INFANT FORMULA

isdi

International Special
Dietary Foods Industries

DISCLAIMER

This guidance document is intended to provide information on Infant Formula in the context of the Codex Alimentarius. 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 italic are directly taken from Codex texts.***

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USER GUIDE

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

PURPOSE OF THE BROCHURE
The brochure provides the international background regarding Infant Formula based on SECTION A of the STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS (**CXS 72-1981**) which defines at international level this category of products. The brochure will exclusively describe SECTION A: STANDARD FOR INFANT FORMULA and will not address FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS. These formulas are included in the ISDI brochure on Foods for Special Medical Purposes (FSMP). **Please click here** to access the ISDI brochure on FSMP.

This brochure does not cover Follow-up formula products (Standard for Follow-up formula - **CXS 156-1987**).

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 purpose and aims to facilitate the reading and understanding of:
• SECTION A: STANDARD FOR INFANT FORMULA

The brochure can be used as a support for Food Business Manufacturers 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, FSDU, FSMP or other specialised nutrition products in each country and should not be considered in isolation.

THE BREASTMILK SUBSTITUTE

The best start babies can have is to be breastfed as it provides all the energy and nutrients they need for healthy growth and development in the first months of life. It is the first milestone in establishing the foundation for future health.

However, when breastmilk is not an option for an infant or the infant is partially breastfed, breastmilk substitutes (i.e. Infant Formula) are the only proven nutritious alternative recognised by the WHO.

Infant Formula was developed 150 years ago to reduce infant mortality and morbidity for those babies who were not being breastfed. ISDI and its members continue the research to provide a product that resembles breast milk as closely as possible and meets the nutritional needs of a vulnerable infant population. Infant Formula reflects these benefits on growth, immune response, gut flora and cognitive development.

ISDI and its members continue the research aimed at providing a product that benchmarks breast milk as closely as possible and meets the nutritional needs of a vulnerable infant population. Infant Formula contains essential nutrients required for growth and development. Products may also contain optional ingredients to further support immune response, gut flora and cognitive development.
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 safe ingredients are used, the manufacturing process is scrutinised and the end product is tested.

Only Infant Formula can give the assurance of safe, high quality nutrition for those infants that are not breastfed.

This is the very reason of the existence of the CODEX STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL PURPOSES INTENDED FOR INFANTS (**CXS 72-1981**) established in 1981 and lastly revised in 2007 and amended in 2020.

It is the responsibility of the manufacturers to ensure that Infant Formula comply with the requirements established by the Codex Alimentarius including those established by CODEX STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS **CXS 72-1981** in terms of composition, packaging and labelling – without prejudice to national or regional regulations and interpretations.

INFANT FORMULA IN THE CODEX ALIMENTARIUS FSDU FRAMEWORK

In July 2007, the Codex Alimentarius Commission adopted the revised Infant Formula Standard (**CODEX STAN 1981 - 72, revision 2007**) initially issued in 1981.

The revised Codex Infant Formula Standard is a global regulatory reference based on the latest scientific evidence available at that time.

While the Standard aims to harmonize rules, some provisions are left to national authority decisions.

The revised Standard is subdivided into two sections.
1. Section A referring to Infant Formula for healthy infants,
2. Section B, referring to formulas for special medical purposes intended for infants (FSMP).

To be noted:
The brochure will exclusively describe SECTION A: STANDARD FOR Infant Formula and will not address FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS

OTHER CODEX STANDARDS, GUIDANCE, AND CODES APPLICABLE TO INFANT FORMULA

Specific requirements applying to Infant Formula from the FSDU codex standard
SEE ISDI BROCHURE ON FSDU

Requirements applicable to Food for Special Dietary Use (FSDU) as defined in the General Standard for the labelling of and claims for prepackaged Foods for Special Dietary Use (**CODEX STAN 146-1985**) are applicable to Infant Formula unless specific provisions are included in the SECTION A of the STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS (**CXS 72-1981**).

In addition to the FSDU requirements applicable to Infant Formula, many other Codex Standards, Guidance and Codes are applicable to Infant Formula. The graph below is a simplified and non-exhaustive representation of this interaction between various Codex Texts.
The Infant Formula Standard should therefore never be read in isolation and should always be considered in conjunction with other relevant Codex texts. It is the responsibility of the Food Business Manufacturer to assess all the relevant Codex and national/regional requirements applicable to Infant Formula before marketing the product.

In the case of the SECTION A of the STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS (**CXS 72-1981**), ISDI notes the existence of the Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses intended for Infants and Young Children - **CXG 10-1979**.
This provides a non-exhaustive list of nutrient compounds that can be used in Infant Formula (See section on Optional ingredient).

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 establishes that an Infant Formula can be in liquid or powedered form. It is therefore clear that this Codex Standard in its entirety applies 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 (1981), the Global Strategy for Infant and Young Child Feeding and World Health Assembly resolution WHA54.2 (2001).

ISDI comment
Point 1.4 references specific WHO documents and recommendations that have been taken into account in this section of the standard. The key principle encapsulated in these recommendations is that the marketing and sales practices for Infant Formula should not undermine breastfeeding.

2. DESCRIPTION

2.1 Product Definition

2.1.1 Infant Formula means a breast-milk 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 point 1.3 above and 2.1.1 establish the fundamental notion that Infant Formula is a standardized commodity to be used as a breast milk substitute which satisfies by itself 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 an essential point of differentiation from follow-up formulas for older infants which are de signed for older infants and drinks for young children with added nutrients, or 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 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 enable 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
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**) and the term young children in the Codex Standard for follow-up formula (**CXS 156-1987**).

Therefore, in a Codex Alimentarius perspective the following definitions also apply:
Older infant: The term older infant means a person from the age of 6 months and not more than 12 months of age
Young children: The term young child means a person from the age of more than 12 months up to the age of three years (36 months)

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Essential Composition

3.1.1 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 this information on Gluten Free cannot be provided on Infant Formula labels, without prejudice of national regulations. **Further reading: ISDI brochure on Gluten Free Foods** brochure and wording in relation to Infant Formula prohibited from labelling Gluten Free.

ISDI notes that the Codex standard also covers non-cows' milk based Infant Formula, including products based on milk of other animals' origin, products based on vegetable protein (s) or a mixture thereof. All sources of protein shall be suitablefor 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 (250 kJ) and not more than 70 kcal (295 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 (GUL)1, as appropriate. The general principles for establishing these levels are identified in Annex II of this Standard.

1) 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 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.

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

Unit	*Minimum*	*Maximum*	*GUL*
g/100 kcal	*1.8* [5),6)]	*3.0*	-
g/100 kJ	*0.45* [5),6)]	*0.7*	-

2) 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 quantity and quality (essential and semi essential amino acid profile; Annex 1 of **CODEX STAN 72-1981**). Recognition is given to dairy commodity standards using a NCF of 6.38

3) For an equal energy value the formula must contain an available quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast-milk 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 formula needs to meet the minimum for each individual amino acid with the exceptions for those mentioned where they may be summed i.e. tyrosine and phenylalanine may be added together and, methionine and cysteine may be added together, only if the ratio of methionine and cysteine, in the formula, is less than 2:1.
Manufacturers would generally consider using the option of the sum dependin on the formula.
For example, according to the Codex Standard, Cysteine should be minimum 21mg/g protein (38mg/100kcal). Methionine should be 14mg/g protein (24mg/100kcal). In that case, the sum of methionine + cysteine minimum per CODEX is 35mg/g protein (62mg/100kcal). The combined concentrations of methionine and cysteine in the formula must be a minimum of 35mg/g protein (62mg/100kcal) AND have a ratio less than 2:1, to be acceptable.

	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 Mexico (n=40)		Houston (n=40)		Pooled banked milk at > 1 month		Milk at 21 days - 2 months				
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 nitro-gen	g protein	100 kcal
Cysteine	111	32	173	50	108	31	101	29	167	48	134	39	133	38	118	34	131	21	38

ISDI comment
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.

4) Isolated amino acids may be added toInfant 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.

5) 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. ForInfant Formula based on soy protein isolate, a minimum value of 2.25 g/100 kcal (0.5 g/100 kJ) applies.

6) 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 5 and 6 give further recognition to permitted protein sources in Infant Formula products, while also clarifying that there is a higher minimum protein requirement for soy protein isolate formula.

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.

'Clinical evaluation' is required to demonstrate that the formula at these protein levels supports an infant's normal growth. Randomized, controlled, parallel study in relevant infants may be used or scientific evidence may be acceptable.

ISDI notes that a number of national regulations do not stipulate 'clinical evaluation' for formula that meets compositional requirements, contains permitted protein sources and meets/ exceeds the stated regulatory protein minimum e.g. 1.8g/100kcal for milk protein. This recognises the evidence that has built on the safety of protein levels at the regulated minimum since the Infant Formula standard was revised in 2007.

b) Lipids

Total fat [7), 8)]

Unit	*Minimum*	*Maximum*	*GUL*
g/100 kcal	*4.4*	*6.0*	-
g/100 kJ	*1.05*	*1.4*	-

7) Commercially hydrogenated oils and fats shall not be used in Infant Formula.

8) Lauric and myristic acids 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 infant formulae. The erucic acid content shall not exceed 1% of total fatty acids. The total content of phospholipids should not exceed 300 mg/100 kcal(72 mg/100 kJ).

Linoleic acid			
Unit	***Minimum***	***Maximum***	***GUL***
mg/100 kcal	*300*	*-*	*1400*
mg/100 kJ	*70*	*-*	*330*
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 and alpha-linolenic acid, are essential components of Infant Formula and composition levels are prescribed in the Codex Standard. Fat is an important dense source of energy, it facilitates the absorption of fat-soluble dietary components such as vitamins and supplies essential fatty acids (α-linolenic acid (ALA) and linoleic acid (LA)) to the body (EFSA, 2013).
One of the main functions of LA (C18:2 n-6) and ALA (C18:3 n-3) is the regulation of cell membrane fluidity and acting as precursors for the LC-PUFAs arachidonic acid (ARA), eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) from which eicosanoids and docosanoids can be formed. In particular, DHA is needed for the normal development of the nervous system and the retina and accumulates in fetal brain and retina during pregnancy and in early childhood (Koletzko et al., 2008).[1]

c) Carbohydrates

Total carbohydrates [9)]			
Unit	***Minimum***	***Maximum***	***GUL***
g/100 kcal	*9.0*	*14.0*	*-*
g/100 kJ	*2.2*	*3.3*	*-*

9) Lactose and glucose polymers should be the preferred carbohydrates in formula based on cows' milk protein and hydrolysed protein. Only precooked and/or gelatinised starches gluten-free by nature may be added to Infant Formula up to 30% 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 unrecognised hereditary fructose intolerance.

ISDI Comment
ISDI notes the intention of these clauses are to highlight preferred CHO sources, limit the direct addition of the sugars, sucrose and fructose, and to manage sweetness. The text highlights 'sucrose, unless needed, and fructose..', as for example in certain cases these sugars can be present in low levels in other ingredients e.g. FOS or used to improve palatability of hydrolysed formula.

d)	Vitamins			
	Vitamin A			
	Unit	**Minimum**	**Maximum**	**GUL**
	µg RE[10]/100 kcal	60	180	-
	µg RE[10]/100 kJ	14	43	-

10) expressed as retinol equivalents (RE).

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

Vitamin D_3			
Unit	**Minimum**	**Maximum**	**GUL**
µg RE[11]/100 kcal	1	2.5	-
µg RE[11]/100 kJ	0.25	0.6	-

11) Calciferol 1 µg calciferol = 40 IU vitamin D

[1] *EFSA (2013). Scientific Opinion on nutrient requirements and dietary intakes of infants and young children in the European Union, EFSA Journal 2013;11(10):3408 Koletzko B, Lien E, Agostoni C, Bohles H, Campoy C, Cetin I, Decsi T, Dudenhausen JW, Dupont C, Forsyth S, Hoesli I, Holzgreve W, Lapillonne A, Putet G, Secher NJ, Symonds M, Szajewska H, Willatts P and Uauy R on behalf of the World Association of Perinatal Medicine Dietary Guidelines Working Group, 2008. The roles of long-chain polyunsaturated fatty acids in pregnancy, lactation and infancy: review of current knowledge and consensus recommendations. Journal of Perinatal Medicine, 36, 5-14.*

ISDI Comment

Although the Infant Formula Standard only includes vitamin D3 (Cholecalciferol), ISDI notes that the Advisory List of Nutrient (**CAC/GL 10-1979**) includes vitamin D2 (Ergoc-alciferol) as a source of vitamin D in Infant Formula.

ISDI also notes that Vitamin D, rather than vitamin D3 is specified in the compositional requirements agreed for Follow-up Formulas for Older Infants as part of the review of the Follow-Up Formula standard currently in progress.

Per point 3.4 of this Standard, that states that "Vitamins and minerals added in accordance with Section 3.1.3 (d and e) and other nutrients added in accord-ance with 3.2.1 should be selected from the Advisory lists of nutrient com-pounds for use in foods for special dietary uses intended for infants and young children (**CXG 10-1979**)", ISDI considers that Vit D2 and D3 can be used as sources of Vitamin D in Infant Formula. This interpretation is without prejudice to national regulations and interpretations.

ISDI notes the importance of allowing Vitamin D2 in order to allow for vegetarian Infant Formula.

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

12) 1 mg α-TE (alpha-tocopherol equivalent) = 1 mg d-α-tocopherol

13) 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	*1*	*-*	*6.5*

ISDI Comment
ISDI notes that the Advisory List of Nutrient (**CAC/GL 10-1979**) for Vitamin K1 refers to Phytomenadione (2-Methyl-3-phytyl-1,4-naphthoquinone/Phylloquinone/ Phytonadione)

Thiamin			
Unit	***Minimum***	***Maximum***	***GUL***
µg/100 kcal	*60*	*-*	*300*
µg/100 kJ	*14*	*-*	*672*
Riboflavin			
Unit	***Minimum***	***Maximum***	***GUL***
µg/100 kcal	*80*	*-*	*500*
µg/100 kJ	*19*	*-*	*119*
Niacin [14)]			
Unit	***Minimum***	***Maximum***	***GUL***
µg/100 kcal	*300*	*-*	*1500*
µg/100 kJ	*70*	*-*	*360*

14) Niacin refers to preformed niacin.

Vitamin B_6			
Unit	***Minimum***	***Maximum***	***GUL***
µg/100 kcal	*35*	*-*	*175*
µg/100 kJ	*8.5*	*-*	*45*
Vitamin B_{12}			
Unit	***Minimum***	***Maximum***	***GUL***
µg/100 kcal	*0.1*	*-*	*1.5*
µg/100 kJ	*0.025*	*-*	*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	*2.5*	*-*	*12*

Vitamin C [15)]			
Unit	***Minimum***	***Maximum***	***GUL***
µg/100 kcal	*10*	*-*	*70[16)]*
µg/100 kJ	*2.5*	*-*	*17[16)]*

15) Expressed as ascorbic acid.

16) 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 aime*d for.*

Biotin			
Unit	***Minimum***	***Maximum***	***GUL***
µg/100 kcal	*1.5*	*-*	*10*
µg/100 kJ	*0.4*	*-*	*2.4*

e) Minerals and Trace Elements

Iron			
Unit	***Minimum***	***Maximum***	***GUL[17)]***
mg/100 kcal	*0.45*	*-*	*-*
mg/100 kJ	*0.1*	*-*	*-*

17) Levels may need to be determined by national authorities.

ISDI COMMENT
ISDI notes that for Iron, the minimum in Codex is 0.45 mg/100 kcal while the maximum is left open.

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[18)]*
mg/100 kJ	*6*	*-*	*24[18)]*

18) This GUL should accommodate higher needs with soy formula.

ISDI COMMENT
According to footnote 18 and for clarity purpose, ISDI notes that these GUL of 100 mg/100 kcal/ 24 mg/100 kJ for phosphorus are also adequate for 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	5	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	-	100
µg/100 kJ	0.25	-	24
Iodine			
Unit	**Minimum**	**Maximum**	**GUL**
µg/100 kcal	10	-	60
µg/100 kJ	2.5	-	14
Selenium			
Unit	**Minimum**	**Maximum**	**GUL**
µg/100 kcal	1	-	9
µg/100 kJ	0.24	-	2.2
Copper [19)]			
Unit	**Minimum**	**Maximum**	**GUL**
µg/100 kcal	35	-	120
µg/100 kJ	8.5	-	29

19) 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	-	9.5
	L-Carnitine			
	Unit	**Minimum**	**Maximum**	**GUL**
	mg/100 kcal	1.2	N.S.	-
	mg/100 kJ	0.3	N.S.	-

ISDI comment:
ISDI considers essential to highlight the importance of the macro and micro-nutrients listed in section 3.1 Essential Composition of SECTION A: STANDARD FOR INFANT FORMULA, which are mandated to ensure the product is nutritionally adequate. This is critical for the growth and development of infants who rely on Infant Formula as the sole source of nutrition, during the first months of life, until the introduction of complementary feeding.
Infant Formula must contain the listed nutrients within the minimum and maximum or guid-ance upper level (GUL), as appropriate. When establishing these values, both the nutritional adequacy and safety have been considered. To determine upper levels, a science-based risk assessment approach is used. When there is insufficient information for the assessment, guidance upper levels are estab-lished.
The purpose of the GULs is to provide guidance to manufacturers and they are not the same as maximum limits. For more information about the intention and use of GULs, refer to Section 3.1.3 of SECTION A: STANDARD FOR INFANT FORMULA and the footnote 1 that stipulates:

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 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 GENERAL PRINCIPLES FOR ESTABLISHING MINIMUM AND MAXIMUM VALUES FOR THE ESSENTIAL COMPOSITION OF INFANT FORMULA.
Other optional ingredients covered in the next section can further support an infant growth and development, but the essential composition established by the Codex Standard in Section 3 has a proven history of safe use and suitability for the growth and development of an infant.

3.2 Optional ingredients

3.2.1 In addition to the compositional requirements listed under 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 of 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 authorizes the addition of optional ingredients found in human milk as well as other optional ingredients providing outcomes for formula-fed infants similar to outcomes for breast-fed infants.
The optional ingredient provision gives the ability to include additional ingredients that are not specifically defined in the Infant Formula Standard. The burden of proof, how-ever, is on the manufacture to ensure the two major criteria defined in 3.2 Optional ingredients are met. 1) The ingredient safety must be scientifically demonstrated and 2) the concentration of the ingredient in Infant Formula must consider levels found in breastmilk and/or shown to confer benefits similar to outcomes observed in breast-fed infants. This is a critical concept to enable the continuous development of Infant Formula.
Scientific substantiation to support that optional ingredients are safe and suitable for their use in Infant Formula may include clinical and/or non-clinical data e.g. animal and in-vitro studies.

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	-	3	-

Total nucleotides
Levels may need to be determined by national authorities.

Docosahexaenoic Acid [20)]			
Unit	**Minimum**	**Maximum**	**GUL**
% of fatty acids	-	-	0.5

20) 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:
3.2.3 provides a non-exclusive list of optional ingredients which may be added.
3.2.4 clarifies that only L(+) lactic acid producing cultures may be used that fulfil the requirements as set out for optional ingredients.

ISDI notes that this requirement means that L(+) lactic acid producing cultures may be added in Infant Formula. This could be in particular for acidification purposes or for the purpose of conferring specific physiological effects

Upper nutrient levels to be defined by national authorities
The Standard empowers national authorities to set the maximum or guidance upper levels for iron, nucleotides and DHA:ARA ratio as no global consensus could be reached on their upper levels during the CCNFSDU discussion. Nucleotides: The Standard leaves open the maximum level for total nucleotides, as well as the levels of each of the five individual component nucleotides. DHA:ARA: The Standard establishes a GUL for DHA of 0.5% of total fatty acids with at least 1:1 DHA:ARA, and EPA no greater than DHA). Minimum and maximum levels for DHA are left open in the Standard and subject to local regulation.

3.3 Fluoride

Fluoride should not be added to Infant Formula. In any case its level should not exceed 100 µg /100 kcal (24µg/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 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).

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

ISDI comment
Food additives are substances intentionally added to food for a technological purpose in the manufacture, processing, or shelf stability of that product (**Codex Stan 192-1995**). Codex has a fundamental principle that the use and level of food additives should be limited as much as possible in Infant Formula, and in 1971 JECFA established a list of functional classes of food additives appropriate for use in these products: acidity regulators, antioxidants, emulsifiers, stabilizers, thickeners, and packaging gases (**JECFA 1971 report reference**).
The additives authorized for use in Infant Formula are provided in Section 4 of the Infant Formula Standard (**CXS 72-1981**). The maximum addition rates for these additives are specified as in 100 ml of product, ready for consumption prepared following manufac-turer's instructions. The Codex General Standard for Food Additives (GSFA, **CXS 192-1995**) also lists additives authorized for use inInfant Formula in Table 1 and Table 2, al though it should be noted that the Codex Committee on Food Additives (CCFA) is undertaking an effort to align all of the food additive provisions in the GSFA with the provisions in commodity standards such as theInfant Formula Standard (**CXS 72-1981**). ISDI is actively participating in this alignment process to ensure that there is a one-to-one correlation between the additive provisions in the Infant Formula standard and those in the GSFA.
For further information on food additives in Infant Formula, please refer to the ISDI **Brochure**.
ISDI also notes that flavours are not authorized in Infant Formula.

5. CONTAMINANTS

The products covered by this Standard shall comply with the Maximum Levels of the General Standard for Contaminants and Toxins in Food and Feed (CXS 193-1995).
The products covered by this Standard shall comply with the maximum residues limits for pesticides established by the Codex Alimentarius Commission.

6. HYGIENE

6.1 It is recommended that the product covered by the provisions of this standard be prepared and handled in accordance with the appropriate sections of the General Principles of Food Hygiene (CXC 1-1969), and other relevant Codex texts such as the Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (CXC 66-2008).

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).

ISDI comment
The Standard includes hygiene criteria as defined by the International Code of Hygienic Practice for Foods for Infants and Children.

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 CONTAINER

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 (5-8 oz.); and
(iii) not less than 90% 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 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 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.

ISDI comments:
The practical implication is that claims on Infant Formula and FSMP for infants are prohibited unless national authorities lay down specific legislation on claims. ISDI notes that substantiated nutrition and health claims provide sound information to consumers to make informed choice at point of retail. Include reference on future claims brochure?

In addition to these requirements the following specific provisions apply:

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 grammes of protein, carbohydrate and fat per 100 grammes or per 100 milliliters of the food as sold as well as per 100 milliliters of the food ready for use, when prepared according to the instructions on the label.

ISDI comment: See the Label Overview – Appendix 1

b) the total quantity of each vitamin, mineral, choline as listed in paragraph 3.1.3 and any other ingredient as listed in paragraph 3.2 of this Standard per 100 grammes or per 100 milliliters of the food as sold as well as per 100 milliliters 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 (or per 100 kilojoules) is permitted.

ISDI comment: See the Label Overview – Appendix 1

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.

ISDI comment
See the Label Overview – Appendix 1. ISDI notes the provisions in the General Standard for Labelling of prepackaged foods (Section 4, 5 and 8 in particular) (**CXS 1-1985**). In more recent, Codex Alimentarius texts, for consistency purpose, Codex cross references the relevant texts.

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 accord *ance 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 "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 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 six 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.

The use of specific labels for different types of formula – infant formulas, follow-up formulas and growing-up milks – 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 Infant Formula and Formulas for Special Medical Purposes Intended for Infants (**CXS 72-1981**)

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

ISDI reemphasizes that the nutritional compositional requirements of Infant Formula are tailored to meet the particular nutritional needs of 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.). Infant Formulas 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 Infant Formula 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".

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) relevant to the provisions in this Standard, shall be used.

[ANNEX I Essential and semi-essential amino acids in breast milk]

[ANNEX II GENERAL PRINCIPLES FOR ESTABLISHING MINIMUM AND MAXIMUM VALUES FOR THE ESSENTIAL COMPOSITION OF INFANT FORMULA]

Annex I

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*

	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**
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	*105*	315	50	*90*

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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 breast-milk.

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. The approach to setting maximum and upper guidance values 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. Overages 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, and

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

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

Sources of protein
May be labelled "Infant Formula Based on Cows' Milk"
Neither milk nor milk derivative => the product must be labelled with "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 / 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 and for food additives. In addition, appropriate class names for these ingredients and additives may be included on the label.*
  - *Added water*
  - *Compound ingredient*
  - *Allergens highlighted. Infant formula products cannot be labelled "gluten free" as per section 3.1 All ingredients and food additives shall be gluten-free.*
  - *Alternative to label the product as reconstituted where relevant*
  - *Class names can be used*
  - *Food Additives => functional class + name or INS number (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*

- *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
Any special conditions for the storage of the food shall be declared on the label where they are required to support the integrity of the food and, where a date mark is used, the validity of the date depends thereon

- *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.*

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:

- *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.*

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 requirements*

Prohibited:

- *No pictures of infants and women nor any other picture or text which idealizes the use of infant formula.*
- *"Humanized", "maternalized" or other similar terms*
- *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 (GSLPF) - CXS 1-1985

Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants - CXS 72-1981

ISDI clarifications

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

APPENDIX II

LABELLING CONSIDERATIONS - Relevant concepts and guidance from WHO and WHA documents that have been incorporated into the CODEX STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS **CXS 72-1981**

WHO International Code of Marketing of Breast- milk Substitutes Extracts referring to the Labelling of Breast-milk Substitutes	INFANT FORMULA CODEX STANDARD - CXS 72-1981	ISDI COMMENT
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	***Section 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.*** ***Section 9.5.3 The label shall carry clear graphic instructions illustrating the method of preparation of the product.*** ***Section 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.*** ***Section 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 aquivalent;*** ***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 an independent health worker as to the need for its use and the proper method of use.*** ***Section 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.*** ***Section 9.6.3 The terms "humanized", "maternalized" or other similar terms shall not be used.***	ISDI notes that the labelling section of the Infant Formula Commodity Standard product has taken into consideration the **WHO International Code of Marketing of Breast- milk Substitutes.**

WHO International Code of Marketing of Breast- milk Substitutes Extracts referring to the Labelling of Breast-milk Substitutes	INFANT FORMULA CODEX STANDARD - CXS 72-1981	ISDI COMMENT
9.2 Manufacturers and distributors of Infant Formula should ensure that each container as 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;	***Section 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:*** ***Section 9.6.1 a) the words "important notice" or their equivalent;***	ISDI notes that the labelling section of the Infant Formula Commodity Standard product has taken into consideration the **WHO International Code of Marketing of Breast-milk Substitutes.**
(b) a statement of the superiority of breastfeeding;	***Section 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;***	ISDI notes that the labelling section of the Infant Formula Commodity Standard product has taken into consideration the **WHO International Code of Marketing of Breast-milk Substitutes.**
(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;	***Section 9.6.1 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.***	ISDI notes that the labelling section of the Infant Formula Commodity Standard product has taken into consideration the **WHO International Code of Marketing of Breast-milk Substitutes**.
(d) instructions for appropriate preparation, and a warning against the health hazards of inappropriate preparation	***Section 9.5.4 The directions should be accompanied by a warning about the health hazards of inappropriate preparation, storage and use.***	ISDI notes that the labelling section of the Infant Formula Commodity Standard product has taken into consideration the **WHO International Code of Marketing of Breast-milk Substitutes.**
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.	***Section 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.*** ***Section 9.6.3 The terms "humanized", "maternalized" or other similar terms shall not be used.*** ***Section 9.5.3 The label shall carry clear graphic instructions illustrating the method of preparation of the product.***	ISDI notes that the labelling section of the Infant Formula Commodity Standard product has taken into consideration the **WHO International Code of Marketing of Breast-milk Substitutes.** ISDI also notes that considering the importance of the safe use of the products and of proper information for use, the Codex Alimentarius commodity Standards goes a step further than the WHO International Code of Marketing of Breast- milk Substitutes with section 9.5.3 of labelling requirements by making graphic instructions illustrating the method of preparation of the product mandatory. This section 9.5.3 was strongly supported by ISDI when adopted by the Codex Alimentarius.

WHO International Code of Marketing of Breast- milk Substitutes Extracts referring to the Labelling of Breast-milk Substitutes	INFANT FORMULA CODEX STANDARD - CXS 72-1981	ISDI COMMENT
The terms "humanized", "maternalized" or similar terms should not be used.	***Section 9.6.3 The terms "humanized", "maternalized" or other similar terms shall not be used.***	ISDI notes that the labelling section of the Infant Formula Commodity Standard product has taken into consideration the **WHO International Code of Marketing of Breast-milk Substitutes.**
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.	***Section 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 IF. No product other than IF 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.*** ***Section 2.1.1 Infant Formula means a breast-milk 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.*** ***Section 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.*** ***Section 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.*** ***Section 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.***	ISDI notes that the Infant Formula Commodity Standard has taken into consideration the **WHO International Code of Marketing of Breast-milk Substitutes.** In line with the Codex Standard ISDI considers that only products that comply with the criteria laid down in the provisions of the Codex Standard can be accepted for marketing as Infant Formula. The elements that frame how the products should be reconstituted - where necessary – are also strictly limited in the Codex Standard.

WHO International Code of Marketing of Breast- milk Substitutes Extracts referring to the Labelling of Breast-milk Substitutes	INFANT FORMULA CODEX STANDARD - CXS 72-1981	ISDI COMMENT
9.4 The label of food products within the scope of this Code should also state all the following points: (a) the ingredients used;	***Section 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.***	ISDI notes that the IF Commodity Standard has taken into consideration the **WHO International Code of Marketing of Breast- milk Substitutes.**
(b) the composition/analysis of the product;	***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 grammes of protein, carbohydrate and fat per 100 grammes 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 paragraph 3.1.3 and any other ingredient as listed in paragraph 3.2 of this Standard per 100 grammes 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.*** ***c) In addition, the declaration of nutrients in a) and b) per 100 kilocalories (or per 100 kilojoules) is permitted.***	ISDI notes that the Infant Formula Commodity Standard has taken into consideration the **WHO International Code of Marketing of Breast-milk Substitutes.**
(c) the storage conditions required; and	***Section 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.***	ISDI notes that the Infant Formula Commodity Standard has taken into consideration the **WHO International Code of Marketing of Breast-milk Substitutes.** In more recent Codex Standards, the specific commodity Standard cross reference the requirements from section 4.7.1 of the **General Standard for the Labelling of Prepackaged Foods**, as these requirements are common to prepackaged foods.

WHO International Code of Marketing of Breast- milk Substitutes Extracts referring to the Labelling of Breast-milk Substitutes	INFANT FORMULA CODEX STANDARD - CXS 72-1981	ISDI COMMENT
(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.	***Section 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.***	ISDI notes that the Infant Formula Commodity Standard has taken into consideration the **WHO International Code of Marketing of Breast-milk Substitutes** (cf. lot identification, date marking & storage instructions).
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.	***Section 6. HYGIENE*** ***Section 6.1 It is recommended that the product covered by the provisions of this standard be prepared and handled in accordance with the appropriate sections of the General Principles of Food Hygiene (CXC 1-1969), and other relevant Codex texts such as the Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (CXC 66-2008).*** ***Section 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).***	ISDI notes that the Infant Formula Commodity Standard has taken into consideration the **WHO International Code of Marketing of Breast-milk Substitutes.**

Guidance on ending the inappropriate promotion of foods for infants and young children	INFANT FORMULA CODEX STANDARD - CXS 72-1981	ISDI COMMENT
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.	***Section 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 six months.*** ***Section 9.1.1 The text of the label and all other information accompanying the product shall be written in the appropriate language(s).*** ***Section 9.6.1 Labels should not discourage breastfeeding.*** ***Section 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;***	ISDI notes that the Infant Formula Commodity Standard has taken into consideration the **WHO Guidance on ending the inappropriate promotion of foods for infants and young children.**
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 breastfeeding, 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 endorsement by a professional or other body, unless this has been specifically approved by relevant national, regional or international regulatory authorities.	***Section 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 "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 an independent health worker as to the need for its use and the proper method of use.*** ***Section 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.*** ***Section 9.6.3 The terms "humanized", "maternalized" or other similar terms shall not be used.*** ***Section 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 six months.***	ISDI notes that the labelling section of the Infant Formula Commodity Standard product has taken into consideration the **WHO Guidance on ending the inappropriate promotion of foods for infants and young children**. ISDI notes that other elements in this section of the WHO Guidance on ending the inappropriate promotion of foods for infants and young children are of a policy nature and not relevant per se for the specific commodity requirements and often covered otherwise in the broader local context.

Guidance on ending the inappropriate promotion of foods for infants and young children	INFANT FORMULA CODEX STANDARD - CXS 72-1981	ISDI COMMENT
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).	***Section 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 notes that the elements from the **WHO Guidance on ending the inappropriate promotion of foods for infants and young children** that are of relevance for the commodity standard and label have been taken into account. ISDI members comply with all laws and regulations in the countries in which they operate and have extensive internal approval and audit processes in place to ensure their online and offline content meets all legal, regulatory and nutritional science requirements. In addition, manufacturers of infant and young child nutrition have their own internal and external mechanisms for policy compliance. Furthermore, some BMS manufacturers raise awareness of the WHO Code among the main online marketplaces and search engines. They also actively raise awareness among third party retailers of the WHO Code and applicable laws through education and training and monitor independent websites to identify regulatory and compliance issues. Our members further support efforts by national governments to ensure compliance with all national laws and regulations.

WHA 69.9 Ending inappropriate promotion of foods for infants and young children	INFANT FORMULA CODEX STANDARD - CXS 72-1981	ISDI COMMENT
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		ISDI notes that 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 and other provision of the relevant Codex Standard. ISDI would also emphasize the advice and conclusions of CCEXEC75: In June 2018 , the Codex Executive Committee ("CCEXEC") recommended to CCNFSDU that only references consistent with the mandate of Codex that have scientific relevance should be considered: • With regard to references to WHO/WHA documents in the draft CCNFSDU text on follow-up formula, CCEXEC75 provided the following advice intended to assist CCNFSDU in moving forward: > references should be considered on a case-by-case basis; > references may provide context and additional information to assist members in understanding and use of Standards; > concepts and technical information could be incorporated into the text of the Standard itself, rather than referencing sources external to Codex; and > references must be relevant to the scope of the Standard itself, fall within the mandate of Codex, have a scientific basis, and have been developed through a transparent process.

[2] Paragraph 14, report of CCEXEC75: **https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-702-75%252FReport%252FFINAL%252FREP18_EXEC2e.pdf**.

WHA 63.32	INFANT FORMULA CODEX STANDARD - CXS 72-1981	ISDI COMMENT
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 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.***	ISDI notes that the elements of resolution WHA 63.32 of relevance for the Infant Formula commodity standard and label are being reflected in the Codex Standard.

Global Strategy for Infant and Young Child Feeding and World Health Assembly resolution WHA 54.2 (2001)	INFANT FORMULA CODEX STANDARD - CXS 72-1981	ISDI COMMENT
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 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.***	ISDI notes that the elements of the **Global Strategy for Infant and Young Child Feeding** and World Health Assembly resolution **WHA 54.2 (2001)** of relevance for the infant formula commodity standard and label are being reflected in the Codex Standard.
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, ISDI notes that the labelling section of the product has taken into consideration the International Code and WHA resolutions.

WHA 61.2	INFANT FORMULA CODEX STANDARD - CXS 72-1981	ISDI COMMENT
3) to implement, through application and wide dissemination, the WHO/ FAO guidelines on safe preparation, storage and handling of powdered infant formula in order to minimize the risk of bacterial infection and, in particular, ensure that the labelling of powdered formula conforms with the standards, guidelines and recommendations of the Codex Alimentarius Commission and taking into account resolution **WHA58.32**;		ISDI notes that the labelling section of the Codex Infant Formula commodity standard has taken into consideration the elements highlighted by the resolution WHA 61.2.

International Special
Dietary Foods Industries