CODEX STANDARD 156-1987 FOR FOLLOW-UP FORMULA FOR OLDER INFANTS AND PRODUCT FOR YOUNG CHILDREN*

**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.*

Guidance Document Prepared by ISDI

International Special
Dietary Foods Industries

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DISCLAIMER
This guidance document is intended to provide information supporting the transition from the Standard for Follow-up formula of Codex Alimentarius to the new Standard for Follow-up formula for older infant and Products for Young Children*. It is for general information purposes only and does not constitute legal or other professional advice. It does not replace the relevant Codex Standards and should be read in conjunction with all the relevant texts at Codex Alimentarius level. The information provided is without prejudice to national or regional regulations and interpretations. A full and updated list of Codex texts (standards, guidelines and codes of practice) contained within this document can be found on the Codex website. **Sections in black are directly taken from Codex texts.**

*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.

TARGET GROUP

The audience for the brochure is food business manufacturers and national authorities.

PURPOSE OF THE BROCHURE

The brochure provides the background regarding the new Standard for Follow-up Formula for Older Infants and Product for Young Children* CXS 156-1987 which defines at international level these two categories of products. These products are considered food for special dietary use (FSDU) – more information can be found in the ISDI brochure on FSDU.

This brochure aims to facilitate the transition from the Standard for follow-up formula of Codex Alimentarius to the new Standard for Follow-up formula for older infants and Product for Young Children*. It also provides background information to facilitate the understanding of the revised Standard.

The CODEX ALIMENTARIUS international food standards, guidelines, and codes of practice contribute to the safety, quality, and fairness of international food trade. Codex standards are based on sound science provided by independent international risk assessment bodies or ad hoc consultations organised by FAO and WHO.

The brochure is for general information purposes and aims to facilitate the reading and understanding of:

- **PART A: FOLLOW-UP FORMULA FOR OLDER INFANTS**
- **PART B: PRODUCT FOR YOUNG CHILDREN***

The brochure can be used as support for Food Manufacturers as educational material (e.g. internal training) or as a background element for discussions with national authorities. The brochure does not consider the specific regulations of Follow-up formula for older infants and Product for Young Children*, Foods for Special Dietary Uses (FSDU) or other specialised nutrition products in each country and should not be considered in isolation.

INTRODUCTION

In November 2023, the Codex Alimentarius Commission adopted the revised Standard for Follow-up formula (CXS 156-1987), initially issued in 1987.

ISDI welcomes the new Codex Alimentarius Standard for Follow-up formula for Older Infants and Product for Young Children*. This revision of the existing Standard allowed for a global upgrade of these products to the latest scientific developments, for the benefit of the two age groups: older infants and young children. As a Codex Observer, ISDI has accompanied these discussions and provided scientific support throughout the revision process.

2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2021	2023
CCNFSDU32 agrees for New-Zealand to establish a discussion paper for the revision of the Standard.	CCNFSDU33 New-Zealand presents a discussion paper for the revision of the Standard on Follow-up Formula. There is ***no time to discuss the matter.***	CCNFSDU34 agrees on the new work to revise the Standard on Follow-up Formula with New-Zealand as chair of an EWG with France and Indonesia as co-chair.	CCNFSDU35 retains the Draft Review at Step 4. New-Zealand to establish discussion paper on nutrition composition.	CCNFSDU36 agrees to return the revision to Step 2. The focus is on essential composition.	CCNFSDU37 agreed on a division between older infants and young children. The part FUFOI is at Step 5, the part on young children at Step 2/3.	CCNFSDU38 Essential composition at Step 4.	CCNFSDU39 Essential composition at Step 5, discussion on labelling (part on older infants).	CCNFSDU40 agrees for a Section (older infants) at Step 5. Defer the discussion on Section B (Young Children) labelling and definition.	CCNFSDU41 agrees for Section B Labelling and definition at step 5. Section A labelling and definition and A&B composition at Step 7.	CCNFSDU42 holds sections A and B at Step 7 except remaining Section at Step 4 (but no further discussion. Preamble and Structure at Step 3).	CCNFFSDU43 finalises the structure and the preamble. The final text is sent to CAC46 for formal adoption.

Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) timeline.

The revised Standard for Follow-up formula CXS 156-1987 is a global regulatory reference based on the latest scientific evidence available.

While the Standard aims to harmonize rules, some provisions are left to national authorities to decide and are identified accordingly in this brochure, which also includes ISDI recommendations where relevant.

ISDI also calls on competent national authorities to include fair transition measures when implementing the new standard into national legislation. Transitional measures are important to maintain market access to the products. ISDI estimates a transition period of 36 months is ideal to ensure product continuity while the new formulations and products based on the new Standard can be gradually introduced in the supply (See Transition section).

For ease of reading this brochure refers to Part A for Follow-up Formula for Older Infants or Part B for Product for Young Children*.

OVERVIEW OF THE CHANGES

The revised Standard is subdivided into two parts.

1. **Part A** referring to Follow-Up Formula for older infants (FUF),
2. **Part B**, referring to Product for Young Children (PYC).

*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.

	OLD	NEW	
	FUF 6-36 (OLD STD 156-1987)	**PART A - FUF OLDER INFANTS 6-12**	**PART B - PRODUCTS FOR YOUNG CHILDREN 12-36**
Role	Liquid part of progressively diversified diet	Liquid part of progressively diversified diet	Complementary/ Supplementary liquid nutrition Cannot be sole source of nutrition
Definition	Follow-up formula means a food intended for use as a liquid part of the weaning diet for the infant from the 6th month on and for young children	Follow-up formula for older infants means a product, manufactured for use as a Breast Milk Substitute, as a liquid part of a diet for older infants when progressively diversified complementary feeding is introduced	Drink/product for young children with added nutrients or Drink for Young Children means a product manufactured for use as liquid part of the diversified diet of young children.* ** In some countries these products are regulated as BMS*
Mandatory # Vitamins and Minerals	22	**25**	**8** (See PART A / FUFOI for 17 others)
Macronutrients Profile	**Energy:** [60 – 85] kcal/100 ml **Protein:** [3.0 – 5.5] g/100 kcal (High) **Carbohydrates NS:** (generally high) **Fat:** [3.0 – 6.0] g/100 kcal	**Energy decreased:** [60 – 70] kcal/100 ml **Protein decreased:** [1.8* – 3.0] g/100 kcal **Carbohydrates minimum and maximum limit:** [9.0 – 14.0] g/100 kcal 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. **Fat adjusted:** [4.4 – 6.0] g/100 kcal ** Country specific: Down to 1.6*	**Energy decreased:** [60 – 70] kcal/100ml **Protein decreased:** [1.8 – NS] g/100 kcal **Carbohydrates minimum and maximum limit:** [NS – 12.5*] g/100 kcal 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. Mono- and disaccharides, other than lactose, should not exceed 2.5 g/100 kcal. Country Specific 1.25 g/100 kcal. Sucrose and/or fructose should not be added. **Fat adjusted:** [3.5 – NS] g/100 kcal ** Country specific: Up to 14*
DHA/AA (if added)	NS	**If added** 20-30 mg/100 kcal	**If added** Sufficient amounts to achieve the intended effect
Flavours	Allowed	Not allowed	Allowed* ** National restrictions possible*
Specific labeling requirement	3 basic label requirements: • FUF shall not be introduced before 6 months • Other foods needed in addition to FUF • Not a BMS or presented as such	Additional labelling requirements: (See more in Apendix II) **Key principles** • No picture of infants, young children and women that idealize the product • Product differentiation	Additional labelling requirements: (See more in Apendix III) **Key principles** • No picture of infants, young children and women that idealize the product • Product differentiation

Important: This is Codex Alimentarius only. A country may choose to adopt different components (for e.g. additional mandatory nutrients)

PART A

ESSENTIAL COMPOSITION

Protein

Lipids (Total fat, α-Linolenic acid and Linoleic acid)

Carbohydrates

Vitamins
Vitamin A
Vitamin D
Vitamin E
Vitamin K
Thiamin (Vitamin B_1)
Riboflavin (Vitamin B_2)
Niacin
Vitamin B_6
Vitamin B_{12}
Pantothenic acid
Folic Acid
Vitamin C
Biotin

Minerals and Trace elements
Iron
Calcium
Phosphorus
Magnesium
Sodium
Chloride
Potassium
Manganese
Iodine
Selenium
Copper
Zinc

OPTIONAL INGREDIENTS

Optional ingredients listed & with specific ranges

Taurine
Total nucleotides
Docosahexaenoic acid
Choline
Myo-inositol
L-carnitine
L (+) lactic acid-producing cultures

Non exhaustive List or Specified of Optional Ingredients

- *Demonstrated safety and suitability*
- *Sufficient amounts to achieve the intended effect, taking into account levels in human milk*

PART B

ESSENTIAL COMPOSITION

Protein

Lipids (Total fat, α-Linolenic acid and Linoleic acid)

Carbohydrates

Vitamins
Vitamin A
Vitamin C
Vitamin D
Riboflavin (Vitamin B_2)
Vitamin B_{12}

Minerals and Trace elements
Iron
Calcium
Zinc

OPTIONAL INGREDIENTS

Optional nutrients with specific range based on Essential Composition from Part A

Vitamins
Vitamin E
Vitamin K
Thiamin (Vitamin B_1)
Niacin
Vitamin B_6
Pantothenic acid
Folic Acid
Biotin

Minerals and Trace elements
Phosphorus
Magnesium
Sodium
Chloride
Potassium
Manganese
Iodine
Selenium
Copper

Non exhaustive Optional Ingredients including optional ingredients listed without specific range

Taurine
Total nucleotides
Docosahexaenoic acid
Choline
Myo-inositol
L-carnitine
L (+) lactic acid-producing cultures

- *Demonstrated safety and suitability*
- *Sufficient amounts to achieve the intended effect, taking into account levels in human milk*

Part B optional nutrients with specific ranges based on "Essential Composition" from Part A

IMPORTANT:
This is based on the new Standard 156-1987. A country may deviate (e.g. additional mandatory nutrients)

Following decisions taken at the Forty-sixth Session of the Codex Alimentarius Commission in December 2023, the food additives provisions in this standard have been included in the *General Standard for Food Additives* (GSFA) CXS 192-1995[1] in line with the process of alignment of all food additive provisions with the GSFA.

ISDI Comment

See more in section A.4 and B.4

PREAMBLE

ISDI Comment

The following preamble was adopted by Codex Alimentarius. ISDI notes that a preamble is not required in Codex Alimentarius Standard and that several countries expressed reservations about either paragraph 2 or 3 or both.

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.

ISDI notes that the first paragraph of the preamble is a factual statement.

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* (WHO, 1981) [2], as per the national/regional context.

The United States, Panama and Costa Rica expressed a reservation of this paragraph at the final adoption (see CAC46 Report)

ISDI notes that the second paragraph states obvious elements and recommendations, in relation to the competence of countries in establishing health policies and the role of recommendations from the WHO 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.

This third paragraph reflects the process to adopt the Standard and the fact that these different documents were 'considered' during the discussions.

However, ISDI recalls that CCNFSDU39 noted that *"some WHA resolutions went beyond the mandate of Codex and therefore was inappropriate to reference them"*.

ISDI notes that, as a matter of international law, WHA resolutions and guidance and the WHO Code do not meet the requirements for an international standard and thus are inappropriate for inclusion or reference in Codex. Referencing them into an international standard, like Codex Alimentarius, would create the impression that the WHO instruments are legally binding and meet the procedural requirements of Codex.

ISDI also notes that relevant World Health Organization (WHO) guidelines and policies and World Health Assembly (WHA) resolutions were already considered in the development of this Standard. Appendix IV of this brochure refers to work carried out by New Zealand as chair of the CCNFSDU electronic Working Group in charge of the revision of the Follow-Up Formula standard to emphasize the relevant concepts and technical guidance in WHO/WHA documents that were considered to establish the labelling section and other provisions in the draft standard for Follow-up formula for Older Infants and Product for Young Children.

PART 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.

ISDI comment

The Standard contains specific conditions for compositional, quality, safety, labelling, analytical and sampling requirements. Analytical and sampling requirements are under the remit of testing requirements.

Only those products that comply with the full requirements of Part A of this Standard may be presented as Follow-up formula for Older Infants.

ISDI notes that the scope explicitly establishes that a Follow-up formula for older infants can be in liquid or powdered form. It is therefore clear that this Codex Standard applies in its entirety to both forms.

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.

ISDI comment

ISDI notes that point 2.1.1 establishes the fundamental notion that Follow-up formula for older infants is a standardized commodity to be used as a breast-milk substitute. However contrary to infant formula, it is not highlighted that the product should satisfy by itself the nutritional requirements of normal healthy older infants but clearly establishes that the product is to accompany the "progressively diversified complementary feeding".

This ability to provide a sole source of nutrition for infants is an essential point of differentiation with Infant formula, which leads certain countries to only classify infant formula as a breast-milk substitute for that very reason, especially in a food safety perspective.

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.

ISDI comment

ISDI notes that this article highlights the importance of process and packaging for such sensitive products. Indeed, food processing plays an essential role in ensuring food safety by eliminating micro-organisms

and toxins, and with adapted packaging, they both help to minimize the food safety risk for these vulnerable target population, preserve certain nutrients and protect the final products during storage and distribution.

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

ISDI comment

ISDI notes that the term older infant is also defined in the Codex Guidelines on formulated complementary foods for older infants and young children CAC/GL 8-1991 and the term young children in the previous Codex Standard for Follow-up formula CXS 156-1987

ISDI considers it important to emphasize the specific age group covered and role of this product.

Age group: Follow-up formula for Older Infants is intended for the age group of older infants only: from 6 months of age until 12 months (not more than 12 months). These products are not intended for young children. Separate requirements for Products for young children are detailed in Section B.

Role of product: These products are intended for use as a liquid part of the weaning diet of older infants when progressively diversified complementary feeding is introduced, but the definition in the revised Standard additionally states these products for older infants (6-12 months) are used as a breast-milk substitute. This is a significant change from the old Standard on Follow-up Formula which was explicitly stating that Follow-up Formula are not breastmilk substitutes.

Liquid or Powdered form: ISDI notes that the scope does not explicitly establish that Follow-up formula for older infants can be in liquid or powdered form. It is however clear that this Codex Standard in its entirety applies to both forms.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

Overview of composition requirements

ESSENTIAL COMPOSITION (Part A, point 3.1.3)	OPTIONAL INGREDIENTS (Part A, point 3.2)
Protein	Point 3.2.1 & 3.2.2: Non-exhaustive List or Specified of Optional Ingredients
Lipids (Total fat, αLinolenic acid and Linoleic acid)	Point 3.2.3: Optional ingredients with specific ranges
Carbohydrates	Taurine
VITAMINS	Total nucleotides
Vitamin A	Docosahexaenoic acid
Vitamin D	Choline
Vitamin E	Myo-inositol
Vitamin K	L-carnitine
Thiamin (Vitamin B_1)	L (+) lactic acid-producing cultures
Riboflavin (Vitamin B_2)	
Niacin	
Vitamin B_6	
Vitamin B_{12}	
Pantothenic acid	
Folic Acid	
Vitamin C	
Biotin	
MINERALS AND TRACE ELEMENTS	
Iron	
Calcium	
Phosphorus	
Magnesium	
Sodium	
Chloride	
Potassium	
Manganese	
Iodine	
Selenium	
Copper	
Zinc	

Key:

Mandatory ingredients from Essential Composition in Section A point 3.1.3 – i.e. for FOLLOW-UP FORMULA FOR OLDER INFANTS

Non exhaustive or specified list of Optional Ingredients from point 3.2 Part A (i.e. FOLLOW-UP FORMULA FOR OLDER INFANTS) based on principles established in 3.2.1 & 3.2.3

- *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.*
- *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.*

Specific Optional Ingredients with levels/range as established in Part A point 3.2.3 (i.e. Follow-up formula for older infants.)

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)[i] as appropriate.

[Footnote] i: 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.

ISDI comment

Follow-up Formula for Older Infants may be based on cow's milk, the milk of any other animal or mixture and/or other ingredients which include plant-based proteins providing the nutritional safety and suitability that has been scientifically demonstrated to ensure adequate growth of older infants. This approach allows flexibility for the use of new protein sources in these products with robust scientific assessment of safety and suitability for this population.

ISDI notes that in section 3.1.1 the general use of the term "milk" should be understood as referring to whole or skimmed milk. In line with the current practice, ISDI also notes that the Standard allows for the use of whole or skimmed milk as such or with minor modification that does not substantially impair the vitamins and mineral content of the milk[1].

Guidance Upper Levels (GULs): The concept of GUL was recognised and established in the Standard for Infant Formula (CODEX STAN 72, 1982). ISDI fully supports the concept which was captured in Footnote 1 in Section 3.1.1. When there is insufficient information for the assessment, guidance upper levels are established on the basis of manufacturing, stability and/or shelf life (Mclean paper et al., 2010). The purpose of the GULs is to provide guidance to manufacturers and they are not the same as maximum limits. GULs are applied as maximum levels except for the circumstances described where they may be exceeded due to ingredient composition or technological reasons.

1: ISDI notes the difference in text compared to the previous *Standard for Follow-up formula* CXS 156-1987 – See Appendix VI in section 3.3.1.2 which referred to the fact that 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% of the total protein.

a) Protein [1), 2), 3)]			
UNIT	MINIMUM	MAXIMUM	GUL
g/100 kcal	1.8 [4), 5)]	3.0	-
g/100 kJ	0.43 [4), 5)]	0.72	-

ISDI comment:
Compared to the previous Codex Standard for Follow-up formula, the minimum protein has been reduced from 3 g/100 kcal to 1.8 g/100 kcal (for cow and goat's milk-based products).

ISDI recalls that the lower protein level was made possible following an EFSA opinion.

ISDI notes that other minimum levels may need to be applied for formulas based on other animal milk.

Background

Protein requirements have been recently estimated to be lower than previous estimates primarily as a result of changes in the reference body weights used. Additionally, several dietary surveys of protein intakes in older infants (6-12 months) have identified that average protein intakes are adequate and above minimum requirements for the majority of this age group.

A WHO/FAO/UNU review of protein requirements calculated protein requirements based on the factorial method which takes into consideration the protein required for maintenance and growth WHO/FAO/UNU 2007. The calculations are based on maintenance of requirements of 0.66 g/kg body weight per day and a protein efficiency utilization of 58%. In 2013, the published opinion by EFSA regarding nutrient requirements and dietary intakes for infants and young children in the European Union used a similar approach (EFSA, 2013).

Newer estimates of protein requirements are lower as compared to previous ones primarily as a result of changes in the reference body weights previously used. Almost all the latest derived values are based on the WHO/FAO/UNU report requirements per kg bodyweight CX/NFSDU 14/36/7, 2014. Protein requirements for 6-12 month older infants calculated from WHO/FAO/UNU protein requirements (WHO/FAO/UNU 2007) using WHO weight-for-age growth standards (WHO 2006) result in 10.2 g/kg bodyweight.

ISDI refers to the minimum protein level of follow-up formula for older infants to the proposal by the Early Nutrition Academy (ENA), which developed compositional recommendations for follow-up formula (Koletzko, 2013). Population reference intakes (PRI) for the dietary protein intake to meet the needs of basically all infants in the population with adequate safety margin was considered at 1.31 g protein/kg body weight at 6 months and at 1.14 g protein/kg body weight at 12 months (WHO, 2007; EFSA, 2012). Using a daily energy intake of 80 kcal/kg bodyweight this translated into a protein density for follow-up formula for older infants of 1.64 g/100 kcal and 1.43 g/100 kcal, using a PRI of 1.31 and of 1.14 g protein /kg at 6 months and 12 months, respectively (Koletzko, 2013). Therefore, the ENA (Koletzko, 2013) recommends setting the minimum protein level of cow's milk-based follow-up formula for older infants at 1.65 g/100 kcal, taking into consideration good protein quality with an adequate content of bioavailable essential amino acids.

In addition to establishing nutritionally safe and adequate minimum protein levels for follow-up formula for older infants, several national and regional surveys of dietary protein intakes of older infants and young children are to be taken into consideration. The results of these dietary surveys have consistently identified that average protein intakes in this age group are adequate for the majority of infants and young children (Agostoni 2006). A study conducted in France showed that infants and young children have protein intakes above the recommended dietary requirements (SFAE, 2014). Similarly, surveys conducted on infants in selected Asian countries indicated average protein intakes ranged from 14 to 50 g/day (Poh, 2013; FNRI, 2008; Nguyen, 2013; Rojroongwasinkul, 2013).

[Footnote] 1): 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.

ISDI comment

ISDI considers that for finished Follow-up Formula for older infants using the default conversion factor of 6.25 as specified to calculate the protein content from the total crude protein nitrogen content as determined by Kjeldahl or similar methods, continues to be a practical approach. This conversion factor has to be used whatever the protein source (milk, plant-based...) unless a scientific justification is available. It is noted that this conversion factor is the same as used for Infant Formula in Codex CXS 72-1981.

[Footnote] 2): 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[3]; 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.

ISDI Comment:

In the footnote 3, the statement ***'nevertheless*** *for calculation purposes the concentrations of tyrosine and phenylalanine* ***may be*** *added together' means:*

- The calculation can be done based on the 2 amino acids summed together instead of the individual concentrations. This applies to tyrosine and phenylalanine, and also to methionine and cysteine. The quantity of other amino acids is considered individually.
- It is still possible to consider the individual values for tyrosine and phenylalanine, as well as methionine and cysteine, but this is not mandatory.

These two ways of calculation are two different options and are not cumulative requirements.

[Footnote] 3): 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.

[Footnote] 4): 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.

ISDI comment:

The minimum protein has been reduced from 3 g/100 kcal to 1.8 g/100 kcal (for cow and goat's milk-based products). ISDI notes that other minimum levels may need to be applied for formulas based on other animal milks.

The minimum protein for soy-based products is 2.25 g/100 kcal.

The application of appropriate minimum protein levels for different protein sources is in alignment with the requirement in clause 3.1.1 that formulas must be scientifically demonstrated for nutritional safety and suitability to support adequate growth for older infants.

[Footnote] 5): 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.

ISDI comment:

ISDI notes that a further reduction to 1.6g protein/100 kcal could be applied for products based on non-hydrolysed milk protein and should be evaluated for their safety and suitability and assessed by a competent national and/or regional authority based on scientific substantiation.

- The Standard states that hydrolysed protein formulations should be evaluated for their safety and suitability and assessed by a competent national and/or regional authority based on clinical evidence. ISDI would like to highlight that in the Standard for Infant Formula, there is no requirement for clinical evidence to demonstrate nutritional suitability and safety for hydrolysed formulas with protein levels higher than 2.25 g/100 kcal.

  ISDI recommends that national/regional authorities apply the same principle to Follow-up Formula for Older Infants when transferred to national regulations noting that clinical studies are less relevant for older infants than infants under 6 months. This is because older infants have a progressively diversified diet and do not rely on formula as a sole source of nutrition.

- 'Scientific evidence' when requested means that scientific substantiation needs to be provided. It could use existing clinical evidence where appropriate and justified and does not necessarily imply that manufacturers need to conduct new clinical studies on the specific product. Scientific substantiation also includes data such as the overall dietary intakes of the local population.

- In all cases, in addition to the corresponding minimum and maximum levels of proteins, the required amino acid profile must be met based on Annex I from the Standard for Infant Formula as stated in Footnote 3 and is outlined here:

Essential and semi-essential amino acids in breast-milk*

For the purpose of this Standard the essential and semi-essential amino acids in human milk from published studies which report measurements of the total nitrogen content and/or the calculation method of the protein content, expressed as mg per g of nitrogen and as mg per 100 kcal are listed. The average level of an amino acid (mg per g of nitrogen) from each study was used to calculate the corresponding amino acid content per 100 kcal of an infant formula with the minimum protein content of 1.8 g/ 100 kcal accepted in this Standard (mg amino acid/g nitrogen in breast-milk divided by the nitrogen conversion factor of 6.25 and multiplied by 1.8). The mean of the sums of the average amino acid levels from all studies was converted in the same manner to the average amounts of an amino acid per g of protein (total nitrogen x 6.25) and per 100 kcal of energy (columns 19 and 20 of the table). National authorities may use all of the listed values.

* Adapted from Koletzko B, Baker S, Cleghorn G, et al, Global standard for the composition of infant formula: Recommendations of ESPGHAN coordinated international expert group. J Pediatr Gastroenterol Nutr. 2005;41:584-599.

	Lönnerdal &Forsum (1985)		**Darragh & Moughan (1998)**		**Bindels & Harzer (1985)**		**Janas et al. (1987)**		**Villalpando et al. (1998)**				**Räihä et al. (2002) mod Nayman et al. (1979)**		**Yonekubo et al. (1991)**		**Mean of all amino acids contents**		
	Pooled banked milk at 4-16 weeks		**Pooled over 20 days at 10-14 weeks (n=20)**		**24 hours, pooled at 5 weeks (n=10)**		**24 hours, pooled at 8 weeks (n=10)**		**24 hours, pooled at 4-6 months**				**Pooled banked milk at >1 month**		**Milk at 21 days –2 months**				
									Mexico (n=40)		**Houston (n=40)**								
mg amino acid per	g N	100 kcal	g N	100 kcal	g N	100 kcal	g N	100 kcal	g N	100 kcal	g N	100 kcal	g N	100 kcal	g N	100 kcal	g nitrogen	g protein	100 kcal
Cysteine	111	*32*	173	*50*	108	*31*	101	*29*	167	*48*	134	*39*	133	*38*	118	*34*	131	21	*38*
Histidine	111	*32*	156	*45*	255	*73*	112	*32*	112	*32*	108	*31*	122	*35*	150	*43*	141	23	*41*
Isoleucine	242	70	333	96	376	108	306	88	292	84	331	95	300	86	374	108	319	51	92
Leucine	457	*132*	598	*172*	713	*205*	611	*176*	528	*152*	541	*156*	572	*165*	667	*192*	586	94	*169*
Lysine	314	*90*	406	*117*	522	*150*	365	*105*	366	*105*	408	*118*	361	*104*	421	*121*	395	63	*114*
Methionine	78	*22*	90	*26*	89	*26*	73	*21*	99	*29*	76	*22*	83	*24*	92	*26*	85	14	*24*
Phenylalanine	153	*44*	243	*70*	344	*99*	183	*53*	440	*127*	439	*126*	217	*62*	240	*69*	282	45	*81*
Threonine	217	*62*	316	*91*	344	*99*	251	*72*	248	*71*	242	*70*	256	*74*	269	*77*	268	43	*77*
Tryptophan	NA		NA		172	*50*	79	*23*	112	*32*	89	*26*	111	*32*	122	*35*	114	18	*33*
Tyrosine	201	*58*	241	*69*	369	*106*	191	*55*	292	*84*	299	*86*	233	*67*	249	*72*	259	42	*75*
Valine	253	*73*	327	*94*	376	*108*	267	*77*	286	*82*	331	*95*	317	*91*	364	*103*	315	50	*90*

References

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Darragh AJ, Moughan PJ (1998) The amino acid composition of human milk corrected for amino acid digestibility. Br. J. Nutr. 80: 25-34

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Yonekubo A, Onoda T, Humikara M, Hudohta K, Yamamoto Y. (1989) Total and free amino acid composition of the Japanese breast-milk. J Jap Soc Nutr Food Sci 42: 194

b. Lipids			
Total Fat [6), 7)]			
UNIT	**MINIMUM**	**MAXIMUM**	**GUL**
g/100 kcal	4.4	6.0	-
g/100 kJ	1.1	1.4	-

ISDI comment

ISDI notes that the minimum fat content for Follow-up Formula for Older Infants has increased from 3 g/100 kcal to 4.4 g/100 kcal.

[Footnote] 6): Partially hydrogenated oils and fats shall not be used in follow-up formula for older infants.

ISDI comment

This clause should effectively eliminate industrial Trans-fatty acids sourced from vegetable oils from these products. The use of fully hydrogenated vegetable oils is not excluded as they can be free of trans-fatty acids and may need to be added to provide the appropriate fatty acid profile.

[Footnote] 7): 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).

ISDI comment

An upper limit for lauric acid (C12:0) and myristic acid (C14:0) is set similar to that in the Codex Standard Infant Formula because of their potential hypercholesterolaemic and atherogenic effects, which is more pronounced than other saturated fatty acids. The maximum level of trans-fatty acids at 3% is the same as applied in the Codex Standard for Infant Formula. This maximum is intended to allow for the use of milk fat in these products[2].

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	
MINIMUM	**MAXIMUM**
5:1	15:1

[2] Report of the Scientific Committee on Food on the Revision of Essential Requirements of Infant Formulae and Follow-on Formulae (europa.eu)

c. Carbohydrates			
Available carbohydrates [8)]			
UNIT	**MINIMUM**	**MAXIMUM**	**GUL**
g/100 kcal	9.0	14.0	-
g/100 kJ	2.2	3.3	-

[Footnote] 8): 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 percent of available carbohydrate.

ISDI comment

ISDI notes that the minimum and maximum levels and footnote 8 are aligned with the Standard for Infant Formula CXS 72 1981. For reference, see also ISDI Brochure on Label Tolerance.

4. Vitamins

ISDI comment

The revised Follow-up Formula for older infants integrates the latest scientific evidence to the optimal health and growth path of older infants. It was decided to set a higher number of mandatory requirements and revise the nutrient levels. The table below highlights the evolution of the Codex Follow-up Formula for older infants (Part A).

VITAMINS	MINERALS
Vitamin A	Iron
Vitamin D	Calcium*
Vitamin E*	Phosphorus*
Vitamin K*	Magnesium*
Thiamin (Vitamin B^1)*	Sodium
Riboflavin (Vitamin B^2)*	Chloride
Niacin*	Potassium
Vitamin B^6*	Manganese*
Vitamin B^{12}*	Iodine*
Pantothenic acid*	Selenium*
Folic Acid*	Copper*
Vitamin C*	Zinc*
Biotin*	

*: a GUL is set instead of a maximum level.

Key: Nutrients are colour-coded based on comparison with the previous Standard.

	Lower maximum level
	New mandatory ingredient
	New maximum

ISDI notes that required minimum levels are met throughout the shelf-life of the formula and are included in the maximum value. Shelf-life degradation may occur for some micronutrients (such as Vit A) but depends on the form of the product (powder, concentrated liquid or ready-to-feed), the packaging, the filling environment (inert atmosphere or not), and the storage conditions as well as assigned shelf life.

For further information on label tolerance, please see the ISDI brochure.

Vitamin A			
UNIT	**MINIMUM**	**MAXIMUM**	**GUL**
µg RE[9]/100 kcal	75	180	-
µg RE[9]/100 kJ	18	43	-

[Footnote] 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.

ISDI comment:
Vitamin A in the follow-up formula is derived principally from its specific addition at the time of manufacture. Only a small percentage of preformed vitamin A comes from inherent levels in ingredients.

Vitamin D			
UNIT	**MINIMUM**	**MAXIMUM**	**GUL**
µg[10] /100 kcal	1.0	3.0	-
µg[10] /100 kJ	0.24	0.72	-

[Footnote] 10): Calciferol. 1 µg calciferol = 40 IU Vitamin D.

Vitamin E			
UNIT	**MINIMUM**	**MAXIMUM**	**GUL**
mg α-TE[11] /100 kcal	0.5 [12]	-	5
mg α-TE[11] /100 kJ	0.12 [12]	-	1.2

[Footnote] 11): 1 mg α-TE (alpha-tocopherol equivalents) = 1 mg d-α-tocopherol

[Footnote] 12): 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 αTE /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 eicosapentanoic 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

ISDI comment:
The nutritional suitability and safety of use of a minimum vitamin K level at 4 µg/100 kcal for follow-up formulas for older infants has most recently been substantiated by the ENA proposal for the compositional requirements for follow-up formula for older infants (Koletzko, 2013).

Thiamine			
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 [13)]			
UNIT	**MINIMUM**	**MAXIMUM**	**GUL**
µg /100 kcal	300	-	1500
µg /100 kJ	72	-	359

13) 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[14)]			
UNIT	**MINIMUM**	**MAXIMUM**	**GUL**
µg /100 kcal	10	-	70 [15)]
µg /100 kJ	2.4	-	17 [16)]

[Footnote] 14): Expressed as L-ascorbic acid

[Footnote] 15): 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 [16)]			
UNIT	MINIMUM	MAXIMUM	GUL
mg /100 kcal	1.0	2.0	-
mg /100 kJ	0.24	0.48	-

[Footnote] 16): 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 [17)]
mg /100 kJ	6	-	24 [18)]

[Footnote] 17): This GUL should accommodate higher needs with follow-up formula for older infants based on soy protein isolate.

Ratio calcium/phosphorus	
MINIMUM	MAXIMUM
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 [18]			
UNIT	MINIMUM	MAXIMUM	GUL
µg /100 kcal	35	-	120
µg /100 kJ	8	-	29

[Footnote] 18): 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.

ISDI notes that copper levels of ready-to-use follow-up formula for older infants are influenced by the copper level of water used for the formula preparation. There is no loss of copper over shelf life.

As expressed during the discussion, ISDI is of the view that a GUL of 250 µg/100 kcal is preferred, based on the recommendation of the International Expert Group coordinated by the Early Nutrition Academy (Koletzko, 2013).

Zinc [19]			
UNIT	MINIMUM	MAXIMUM	GUL
mg /100 kcal	0.5	-	1.5
mg /100 kJ	0.12	-	0.36

[Footnote] 19): For follow-up formula for older infants based on soy protein isolate a minimum value of 0.75 mg/100 kcal (0.18 mg/100 kJ) applies.

3.2 Optional Ingredients

ISDI Comment

The revised Standard continues to authorize the use of optional ingredients added for a nutritional purpose, which are safe and demonstrated by scientific evidence to be added in sufficient quantities to deliver the intended effect.

Levels used should be sufficient to deliver the intended effect and where relevant take into account the levels found in human milk.

In addition, specific criteria have been set for the optional addition of Taurine, Total Nucleotides, DHA, Choline, Myo-inositol, L-Carnitine and L(+) lactic acid-producing cultures. Please note, that this is not an exhaustive list and other optional ingredients may be added, provided they meet the conditions established by the Standard (see details from the Standard below).

3.2.1 In addition to the compositional requirements listed under Section 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.

ISDI comment
ISDI notes the importance of sections 3.2.1 and 3.2.2 to ensure scientific developments and innovation by allowing for the addition of optional ingredients to Follow-up formula for older infants.

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.

ISDI comment
ISDI notes the importance of section 3.2.3 which establishes a NON-EXHAUSTIVE list of optional ingredients. Other optional ingredients can be added in line with sections 3.2.1 and 3.2.2.

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 [20)]			
UNIT	**MINIMUM**	**MAXIMUM**	**GUL**
mg /100 kcal	-	-	30
mg /100 kJ	-	-	7

[Footnote] 20): 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.

ISDI comment
ISDI notes that if DHA is added, the minimum of DHA should be 20mg/100kcal and the ARA must be added at the same level or higher. Due to the variability of DHA intake in the diversified diet of older infants, ISDI strongly supported the introduction of the footnote "Competent national and/or regional authorities may deviate from the above conditions, as appropriate for the nutritional needs of their population". This is an essential element to allow for deviations taking into account the nutritional needs of countries' populations. Such flexibility represents also a positive element as it allows competent national and/or regional authorities to provide flexibility as science evolves.

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.

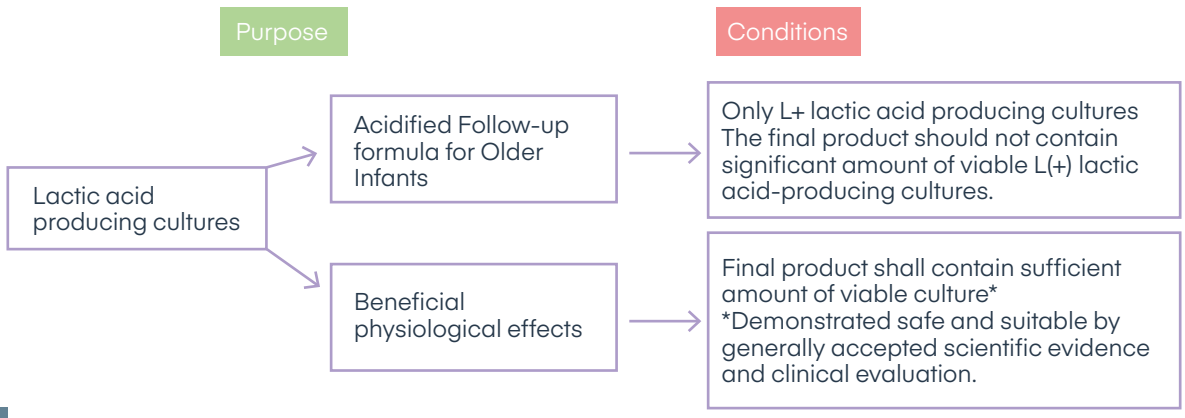
ISDI comment
Use of lactic acid-producing cultures

The revised standard clarifies that L(+) lactic acid-producing cultures may be added for acidification purposes or for the purpose of conferring specific physiological effects as demonstrated in the diagram below:

When added to achieve acidification, formula are fermented with the help of (L+) acid bacteria that convert lactose into lactic acid during the production process. L(+) lactic acid bacteria are no longer active in the finished products as they are subject to heat treatment after fermentation. If there are residual amounts of viable L(+) lactic acid bacteria these should not pose any health risk.

The addition of bacteria strains for the purpose of conferring beneficial physiological effects must meet the criteria specified in sections 3.3.2.1 and 3.3.2.2 for optional ingredients which stipulates that:

- They may be added only if safety and suitability is demonstrated by generally accepted scientific evidence and is in addition clinically evaluated.
- 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.[4]

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

ISDI notes that the previous Standard listed the authorised additives for this category.

Following decisions taken at the Forty-sixth Session of the Codex Alimentarius Commission in December 2023, the food additives provisions in this standard have been included in the *General Standard for Food Additives* (GSFA) CXS 192-1995[1] in line with the process of alignment of all food additive provisions with the GSFA.

Codex is establishing the "General Standard on Food Additives" (GSFA) as the only source listing approved additives in foods (incl Follow-up formula) and has agreed on the following language following the completion of the alignment work for CXS 156-1987, whereby the table was replaced by this general reference to the GFSA.

4.1

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

The 53rd session of the Codex Committee on Food Additives has validated the list at its meeting in March 2023.

4.2 Flavourings

No flavourings are permitted in this product.

ISDI Comment:
ISDI notes that compared to the previous standard, flavourings are not permitted in Follow-up formula for older infants. Flavourings authorised in section B were authorised for the Follow-up formula for older infants in the previous standard. The motivation to change is that Follow-up formula for older infants is now defined as a breast-milk

substitute.

Older infants are progressively introduced to a variety of products that may contain flavourings as seen in the following Codex Standard examples:

CATEGORY	BABY FOODS CXS 73-1981 (as ready-to-eat)	Cereal-Based Foods CXS 74-1981 (as ready-to-eat)
Natural Fruit Extracts	-	GMP
Vanilla Extract	GMP	GMP
Ethyl vanillin	7 mg/100 g	7 mg/100 g
Vanillin	7 mg/100 g	7 mg/100 g

Flavourings remain important in these foods to support taste development and food acceptance.

Where flavourings are used in foods for young children, they are used:

- To supplement or restore an existing flavour
- To impart their flavour to the finished product, and/or
- To modify any undesirable flavour characteristics inherent to a product

4.3 Carry-Over Principle

Only the food additives listed in food category 13.1.2 (Follow-up formulae) of the *General Standard for Food Additives* CXS 192-1995[1] 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[4] 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[1].

ISDI Comment:
ISDI notes that as a result of the alignment work, the carry-over section has a slight rewording to reference the GSFA.

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[5].

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[6], and other relevant Codex texts such as the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children* CXC 66-2008[7], 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[8] and the *Code of Hygienic Practice for Low and Acidified Low-acid Canned Foods* CXC 23-1979[9], 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[10].

ISDI Comment

ISDI highlights the strict safety measures taken by the industry to prevent, reduce and control the potential microbiological risks of these products, and therefore recommends that:

- the consumers strictly follow manufacturers' instructions for the hygienic preparation of infant formulae,
- the baby is immediately fed with freshly prepared formula.

Regarding the reconstitution of formulae at 70°C, in our view it is not considered the unique and most effective option to reduce potential microbiological risks, as it is difficult to follow/implement in practice, while introducing specific risks such as scalding and degradation of functional formula properties.

For further information see the ISDI position.

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 150-250g (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[11], the *Guidelines on Nutrition Labelling* CXG 2-1985[12] and the *Guidelines for Use of Nutrition and Health Claims* CXG 23-1997[13] 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.

ISDI comments

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 continues to apply to Follow-up Formula for Older Infants. While this was not specified in the old Follow-up Formula

Standard, it is now explicitly mentioned in the revised Standard.

Nutrition and health claims are permissible for this age group in national jurisdictions which permit them.

ISDI notes that substantiated nutrition and health claims provide sound information to consumers to make informed choices.

For further information see ISDI Brochure on FSDU & Claims.

Please note that Appendix II provides a Mock-up of mandatory labelling requirements for Follow-up formula for Older Infants based on Codex Alimentarius.

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 shall be Follow-up Formula for Older Infants as defined in Section 2.1, or any appropriate designation indicating the true nature of the product, in accordance with national or regional usage.

ISDI comments

The name of the product must be specified on the label and all other information accompanying the product by either Follow-up Formula for Older Infants or any appropriate designation in accordance with national or regional usage which indicates the true nature of the product. This last element is essential as it ensures that the local name that is most appropriate and understood by a given population can be used. For example, in some countries the name "Follow-on Formula" can be used (e.g. EU, Australia and New Zealand).

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.

ISDI Comment:

Please also refer to section 3.1.1-3.1.3 above.

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.

ISDI comments

Allergen labelling for this product needs to follow the normal rules valid for all food products and described in the General Standard for the Labelling of Prepackaged Foods (CXS 1-1985). The above requirements need to be implemented in order to facilitate a better understanding among parents and caregivers.

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 or 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 Pre-packaged Foods CXS 1-1985.[11]

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.

ISDI Comment

ISDI would like to hereby highlight the strict safety measures taken by the industry to prevent, reduce and control the potential microbiological risks of these products, and therefore recommends that:

- the consumers strictly follow manufacturers' instructions for the hygienic preparation of infant formulae,
- the baby is immediately fed with freshly prepared formula.

Regarding the reconstitution of formulae at 70°C, in our view it is not considered the unique and most effective option to reduce potential microbiological risks, as it is difficult to follow/implement in practice, while introducing specific risks such as scalding and degradation of functional formula properties.

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

ISDI comment

The additional labelling requirements are implementing the considerations of relevant concepts and technical guidance in WHO/WHA documents for the labelling and other provisions in the draft standard for follow-up formula, as highlighted by a working document developed by New Zealand as chair of work regarding the revision of the Follow-up formula Codex Alimentarius Standard.

This essential work is reproduced in Appendix IV of this brochure.

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 "Breast-milk is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breast-milk;

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'.

ISDI comment

All statements under 8.6.1 need to be presented on the label.

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 breast-milk, or suggests that the product is similar, equivalent to or superior to breast-milk;

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.

ISDI comment

Section 8.6.2 refers to representation through text or picture that should not:

- idealize the use of Follow-up Formula for Older Infants,
- suggest the use of the product for infants under 6 months,
- recommend or promote bottle feeding,
- undermine or discourage breast-feeding or suggest that the product is similar, equivalent or superior to breast-milk.

ISDI notes the strict prohibition of *pictures of infants, young children and women, text, or representation. However, it is allowed to present pictures, texts or representation that to do not:*

- *idealize the use of Follow-up Formula for Older Infants;*
- *suggest use for infants under the age of 6 months (including references to milestones and stages);*
- *recommend or promote bottle feeding;*
- *undermine or discourage breastfeeding; or that makes a comparison to breast-milk, or suggests that the product is similar, equivalent to or superior to breast-milk;*
- *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*

Section 8.6.2.2 refers to representation that suggest the use for infants under the age of 6 months is not permitted by references to milestones and stages. Milestones and stages may be used in compliance with all other relevant labelling requirements provided it is not used to suggest use of product for infants under 6 months of age.

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

ISDI comment

Section 8.6.3 re-states the requirement in the old standard that 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/Product for young children with added nutrients or Drink 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/Product for young children with added nutrients or Drink for young children, or formula for special medical purposes intended for infants, including numbers, text, statements, or images of these products.

ISDI comment

8.6.4 and 8.6.5 are newly introduced statements in the Standard.

8.6.4 states that labelling of Follow-up Formula for Older Infants should be sufficiently distinct and enable consumers to make clear distinction between Infant Formula, Product for young children, or formula for

special medical purposes intended for infants, in particularly by text, images and colours.

8.6.5, similarly, states that the labelling of Follow-up Formula for Older Infants should not directly refer to Infant Formula, Product for young children, or formula for special medical purposes intended for infants as to avoid risk of confusion between the products.

The use of specific labels for different types of formula – infant formulas, follow-up formula for older infant and products for young children – encourages age-appropriate use of these products as children grow. It also helps differentiate these products and identify potential allergens.

Front of Pack Nutrition Labelling (FOPNL)

FOPNL established for adult general healthy population are not suitable for infants and young children. Products specifically formulated for this target population should be excluded from FOPNL. The Codex Guidelines (Annex 2 of Guidelines on Nutrition Labelling CXG 2-1985) directly excludes the Standard for Follow-up formula (CXS 156-1987) and therefore the categories covered by the revised standard are also excluded.

For further information, please see ISDI Brochure on Front of Pack Nutrition labelling.

ISDI reemphasizes that the nutritional compositional requirements of Follow-up formula for older infants are tailored to meet the particular nutritional needs of older infants and are based on science including the dietary recommendations of recognised authoritative scientific bodies (RASBs) (e.g. energy contribution from macronutrients, the contribution of micronutrients to recommended daily intake, etc.).

Follow-up formulas for older infants are standardized by Codex and must follow stricter food composition and safety requirements in comparison with foods for the general population. Applying FOPNL schemes and nutrient profiles developed for the adult healthy population on Follow-up formula for older infants and other food for special dietary uses would mislead consumers and prevent them from making informed choices adapted to their nutritional needs. It would unjustifiably discriminate against these categories and undermine the purpose of the products.

ISDI considers that this is also in line with the recommendation from WHO in the scope section of "WHO Guiding principles and framework manual for front-of-pack labelling for promoting healthy diet" where the rationale for excluding standardized foods for infants and young children is that they have "strict compositional criteria; hence, promoting reformulated products is not appropriate".

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[14] relevant to the provisions in this standard, shall be used.

PART B
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.

ISDI comment

Part B of the Standard was newly drafted. The text in this Part applies to all products falling under the category of product/drink for young children with added nutrients or product/drink for young children.

The Standard contains specific compositional, quality, safety, labelling, analytical and sampling requirements. ISDI notes that analytical and sampling requirements are under the remit of testing requirements.

It is emphasized that only those products that comply with the full requirements of Part B of this Standard may be presented as product/drink for young children with added nutrients or product/drink for young children.

ISDI notes that the scope explicitly establishes that product/drink for young children with added nutrients or product/drink for young children can be in liquid or powdered form. It is therefore clear that this Codex Standard in its entirety applies to both forms.

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[i].

[Footnote] i: In some countries these products are regulated as breast-milk substitutes.

ISDI comment

ISDI notes that point 2.1.1 establishes the fundamental notion that product for young children with added nutrients or product/drink for young children is a standardized commodity for use as a liquid part of the diversified diet of young children. It is therefore clear that this product cannot satisfy by itself the nutritional requirements of young children, as the diet is fully diversified.

The Standard does not define the product as a breast-milk substitutes and simply stipulates in footnote i that in some countries these products are regulated as breast-milk substitutes.

ISDI points out that product/drink for young children with added nutrients or product/drink for young children are specifically formulated for young children 12 to 36 months of age and provide key nutrients to contribute to appropriate nutrient intakes as part of the total diet. The product/drink for young children with added nutrients or product/drink

for young children can be used as part of the complementary feeding.

ISDI recalls that the new Standard will lead to new product formulations, as none of the current Follow-up formula in the world meet the requirements that this new standard establishes. There are only 8 mandatory micronutrients (Vitamin A, Vitamin D, Riboflavin [Vitamin B_2], Vitamin B_{12}, Iron, Calcium, Zinc) in this standardised product which therefore should not be used a sole source of nutrition, as this would represent a major nutritional safety risk. ISDI calls on national authorities to reflect on these elements regarding the limited number of micronutrients compared to those mandatorily required in infant formula and Follow-up formula for older infants.

ISDI has urged all along the discussions at Codex Alimentarius to avoid confusion and flagged the inherent risk of footnote 13 undermining the clarity and overall objective of a Codex Standard which should be clear, science-based and unambiguous.

ISDI urges national authorities when implementing the Standard and its members where possible, based on the local regulation to further clarify on the label that "This product is not formulated as a substitute for breast-milk and is not to be used as a sole source of nutrition" (See Labelling section and Appendix III).

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.

ISDI comment

ISDI notes that this article highlights the importance of process and packaging for such sensitive products. Indeed, food processing plays an essential role in ensuring food safety by eliminating micro-organisms and toxins, and with adapted packaging, they both help to minimize food safety risk for these vulnerable target population, preserve certain nutrients and protect the final products during storage and distribution.

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)

ISDI comment

The age definition completes the product definition.

ISDI notes that the term older infant is also defined in the Codex Guidelines on formulated complementary foods for older infants and young children CAC/GL 8-1991 and the term young children in the (former) Codex Standard for Follow-up formula (CXS 156-1987).

ISDI considers it important to emphasize the specific age group covered and role of this product.

Age group: product/drink for young children with added nutrients or product/drink for young children is intended for the age group of young children only i.e., from more than 12 months of age up to the age of three years = 36 months. The product is intended to be a liquid part of the young child's diet and it is not to be used as the sole source of nutrition.

Definition: product/drink for young children with added nutrients or product/drink for young children has been defined as a product manufactured for use as a liquid part of the diversified diet of young children. As captured in the report of the CAC43 (2020), it was confirmed that the intent of footnote 13 is to "provide factual information". Therefore, footnote 13 is not considered a regulatory guidance.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

Essential Composition

ESSENTIAL INGREDIENTS	OPTIONAL INGREDIENTS
Protein	Optional nutrients with specific range based on Essential Composition criteria in Section 3.1.3 Part A (i.e. Follow-Up Formula for older infants)
Lipids (Total fat, αLinolenic acid and Linoleic acid)	
Carbohydrates	
VITAMINS	**VITAMINS**
Vitamin A	
Vitamin C	
Vitamin D	
Riboflavin (Vitamin B_2)	Vitamin E
Vitamin B_{12}	Vitamin K
	Thiamin (Vitamin B^1)
	Niacin
	Vitamin B^6
	Pantothenic acid
	Folic Acid
	Biotin
MINERALS AND TRACE ELEMENTS	**MINERALS AND TRACE ELEMENTS**
Iron	Phosphorus
Calcium	Magnesium
Zinc	Sodium
	Chloride
	Potassium
	Manganese
	Iodine
	Selenium
	Copper
	Non exhaustive or specified list of Optional Ingredients from point 3.2 Part B including the Specific Optional Ingredients from with levels/range as established in Part A point 3.2.3 (i.e. Follow-Up formula for older infants) that follow the generic principles established in Part B point 3.2.1 & 3.2.2 Choline Myo-inositol L-carnitine L (+) lactic acid-producing cultures

Key:

Mandatory ingredients from Essential Composition in Part B – i.e. for Product for Young Children

Based on Part B point 3.2.3: Optional nutrients from the Essential Composition criteria in Section 3.1.3 Part A for which the permitted range of levels established in Part A point 3.1.3 should be followed.

ISDI notes and this is a key principle that Competent national and/or regional authorities should put in place the exact system proposed by the Codex Alimentarius Standard, meaning manufacturers are provided with the possibility to include optional nutrients from the essential composition of Follow-up formula for Older Infants in Part A, provided these optional nutrients meet the levels established by Part A.

It is essential to highlight that the Standard does not invite Competent national and/or regional authorities to select or establish specific provisions for these optional nutrients taken separately among this list, as this would lead to unjustified trade barriers, except in case of specific nutritional needs of the local population and with scientific justification.

Based on Part B point 3.2.1 and 3.2.2: Non exhaustive or specified list of Optional Ingredients including the Specific Optional Ingredients from with levels/range as established in Part A point 3.2.3 that follow the generic principles established in Part B point 3.2.1 & 3.2.2:

- *Other ingredients or substances may be added to the product 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 do not have to follow the criteria from Part A as not part of the essential composition of Follow-up formula for Older Infants (3.1 Part A). Thus, the mins/max/GULs (from 3.2.3 Part A) do not apply.*
- *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.*

3.1 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.

ISDI comment

ISDI notes that in section 3.1.1 the general use of the term "milk" should be understood as referring to whole or skimmed milk. In line with the current practice ISDI also notes that the Standard allows for the use of whole or skimmed milk as such or with minor modification that does not substantially impair the vitamins and mineral content of the milk.[4]

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)[ii], as appropriate. The general principles for establishing these levels are identified in Annex I of this standard.

[Footnote] ii: 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.

ISDI comment

Product for young children has evolved significantly to reflect the latest science for feeding young children and safe and suitable products. The principles of the revision have undertaken scientific evidence from various RASBs (Recognized Authoritative Scientific Bodies), cow's milk nutrition profile, expert recommendations, current gaps in young children's nutritional intakes and overall nutritional requirements for young children.

The product for young children were defined according to the following three principles:

1. contribution to the nutritional needs of young children where the consumption of the nutrient is inadequate on a global scale; and/or
2. contribution of adequate amounts of key nutrients from cow's milk, where such nutrients are key contributors to the diet of young children; and/or
3. the nutritional quality and integrity of product to ensure nutritional safety.

[4] ISDI notes the difference in text compared to the previous Standard for Follow-up formula (CXS 156-1987) in section 3.3.1.2 which was referring to the fact that 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% of the total protein.

Product for young children could be based on cow's milk or any other animal or mixture thereof and/or other ingredients (including plant-based proteins). ISDI notes that the product should be safe and suitable for feeding young children.

Guidance Upper Levels (GULs): The concept of GUL was recognised and established in the Standard for Infant Formula CXS 72-1981. ISDI fully supports the concept which was captured in Footnote 1 in Section 3.1.1. When there is insufficient information for the assessment, guidance upper levels are established on the basis of manufacturing, stability and/or shelf life (Mclean paper et al., 2010). The purpose of the GULs is to provide guidance to manufacturers and they are not the same as maximum limits. GULs are applied as maximum levels except for the circumstances described where they may be exceeded due to ingredient composition or technological reasons.

a. Protein[1) 2)]			
UNIT	**MINIMUM**	**MAXIMUM**	**GUL**
g/100 kcal	1.8	-	-
g/100 kJ	0.43	-	-

[Footnote] 1): 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.

[Footnote] 2): 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 90. 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.

ISDI comment

- One of the major changes to the Product for young children has been to reduce protein levels from 3 g/100 kcal to 1.8 g/100 kcal. A maximum protein level has not been established but protein levels are constrained due to the minimum fat and maximum energy levels specified.
- The permitted protein levels reflect the revised WHO guidelines on protein requirements WHO 2007, and a key principle for the mandatory composition of these products to support contribution of adequate amounts of key nutrients from milk.

ISDI considers that for finished product for young children using the default conversion factor of 6.25 as specified to calculate the protein content from the total crude protein nitrogen content as determined by Kjeldahl or similar methods, continues to be a practical approach. This conversion factor has to be used whatever the protein source (milk, plant-based...), unless a scientific justification is available. To be noted that this conversion factor is the same as used for Infant Formula in Codex CXS 72-1981.

b. Lipids[3]			
Total fat			
UNIT	**MINIMUM**	**MAXIMUM**	**GUL**
g/100 kcal	3.5	-	-
g/100 kJ	0.84	-	-

[Footnote] 3): Partially hydrogenated oils and fats shall not be used in the product as defined in Section 2.1.

ISDI comment

This clause should effectively eliminate industrial Trans-fatty acids sourced from vegetable oils from these products. The use of fully hydrogenated vegetables oils are not excluded as they can be free of trans-fatty acids and may need to be added to provide the appropriate fatty acid profile.

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	-	-

ISDI comment

The fat requirements are also set to provide flexibility whilst meeting nutritional needs of young children. A minimum fat of 3.5 g/100 kcal was applied to reflect fat levels of reduced fat cow's milk.

Minimum requirements for Linoleic and α-Linolenic acid are the only fatty acid requirements specified for this product in order to deliver the essential fatty acids for young children as these were found to be widely inadequate in the normal diets of children.

c. Carbohydrates			
available carbohydrates [4)5)]			
UNIT	**MINIMUM**	**MAXIMUM**	**GUL**
g/100 kcal	-	12.5[6]	-
g/100 kJ	-	3.0	-

[Footnote] 4): 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.

ISDI comment

ISDI strongly supports the concept that Lactose should be the preferred carbohydrate in products based on milk protein.

Regarding the second sentence and the *"and in no case be sweeter than lactose"* provision, ISDI notes that CCMAS41 informed CCNFSDU42 that currently: "There are no known validated methods to measure sweetness of carbohydrate sources and therefore no way to determine compliance for such a provision".

ISDI notes that, at time of publication of this Brochure, the discussion on this provision is being continued in CCNFSDU and CCMAS.

For clarification purpose, ISDI urges national authorities when implementing to clarify that there is no possibility to determine compliance for such a provision, which means practically that it is not possible to request any types of certificates of conformity regarding this provision for the trading of these specific commodities.

The revised Standard Part B is establishing the most restrictive framework for carbohydrates in any Codex Alimentarius commodity standard. As expressed by several countries during the discussions, it is impossible at this stage to design a "sweet" product. Therefore, ISDI does not recommend integrating the concept "and in no case be sweeter than lactose" when implementing the Standard at national level.

On this point, see the positions of AOAC, IDF & ISO and their opinion paper on this topic published as a CRD at CCNFSDU43.

[Footnote] 5): 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.

ISDI comment

Mono- and disaccharides, other than lactose, must not be higher than 2.5 g/100 kcal in the finished product. This level represents the WHO Guidelines on sugars at 10% energy.

ISDI strongly recommends that this specification is not further restricted to a limit of 1.25g/100 kcal but to keep 2.5 g/100 kcal. The 1.25g/100 kcal level is based on 5% of energy and has been extrapolated from a conditional recommendation by the WHO guiding free sugar intake as a proportion of total energy of the total diet. In addition, it should be noted that this product is only one part of the young child's diet.

[Footnote] 6): 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.

ISDI comment

The maximum level of available carbohydrate is set at 12.5 g/100 kcal, however if the protein level of the product is below 3 g/100 kcal, then the maximum level of carbohydrate can be extended to 14 g/100 kcal. This is to allow flexibility in relationship between the macronutrients and total energy of the product. The footnote therefore allows flexibility in nutrition and composition of the product based on scientific recommendations.

ISDI additional comment on carbohydrates requirements

ISDI strongly supports the efforts to introduce requirements for carbohydrates and sugars other than lactose. The revised Follow-up Formula Standard takes a significant step forward to amend this

section. It is critical that footnote 6 is both objective and enforceable, once transposed into regional/national legislation.

ISDI's interpretation of the clause has the following elements for consideration:

- Lactose is the preferred source of carbohydrate for products based on milk protein, with exception to low lactose products based on milk protein.
- For non-milk-based protein products, other sources of carbohydrates can be used for example hydrolysed starches. This is a critical element since these products do not contain inherent lactose and therefore other sources must be permitted to provide the required energy.
- Sucrose and fructose should not be added (regardless of source of protein).
- With regard to sweetness, it is also important to note that the use of artificial sweeteners or high intensity sweeteners is not permitted in these products.

d. Vitamins

ISDI comment
The Product for young children includes a list of eight nutrients with mandatory criteria compared to twenty-five nutrients in Follow-up Formula for older infants. Part B reflects the composition and role of the product and reflects latest scientific evidence.

Vitamin A			
UNIT	**MINIMUM**	**MAXIMUM**	**GUL**
µg RE [7] /100 kcal	60	180	-
µg RE [7] /100 kJ	14	43	-

The European Union, Norway and Switzerland expressed reservations about the maximum level of Vitamin A as the current level was too high and would lead to the upper tolerable intake levels being exceeded (see CAC46 Report)

[Footnote] 7): 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[8]			
UNIT	**MINIMUM**	**MAXIMUM**	**GUL**
µg RE [9] /100 kcal	1.5	4.5	-
µg RE [9] /100 kJ	0.36	1.1	-

[Footnote] 8: Competent national and/or regional authorities may deviate from the conditions as appropriate for the nutritional needs of their population.

ISDI comment
ISDI welcomes the possibility to deviate from the from the vitamin D requirements. This is an essential element to allow for deviations taking into account the nutritional needs of countries' populations. Such flexibility represents also a positive element as it allows competent national and/or regional authorities to provide flexibility as science evolves.

[Footnote] 9): 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[10)]			
UNIT	MINIMUM	MAXIMUM	GUL
mg /100 kcal	10	-	70
mg /100 kJ	2.4	-	17

[Footnote] 10): expressed as L-ascorbic acid

E- Minerals and Trace Elements			
Iron [11)]			
UNIT	MINIMUM	MAXIMUM	GUL
mg /100 kcal	1.0	3.0	-
mg /100 kJ	0.24	0.72	-

[Footnote] 11): 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.

ISDI Comment

ISDI cautioned during the discussions against the vilification of sodium chloride in a product standard without further elements of context. ISDI understands that the rationale for establishing this sodium chloride provision during the discussions that led to the revision of the Standard was to increase the nutritional safety of the products by prohibiting the addition of sodium chloride, without impacting the inherent levels of sodium in cow's milk.

ISDI has considered this further and believes the decision if misinterpreted could create misalignment with CAC/GL 10-1979 and other parts of CODEX STAN 156-1987. Furthermore, it does not ensure nutritional integrity, one of the key principles used to determine the mandatory composition for this category.

ISDI notes that sodium is part of the Essential Composition of Follow-up formula for Older Infants (Part A, point 3.1.3). ISDI considers it essential to clarify that sodium is an important nutrient for young children that can, based on section 3..2.3, be added as an optional ingredient. If the inherent content in milk is not sufficient to meet the requirements established for Follow-up formula for Older Infants in Part A, additional sources of sodium should be added, provided as per Part B that the source is not sodium chloride.

ISDI notes that if misinterpreted, the prohibition on the use of sodium chloride coupled with the absence of a maximum level for total sodium (i.e. inherent and added sodium), does not protect the nutritional integrity of the product. Furthermore, this approach is not in line with recommendations of numerous authorities across the globe to control or reduce sodium intake in children (see for instance EFSA Opinion on Dietary References on Sodium, 2019).

Sodium is inherently present in cow's milk. Most sodium in follow-up formula comes from the inherent levels; however, small quantities may be added:

1. CAC/GL 10-1979 permits the addition of sodium as a nutrient compound in foods for special dietary uses intended for infants and young children. Permitted sources of sodium in Infant Formula, Follow-up formula and Foods for special medical purposes intended for infants, include but are not limited to sodium chloride. Permitted sources are: Sodium carbonate, Sodium hydrogen carbonate (Sodium bicarbonate), Sodium chloride, Trisodium citrate (Sodium citrate), Sodium gluconate, Sodium L-lactate, Sodium dihydrogen phosphate (Sodium phosphate, monobasic), Disodium hydrogen phosphate (Sodium phosphate, dibasic), Trisodium phosphate (Sodium phosphate, tribasic), Sodium hydroxide, Sodium sulphate. Sodium is primarily added to product for young children to balance the variability in the inherent levels of sodium in cow's milk and thus ensure the production of a high quality consistent product.

2. CODEX STAN 156-1987 also permits the addition of certain food additives to products for young children (these additives have a technological need and have undergone safety assessment by JECFA). A number of food additives within the category 'pH adjusting agents' are sodium salts, i.e. Sodium hydrogen carbonate, Sodium carbonate, Sodium citrate, Sodium hydroxide.

As a conclusion, all permitted substances such as additives, vitamins and minerals are authorized except NaCl.

Based on section 3.2.3, in Products for Young Children, all sources of sodium (i.e. inherent & added) must not exceed the maximum level for sodium specified in Part A, i.e. 60 mg /100kcal.

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 breast-milk, 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.

ISDI comment

This section highlights that the list of essential composition criteria and nutrient levels could be expanded by national or regional authorities, provided they are chosen from the essential composition criteria of Follow-up Formula for older Infants if the addition is mandatory (3.1.3 Part A). These levels may be modified if the nutritional needs of the local population require such changes and can take into account the inherent quantity of nutrients in cow's milk.

ISDI also recalls that deviations should be based on scientific data, risk assessment and intake levels surveys informing the specific need for such a deviation.

3.2 Optional Ingredients

3.2.1 In addition to the compositional requirements listed under 3.1.3 Section B, 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.

ISDI comment

The principles of optional ingredients are outlined in the following step approach:

1. Optional Ingredients or substances may be added if they have been evaluated by national and/or regional authorities based on scientific substantiation to be safe and suitable at the level of use for the particular nutritional purpose.

2. Optional nutrients when chosen from the essential composition criteria in Section 3.1.3 Part A should follow the permitted range of levels in that section.

3. The nutrient levels from bullet point 2 could be amended by national and/or regional authorities if it is scientifically justified based on nutritional needs of local population and can take into account the inherent quantity of nutrients in cow's milk.

4. Optional Ingredients included in the non-exhaustive list of permitted optional ingredients listed in Section 3.2.3 Part A of Follow-up Formula for older infants may be added.

5. For the ingredients not in the essential composition in Section 3.1.3 Part A (bullet point 4), the section on optional ingredients under point 1 shall apply; meaning the optional ingredient should be evaluated by national and/or regional authorities based on scientific substantiation to be safe and suitable at the level of use for the particular nutritional purpose.

ISDI notes therefore that when products for young children formulations include the following nutrients or substances from the essential composition of Follow-up formula for Older Infants (Part A), the levels established in this section are the reference, unless provided otherwise by national authorities:

VITAMINS

- Vitamin E
- Vitamin K
- Thiamin (Vitamin B_1)
- Niacin
- Vitamin B_6
- Pantothenic acid
- Folic Acid
- Vitamin C
- Biotin

MINERALS AND TRACE ELEMENTS

- Phosphorus
- Magnesium
- Sodium
- Chloride
- Potassium
- Manganese
- Iodine
- Selenium
- Copper

ISDI notes and this is a key principle that Competent national and/or regional authorities should put in place the exact system proposed by the Codex Alimentarius Standard, meaning manufacturers are provided with the possibility to include optional nutrients from the essential composition of follow-up formula for older infants in Part A, provided these optional nutrients meet the levels established by Part A.

It is essential to highlight that the Standard does not invite Competent national and/or regional authorities to select or establish specific provisions for these optional nutrients taken separately among this list, as this would lead to unjustified trade barriers, except in case of specific nutritional needs.

ISDI also emphasizes that for optional ingredients or substances from Follow-up formula for older infant (Part A), either defined or not in Part A, the principles 3.2.1 and 3.2.2 apply, meaning that the levels should

be based on sufficient amounts to achieve the intended effect, to be determined by manufacturer taking into consideration that these optional ingredients/substances have been evaluated by national and/or regional authorities and demonstrated by generally accepted scientific evidence.

This is the case for:

- Taurine
- Total nucleotides
- Docosahexaenoic acid
- Choline
- Myo-i.nositol
- L-carnitine
- L (+) lactic acid-producing cultures
- Taurine, DHA & ARA, Choline, Myo-Inositol are optional ingredients in Follow-up formula (3.2 Part A) with defined criteria. They are not part of the essential composition of Follow-up formula for older infants (3.1 Part A). Therefore, the requirements described in 3.2.3 Part A do not apply to these ingredients when used in Product for Young Children.
- Thus, the mins/max/GULs described in 3.2.3 Part A do not apply to these nutrients when added to Product for Young Children.
- Specifically, in the case of DHA, the requirement for the addition of ARA at least at the same level as DHA does not apply to Product for Young Children.
- The level of these optional ingredients for Product for Young Children is to be determined following the principle established in 3.2.2 Part B (sufficient amounts to achieve the intended effect for young children).
- This means that the level must be defined on a case-by-case by the manufacturer. For instance, the addition of ARA when DHA is added is not mandatory. However, if ARA is added, the level needs to be defined on a case-by-case basis by the manufacturer. This is in line with the "science-based flexibility" intended by Codex.

For further details, see Appendix I developed by ISDI for comparison purposes.

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

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[4].

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

ISDI notes that the previous Standard listed the authorised additives for this category.

Following decisions taken at the Forty-sixth Session of the Codex Alimentarius Commission in December 2023, the food additives provisions in this standard have been included in the *General Standard for Food Additives* (GSFA) CXS 192-1995[1] in line with the process of alignment of all food additive provisions with the GSFA.

Codex is establishing the "General Standard on Food Additives" (GSFA) as the only source listing approved additives in foods (incl Follow-up formula) and has agreed on the following language following the completion of the alignment work for CXS 156-1987, whereby the table was replaced by this general reference to the GFSA.

4.1

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

The 53rd session of the Codex Committee on Food Additives has validated the list at its meeting in March 2023.

4.2 Flavourings [12)]

NAME OF FLAVOURING	MAXIMUM USE LEVEL
Natural Fruit Extracts	GMP
Vanilla Extract	GMP
Ethyl vanillin	50 mg/kg
Vanillin	50 mg/kg

The flavourings used in products covered by this Standard should comply with the *Guidelines for the Use of Flavourings* CXG 66-2008[15].

[Footnote] 12): National and/or regional authorities may restrict or prohibit the use of the listed flavourings.

ISDI comment

ISDI notes that the list of flavourings has not changed from the old standard.

ISDI notes that CCNFSDU originally expressed the Maximum Limits for Ethyl vanillin and Vanillin as 5 mg/100 mL. However this was converted by CCFA53 as 50 mg/kg, to align with the standardized Maximum Limits expression for flavours.

ISDI encourages national authorities to not restrict or prohibit the use of the listed flavourings.

Young children consume a variety of products that may contain flavourings as seen in the following Codex Standard examples:

CATEGORY	BABY FOODS CXS 73-1981 (as ready-to-eat)	Cereal-Based Foods CXS 74-1981 (as ready-to-eat)
Natural Fruit Extracts	-	GMP
Vanilla Extract	GMP	GMP
Ethyl vanillin	7 mg/100 g	7 mg/100 g
Vanillin	7 mg/100 g	7 mg/100 g

Flavourings are generally used at lower concentrations in foods for young children compared with foods for the general population. CCNFSDU42 recognised that Product for Young Children was "consumed by children who were being exposed to many different flavourings and tastes as they are moving to family foods and therefore there was no need to limit the use of flavourings for that age group. Currently permitted flavourings are not sweeteners. They do not add a sweet taste and are used for reasons of palatability, and there was no scientific evidence to support the restriction of the use of flavourings as expressed in the CCNFSDU42 report.

Flavourings remain important in these foods to support taste development and food acceptance.

Where flavourings are used in foods for young children, they are used:

- To supplement or restore an existing flavour
- To impart their flavour to the finished product, and/or
- To modify any undesirable flavour characteristics inherent to a product

4.3 Carry-Over Principle

Only the food additives listed in food category 13.1.2 (Follow-up formulae) of the General Standard for Food Additives CXS 192-1995[1] 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[4] 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[5].

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[6], and other relevant Codex texts such as the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children* CXC 66-2008[7], 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[8] and the *Code of Hygienic Practice for Low and Acidified Low-acid Canned Foods* CXC 23-1979[9], 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[10].

ISDI Comment

ISDI highlights the strict safety measures taken by the industry to prevent, reduce and control the potential microbiological risks of these products, and therefore recommends that:

- The consumers strictly follow manufacturers' instructions for the hygienic preparation of infant formulae,
- The baby is immediately fed with freshly prepared formula.

Regarding the reconstitution of formulae at 70°C, in our view, it is not considered the unique and most effective option to reduce potential microbiological risks, as it is difficult to follow/implement in practice while introducing specific risks such as scalding and degradation of functional formula properties. For further information, see the ISDI position.

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 Pre-packaged Foods* CXS 1-1985[11], the *Guidelines on Nutrition Labelling* CXG 2-1985[12] and the *Guidelines for Use of Nutrition and Health Claims* CXG 23-1997[13] 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.

ISDI comment

Nutrition and health claims are permissible for this age group in national jurisdictions which permit them.

ISDI notes that substantiated nutrition and health claims provide sound information to consumers to make informed choices at point of retail.

For further information see ISDI Brochure on FSDU & Claims.

Please note that Appendix III provides a Mock-up of mandatory Labelling Requirements for Product for Young Children based on Codex Alimentarius.

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 shall be "Drink/Product for Young Children with Added Nutrients" or "Drink for Young Children" as defined in Section 2.1, or any appropriate designation indicating the true nature of the product, in accordance with national or regional usage.

ISDI comment

The name of the product must be specified on the label and all other information accompanying the product by either Product for Young Children, or any appropriate designation indicating the true nature of the product, in accordance with national or regional usage.

National/regional examples: Australia and New Zealand – Toddler Milks, Indonesia – Growing-up Milk, China – Young Child Formula, South Africa – Growing-up Formula

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/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".

ISDI comment

Please also refer to sections 3.1.1-3.1.3 above.

b) If [name of plant] is the only source of protein*, the product may be labelled "Drink/Product for Young Children with Added Nutrients Based on [name of plant] protein" or "Drink 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/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 "Drink/Product for Young Children with Added Nutrients Based on [name of plant] protein and [name of animal] milk protein" or "Drink for Young Children 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.

ISDI comment

8.1.3 states that the source of protein must be clearly stated on the label. The Standard also permits the use of a combination of animal milk and plant as sources of protein. In all cases, the use of amino acids to improve protein quality when needed is not affected by the labelling of the source of protein.

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; and

c) in addition, the declaration of nutrients in a) and b) per 100 kcal or per 100 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*. CXS 1 1985[11].

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.

ISDI comments

8.5. Ready-to use products in liquid form should be consumed directly and concentrated or powdered form that require reconstitution, must be prepared with potable water that is safe or has been rendered safe by previous boiling. For further guidance on hygiene, please refer to ISDI comments in Part B: Product for young children: 6. Hygiene.

Adequate directions for appropriate preparation must also be indicated, including graphic instructions illustrating the method of preparation and warning information about the health hazards of inappropriate preparation, storage and use.

The label should also include a statement that the product should not be introduced before 12 months of age and not to be used as a sole source of nutrition as mentioned in Section 9.5.6.

ISDI notes that common labelling information based on the old Follow-up Formula Standard's additional labelling requirement was a statement that "This product is not formulated as a substitute for breast-milk and is not to be used as a sole source of nutrition". Such a statement would continue to be in line with section 9.5.6 and sections 8.6.4 and 8.6.5 and is considered essential by ISDI.

8.6 Additional Labelling Requirements

ISDI comment

The additional labelling requirements are implementing the considerations of relevant concepts and technical guidance in WHO/WHA documents for the labelling and other provisions in the draft standard for follow-up formula, as highlighted by a working document developed by New Zealand as chair of work regarding the revision of the Follow-up formula Codex Alimentarius Standard.

This essential work is reproduced in Appendix IV of this brochure.

ISDI also recalls that, throughout different jurisdictions, these products are not regulated as breast-milk substitutes. The Product for Young Children are not formulated to provide the full suite of essential nutrients provided by breast-milk milk substitutes. Rather, the Product for Young Children only has 8 mandatory micronutrients and therefore cannot be used as a sole source of nutrition. If presented as a breast-milk substitute, there will be an increased risk of these products being inadvertently misused, resulting in serious health consequences for these vulnerable age groups.

This section should be applied in conjunction with the general principles of the Codex Standard for the Labelling of Prepackaged Foods (CXS 1-1985) which requires that "prepackaged food shall not be described or presented on any label or in any labelling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect."

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 breast-milk, or suggests that the product is similar, equivalent to or superior to breast-milk;

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

ISDI comment

8.6.3 states that the label of the product shall have no pictures of infants, older infants, young children and women or any other picture or text that: undermines or discourages breastfeeding; makes a comparison to breast-milk, suggests that the product is similar, equivalent to or superior to breast-milk; might convey an endorsement or anything that may be construed as an endorsement by a professional or any other body (unless it has been approved by relevant national or regional regulatory authorities).

This also means that picture, text, or representation that does not:

Undermine or discourage breastfeeding; or make a comparison to breast-milk, or suggest that the product is similar, equivalent to or superior to breast-milk;

Or 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 are allowed.

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.

Front of Pack Nutrition Labelling (FOPNL)

FOPNL established for adult general healthy population are not suitable for infants and young children. Products specifically formulated for this target population should be excluded from FOPNL. The Codex Guidelines (Annex 2 of *Guidelines on Nutrition Labelling* CXG 2-1985 directly excludes the *Standard for Follow-up formula* CXS 156-1987 and therefore the categories covered by the revised standard are also excluded.

For further information, please see ISDI Brochure on Front of Pack Nutrition labelling.

ISDI reemphasizes that the nutritional compositional requirements of Follow-up formula for older infants are tailored to meet the particular nutritional needs of older infants and are based on science including the dietary recommendations of recognized authoritative scientific bodies (RASBs) (e.g. energy contribution from macronutrients, the contribution of micronutrients to recommended daily intake, etc.).

Follow-up formula for older infants are standardized by Codex and must follow stricter food composition and safety requirements in comparison with foods for the general population. Applying FOPNL schemes and nutrient profiles developed for the adult healthy population on Follow-up formula for older infants and other food for special dietary uses would mislead consumers and prevent them from making informed choices adapted to their nutritional needs. It would unjustifiably discriminate against these categories and undermine the purpose of the products.

ISDI considers that this is also in line with the recommendation from WHO in the scope section of "WHO Guiding Principles and framework manual for front-of-pack labelling for Promoting Healthy Diet" where the rationale for excluding standardized foods for infants and young children is that they have "strict compositional criteria; hence, promoting reformulated products is not appropriate".

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)[14] relevant to the provisions in this standard, shall be used.

NOTES

[1]FAO and WHO. 1995. *General Standard for Food Additives*. Codex Alimentarius Standard, No. CXS 192-1995. Codex Alimentarius Commission. Rome.

[2]World Health Organization (WHO). 1981. *International Code of Marketing of Breast-Milk Substitutes*. https://www.who.int/publications/i/item/9241541601

[3]FAO and WHO. 1981. *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants*. Codex Alimentarius Standard, No. CXS 72-1981. Codex Alimentarius Commission. Rome.

[4]FAO and WHO. 1979. *Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses intended for Infants and Young Children*. Codex Alimentarius Guideline, No. CXG 10-1979. Codex Alimentarius Commission. Rome.

[5]FAO and WHO. 1995. *General Standard for Contaminants and Toxins in Food and Feed*. Codex Alimentarius Standard, No. CXS 193-1995. Codex Alimentarius Commission. Rome.

[6]FAO and WHO. 1969. *General Principles of Food Hygiene*. Codex Alimentarius Code of Practice, No. CXC 1-1969. Codex Alimentarius Commission. Rome.

[7]FAO and WHO. 2008. *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children*. Codex Alimentarius Code of Practice, No. CXC 66-2008. Codex Alimentarius Commission. Rome.

[8]FAO and WHO. 1993. *Code of Hygienic Practice for Aseptically Processed and Packaged Low-acid Foods*. Codex Alimentarius Code of Practice, No. CXC 40-1993. Codex Alimentarius Commission. Rome.

[9]FAO and WHO. 1979. *Code of Hygienic Practice for Low and Acidified Low-acid Canned Foods*. Codex Alimentarius Code of Practice, No. CXC 23-1979. Codex Alimentarius Commission. Rome.

[10]FAO and WHO. 1997. *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods*. Codex Alimentarius Guideline, No. CXG 21-1997. Codex Alimentarius Commission. Rome.

[11]FAO and WHO. 1985. *General Standard for the Labelling of Pre-packaged Foods*. Codex Alimentarius Standard, No. CXS 1-1985 Codex Alimentarius Commission. Rome.

[12]FAO and WHO. 1985. *Guidelines on Nutrition Labelling*. Codex Alimentarius Guideline No. CXG 2-1985. Codex Alimentarius Commission. Rome.

[13]FAO and WHO. 1997. *Guidelines for Use of Nutrition and Health Claims*. Codex Alimentarius Guideline, No. CXG 23-1997. Codex Alimentarius Commission. Rome.

[14]FAO and WHO. 1999. *Recommended Methods of Analysis and Sampling*. Codex Alimentarius Standard, No. CXS 234-1999. Codex Alimentarius Commission. Rome.

[15]FAO and WHO. 2008. *Guidelines for the Use of Flavourings*. Codex Alimentarius Guideline, No. CXG 66-2008. Codex Alimentarius Commission. Rome.

TRANSITION

ISDI notes the importance of ensuring a smooth transition to new national regulatory frameworks based on the revised Standard.

ISDI recommends once a national framework is adopted for:

- A transition of three years with exhaustion of stocks;
- The general possibility for companies to put products on the market when they are compliant with the new regulation ahead of the transition deadlines.

ISDI emphasizes that the changes are not related to food safety. The transition should allow for the coexistence of products for a certain time.

The Follow-up formula for Older Infants and Product for Young Children undertake fundamental changes with the revised Standard. Manufacturers will need time to adapt to the new requirements once adopted at the national level.

In addition, as foods for special dietary uses, these products tend to be traded more globally than general food. Smooth transitions at national levels should help as the global regulatory landscape for these products will evolve at different speeds, following the publication of the new Codex Standard.

APPENDIX I: Comparison of the Composition criteria Follow-up formula for Older Infants vs. old Standard 6-36m

NUTRIENT	REVISED CODEX STANDARD FOR FUF (6-12 MONTHS)		FOR REFERENCE - CURRENT CODEX STANDARD (CXS 156-1987)	
	MIN	MAX (FOOTNOTE 1)	MIN	MAX
Energy (kcal/100ml)	60	70	60	85
Protein (g/100 kcal) Footnote 1), 2) & 3)	1.8 (NOTE D) Footnote 4) & 5)	3,0	3	5,5
Formula based on soy protein	2.25 Footnote 4)	3,0		
Formula based on non-hydrolysed protein	1.6 (NOTE D) Footnote 5)	3,0		
Total Fat (g/100 kcal) Footnote 6) & 7)	4,4	6	3	6
Lauric + Myristic acids (% of total fatty acids)	NS	20		
Trans-fatty acids (% of total fatty acids)	NS	3		
Erucic acid (% of total fatty acids)	NS	1		
Phospholipids (mg/100kcal)	NS	300		
Linoleic acid (mg/100 kcal)	300	1400*	300	NS
Alpha-Linolenic acid (mg/100 kcal)	50	NS		
Ratio LA:ALA	5:1	15:1		
DHA (mg/100kcal)	20 Footnote 20)	30*		
Available/Total Carbohydrates (g/100 kcal) Footnote 8)	9 (available)	14 (available)	NS (available - NOTE A)	NS (available - NOTE A)
Lactose	Lactose and glucose polymers should be the preferred carbohydrates in follow-up formula for older infants based on milk protein and hydrolysed protein.			
Sugars other than lactose	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 carbohydrate.			
Other sources of CHO	Only precooked and/or gelatinised starches gluten-free by nature may be added			
Vitamin A (mcg RE/100 kcal) Footnote 9)	75	180	75	225
Vitamin D (mcg/100 kcal) Footnote 10)	1	3	1	3
Vitamin E (mg α-TE/100 kcal) Footnote 12 & 13	0,5	5*	0.7 IU /g linoleic acid (NOTE E)	NS
Vitamin K (mcg/100kcal)	4	27*	4	NS
Thiamin (Vitamin B_1) (mcg/100kcal)	60	300*	40	NS
Riboflavin (Vitamin B_2) (mcg/100kcal)	80	500*	60	NS
Niacin (mcg/100kcal) Footnote 13)	300	1500*		
Vitamin B_6 (mcg/100kcal)	35	175*	45 (NOTE C)	NS

Vitamin B_{12} (mcg/100 kcal)	0,1	1.5*	0,15	NS
Pantothenic acid (mcg/100kcal)	400	2000*	300	NS
Folic acid (mcg/100 kcal)	10	50*	4	NS
Vitamin C (Ascorbic acid) (mg/100 kcal) Footnote 14)	10	70* Footnote 15)	8	NS
Biotin (Vitamin H) (mcg/100kcal)	1,5	10*	1,5	NS
Iron (mg/100 kcal)	1	2	1	2
Iron in FUF based on soy protein isolate (mg/100kcal) Footnote 16)	1,5	2,5		
Calcium (mg/100 kcal)	50	180*	90	NS
Phosphorus (mg/100 kcal)	25	100* Footnote 17)	60	NS
Ratio Ca:P	1:1	2:1	1	2
Magnesium (mg/100kcal)	5	15*	6	NS
Sodium (mg/100 kcal)	20	60	20	85
Chloride (mg/100kcal)	50	160	55	NS
Potassium (mg/100kcal)	60	180	80	NS
Manganese (mcg/100kcal)	1	100*		
Iodine (mcg/100 kcal)	10	60*	5	NS
Selenium (mcg/100kcal)	2	9*		
Copper (mcg/100kcal) Footnote 18)	35	120*		
Zinc (mg/100 kcal)	0,5	1.5*	0,5	NS
Zinc in FUF based on soy protein isolate (mg/100kcal) Footnote 19)	0,75	1.5*		
Nicotinamide (mcg/100kcal)	NS	NS	250	NS
Taurine (mg/100kcal)	NS	12		
Total nucleotides (mg/100kcal)	Levels may need to be determined by national authorities			
Choline (mg/100kcal)	NS	50*		
Myo-Inositol (mg/100kcal)	NS	40*		
L-carnitine (mg/100kcal)	levels may need to be determined by competent national authorities			
Bacterial cultures	NOTE B		L(+) lactic acid producing cultures listed as a food additive only	

KEY	
	Optional nutrient/ingredient
	difference between revised FuF standard & current IF standard (in either min, max &/or GUL)
*	GUL, rather than MAX applies
Footnote i)	In case where the GUL applies; 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 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.
Footnote 1)	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.
Footnote 2)	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 (breast-milk 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.
Footnote 3)	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
Footnote 4)	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 based on soy protein isolate, a minimum value of 2.25 g/100 kcal (0.54 g/100 kJ) applies.
Footnote 5)	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.
Footnote 6)	Partially hydrogenated oils and fats shall not be used in follow-up formula for older infants.
Footnote 7)	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).
Footnote 8)	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 carbohydrate.
Footnote 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.
Footnote 10)	Calciferol. 1 µg calciferol = 40 IU Vitamin D.
Footnote 11)	1 mg α-TE (alpha-tocopherol equivalents) = 1 mg d-α-tocopherol
Footnote 12)	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 αTE /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 eicosapentanoic acid (20:5 n-3); 1.5 mg α-TE/g docosahexaenoic acid (22:6 n-3).
Footnote 13)	Niacin refers to preformed niacin
Footnote 14)	expressed as L-ascorbic acid
Footnote 15)	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.
Footnote 16)	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.
Footnote 17)	This GUL should accommodate higher needs with follow-up formula for older infants based on soy protein isolate.
Footnote 18)	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.
Footnote 19)	For follow-up formula for older infants based on soy protein isolate a minimum value of 0.75 mg/100 kcal (0.18 mg/100 kJ) applies.
Footnote 20)	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.
NOTE A	The product shall contain nutritionally available carbohydrates suitable for the feeding of the older infant and the young child in such quantities as to adjust the product to the energy density in accordance with the requirements set out in Section 3.1.
NOTE B	Only L (+) lactic producing cultures may be used for the purpose of producing acidified follow-up formula for older infants. The acidified final formula 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.
NOTE C	Formulas should contain a minimum of 15 µg Vitamin B_6 per gramme of protein.
NOTE D	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 based on non hydrolysed milk protein can be accepted. Such Follow-up formula and follow-up formula 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.
NOTE E	Or per g polyunsaturated fatty acids, expressed as linoleic acid. But in no case less than 0.7 I.U./100 available calories.

APPENDIX II:

Mock-up of mandatory Labelling Requirements for **"Follow-up Formula for Older Infants"** based on Codex Alimentarius

Name of the food: "Follow-up formula for older infants"
or any appropriate designation indicating the true nature of the product, in accordance with national usage

Sources of protein
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

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

List of Ingredients:
Ingredients:
- Appropriate title which consists of or includes the term 'ingredient'
- Listed in descending order of ingoing weight (m/m) at the time of the manufacture of the food /Listed in descending order of ingoing weight / 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
  - 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
- Added water
- Compound ingredients
- Allergens highlighted.
- Alternative to label the product as reconstituted where relevant
- Class names can be used
- Food Additives => functional class + name or INS number
- Quantitative ingredients declaration - if relevant

- Net content drained weight
  - Volume or weight in the metric system ("System International" units)

Name and address: name and address of the manufacturer and/or packer and/or distributor, importer, exporter or vendor of the food shall be declared

Country of origin: mandatory only if its omission would mislead or deceive the consumer

Lot identification: Each container shall be embossed or otherwise permanently marked in code or in clear to identify the producing factory and the lot

Date marking & storage instructions
When a food must be consumed before a certain date to ensure its safety and quality the "Use–by Date" or "Expiration Date" shall be declared.
Where practicable, storage instructions shall be in close proximity to the date marking

Declaration of Nutritive Value*
Energy, (kcal) and/or (kJ),
Protein (g),
Carbohydrate (g)
Fat
Vitamins & Minerals

** 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. In addition, declaration per 100 kcal or kJ is permitted*

Instructions for Use / Information for Use:
- 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
- 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
- The label shall carry clear graphic instructions illustrating the method of preparation of the product
- The directions should be accompanied by a warning about the health hazards of inappropriate preparation, storage and use
- Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label
- 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

Additional Labelling Requirements:
- 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'**

Prohibited:
- No pictures of infants, young children and women nor a picture, text, or representation that might:
  a. Idealize the use of Follow-up formula for older infants
  b. Suggest use for infants under the age of 6 months (including references to milestones and stages)
  c. Recommend or promote bottle feeding
  d. Undermine or discourage breastfeeding; or that makes a comparison to breastmilk, or suggests that the product is similar, equivalent to or superior to breastmilk
  e. 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
- It is allowed to present pictures, texts or representation that do respect the points above
- No use of the terms "humanized", "maternalized" or other similar terms

Distinction
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

Reference to other products
No reference r 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

ISDI comment:*
Important to note: Follow-up formula for older infants are excluded from Front of Pack Nutrition Labelling (FOPNL) - see Annex 2 of Guidelines on Nutrition Labelling CXG 2-1985

Legend: General standard for labelling of Prepackaged Foods (GSLPF) - CXS 1-1985 | Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants - CXS 72-1981 | ISDI clarifications

APPENDIX III:

Mock-up of mandatory Labelling Requirements for **"Product for Young children"** based on Codex Alimentarius

Name of the food: "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
Sources of protein **a)** If [name of animal] milk is the only source of protein*, the product may be labelled [Product name] based on [name of animal] milk protein" **b)** If [name of plant] is the only source of protein*, the product may be labelled [Product name] 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 [Product name] 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 **No milk or milk derivative:** A product which contains neither milk nor any milk derivative shall be labelled "contains no milk or milk products" or an equivalent phrase

List of Ingredients:
Ingredients:
• Appropriate title which consists of or includes the term 'ingredient'
• Listed in descending order of ingoing weight (m/m) at the time of the manufacture of the food /Listed in descending order of ingoing weight / 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.
  • 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.
• Added water
• Compound ingredients
• Allergens highlighted.
• Alternative to label the product as reconstituted where relevant
• Class names can be used
• Food Additives => functional class + name or INS number
• Quantitative ingredients declaration - if relevant

• Net content drained weight • Volume or weight in the metric system ("System International" units)
Name and address: name and address of the manufacturer and/or packer and/or distributor, importer, exporter or vendor of the food shall be declared
Country of origin: mandatory only if its omission would mislead or deceive the consumer
Lot identification: Each container shall be embossed or otherwise permanently marked in code or in clear to identify the producing factory and the lot.
Date marking & storage instructions When a food must be consumed before a certain date to ensure its safety and quality the "Use–by Date" or "Expiration Date" shall be declared. Where practicable, storage instructions shall be in close proximity to the date marking.

Declaration of Nutritive Value*
Energy, (kcal) and/or (kJ),
Protein (g),
Carbohydrate (g)
Fat
Vitamins & Minerals

** 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. In addition, declaration per 100 kcal or kJ is permitted*

Instructions for Use / Information for Use:
- 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
- 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
- The label shall carry clear graphic instructions illustrating the method of preparation of the product.
- The directions should be accompanied by a warning about the health hazards of inappropriate preparation, storage and use
- Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label
- The label of the product 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 such as "This product is not formulated as a substitute for breast-milk and is not to be used as a sole source of nutrition"

Additional Labelling Requirements:
- 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 children

Prohibited:
- No image, text or representation, including pictures of feeding bottles, that could undermine or discourage breastfeeding or which idealises the use of the product
- No use of the terms "humanized", "maternalized" or other similar terms
- No pictures of infants, older infants, young children and women or any other picture, text, or representation that:
  a. undermines or discourages breastfeeding; or that makes a comparison to breastmilk, or suggests that the product is similar, equivalent to or superior to breastmilk;
  b. 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.
- It is allowed to present pictures, texts or representation that do respect the points above

Distinction
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

Reference to other products
No reference r 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

ISDI comment:*
Important to note: Products for young children is excluded from Front of Pack Nutrition Labelling (FOPNL) - see Annex 2 of Guidelines on Nutrition Labelling CXG 2-1985

Legend: General standard for labelling of Prepackaged Foods (GSLPF) - CXS 1-1985 | Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants - CXS 72-1981 | ISDI clarifications

APPENDIX IV: Relevant concepts and guidance from WHO and WHA documents that have been incorporated into the Codex Standard (CXS 156-1987)

Source; CRD 2 (link) tabled at CCNFSDU43

Table 1: Concepts and guidance from WHO and WHA documents that have been incorporated into draft standard text

Document	Draft text is as per CCNFSDU41 report Appendices II and IV. Text for Follow-up formula for older infants has been agreed to by the Committee, endorsed by CCFL45, adopted by CAC42, and is held at Step 7. Note: 9.6.5 for Follow-up Formula for Older Infants has been sent to CCFL46 for endorsement, the rest of the labelling provisions were endorsed by CCFL45. Text for Drink/product for young children with added nutrients, Drink for young children in *blue italics* has been adopted by CAC43, sent to CCFL46 for endorsement, and is up for discussion at Step 7 at CCNFSDU42.	
WHO INTERNATIONAL CODE OF MARKETING OF BREAST-MILK SUBSTITUTES	**FOLLOW-UP FORMULA FOR OLDER INFANTS**	**DRINK/PRODUCT FOR YOUNG CHILDREN WITH ADDED NUTRIENTS, DRINK FOR YOUNG CHILDREN**
9.1 Labels should be designed to provide the necessary information about the appropriate use of the product, and so as not to discourage breast-feeding.	**9.5.2** 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. **9.6.1** Labels should not discourage breastfeeding. Each container label shall have a clear, conspicuous and easily readable message which includes the following points: .... 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.	***9.5.2*** *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.* ***9.6.2*** *Labels should not discourage breastfeeding. Each container label shall have a clear, conspicuous and easily readable message which includes the following points:...* *b) a statement that the mother/ caregiver should seek advice of a health worker on proper feeding of the young child.*
9.2 Manufacturers and distributors of infant formula should ensure that each container has a clear, conspicuous, and easily readable and understandable message printed on it, or on a label which cannot readily become separated from it, in an appropriate language, which includes all the following points: a) the words "Important Notice" or their equivalent;	**9.6.1** 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;	***9.6.2*** *Labels should not discourage breastfeeding. Each container label shall have a clear, conspicuous and easily readable message which includes the following points:*
(b) a statement of the superiority of breastfeeding;	**9.6.1 b)** the statement "Breast-milk is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breast- milk;	***9.6.2*** *a) the statement "Breastfeeding is recommended up to two years and beyond."*
(c) a statement that the product should be used only on the advice of a health worker as to the need for its use and the proper method of use;	**9.6.1 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.	***9.6.2*** *b) a statement that the mother/ caregiver should seek advice of a health worker on proper feeding of the young child.*

(d) instructions for appropriate preparation, and a warning against the health hazards of inappropriate preparation	**9.5.2** 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. **9.5.3** The label shall carry clear graphic instructions illustrating the method of preparation of the product. **9.5.4** The directions should be accompanied by a warning about the health hazards of inappropriate preparation, storage and use.	***9.5.2*** *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.* ***9.5.3*** *The label shall carry clear graphic instructions illustrating the method of preparation of the product.* ***9.5.4*** *The directions should be accompanied by a warning about the health hazards of inappropriate preparation, storage and use.*
Neither the container nor the label should have pictures of infants, nor should they have other pictures or text which may idealize the use of infant formula. They may, however, have graphics for easy identification of the product as a breastmilk substitute and for illustrating methods of preparation.	**9.5.2** The label shall have no pictures of infants, young children and women nor any other picture, text, or representation that might: **9.5.2.1** idealize the use of Follow-up Formula for Older Infants;	***9.6.1*** *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.*
The terms "humanized", "maternalized" or similar terms should not be used.	**9.6.3** The terms "humanized", "maternalized" or other similar terms shall not be used.	
9.3 Food products within the scope of this Code, marketed for infant feeding, which do not meet all the requirements of an infant formula, but which can be modified to do so, should carry on the label a warning that the unmodified product should not be the sole source of nourishment of an infant. Since sweetened condensed milk is not suitable for infant feeding, nor for use as a main ingredient of infant formula, its label should not contain purported instructions on how to modify it for that purpose.	**9.5.6** 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.	***9.5.6*** *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.*
9.4 The label of food products within the scope of this Code should also state all the following points: (a) the ingredients used;	**9.2.1** A complete list of ingredients shall be declared on the label...	***9.2.1*** *A complete list of ingredients shall be declared on the label...*
(b) the composition/analysis of the product;	**9.3** Declaration of Nutritive Value This section includes requirements for full declaration of the nutritional values of the product	***9.3 Declaration of Nutritive Value*** *This section includes requirements for full declaration of the nutritional values of the product*
(c) the storage conditions required; and	**9.4.1** The date marking and storage instructions shall be in accordance with section 4.7 of the General Standard for the Labelling of Prepackaged Foods. **9.4.2** Where practicable, storage instructions shall be in close proximity to the date marking.	***9.4.1*** *The date marking and storage instructions shall be in accordance with section 4.7 of the General Standard for the Labelling of Prepackaged Foods.* ***9.4.2*** *Where practicable, storage instructions shall be in close proximity to the date marking.*
(d) the batch number and the date before which the product is to be consumed, taking into account the climatic and storage conditions of the country concerned.	**9.4.1** The date marking and storage instructions shall be in accordance with section 4.7 of the General Standard for the Labelling of Prepackaged Foods. **9.4.2** Where practicable, storage instructions shall be in close proximity to the date marking.	***9.4.1*** *The date marking and storage instructions shall be in accordance with section 4.7 of the General Standard for the Labelling of Prepackaged Foods.* ***9.4.2*** *Where practicable, storage instructions shall be in close proximity to the date marking.*

10.1 The quality of products is an essential element for the protection of the health of infants and therefore should be of a high recognized standard	Proposed text to be discussed at CCNFSDU42: 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.	Proposed text to be discussed at CCNFSDU42: 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.
10.2 Food products within the scope of this Code should, when sold or otherwise distributed, meet applicable standards recommended by the Codex Alimentarius Commission and also the Codex Code of Hygienic Practice for Foods for Infants and Children.	Proposed text to be discussed at CCNFSDU42: **6. HYGIENE** 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) [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)] 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).	Proposed text to be discussed at CCNFSDU42: **6. HYGIENE** 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) [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)] 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).
GUIDANCE ON ENDING THE INAPPROPRIATE PROMOTION OF FOODS FOR INFANTS AND YOUNG CHILDREN	**FOLLOW-UP FORMULA FOR OLDER INFANTS**	**DRINK/PRODUCT FOR YOUNG CHILDREN WITH ADDED NUTRIENTS, DRINK FOR YOUNG CHILDREN**
Recommendation 4. The messages used to promote foods for infants and young children should support optimal feeding and inappropriate messages should not be included. Messages about commercial products are conveyed in multiple forms, through advertisements, promotion and sponsorship, including brochures, online information and package labels. Irrespective of the form, messages should always: include a statement on the importance of continued breastfeeding for up to two years or beyond and the importance of not introducing complementary feeding before 6 months of age; include the appropriate age of introduction of the food (this must not be less than 6 months); be easily understood by parents and other caregivers, with all required label information being visible and legible.	**9.5.6** 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. **9.5.6.1** 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 "Breast-milk is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breast- milk; **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'.	***9.5.6*** *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.* ***9.6.2*** *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.*

Messages should not: include any image, text or other representation that might suggest use for infants under the age of 6 months (including references to milestones and stages); include any image, text or other representation that is likely to undermine or discourage breast-feeding, that makes a comparison to breast-milk, or that suggests that the product is nearly equivalent or superior to breast-milk; recommend or promote bottle feeding; convey an endorsement or anything that may be construed as an endorse-ment by a professional or other body, unless this has been specifically ap-proved by relevant national, regional or international regulatory authorities.	**9.6.2** The label shall have no pictures of infants, young children and women nor any other picture, text, or representation that might: **9.6.2.1** idealize the use of Follow-up Formula for Older Infants; **9.6.2.2** suggest use for infants under the age of 6 months (including references to milestones and stages); **9.6.2.3** recommend or promote bottle feeding; **9.6.2.4** undermine or discourage breastfeeding; or that makes a comparison to breast-milk, or suggests that the product is similar, equivalent to or superior to breast- milk; **9.6.2.5** 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.	***9.6.1*** *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.* ***9.6.2*** *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.* ***9.6.3*** *The label shall have no pictures of infants, older infants, young children and women or any other picture, text, or representation that:* ***9.6.3.1*** *undermines or discourages breastfeeding; or that makes a comparison to breast-milk, or suggests that the product is similar, equivalent to or superior to breast-milk;* ***9.6.3.2*** *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*
Recommendation 5 There should be no cross-promotion to promote breast-milk substitutes indirectly via the promotion of foods for infants and young children. • The packaging design, labelling and materials used for the promotion of complementary foods must be different from those used for breast-milk substitutes so that they cannot be used in a way that also promotes breastmilk substitutes (for example, different colour schemes, designs, names, slogans and mascots other than company name and logo should be used). • Companies that market breast-milk substitutes should refrain from engaging in the direct or indirect promotion of their other • food products for infants and young children by establishing relationships with parents and other caregivers (for example through baby clubs, social media groups, childcare classes and contests).	**9.6.4** Follow-up formula for older in-fants shall be distinctly labelled in such a way as to avoid any risk of confusion between Infant Formula, Drink/Product for young children with added nutri-ents or Drink 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. ***9.6.5*** *The labelling of follow-up formula for older infants shall not refer to infant formula, Drink/Product for young children with added nutrients or Drink for young children, or formula for special medical purposes intended for infants, including numbers, text, statements, or images of these products.*	***9.6.4*** *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.* ***9.6.5*** *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.*

WHA 69.9 ENDING INAPPROPRIATE PROMOTION OF FOODS FOR INFANTS AND YOUNG CHILDREN	FOLLOW-UP FORMULA FOR OLDER INFANTS	DRINK/PRODUCT FOR YOUNG CHILDREN WITH ADDED NUTRIENTS, DRINK FOR YOUNG CHILDREN
Recognizing that the Codex Alimentarius Commission is an intergovernmental body which is the principal organ of the joint FAO/WHO food standards programme and that it is the appropriate body for establishing international standards on food products, and that reviews of Codex standards and guidelines should give full consideration to WHO guidelines and recommendations, including the International Code of Marketing of Breast-milk Substitutes and relevant Health Assembly resolutions	As shown above, 'full consideration to WHO guidelines and recommendations, including the International Code of Marketing of Breast-milk Substitutes and relevant Health Assembly resolutions' has been given and concepts incorporated within the labelling provisions.	As shown above, 'full consideration to WHO guidelines and recommendations, including the International Code of Marketing of Breast-milk Substitutes and relevant Health Assembly resolutions' has been given and concepts incorporated within the labelling provisions.
WHA 63.32	**FOLLOW-UP FORMULA FOR OLDER INFANTS**	**DRINK/PRODUCT FOR YOUNG CHILDREN WITH ADDED NUTRIENTS, DRINK FOR YOUNG CHILDREN**
and to ensure that nutrition and health claims shall not be permitted for foods for infants and young children, except where specifically provided for in relevant Codex Alimentarius standards or national legislation	**9. 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.	**9. 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 except where specifically provided for in relevant Codex Standards or national legislation.
WHA 54.2	**FOLLOW-UP FORMULA FOR OLDER INFANTS**	**DRINK/PRODUCT FOR YOUNG CHILDREN WITH ADDED NUTRIENTS, DRINK FOR YOUNG CHILDREN**
conscious of the need for the Codex Alimentarius Commission to take the International Code and subsequent relevant Health Assembly resolutions into consideration in dealing with health claims in the development of food standards and guidelines;	**9. 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.	**9. 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 except where specifically provided for in relevant Codex Standards or national legislation.
strengthen national mechanisms to ensure global compliance with the International Code of Marketing of Breast-milk Substitutes and subsequent relevant Health Assembly resolutions, with regard to labelling as well as all forms of advertising, and commercial promotion in all types of media, to encourage the Codex Alimentarius Commission to take the International Code and relevant subsequent Health Assembly resolutions into consideration in developing its standards and guidelines; and to inform the general public on progress in implementing the Code and subsequent relevant Health Assembly resolutions	As shown above, the labelling section of the product has taken into consideration the International Code and WHA resolutions	As shown above, the labelling section of the product has taken into consideration the International Code and WHA resolutions.

APPENDIX V: The Use of Flavourings – Further Clarifications

Human milk is rich in flavours (Leathwood 2005), including vanilla (Mennella and Beauchamp 1996; Cooke and Fildes 2011), and it is thought that the presence of these flavours in human milk contributes to broader acceptance of diverse foods/tastes (Leathwood and Maier 2005; Cooke and Fildes 2011).

Infants of women who do not breastfeed should be exposed to a variety of flavours, particularly those associated with fruits and vegetables, first while the mother is pregnant and then beginning at an early age" (Beauchamp and Mennella 2009).

In addition, the conclusions of the 1971 FAO/WHO Meeting on Additives in Baby Food, states that while flavours are not necessary in infant formula, "babies over 12 weeks of age may be capable of distinguishing flavours" and "In certain processes, however, such as sterilization or deaeration, it is not always possible to retain the original flavour. In such cases, the restoration of desirable natural flavours may be justified."

Flavourings are generally used at lower concentrations in foods for older infants compared with foods for general population and primarily for the purpose of modifying undesirable flavour characteristics inherent to a product to improve palatability.

Flavourings: Single Substances and Complex Materials

Flavouring substance	Flavouring Complexes
Single, chemically defined substances e.g., vanillin, ethyl vanillin	Preparations, complexes, complex materials e.g. vanilla extract, natural fruit extracts
Can be natural or synthetic	Extracts, essences, essential oils and oleoresins from botanical/ natural origins
Often compounded (mixed) to form "formulated" flavourings	Compounded or used as-is

Q: What is a "Vanilla Extract"?

A: Vanilla extracts may have different specific regulatory definitions around the world, but in general they are all produced using methods described by Codex Guideline (CAC/GL 66-2008) for "natural flavouring complexes." Vanilla extracts are often prepared by solvent extraction of vanilla beans using a mixture of ethyl alcohol and water. This process captures the principle flavour and aroma compounds. This extraction is considered a physical process that may result in unavoidable but unintentional changes in the components of the flavouring.

Q: What is a "Natural Fruit Extract"?

A: Natural fruit extracts are covered by the definition of "natural flavouring complexes" contained in the Codex Guidelines for the Use of Flavourings (CAC/GL 66-2008), and are generally flavouring substances obtained from fruit through physical, chemical, or microbiological processes that do not intentionally change the components of the starting material.

Q: Why does the Codex Follow-Up Formula standard use "Natural Fruit Extract" instead of "Natural Flavouring Complex"?

A: The Codex Follow-Up Formula Standard (Codex STAN 156-1987) was adopted twenty years before the adoption of the Codex Guidelines for the Use of Flavourings (CAC/GL 66-2008). Therefore, when the Follow-Up Formula Standard was adopted, there were no Codex definitions for flavouring substances. Under the Codex Guideline for the Use of Flavourings, "Natural Fruit Extract" and "Vanilla Extract" would both fall under the definition of "Natural Flavouring Complexes".

Q: What differentiates a "natural flavouring substance" from a "synthetic flavouring substance"?

A: The characteristic that differentiates "natural" from "synthetic" flavouring substances is the origin of the flavouring substance. As described in the Codex Guidelines for the Use of Flavourings (CAC/GL 66-2008), natural flavouring substances must be derived from materials of plant or animal origin, while synthetic flavouring substances are formed by chemical synthesis. Thus, a "natural" banana flavour must be produced from banana as a starting material using physical processes, whereas a "synthetic" banana flavouring would be produced from defined chemical synthesis. In many cases the "natural" and "synthetic" versions of the flavour are chemically identical. For instance, isoamyl acetate derived from bananas is chemically identical to chemically-synthesized isoamyl acetate (JECFA #307), and vanillin derived from vanilla beans is chemically identical to chemically-synthesized vanillin (JECFA #889). For natural and synthetic substances both need to meet JECFA specifications.

Q: What is the difference between a "natural flavouring substance" and a "natural flavouring complex"?

A: Natural flavouring "substances" and "complexes" are differentiated by whether they are a single chemically defined substance or a preparation/mixture of substances. Both must be sourced from a material of plant or animal origin and must be produced using physical processes that do not intentionally change the components of the starting material. In broader terms, while a "natural flavouring substance" may be a single chemical compound, a "natural flavouring complex" is a complex mixture extracted from the starting material. For illustrative purposes, vanillin or ethyl vanillin purified from vanilla beans would be "natural flavouring substances". Alternatively, a crude extract of vanilla beans using ethyl alcohol and water would be considered a "natural flavouring complex" and would contain multiple flavour and aroma compounds including vanillin, ethyl vanillin, and other similar compounds present in the vanilla beans. In the context of the Codex Follow-Up Formula Standard (Codex STAN 156-1987), natural fruit extracts and vanilla extracts would both be classified as "natural flavouring complexes".

Q: What are the numbers assigned to flavours by JECFA?

A: JECFA has an established process for evaluating the safety of flavouring substances, and a list of JECFA-evaluated flavouring substances is maintained on the Codex (CXA 6-2019) and JECFA websites. Flavours that have been evaluated and for which there are no safety concerns are assigned a number. For example, vanillin has been assigned JECFA #889, and ethyl vanillin has been assigned JECFA #893.

Q: Do natural fruit extracts and vanilla extracts have JECFA numbers?

A: No natural fruit extracts or vanilla extracts have been assigned JECFA numbers to date.

As there are no safety concerns with these flavouring complexes, JECFA safety assessments have not been undertaken. Natural fruit extracts is a broad term that covers natural flavouring complexes derived from any fruit. A JECFA number would not be assigned to "natural fruit extracts", but rather a unique JECFA number would be assigned to specific extracts from every fruit. Vanilla extracts could be assigned one or more JECFA numbers, depending on the similarities and differences between the different vanilla extracts that are being used as natural flavouring complexes.

Q: Has JECFA given advice on the use of flavourings in products for older infants and/or young children?

A: In the 1971 FAO/WHO report on Additives in Baby Foods, it is noted that older infants (older than 12 weeks of age) may be capable of distinguishing flavours. The report notes that some food manufacturing processes, such as sterilization or deaeration, can have a negative impact on the original flavour of products, which justifies the use of flavourings. Thus, use of flavourings in products for older infants may be justified.

Q: How does JECFA evaluate the safety of flavourings in products for older infants and/or young children?

A: The safety of flavouring substances considers all potential uses of flavourings, in all product categories. This includes many foods that would be consumed by older infants and young children. As such, any flavouring substance that has been evaluated by JECFA and has a JECFA Number assigned to it has been determined to be safe for any food categories, covering consumption by infants and young children. Furthermore, the 1971 FAO/WHO report on Additives in Baby Foods concluded that "Before a food additive is regarded as safe for use in food intended for infants up to 12 weeks of age, the toxicological studies should be extended to include animals in the corresponding period of life." However, there were no additional distinctions made for the safety assessment of additives in products for older infants and young children (older than 6 months of age).

References

Beauchamp, G. K. and J. A. Mennella (2009). "Early flavor learning and its impact on later feeding behavior." J Pediatr Gastroenterol Nutr **48 Suppl 1**: S25-30.

Cooke, L. and A. Fildes (2011). "The impact of flavour exposure in utero and during milk feeding on food acceptance at weaning and beyond." Appetite **57**(3): 808-811.

Leathwood,P. and A. Maier. Early influences on taste preferences. In : *Feeding during late infancy and early childhood: Impact on health*. Karger Publishers, 2005. p. 127-141.

Mennella, J. A. and G. K. Beauchamp (1996). "The human infants' response to vanilla flavors in mother's milk and formula." Infant Behavior and Development **19**(1): 13-19.

APPENDIX VI: Former Standard on Follow-Up Formula (CXS 156-1987)

Adopted in 1987. Amended in 1989, 2011, 2017.

1. SCOPE

This standard applies to the composition and labelling of follow-up formula.

It does not apply to foods covered by the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-1981).

2. DESCRIPTION

2.1 Definitions

2.1.1 ***Follow-up formula*** means a food intended for use as a liquid part of the weaning diet for the infant from the 6th month on and for young children.

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

2.1.3 The term ***young children*** means persons from the age of more than 12 months up to the age of three years (36 months).

2.1.4 The term ***calorie*** means a kilocalorie (kcal). 1 kilojoule (kJ) is equivalent to 0.239 calories (kcal).

2.2 ***Follow-up formula*** is a food prepared from the milk of cows or other animals and/or other constituents of animal and/or plant origin, which have been proved to be suitable for infants from the 6th month on and for young children.

2.3 ***Follow-up formula*** is a food processed by physical means only so as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution.

2.4 ***Follow-up formula***, when in liquid form, is suitable for use either directly or diluted with water before feeding, as appropriate. In powdered form it requires water for preparation. The product shall be nutritionally adequate to contribute to normal growth and development when used in accordance with its directions for use.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Energy Content

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).

3.2 Nutrient Content

Follow-up formula shall contain the following nutrients at minimum and maximum levels indicated below:

3.2.1 Protein

3.2.1.1 Not less than 3.0 g per 100 available calories (or 0.7 g per 100 available kilojoules) of protein of nutritional quality equivalent to that of casein or a greater quantity of other protein in inverse proportion to its nutritional quality. The quality 1 of the protein shall not be less than 85% of that of casein. The total quantity of protein shall not be more than 5.5 g per 100 available calories (or 1.3 g per 100 available kilojoules).

3.2.1.2 Essential amino acids may be added to follow-up formula only to improve its nutritional value. 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.

3.2.2 Fat

3.2.2.1 Not less than 3 g and not more than 6 g per 100 calories (0.7 and 1.4 g per 100 available kilojoules).

3.2.2.2 The level of linoleic acid (in the form of a glyceride) shall not be less than 300 mg per 100 calories (or 71.7 mg per 100 available kilojoules).

3.2.3 Carbohydrates

The product shall contain nutritionally available carbohydrates suitable for the feeding of the older infant and the young child in such quantities as to adjust the product to the energy density in accordance with the requirements set out in Section 3.1.

[1] Protein quality shall be determined provisionally using the PER method as laid down in the section dealing with methods of analysis.

VITAMINS AND MINERALS

AMOUNTS PER 100 AVAILABLE CALORIES			AMOUNTS PER 100 AVAILABLE KILOJOULES	
3.2.4 Vitamins other than Vitamin E	**Minimum**	**Maximum**	**Maximum**	**Maximum**
Vitamin A	250 I.U. or 75 µg expressed as retinol	750 I.U. or 225 µg expressed as retinol	60 I.U. or 18 µg expressed as retinol	180 I.U. or 54 µg expressed as retinol
Vitamin D	40 I.U. or 1 µg	120 I.U. or 3 µg	10 I.U. or 0.25 µg	30 I.U. or 0.75 µg
Ascorbic Acid (Vitamin C)	8 mg	N.S.[2]	1.9 mg	N.S.[2]
Thiamine (Vitamin B1)	40 µg	N.S.[2]	10 µg	N.S.[2]
Riboflavin (Vitamin B2)	60 µg	N.S.[2]	14 µg	N.S.[2]
Nicotinamide	250 µg	N.S.[2]	60 µg	N.S.[2]
Vitamin B6[3]	45 µg	N.S.[2]	11 µg	N.S.[2]
Folic acid	4 µg	N.S.[2]	1 µg	N.S.[2]
Pantothenic acid	300 µg	N.S.[2]	70 µg	N.S.[2]
Vitamin B12	0.15 µg	N.S.2	0.04 µg	N.S.[2]
Vitamin K1	4 µg	N.S.[2]	1 µg	N.S.[2]
Biotin (Vitamin H)	1.5 µg	N.S.[2]	0.4 µg	N.S.[2]
3.2.5 Vitamin E (α-tocopherol compounds)	0.7 I.U./g linoleic acid[3], but in no case less than 0.7 I.U./100 available calories	N.S.[2]	0.7 I.U./g linoleic acid[4], but in no case less than 0.15 I.U./100 available kilojoules	N.S.[2]
3.2.6 Minerals				
Sodium (Na)	20 mg	85 mg	5 mg	21 mg
Potassium (K)	80 mg	N.S.[2]	20 mg	N.S.[2]
Chloride (Cl)	55 mg	N.S.[2]	14 mg	N.S.[2]
Calcium (Ca)[5]	90 mg	N.S.[2]	22 mg	N.S.[2]
Phosphorus (P)[6]	60 mg	N.S.[2]	14 mg	N.S.[2]
Magnesium (Mg)	6 mg	N.S.[7]	1.4 mg	N.S.[2]
Iron (Fe)	1 mg	2 mg	0.25 mg	0.50 mg
Iodine (I)	5 µg	N.S.[2]	1.2 µg	N.S.[2]
Zinc (Zn)	0.5 mg	N.S.2	0.12 mg	N.S.2

2 N.S. = Not specified
3 Formulas should contain a minimum of 15 µg Vitamin B6 per gramme of protein. See Section 3.2.1.1.
4 Or per g polyunsaturated fatty acids, expressed as linoleic acid.
5 The Ca:P ratio shall be not less than 1.0 and not more than 2.0.
6 The Ca:P ratio shall be not less than 1.0 and not more than 2.0
7 N.S. = Not specified

3.3 Ingredients

3.3.1 Essential Ingredients

3.3.1.1 Follow-up formula shall be prepared from the milk of cows or of other animals and/or other protein products of animal and/or plant origin which have been proved suitable for infants from the 6th month on and for young children and from other suitable ingredients necessary to achieve the essential composition of the product as set out in Sections 3.1 and 3.2 above.

3.3.1.2 Follow-up formula based on milk shall be prepared from ingredients as set out i n Section 3.3.1.1 above except that a minimum of 3 g per 100 available Calories (or 0.7 g per 100 kilojoules) 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% of the total protein.

3.3.2 Optional Ingredients

3.3.2.1 In addition to the vitamins and minerals listed under 3.2.4 to 3.2.6, other nutrients may be added when required to ensure that the product is suitable to form part of a mixed feeding scheme intended for use from the 6th month on.

3.3.2.2 The usefulness of these nutrients shall be scientifically shown.

3.3.2.3 When any of these nutrients is added, the food shall contain significant amounts of these nutrients, based on the requirements of infants from the 6th month on and young children.

3.4 Purity Requirements

3.4.1 General

All ingredients shall be clean, of good quality, safe and suitable for ingestion by infants from the 6th month on and young children. They shall conform with their normal quality requirements, such as colour, flavour and odour.

3.4.2 Vitamin Compounds and Mineral Salts

3.4.2.1 Vitamin compounds and mineral salts used in accordance with Sections 3.3.1 and 3.3.2 should be selected from the Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses intented for Infants and Children (CXG 10-1979).

3.4.2.2 The amounts of sodium derived from vitamin and mineral ingredients shall be within the limit for sodium in Section 3.2.6.

3.5 Consistency and Particle Size

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

3.6 Specific Prohibition

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

4. FOOD ADDITIVES

The following additives are permitted:

		Maximum Level in 100 ml of Product Ready-for-Consumption
4.1	**Thickening Agents**	
4.1.1	Guar gum	} 0.1 g
4.1.2	Locust bean gum	}
4.1.3	Distarch phosphate	} 0.5 g singly or in
4.1.4	Acetylated distarch phosphate	} combination in soy-based } products only
4.1.5	Phosphated distarch phosphate	} }
4.1.6	Acetylated distarch adipate	} 2.5 g singly or in } combination in hydrolyzed } protein and/or amino acid- } based products only
4.1.7	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
4.1.8	Pectins	1 g
4.2	**Emulsifiers**	
4.2.1	Lecithin	0.5 g
4.2.2	Mono- and Diglycerides	0.4 g
4.3	**pH-Adjusting Agents**	
4.3.1	Sodium hydrogen carbonate	}
4.3.2	Sodium carbonate	}
4.3.3	Sodium citrate	}
4.3.4	Potassium hydrogen carbonate	}
4.3.5	Potassium carbonate	} Limited by Good
4.3.6	Potassium citrate	} Manufacturing Practice
4.3.7	Sodium hydroxide	} within the limits for sodium in
4.3.8	Potassium hydroxide	} Section 3.2.6
4.3.9	Calcium hydroxide	}
4.3.10	L (+) Lactic acid	
4.3.11	L (+) Lactic acid	} producing cultures
		}
4.3.12	Citric acid	}
4.4	**Antioxidants**	
4.4.1	Mixed tocopherols concentrate	} 3 mg singly or in } combination 4.4.2 α-Tocopherol }
4.4.3	L-Ascorbyl palmitate	} 5 mg singly or in
4.4.4	L-Ascorbic acid and its Na, Ca salts	} combination, expressed as } ascorbic acid (see Section 3.2.6)
4.5	**Flavourings**	
4.5.1	Natural Fruit Extracts	GMP
4.5.2	Vanilla extract	GMP
4.5.3	Ethyl vanillin	5 mg
4.5.4	Vanillin	5 mg

4.6 Carry-Over Principle Section

4.1 of the General Standard for Food Additives (CXS 192-1995) shall apply.

5. CONTAMINANTS

5.1 Pesticide Residues

The product shall be prepared with special care under good manufacturing practices, so that residues of those pesticides which may be required in the production, storage or processing of the raw materials or the finished food ingredient do not remain, or, if technically unavoidable, are reduced to the maximum extent possible.

5.2 Other Contaminants

The product shall be free from residues of hormones and antibiotics, as determined by means of agreed methods of analysis, and practically free from other contaminants, especially pharmacologically active substances.

6. HYGIENE

6.1 To the extent possible in good manufacturing practice, the product shall be free from objectionable matter.

6.2 When tested by appropriate methods of sampling and examination, the product: a) shall be free from pathogenic microorganisms; b) shall not contain any substances originating from microorganisms in amounts which may represent a hazard to health; and c) shall not contain any other poisonous or deleterious substances in amounts which may represent a hazard to health.

6.3 The product shall be prepared, packed and held under sanitary conditions and should comply with the relevant provisions of the Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (CXC 662008).

7. PACKAGING

7.1 The product shall be packed in containers which will safeguard the hygienic and other qualities of the food. When in liquid form, the product shall be packed in hermetically sealed containers; nitrogen and carbon dioxide may be used as packing media.

7.2 The containers, including packaging materials, shall be made only of substances which are safe and suitable for their intended uses. Where the Codex Alimentarius Commission has established a standard for any such substance used as packaging materials, that standard shall apply.

8. 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 1/2 oz.); (ii) not less than 85% v/v for products in the weight range 150-250 g (5 1/2 - 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.

9. LABELLING

In addition to the requirements of the General Standard for the Labelling of Prepackaged Foods (CXS 1-1985), the following specific provisions apply:

9.1 The Name of the Food

9.1.1 The name of the food shall be "Follow-up Formula". In addition thereto, any appropriate designation may be used in accordance with national usage.

9.1.2 Those products which are prepared from whole or skimmed milk in accordance with Section 3.3.1.2 and where 90% or more of the protein is derived from whole or skimmed milk as such, or with minor modification that does not substantially impair the vitamin and mineral content of the milk, may be labelled "Follow-up Formula based on milk".

9.1.3 All sources of protein shall be clearly shown on the label in close proximity to the name of the food in descending order of proportion by weight.

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

9.2 List of Ingredients

The declaration of the list of ingredients shall be in accordance with Sections 4.2.1, 4.2.2 and 4.2.3 of the General Standard for the Labelling of Prepackaged Foods except that in the case of added vitamins and added minerals, these ingredients shall be arranged as separate groups for vitamins and minerals, respectively, and within these groups the vitamins and minerals need not be listed in descending order of proportion.

9.3 Declaration of Nutritive Value

The declaration of nutrition information shall contain the following information in the following order: (a) The amount of energy, expressed in Calories (kcal) and/or kilojoules (kJ) per 100 g of the food as sold as well as per specified quantity of the food as suggested for consumption. (b) The number of grammes of protein, carbohydrate and fat per 100 g of the food as sold as well as per specified quantity of the food as suggested for consumption. In addition, the declaration per 100 calories (or per 100 kilojoules) is permitted. (c) The total quantity of each vitamin, mineral and any optional ingredient, as listed in Section 3.3.2 of this standard per 100 g of the food as sold as well as per specified quantity of the food as suggested for consumption. In addition, the declaration per 100 calories (or per 100 kilojoules) is permitted.

9.4 Date Marking and Storage

Instructions In addition to the declaration of date marking and storage instructions in accordance with Sections 4.7.1 and 4.7.2 of the General Standard for the Labelling of Prepackaged Foods, the following provisions apply:

9.4.1 Storage of Opened Food

Storage instructions of opened packages of a food for special dietary uses shall be included on the label if necessary to ensure that the opened product

maintains its wholesomeness and nutritive value. A warning should be included on the label if the food is not capable of being stored after opening or is not capable of being stored in the container after opening.

9.5 I nformation for Utilization

9.5.1 Directions as to the preparation and use of the food, and its storage and keeping after the container has been opened shall appear on the label.

9.5.2 The labelling of a Follow-up Formula shall include a statement that Follow-up Formula shall not be introduced before the 6th month of life.

9.5.3 Information that infants and children fed Follow-up Formula shall receive other foods in addition to the food shall appear on the label.

9.6 Additional Requirements

The products covered by this standard are not breast-milk substitutes and shall not be presented as such.

10. METHODS OF ANALYSIS AND SAMPLING

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

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