

International Special
Dietary Foods Industries

Guidance on
Infant formula



Disclaimer

This guidance document provides an overview of Infant Formula in the context of Codex Alimentarius. It is intended 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 applicable Codex texts. The information provided is without prejudice to national or regional regulations and interpretations. A complete and up-to-date list of Codex texts (**standards**, **guidelines** and **codes of practice**) referenced in this document is available on the Codex website. Text presented in ***italic is reproduced directly from Codex documents.***

This brochure was originally developed in 2022 under the coordination of Xavier Lavigne (ISDI Board Member) and Marian Brestovansky (former ISDI Secretariat), with contributions from members of the ISDI Working Group on Infant and Young Child Nutrition.

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User guide

TARGET GROUP

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

PURPOSE OF THE BROCHURE

The brochure provides the international background regarding Infant Formula based on the **Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CXS 72-1981)** which establishes the internationally recognised definition and requirements for this category of products.

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 focuses exclusively on **Section A: Standard for Infant Formula** and does not cover **Section B: Formulas for Special Medical Purposes Intended for Infants**. Information on these products is available in the ISDI brochure on Foods for Special Medical Purposes (FSMP).

This brochure does not cover follow-up formula for older infants or product for young children (**Codex Standard for Follow-up Formula for Older Infants and Product for Young Children - CXS 156-1987**).

The brochure is for general information purposes and aims to facilitate the reading and understanding of **Section A of the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CXS 72-1981)**. The brochure can be used as a support for Food Business Operators as an educational material (e.g. internal trainings) or as a background element for discussions with national authorities regarding infant formula.

The brochure does not consider the specific regulations of infant formula, foods for special dietary uses (FSDU), foods for special medical purposes (FSMP) or other specialised nutrition products in each country and should not be considered in isolation.

A. Infant formula – a unique concept

Breastfeeding provides the best start in life for infants, delivering the energy and nutrients needed for healthy growth and development during the first months of life. It represents the first milestone in establishing the foundation for lifelong health.

When breastfeeding is not possible, or when an infant is only partially breastfed, infant formula is the only scientifically validated nutritional alternative recognised by the World Health Organization (WHO) for meeting infants' nutritional needs.

Infant formula was first developed more than 150 years ago to help reduce infant mortality and morbidity among babies who could not be breastfed. Since then, continuous scientific advances have improved both its safety and nutritional composition.

ISDI and its members continue to invest in research and innovation to develop infant formulas that aim to reflect the composition and functionality of breast milk as closely as possible, while meeting the specific nutritional requirements of infants.

Infant formula provides essential nutrients necessary for normal growth and development and may also include additional ingredients designed to support areas such as immune function, gut microbiota development and cognitive development, where supported by scientific evidence and regulatory requirements.

> ***Infant formula was first developed more than 150 years ago to help reduce infant mortality and morbidity among babies who could not be breastfed. Since then, continuous scientific advances have improved both its safety and nutritional composition.***

Infant formula is the most tightly regulated nutrition product in the world and its composition must comply with strict international and local regulatory standards and guidelines to ensure that infants receive the appropriate nutrition they need as they grow. The entire supply chain is monitored to make certain high quality and safe ingredients are used, the manufacturing process is scrutinised and the end product is tested.

For more information, please see the ISDI factsheet on the safety of powdered infant formula.

THE IMPORTANCE OF APPROPRIATE TERMINOLOGY

Proper care should be taken in the terminology used to refer to infant formula. Inappropriate or misleading language can lead to unintended consequences. Misused terms may reflect bias, perpetuate misconceptions or be employed to provoke emotional reactions, discredit the product or generate attention without regard for accuracy or impact.

'Infant Formula' is the appropriate term, as defined by Codex Alimentarius, and alternative terms may not reflect this regulated definition. These terms include:

- **'Formula milk'**: This term is imprecise and should be avoided. It does not reflect the regulated definition of infant formula and may cause confusion as the term is vague or generic, excludes plant-based products and may refer to a group of products.
- **'Commercial'**: Infant formula is by definition a commercial product, subject to meeting the requirements of a strict regulatory framework, as well as often registration or notification requirements before being marketed. 'Commercial', therefore, is a redundant term in relation to infant formula and potentially misleading as it implies the existence of noncommercial alternatives, such as homemade infant formula, which do not meet regulatory standards and may pose serious health risks.
- Furthermore, **'commercial milk formula'** is a specific term that is increasingly used, often explicitly to 'highlight the artificial and ultraprocessed nature of formula products' (see Marketing of commercial milk formula: a system to capture parents, communities, science, and policy). This term is imprecise, inappropriate and potentially misleading.
- **'Breast-milk substitute' or 'human milk substitute'**: The International Code of Marketing of Breast-milk Substitutes defines a breast-milk substitute as 'any food being marketed or otherwise represented as a partial or total replacement for breast-milk, whether or not suitable for that purpose.' As a term, it refers more to marketing than products. In this respect, the term is not defined by Codex Alimentarius and there is no universally accepted understanding of what products constitute a breast-milk substitute.

In addition, terms like **'ultra-processed'** and **'artificial'** should be avoided, as they lack harmonised regulatory definitions and may carry negative connotations. Their use can mislead consumers regarding the nutritional suitability of infant formula and may contribute to its inappropriate avoidance or replacement, despite its essential role in infant nutrition.

SAFE AND HIGH QUALITY NUTRITION

Only infant formula can give the assurance of safe, high quality nutrition for those infants that are not breastfed. This is the very reason for the existence of the **Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CXS 72-1981)** established in 1981, revised in 2007 and last amended in 2024.

It is the responsibility of the manufacturers to ensure that infant formula complies with the requirements established by Codex Alimentarius, including those established by the **Codex Standard (CXS 72-1981)** in terms of composition, packaging and labelling – without prejudice to national or regional regulations and interpretations.

B. Infant Formula in the Codex Alimentarius framework

THE CODEX INFANT FORMULA STANDARD

CODEX ALIMENTARIUS
INTERNATIONAL FOOD STANDARDS

The **Codex Standard for Infant Formula and Formulas for Special Medical Purposes intended for Infants (CXS 72-1981)** was originally adopted in 1981 and a comprehensive revision was adopted in 2007 by the Codex Alimentarius Commission (last amended in 2024).

The revised Standard serves as the principial international reference for infant formula. It establishes requirements relating to composition, quality, safety and labelling, and was developed on the basis of the latest scientific knowlegde available at the time of its revision. While the standard promotes international harmonisation, certain provisions allow for implementation decisions at national level. The Standard is divided into two sections.

1. Section A: Standard for Infant Formula

2. Section B: Formulas for Special Medical Purposes Intended for Infants

This brochure focuses exclusively on **Section A: Standard for Infant Formula** and does not address **Section B: Formulas for Special Medical Purposes Intended for Infants.**

THE BROADER CODEX FRAMEWORK

The infant formula standard should not be considered in isolation. CXS 72-1981 contains references to a number of additional Codex standards, guidelines and codes of practice that are also relevant to the manufacturing, composition, analysis, safety and labelling of infant formula.

Consequently, food business operators should assess the applicability of all relevant codex texts, together with national and regional requirements, when developing and marketing infant formula products. The following table provides a simplified overview of the Codex framework applicable to infant formula.

Directly applicable Codex texts	Horizontal (generally applicable) Codex texts	
CXS 72-1981: Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants	**Hygiene**	**CXC 1-1969**: General Principles of Food Hygiene **CXG 21-1997**: Principles and Guidelines for the establishment application of Microbiological criteria related to foods and
CXS 146-1985: General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses	**Additives**	**CXS 192-1995:** General Standard for Food Additives
	Contaminants	**CXS 193-1995**: General Standard for Contaminants in Food and Feed
CXG 10-1979: Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children	**Methods of analysis**	**CXS 234-1999**: Recommended Methods of Analysis and Sampling
CXC 66-2008: Code of Hygienic Practice for Powdered Infant Formulae for Infants and Young Children	**Labelling & claims**	**CXG 1-1985:** General Standard for the Labelling of Pre-packaged Foods **CXG 2-1985:** Guidelines on Nutrition Labelling **CXG 23-1997:** Guidelines for Use of Nutrition and Health Claims

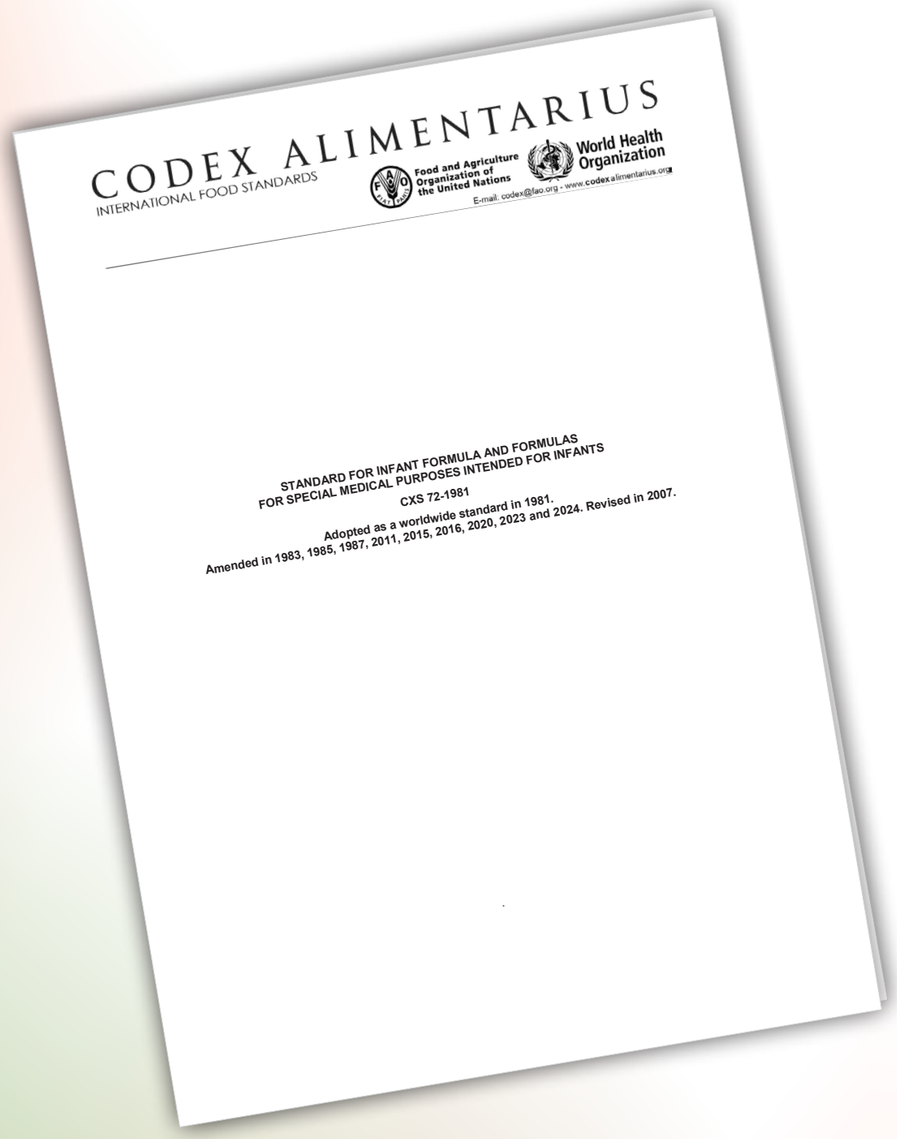
C. CXS 72-1981: Standard for Infant Formula and Formulas for Special Medical Purposes intended for Infants (Section A)

This section aims to describe and provide commentary on the Codex Standard for Infant formula and Formulas for Special Medical Purposes Intended for Infants (CXS 72-1981), with a focus on section A.

The Standard is shown through direct extracts, while boxed text reflects ISDI's own comments and interpretations.

The subsections below follow the structure of the standard, with each provision outlined and, where appropriate, commented on by ISDI.

All Codex texts are available on the Codex website: [Standards, Guidelines, Codes of Practice]


CODEX ALIMENTARIUS
INTERNATIONAL FOOD STANDARDS
Food and Agriculture Organization of the United Nations
World Health Organization
E-mail: codex@fao.org - www.codexalimentarius.org
STANDARD FOR INFANT FORMULA AND FORMULAS
FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS
CXS 72-1981
Adopted as a worldwide standard in 1981.
Amended in 1983, 1985, 1987, 2011, 2015, 2016, 2020, 2023 and 2024. Revised in 2007.

SECTION A: STANDARD FOR INFANT FORMULA

PREAMBLE

This standard is divided into two sections. Section A refers to infant formula, and Section B deals with formulas for special medical purposes intended for infants.

1. SCOPE

1.1 This section of the standard applies to infant formula in liquid or powdered form intended for use, where necessary, as a substitute for human milk in meeting the normal nutritional requirements of infants.

ISDI comment

ISDI notes that the scope explicitly states that an Infant Formula may be presented in either liquid or powdered form. It is therefore clear that this Codex Standard applies in its entirety to both forms.

1.2 This section of the standard contains compositional, quality and safety requirements for infant formula.

1.3 Only products that comply with the criteria laid down in the provisions of this section of this standard would be accepted for marketing as infant formula. No product other than infant formula may be marketed or otherwise represented as suitable for satisfying, by itself, the nutritional requirements of normal healthy infants during the first months of life.

1.4 The application of this section of the standard should take into account the recommendations made in the *International Code of Marketing of Breast-milk Substitutes* (WHO, 1981), the *Global Strategy for Infant and Young Child Feeding and World Health Assembly resolution WHA54.2* (2001).

ISDI comment

Point 1.4 refers to specific WHO documents and recommendations that have been taken into account in this section of the standard. The overarching principle reflected in these recommendations is that the marketing and sales practices of Infant Formula should not undermine breastfeeding.

If you would like to explore how concepts from WHO and WHA documents have been incorporated into other sections of the Infant formula standard, particularly those related to labelling, please refer to Appendix III of this brochure (published separately as a standalone document): "Labelling Considerations: relevant concepts and guidance from WHO and WHA documents that have been incorporated into the Codex standard for infants formula and formulas for special medical purposes intended for infants CXS 72-1981)".

2. DESCRIPTION

2.1 Product definition

2.1.1 Infant formula means a breastmilk substitute specially manufactured to satisfy, by itself, the nutritional requirements of infants during the first months of life up to the introduction of appropriate complementary feeding.

ISDI comment

ISDI notes that points 1.3 and 2.1.1 establish the fundamental principle that Infant Formula is a standardised product intended to be used as a breast-milk substitute and that, by itself, satisfies the nutritional requirements of normal healthy infants during the first months of life.

This ability to provide a sole source of nutrition for infants from birth is a key point of differentiation from follow-up formulas for older infants, drinks for young children with added nutrients and complementary foods.

2.1.2 The product 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 processing and packaging for such sensitive products. Indeed, food processing plays an essential role in ensuring food safety by eliminating micro-organisms and toxins. Combined with appropriate packaging, these measures help minimise food safety risk for this vulnerable target population, preserve certain nutrients, and protect the final products during storage and distribution.

Because Infant Formula is specially processed or formulated, terms such as “ultraprocessed” and “artificial” are sometimes incorrectly used to describe them, even though these terms lack commonly accepted regulatory meanings and definitions.

2.2 Other definitions

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

ISDI comment

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

Therefore, in the context of the Codex Alimentarius the following definitions apply:

- Older infant: a person from the age of 6 months and not more than 12 months of age
- Young child: a person from the age of more than 12 months up to the age of three years (36 months)

Under the FSDU standard, all products intended for infants and young children below 36 months of age are classified as Foods for Special Dietary Use (FSDU).

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Essential composition

3.1.1 Infant formula 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 suitable for infant feeding. The nutritional safety and adequacy of infant formula shall be scientifically demonstrated to support growth and development of infants. All ingredients and food additives shall be gluten free.

ISDI comment

ISDI notes that all ingredients and food additives shall be suitable for infant feeding. In addition, all ingredients and food additives shall be gluten free. ISDI also notes that, without prejudice to national regulations, this information cannot be provided on Infant Formula labels. For further information, please refer to the ISDI brochure on Gluten Free Foods and the specific wording regarding the prohibition of “gluten-free” labelling for Infant Formula.

ISDI notes that the Codex standard also covers Infant Formula not based on cow’s milk, including products based on milk from other animals, products based on vegetable protein(s) or a mixture thereof. All protein sources shall be suitable for infant feeding.

This means vegetable protein(s) based products are also covered by the Codex Standard provided they meet the minimum composition and other requirements established in the Standard and other relevant Codex texts.

3.1.2 Infant formula prepared ready for consumption in accordance with instructions of the manufacturer 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 Infant formula prepared ready for consumption shall contain per 100 kcal (100 kJ) the following nutrients with the following minimum and maximum or guidance upper levels (GULs),[i] as appropriate. The general principles for establishing these levels are identified in Annex II of this standard.

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 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 infant formulas should usually not exceed the GULs unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formulas 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

More background on the principles for establishing minimum and maximum values can be found in Annex II.

Other optional ingredients covered in the next section can further support infant growth and development, but the essential composition established by the Codex Standard has a proven history of safe use and suitability for the growth and development of an infant.

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	-

[1)] For the purpose of this standard, the calculation of the protein content of the final product prepared 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. The value of 6.38 is generally established as a specific factor appropriate for conversion of nitrogen to protein in other milk products, and the value of 5.71 as a specific factor for conversion of nitrogen to protein in other soy products.

ISDI comment

ISDI notes that the nitrogen conversion factor (NCF) of 6.25 is established as a general conversion factor for finished Infant Formula products and is used for the determination of protein quantity and quality, including the assessment of essential and semi essential amino acid profile (Annex 1 of CXS 72-1981). Recognition is given to dairy commodity standards that use an NCF of 6.38.



Infant formula composition is not determined by individual nutrient requiremaents alone. Codex requirements for protein, carbohydrates, fats, and energy must be considered together, creating a carefully balanced nutritional framework. ISDI's interactive Macronutrient Calculator demonstrates how these requirements are interconnected and how adjustments to one macronutrient can influence the overall formulation.

[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); nevertheless for calculation purposes, the concentrations of tyrosine and phenylalanine may be added together. The concentrations of methionine and cysteine may be added together if the ratio is less than 2:1; in the case that the ratio is between 2:1 and 3:1, the suitability of the formula has to be demonstrated by clinical testing.

ISDI comment

ISDI notes that infant formula shall meet the minimum for each individual amino acid, with the exceptions specified in the standard where certain amino acids may be considered as a sum.

Specifically, tyrosine and phenylalanine may be added together and, methionine and cysteine may be added together, provided that the ratio of methionine and cysteine in the formula is less than 2:1. Manufacturers may consider using the option of expressing these amino acids as a sum depending on the composition of the formula.

For example, according to the Codex Standard, the minimum requirement for Cysteine is 21mg/g protein (38mg/100kcal) (see Annex 1), while the minimum requirement for methionine is 14mg/g protein (24mg/100kcal). In this case, the combined minimum requirement for methionine plus cysteine is 35mg/g protein (62mg/100kcal). Therefore, the combined concentrations of methionine and cysteine in the formula must be at least 35mg/g protein (62mg/100kcal) AND the ratio of methionine to cysteine must be less than 2:1, in order to meet the Codex requirements.

NOTE: If the ratio of methionine to cysteine is between 2:1 and 3:1, then the suitability of the formula has to be demonstrated by clinical testing.

[3)] Isolated amino acids may be added to infant formula 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.

[4)] The minimum value applies to cows' milk protein. For infant formula based on non-cows' milk protein other minimum values may need to be applied. For infant formula based on soy protein isolate, a minimum value of 2.25 g/100 kcal (0.54 g/100 kJ) applies.

[5)] Infant formula based on non-hydrolysed milk protein containing less than 2 g protein/100 kcal and infant formula based on hydrolysed protein containing less than 2.25 g protein/100 kcal should be clinically evaluated.

ISDI comment

Footnotes 4 and 5 further recognise the permitted protein sources for Infant Formula products, while also clarifying that soy protein isolate-based formula is subject to higher minimum protein requirement.

ISDI notes the use of the term 'clinically evaluated' in relation to both intact milk protein formula containing 1.8 to <2g protein/100kcal and hydrolysed protein containing 1.8g to <2.25g/100kcal. A clinical evaluation is required to demonstrate that the formula, at these protein levels, supports normal infant growth. This may be established through a randomised, controlled, parallel study in the relevant infant population, or through acceptable scientific evidence.

ISDI notes that a number of national regulations do not require 'clinical evaluation' for formula that meet compositional requirements, contain permitted protein sources and meet or exceed the established regulatory minimum protein levels (e.g. 1.8g/100kcal for milk protein). This reflects the body of evidence accumulated on the safety of protein levels at the regulated minimum since the revision of the Infant Formula standard in 2007.

b) Lipids

Total fat[6), 7)]

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

[6)] Commercially hydrogenated oils and fats shall not be used in infant formula.

[7)] Lauric and myristic acids are constituents of fats, but combined shall not exceed 20 percent of total fatty acids. The content of trans fatty acids shall not exceed 3 percent of total fatty acids. Trans fatty acids are endogenous components of milkfat. The acceptance of up to 3 percent of trans fatty acids is intended to allow for the use of milkfat in infant formulae. The erucic acid content shall not exceed 1 percent of total fatty acids. The total content of phospholipids should not exceed 300 mg/100 kcal (72 mg/100 kJ).

Linoleic acid

Unit	Minimum	Maximum	GUL
mg/100 kcal	300	-	1 400
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/α-linolenic acid

Min	Max
5:1	15:1

ISDI comment

Fat and the fatty acids linoleic acid (LA) and alpha-linolenic acid (ALA) are essential components of Infant Formula and their composition levels are prescribed in the Codex Standard. Fat provides a dense source of energy, facilitates the absorption of fat-soluble dietary components, such as vitamins, and supplies essential fatty acids, including ALA and LA, to the body (EFSA, 2013).

One of the main functions of LA (C18:2 n-6) and ALA (C18:3 n-3) is to regulate the cell membrane fluidity and serve as precursors for the long chain polyunsaturated fatty acids(LC-PUFAs) arachidonic acid (ARA), eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) from which eicosanoids and docosanoids can beformed. In particular, DHAcontributes to thenormal development of the nervous system and retina and accumulates in the fetal brain and retina during pregnancy and early childhood (Koletzko et al., 2008).

Scientific Opinion on nutrient requirements and dietary intakes of infants and young children in the European Union, EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA). 2013. DOI:10.2903/j.efsa.2013.3408.
The roles of long-chain polyunsaturated fatty acids in pregnancy, lactation and infancy: review of current knowledge and consensus recommendations, Koletzko B et al. 2008. DOI:10.1515/JPM.2008.001.

c) Carbohydrates

Available carbohydrates[8)]

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

[8)] Lactose and glucose polymers should be the preferred carbohydrates in formula based on cows' milk protein and hydrolysed protein. Only precooked and/or gelatinized starches gluten free by nature may be added to infant formula up to 30 percent of total carbohydrates and up to 2 g/100 ml.

Sucrose, unless needed, and the addition of fructose as an ingredient, should be avoided in infant formula because of potential life-threatening symptoms in young infants with unrecognized hereditary fructose intolerance.

ISDI comment

ISDI notes that the intention of these clauses is to highlight preferred carbohydrate sources, limit the direct addition of the sugars sucrose and fructose, and manage sweetness. The text refers to sucrose, unless needed, and fructose, to acknowledge that, in certain cases, these sugars may be present in low levels as a result of other ingredients (e.g. fructooligosaccharides) or may be used to improve the palatability of hydrolysed formula.

d) Vitamins

Vitamin A

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

[9)] Expressed as retinol equivalents (RE).

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

Vitamin D_3

Unit	Minimum	Maximum	GUL
µg[10)]/100 kcal	1.0	2.5	-
µg[10)]/100 kJ	0.24	0.6	-

[10)] Calciferol 1 µg calciferol = 40 IU vitamin D

ISDI comment

Although the Infant Formula Standard only specificies vitamin D_3 (Cholecalciferol), ISDI notes that the Advisory List of Nutrient compounds for use in foods for special dietary uses intended for infants and young children (CAG 10-1979) includes vitamin D_2 (Ergocalciferol) as a source of vitamin D for use in Infant Formula.

ISDI also notes that vitamin D, rather than specifically vitamin D_3 is specified in the compositional requirements in the Codex Standard for Follow-up formula for Older Infants and Product for Young Children (CXS 156-1987).

Based on point 3.4 of the Infant Formula Standard, which states that "Vitamins and minerals added in accordance with Section 3.1.3 (d and e) and other nutrients added in accordance with 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)", ISDI considers that both vitamin D_2 and vitamin D_3 may be used as sources of Vitamin D in Infant Formula. This interpretation is without prejudice to national regulations and their interpretations.

ISDI also notes the importance of allowing vitamin D_2 as it enables the formulation of vegetarian infant formulas.

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

[11] 1 mg α-TE (alpha-tocopherol equivalent) = 1 mg d-α-tocopherol.

[12] Vitamin E content 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 -TE/g linoleic acid (18:2 n-6); 0.75 α-TE/g α-linolenic acid (18:3 n-3); 1.0 mg α-TE/g arachidonic acid (20:4 n-6); 1.25 mg α-TE/g eicosapentaenoic acid (20:5 n-3); 1.5 mg α-TE/g docosahexaenoic acid (22:6 n-3).

Vitamin K

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

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

ISDI comment

ISDI notes that the Advisory List of Nutrient Compounds for use in foods for special dietary uses intended for infants and young children (CXG 10-1979) refers to Phytomenadione (2-Methyl-3-phytyl-1,4-naphthoquinone/ Phylloquinone/Phytonadione) as a source of vitamin K1.

Niacin[13]

Unit	Minimum	Maximum	GUL
µg/100 kcal	300	-	1 500
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	-	2 000
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
mg/100 kcal	10	-	70[15]
mg/100 kJ	2.4	-	17[15]

[14] Expressed as L-ascorbic acid.

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

Biotin

Unit	Minimum	Maximum	GUL
µg/100 kcal	1.5	-	10
µg/100 kJ	0.436	-	2.4

e) Minerals and trace elements

Iron

Unit	Minimum	Maximum	GUL[16]
mg/100 kcal	0.45	-	-
mg/100 kJ	0.1	-	-

[16] Levels may need to be determined by national authorities.

ISDI comment

ISDI notes that, for Iron, the Codex Standard establishes a minimum level of 0.45 mg/100 kcal while no maximum level is specified.

Calcium

Unit	Minimum	Maximum	GUL
mg/100 kcal	50	-	140
mg/100 kJ	12	-	35

Phosphorus

Unit	Minimum	Maximum	GUL
mg/100 kcal	25	-	100[17]
mg/100 kJ	6	-	24[17]

[17] This GUL should accommodate higher needs for infant formula based on soy protein isolate.

ISDI comment

According to footnote 17, and for clarity purposes, ISDI notes that these GULs of 100 mg/100 kcal (24 mg/100 kJ) for phosphorus are also applicable to soy-based formula.

Ratio calcium/phosphorus

Min	Max
1:1	2:1

Magnesium

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

Sodium

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

Chloride

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

Potassium

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

Manganese

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

Iodine

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

Selenium

Unit	Minimum	Maximum	GUL
µg/100 kcal	1	-	9
µg/100 kJ	0.24	-	2.2

Copper[18)]

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

[18)] Adjustment may be needed in these levels for infant formula made in regions with a high content of copper in the water supply.

Zinc

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

f) Other substances

Choline

Unit	Minimum	Maximum	GUL
mg/100 kcal	7	-	50
mg/100 kJ	1.7	-	12

Myo-Inositol

Unit	Minimum	Maximum	GUL
mg/100 kcal	4	-	40
mg/100 kJ	1	-	10

L-Carnitine

Unit	Minimum	Maximum	GUL
mg/100 kcal	1.2	N.S.	-
mg/100 kJ	0.3	N.S.	-

ISDI comment

ISDI considers it essential to highlight the importance of the macro and micronutrients listed in section 3.1 Essential Composition of SECTION A: STANDARD FOR INFANT FORMULA, which are required to ensure the nutritional adequacy of the product . This is particularly critical for the growth and development of infants who rely on Infant Formula as their sole source of nutrition during the first months of life, until the introduction of complementary feeding.

Infant Formula shall contain the listed nutrients within the established minimum and maximum or **guidance upper level (GUL)**, as appropriate. In establishing these values, both nutritional adequacy and safety considerations have been taken into account. The determination of upper levels follows a science-based risk assessment approach. Where insufficient information is available to perform such an assessment, guidance upper levels are established.

The purpose of the GULs is to provide guidance to manufacturers and they should not be considered equivalent to maximum limits. For further information on the intent and application of GULs, please refer to Section 3.1.3 of SECTION A: STANDARD FOR INFANT FORMULA and footnote 1.

3.2 Optional ingredients

3.2.1 In addition to the compositional requirements listed under Section A 3.1.3, other ingredients may be added in order to provide substances ordinarily found in human milk and to ensure that the formulation is suitable as the sole source of nutrition for the infant or to provide other benefits that are similar to outcomes of populations of breastfed babies.

3.2.2 The suitability for the particular nutritional uses for infants and the safety of these substances shall be scientifically demonstrated. The formula shall contain sufficient amounts of these substances to achieve the intended effect, taking into account levels in human milk.

ISDI comment

This section permits the addition of optional ingredients naturally found in human milk, as well as other optional ingredients that have been shown to provide outcomes in formula-fed infants similar to those observed in breast-fed infants.

The provision for optional ingredients allows manufacturers to include additional ingredients that are not specifically listed in the Infant Formula Standard. However, the burden of demonstrating compliance with the two criteria established in Section 3.2 Optional ingredients rests with the manufacturer: 1) the safety of the ingredient must be scientifically demonstrated; and 2) the level of the ingredient in Infant Formula must take into consideration levels found in breastmilk and/or levels shown to provide benefits similar to outcomes observed in breast-fed infants. This principle is essential to enable the continued development of Infant Formula.

Scientific substantiation supporting the safety and suitability of optional ingredients for use in Infant Formula may include clinical and/or non-clinical data, such as animal and in-vitro studies.

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3.2.3 The following substances may be added in conformity with national legislation, in which case their content per 100 kcal (100 kJ) in the infant formula ready for consumption shall not exceed:

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[19)]

Unit	Minimum	Maximum	GUL
% of fatty acids	-	-	0.5

[19)] If docosahexaenoic acid (22:6 n-3) is added to infant formula, 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. National authorities may deviate from the above conditions, as appropriate for the nutritional needs.

3.2.4 Only L(+) lactic acid-producing cultures may be used.

ISDI comment

Section 3.2.3 provides a non-exchaustive list of optional ingredients that may be added to Infant Formula.

Section 3.2.4 clarifies that only L(+) lactic acid producing cultures meeting the requirements established for optional ingredients may be used.

ISDI notes that this provision allows the addition of L(+) lactic acid producing cultures in Infant Formula, in particular for acidification purposes or to confer specific physiological effects.

Upper nutrient levels to be defined by national authorities

The Standard allows national authorities to establish maximum levels or guidance upper levels (GULs) for iron, nucleotides and DHA:ARA ratios as no global consensus could be reached on their upper levels during the CCNFSDU discussion.

For nucleotides, the Standard does not specify a maximum level for total nucleotides or for the levels of each of the five individual nucleotides.

For the DHA/ARA ratio, the Standard establishes a GUL for DHA of 0.5% of total fatty acids, a minimum ratio of 1:1, and an EPA level not exceeding the DHA level). Minimum and maximum levels for DHA are not specified in the Standard and remain subject to local regulations.

3.3 Fluoride

Fluoride should not be added to infant formula. In any case its level should not exceed 100 µg/100 kcal (24 µg/100 kJ) in infant formula prepared ready for consumption as recommended by the manufacturer.

3.4 Vitamin compounds and mineral salts

Vitamins and minerals added in accordance with Section A 3.1.3 (d and e) and other nutrients added in accordance with Section A 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]

3.5 Consistency and particle size

When prepared according to the label directions for use, the product shall be free of lumps and of large coarse particles and suitable for adequate feeding of young infants.

3.6 Purity requirements

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

3.7 Specific prohibitions

The product and its component shall not have been treated by ionizing irradiation.

4. FOOD ADDITIVES

4.1 Acidity regulators, antioxidants, carriers, emulsifiers, packaging gases and thickeners used in accordance with Table 1 and Table 2 of the *General standard for food additives* (CXS 192-1995)[1] in food category 13.1.1 (Infant formulae) are acceptable for use in foods conforming to this standard.

4.2 Only the food additives listed in food category 13.1.1 (Infant formulae) of the above-mentioned standard (CXS 192-1995)[1] may be present in the foods conforming to 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

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

Food additives are substances intentionally added to food for a technological purpose during the manufacture, processing or preservation of the product (Codex General Standard for food additives, CXS 192-1995). Codex establishes the fundamental principle that the use and level of food additives in Infant Formula should be limited as much as possible. In 1971, JECFA established a list of functional classes of food additives considered appropriate for use in these products including acidity regulators, antioxidants, emulsifiers stabilisers, thickeners and packaging gases. ISDI also notes that flavours are not authorised in Infant Formula.

The food additives authorised for use in Infant Formula are specified in the Codex General Standard for Food Additives (GSFA, CXS 192-1995) in tables 1 and 2, under food category 13.1.1. Section 6 of the preamble to the GSFA indicates that *"Unless otherwise specified, maximum use levels for additives in Tables 1 and 2 are set on the final product as consumed."* Therefore, the additive provisions in the GSFA for infant formula apply to all infant formula products as they are consumed, following preparation. This means that:

The maximum level (ML) applies directly to liquid products sold "ready to feed";

The ML would need to be adjusted for products that require reconstitution prior to feeding, including both concentrated liquid products and powdered products;

In cases where the ML requires adjustment, the adjustment should be based on manufacturers' preparation instructions.

For example, if an additive ML is 100 mg/L in the GSFA and the product is a concentrated liquid that should be diluted 2x with water prior to consumption, then the ML for the additive in the product as sold (prior to reconstitution) would be 200 mg/L, reflecting that the concentration of the additive in the product following reconstitution would be ½ the amount in the product as sold.

The relevant infant formula provisions from the GSFA can be found in Appendix II of this brochure.

Please refer to the ISDI brochure on Food Additives in Infant Formula for further information.

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 residues limits for pesticides established by the Codex Alimentarius Commission (CAC).

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]

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 food* (CXG 21-1997).[8]

ISDI comment

The Standard includes hygiene criteria as defined by the International Code of Hygienic Practice for powdered formulae for Infants and young Children (CXC 66-2008).

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.

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

8. FILL OF CONTAINER

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

a) not less than 80 percent v/v for products weighing less than 150 g (5 oz);

b) not less than 85 percent v/v for products in the weight range 150–250 g (5-8 oz); and

c) not less than 90 percent v/v for products weighing more than 250 g (8 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 completely filled.

9. LABELLING

The requirements of the *General standard for the labelling of pre-packaged foods* (CXS 1-1985),[9] the *Guidelines on nutrition labelling* (CXG 2-1985)[10] and the *Guidelines for use of nutrition and health claims* (CXG 23-1997)[11] apply to infant formula and formula for special medical purposes for infants. 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. In addition to these requirements the following specific provisions apply:

ISDI comment

The practical implication is that claims on Infant Formula and FSMP intended for infants are prohibited unless national authorities establish specific legislation permitting such claims. ISDI notes that substantiated nutrition and health claims can provide consumers with reliable information to support informed choices at the point of purchase. Please refer to the ISDI brochure on Foods for Special Dietary Uses & Claims for further information.

9.1 The name of the food

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

9.1.2 The name of the product shall be either "Infant formula" or any appropriate designation indicating the true nature of the product, in accordance with national usage.

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

9.1.4 If cows' milk is the only source of protein, the product may be labelled "Infant formula based on cows' milk".

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

9.2 List of ingredients

9.2.1 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.

9.2.2 The specific name shall be declared for ingredients of animal or plant origin and for food additives. In addition, appropriate class names for these ingredients and additives may be included on the label.

9.3 Declaration of nutritive value

The declaration of nutrition information 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 grams or per 100 millilitres of the food as sold as well as per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.

b) the total quantity of each vitamin, mineral, choline as listed in Section A 3.1.3 and any other ingredient as listed in Section A 3.2 of this standard per 100 grams or per 100 millilitres of the food as sold as well as per 100 millilitres 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 kilocalories (or per 100 kilojoules) is permitted.

ISDI comment

Infant formula like any other food products including Foods for Special Dietary Uses are subject to label tolerance. Label tolerance is the acceptable difference between the value declared in the nutrient declaration on the label of the product and the value obtained by analysis from the time of manufacture through to the end of the product shelf-life. It is to be distinguished from the permissible range of the nutrient content allowed in the product such as regulatory limits of nutrients taking into account minimum and maximum levels for a particular product category: Foods for Special Medical Purposes (FSMPs), infant formula, follow-up formula, etc. The minimum specifications must ensure adequate nutrition is delivered to the end user.

For more details on label tolerance, see the ISDI Guidelines on Setting Tolerances for Nutrient Values Declared on Labels for Foods for Special Dietary Uses (FSDU).

9.4 Date marking and storage instructions

9.4.1 The date of minimum durability (preceded by the words "best before") shall be declared by the day, month and year in uncoded numerical sequence, except that for products with a shelf life of more than three months, the month and year will suffice. The month may be indicated by letters in those countries where such use will not confuse the consumer.

In the case of products requiring a declaration of month and year only, and the shelf life of the product is valid to the end of a given year, the expression "end (stated year)" may be used as an alternative.

9.4.2 In addition to the date, any special conditions for the storage of the food shall be indicated if the validity of the date depends thereon.

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

9.5 Information for use

9.5.1 Products in liquid form may be used either directly or in the case of concentrated liquid products, must be prepared with water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. Products in powder form should be reconstituted with water that is safe or has been rendered safe by previous boiling for preparation. Adequate directions for the appropriate preparation and handling should be in accordance with good hygienic practice.

9.5.2 Adequate directions for the appropriate preparations and use of the product, including its storage and disposal after preparation, i.e. that formula remaining after feeding should be discarded, shall appear on the label and in any accompanying leaflet.

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.

9.5.5 Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label and in any accompanying leaflet.

9.6 Additional labelling requirements

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;

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

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

9.6.2 The label shall have no pictures of infants and women nor any other picture or text which idealizes the use of infant formula.

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

9.6.4 Information shall appear on the label to the effect that infants should receive complementary foods in addition to the formula, from an age that is appropriate for their specific growth and development needs, as advised by an independent health worker, and in any case from the age over 6 months.

9.6.5 The products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula, and formula for special medical purposes.

ISDI comment

The use of specific labels for infant formulas, follow-up formulas and product for young children supports the age-appropriate use of these products as children grow. It also helps distinguish between these products and facilitates the identification of potential allergens.

For a comprehensive overview of the labelling requirements for infant formula, please refer to Appendix I of this brochure. It compiles both the specific labelling requirements for infant formula and the general labelling provisions applicable to this product category, as set out the General Standard for Labelling of prepackaged foods (CXS 1-1985).

Front of Pack Nutrition Labelling (FOPNL)

FOPNL schemes developed for the general healthy adult population are not appropriate for infants and young children. Products specifically formulated for this target population should therefore be excluded from the scope of FOPNL schemes.

The Codex Guidelines on Nutrition Labelling (CXG 2-1985) in Annex 2, explicitly excludes products covered by the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CXS 72-1981). Please refer to the ISDI brochure on Foods for Special Dietary Uses and Front of Pack Nutrition Labelling for further information.

ISDI re-emphasises that the compositional requirements for Infant Formula are specifically designed to meet the nutritional needs of infants and are based on robust scientific evidence, including the recommendations of recognised authoritative scientific bodies (RASBs) (e.g. energy contribution from macronutrients and the

contribution of micronutrients to recommended daily intakes). Infant Formula is standardised under Codex and is subject to more stringent compositional and food safety requirements than foods intended for the general population.

Applying FOPNL schemes and nutrient profiling models developed for the general adult healthy population to Infant Formula and other food for special dietary uses would mislead consumers and hinder informed choices that reflect the specific nutritional needs of these vulnerable population groups. It would also unjustifiably discriminate against these product categories and undermine their intended purpose. ISDI considers that this position is consistent with the "WHO Guiding principles and framework manual for front-of-pack labelling for promoting healthy diet". In the scope section, WHO explains that standardised foods for infants and young children have "strict compositional criteria; hence, promoting reformulated products is not appropriate".

10. 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)[12] relevant to the provisions in this standard, shall be used.

ISDI comment

Test methods play an essential role in ensuring the safety and nutritional quality of infant formulas. CXS 234-199 specifies internationally recognised methods of analysis for a wide range of food categories, including methods specifically applicable to foods for special dietary uses (FSDU) and infant formula.

To facilitate the use of these methods, ISDI has developed a website that provides a comprehensive guide to the analytical methods for nutrients in FSDU, including infant formula. The platform is based on the methods included in CXS 234-1999 and also contains additional internationally recognised methods where relevant. It is intended to assist authorities, laboratories and industry professionals in identifying internationally recognised analytical methods and to support harmonised application of testing methods worldwide. It serves as a practical reference reflecting the global consensus on methods of analysis for special dietary foods.



Annex I

Essential and semi-essential amino acids in breastmilk*

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 breastmilk 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.

	Lönnerdal and Forsum (1985)		Darragh and Moughan (1998)		Bindels and 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 acid 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 k cal	g N	100 k cal	g N	100 k cal	g N	100 k cal	g N	100 kc al	g N	100 kc al	g N	100 kcal	g N	100 k cal	g nitroge n	g protei n	100 kc al
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*

	Lönnerdal and Forsum (1985)		Darragh and Moughan (1998)		Bindels and 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 acid 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 k cal**	**g N**	**100 k cal**	**g N**	**100 k cal**	**g N**	**100 k cal**	**g N**	**100 kc al**	**g N**	**100 kc al**	**g N**	**100 kcal**	**g N**	**100 k cal**	**g nitroge n**	**g protei n**	**100 kc al**
Methionine	78	*22*	90	*26*	89	*26*	73	*21*	99	*29*	76	*22*	83	*24*	92	*26*	85	14	*24*
Phenylalani ne	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	*105*	315	50	*90*

References

Bindels JG, Harzer G (1985) Aminosäuren- und Proteinzusammensetzung der Frauenmilch im Verlauf der Laktation. *Ernährungs-Umschau* 32: 223–224.

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

Janas LM, Picciano MF, Hatch TF (1987) Indices of protein metabolism in term infants fed either human milk or formulas with reduced protein concentration and various whey/casein ratios. *J. Pediatr.* 110: 838–848.

Lönnerdal B, Forsum E (1985) Casein content of human milk. *Am. J. Clin. Nutr.* 41: 113–120.

Räihä NCR, Fazzolari-Nesci A, Cajozzo C, Puccio G, Monestier A, Moro G, Minoli I, Haschke-Becher E, Bachmann C, Van't Hof M, Carrié Fässler A-L, Haschke F (2002) Whey predominant, whey modified infant formula with protein/energy ratio of 1.8 g/100 kcal: adequate and safe for term infants from birth to four months. *J. Pediatr. Gastroenterol. Nutr.* 35: 275–281.

Villalpando S, Butte NF, Flores-Huerta S, Thotathuchery M (1998) Qualitative analysis of human milk produced by women consuming a maize-predominant diet typical of rural Mexico. *Ann. Nutr. Metab.* 42: 23–32.

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.

Annex II

GENERAL PRINCIPLES FOR ESTABLISHING MINIMUM AND MAXIMUM VALUES FOR THE ESSENTIAL COMPOSITION OF INFANT FORMULA

1. The goal of establishing minimum and maximum values is to provide safe and nutritionally adequate infant formula products that meet the normal nutritional requirements of infants.

2. A nutritionally adequate infant formula will promote growth and development consistent with science-based standards and meet the nutritional requirements of infants when fed as a sole source of nutrition during the first months of life up to the introduction of appropriate complementary feeding.

3. The values to be established are based on an independent evaluation, in particular of the scientific evidence of the amounts needed to meet the nutritional requirements of infants, considering relevant human infant studies and the composition of breastmilk.

4. In addition to the principles set out in No. 3, when setting minimum and maximum values, consideration will also be given to the safety of such values.

   For nutrients with a documented risk of adverse health effects the upper levels to be taken into account will be determined using a science-based risk assessment approach. Where scientific data are not sufficient for a science-based risk assessment, consideration should be given to an established history of apparently safe use of the nutrient in infants, as appropriate. Values derived on the basis of meeting the nutritional requirements of infants and an established history of apparently safe use should be considered as interim guidance upper levels (GULs). The approach to setting maximum and GULs shall be made transparent and comprehensible.

5. When establishing minimum and maximum amounts, the following should also be taken into account:

   a) bioavailability, processing losses and shelf-life stability from the ingredients and formula matrix;

   b) total levels of a nutrient in infant formula, taking into account both naturally occurring nutrients in the ingredients and added nutrients; and

   c) the inherent variability of nutrients in ingredients and in water that may be added to the infant formula during manufacture.

6. Averages for individual nutrients, as appropriate, to ensure that the required minimum levels are met throughout the shelf life of the formula, will be included in the maximum value.

7. In establishing minimum or maximum amounts of nutrients per 100 kcal (or per 100 kJ) of infant formula based on consideration of reference values for the nutrients expressed as units per daily intake or per kilogram of body weight, the following assumptions will be considered:

   a) the mean intake of prepared formula for infants from birth to six months of age is 750 ml per day;

   b) a representative body weight for an infant over this period is 5 kg; and

   c) a representative caloric intake of an infant over this period is 500 kcal per day (or 100 kcal/kg/day).

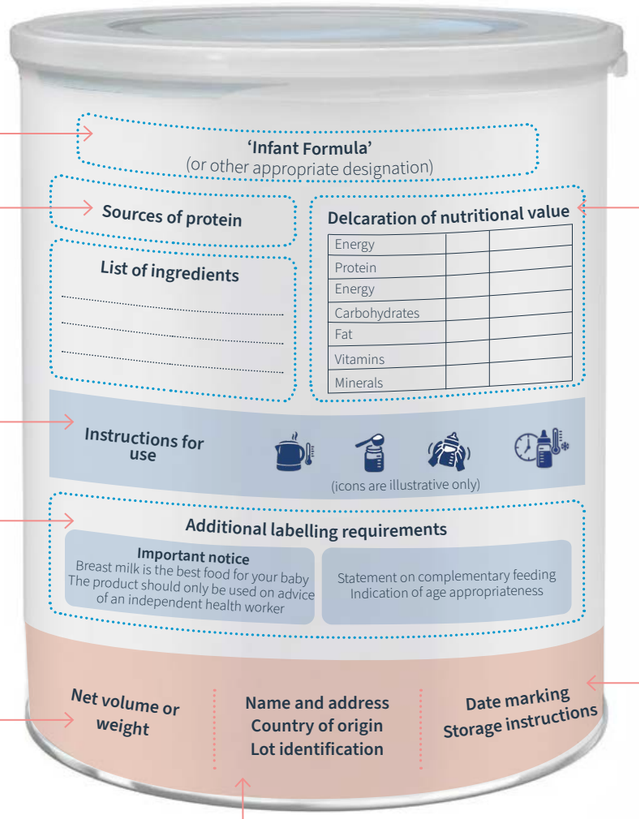
Modifications of the approach may be needed when there is justification for deviating from one or more of these assumptions with regard to the specific formula product or specific infant population group.

APPENDIX I: Mock-up of mandatory labelling requirements for Infant Formula based on Codex Alimentarius

Sources of protein
If cow's milk is the only source of protein: May be labelled "Infant Formula Based on Cow's Milk"

If the product contains Neither milk nor milk derivative => the product shall be labelled with "contains no milk or milk products" or an equivalent phrase

Name of the food: 'Infant Formula'
or any appropriate designation indicating the true nature of the product, in accordance with national usage.



List of 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 / 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.

    The specific name shall be declared for ingredients of animal or plant origin
- Added water
- Compound ingredient
- Allergens highlighted. Infant formula products cannot be labelled "glutenfree" as per section 3.1 All ingredients and food additives shall be glutenfree.
- Class names can be used
- Food Additives => Names and INS number shall be declared. Appropriate functional class may be included on the label (For further details see ISDI Brochure on "Use of additives in infant formula and formulas for special medical purposes intended for infants")
- Quantitative ingredients declaration - if relevant

Instructions for Use / Information for use
- Products in liquid form may be used either directly or in the case of concentrated liquid products, must be prepared with water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use Products in powder form should be reconstituted with water that is safe or has been rendered safe by previous boiling for preparation. Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.
- Adequate directions for the appropriate preparations and use of the product, including its storage and disposal after preparation, i.e. that formula remaining after feeding should be discarded, shall appear on the label and in any accompanying leaflet.
- Clear graphic instructions illustrating the method of preparation of the product
- 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 and in any accompanying leaflet.

Declaration of Nutrition Value
It shall contain the following information which should be in the following order
- Energy (kcal and/or kJ)
- Protein (g)
- Carbohydrate (g)
- Fat
- Total quantity of each Vitamin, mineral, choline listed in section 3.1.3. and any other
- ingredient as listed in paragraph 3.2. of this standard
- * 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

*Important: Infant formula are excluded from Front of Pack Nutrition Labelling (FOPNL) - see Annex 2 of Guidelines on Nutrition Labelling CXG 2-1985

Additional labelling requirements
- "Important Notice" or their equivalent
- "Breast milk is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breast milk
- "The product should only be used on advice of an independent health worker as to the need for its use and the proper method of use."
- Information shall appear on the label to the effect that infants should receive complementary foods in addition to the formula, from an age that is appropriate for their specific growth and development needs, as advised by an independent health worker, and in any case from the age over six months.
- The products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula, and formula for special medical purposes.
- Indication of age or from birth onward in line with 9.6.5 and with national

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

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.

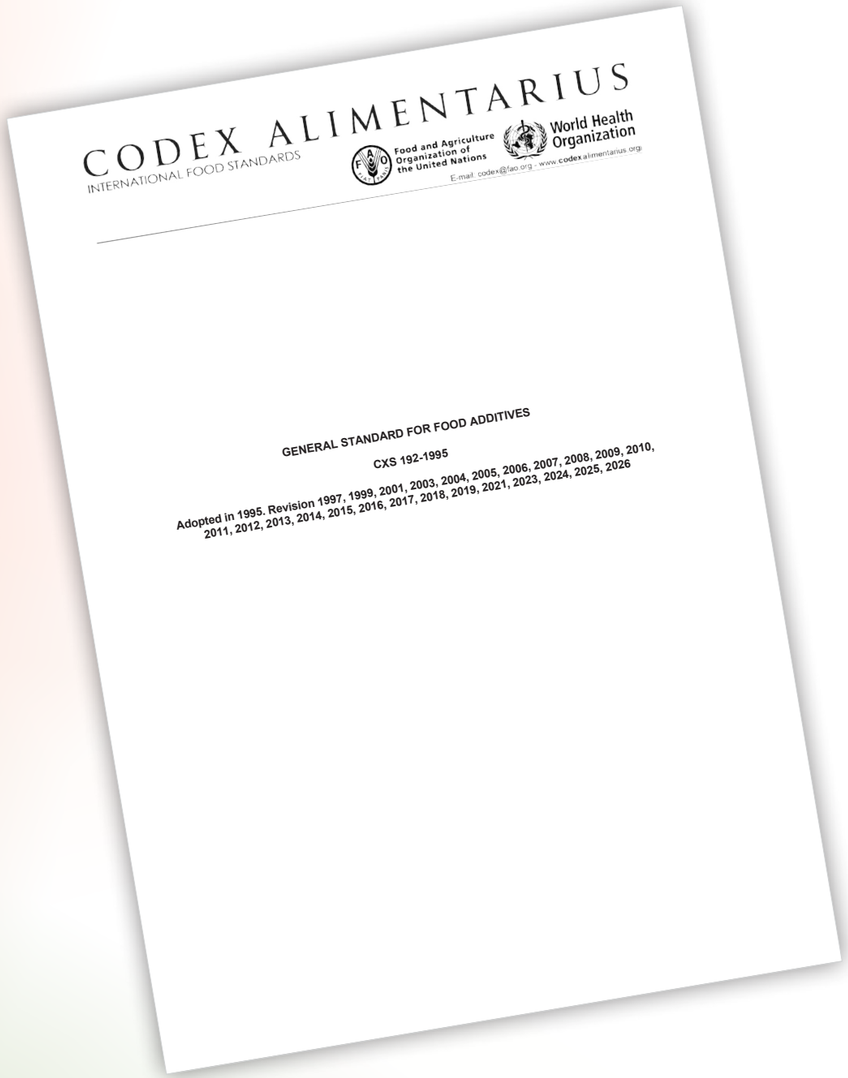
In date marking & storage instructions
- Minimum durability (preceded by the words "best before") shall be declared by the day, month and year in uncoded numerical sequence except that for products with a shelf-life of more than three months, the month and year will suffice. The month may be indicated by letters in those countries where such use will not confuse the consumer.
- In addition to the date, any special conditions for the storage of the food shall be indicated if the validity of the date depends thereon. Where practicable,storage instructions shall be in close proximity to the date marking.

Prohibited

1. No pictures of infants and women nor any other picture or text which idealizes the use of infant formula.
2. "Humanized ", "maternalized" or other similar terms
3. Prohibition on the use of nutrition and health claims except where specifically provided for in relevant Codex Standards or national legislation.

Legend
- General Standard for the Labelling of Prepackaged Foods (CXS 1-1985)
- Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CXS 72-1981)
- ISDI clarifications

APPENDIX II: Infant Formula provisions in the Codex General Standard for Food Additives (CXS 192-1995)



CODEX ALIMENTARIUS
INTERNATIONAL FOOD STANDARDS

Food and Agriculture Organization of the United Nations
World Health Organization

E-mail: codex@fao.org - www.codexalimentarius.org

GENERAL STANDARD FOR FOOD ADDITIVES

CXS 192-1995

Adopted in 1995. Revision 1997, 1999, 2001, 2003, 2004, 2005, 2006, 2007, 2008, 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017, 2018, 2019, 2021, 2023, 2024, 2025, 2026

Table Two

Food Category No. 13.1.1 Infant formulae

Additive	INS	Year Adopted	Max Level	Notes
ASCORBYL ESTERS	304, 305	2026	10 mg/kg	187 & 551
CALCIUM HYDROXIDE	526	2026	2000 mg/kg	55 & 551
CARBON DIOXIDE	290	2015	GMP	59
CAROB BEAN GUM	410	2026	1000 mg/kg	551
CARRAGEENAN	407	2026	300 mg/kg	584 & 551
CITRIC ACID	330	2026	GMP	551
CITRIC AND FATTY ACID ESTERS OF GLYCEROL	472c	2026	9000 mg/kg	380 & 551
GUM ARABIC (ACACIA GUM)	414	2026	10 mg/kg	589 & 551
LACTIC ACID, L-, D- and DL-	270	2026	GMP	83 & 551
LECITHIN	322(i)	2026	5000 mg/kg	585 & 551
MANNITOL	421	2026	10 mg/kg	589 & 551
MONO- AND DI-GLYCERIDES OF FATTY ACIDS	471	2026	4000 mg/kg	585 & 551
NITROGEN	941	2015	GMP	59
PHOSPHATES	338; 339(i)-(iii); 340(i)-(iii); 341(i)-(iii); 342(i)-(ii); 343(i)-(iii); 450(i)-(iii),(v)-(vii), (ix); 451(i),(ii); 452(i)-(v); 542	2026	450 mg/kg	33, 230, 586, 587 & 551
POTASSIUM CARBONATE	501(i)	2026	2000 mg/kg	55 & 551
POTASSIUM DIHYDROGEN CITRATE	332(i)	2026	GMP	55 & 551
POTASSIUM HYDROGEN CARBONATE	501(ii)	2026	2000 mg/kg	55 & 551
POTASSIUM HYDROXIDE	525	2026	2000 mg/kg	55 & 551
SILICON DIOXIDE, AMORPHOUS	551	2026	10 mg/kg	589 & 551
SODIUM ASCORBATE	301	2026	75 mg/kg	83, 551 & 591
SODIUM CARBONATE	500(i)	2026	2000 mg/kg	55 & 551
SODIUM DIHYDROGEN CITRATE	331(i)	2026	GMP	55 & 551
SODIUM HYDROGEN CARBONATE	500(ii)	2026	2000 mg/kg	55 & 551
SODIUM HYDROXIDE	524	2026	2000 mg/kg	55 & 551
STARCH SODIUM OCTENYL SUCCINATE	1450	2026	20000 mg/kg	376, 590 & 551
TOCOPHEROLS	307a, b, c	2026	10 mg/kg	416 & 551
TRIPOTASSIUM CITRATE	332(ii)	2026	GMP	55 & 551
TRISODIUM CITRATE	331(iii)	2026	GMP	55 & 551

NOTES

Note 14: For use in hydrolyzed protein liquid formula only
Note 33: As phosphorus
Note 55: Within the limits for sodium, calcium, and potassium specified in the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CXS 72-1981): singly or in combination with other sodium, calcium, and/or potassium salts.
Note 59: For use as a packaging gas only
Note 83: L(+) form only
Note 150: For use in soy-based formula only
Note 187: Ascorbyl palmitate (INS 304) only
Note 230: For use as an acidity regulator only
Note 284: Singly or in combination: INS 1412, 1413, 1414 and 1440 in products conforming to the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981)
Note 292: Except for use in hydrolyzed protein and/or amino acid-based formula at 25 000 mg/kg
Note 376: For use in hydrolyzed protein and/or amino acid based infant formula only
Note 416: Tocopherol concentrate, mixed (INS 307b) only
Note 551: Maximum use level is expressed as mg additive/L of food
Note 584: For use in liquid infant formula except for use in hydrolysed protein and/or amino acid based liquid infant formula at 1000 mg/kg
Note 586: For use in products conforming to the Standard for Infant Formula and Formula for Special Medical Purposes Intended for Infants (CXS 72-1981): Sodium dihydrogen phosphate (INS 339(i)), Disodium hydrogen phosphate (INS 339(ii)), Trisodium phosphate (INS 339(iii)), Potassium dihydrogen phosphate (INS 340(i)), Dipotassium hydrogen phosphate (INS 340(ii)), and Tripotassium phosphate (INS 340(iii)) only, singly or in combination
Note 587: Within the limits for sodium, potassium and phosphorus specified in the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CXS 72-1981).
Note 589: For use as a nutrient carrier in a raw material or other ingredient
Note 590: For use as a nutrient carrier in a raw material or other ingredient at 100 mg/kg in the food as consumed Note 591: For use as a nutrient carrier in a raw material or other ingredient, in coating of nutrient preparations containing polyunsaturated fatty acids

ISDI comment

Following CCFA56, provisions for Acetylated Distarch Phosphate (INS 1414), Distarch Phosphate (INS 1412), Guar Gum (INS 412), Hydroxypropyl Starch (INS 1440), and Phosphated Distarch Phosphate (INS 1413) were removed from Category 13.1.1 (Infant Formulae) of the GSFA. This decision formed part of the broader review of additives used in infant formula and reflected the conclusion that these additives were no longer widely used. Four of the five substances belong to the modified starch category, suggesting that more technologically advanced alternatives may now be available.

ISDI fully supports the principle that the use of food additives in infant formula should be restricted to cases where there is a demonstrated technological need and established safety for the sensitive populations consuming these products. In line with this principle, ISDI has actively contributed industry expertise and technical input throughout the review process and supported the revocation of these additives.

At the same time, the successful removal of unnecessary additives should not be interpreted as evidence that all additive use can be eliminated from infant formula. Certain additives continue to fulfil essential technological functions that help ensure product safety, quality, stability, and nutritional integrity. Industry therefore remains committed to keeping additive use, and resulting consumer exposure, as low as reasonably achievable, consistent with the General Principles for the Use of Food Additives in the GSFA and the objective of maintaining the highest level of consumer protection.

For further information on the use of additives in infant formula, please refer to ISDI's brochure on this topic.

Scan the QR code for Appendix III

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