (m/m)	34.0	34.0	34.0	34.0
4.	Insolubility Index, ml, maximum	1.5	1.5	1.5	1.5
5.	Total ash (on moisture, added sugar and fat free basis), maximum, %, (m/m)	9.3	9.3	9.3	9.3
6.	Acid Insoluble ash, maximum, %, (m/m)	0.1	0.1	0.1	0.1
7.	***Added sugar (as sucrose), maximum, %, (m/m)	18.0	18.0	18.0	18.0
8.	Titrateable acidity, maximum, % (as lactic acid)	1.5	1.5	1.5	1.2
9.	Scorched particles, maximum	Disc B	Disc B	Disc B	Disc B

** Protein content is 6.38 multiplied by the total nitrogen determined

*** Added sugar up to a level of 24% shall be permissible up to two years from the date of final notification.

3. Food Additives.-

For products covered under this standard, specific food additives specified in Appendix 'A' of these regulations may be used and only within the limits specified.

4. Contaminants, Toxins and Residues.-

The products shall comply with the maximum levels for contaminants specified in the Food Safety and Standards (Contaminants, toxins and Residues) Regulations, 2011.

5. Hygiene.-

(a) The products shall be prepared and handled in accordance with the requirements specified in Schedule 4, as applicable, of the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011.

(b) The products shall conform to the microbiological requirements specified in Appendix 'B' of these regulations.

6. Labelling.-

(a) According to the composition in sub-item (b) of item 2, the name of the food shall be:

- (i) Skimmed Milk Dairy Whitener, or
- (ii) Low Fat Dairy Whitener, or
- (iii) Medium Fat Dairy Whitener, or
- (iv) High Fat Dairy Whitener, as appropriate:

(b) In addition to the labelling requirements mentioned above, the provisions of the Food Safety and Standards (Packaging and Labelling) Regulations, 2011 shall apply to pre-packaged product.

7. Method of Sampling and Analysis.-

The methods of sampling and analysis mentioned in the manuals as specified by the Food Safety and Standards Authority of India from time to time shall be applicable.

2.1.12 Standard for Whey Powder.-

This Standard applies to Whey Powders as defined in item 1 of this sub-regulation.*

1. Description. -

(a) Whey powders are milk products obtained by drying Whey or Acid Whey.

(b) Whey is the fluid milk product obtained during the manufacture of cheese, casein or similar products by separation from the curd after coagulation of milk or of

*This standard should be read along with sub-regulation 2.1.1 relating to General Standard for Milk and Milk Products with reference to the generic provisions pertaining to definitions of milk or milk products and heat treatments, guidelines for use of dairy terms, addition of micronutrients, etc.

products obtained from milk, or both. Coagulation is obtained through the action of, principally, suitable enzymes of non-animal origin.

- (c) **Acid whey** is the fluid milk product obtained during the manufacture of cheese, casein, *paneer*, *channa* or similar products by separation from the curd after coagulation of milk and of products obtained from milk. Coagulation is obtained, principally, by acidification and heating.

2. Essential Composition and Quality Factors. -

(a) Raw materials. -

Whey or Acid whey, as appropriate.

(b) Ingredients. -

Seed lactose in the manufacture of pre-crystallized Whey Powder.

(c) Composition. -

The product shall conform to the compositional specifications provided in the table below:–

Parameter	Whey Powder	Acid Whey Powder
Moisture ⁽ⁱ⁾ , maximum, %, (m/m)	5.0	4.5
Milk fat, maximum, %, (m/m)	2.0	2.0
Milk protein ⁽ⁱⁱ⁾ , minimum, %, (m/m)	10.0	7.0
Lactose content ⁽ⁱⁱⁱ⁾ , as anhydrous lactose, minimum, %, (m/m)	61.0	61.0
pH (in 10% solution)	more than 5.1 ^(iv) --	5.1 ^(v) (maximum)
Total ash, maximum, %, (m/m) (on dry basis)	9.5	15.0

Note(s):

- (i) The water content does not include water of crystallization of the lactose.
(ii) Protein content is 6.38 multiplied by the total nitrogen determined.
(iii) Although the powders may contain both anhydrous lactose and lactose monohydrates, the lactose content is expressed as anhydrous lactose. 100 parts of lactose monohydrate contain 95 parts of anhydrous lactose.
(iv) Or titratable acidity (calculated as lactic acid) <0.35%.
(v) Or titratable acidity (calculated as lactic acid) ≥ 0.35%.

In accordance with the provision of entry (iii) of sub-item(c) of item 3 of sub-regulation 2.1.1 (General Standard for Milk and milk products), whey powders may be modified in composition to meet the desired end-product composition, for instance, neutralization or demineralization. However, compositional modifications beyond the minimum or maximum specified above for milk protein and water are not permitted.

3. Food Additives. -

For products covered under this standard, specific food additives specified in Appendix 'A' of these regulations may be used and only within the limits specified.

4. Contaminants, Toxins and Residues. -

The products shall comply with the limits stipulated under the Food Safety and Standards (Contaminants, toxins and Residues) Regulations, 2011.

5. Hygiene. -

(a) The products shall be prepared and handled in accordance with the requirements specified in Schedule 4, as applicable, of the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011 and such other guidelines as specified from time to time under the provisions of the Food Safety and Standard Act, 2006.

(b) The products shall conform to the microbiological requirements specified in Appendix 'B' of these regulations.

6. Labelling. -

(a) According to the composition in sub-item (c) of item 2, the name of the food shall be:

- (i) Whey Powder, or
- (ii) Acid Whey Powder, as appropriate:

(b) In addition to the labelling requirements mentioned above, the provisions of the Food Safety and Standards (Packaging and Labelling) Regulations, 2011 shall apply to pre-packaged product.

7. Method of Sampling and Analysis.-

The methods of sampling and analysis mentioned in the manuals as specified by the Food Safety and Standards Authority of India from time to time shall be applicable.

2.1.13 Standard for Fermented Milk Products

This Standard applies to fermented milks, including, heat-treated fermented milks, concentrated fermented milks and composite milk products based on these products in conformity with the definitions given in item 1 of this sub-regulation.*

1. Description.-

*This standard should be read along with sub-regulation 2.1.1 relating to General Standard for Milk and Milk Products with reference to the generic provisions pertaining to definitions of milk or milk products and heat treatments, guidelines for use of dairy terms, addition of micronutrients, etc.

(a) Fermented Milk is a milk product obtained by fermentation of milk, which may have been manufactured using other permitted raw material, by the action of suitable microorganisms and resulting in lowering of pH with or without coagulation (iso-electric precipitation). Fermented milk may be heat treated after fermentation. The raw material used shall be subjected to a heat treatment as defined in the General Standard for Milk and Milk Products.

Certain fermented milks are characterised by specific starter culture(s) used for fermentation as follows:

<i>Dahi</i> (Curd)	Lactic acid bacteria
Yoghurt	Symbiotic cultures of <i>Streptococcus thermophilus</i> and <i>Lactobacillus delbrueckii</i> sub sp. <i>bulgaricus</i>
Alternate Culture Yoghurt	Cultures of <i>Streptococcus thermophilus</i> and <i>Lactobacillus species</i>
Acidophilus milk	<i>Lactobacillus acidophilus</i> .

Other harmless microorganisms than those constituting the specific starter cultures specified above may also be added.

(b) Flavoured fermented milk are composite milk products, as defined in sub-regulation 2.1.1, obtained from fermented milks and which contain a maximum of 50% (m/m) of permitted non-dairy ingredients including flavourings. The non-dairy ingredients can be mixed prior to or after fermentation:

Provided that flavoured *dahi* shall only be sold in pre-packaged form.

(c) Drinks based on fermented milk are composite milk products, as defined in sub-regulation 2.1.1, obtained by mixing fermented milks as described in sub-item (a) of item 1 with potable water with or without the addition of whey, other milk and milk products, other permitted non-dairy ingredients and flavours. Drinks based on fermented milk contain a minimum of 40% (m/m) fermented milk. Other microorganisms than those constituting the specific starter cultures may be added. Drinks based on fermented milk include products such as *lassi*, *chhaach*, *buttermilk*, etc.

(d) Concentrated Fermented Milk is fermented milk, the protein of which has been increased prior to or after fermentation.

(i) Chakka means the fermented and concentrated milk product obtained by (partial) removal of the whey from plain *dahi* or plain yoghurt or by any other process which leads to a product of same composition and characteristics. It shall have white to pale yellow colour and uniform semi-solid consistency. It shall not be moldy and shall be free from signs of free fat and water. It shall be smooth and not appear dry. The milk from which *dahi* or yoghurt is prepared for manufacturing

chakka shall be subjected to a heat treatment as defined in the sub-regulations 2.1.1 (General Standard for Milk and Milk Products).

- (ii) **Shrikhand** means the semi-soft concentrated composite milk product obtained from *chakka*, or skimmed milk *chakka* to which milk fat and sugar is added or by any other process which leads to a product of same composition and characteristics. It may also contain permitted non-dairy ingredients.

2. Essential Composition and Quality Factors.-

(a) Raw materials.-

- (i) milk;
- (ii) concentrated milk and dried milk;
- (iii) cream, butter, butter oil and anhydrous milk fat;
- (iv) potable water for use in reconstitution or recombination or drinks based on fermented milks.

(b) Permitted ingredients.-

- (i) starter cultures of harmless microorganisms, including those specified in sub-item (a) of item 1;
- (ii) other suitable and harmless microorganisms;
- (iii) salt;
- (iv) sugar (*only in Flavoured Fermented Milks, Drinks based on Fermented Milks, Yoghurt, Dahi and Shrikhand*);
- (v) nutritive sweeteners other than sugar (*only in Flavoured Fermented Milks, Drinks based on Fermented Milks, Yoghurt and pre-packaged Dahi*);
- (vi) non-dairy ingredients such as fruits and vegetables and their products thereof such as juices, purees, pulps, preparations and preserves derived therefrom, cereals and cereal products, coconut and coconut products, honey, chocolate, nuts, coffee, spices, condiments, culinary herbs and other harmless natural flavouring foods (*only in Flavoured Fermented Milks, Drinks based on Fermented Milks and Shrikhand*);
- (vii) milk and milk products (*only in Drinks based on Fermented Milks*);
- (viii) Prebiotics and Probiotics;
- (ix) Starch (*only in fermented milks heat treated after fermentation, flavoured fermented milks and drinks based on fermented milks*)

Provided that it is added only in amounts functionally necessary as governed by Good Manufacturing Practice, taking into account any use of the stabilizers or thickeners as specified in Appendix 'A' of these regulations. Starch may be added either before or after adding the non-dairy ingredients.

(c) Composition:

- (i) The starter microorganisms shall be viable, active and abundant in the product up to the date of minimum durability. The sum of microorganisms constituting the starter culture defined in sub-item (a) of item 1 shall not be less than 10^7 cfu/g. The labelled microorganisms, when specific microorganisms other than those specified

in sub-item (a) of item 1 are added and a content claim is made on label, shall not be less than 10^6 cfu/g. If the product is heat treated after fermentation these requirements for viable microorganisms do not apply;

- (ii) Fermented milks shall have a minimum milk protein content of 2.9 % (m/m) and minimum titratable acidity of 0.45% (m/m as lactic acid) unless otherwise specified. In case of Flavoured Fermented Milks and Drinks based on Fermented Milks, these specifications apply to the Fermented Milk Part unless otherwise specified;
- (iii) Plain *Dahi* shall have the same minimum percentage of milk fat and milk solids-not-fat as that of the milk, as provided for in the Standard for Milk, from which it is prepared. Where plain *Dahi* is sold or offered for sale without any indication of class of milk, the Standards prescribed for *Dahi* prepared from mixed milk shall apply;
- (iv) Yoghurt (including Flavoured Yoghurt) and Flavoured *Dahi* shall conform to the following compositional specifications:-

Parameter	Yoghurt and Flavoured <i>Dahi</i>	Partly skimmed Yoghurt And Flavoured Partly Skimmed <i>Dahi</i>	Skimmed Yoghurt And Flavoured Skimmed <i>Dahi</i>
Milk Fat, % , (m/m)	Not less than 3.0 and not more than 15	More than 0.5 and Less than 3.0	0.5 (maximum)
Milk solids-not-fat, minimum, % , (m/m)	8.5	8.5	8.5
Milk protein*, minimum, % , (m/m)	2.9	2.9	2.9
Titratable acidity, minimum, % (as lactic acid)	0.6	0.6	0.6

* Protein content is 6.38 multiplied by the total nitrogen determined

Note:

- When sold without any indication, the product shall conform to the Standards of 'Yoghurt' or 'Flavoured *Dahi*', as appropriate. The term 'flavoured' covers sweetened, flavoured and fruit variants, labelled in accordance with sub-item (b) of item 6 below. For the use of probiotics in dairy products; the 'Indian Council Medical Research Guidelines for Evaluation of Probiotics in Food shall be followed.

- (v) *Chakka* shall conform to the following compositional specifications:-

Parameter		Chakka	Skimmed Milk Chakka	Full Cream Chakka
1	Total solids, minimum, % , (m/m)	30.0	20.0	28.0
2	Milk fat, % , (m/m), on dry	33.0	5.0	38.0

	basis	(minimum)	(maximum)	(minimum)
3	Milk protein*, minimum, %, (m/m), on dry basis	30.0	60.0	30.0
4	Titratable acidity, maximum, % (as lactic acid)	2.5	2.5	2.5
5	Total Ash, maximum, %, (m/m), on dry basis	3.5	5.0	3.5

* Protein content is 6.38 multiplied by the total nitrogen determined

Note: When sold without any indication, the product shall conform to the standards of 'Chakka'.

(vi) *Shrikhand* shall conform to the following compositional specifications:-

Parameter	Shrikhand	Full Cream Shrikhand	Fruit Shrikhand
Total solids, minimum, %, (m/m)	58.0	58.0	58.0
Milk fat, minimum, %, (m/m), on dry basis	8.5	10.0	7.0
Milk protein*, minimum, %, m/m, (on dry basis)	9.0	7.0	6.0
Titratable acidity, maximum, % (as lactic acid)	1.4	1.4	1.4
Sugar (sucrose), maximum, %, m/m (on dry basis)	72.5	72.5	72.5
Total Ash, maximum, %, m/m (on dry basis)	0.9	0.9	0.9

* Protein content is 6.38 multiplied by the total nitrogen determined

(d) **Essential manufacturing characteristic:** Whey removal after fermentation is not permitted in the manufacture of fermented milks, except for concentrated fermented milk.

3. Food Additives. -

For products covered under this standard, specific food additives specified in Appendix 'A' of these regulations may be used and only within the limits specified.

4. Contaminants, Toxins and Residues.-

The products shall comply with Food Safety and Standards (Contaminants, toxins and Residues) Regulations, 2011.

5. Hygiene.-

(a) The products shall be prepared and handled in accordance with the requirements specified in Schedule 4, as applicable, of the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011 and such guidelines as specified from time to time under the provisions of the Food Safety and Standard Act, 2006.

(b) The products shall conform to the microbiological requirements specified in Appendix 'B' of these regulations.

6. Labelling.-

(a) Name of the food.-

- (i) The name of the products covered by sub-item (a) and (b) of item 1 shall be 'Fermented Milk':

Provided that the name 'Fermented Milk' may be replaced with designations *Dahi*, Curd and Yoghurt if the product complies with the relevant provisions of this Standard.

The designation 'Yoghurt or *Dahi*' may be used in connection with the term "frozen":

Provided that,-

- the product submitted to freezing complies with the requirements in this Standard;
- the specific starter cultures can be reactivated in the specified numbers by thawing; and
- the frozen product is named as such and is sold for direct consumption only.

- (ii) Yoghurt or *Dahi* containing non-dairy ingredients may be designated as 'Sweetened or Flavoured Yoghurt or *Dahi*', as appropriate. Yoghurt or *Dahi* containing fruits may be designated as 'Fruit Yoghurt or *Dahi*', as appropriate.

The name of the products defined in sub-item (c) of item 1 shall be '*Drinks based on Fermented Milk*' or may be designated with other recognized specific names like *lassi*, *chhaas* etc. When flavoured, the designation shall include the name of the principal flavouring substance(s) or flavour(s) added.

- (iii) The name of the products covered by item (i) of sub-item (d) of item 1 shall be '*Chakka*'.

- (iv) The name of the products covered by item (ii) of sub-item (d) of item 1 shall be '*Shrikhand*'.

- (v) Products obtained from fermented milk(s) heat treated after fermentation shall be named "Heat Treated _____", the blank being replaced by the term "Fermented Milk" or another permitted designation or name as appropriate.
- (vi) The designation of Flavoured Fermented Milks shall include the name of the principal flavouring substance(s) or flavour(s) added.
- (vii) Fermented milks to which only nutritive carbohydrate sweeteners have been added, may be labelled as "sweetened _____", the blank being replaced by the term "Fermented Milk" or another permitted designation or name as appropriate.
- (b) The type of *dahi*, yoghurt, *chakka* or *shrikhand* shall be always declared on the label or otherwise if the product is not pre-packaged such declaration to be given on the container from which product will be offered to the consumer.
- (c) When cultures of *Bifidobacterium bifidum* and *Lactobacillus acidophilus* and other cultures of suitable lactic acid producing harmless bacteria are added, a declaration to this effect shall be made on the label or otherwise if the product is not pre-packaged.
- (d) In addition to the labelling requirements mentioned above, the provisions of the Food Safety and Standards (Packaging and Labelling) Regulations, 2011, shall apply to pre-packaged product.

7. Method of Sampling and Analysis.-

The methods of sampling and analysis mentioned in the manuals as specified by the Food Safety and Standards Authority of India from time to time shall be applicable.

2.1.14 Standard for Ice Cream, *Kulfi*, Chocolate Ice Cream, Softy Ice-Cream, Milk Ice, Milk Lolly and Dried Ice Cream Mix.-

This Standard applies to Ice Cream and *Kulfi* and their variants, milk ice and milk lolly, and dried ice-cream mix in conformity with the definitions given in item 1 of this sub-regulation.*

1. Description. -

- (a) Ice-Cream, *Kulfi*, Chocolate Ice Cream or Softy Ice-Cream means the frozen milk product conforming to the composition specified in entry (i) of sub-item (c) of item 2, obtained by freezing a pasteurized mix prepared from milk or other products derived from milk, or both, with or without addition of nutritive sweeteners and other permitted non-dairy ingredients. The said product may contain incorporated

*This standard should be read along with sub-regulation 2.1.1 relating to General Standard for Milk and Milk Products with reference to the generic provisions pertaining to definitions of milk or milk products and heat treatments, guidelines for use of dairy terms, addition of micronutrients, etc.

air and shall be frozen hard except in case of softy ice-cream where it can be frozen to a soft consistency.

- (b) Milk Ice or Milk Lolly means the product conforming to the composition specified in entry (ii) of sub-item (c) of item 2, obtained by freezing a pasteurized mix prepared from milk or other products derived from milk with or without the addition of nutritive sweeteners and other permitted non-dairy ingredients. The said product shall be frozen hard.
- (c) Dried Ice-Cream Mix means the product in a powder form which on addition of prescribed amount of water and freezing shall result in a product similar in characteristics to the respective product described in the sub-item (a) of item 1.

2. Essential Composition and Quality Factors. -

(a) Raw Material. -

Milk and milk products.

(b) Permitted ingredients. -

- (i) sugar and other nutritive sweeteners (e.g. *jaggery*, dextrose, fructose, liquid glucose, dried liquid glucose, high maltose corn syrup, honey etc.);
- (ii) potable water;
- (iii) starch, provided it is added only in amounts functionally necessary as governed by Good Manufacturing Practice, taking into account any use of the stabilizers or thickeners as specified in Appendix 'A' of these regulations.;
- (iv) other non-dairy ingredients - fruit and fruit products, eggs and egg products, coffee, cocoa, chocolate, confectionary, condiments, spices, ginger and nuts; bakery products such as cake or cookies.

(c) Composition.-

The product shall conform to the compositional specifications provided in the table below:–

(i) Ice cream, *Kulfi*, Chocolate Ice cream and Softy Ice Cream

Parameter	Ice cream or <i>Kulfi</i> or Chocolate ice cream or softy ice cream	Medium Fat Ice Cream or <i>Kulfi</i> or Chocolate ice cream or softy ice cream	Low Fat Ice Cream or <i>Kulfi</i> or Chocolate ice cream or softy ice cream
Total Solids, minimum, (m/m) %,	36.0	30.0	26.0
Weight, minimum, g/l	525.0	475.0	475.0
Milk Fat, %, (m/m)	10.0 (minimum)	More than 2.5 and less than 10.0	2.5 (maximum)
Milk Protein*,	3.5	3.5	3.0

minimum, (m/m)	%,			
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* Protein content is 6.38 multiplied by the total nitrogen determined

Note(s):

(i) In case where coating, base or layer of non-dairy ingredients forms a separate part of the product, only the Ice Cream portion shall conform to the respective composition.

(ii) When any type of ice cream, *kulfi*, chocolate ice cream or softy ice cream is offered for sale in contravention of the requirements of sub-item (b) of item 6, the standards prescribed for the type ice cream, *kulfi*, chocolate ice cream or softy ice cream as per this sub-regulation shall apply.

(ii) Milk Ice or Milk Lolly.-

Parameter	Milk ice or Milk lolly
Total Solids, minimum, %, (m/m)	20.0
Milk Fat, maximum, %, (m/m)	2.0
Milk Protein*, minimum, %, (m/m)	3.5

* Protein content is 6.38 multiplied by the total nitrogen determined

Note: In case where base or layer of non-dairy ingredients forms a separate part of the product, only the milk ice or milk lolly portion shall conform to the above composition.

(iii) Dried Ice Cream Mix.-

The said product on addition of water shall give a product conforming to the composition, except the 'weight', as specified in the entry (i) of sub-item (c) of item 2 for the respective product described in sub-item (a) of item 1. The moisture content of the dried product shall not be more than 4.0 % (m/m).

3. Food Additives. -

- (a) For products covered under this standard, specific food additives specified in Appendix 'A' of these regulations may be used and only within the limits specified.
- (b) The food additive use level specified in Appendix 'A' of these regulations shall apply to the product after reconstitution in respect of dried Ice Cream Mix.

4. Contaminants. -

The products shall comply with the limits stipulated in the Food Safety and Standards (Contaminants, toxins and Residues) Regulations, 2011.

5. Hygiene.-

- (a) The products shall be prepared and handled in accordance with the requirements specified in Schedule 4, as applicable, of the Food Safety and Standards (Licensing

and Registration of Food Businesses) Regulations, 2011 and such other guidelines as specified from time to time under the provisions of the Food Safety and Standard Act, 2006.

- (b) The products shall conform to the microbiological requirements specified in Appendix 'B' of these regulations.

6. Labelling.-

(a) Name of the Food.-

- (i) The name of the product covered by sub-item (a) of item 1 shall be 'Ice Cream', 'Kulfi', 'Chocolate Ice Cream' or 'Softy Ice Cream'.
- (ii) The name of the product covered by sub- item (b) of item 1 shall be 'Milk Ice' or 'Milk Lolly'.
- (iii) The name of the product covered by sub- item (c) of item 1 shall be 'Dried Ice Cream Mix'.

- (b) The type, as per item (i) of sub- item (c) of item 2, of ice cream, *kulfi*, chocolate ice cream or softy ice cream shall always be indicated on the label of the product. For softy ice cream offered for sale directly from the freezer without prepackaging, the type of product shall be displayed in a manner and at a place that is clearly visible to the consumer.

- (c) Every package of ice cream, *kulfi*, chocolate ice cream and softy ice cream containing starch shall have a declaration on its label as specified in sub-regulation 2.7.1 (2) of Food Safety and Standards (Packaging and Labelling) Regulations, 2011.

- (d) In addition to the above mentioned labelling requirements, the provisions of the Food Safety and Standards (Packaging and Labelling) Regulations, 2011, shall apply to pre-packaged product.

7. Method of Sampling and Analysis.-

The methods of sampling and analysis mentioned in the manuals as specified by the Food Safety and Standards Authority of India from time to time shall be applicable.

2.1.15 Standard for Frozen Desserts or Confections with Added Vegetable Oil/ Fat or Vegetable Protein, or both

This Standard applies to Frozen Desserts or Confections in conformity with the definitions in item 1 of this sub-regulation.*

1. Definition.-

*This standard should be read along with sub-regulation 2.1.1 relating to General Standard for Milk and Milk Products with reference to the generic provisions pertaining to definitions of milk or milk products and heat treatments, guidelines for use of dairy terms, addition of micronutrients, etc.

(a) Frozen Dessert or Frozen Confection means the product obtained by freezing a pasteurised mix prepared with edible vegetable oils or fats, having a melting point of not more than 37⁰ C or vegetable protein products, or both. It may also contain milk fat and other milk solids with the addition of nutritive sweeteners and other permitted non-dairy ingredients. The said product may contain incorporated air and may be frozen hard or frozen to a soft consistency.

(b) Dried Frozen Dessert Mix or Dried Frozen Confection Mix means the product in a powder form which on addition of prescribed amount of water and freezing shall give a product similar in characteristics to frozen dessert as described in sub-item (a).

2. Essential Composition and Quality Factors.-

(a) Raw Material.-

- (i) Milk and/or milk products;
- (ii) Vegetable oils or fats;
- (iii) Vegetable protein products.

(b) Permitted ingredients.-

- (i) sugar and other nutritive sweeteners (e.g. jaggery, dextrose, fructose, liquid glucose, dried liquid glucose, high maltose corn syrup, honey etc.);
- (ii) potable water;
- (iii) starch, provided it is added only in amounts functionally necessary as governed by Good Manufacturing Practice, taking into account any use of the stabilizers or thickeners as specified in Appendix 'A' of these regulations.;
- (iv) other non-dairy ingredients - fruit and fruit products, eggs and egg products, coffee, cocoa, chocolate, confectionary, condiments, spices, ginger and nuts; bakery products such as cake or cookies.

(c) Composition.-

The product shall conform to the compositional specifications provided in the table below:-

(i) Frozen Dessert or Frozen Confection

Parameter	Frozen Dessert or Frozen Confection	Medium fat Frozen Dessert or Frozen Confection	Low fat Frozen Dessert or Frozen Confection
Total Solids, minimum, %, (m/m)	36.0	30.0	26.0
Weight, minimum, (g/l)	525.0	475.0	475.0
Total Fat, %, (m/m)	10 (minimum)	More than 2.5 and less than 10.0	2.5 (maximum)
Protein*, minimum, % (m/m)	3.5	3.5	3.0

* Protein content is 6.25 multiplied by the total nitrogen determined

Note(s):

(1) In case where coating, base or layer of non-dairy ingredients forms a separate part of the product, only the Frozen Dessert or Frozen Confection portion shall conform to the respective composition.

(2) When any type of Frozen Dessert or Frozen Confection is offered for sale in contravention of the requirements of sub-item (b) of item 6, the Standards prescribed for these types of Frozen Desserts or Frozen Confections as per this item shall apply.

(ii) Dried Frozen Dessert Mix or Dried Frozen Confection Mix

The product on addition of water shall give a product conforming to the composition, except the 'weight', as specified in the entry (i) of sub- item (c) of item 2 for the respective product described in the sub- item (a) of item 1. The moisture content of the dried product shall not be more than 4.0 % (m/m).

3. Food Additives. -

(a) For products covered under this standard, specific food additives specified in Appendix 'A' of these regulations may be used and only within the limits specified.

(b) The food additive use level specified in Appendix 'A' of the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011 shall apply to the product after reconstitution in respect of Dried Frozen Dessert Mix or Dried Frozen Confection Mix.

4. Contaminants, Toxins and Residues. -

The products shall comply with the limits stipulated in the Food Safety and Standards (Contaminants, toxins and Residues) Regulations, 2011.

5. Hygiene.-

(a) The products shall be prepared and handled in accordance with the requirements specified in Schedule 4, as applicable, of the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011 and such guidelines as specified from time to time under the provisions of the Food Safety and Standard Act, 2006.

(b) The products shall conform to the microbiological requirements specified in Appendix 'B' of these regulations.

6. Labelling .-

(a) Name of the food.-

(i) The name of the product covered by sub-item (a) of item 1 shall be 'Frozen Dessert or Frozen Confection'.

(ii) The name of the product covered by sub-item (b) of item 1 shall be 'Dried Frozen Dessert or Dried Frozen Confection'.

(b) The type, as per entry (i) of sub-item (c) of item 2, of Frozen Dessert or Frozen Confection shall be indicated on the label of the product. For soft consistency products offered for sale directly from the freezer without any pre-packaging, the type of product shall be displayed in a manner and at a place that is clearly visible to the consumer.

(c) Every package of Frozen Desert or Frozen Confection shall bear the following label, namely:–

“Contains % Milk Fat* Edible Vegetable Oil* and Vegetable Fat* and Vegetable Protein Product”

**strike out whatever is not applicable*

(d) In addition to the above-mentioned labelling requirements, the provisions of the Food Safety and Standards (Packaging and Labelling) Regulations, 2011, shall apply to pre-packaged product.

7. Method of Sampling and Analysis.-

The methods of sampling and analysis mentioned in the manuals as specified by the Food Safety and Standards Authority of India from time to time shall be applicable.

2.1.16 Standard for *Chhana* and *Paneer*.-

This Standard applies to *Chhana* and *Paneer* as defined in the item 1 of this sub-regulation. *

1. Definition. -

Chhana or *Paneer* means the product obtained from any variant of milk**, with or without added milk solids, by precipitation with permitted acidulants and heating.

2. Essential Composition and Quality Factors.-

(a) Raw materials.-

(i) Milk

(ii) Milk solids

(b) Permitted ingredients.-

(i) Acidulants such as lactic acid, citric acid, malic acid, vinegar, glucono delta lactone, sour whey;

*This standard should be read along with sub-regulation 2.1.1 relating to General Standard for Milk and Milk Products with reference to the generic provisions pertaining to definitions of milk or milk products and heat treatments, guidelines for use of dairy terms, addition of micronutrients, etc.

** As defined in item 1 of the sub-regulation 2.1.2 (Standard for Milk).

(ii) spices and condiments (for flavoured *paneer* only);

(iii) salt (for flavoured *paneer* only).

(c) Composition. -

The product shall conform to the compositional specifications provided in the table below:–

Parameter	<i>Chhana or Paneer</i>	<i>Low fat Chhana or Paneer</i>
Moisture, maximum, %, (m/m)	65.0 (for <i>Chhana</i>) 60.0 (for <i>Panner</i>)	65.0 (for <i>Chhana</i>) 60.0 (for <i>Panner</i>)
Milk fat, %, (m/m), dry matter basis	50.0 (minimum)	15.0 (maximum)

3. Food Additives. -

For products covered under this standard, specific food additives specified in Appendix 'A' of these regulations may be used and only within the limits specified.

4. Contaminants, Toxins and Residues. -

The products shall comply with the limits stipulated in the Food Safety and Standards (Contaminants, toxins and Residues) Regulations, 2011.

5. Hygiene. -

(a) The products shall be prepared and handled in accordance with the requirements specified in Schedule 4, as applicable, of the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011 and such guidelines as specified from time to time under the provisions of the Food Safety and Standard Act, 2006.

(b) The products shall conform to the microbiological requirements specified in Appendix 'B' of these regulations.

6. Labelling. -

(a) The name of the product shall be '*Chhana*', '*Paneer*', '*Low Fat Chhana*' or '*Low Fat Paneer*' depending upon the composition as per the sub-item (b) of item 2.

(b) *Low Fat Channa* and *Low Fat Paneer* shall be sold in sealed package only and shall bear the following label declaration:

"LOW FAT PANEER or LOW FAT CHHANA"

(c) In addition to the above-mentioned labelling requirements, the provisions of the Food Safety and Standards (Packaging and Labelling) Regulations, 2011, shall apply to pre-packaged product.

7. **Method of Sampling and Analysis.-**

The methods of sampling and analysis mentioned in the manuals as specified by the Food Safety and Standards Authority of India from time to time shall be applicable.

2.1.17 **Standard for Cheese and Cheese Products.-**

This Standard applies to Cheese, Processed Cheese and Processed Cheese Spreads as defined in the item 1 of this sub-regulation.*

1. **Description. -**

Cheese is the ripened or unripened soft, semi-hard, hard, or extra-hard product, which may be coated with food grade waxes or polyfilm, and in which the whey protein/ casein ratio does not exceed that of milk. Cheese is obtained by:

(i) coagulating wholly or partly the protein of milk, skimmed milk, partly skimmed milk, cream, whey cream or buttermilk, or any combination of these materials, through the action of suitable enzymes of non-animal origin or other suitable coagulating agents, with or without use of harmless lactic acid bacteria and flavour producing bacteria, and by partially draining the whey resulting from the coagulation, while respecting the principle that cheese-making results in a concentration of milk protein (in particular, the casein portion), and that consequently the protein content of the cheese will be distinctly higher than the protein level of the blend of the above milk materials from which cheese was made;

(ii) processing techniques involving coagulation of the protein of milk or products obtained from milk, or both, which give an end-product with similar physical, chemical and organoleptic characteristics as the product specified in entry (i) above.

All cheese shall be made from milk which is subject to heat treatment at least equivalent to that of pasteurization.

(a) Ripened Cheese means cheese which is not ready for consumption shortly after manufacture but which must be held for some time at such temperature and under such other conditions as will result in necessary biochemical and physical changes characterizing the cheese in question.

(b) Mould Ripened Cheese means ripened cheese in which the ripening has been accomplished primarily by the development of characteristic mould growth through the interior and/ or on the surface of the cheese.

*This standard should be read along with sub-regulation 2.1.1 relating to General Standard for Milk and Milk Products with reference to the generic provisions pertaining to definitions of milk or milk products and heat treatments, guidelines for use of dairy terms, addition of micronutrients, etc.

(c) Unripened Cheese including fresh cheese means cheese which is ready for consumption shortly after manufacture.

(b) Individual or Named Variety Cheese is a cheese, as defined in item 1 of this sub-regulation, that is designated with its well-established unique name as provided below.

(ba) Cheddar Cheese means ripened hard cheese obtained by coagulating heated or pasteurised milk with cultures of harmless lactic acid producing bacteria, suitable enzymes of non-animal origin or other suitable coagulating enzymes. It shall be in the form of hard pressed block and it may have a coating of food grade waxes or wrapping of cloth or polyfilm. It shall have firm, smooth and waxy texture with a pale straw to orange colour without any gas holes.

(bb) Danbo Cheese means ripened semi hard cheese obtained by coagulating heated or pasteurised milk with cultures of harmless lactic acid producing bacteria, suitable enzymes of non-animal origin or other suitable coagulating enzymes. It shall be smooth in appearance with firm texture and uniform yellow colour and may be coated with food grade waxes or wrapping of cloth or polyfilm.

(bc) Edam Cheese means the ripened semi hard cheese obtained by coagulating heated or pasteurised milk with cultures of harmless lactic acid producing bacteria, suitable enzymes of non-animal origin or other suitable coagulating enzymes. It shall have a firm texture suitable for cutting with a yellowish colour and may have a hard rind which may be coated with food grade waxes, wrapping of cloth, polyfilm or vegetable oil.

(bd) Gouda Cheese means ripened semi hard cheese obtained by coagulating milk with cultures of harmless lactic acid producing bacteria, suitable enzymes of non-animal origin or other suitable coagulating enzymes. It shall have firm texture suitable for cutting, straw to yellowish colour which may have a hard rind coated with food grade waxes, wrapping of cloth, or vegetable oil.

(be) Havarti Cheese means ripened semi hard cheese obtained by coagulating milk with cultures of harmless lactic acid producing bacteria, suitable enzymes of non-animal origin or other suitable coagulating enzymes. It shall have firm texture suitable for cutting, a light yellow colour and may have a semi soft slightly greasy rind.

- (bf) Tilsiter** means ripened semi hard cheese obtained by coagulating milk with cultures of harmless lactic acid producing bacteria and cultures of *Bacterium linens*, suitable enzymes of non-animal origin or other suitable coagulating enzymes. It shall have firm texture suitable for cutting, with an ivory to yellow colour with a firm rind which may show red and yellow smear producing bacteria or coated with food grade waxes or wrapping of cloth or polyfilm after removal of the smear.
- (bg) Cottage Cheese and Creamed Cottage Cheese** means soft unripened cheese obtained by coagulation of pasteurised skimmed milk with cultures of harmless lactic acid bacteria with or without the addition of suitable enzymes of non-animal origin or other suitable coagulating enzymes. Creamed Cottage Cheese is cottage cheese to which a pasteurised creaming mixture of cream, skimmed milk, condensed milk, non-fat dry milk, dry milk protein, Sodium or Potassium or Calcium or Ammonium caseinate is added. It shall have a soft texture with a natural white colour. It may contain spices, condiments, seasonings and fruits pulp.
- (bh) Cream Cheese (Rahmfrischkase)** means soft, unripened cheese obtained by coagulation of pasteurised milk and pasteurised cream with cultures of harmless lactic acid producing bacteria with or without the addition of suitable enzymes of non-animal origin or other suitable coagulating enzymes. It shall have a soft smooth texture with a white to light cream colour. It may contain spices, condiments, seasonings and fruit pulp.
- (bi) Coulommiers Cheese** means soft unripened cheese obtained by coagulation of milk with cultures of harmless lactic acid producing bacteria and suitable enzymes of non-animal origin or other suitable coagulating enzymes and moulds characteristic of the variety. It shall have soft texture and white to cream yellow colour and may show presence of white mould including orange or red spots on the surface.
- (bj) Camembert Cheese** means ripened soft cheese obtained by coagulating milk of with cultures of harmless lactic acid producing bacteria and cultures of *Penicillium caseicolum* and *Bacterium linens*, suitable enzymes of non-animal origin or other suitable coagulating enzymes. It may be in the form of flat cylindrical shaped cheese covered with white mould (*Penicillium caseicolum*) with occasional orange coloured spots (*Bacterium linens*).
- (bk) Brie Cheese** means soft ripened cheese obtained by coagulating milk with cultures of harmless lactic acid producing bacteria and cultures of *Penicillium caseicolum* and *Bacterium linens*, suitable enzymes of non-animal origin and other suitable coagulating enzymes. It shall be white to

creamy yellow in colour with a smooth texture showing presence of white mould (*Penicillium caseicolum*) with occasional orange coloured spots (*Bacterium linens*) on the rind.

- (bl) Saint Paulin** means ripened semi hard cheese obtained by coagulating milk with suitable enzymes of non-animal origin, cultures of harmless lactic acid producing bacteria or other suitable coagulating enzymes. It shall be white to yellow in colour with a firm and flexible texture and a hard rind which may be coated with food grade waxes or polyfilm.
- (bm) Samsoe** means hard ripened cheese obtained by coagulating milk with suitable enzymes of non-animal origin and cultures of harmless lactic acid producing bacteria or suitable coagulating enzymes. It shall be yellow in colour with a firm texture suitable for cutting and may have a rind with or without food grade waxes or polyfilm coating.
- (bn) Emmental or Emmentaler** means hard ripened cheese with round holes obtained by coagulating milk with suitable enzymes of non-animal origin, cultures of harmless lactic acid producing bacteria or other suitable coagulating enzymes. It shall have a light Yellow colour and a firm texture suitable for cutting and may have a hard rind.
- (bo) Provolone** means pasta filata cheese obtained by coagulating milk with cultures of harmless lactic acid producing bacteria, suitable enzymes of non-animal origin or other suitable coagulating enzymes. It may be smoked. It shall be white to yellow straw in colour with a fibrous or smooth body and rind which may be covered with vegetable fat or oil, food grade waxes or polyfilm.
- (bp) Extra Hard Grating Cheese** means ripened cheese obtained by coagulating milk with cultures of harmless lactic acid producing bacteria, non-animal rennet, or other suitable coagulating enzymes. It may have slightly brittle texture and an extra hard rind which may be coated with vegetable oil, food grade waxes or polyfilm.
- (c) Cheese Products** are the products prepared from cheese(s) with other milk products and may contain permitted non-dairy ingredients.
- (ca) Processed Cheese** means the product obtained by grinding, mixing, melting and emulsifying one or more varieties of cheeses with the aid of heat and emulsifying agents and may contain cream, butter, butter oil and other milk products. It may also contain non-dairy ingredients not exceeding one sixth of the weight of the total solids of the final product on dry matter basis.
- (cb) Processed Cheese Spread** means the product obtained by grinding, mixing, melting and emulsifying one or more varieties of cheese with emulsifying agents with the aid of heat and may contain cream, butter oil and other dairy products. It may also contain natural carbohydrate sweetening agents and other non-dairy ingredients not exceeding one sixth of the weight of total solids of the final product on dry weight basis.

2. Essential Composition and Quality Factors.-

(a) Raw materials. -

Milk and products obtained from milk.

(b) Permitted ingredients. -

- Starter cultures of harmless lactic acid, and flavour producing bacteria and cultures of other harmless microorganisms;
- Safe and suitable enzymes (non-animal origin);
- Sodium chloride;
- Potable water;
- Non-dairy ingredients: Vinegar or acetic acid, spices, condiments and other vegetable seasoning and foods, other than sugars, properly cooked or prepared for flavouring and characterization of the product (*In Cheese Products only*);
- Natural carbohydrate sweetening agents: Sucrose, dextrose, corn syrup, corn syrup solids, honey, maltose, malt syrup and hydrolysed lactose (*In Processed Cheese Spreads only*).

(c) Composition. -

The product shall conform to the compositional specifications provided in the table below:–

Product		Moisture, Maximum, % (m/m)	Milk fat, Minimum, % (dry basis)	Lactose, Maximum, % (m/m)
i.	Cheese			
a.	Hard- Pressed Cheese	39.0	48.0	--
b.	Semi Hard –Cheese	45.0	40.0	--
c.	Semi-Soft Cheese	52.0	45.0	--
d.	Soft Cheese	80.0	20.0	--
e.	Extra Hard Cheese	36.0	32.0	--
f.	Mozzarella Cheese	60.0	35.0	--
g.	Pizza Cheese	54.0	35.0	--
ii.	Extra Hard Grating Cheese	36.0	32.0	--
iii.	Named variety cheeses			
a.	Cheddar	39.0	48.0	--
b.	Danbo	39.0	45.0	--
c.	Edam	46.0	40.0	--
d.	Gouda	43.0	48.0	--
e.	Havarti			
	- Havarti	48.0	45.0	--
	- 30% Havarti	53.0	30.0	--
	- 60% Havarti	60.0	60.0	--
f.	Tilsiter			
	- Tilsiter	47.0	45.0	--
	- 30% Tilsiter	53.0	30.0	--
	- 60% Tilsiter	39.0	60.0	--

Product		Moisture, Maximum, (m/m)	%	Milk fat, Minimum, % (dry basis)	Lactose, Maximum, % (m/m)
g.	Cottage Cheese and Creamed Cottage Cheese	80.0		*	--
h.	Cream cheese	55.0		70.0	--
i.	Coulommiers	56.0		46.0	
j.	Camembert				
	- 30% Camembert	62.0		30.0	--
	- 40% Camembert	59.0		40.0	--
	- 45% Camembert	57.0		45.0	--
	- 55% Camembert	52.0		55.0	--
k.	Brie	56.0		40.0	--
l.	Saint Paulin	56.0		40.0	--
m.	Samsoe				
	- Samsoe	44.0		45.0	--
	- 30% Samsoe	50.0		30.0	--
n.	Emmental	40.0		45.0	--
o.	Provolone				
	- Smoked	45.0		45.0	--
	- Unsmoked	47.0		45.0	--
iv.	Cheese products				
a.	Processed Cheese	47.0 (50% for chiplets (packed sliced processed cheese), when sold in a package other than tin		40.0	5.0
b.	Processed Cheese Spread	60.0		40.0	5.0

* Milk fat, Minimum 4% (m/m) for creamed cottage cheese.

3. Food Additives and Processing Aids.-

For products covered under this standard, specific food additives specified in Appendix 'A' of these regulations may be used and only within the limits specified.

4. Contaminants, Toxins and Residues. -

The products shall comply with the limits stipulated under the Food Safety and Standards (Contaminants, toxins and Residues) Regulations, 2011.

5. Hygiene.-

- (a) The products shall be prepared and handled in accordance with the guidelines specified in Schedule 4, as applicable, of the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011 and such guidelines as specified from time to time under the provisions of the Food Safety and Standard Act, 2006.

- (b) The products shall conform to the microbiological requirements specified in Appendix 'B' of these regulations.

6. Labelling.-

- (a) The name of the food product shall be "Cheese". However, the word "Cheese" may be omitted in the designation of an individual cheese variety as per the sub-item (b) of item 1.
- (b) Every package of Cheese (hard), surface treated with Natamycin, shall bear the following label, namely,—

SURFACE TREATED WITH NATAMYCIN

- (c) Every package of Cheese(s), if coated or packed in food grade waxes polyfilm or wrapping of cloth, shall bear the following label, namely,—

REMOVE THE OUTER PACKING BEFORE CONSUMPTION

- (d) In addition to the above-mentioned labelling requirements, the provisions of the Food Safety and Standards (Packaging and Labelling) Regulations, 2011, shall apply to pre-packaged product.

7. Method of Sampling and Analysis.-

The methods of sampling and analysis mentioned in the manuals as specified by the Food Safety and Standards Authority of India from time to time shall be applicable.

2.1.18 Standard for Edible Casein Products.-

This Standard applies to Edible Casein products as defined in item 1 of this sub-regulation.

1. Description.-

- (a) **Edible Casein** products mean the products obtained by separating, washing and drying the coagulum of skimmed milk or of other products obtained from milk;
- (b) **Edible Acid Casein** means the product obtained by separating, washing and drying the acid precipitated coagulum of skimmed milk or of other products obtained from milk;
- (c) **Edible Rennet Casein** means the product obtained after washing and drying the coagulum remaining after separating the whey from the skimmed milk or of other products obtained from milk, or both, which has been coagulated by non-animal rennet or by other coagulating enzymes;
- (d) **Edible Caseinate** means the dry product obtained by reaction of edible casein or casein curd coagulum with food grade neutralising agents followed by drying.

2. Essential Composition and Quality Factors.-

(a) Raw Material.-

Skimmed milk and other suitable products obtained from milk.

(b) Ingredients.-

- edible acids;
- starter cultures of harmless lactic acid producing bacteria;
- non-animal rennet or other safe and suitable coagulating enzymes;
- potable water;
- neutralizing agents.

(c) Composition.-

The product shall conform to the compositional specifications provided in the table below:—

Parameter	Edible Acid Casein	Edible Rennet Casein	Edible Caseinate
Moisture ⁽ⁱ⁾ , maximum, % (m/m)	12.0	12.0	8.0
Milk fat, maximum, %, (m/m)	2.0	2.0	2.0
Milk protein ⁽ⁱⁱ⁾ , minimum, %, (m/m), dry matter basis	90.0	84.0	88.0
Casein in protein, minimum, %, (m/m)	95.0	95.0	95.0
Lactose ⁽ⁱⁱⁱ⁾ , maximum, %, (m/m)	1.0	1.0	1.0
Total ash including P ₂ O ₅ , %, (m/m)	2.5 (maximum)	7.5 (minimum)	--
Free acid, maximum, ml of 0.1 N sodium hydroxide per g	0.27	--	--
pH (in 10% solution), maximum	--	--	8.0

Note(s):

(i) The water content does not include water of crystallization of the lactose.

(ii) Protein content is 6.38 multiplied by the total nitrogen determined.

(iii) Although the powders may contain both anhydrous lactose and lactose monohydrates, the lactose content is expressed as anhydrous lactose. 100 parts of lactose monohydrate contain 95 parts of anhydrous lactose.

3. Food Additives.-

For products covered under this standard, specific food additives specified in Appendix 'A' of these regulations may be used and only within the limits specified.

4. Contaminants, Toxins and Residues. -

The products shall comply with the Food Safety and Standards (Contaminants, toxins and Residues) Regulations, 2011.

5. Hygiene. -

- (a) The products shall be prepared and handled in accordance with the requirements specified in Schedule 4, as applicable, of the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011 and such guidelines as specified from time to time under the provisions of the Food Safety and Standard Act, 2006.
- (b) The products shall conform to the microbiological requirements specified in Appendix 'B' of these regulations.

6. Labelling. -

- (a) According to the composition in sub-item (c) of item 2, the name of the product shall be Edible Acid Casein or Edible Rennet Casein or Edible Caseinate. Edible Caseinate shall also be qualified by the name of the cation in the neutralizing agent used.
- (b) In addition to the above-mentioned labelling requirements, the provisions of the Food Safety and Standards (Packaging and Labelling) Regulations, 2011, shall apply to pre-packaged product.

7. Methods of Sampling and Analysis.-

The methods of sampling and analysis mentioned in the manuals as specified by the Food Safety and Standards Authority of India from time to time shall be applicable.

2.1.19 Foods for infant nutrition

Infant Milk Substitutes

1. Infant Milk Food means the product 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/maltodextrin, maltose and lactose; salts like phosphates and citrates; vitamins A, D, E, B Group, Vitamin C and other vitamins; and minerals like iron, copper, zinc and iodine. The source of Mineral Salts and Vitamin Compounds may be used from:-

1. Calcium (Ca) - Calcium carbonate, Calcium chloride, Calcium citrate, Calcium phosphate monobasic, Calcium phosphate dibasic, Calcium phosphate tribasic;
2. Phosphorous (P) - Calcium phosphate monobasic, Calcium phosphate dibasic, Calcium phosphate tribasic, Magnesium phosphate dibasic, Potassium phosphate dibasic;
3. Chloride (Cl) - Calcium chloride, Choline chloride, Magnesium chloride, Manganese chloride, Sodium chloride, Sodium chloride iodized;
4. Iron (Fe) - Ferrous citrate, Ferrous lactate, Ferrous sulphate, Ferric

- pyrophosphate;
5. Magnesium (Mg) - Magnesium chloride, Magnesium oxide, Magnesium phosphate dibasic;
 6. Sodium (Na) - Sodium bicarbonate, Sodium chloride, Sodium chloride iodized, Sodium citrate, Sodium phosphate monobasic;
 7. Potassium (K) - Potassium phosphate dibasic;
 8. Copper (Cu) - Cupric citrate, Cupric sulphate;
 9. Iodine (I) - Potassium iodide, Sodium iodide;
 10. Zinc (Zn) - Zinc sulphate;
 11. Manganese (Mn) - Manganese chloride, Manganese sulphate;
 12. Vitamin A - Retinyl acetate, Retinyl palmitate, Retinyl propionate;
 13. Provitamin A - Beta-carotene;
 14. Vitamin D - Vitamin D₂ - Ergocalciferol, Vitamin D₃ - Cholecalciferol, Cholecalciferol-cholesterol;
 15. Vitamin E - d-alpha-tocopherol, dl-alpha-tocopherol, d-alpha-tocopheryl acetate, dl-alpha-tocopheryl acetate, d-alpha-tocopheryl succinate, dl-alpha-tocopheryl succinate;
 16. Thiamine (Vitamin B₁) - Thiamine chloride hydrochloride, Thiamine mononitrate;
 17. Riboflavin (Vitamin B₂) - Riboflavin, Riboflavin 5' -phosphate sodium;
 18. Niacin - Nicotinamide, Nicotinic acid;
 19. Vitamin B₆ - Pyridoxine hydrochloride;
 20. Biotin (Vitamin H) - d-biotin;
 21. Folacin - Folic acid;
 22. Pantothenic acid - Calcium pantothenate, Panthenol;
 23. Vitamin B₁₂ - Cyanocobalamin, Hydroxycobalamin;
 24. Vitamin K - Phytylmenaquinone;
 25. Vitamin C - Ascorbic acid, Sodium ascorbate, Calcium ascorbate, Ascorbyl-6-palmitate;
 26. Choline - Choline bitartrate, Choline chloride;
 27. Inositol;
 28. Selenium - Sodium selenite.

The product shall be free of lumps and shall be uniform in appearance. It shall be free from starch and added antioxidants. It shall also be free from dirt, extraneous matter, preservatives and added colour and flavour and from any material which is harmful to human health. It shall not have rancid taste or musty odour. It shall not contain food additives.

It shall conform to the following requirements, namely: -

1.	Moisture, per cent. by weight (not more than)	4.5
2.	Total milk protein, per cent. by weight (not less than)	12.0
3.	Milk fat, per cent. by weight (not less than)	18.0
4.	Total ash, per cent. by weight (not more than)	8.5
5.	Ash insoluble in dilute Hydrochloric acid, per cent. by weight (not more than)	0.1

6.	Solubility:	
	Solubility Index (ml), maximum	2.0
	Solubility, per cent. by weight (not less than)	98.5
7.	Vitamin A (as retinol), µg per 100 g (not less than)	350
8.	Added Vitamin D (expressed as Cholecalciferol or Ergocalciferol) µg, per 100g (not less than)	4.5
9.	Vitamin C, mg per 100 g (not less than)	35
10.	Thiamine, µg per 100 g (not less than)	185
11.	Riboflavin, µg per 100 g (not less than)	275
12.	Niacin, µg per 100 g (not less than)	1160
13.	Pyridoxine, µg per 100 g (not less than)	160
14.	Folic acid, µg per 100 g (not less than)	20
15.	Pantothenic acid, mg per 100 g (not less than)	1.4
16	Vitamin B ₁₂ , µg per 100 g (not less than)	0.7
17	Choline, mg per 100 g (not less than)	32
18	Vitamin K, µg per 100 g (not less than)	18
19	Biotin, µg per 100 g (not less than)	7.0
20	Sodium, mg per 100 g (not less than)	90
21	Potassium, mg per 100 g (not less than)	370
22	Chloride, mg per 100 g (not less than)	250
23	Calcium, mg per 100 g (not less than)	230
24	Phosphorous, mg per 100 g (not less than)	115
25	Magnesium, mg per 100 g (not less than)	22
26	Iron, mg per 100 g (not less than)	5.0
27	Iodine, µg per 100 g (not less than)	20
28	Copper, µg per 100 g (not less than)	280
29	Zinc, mg per 100 g (not less than) and not more than (mg)	2.5 5.0
30	Manganese, µg per 100g (not less than)	20
31	Selenium, µg per 100 g (not less than)	14
32	Bacterial count, per g. (not more than)	10,000
33	Coliform count absent in	0.1 g
34	Yeast and mould count absent in	0.1 g
35	Salmonella and Shigella absent in	25 g
36	E. coli absent in	0.1 g
37	Staphylococcus aureas absent in	0.1 g

It shall be packed in hermetically sealed, clean and sound containers or in flexible pack made from film or combination or any of the substrate made of Board paper, polyethylene, polyester metallised film or in such a way to protect from deterioration.

It may be packed in nitrogen or a mixture of nitrogen and carbon dioxide.

2. Infant formula means the product prepared by spray drying of the milk of cow or buffalo or mixture thereof. The milk may be modified by partial removal/substitution of milk fat with vegetable oils rich in polyunsaturated fatty acids and/or by different milk

solids; carbohydrates such as sucrose, dextrose and dextrans/ maltodextrin, maltose and lactose; salts such as phosphates and citrates; vitamins A, D, E, B and C group and other vitamins; minerals such as iron, copper, zinc and iodine and others. Vegetables oils rich in polyunsaturated fatty acids shall be added to partially substitute milk fat to an extent that the product shall contain a minimum of 12 per cent. by weight of milk fat and a minimum of linoleate content of 1.398 g per 100 g. of the product.

It may contain algal and fungal oil as sources of Docosahexaenoic Acid (DHA) and Arachidonic Acid (ARA) from *Cryptocodinium cohnii*, *Mortierella alpine*, *Schizochytrium* sp., and *Ulkenia* sp. At the level of maximum 0.5 per cent. DHA of total fatty acids and ratio of ARA:DHA as 1:1 minimum:

Provided that DHA content shall not be less than 0.2 per cent. of total fatty acids, if a claim related to the addition of DHA is made.

The products shall also contain a minimum of 0.70 I.U. of vitamin E per 100 kcal. It may contain in addition to the vitamins and minerals listed, other nutrients may be added when required in order to provide nutrients ordinarily found in human milk such as, -

1.	Carotenes	Not less than 0.25 mg/L
2.	Fluorine	Not less than 0.107 mg/L
3.	Amino acids	Not less than 9 mg/L (only L forms of amino acids should be used)
4.	Non-protein nitrogen	Not less than 173 mg/L
5.	Nucleotides	Not less than 11.7 mg/L
6.	Carnitine	Not less than 11.27 µg/L
7.	Lactalbumin	Not less than 1.4 g/L
8.	Lactoferrin	Not less than 0.27 g/L
9.	Lysozyme	Not less than 0.8 g/L
10.	Fucose	Not less than 1.3 g/L
11.	Glucosamine	Not less than 0.7 g/L
12.	Inositol	Not less than 0.39 g/L
13.	Citric acid	Not less than 0.35 g/L
14.	Cholesterol	Not less than 88 mg/L
15.	Lipid Phosphorus	Not less than 7 mg/L
16.	Prostaglandins	Not less than PGE 150 mg/L Not less than PGF 400 mg/L

When any of these nutrients is added, the amount of these added nutrients shall be declared on the label, which should be not less than mentioned. It may contain medium chain triglycerides, taurine, molybdenum and chromium.

The source of Mineral Salts and Vitamin Compounds may be used from:-

- (1) Calcium (Ca) - Calcium carbonate, Calcium chloride, Calcium citrate, Calcium phosphate monobasic, Calcium phosphate dibasic, Calcium phosphate tribasic;
- (2) Phosphorous (P) - Calcium phosphate monobasic, Calcium phosphate dibasic, Calcium phosphate tribasic, Magnesium phosphate dibasic, Potassium phosphate dibasic;
- (3) Chloride (Cl) - Calcium chloride, Choline chloride, Magnesium chloride, Manganese chloride, Sodium chloride, Sodium chloride iodized;
- (4) Iron (Fe) - Ferrous citrate, Ferrous lactate, Ferrous sulphate, Ferric pyrophosphate;

- (5) Magnesium (Mg) - Magnesium chloride, Magnesium oxide, Magnesium phosphate dibasic;
- (6) Sodium (Na) - Sodium bicarbonate, Sodium chloride, Sodium chloride iodized, Sodium citrate, Sodium phosphate monobasic;
- (7) Potassium (K) - Potassium phosphate dibasic;
- (8) Copper (Cu) - Cupric citrate, Cupric sulphate;
- (9) Iodine (I) - Potassium iodide, Sodium iodide;
- (10) Zinc (Zn) - Zinc sulphate;
- (11) Source of Manganese (Mn) - Manganese chloride, Manganese sulphate.

Vitamins

- 1. Vitamin A - Retinyl acetate, Retinyl palmitate, Retinyl propionate;
- 2. Provitamin A - Beta-carotene;
- 3. Vitamin D - Vitamin D₂ - Ergocalciferol, Vitamin D₃ - Cholecalciferol, Cholecalciferol-cholesterol;
- 4. Vitamin E - d-alpha-tocopherol, dl-alpha-tocopherol, d-alpha-tocopheryl acetate, dl-alpha-tocopheryl acetate, d-alpha-tocopheryl succinate, dl-alpha-tocopheryl succinate;
- 5. Thiamine (Vitamin B₁) - Thiamine chloride hydrochloride, Thiamin mononitrate;
- 6. Riboflavin (Vitamin B₂) - Riboflavin, Riboflavin 5' -phosphate sodium;
- 7. Niacin - Nicotinamide, Nicotinic acid;
- 8. Vitamin B₆ - Pyridoxine hydrochloride;
- 9. Biotin (Vitamin H) - d-biotin;
- 10. Folic acid - Folic acid;
- 11. Pantothenic acid - Calcium pantothenate, Panthenol;
- 12. Vitamin B₁₂ - Cyanocobalamin, Hydroxycobalamin;
- 13. Vitamin K - Phytylmenaquinone;
- 14. Vitamin C - Ascorbic acid, Sodium ascorbate, Calcium ascorbate, Ascorbyl-6-palmitate;
- 15. Choline - Choline bitartrate, Choline chloride;
- 16. Inositol;
- 17. Selenium - Sodium selenite.

The product shall be free of lumps and shall be uniform in appearance. It shall be free from added starch, added colour and added flavour. It shall not have rancid taste and musty odour.

It may contain food additive listed below, -

Food Additives	Maximum level in 100 ml of the ready-to-drink product
pH – adjusting agents Sodium hydroxide Sodium hydrogen carbonate Sodium carbonate Potassium hydroxide Potassium hydrogen carbonate Potassium carbonate Calcium hydroxide	Limited by Good Manufacturing Practice and within the limits for Sodium and Potassium in all types of infant formulae

Sodium citrate Potassium citrate L (+) Lactic acid producing cultures Citric acid	Limited by Good Manufacturing Practice in all types of infant formulae
Antioxidants Mixed tocopherols concentrate and L-Ascorbyl palmitate	1 mg in all types of infant formulae
Mono and Diglycerides	0.4 g

It shall conform to the following requirements namely:

1.	Moisture, per cent. by weight (not more than)	4.5
2.	Total milk protein, per cent. by weight (not less than) and not more than	10.0 16.0
3.	Total fat, per cent. by weight (not less than)	18.0
	Milk Fat, per cent. by weight (not less than)	12.0
	Linoleate, g per 100 g (not less than)	1.398
4.	Total ash, per cent. by weight (not more than)	8.5
5	Ash insoluble in dilute Hydrochloric acid, per cent. by weight (not more than)	0.1

6	Solubility: (a) Solubility Index (ml), maximum	2.0
	(b) Solubility per cent. by weight (not less than)	98.5
7.	Vitamin A (as retinol), µg per 100 g (not less than)	350
8.	Added Vitamin D (expressed as Cholecalciferol or Ergocalciferol), µg per 100g (not less than)	4.5
9.	Vitamin C, mg per 100 g (not less than)	35
10.	Thiamine, µg per 100 g (not less than)	185
11.	Riboflavin, µg per 100 g (not less than)	275
12.	Niacin, µg per 100 g (not less than)	1160
13.	Pyridoxine, µg per 100 g (not less than)	160
14.	Folic acid, µg per 100 g. (not less than)	20
15.	Pantothenic acid, mg per 100 g (not less than)	1.4
16.	Vitamin B ₁₂ , µg per 100 g (not less than)	0.7
17.	Choline, mg per 100 g (not less than)	32
18.	Vitamin K, µg per 100 g (not less than)	18
19.	Biotin, µg per 100 g (not less than)	7.0

20.	Vitamin E (as a-tocopherol compounds), IU per 100 g (not less than)	3.15
21.	Sodium, mg per 100 g (not less than)	90
22.	Potassium, mg per 100 g (not less than)	370
23.	Chloride, mg per 100 g (not less than)	250
24.	Calcium, mg per 100 g (not less than)	230
25.	Phosphorous, mg per 100 g (not less than)	115
26.	Magnesium, mg per 100 g (not less than)	22
27.	Iron, mg per 100 g (not less than)	5.0
28.	Iodine, µg per 100 g (not less than)	20
29.	Copper, µg per 100 g (not less than)	280
30.	Zinc, mg per 100 g (not less than) and not more than (mg)	2.5 5.0
31	Manganese, µg per 100g (not less than)	20
32.	Selenium, µg per 100 g (not less than)	14
33.	Bacterial count, per g (not more than)	10,000
34.	Coliform count absent in	0.1 g
35.	Yeast and mould count absent in	0.1 g
36.	Salmonella and Shigella absent in	25 g
37.	E. coli absent in	0.1 g
38.	Staphylococcus aureas absent in	0.1 g

Premature/Low birth weight infant milk substitutes-

Provided that the premature/low birth weight infant milk substitutes shall also meet the following requirement in addition to the requirements mentioned above: -

1. Protein shall be 2.25 - 2.75 g per 100 kcal;
2. Mineral contents shall not be less than 0.5 g per 100 kcal. The Calcium: Phosphorous ratio shall be 2:1. The Sodium, Potassium and Chloride combined together shall be not less than 40 milli equivalent per litre;
3. Whey: Casein ratio shall be 60:40. Essential amino acids should include taurine, cystine, tyrosine and histidine;

Lactose free infant milk substitute

Lactose and sucrose free infant milk substitute Sucrose free infant milk substitute:

Provided that the lactose free or lactose and sucrose free or sucrose free infant milk substitutes shall also meet the following requirement in addition to the requirements mentioned in the standard, provided that in these three products edible vegetable oil may be used in place of milk fat and lecithin may be used as an emulsifier: -

1. Soy protein-based, lactose-free formula shall have soy-protein and carbohydrate as glucose, dextrose, dextrin/maltodextrin, maltose and/or sucrose;
2. Lactose-free cow's/buffalo's milk-based formulas shall have carbohydrate as glucose, dextrose, dextrin/maltodextrin, maltose and sucrose:

Provided also that the lactose free or lactose and sucrose free or sucrose free infant milk substitutes shall conform to the following

requirements, except the requirements of milk protein and milk fat, in the following manner, namely: -

- (a) total protein, per cent. By weight shall not be less than 10.0 per cent. and not more than 16 per cent;
- (b) total fat, per cent by weight shall not be less than 18.0 per cent.; and
- (c) the lactose in the product claimed to be lactose free shall not exceed 0.05 per cent.

Hypoallergenic infant milk substitutes

Provided that the Hypoallergenic infant milk substitutes shall also meet the following requirement in addition to the requirements mentioned in the standard: -

1. Protein shall be hydrolyzed whey or casein or;
2. 100% free amino acids as a protein source;

It shall be packed in hermetically sealed, clean and sound containers or in flexible pack made from film or combination or any of the substrate made of Board paper, polyethylene, polyester metallised film or in such a way to protect from deterioration. It shall be packed in nitrogen or a mixture of nitrogen and carbon dioxide.”

Infant Foods

3. Milk-cereal based complementary food milk-cereal based complementary food commonly called as weaning food or supplementary food means foods based on milk, cereal and/or legumes (pulses), soyabean, millets, nuts and edible oil seeds, processed to low moisture content and so fragmented as to permit dilution with water, milk or other suitable medium.

Milk-cereal based complementary food is intended to supplement the diet of infants after the age of six months.

Milk cereal based complementary food are obtained from milk, variety of cereals, pulses, soyabean, millets, nuts and edible oil seeds after processing. It may contain edible vegetable oils, milk solid, various carbohydrates such as sucrose, dextrose, dextrans/ maltodextrin, maltose and lactose, calcium salts; phosphates and citrates and other nutritionally significant minerals and vitamins. It shall contain a minimum of 10 per cent milk protein by weight of the product. It shall also contain minimum 5 per cent milk fat by weight. It shall not contain hydrogenated fats containing trans-fatty acids. It may contain fungal alfa amylase upto a maximum extent of 0.025 per cent. by weight, fruits and vegetables, egg or egg products. It may also include amino acids such as lysine, methionine, taurine, carnitine etc.

The source of Vitamin Compounds and Mineral Salts may be used from, -

1. Calcium (Ca) - Calcium carbonate, Calcium phosphate tribasic, Calcium sulphate;
2. Phosphorous (P) - Calcium phosphate tribasic;
3. Chloride (Cl) - Sodium chloride;
4. Iron (Fe) - Hydrogen reduced iron, Electrolytic iron;
5. Magnesium (Mg) - Magnesium chloride, Magnesium oxide, Magnesium phosphate dibasic;
6. Sodium (Na) - Sodium chloride;
7. Zinc (Zn) - Zinc sulphate;

Vitamins

1. Vitamin A - Retinyl acetate, Retinyl palmitate, Retinyl propionate;
2. Provitamin A - Beta-carotene;
3. Vitamin D - Vitamin D₂ -Ergocalciferol, Vitamin D₃ -Cholecalciferol, Cholecalciferol-cholesterol;
4. Vitamin E - d-alpha-tocopherol, dl-alpha-tocopherol, d-alpha-tocopheryl acetate, dl-alpha-tocopheryl acetate, d-alpha-tocopheryl succinate, dl-alpha-tocopheryl succinate;
5. Thiamine (Vitamin B₁) - Thiamine chloride hydrochloride, Thiamine mononitrate;
6. Riboflavin (Vitamin B₂) -Riboflavin, Riboflavin 5' -phosphate sodium;
7. Niacin - Nicotinamide, Nicotinic acid;
8. Vitamin B₆ - Pyridoxine hydrochloride;
9. Biotin (Vitamin H) - d-biotin;
10. Folacin - Folic acid;
11. Pantothenic acid - Calcium pantothenate, Panthenol;
12. Vitamin B₁₂ - Cyanocobalamin, Hydroxycobalamin;
13. Vitamin K - Phytylmenaquinone;
14. Vitamin C - Ascorbic acid, Sodium ascorbate, Calcium ascorbate, Ascorbyl-6-palmitate;
15. Choline - Choline bitartrate, Choline chloride;
16. Inositol;
17. Selenium- Sodium selenite.

It shall be in the form of powder, small granules or flakes, free from lumps and shall be uniform in appearance.

It shall be free from dirt and extraneous matter and free from preservatives and added colour and flavour. It shall be free from any material, which is harmful to human health.

It may contain the following additives, -

Emulsifiers	Maximum level in 100 g of the product on a dry weight basis
Lecithin	1.5 g
Mono and Diglycerides	1.5 g
PH – adjusting agents Sodium hydrogen carbonate Sodium carbonate Sodium citrate Potassium hydrogen carbonate Potassium carbonate Potassium citrate Sodium hydroxide Calcium hydroxide Potassium hydroxide L (+) Lactic acid Citric acid	Limited by Good Manufacturing Practice within the limit for sodium

Antioxidants	
Mixed tocopherols concentrate ∞- Tocopherol	300 mg/ kg fat, singly or in combination
L-Ascorbyl Palmitate	200 mg/ kg fat

It shall conform to the following requirements, namely: -

1.	Moisture, per cent. by weight (not more than)	5.0
2.	Total protein, per cent. by weight (not less than)	15.0
3.	Fat, per cent. by weight (not less than)	7.5
4.	Total Carbohydrate, per cent. by weight (not less than)	55.0
5.	Total ash, per cent. by weight (not more than)	5.0
6.	Ash insoluble in dilute Hydrochloric acid, per cent. by weight (not more than)	0.1
7.	Crude fibre (on dry basis) per cent. by weight (not more than)	1.0
8.	Vitamin A (as retinol) µg per 100 g (not less than)	350
9.	Added Vitamin D, µg per 100 g (expressed as Cholecalciferol or Ergocalciferol (not less than)	5
10.	Vitamin C, mg per 100 g (not less than)	25
11.	Thiamine (as hydrochloride), mg per 100 g (not less than)	0.5
12.	Riboflavin, mg per 100 g (not less than)	0.3
13.	Niacin, mg per 100 g (not less than)	3.0
14.	Folic acid, µg per 100 g (not less than)	20
15.	Iron, mg per 100 g (not less than)	5.0
16.	Zinc, mg per 100 g (not less than)	2.5
	and not more than (mg)	5.0
17.	Bacterial count, per g (not more than)	10,000
18.	Coliform count absent in	0.1 g
19.	Yeast and mould count absent in	0.1 g
20.	Salmonella and Shigella absent in	25 g
21.	E. coli absent in	0.1 g
22.	Staphylococcus aureas absent in	0.1 g

It shall be packed in hermetically sealed, clean and sound containers or in flexible pack made from film or combination or any of the substrate made of Board paper, polyethylene, polyester metallised film or in such a way to protect from deterioration.

4. Processed cereal based complementary food commonly called as weaning food or supplementary food means foods based on cereal and/or legumes (pulses), soyabean, millets, nuts and edible oil seeds, processed to low moisture content and so fragmented as to permit dilution with water, milk or other suitable medium.

Processed cereal based complementary food are intended to supplement the diet of infants after the age of six months and up to the age of two years.

Processed cereal based complementary food are obtained from variety of cereals, pulses, soyabean, millets, nuts and edible oil seeds after processing. It shall contain milled cereal and legumes combined not less than 75 per cent. Where the product is intended to be mixed with water before consumption, the minimum content of protein shall not be less than 15 per cent. on a dry weight basis and the PER shall not be less than 70 per cent. of that of casein. The sodium content of the products shall not exceed 100 mg/100 g of the ready-to-eat product.

Hydrogenated fats containing trans-fatty acids shall not be added to the products. It may also contain following ingredients: - protein concentrates, essential amino acids (only natural L forms of amino acids shall be used), iodized salt; milk and milk products; eggs; edible vegetable oils and fats; fruits and vegetables; various carbohydrates such as sucrose, dextrose, dextrin, maltose dextrin, lactose, honey, corn syrup; malt; potatoes.

The source of Vitamin Compounds and Mineral Salts may be used from,-

1. Calcium (Ca) - Calcium carbonate, Calcium phosphate tribasic, Calcium sulphate;
2. Phosphorous (P) - Calcium phosphate tribasic, Phosphoric acid;
3. Chloride (Cl) - Sodium chloride, Hydrochloric acid;
4. Iron (Fe) - Hydrogen reduced iron, Electrolytic iron;
5. Sodium (Na) - Sodium chloride;
6. Zinc (Zn) - Zinc acetate, Zinc chloride, Zinc oxide, Zinc sulphate;

Vitamins

1. Vitamin A - Retinyl acetate, Retinyl palmitate, Retinyl propionate;
2. Provitamin A - Beta-carotene;
3. Vitamin D - Vitamin D₂ - Ergocalciferol, Vitamin D₃ - Cholecalciferol, Cholecalciferol-cholesterol;
4. Vitamin E - d-alpha-tocopherol, dl-alpha-tocopherol, d-alpha-tocopheryl acetate, dl-alpha-tocopheryl acetate, d-alpha-tocopheryl succinate, dl-alpha-tocopheryl succinate;
5. Thiamine (Vitamin B₁) - Thiamine chloride hydrochloride, Thiamine mononitrate;
6. Riboflavin (Vitamin B₂) - Riboflavin, Riboflavin 5' -phosphate sodium;
7. Niacin - Nicotinamide, Nicotinic acid;
8. Vitamin B₆ - Pyridoxine hydrochloride;
9. Biotin (Vitamin H) - d-biotin;
10. Folacin - Folic acid;
11. Pantothenic acid - Calcium pantothenate, Panthenol;
12. Vitamin B₁₂ - Cyanocobalamin, Hydroxycobalamin;
13. Vitamin K - Phytylmenaquinone;
14. Vitamin C - Ascorbic acid, Sodium ascorbate, Calcium ascorbate, Ascorbyl-6-palmitate;
15. Choline - Choline bitartrate, Choline chloride;
16. Inositol;
17. Selenium- Sodium selenite.

It shall be in the form of powder, small granules or flakes, free from lumps and

shall be uniform in appearance.

All ingredients, including optional ingredients, shall be clean, safe, suitable and of good quality. It shall be free from preservatives, added colour and flavour.

It may contain the following food additives: -

<i>Name of the Food Additives</i>	<i>Maximum Level in a 100 g of Product on a dry weight basis</i>
Emulsifiers	
Lecithin	1.5 g
Mono and Diglycerides	1.5 g
pH adjusting agents	
Sodium hydrogen carbonate	Limited by Good Manufacturing Practice and within the limits for sodium
Potassium hydrogen carbonate Calcium carbonate}	Limited by Good Manufacturing Practice
L(+) lactic acid	1.5 g
Citric acid	2.5 g
Antioxidants	
Mixed tocopherols concentrate Alpha-tocopherol	300 mg/kg fat, singly or in combination
L-Ascorbyl palmitate	200 mg/kg fat
L-Ascorbic acid and its sodium and potassium salts	50 mg, expressed as ascorbic acid and within limits for sodium
Enzymes	
Malt carbohydrates	Limited by Good Manufacturing Practice
Leavening Agents	
Ammonium carbonate} Ammonium hydrogen carbonate}	Limited by Good Manufacturing Practice

It shall also conform to the following requirements namely: -

1.	Moisture, per cent. by weight (not more than)	4.0
2.	Total protein, per cent. by weight (not less than)	15.0
3.	Total Carbohydrate, per cent. by weight (not less than)	55.0
4.	Total ash, per cent. by weight (not more than)	5.0
5.	Ash insoluble in dilute Hydrochloric acid, per cent. by weight (not more than)	0.1
6.	Crude fibre (on dry basis) per cent. by weight (not more than)	1.0
7.	Vitamin A (as retinol), µg per 100 g (not less than)	350
8.	Added Vitamin D, µg per 100 g (expressed as Cholecalciferol or Ergocalciferol (not less than)	5
9.	Vitamin C, mg per 100 g (not less than)	25
10.	Thiamine (as hydrochloride), mg per 100 g (not less than)	0.5
11.	Riboflavin, mg per 100 g (not less than)	0.3
12.	Niacin, mg per 100 g (not less than)	3.0
13.	Folic acid, µg per 100 g (not less than)	20.0
14.	Iron, mg per 100 g (not less than)	5.0

15.	Zinc, mg per 100 g (not less than)	2.5
	and not more than (mg)	5.0
16.	Bacterial count, per g. (not more than)	10,000
17.	Coliform count absent in	0.1 g
18.	Yeast and mould count absent in	0.1 g
19.	Salmonella and Shigella absent in	25 g
20.	E. coli absent in	0.1 g
21.	Staphylococcus aureus absent in	0.1 g

It shall be packed in hermetically sealed clean and sound containers or in flexible pack made from film or combination of any or the substrate made of board paper, polyethylene, polyester, metalised film or aluminium foil in such a way to protect from deterioration:

Provided that the processed cereal based complementary foods for use in specific conditions, where protein needs to be restricted and where other cereals like wheat, soya, legumes and milk cannot be used, such processed cereal based complementary foods shall be prepared with single cereal like rice or ragi, which shall have the minimum protein content of 6-9 per cent., such products shall be conspicuously labelled, "Processed Mono Cereal Based Complementary Food for use in specific conditions under medical guidance only".

5. Follow-Up Formula-Complementary Food means the product prepared by spray drying of the milk of cow or buffalos or mixture thereof. It may contain vegetable protein. Follow-up formula based on milk shall be prepared from ingredients mentioned below except that a minimum of 3 g per 100 available Calories (or 0.7 g per 100 kJ) of protein shall be derived from whole or skimmed milk as such, or with minor modification that does not substantially impair the vitamin or mineral content of the milk and which represents a minimum of 90 per cent. of the total protein.

It may contain algal and fungal oil as sources of Docosahexaenoic Acid (DHA) and Arachidonic Acid (ARA) from *Cryptocodinium cohnii*, *Mortierella alpine*, *Schizochytrium* sp., and *Ulkenia* sp. At the level of maximum 0.5 per cent. DHA of total fatty acids and ratio of ARA:DHA as 1:1 minimum:

Provided that DHA content shall not be less than 0.2 per cent. of total fatty acids, if a claim related to the addition of DHA is made.

Follow-up formula for use as a liquid part of the complementary diet for infants after the age of six months and up to the age of two years when prepared in accordance with the instructions for use, 100 ml of the ready-for-consumption product shall provide not less than 60 kcal (or 250 kJ) and not more than 85 kcal (or 355 kJ).

Follow-up formula shall contain the following nutrients indicated below,

(1) Protein - Not less than 3.0 g per 100 available calories (or 0.7 g per 100 available kJ).

Not more than 5.5 g per 100 available calories (or 1.3 g per 100 available kJ).

(Protein shall be of nutritional quality equivalent to that of casein or a greater quantity of other protein in inverse proportion to its nutritional quality. The quality of the protein shall not be less than 85 per cent. of that of casein).

Essential amino acids may be added to follow-up formula to improve its nutritional value. Only L forms of amino acids shall be used.

(2) Fat - Not less than 4 g per 100 available calories (0.93 g per 100 available kJ)

Not more than 6 g per 100 available calories (1.4 g per 100 available kJ)

Linoleic acid (in the form of glyceride) - Not less than 310 mg (per 100 Calories or 74.09 mg per 100 available kJ)

The products shall contain nutritionally available carbohydrates suitable for the feeding of the older infant and young child in such quantities as to adjust the product to the energy density in accordance with the requirements given above.

It may also contain other nutrients when required to ensure that the product is suitable to form part of a mixed feeding scheme intended for use after six months of age. When any of these nutrients is added, the food shall contain not less than Recommended Dietary Allowances (RDA) amounts of these nutrients.

The source of Mineral Salts and Vitamin Compounds may be used from, -

1. Calcium (Ca)-Calcium carbonate, Calcium chloride, Calcium citrate, Calcium phosphate monobasic, Calcium phosphate dibasic, Calcium phosphate tribasic;
2. Phosphorous (P)- Calcium phosphate monobasic, Calcium phosphate dibasic, Calcium phosphate tribasic, Magnesium phosphate dibasic, Potassium phosphate dibasic;
3. Chloride (Cl)-Calcium chloride, Choline chloride, Magnesium chloride, Manganese chloride, Sodium chloride, Sodium chloride iodized;
4. Iron (Fe)- Ferrous citrate Ferrous lactate, Ferrous sulphate, Ferric pyrophosphate;
5. Magnesium (Mg)- Magnesium chloride, Magnesium oxide, Magnesium phosphate dibasic;
6. Sodium (Na)- Sodium bicarbonate, Sodium chloride, Sodium chloride iodized, Sodium citrate, Sodium phosphate monobasic;
7. Potassium (K)- Potassium phosphate dibasic;
8. Copper (Cu)- Cupric citrate, Cupric sulphate;
9. Iodine (I)-Potassium iodide, Sodium iodide;
10. Zinc (Zn)- Zinc sulphate;
11. Source of Manganese (Mn)- Manganese chloride, Manganese sulphate.

Vitamins

1. Vitamin A - Retinyl acetate, Retinyl palmitate, Retinyl propionate;
2. Provitamin A - Beta-carotene;
3. Vitamin D - Vitamin D₂ - Ergocalciferol, Vitamin D₃ - Cholecalciferol, Cholecalciferol-cholesterol;
4. VitaminE-d-alpha-tocopherol, dl-alpha-tocopherol, d-alpha-tocopheryl acetate, dl-alpha-tocopheryl acetate, d-alpha-tocopheryl succinate, dl-alpha-tocopheryl succinate;
5. Thiamine (Vitamin B₁) - Thiamine chloride hydrochloride, Thiamine mononitrate;
6. Riboflavin (Vitamin B₂) - Riboflavin, Riboflavin 5' -Phosphate sodium;
7. Niacin-Nicotinamide, Nicotinic acid;
8. Vitamin B₆ - Pyridoxine hydrochloride;
9. Biotin (Vitamin H) - d-biotin;

10. Folacin - Folic acid;
11. Pantothenic acid - Calcium pantothenate, Panthenol;
12. Vitamin B₁₂ - Cyanocobalamin, Hydroxycobalamin;
13. Vitamin K - Phytylmenaquinone;
14. Vitamin C - Ascorbic acid, Sodium ascorbate, Calcium ascorbate, Ascorbyl-6-palmitate;
15. Choline - Choline bitartrate, Choline chloride;
16. Inositol;
17. Selenium - Sodium selenite.

The product shall be free of lumps and shall be uniform in appearance. It shall be free from added starch and added colour and flavour. It shall not have rancid taste and musty odour.

It may contain the following additives, -

	<i>Maximum Level in 100 ml of Product Ready-for-Consumption</i>
pH-Adjusting Agents Sodium hydrogen carbonate} Sodium carbonate} Sodium citrate} Potassium hydrogen carbonate} Potassium carbonate} Potassium citrate} Sodium hydroxide} Calcium hydroxide} Potassium hydroxide} L(+) Lactic acid} Citric acid}	Limited by Good Manufacturing Practice within the limit for sodium
Antioxidants	
Mixed tocopherols concentrate} ∞ - Tocopherol}	3 mg singly or in combination
L-Ascorbyl palmitate}	5 mg singly or in combination.

It shall also conform to the following requirements, -

S. No.	Characteristics	Requirements
1.	Moisture, per cent. by weight (not more than)	4.5
2.	Total milk protein, per cent. by weight (not less than) and (not more than)	13.5 24.75
3.	Total fat, per cent. by weight (not less than) and (not more than)	18.0 27.0
	Linoleate per 100 g (not less than)	1.398
4.	Total ash, per cent. by weight (not more than)	8.5

5.	Ash insoluble in dilute Hydrochloric acid, per cent. by weight (not more than)	0.1
6.	Solubility:	
	Solubility Index (ml), maximum	2.0
	Solubility per cent. by weight (not less than)	98.5
7.	Vitamin A (as retinol), µg per 100 g (not less than)	350
8.	Added Vitamin D (expressed as Cholecalciferol or Ergocalciferol), µg per 100 g (not less than)	4.5
9.	Vitamin C, mg per 100 g (not less than)	36
10.	Thiamin, µg per 100 g (not less than)	180
11.	Riboflavin, µg per 100 g (not less than)	270
12.	Niacin, µg per 100 g (not less than)	1125
13.	Pyridoxine, µg per 100 g (not less than)	202.50
14.	Folic acid, µg per 100 g (not less than)	20.0
15.	Pantothenic acid, mg per 100 g (not less than)	1.35
16.	Vitamin B12, µg per 100 g (not less than)	0.675
17.	Choline, mg per 100 g (not less than)	32
18.	Vitamin K, µg per 100 g (not less than)	18
19.	Biotin, µg per 100 g (not less than)	6.75
20.	Vitamin E (as a- tocopherol compounds), I.U. per 100g (not less than)	3.15
21.	Sodium, mg per 100 g (not less than)	90
22.	Potassium, mg per 100 g (not less than)	360
23.	Chloride, mg per 100 g (not less than)	247.50
24.	Calcium, mg per 100 g (not less than)	405
25.	Phosphorous, mg per 100 g (not less than)	270
26.	Magnesium, mg per 100 g (not less than)	27
27.	Iron, mg per 100 g (not less than)	5
28.	Iodine, µg per 100 g (not less than)	22.50
29.	Copper, µg per 100 g (not less than)	280
30.	Zinc, mg per 100 g (not less than) and not more than (mg)	2.5 5.0
31.	Manganese, µg per 100 g (not less than)	20
32.	Selenium, µg per 100 g (not less than)	14
33.	Bacterial count, per g (not more than)	10,000
34.	Coliform count absent in	0.1g
35.	Yeast and mould count absent in	0.1g
36.	Salmonella and Shigella absent in	25 g
37.	E. coli absent in	0.1g
38.	Staphylococcus aureas absent in	0.1g

It shall be packed in hermetically sealed, clean and sound containers or in flexible pack made from film or combination or any of the substrate made of Board paper, polyethylene, polyester metallised film or in such a way to protect from deterioration. It shall be packed in nitrogen or a mixture of nitrogen and carbon dioxide.

2.1.20 Standards for Edible Lactose.-

This Standard applies to Edible Lactose as defined in item 1 of this sub-regulation.*

1. Description.-

Lactose is a white to light yellow crystalline, slightly sweet disaccharide sugar found in milk.

2. Essential Composition and Quality Factors.-

(a) Raw Materials.-

- Whey

(b) Composition.-

Sl. No.	Parameters	Limits
1.	Total moisture, maximum, %, (m/m)	6.0
2.	Lactose, minimum, %, (m/m), on dry basis	99.0
3.	Sulphated ash, maximum, %, (m/m)	0.3
4.	pH (10% solution)	4.5-7.0
5.	Scorched particle, maximum	Disc B

3. Food Additives.-

For products covered under this standard, specific food additives specified in Appendix 'A' of these regulations may be used and only within the limits specified.

4. Contaminants, Toxins and Residues.-

The products shall comply with the limits stipulated under the Food Safety and Standards (Contaminants, toxins and Residues) Regulations, 2011.

5. Hygiene.-

(a) The products shall be prepared and handled in accordance with the requirements specified in the Schedule 4, as acceptable, of the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011 and any such guidelines provided from time to time under the provisions of the Food Safety and Standard Act, 2006.

(b) The products shall conform to the microbiological requirements specified in Appendix 'B' of these regulations.

6. Labelling.-

*This standard should be read along with sub-regulation 2.1.1 relating to General Standard for Milk and Milk Products with reference to the generic provisions pertaining to definitions of milk or milk products and heat treatments, guidelines for use of dairy terms, addition of micronutrients, etc.

- (a)** The name of the product shall be edible lactose.
- (b)** The provisions of the Food Safety and Standards (Packaging and Labelling) Regulations, 2011 shall apply to pre-packaged product.

7. Methods of Sampling and Analysis.-

The methods of sampling and analysis mentioned in the manuals as specified by the Food Safety and Standards Authority of India from time to time shall be applicable.”.