For background information, please see CL 2023/68/OCS - CAC

Codex Members and Observers are invited to submit comments on the revised Standard.

Comments should address **whether the revised Standard is ready for adoption or not;** and if not, provide the rationale and proposals to facilitate adoption. Comments should be provided in conformity with the *Procedure for the Elaboration of Codex Standards and Related Texts (*Part 3 – *Uniform Procedure for the Elaboration of Codex Standards and Related Texts,* Procedural Manual of the Codex Alimentarius Commission.

STANDARD FOR FOLLOW-UP FORMULA FOR OLDER INFANTS AND PRODUCT FOR YOUNG CHILDREN*

(For adoption at Step 5/8 and 8)

*Other equivalent names for this product are Drink for young children with added nutrients, or Product for young children with added nutrients, or Drink for young children.

PREAMBLE

This Standard is divided into two sections. Section A refers to Follow-up Formula for Older Infants, and Section B deals with Drink for Young Children with Added Nutrients, or Product for Young Children with Added Nutrients, or Drink for Young Children, or Product for Young Children.

The application of this Standard should be consistent with national/regional health and nutrition policies and relevant national/regional legislation and take into account the recommendations made in the International Code of Marketing of Breast-milk Substitutes, as per the national/regional context.

Relevant World Health Organization (WHO) guidelines and policies and World Health Assembly (WHA) resolutions were considered in the development of this Standard and may provide further guidance to countries.

SECTION A: FOLLOW-UP FORMULA FOR OLDER INFANTS

1 SCOPE

1.1 This section of the Standard applies to Follow-up formula for older infants, as defined in Section 2.1, in liquid or powdered form.

1.2 This section of the Standard contains compositional, quality, safety, labelling, analytical and sampling requirements for Follow-up formula for older infants.

1.3 Only products that comply with the criteria laid down in the provisions of this Section of this Standard shall be presented as Follow-up formula for older infants.

2 DESCRIPTION

2.1 Product Definition

2.1.1 **Follow-up formula for older infants** means a product, manufactured for use as a breastmilk-substitute, as a liquid part of a diet for older infants when progressively diversified complementary feeding is introduced.

2.1.2 Follow-up formula for older infants is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold.

2.2 Other Definitions

2.2.1 The term **infant** means a person of not more than 12 months of age.

2.2.2 The term **older infant** means a person from the age of 6 months and not more than 12 months of age

3 ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Essential Composition

3.1.1 Follow-up formula for older infants is a product based on milk of cows or other animals or a mixture thereof and/or other ingredients which have been proven to be safe and suitable for the feeding of older infants. The nutritional safety and adequacy of follow-up formula for older infants shall be scientifically demonstrated to support growth and development of older infants.

3.1.2 When prepared ready for consumption in accordance with the instructions of the manufacturer, the products shall contain per 100 ml not less than 60 kcal (251 kJ) and not more than 70 kcal (293 kJ) of energy.

3.1.3 Follow-up formula for older infants prepared ready for consumption shall contain per 100 kcal (100 kJ) the following nutrients with the following minimum and maximum or guidance upper levels (GUL) [1)] as appropriate.

a) Protein [2), 3), 4)]

Unit	Minimum	Maximum	GUL
g/100 kcal	1.8 [5), 6)]	3.0	-
g/100 kJ	0.43 [5), 6)]	0.72	-

[2)] For the purpose of this standard the calculation of the protein content of the final product ready for consumption should be based on N x 6.25, unless a scientific justification is provided for the use of a different conversion factor for a particular product**.** The protein levels set in this standard are based on a nitrogen conversion factor of 6.25. For information the value of 6.38 is used as a specific factor appropriate for conversion of nitrogen to protein in other Codex standards for milk products.

[3)] For an equal energy value the formula must contain an available quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein (breastmilk as defined in Annex I of the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-1981)); nevertheless for calculation purposes the concentrations of tyrosine and phenylalanine may be added together and the concentrations of methionine and cysteine may be added together.

[4)] Isolated amino acids may be added to follow-up formula for older infants only to improve its nutritional value for infants. Essential and semi-essential amino acids may be added to improve protein quality, only in amounts necessary for that purpose. Only L-forms of amino acids shall be used.

[5)] The minimum value applies to cows' and goats' milk protein. For follow-up formula for older infants based on non-cows' or non-goats' milk protein, other minimum values may need to be applied. For follow-up formula for older infants based on soy protein isolate, a minimum value of 2.25 g/100 kcal (0.54 g/100 kJ) applies.

[6)] A lower minimum protein level between 1.6 and 1.8 g/100 kcal (0.38 and 0.43 g/100 kJ) in follow-up formula for older infants based on non-hydrolysed milk protein can be accepted. Such follow-up formula and follow-up formula for older infants based on hydrolysed protein should be evaluated for their safety and suitability and assessed by a competent national and/or regional authority based on clinical evidence.

b) Lipids

Total Fat [7), 8)]

Unit	Minimum	Maximum	GUL
g/100 kcal	4.4	6.0	-
g/100 kJ	1.1	1.4	-

[7)] Partially hydrogenated oils and fats shall not be used in follow-up formula for older infants.

[1)] Guidance upper levels (GULs) are for nutrients without sufficient information for a science-based risk assessment. These levels are values derived on the basis of meeting nutritional requirements of older infants and an established history of apparent safe use. They may be adjusted based on relevant scientific or technological progress. The purpose of the GULs is to provide guidance to manufacturers and they should not be interpreted as goal values. Nutrient contents in follow-up formula for older infants should usually not exceed the GULs unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of follow-up formula for older infants or due to technological reasons. When a product type or form has ordinarily contained lower levels than the GULs, manufacturers should not increase levels of nutrients to approach the GULs.

[8] Lauric acid and myristic acid are constituents of fats, but combined shall not exceed 20% of total fatty acids. The content of trans fatty acids shall not exceed 3% of total fatty acids. Trans fatty acids are endogenous components of milk fat. The acceptance of up to 3% of trans fatty acids is intended to allow for the use of milk fat in follow-up formula for older infants. The erucic acid content shall not exceed 1% of total fatty acids. The total content of phospholipids should not exceed 300 mg/100 kcal (72 mg/100 kJ).

Linoleic acid

Unit	Minimum	Maximum	GUL
mg/100 kcal	300	-	1400
mg/100 kJ	72	-	335

α-Linolenic acid

Unit	Minimum	Maximum	GUL
mg/100 kcal	50	N.S.*	-
mg/100 kJ	12	N.S.	-

*N.S. = not specified

Ratio Linoleic acid/ α-Linolenic acid

Min	Max
5:1	15:1

c) Carbohydrates

Available carbohydrates [9]

Unit	Minimum	Maximum	GUL
g/100 kcal	9.0	14.0	-
g/100 kJ	2.2	3.3	-

[9] Lactose and glucose polymers should be the preferred carbohydrates in follow-up formula for older infants based on milk protein and hydrolysed protein. Only precooked and/or gelatinised starches gluten-free by nature may be added. Sucrose and/or fructose should not be added, unless needed as a carbohydrate source, and provided the sum of these does not exceed 20% of available carbohydrates.

d) Vitamins

Vitamin A

Unit	Minimum	Maximum	GUL
µg RE[10] /100 kcal	75	180	-
µg RE[10] /100 kJ	18	43	-

[10] expressed as retinol equivalents (RE)

1 µg RE = 3.33 IU Vitamin A = 1 µg all-trans retinol. Retinol contents shall be provided by preformed retinol, while any contents of carotenoids should not be included in the calculation and declaration of vitamin A activity.

Vitamin D

Unit	Minimum	Maximum	GUL
µg[11] /100 kcal	1.0	3.0	-
µg[11] /100 kJ	0.24	0.72	-

[11] Calciferol. 1 µg calciferol = 40 IU Vitamin D.

Vitamin E

Unit	Minimum	Maximum	GUL
mg α-TE[12] /100 kcal	0.5 [13]	-	5
mg α-TE[12] /100 kJ	0.12 [13]	-	1.2

[12] 1 mg α-TE (alpha-tocopherol equivalents) = 1 mg d-α-tocopherol

[13] Vitamin E shall be at least 0.5 mg α-TE per g PUFA, using the following factors of equivalence to adapt the minimal vitamin E content to the number of fatty acid double bonds in the formula: 0.5 mg α-TE/g linoleic acid (18:2 n-6); 0.75 α-TE/g α-linolenic acid (18:3 n-3); 1.0 mg α-TE/g arachidonic acid (20:4 n-6); 1.25 mg α-TE/g eicosapentaenoic acid (20:5 n-3); 1.5 mg α-TE/g docosahexaenoic acid (22:6 n-3).

Vitamin K

Unit	Minimum	Maximum	GUL
µg /100 kcal	4	-	27
µg /100 kJ	0.96	-	6

Thiamin

Unit	Minimum	Maximum	GUL
µg /100 kcal	60	-	300
µg /100 kJ	14	-	72

Riboflavin

Unit	Minimum	Maximum	GUL
µg /100 kcal	80	-	500
µg /100 kJ	19	-	120

Niacin[14)]

Unit	Minimum	Maximum	GUL
µg /100 kcal	300	-	1500
µg /100 kJ	72	-	359

[14)] Niacin refers to preformed niacin

Vitamin B_6

Unit	Minimum	Maximum	GUL
µg /100 kcal	35	-	175
µg /100 kJ	8	-	42

Vitamin B_{12}

Unit	Minimum	Maximum	GUL
µg /100 kcal	0.1	-	1.5
µg /100 kJ	0.02	-	0.36

Pantothenic acid

Unit	Minimum	Maximum	GUL
µg /100 kcal	400	-	2000
µg /100 kJ	96	-	478

Folic acid

Unit	Minimum	Maximum	GUL
µg /100 kcal	10	-	50
µg /100 kJ	2.4	-	12

Vitamin C[15)]

Unit	Minimum	Maximum	GUL
mg /100 kcal	10	-	70 [16)]
mg /100 kJ	2.4	-	17 [16)]

[15)] expressed as L-ascorbic acid

[16)] This GUL has been set to account for possible high losses over shelf-life in liquid products; for powdered products lower upper levels should be aimed for.

Biotin

Unit	Minimum	Maximum	GUL
µg /100 kcal	1.5	-	10
µg /100 kJ	0.36	-	2.4

e) Minerals and Trace Elements

Iron[17)]

Unit	Minimum	Maximum	GUL
mg /100 kcal	1.0	2.0	-

mg /100 kJ	0.24	0.48	-

[17] For follow-up formula for older infants based on soy protein isolate a minimum value of 1.5 mg/100 kcal (0.36/100 kJ) and maximum of 2.5 mg/100 kcal (0.6 mg/100 kJ) applies.

Calcium

Unit	Minimum	Maximum	GUL
mg /100 kcal	50	-	180
mg /100 kJ	12	-	43

Phosphorus

Unit	Minimum	Maximum	GUL
mg /100 kcal	25	-	100 [18]
mg /100 kJ	6	-	24 [18]

[18] This GUL should accommodate higher needs with follow-up formula for older infants based on soy protein isolate.

Ratio Calcium/Phosphorus

Min	Max
1:1	2:1

Magnesium

Unit	Minimum	Maximum	GUL
mg /100 kcal	5	-	15
mg /100 kJ	1.2	-	3.6

Sodium

Unit	Minimum	Maximum	GUL
mg /100 kcal	20	60	-
mg /100 kJ	4.8	14	-

Chloride

Unit	Minimum	Maximum	GUL
mg /100 kcal	50	160	-
mg /100 kJ	12	38	-

Potassium

Unit	Minimum	Maximum	GUL
mg /100 kcal	60	180	-
mg /100 kJ	14	43	-

Manganese

Unit	Minimum	Maximum	GUL
µg /100 kcal	1.0	-	100
µg /100 kJ	0.24	-	24

Iodine

Unit	Minimum	Maximum	GUL
µg /100 kcal	10	-	60
µg /100 kJ	2.4	-	14

Selenium

Unit	Minimum	Maximum	GUL
µg /100 kcal	2	-	9
µg /100 kJ	0.48	-	2.2

Copper[19]

Unit	Minimum	Maximum	GUL
µg /100 kcal	35	-	120
µg /100 kJ	8	-	29

[19] Adjustment may be needed in these levels for follow-up formula for older infants made in regions with a high content of copper in the water supply.

Zinc[20]

Unit	Minimum	Maximum	GUL
mg /100 kcal	0.5	-	1.5
mg /100 kJ	0.12	-	0.36

[20] For follow-up formula for older infants based on soy protein isolate a minimum value of 0.75 mg/100 kcal (0.18 mg/100kJ) applies.

3.2 Optional Ingredients

3.2.1 In addition to the compositional requirements listed under 3.1.3, other ingredients or substances may be added to follow-up formula for older infants where the safety and suitability of the optional ingredient for particular nutritional purposes, at the level of use, is evaluated and demonstrated by generally accepted scientific evidence.

3.2.2 When any of these ingredients or substances is added the formula shall contain sufficient amounts to achieve the intended effect, taking into account levels in human milk.

3.2.3 The following substances may be added in conformity with national legislation, in which case their content per 100 kcal (100kJ) in the follow-up formula for older infants ready for consumption shall not exceed the levels listed below. This is not intended to be an exhaustive list, but provides a guide for competent national and/or regional authorities as to appropriate levels when these substances are added.

Taurine

Unit	Minimum	Maximum	GUL
mg /100 kcal	-	12	-
mg /100 kJ	-	2.9	-

Total nucleotides

Levels may need to be determined by national authorities.

Docosahexaenoic acid[21]

Unit	Minimum	Maximum	GUL
mg /100 kcal	-	-	30
mg /100 kJ	-	-	7

[21] If docosahexaenoic acid (22:6 n-3) is added to follow-up formula for older infants, a minimum level of 20 mg/100 kcal (4.8 mg/100 kJ) should be reached, and arachidonic acid (20:4 n-6) contents should reach at least the same concentration as DHA. The content of eicosapentaenoic acid (20:5 n-3), which can occur in sources of LC-PUFA, should not exceed the content of docosahexaenoic acid. Competent national and/or regional authorities may deviate from the above conditions, as appropriate for the nutritional needs of their population.

Choline

Unit	Minimum	Maximum	GUL
mg /100 kcal	-	-	50
mg /100 kJ	-	-	12

Myo-inositol

Unit	Minimum	Maximum	GUL
mg /100 kcal	-	-	40
mg /100 kJ	-	-	10

L-carnitine

Levels may need to be determined by national authorities.

L (+) lactic acid-producing cultures

Only L (+) lactic acid-producing cultures may be used for the purpose of producing acidified follow-up formula for older infants. The acidified final product should not contain significant amounts of viable L (+) lactic acid-producing cultures, and residual amounts should not represent any health risk.

The safety and suitability of the addition of specific strains of L (+) lactic acid-producing cultures for particular beneficial physiological effects, at the level of use, must be demonstrated by clinical evaluation and generally accepted scientific evidence. When added for this purpose, the final product ready for consumption shall contain sufficient amounts of viable cultures to achieve the intended effect.

3.3 Purity Requirements

3.3.1 General

All ingredients shall be clean, of good quality, safe and suitable for ingestion by older infants. They shall conform with their normal quality requirements, such as colour, flavour and odour.

3.3.2 Vitamin Compounds and Mineral Salts

3.3.2.1 Vitamin compounds and mineral salts used in accordance with Sections 3.1.3 (d) and (e) and 3.2.1 should be selected from the *Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses intended for Infants and Young Children* (CXG 10-1979).

3.3.2.2 The amounts of sodium derived from vitamin and mineral ingredients shall be within the limit for sodium in Section 3.1.3 (e).

3.4 Consistency and Particle Size

When prepared according to the directions of use, the product shall be free of lumps and of large, coarse particles.

3.5 Specific Prohibitions

The product and its components shall not have been treated by ionizing radiation.

4. Food Additives

The following additives are permitted[22)]:

INS	Additive	Maximum level in 100 mL of the product ready for consumption
4.1 Thickeners		
412	Guar gum	0.1 g
410	Carob bean gum	0.1 g
1412	Distarch phosphate	0.5 g singly or in combination in soy-based products only; 2.5 g singly or in combination in hydrolyzed protein and/or amino acid-based products only
1414	Acetylated distarch phosphate	
1413	Phosphated distarch phosphate	
1422	Acetylated distarch adipate	
407	Carrageenan	0.03 g singly or in combination in milk and soy-based products only; 0.1 g singly or in combination in hydrolyzed protein and/or amino acid-based liquid products only
440	Pectins	1 g
4.2 Emulsifiers		
322(i)	Lecithin	0.5 g
471	Mono- and diglycerides of fatty acids	0.4 g

4.3 Acidity Regulators		
500(ii)	Sodium hydrogen carbonate	Limited by GMP Within the limits for sodium in Section 3.1
500(i)	Sodium carbonate	
331(i)	Sodium dihydrogen citrate	
331(iii)	Trisodium citrate	
524	Sodium hydroxide	
501(ii)	Potassium hydrogen carbonate	Limited by GMP
501(i)	Potassium carbonate	
332(i)	Potassium dihydrogen citrate	
332(ii)	Tripotassium citrate	
525	Potassium hydroxide	
526	Calcium hydroxide	Limited by GMP
270	Lactic acid, L-, D-, and DL-	Limited by GMP
330	Citric acid	Limited by GMP
4.4 Antioxidants		
307b	Tocopherols concentrate, mixed	3 mg singly or in combination
307a	Tocopherol, d-alpha	
307c	Tocopherol, dl-alpha	
304	Ascorbyl palmitate	5 mg singly or in combination, expressed as ascorbic acid (INS 300, 301,302,304) Within the limits for sodium in Section 3.1
300	Ascorbic acid, L-	
301	Sodium ascorbate	
302	Calcium ascorbate	
4.5 Packaging Gases		
290	Carbon dioxide	GMP
941	Nitrogen	GMP

[22)] The table of food additive provisions is for information only. Following the completion of the alignment work for CXS 156-1987, the table will be replaced by a general reference to the GSFA as below:

"Acidity regulators, antioxidants, emulsifiers, thickeners, packaging gases used in accordance with Tables 1 and 2 of the *General Standard for Food Additives* (CXS 192-1995) in food category 13.1.2 (Follow-up formulae) are acceptable for use in foods conforming to this Standard."

4.6 Flavourings

No flavourings are permitted in this product.

4.7 Carry-Over Principle

Only the food additives listed in this Section or in the *Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses intended for Infants and Young Children* (CXG 10-1979) may be present in the foods described in Section 2.1 of this Standard, as a result of carry-over from a raw material or other ingredient (including food additive) used to produce the food, subject to the following conditions:

a) The amount of the food additive in the raw materials or other ingredients (including food additives) does not exceed the maximum level specified; and

b) The food into which the food additive is carried over does not contain the food additive in greater quantity than would be introduced by the use of the raw materials or ingredients under good manufacturing practice, consistent with the provisions on carry-over in the Preamble of the *General Standard for Food Additives* (CXS 192-1995).

5. Contaminants

The products covered by this Standard shall comply with the Maximum levels of the *General Standard for Contaminants and Toxins in Food and Feed* (CXS 193-1995).

The products covered by this Standard shall comply with the maximum residue limits for pesticides established by the Codex Alimentarius Commission.

6. Hygiene

6.1 It is recommended that the product covered by the provisions of this standard be prepared and handled in accordance with the appropriate sections of the *General Principles of Food Hygiene* (CXC 1-1969), and other relevant Codex texts such as the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children* (CXC 66-2008), and in the case of liquid formula that has been commercially sterilised should also consider the appropriate sections of the *Code of Hygienic Practice for Aseptically Processed and Packaged Low-acid Foods* (CXC 40-1993) and the *Code of Hygienic Practice for Low and Acidified Low-acid Canned Foods* (CXC 23-1979), as applicable.

6.2 The products should comply with any microbiological criteria established in accordance with the *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21-1997).

7. Fill of Containers

In the case of products in ready-to-eat form, the fill of container shall be:

(i) not less than 80% v/v for products weighing less than 150 g (5 oz.);

(ii) not less than 85% v/v for products in the weight range 150-250 g (5 - 9 oz.); and

(iii) not less than 90% v/v for products weighing more than 250 g (9 oz.) of the water capacity of the container. The water capacity of the container is the volume of distilled water at 20°C which the sealed container will hold when completely filled.

8. LABELLING

The requirements of the *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985), the *Guidelines on Nutrition Labelling* (CXG 2-1985) and the *Guidelines for Use of Nutrition and Health Claims* (CXG 23-1997) apply to Follow-up formula for older infants. These requirements include a prohibition on the use of nutrition and health claims for foods for infants except where specifically provided for in relevant Codex Standards or national legislation.

8.1 The Name of the Product

8.1.1 The text of the label and all other information accompanying the product shall be written in the appropriate language(s).

8.1.2 The name of the product as defined in Section 2.1 shall be Follow-up formula for older infants, or any appropriate designation indicating the true nature of the product, in accordance with national or regional usage.

8.1.3 The sources of protein in the product shall be clearly shown on the label.

a) If [name of animal] milk is the only source of protein*, the product may be labelled ‘Follow-up formula for older infants based on [name of animal] milk protein.

b) If [name of plant] is the only source of protein*, the product may be labelled ‘Follow-up formula for older infants based on [name of plant] protein.

c) If [name of animal] milk and [name of plant] are the sources of protein*, the product may be labelled ‘Follow-up formula for older infants based on [name of animal] milk protein and [name of plant] protein’ or ‘Follow-up formula for older infants based on [name of plant] protein and [name of animal] milk protein’.

* For clarity, addition of individual amino acids where needed to improve protein quality does not preclude use of the above labelling options.

8.1.4 A product which contains neither milk nor any milk derivative shall be labelled "contains no milk or milk products" or an equivalent phrase.

8.2 List of Ingredients

8.2.1 A complete list of ingredients shall be declared on the label in descending order of proportion except that in the case of added vitamins and minerals, these ingredients may be arranged as separate groups for vitamins and minerals. Within these groups the vitamins and minerals need not be listed in descending order of proportion.

8.2.2 The specific name shall be declared for ingredients of animal or plant origin and for food additives. In addition, appropriate functional classes for food additives shall be included on the label. The food additives INS number may also be optionally declared.

8.3 Declaration of Nutritive Value

The declaration of nutrition information for Follow-up formula for older infants shall contain the following information which should be in the following order:

a) the amount of energy, expressed in kilocalories (kcal) and/or kilojoules (kJ), and the number of grams of protein, carbohydrate and fat per 100 g or per 100 ml of the food as sold as well as per 100 ml of the food ready for use, when prepared according to the instructions on the label.

b) the total quantity of each vitamin and mineral as listed in paragraph 3.1.3 of Section A and any other ingredient as listed in paragraph 3.2 of Section A per 100 g or per 100 ml of the food as sold as well as per 100 ml of the food ready for use, when prepared according to the instructions on the label.

c) In addition, the declaration of nutrients in a) and b) per 100 kilocalories (kcal) or per 100 kilojoules (kJ) is permitted.

8.4 Date Marking and Storage Instructions

8.4.1 The date marking and storage instructions shall be in accordance with Section 4.7 of the *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985).

8.4.2 Where practicable, storage instructions shall be in close proximity to the date marking.

8.5 Information for Use

8.5.1 Ready to use products in liquid form should be used directly. Concentrated liquid products and powdered products must be prepared with potable water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.

8.5.2 Adequate directions for the appropriate preparation and use of the product, including its storage and disposal after preparation, i.e. that product remaining after feeding should be discarded, shall appear on the label.

8.5.3 The label shall carry clear graphic instructions illustrating the method of preparation of the product.

8.5.4 The directions should be accompanied by a warning about the health hazards of inappropriate preparation, storage and use.

8.5.5 Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label.

8.5.6 The label of Follow-up formula for older infants shall include a statement that the product shall not be introduced before 6 months of age, is not to be used as a sole source of nutrition and that older infants should receive complementary foods in addition to the product.

8.6 Additional Labelling Requirements

8.6.1 Labels should not discourage breastfeeding. Each container label shall have a clear, conspicuous and easily readable message which includes the following points:

a) the words "important notice" or their equivalent;

b) the statement "Breastmilk is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breastmilk;

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

d) the statement; ‘The use of this product should not lead to cessation of continued breastfeeding’.

8.6.2 The label shall have no pictures of infants, young children and women nor any other picture, text, or representation that might:

8.6.2.1 idealize the use of Follow-up formula for older infants;

8.6.2.2 suggest use for infants under the age of 6 months (including references to milestones and stages);

8.6.2.3 recommend or promote bottle feeding;

8.6.2.4 undermine or discourage breastfeeding; or that makes a comparison to breastmilk, or suggests that the product is similar, equivalent to or superior to breastmilk;

8.6.2.5 convey an endorsement or anything that may be construed as an endorsement by a professional or any other body, unless this has been specifically approved by relevant national or regional regulatory authorities.

8.6.3 The terms "humanized", "maternalized" or other similar terms shall not be used.

8.6.4 Follow-up formula for older infants shall be distinctly labelled in such a way as to avoid any risk of confusion with Infant formula, Drink for young children with added nutrients or Product for young children with added nutrients or Drink for young children or Product for young children, and Formula for special medical purposes intended for infants, in particular as to the text, images and colours used, to enable consumers to make a clear distinction between them.

8.6.5 The labelling of follow-up formula for older infants shall not refer to Infant formula, Drink for young children with added nutrients or Product for young children with added nutrients or Drink for young children or Product for young children, or Formula for special medical purposes intended for infants, including numbers, text, statements, or images of these products.

9. Methods of Analysis and Sampling

For checking the compliance with this Standard, the methods of analysis contained in the *Recommended Methods of Analysis and Sampling* (CXS 234-1999) relevant to the provisions in this standard, shall be used.

SECTION B: DRINK FOR YOUNG CHILDREN WITH ADDED NUTRIENTS OR PRODUCT FOR YOUNG CHILDREN WITH ADDED NUTRIENTS OR DRINK FOR YOUNG CHILDREN OR PRODUCT FOR YOUNG CHILDREN

1 SCOPE

1.1 This section of the Standard applies to the product as defined in Section 2.1, in liquid or powdered form.

1.2 This section of the Standard contains compositional, quality, safety, labelling, analytical and sampling requirements for the product as defined in Section 2.1.

1.3 Only products that comply with the criteria laid down in the provisions of this section of this Standard shall be presented as the product defined in Section 2.1.

2 DESCRIPTION

2.1 Product Definition

2.1.1 **Drink for young children with added nutrients or Product for young children with added nutrients or Drink for young children or Product for young children** means a product manufactured for use as a liquid part of the diversified diet of young children[2)].

2.1.2 Drink for young children with added nutrients or Product for young children with added nutrients or Drink for young children or Product for young children is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold.

2.2 Other Definitions

2.2.1 The term **young child** means a person from the age of more than 12 months up to the age of three years (36 months).

3 ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Essential composition

3.1.1 The product as defined in Section 2.1 is a product based on milk of cows or other animals or a mixture thereof and/or other ingredients which have been proven to be safe and suitable for the feeding of young children. The nutritional safety and adequacy of the product as defined in Section 2.1 shall be scientifically demonstrated to support growth and development of young children.

3.1.2 When prepared ready for consumption in accordance with the instructions of the manufacturer, the products shall contain per 100 ml not less than 60 kcal (251 kJ) and not more than 70 kcal (293 kJ) of energy. National and/or regional authorities can deviate from the minimum energy content in line with national/regional dietary guidelines taking into account the nutritional needs of the local population.

3.1.3 The product as defined in Section 2.1 prepared ready for consumption shall contain per 100 kcal (100 kJ) the following nutrients with the following minimum and maximum or guidance upper levels (GUL)[3)], as appropriate. The general principles for establishing these levels are identified in Annex I of this Standard.

a) **Protein**[3), 4)]

Unit	Minimum	Maximum	GUL
g/100 kcal	1.8	-	-
g/100 kJ	0.43	-	-

[2)] In some countries these products are regulated as breastmilk substitutes

[3)] Guidance upper levels are for nutrients without sufficient information for a science-based risk assessment. These levels are values derived on the basis of meeting nutritional requirements of young children and an established history of apparent safe use. They may be adjusted based on relevant scientific or technological progress. The purpose of the GULs is to provide guidance to manufacturers and they should not be interpreted as goal values. Nutrient contents in the product as defined in Section 2.1 should usually not exceed the GULs unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of the product as defined in Section 2.1 or due to technological reasons. When a product type or form has ordinarily contained lower levels than the GULs, manufacturers should not increase levels of nutrients to approach the GULs.

[3] For the purpose of this Standard the calculation of the protein content of the final product ready for consumption should be based on N x 6.25, unless a scientific justification is provided for the use of a different conversion factor for a particular product**.** The protein levels set in this standard are based on a nitrogen conversion factor of 6.25. For information the value of 6.38 is used as a specific factor appropriate for conversion of nitrogen to protein in other Codex standards for milk products.

[4] PDCAAS is the preferred method to determine protein quality. However, PER can continue to be used. DIAAS could also be considered should it be recognized by FAO in the future. When determined using PDCAAS methodology, appropriate Digestibility values and the reference amino acid pattern (see Table 5 of the Report of the FAO Expert Working Group: Protein quality assessment in follow-up formula for young children and ready to use therapeutic food), the PDCAAS shall be not less than 0.9. In formulations with lower scores the quality and/or quantity of protein should be adjusted to achieve the desired value. Detail on how to calculate the PDCAAS is listed in the Report of the FAO Expert Working Group: Protein quality assessment in follow-up formula for young children and ready to use therapeutic food.

When determined by PER methodology the protein quality shall not be less than 85% of that of casein.

b) Lipids [5]

Total fat

Unit	Minimum	Maximum	GUL
g /100 kcal	3.5	-	-
g /100 kJ	0.84	-	-

[5] Partially hydrogenated oils and fats shall not be used in the product as defined in Section 2.1.

α-Linolenic acid

Unit	Minimum	Maximum	GUL
mg /100 kcal	50	-	-
mg /100 kJ	12	-	-

Linoleic acid

Unit	Minimum	Maximum	GUL
mg /100 kcal	300	-	-
mg /100 kJ	72	-	-

c) Carbohydrates

Available carbohydrates[6), 7)]

Unit	Minimum	Maximum[8)]	GUL
g /100 kcal	-	12.5	-
g /100 kJ	-	3.0	-

[6] Lactose should be the preferred carbohydrate in the product as defined in Section 2.1 based on milk protein. For products based on non-milk protein, carbohydrate sources that have no contribution to sweet taste should be preferred and in no case be sweeter than lactose.

[7] Mono- and disaccharides, other than lactose, should not exceed 2.5 g/100kcal (0.60 g/100kJ). National and/or regional authorities may limit this level to 1.25 g/100 kcal (0.30 g/100 kJ). Sucrose and/or fructose should not be added.

[8] For the product as defined in Section 2.1 with a protein level below 3.0 g/100 kcal a maximum level of available carbohydrates up to 14 g/100 kcal (3.3 g/100 kJ) may be permitted by competent national and/or regional authorities.

d) Vitamins

Vitamin A

Unit	Minimum	Maximum	GUL
µg RE[9)] /100 kcal	60	180	-
µg RE[9] /100 kJ	14	43	-

[9] expressed as retinol equivalents (RE)

1 µg RE = 3.33 IU Vitamin A = 1 µg all-trans retinol. Retinol contents shall be provided by preformed retinol, while any contents of carotenoids should not be included in the calculation and declaration of Vitamin A activity.

Vitamin D [10)]

Unit	Minimum	Maximum	GUL
µg[11)] /100 kcal	1.5	4.5	-
µg[11)] /100 kJ	0.36	1.1	-

[10)] Competent national and/or regional authorities may deviate from the conditions as appropriate for the nutritional needs of their population.

[11)] Calciferol. 1 µg calciferol = 40 IU Vitamin D.

Riboflavin

Unit	Minimum	Maximum	GUL
µg /100 kcal	80	-	650
µg /100 kJ	19	-	155

Vitamin B_{12}

Unit	Minimum	Maximum	GUL
µg /100 kcal	0.1	-	2.0
µg /100 kJ	0.02	-	0.48

Vitamin C[12)]

Unit	Minimum	Maximum	GUL
mg /100 kcal	10	-	70
mg /100 kJ	2.4	-	17

[12)] expressed as L-ascorbic acid

e) Minerals and Trace Elements

Iron[13)]

Unit	Minimum	Maximum	GUL
mg /100 kcal	1.0	3.0	-
mg /100 kJ	0.24	0.72	-

[13)] For the product as defined in Section 2.1 based on soy protein isolate a minimum value of 1.5 mg/100 kcal (0.36 mg/100 kJ) applies.

Calcium

Unit	Minimum	Maximum	GUL
mg /100 kcal	90	-	280
mg /100 kJ	22	-	67

Zinc

Unit	Minimum	Maximum	GUL
mg /100 kcal	0.5	-	1.5
mg /100 kJ	0.12	-	0.36

Sodium chloride should not be added to the product as defined in Section 2.1.

3.1.4 National and/or regional authorities may add mandatory requirements for essential nutrients listed under 3.1.3, Section B. Any additional mandatory nutrients should be chosen from the essential composition of Follow-up formula for older infants under 3.1.3 Section A. If additional mandatory nutrients are added, the nutrient levels must be based on the nutrient composition of follow-up formula for older infants (3.1.3 Section A) which is informed by the composition of breastmilk, and take into account the inherent levels of nutrients in cows' milk.

All nutrient levels may be amended if the nutritional needs of the local population and scientific justification warrants such deviation.

3.2 Optional Ingredients

3.2.1 In addition to the compositional requirements listed under 3.1.3, other ingredients or substances may be added to the product as defined in Section 2.1 where the safety and suitability of the optional ingredient for particular nutritional purposes, at the level of use, is evaluated by national and/or regional authorities and demonstrated by generally accepted scientific evidence. Optional ingredients listed in 3.2.3 Section A are also permitted.

3.2.2 When any of these ingredients or substances is added the product as defined in Section 2.1 shall contain sufficient amounts to achieve the intended effect.

3.2.3 Additional nutrients may also be added to the product as defined in Section 2.1 provided these nutrients are chosen from the essential composition of Follow-up formula for older infants and levels are as per the minimum, maximum, GULs stipulated for follow-up formula for older infants (3.1.3 Section A) and take into account the inherent levels of nutrients in cows' milk; or amended by national and/or regional authorities if the nutritional needs of the local population and scientific justification warrants such deviation.

3.2.4 Ingredients shall not be added with the purpose of imparting or enhancing a sweet taste of the product as defined in Section 2.1.

3.3 Purity Requirements

3.3.1 General

All ingredients shall be clean, of good quality, safe and suitable for ingestion by young children. They shall conform with their normal quality requirements, such as colour, flavour and odour.

3.3.2 Vitamin Compounds and Mineral Salts

Vitamin compounds and mineral salts used in accordance with Sections 3.1.3 (d) and (e) and 3.2.1 should be selected from the *Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses intended for Infants and Young Children* (CXG 10-1979).

3.4 Consistency and Particle Size

When prepared according to the directions of use, the product shall be free of lumps and of large, coarse particles.

3.5 Specific Prohibitions

The product and its components shall not have been treated by ionizing radiation.

4. Food Additives

The following additives are permitted:[14)]

INS	Additive	Maximum level in 100 mL of the product ready for consumption
4.1 Thickeners		
412	Guar gum	0.1 g
410	Carob bean gum	0.1 g
1412	Distarch phosphate	0.5 g singly or in combination in soy-based products only; 2.5 g singly or in combination in hydrolyzed protein and/or amino acid-based products only
1414	Acetylated distarch phosphate	
1413	Phosphated distarch phosphate	
1422	Acetylated distarch adipate	
407	Carrageenan	0.03 g singly or in combination in milk and soy-based products only; 0.1 g singly or in combination in hydrolyzed protein and/or amino acid-based liquid products only
440	Pectins	1 g
4.2 Emulsifiers		
322(i)	Lecithin	0.5 g
471	Mono- and diglycerides of fatty acids	0.4 g

4.3 Acidity Regulators		
500(ii)	Sodium hydrogen carbonate	Limited by GMP
500(i)	Sodium carbonate	
331(i)	Sodium dihydrogen citrate	
331(iii)	Trisodium citrate	
524	Sodium hydroxide	
501(ii)	Potassium hydrogen carbonate	Limited by GMP
501(i)	Potassium carbonate	
332(i)	Potassium dihydrogen citrate	
332(ii)	Tripotassium citrate	
525	Potassium hydroxide	
526	Calcium hydroxide	Limited by GMP
270	Lactic acid, L-, D-, and DL-	Limited by GMP
330	Citric acid	Limited by GMP
4.4 Antioxidants		
307b	Tocopherols concentrate, mixed	3 mg singly or in combination
307a	Tocopherol, d-alpha	
307c	Tocopherol, dl-alpha	
304	Ascorbyl palmitate	5 mg singly or in combination, expressed as ascorbic acid (INS 300, 301,302,304)
300	Ascorbic acid, L-	
301	Sodium ascorbate	
302	Calcium ascorbate	
4.5 Packaging Gases		
290	Carbon dioxide	GMP
941	Nitrogen	GMP

[14)] The table of food additive provisions is for information only. Following the completion of the alignment work for CXS 156-1987, the table will be replaced by a general reference to the GSFA as below:

"Acidity regulators, antioxidants, emulsifiers, thickeners, packaging gases used in accordance with Tables 1 and 2 of the *General Standard for Food Additives* (CXS 192-1995) in food category 13.1.2 (Follow-up formulae) are acceptable for use in foods conforming to this Standard."

4.6 Flavourings [15)]

Natural Fruit Extracts: GMP

Vanilla extract: GMP

Ethyl vanillin (JECFA no. 893): 5 mg/100 ml

Vanillin (JECFA no. 889): 5 mg/ 100 ml

The flavourings used in products covered by this Standard should comply with the *Guidelines for the Use of Flavourings* (CXG 66-2008).

[15)] National and/or regional authorities may restrict or prohibit the use of the listed flavourings.

4.7 Carry-Over Principle

Only the food additives listed in this Section or in the *Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses intended for Infants and Young Children* (CXG 10-1979) may be present in the foods described in Section 2.1 of this Standard, as a result of carry-over from a raw material or other ingredient (including food additive) used to produce the food, subject to the following conditions:

a) The amount of the food additive in the raw materials or other ingredients (including food additives) does not exceed the maximum level specified; and

b) The food into which the food additive is carried over does not contain the food additive in greater quantity than would be introduced by the use of the raw materials or ingredients under good manufacturing practice, consistent with the provisions on carry-over in the Preamble of the *General Standard for Food Additives* (CXS 192-1995).

5. Contaminants

The products covered by this Standard shall comply with the Maximum levels of the *General Standard for Contaminants and Toxins in Food and Feed* (CXS 193-1995).

The products covered by this Standard shall comply with the maximum residue limits for pesticides established by the Codex Alimentarius Commission.

6. Hygiene

6.1 It is recommended that the product covered by the provisions of this Standard be prepared and handled in accordance with the appropriate sections of the *General Principles of Food Hygiene* (CXC 1-1969), and other relevant Codex texts such as the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children* (CXC 66-2008), and in the case of liquid formula that has been commercially sterilised should also consider the appropriate sections of the *Code of Hygienic Practice for Aseptically Processed and Packaged Low-acid Foods* (CXC 40-1993) and the *Code of Hygienic Practice for Low and Acidified Low-acid Canned Foods* (CXC 23-1979), as applicable.

6.2 The products should comply with any microbiological criteria established in accordance with the *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21-1997).

7. Fill of Containers

In the case of products in ready-to-eat form, the fill of container shall be:

(i) not less than 80% v/v for products weighing less than 150 g (5 oz.);

(ii) not less than 85% v/v for products in the weight range 150-250 g (5 - 9 oz.); and

(iii) not less than 90% v/v for products weighing more than 250 g (9 oz.) of the water capacity of the container. The water capacity of the container is the volume of distilled water at 20°C which the sealed container will hold when completely filled.

8. LABELLING

The requirements of the *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985), the *Guidelines on Nutrition Labelling* (CXG 2-1985) and the *Guidelines for Use of Nutrition and Health Claims* (CXG 23-1997) apply to the product as defined in Section 2.1. These requirements include a prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation.

8.1 The Name of the Product

8.1.1 The text of the label and all other information accompanying the product shall be written in the appropriate language(s).

8.1.2 The name of the product as defined in Section 2.1 shall be “Drink for young children with added nutrients” or “Product for young children with added nutrients” or “Drink for young children” or “Product for young children”, or any appropriate designation indicating the true nature of the product, in accordance with national or regional usage.

8.1.3 The sources of protein in the product shall be clearly shown on the label.

a) If [name of animal] milk is the only source of protein*, the product may be labelled “Drink for young children with added nutrients based on [name of animal] milk protein” or “Product for young children with added nutrients based on [name of animal] milk protein” or “Drink for young children based on [name of animal] milk protein” or “Product for young children based on [name of animal] milk protein”.

b) If [name of plant] is the only source of protein*, the product may be labelled “Drink for young children with added nutrients based on [name of plant] protein” or “Product for young children with added nutrients based on [name of plant] protein” or “Drink for young children based on [name of plant] protein” or “Product for young children based on [name of plant] protein”.

c) if [name of animal] milk and [name of plant] are the sources of proteins*, the product may be labelled "Drink for young children with added nutrient based on [name of animal] milk protein and [name of plant] protein" or "Product for young children with added nutrients based on [name of animal] milk protein and [name of plant] protein" or "Drink for young children based on [name of animal] milk protein and [name of plant] protein" or "Product for young children based on [name of animal] milk protein and [name of plant] protein".

* For clarity, addition of individual amino acids where needed to improve protein quality does not preclude use of the above labelling options.

8.1.4 A product which contains neither milk nor any milk derivative shall be labelled "contains no milk or milk products" or an equivalent phrase.

8.2 List of Ingredients

8.2.1 A complete list of ingredients shall be declared on the label in descending order of proportion except that in the case of added vitamins and minerals, these ingredients may be arranged as separate groups for vitamins and minerals. Within these groups the vitamins and minerals need not be listed in descending order of proportion.

8.2.2 The specific name shall be declared for ingredients of animal or plant origin and for food additives. In addition, appropriate functional classes for food additives shall be included on the label. The food additives' INS number may also be optionally declared.

8.3 Declaration of Nutritive Value

The declaration of nutrition information for the product as defined in Section 2.1 shall contain the following information which should be in the following order:

a) the amount of energy, expressed in kilocalories (kcal) and/or kilojoules (kJ), and the number of grams of protein, carbohydrate and fat per 100 g or per 100 ml of the food as sold as well as per 100 ml of the food ready for use, when prepared according to the instructions on the label.

b) the total quantity of each vitamin and mineral as listed in paragraph 3.1.3 of Section B and any other ingredient as listed in paragraph 3.2 of Section B per 100 g or per 100 ml of the food as sold as well as per 100 ml of the food ready for use, when prepared according to the instructions on the label.

c) In addition, the declaration of nutrients in a) and b) per 100 kilocalories (kcal) or per 100 kilojoules (kJ) and/or per serving size, provided that the serving size is quantified on the label, is permitted.

8.4 Date Marking and Storage Instructions

8.4.1 The date marking and storage instructions shall be in accordance with Section 4.7 of the *General Standard for the Labelling of Prepackaged* Foods.

8.4.2 Where practicable, storage instructions shall be in close proximity to the date marking.

8.5 Information for use

8.5.1 Ready to use products in liquid form should be used directly. Concentrated liquid products and powdered products must be prepared with potable water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.

8.5.2 Adequate directions for the appropriate preparation and use of the product, including its storage and disposal after preparation, i.e. that product remaining after feeding should be discarded, shall appear on the label.

8.5.3 The label shall carry clear graphic instructions illustrating the method of preparation of the product.

8.5.4 The directions should be accompanied by a warning about the health hazards of inappropriate preparation, storage and use.

8.5.5 Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label.

8.5.6 The label of the product as defined in Section 2.1 shall include a statement that the product shall not be introduced to infants 12 months of age or less, and is not to be used as a sole source of nutrition.

8.6 Additional Labelling Requirements

8.6.1 The label of the product as defined in Section 2.1 shall have no image, text or representation, including pictures of feeding bottles, that could undermine or discourage breastfeeding or which idealises the use of the product as defined in Section 2.1. The terms 'humanized', 'maternalized' or other similar terms must not be used on the label.

8.6.2 Labels should not discourage breastfeeding. Each container label shall have a clear, conspicuous and easily readable message which includes the following points:

a) the statement "Breastfeeding is recommended up to two years and beyond."

b) a statement that the mother/caregiver should seek advice of a health worker on proper feeding of the young child.

8.6.3 The label shall have no pictures of infants, older infants, young children and women or any other picture, text, or representation that:

8.6.3.1 undermines or discourages breastfeeding; or that makes a comparison to breastmilk, or suggests that the product is similar, equivalent to or superior to breastmilk;

8.6.3.2 might convey an endorsement or anything that may be construed as an endorsement by a professional or any other body, unless this has been specifically approved by relevant national or regional regulatory authorities.

8.6.4 The product as defined in Section 2.1 shall be distinctly labelled in such a way as to avoid any risk of confusion with infant formula, follow-up formula for older infants, and formula for special medical purposes intended for infants**,** in particular as to the text, images and colours used, to enable consumers to make a clear distinction between them.

8.6.5 The labelling of the product as defined in Section 2.1 shall not refer to infant formula, follow-up formula for older infants, or formula for special medical purposes intended for infants, including numbers, text, statements, or images of these products.

9. Methods of Analysis and Sampling

For checking the compliance with this Standard, the methods of analysis contained in the *Recommended Methods of Analysis and Sampling* (CXS 234-1999) relevant to the provisions in this standard, shall be used.