

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
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WORLD
HEALTH
ORGANIZATION



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Agenda Item 4 (b)

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
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**DRAFT REVISED STANDARD FOR INFANT FORMULA AND FORMULAS FOR
SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS:
SECTION B: FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR
INFANTS**

- Comments at Step 6 of the Procedure -

Comments from:

ARGENTINA

BOLIVIA

BRAZIL

CANADA

COSTA RICA

GUATEMALA -1-

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PHILIPPINES

UNITED STATES OF AMERICA

VIETNAM

ISDI - International Special Dietary Foods Industries

ARGENTINA

1. SCOPE

1.1 As regards this section, Argentina agrees and suggests that the brackets around the phrase “[o de los preparados para lactantes]” be deleted from the Spanish version of the document, as they do not appear in the English version.

9. LABELLING

9.5 Information for Use

9.5.1

Regarding this section, Argentina agrees with the deletion of the brackets around the phrase “{for in the accompanying leaflet}”. Further, Argentina believes that any information that is to be declared should appear on the label, rather than on an accompanying leaflet.

Last, Argentina suggests the addition of the full text of items referring readers to Appendix IV Section A, namely 2.1.2, 2.2; 3.3, 3.4, 3.5, 3.6; 4; 5; 6; 7; 8; 9, 9.2, 9.4, 9.5 and 9.6.5.

BOLIVIA

General comments

Bolivia suggests taking into consideration that future revisions of this document and other documents be realized following a logical order. We believe that first of all the comments on Section A of this document should be circulated and that only thereafter the comments on Section B, which is subordinated to Section A, should be released.

Furthermore, we believe that for the sake of comprehensibility and readability of the standard it would be appropriate to write out in full the wording which appears in both Section A and Section B.

Comments regarding the translation

Bolivia would like to draw the attention of the Committee secretariat to some translation errors of the Spanish version where it does not reflect the real sense of the Standard.

In the title, the word “Preparados” should be replaced by “Formulas” which is the correct translation of the English word “Formulas”.

In point 1.1 the wording “las necesidades nutricionales” should be modified into “los requerimientos nutricionales” according to the original English version, i.e. “The nutritional requirements”.

Point 9.2.1 should be revised completely as the Spanish version does not correspond to the English original.

Comments on the Standard

1. SCOPE

1.4 The application of this section of the standard should take into account, as appropriate for the products to which the section applies and the special needs of the infants for whom they are intended, the recommendations made in the International Code of Marketing of Breast-milk Substitutes (1981) and World Health Assembly resolution WHA54.2 (2001) [[WHA 55.25 and WHA 58.32](#)] on the Global Strategy for Infant and Young Child Feeding [[as well as later recommendations on breast-feeding](#)].

Justification

Bolivia requests to add a reference to the World Health Assembly resolutions regarding the production of infant formulas, as these resolutions are considered to be the general international framework for the marketing of these products.

2. DESCRIPTION

2.1 Product definition

2.1.1 Formula for Special Medical Purposes Intended for Infants means a substitute for human milk or infant formula that complies with Section 2, Description, of the Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991) and is specially manufactured to satisfy, ~~by itself,~~ the special nutritional requirements of infants with specific disorders, diseases or medical conditions during the first [\[6\]](#) months of life up to the introduction of appropriate complementary feeding.

Justification

Bolivia suggests to delete the wording “by itself”, because it undermines breast-feeding. Furthermore, we believe that it is important to clearly point out that the Standard covers the first 6 months of life of infants, as the definition under 2.2, which includes infants of 0 to 12 months leads to confusion when applying the Standard.

9. LABELLING

In addition to the requirements of the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985 (Rev. 1-1991)), the following specific provisions apply:

9.1 The Name of the Food

9.1.1 The name of the product shall be “Formula for Special Medical Purposes Intended for Infants” or any appropriate designation indicating the true nature of the product, in accordance with national usage.

Include the following texts of Section A

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

[9.1.3 The sources of protein in the product shall be clearly shown on the label.](#)

[9.1.4 If cow’s milk is the only source of protein, the product may be labelled “Infant Formula Based on Cow's Milk”.\]](#)

Justification

We suggest inserting the full wording of these three points of Section A into this Section for the following reasons;

- It is important to make clear that the declaration shall be made exclusively in the language of the importing country, because a country like Bolivia that imports almost all of these products would not be able to market them unless they were labelled in Spanish.
- The protein source should be declared as these products are intended for special medical purposes so that the information about the protein source plays an important role as regards their prescription.
- The third point complements the above mentioned aspects.

9.5 Information for Use

See Section A 9.5

[\[The label shall contain a legend setting out that such products shall be “sold on medical prescription”.\]](#)

Justification

We suggest inserting a legend setting out that such products shall be “sold on medical prescription”, in order to prevent them to be sold and consumed in an uncontrolled manner.

9.6 Additional Labelling Requirements

9.6.2 A prominent statement indicating that the product is intended as the sole source of nutrition [\[may\]](#) ~~shall~~ appear on the label.

Justification

We suggest replacing the word “shall” by “may” as this depends on the medical condition of the respective infant.

~~9.6.4 Labels and information provided separately from the package should not discourage breastfeeding, unless breastfeeding is contraindicated on medical grounds for the disease(s), disorder(s) or medical condition(s) for which the product is intended.~~

Justification

We suggest deleting this paragraph as it undermines breast-feeding.

9.6.5 see section A 9.6.5

[\[9.6.6 No nutrition and health claims shall be made regarding the dietary properties of the product.\]](#)

Justification

We request that point 9.6.6 of Section A be repeated in Section B. Our request is based on the statement contained in the Guidelines for Use of Nutrition and Health Claims regarding claims on baby foods according to which “Nutrition and health claims shall not be permitted for foods for infants and young children except where specifically provided for in relevant Codex standards or national legislation”. In Bolivia as well as in other countries, nutrition and health claims for this product might be confusing and misleading for the consumer.

BRAZIL

3. Essential Composition and Quality Factors

3.1.3. a) Proteins

2) [For the purpose of this standard, the calculation of the protein content 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 nitrogen source.] The protein levels set in this standard are based on a nitrogen conversion factor of 6.25.

Observation: we propose to exclude the square brackets and to maintain the text above.

Justification: We support the nitrogen conversion fact of 6,25.

3) [Infant formulae based on non-hydrolysed cows' 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.]

Observation: we propose to exclude the square brackets and to maintain the texts above.

Justification: Brazil considers important the clinical evaluation of the infant formulas based on the non-hydrolysed protein of the cow milk with less than 2g/100kcal of protein and of the formulas based on hydrolysed protein with less than 2,25g/100kcal protein, considering that there are evidences that it can have a effect on the child growing and development.

Item 3.1.4. For an equal energy value the formula must contain an available quantity of each essential and semiessential amino acid at least equal to that contained in the reference protein (breast-milk as defined in Annex D); nevertheless for calculation purposes, the concentrations of methionine and cysteine and of tyrosine and phenylalanine may be added together [unless the methionine to cysteine or the phenylalanine to tyrosine ratio are outside the range of 0.7-1.5 : 1].

Observation: We propose to exclude the square brackets and to maintain the texts above.

Justification: Brazil supports the ratio methionine/cysteine, phenylalanine/tyrosine since it's the proportion found in the breast milk.

b) Lipids

5) Lauric and myristic acids are constituents of fats, but combined should not exceed 20% of [total fatty acids]. The content of trans fatty acids shall not be higher than [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 be less than 1% of total fatty acids.

Observation: we propose to exclude the square brackets and to maintain the texts above.

Justification: Brazil supports the maximum limit of 3% (three per cent) since it is not necessary to use only the milky fat to assure the lipidic composition.

C) Carbohydrates

6) 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 may be added to Infant Formula up to 30% of total carbohydrates or up to 2 g/100 ml.

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

Suggestion: we propose to exclude the square brackets and to maintain the text.

d) Vitamins

e) Minerals and trace Elements

Observation: we propose to substitute "Guidance upper level" to "Maximum values"

Justification: according to previous writings and maintaining the general principles which established them, since they are already foreseen in the Appendix II – General Principles for the Establishment of Maximum and Minimum Values for the Essential Composition of Infant Formulas and risk evaluation for nutrients and the temporary utilization of the "guidance upper level" (item 4 – Appendix II).

We stand out that the guidance upper levels is a parameter applied to the feeding and not to a specific food.

Iron**Iron (formula based on cows' milk protein and protein hydrolysate) (mg)**

Per 100 kcal	
Min	Max
0,3 ¹³ 0,5	1,3

13) In populations where infants are at risk of iron deficiency, iron contents higher than the minimum level of 0.3 mg/100 kcal may be appropriate and recommended at a national level.

Iron (formula based on soy protein isolate) (mg)

Per 100 kcal	
Min	Max
0,45 0,5	2,0

Suggestions: we propose to change the minimum values of iron for 0.5mg/100Kcal in the infant formulas based on cow milk proteins and other hydrolysed proteins and based on isolated soy protein, according to the table above.

Justification: there is no scientific evidence about the use of values above 0,5mg/100Kcal of iron in infant formulas that assure the food feeding of the infant. As a reference we cite the following study:

- WALTER, T. et al. Prevention of iron-deficiency anemia: comparison of high- and low-iron formulas in term healthy infants after six months of life. **J Pediatr**, 1998; 132: 635-40.

F) Other Substances:**L-carnitine (mg):**

Per 100 kcal	
Min	Max
1,2	N.S. 2,0

Suggestions: we propose the adoption of the maximum level of 2.0mg/100Kcal for L-Carnitine.

Justification: the value of 2.0mg/100Kcal is the concentration found in the breast milk.

3.2 Optional [or non-mandatory] ingredients

Suggestion: we propose to exclude the text between the square brackets [**or non-mandatory**]

Justification: the expression “optional” is enough to clarify the content of the item.

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.

Suggestion: we propose to exclude the underlined text of item 3.2.1.

Justification: these infant formulas must be closer enough to the breast milk.

Taurine (mg)

Per 100 kcal	Per 100 kJ
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12	3
Total [added] nucleotides mg Per 100 kcal	Per 100 kJ
5	1,2

Suggestion: we propose to exclude the text between the square brackets [added].

Justification: the value of 5mg/100Kcal must refer to the total content of the product nucleotides considering the values present on breast milk.

[3.2.4] Only L(+)lactic acid producing cultures may be used

Suggestion: we propose to exclude the square brackets and to maintain the text.

Justification: there are scientific evidences that demonstrate the safety use of those cultures.

4. Food Additives

The guar gum, carob bean gum (Locust bean gum) and carrageenan must not be used in infant formulas.

Justification: studies of safety use for the age of infant must be elaborated to justify its utilization. In Brazil, the use of these gums is not allowed.

Observations: Brazil will wait the sending of the CX regarding the other additives to propose suggestions, considering what is written on paragraph 109 Alinorm 06/29/06.

9. Labelling

9.1.6 [Products containing not less than 0.5 mg Iron (Fe)/ 100 kilocalories shall be labelled "Infant Formula with added Iron"].

or

[Products containing less than 0.5 mg Iron (Fe)/ 100 kcal shall be labelled with a statement to the effect that when the product is given to infants over the age of four months, their total iron requirements must be met from other additional sources.]

Suggestion: we propose to exclude the item 9.1.6.

Justification: Brazil supports the adoption of 0.5mg/100Kcal of iron as a minimum requirement in the infant formulas composition.

9.5. Information for Use

Suggestion: we propose to exclude the square brackets and to maintain the sentence with the following writing:

Products in liquid form may be used either directly or prepared with safe water and previously boiled water before feeding according to directions for use. Products in powder form also require safe and previously boiled water for preparation.

9.5.1 Adequate directions for the appropriate preparation 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 [or in the accompanying leaflet].

9.5.2 Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label [or in the accompanying leaflet].

Suggestion: we propose to exclude the texts between square brackets on items 9.5.1 e 9.5.2.

Justification: that information must be on the label, and additionally can be on folders, when those are used.

9.5.4 The directions should be accompanied by a warning about the health hazards of inappropriate preparation and /or the declaration that the product should be taken based on the advice of a nutritionist or a medical doctor

Suggestion: we propose to maintain the text and also the inclusion of the underlined item on item 9.5.4 above.

Justification: depending on the national legislation, the infant formulas must be used under a medical or nutritionist prescription and this observation must be part of the norm.

9.6.6 [No [nutrition and] health claims shall be made regarding the dietary properties of the product.]

Suggestion: we propose to exclude the square brackets and to maintain the text of the item 9.6.6.

1. DRAFT REVISED STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS: SECTION B

Suggestion: Brazil maintains the same proposals presented on Section A.

CANADA

• GENERAL COMMENTS

Canada supports a separate section within the Standard for Infant Formula to apply to formula for special medical purposes for infants.

It understood that the content of the sections which refer to Section A, will have to be specifically considered once Section A has been finalized, in view of, for example, the metabolic differences between healthy term infants and those with conditions requiring the use of Formulas for Special Medical Purposes Intended for Infants.

• SPECIFIC COMMENTS

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Essential Composition

3.1.2 Since the products that are the subject of Section B of this Standard are intended to be sole sources of nutrition, it is important that their nutritional safety and adequacy in supporting growth and development in the indicated population be scientifically demonstrated. For greater clarity in this regard, it is recommended that the text in this section parallel that in section 3.1.1 of Section A. The second sentence in the current section will have to be correspondingly modified. In addition, it is recommended that the word “shall” replace “should” in this section.

“3.1.2 The composition of Formula for Special Medical Purposes Intended for Infants shall be based on sound medical and nutritional principles. The nutritional safety and adequacy of the formula shall be scientifically demonstrated to support growth and development in the infants for whom it is intended. Their use shall be demonstrated by scientific evidence to be beneficial in the dietary management of the infants for whom it is intended.”

3.2 Optional ingredients

3.2.3 Delete this subsection; lactic acid is addressed in the Table of Food Additives.

9. LABELLING

It is recommended that all information essential to the proper use of the food be required on the label of the food, i.e. not only in an accompanying leaflet.

9.1 The Name of the Food

This section should also include the requirement in section 9.1.1 of Section A that the text of the label and accompanying information shall be written in the appropriate national language.

9.3 Nutrition Labelling

It is recommended that this section have the same title as the parallel section in Section A: “Declaration of Nutritive Value”. It is further recommended that the declaration of nutritive value be specifically required on the label of the product.

9.5 Information for Use

This section should be titled “Information for Use” as is the parallel section in Section A. The reference to Section 4.5.6 of CODEX STAN 180-1991 currently in section 9.6.3 should be moved to section 9.5 Information for Use (see below). In addition, it is recommended that all the information respecting the use of the product be required on the label of the product, i.e. not only in an accompanying leaflet.

9.6 Additional Labelling Requirements

9.6.1 and 9.6.3 We recommend that the requirements set out in section 9.6.1 be specifically required on the label of the product. In section 9.6.3, the reference to Section 4.5.6 of CODEX STAN 180-1991, which deals with feeding instructions, should be moved to section 9.5 Information for Use. The references in section 9.6.3 to sections 4.5.2 and 4.5.3 of CODEX STAN 180-1991 could be moved to section 9.6.1.

The following revision to the text is recommended:

“9.6.1 The label of Formula for Special Medical Purposes Intended for Infants shall include the information specified in Sections 4.4.1, 4.4.3, 4.4.4, 4.5.1, 4.5.5, 4.5.2 and 4.5.3 of CODEX STAN 180-1991.”

Section 9.6.3 can be deleted and the following two sections renumbered.

COSTA RICA

Discussed text	Position	Justification
4.6 Carry-over of food additives b) [of the carrier substances mentioned in the Advisory List of Vitamin Compounds for Use in Foods for Infants and Children within the limits of the maximum levels stipulated in that List.]	We suggest keeping the sentence and deleting the square brackets.	
9.1 The name of the food 9.1.6 [Products containing not less than 0.5 mg iron	We suggest deleting this section, considering that a minimum iron content will be established for infant formula that	These statements may be confusing, as the wording “Infant Formula with added

<p>(fe)/ 100 kilocalories shall be labelled “infant formula with added iron”.] Or [Products containing less than 0.5 mg iron (fe)/ 100 kcal shall be labelled with a statement to the effect that when the product is given to infants over the age of four months, their total iron requirements must be met from other additional sources.]</p>	<p>will cover the iron requirements from birth to weaning age.</p>	<p>Iron” on the label could be interpreted as meaning that other formulas which are not labelled with such a statement are insufficient to satisfy an infant’s requirements.</p> <p>The minimum values of iron to be set in the standard should be sufficient to make the formulas suitable for feeding infants at least until 6 months of age.</p>
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<p>9.5 Information for use [Products in liquid form may be used either directly or prepared with safe water and previously boiled water before feeding according to directions for use. Products in powder form also require safe and previously boiled water for preparation.</p> <p>9.5.1 Adequate directions for the appropriate preparation 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 [or in the accompanying leaflet].</p> <p>9.5.2 Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label [or in the accompanying leaflet].</p> <p>9.5.3 The label shall carry clear graphic instructions illustrating the method of preparation of the product.</p> <p>9.5.4 The directions should be accompanied by a warning about the health hazards of inappropriate preparation.]</p>	<p>We agree with the sentence in 9.5 and hence with the deletion of the square brackets.</p> <p>We suggest deleting the wording in square brackets in 9.5.1 and 9.5.2.</p>	<p>Indicating information on the appropriate preparation of the product in a leaflet could lead to inappropriate preparation or storage of the product, if such information gets lost, which could have an adverse effect on an infant’s health. The information on the preparation of the product should always appear directly on the label.</p>
<p>9.6 Additional labelling requirements</p> <p>9.6.6 [No [nutrition and] health claims shall be made regarding the dietary properties of the product.]</p>	<p>We suggest rewording the sentence in square brackets in accordance with the modification which has been agreed for section 8.1.1 of the Draft Revised Standard for</p>	<p>The proposed sentence would allow to use only claims regarding nutrients contained in infant formula for which there is scientific support, i.e., in order to be permitted, such</p>

	<p>Processed Cereal-Based Foods for Infants and Young Children. The sentence reads as follows: "Taking into account paragraph 1.4 of the guidelines for use of nutrition and health claims, nutrition claims may be permitted under national legislation for the foods that are the subject of the standard provided that they have been demonstrated in rigorous studies with adequate scientific standards."</p>	<p>statements must not be misleading nor suggest a superiority of the product.</p> <p>Furthermore, after extensive discussion, it was supported by a great majority of the delegations present at the 27th Session of the CCFSU, so that the use of a similar sentence would be consistent with an agreement reached previously.</p>
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GUATEMALA - 1 -

Page	Guatemala Comments	Justification
65 3.1.3 a) Protein Footnote No. 3	It is felt that the difference between the use of non-hydrolysed cow's milk protein and hydrolysed or partly hydrolysed protein should be maintained.	This corresponds to the biological availability of the protein. It is also important to avoid confusion between different products for different uses. The position of the United States of America Department of Agriculture is supported.
65 3.1.3	Eliminate the brackets around (100 kJ) and leave the phrase as follows: <i>...per 100 kcal or 100 kJ...</i>	Prevents confusion caused by the brackets, which might be considered to be a conversion.
65 3.1.4	Delete the paragraph between the square brackets.	The reference to amino acids occurs in Annex 1 which is included in the standard.
66 3.1.5 c) Carbohydrates	Transfer the paragraph in square brackets to Appendix IV (B) of the standard.	The use of saccharose in soya formulas, some hydrolysed or lactose-free formulas improves the flavour of the formula.
68-69 e) Minerals and Trace Elements	It is proposed that the two tables should be maintained differentiating between iron of animal origin and plant origin. We support the footnote 13 of subsection e). However we request that a higher reference level (1.8 mg and 3.0 mg / 100 Kcal respectively) should be provided instead of a maximum level.	Because of iron deficiency in developing countries it is important to ensure that these products have adequate levels of this micronutrient in order to supplement iron deficiencies in accordance with the different nutritional requirements of all countries.
71 3.2.3	Delete the brackets around (100 kilojoules) and leave the phrase as follows: <i>... per 100 kcal or 100 kilojoules ...</i>	Prevents confusion caused by the brackets, which might be considered to be a conversion.
71 3.2.3	In the table which includes the information on nucleotides it is requested that the word [added] be deleted and the total nucleotides in infant formulations be changed to 16 mg/100 kcal.	This decision was taken subsequent to the technical review provided by ISDN, FDA and the report prepared by the Cochrane Office in Mexico.
79 9.5.1 and 9.5.2	Delete what is in brackets: [or in the accompanying leaflet]	The information relating to these products (use, handling, storage and nutrition) should be included in the label (in accordance with the Codex standard on the labelling of these products) in order to avoid any risk of loss of this information.

GUATEMALA - 2 -

SECTION B: FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS

Comments of Guatemala				Justification
Document in English		Document in Spanish		
Page	Text	Page	Text	
NA	NA	Throughout the document	Modify the translation of “formulas for Special Medical Purposes” from “Preparados para usos medicinales especiales” into “Fórmulas con propósitos médicos especiales”.	We think that this wording is much clearer and avoids confusion.
NA	NA	76 Point 3.5	Modify the translation of “ingredients shall be clean” from “ingredientes deberán estar limpios” into “ingredientes deberán estar libres de impurezas”.	We think that this wording is much clearer and avoids confusion.
85 9.1.1	To eliminate “in accordance with nacional usage”.	88 9.1.1	Delete “de conformidad con las costumbres del país”.	Vocabulary may differ between Spanish-speaking countries (in accordance with national usage). This could make it difficult for the producer to use a common labelling (for various countries) for one and the same product.
85 9.5 that indicates to see section A 9.4 (the amendment requested corresponds to Page 78 (9.4, 9.4.1))	To eliminate the word best from “preceded by the words “ best before”	88 9.4 that refers to Point 9.4.1 on Page 82 (the amendment corresponds to Page 82, Point 9.4.1)	Delete the word preferentemente from the sentence “Consumir preferentemente antes del”.	We think that this may apply to a food in general, but not to a formula for special medical purposes intended for infants. In our country this wording could be interpreted as saying that the product would still be safe after the “best before” date elapsed.
85 9.6.3	To eliminate: “or be provided separately from the package”	88 9.6.3	Delete: “o se facilitará en impreso separado del envase”.	Information on the use, handling, storage as well as nutritional information for these products has to be provided on the labelling (in accordance with the Codex standard on the labelling of such products) in order to prevent any risk of losing the information.

Comments of Guatemala				Justification
Document in English		Document in Spanish		
Page	Text	Page	Text	
85 9.6.2	To eliminate all the information included in this digression.	88 9.6.2	Delete all the information included in this Point.	In our opinion, such a decision has to be taken by a health professional, no such suggestion should appear on the label of the product.
85 9.5 that indicates to see section A 9.5 (the amendment requested corresponds to Page 79 (9.5, 9.5.4)	To change "should be" by "must"	88 9.8 that indicates to see page 82, 9.5.4 (the amendment requested corresponds to page 82 (9.5.4)	Change "deberían" by "deberán".	The warning about the health hazards arising from inappropriate preparation should not be optional. Such information should be mandatory.

ISRAEL

1. In due to the Israeli past experience with unsuitable infant formula with a vitamin deficiency, we propose to establish the minimum and the maximum/'Guidance upper levels' nutrient recommendations for infant formula composition to be based on scientific evidence and not on "apparently history of safe use" or "product contents" that may be misleading and not safe.

Under the latest regulations in Israel, we test all batches of locally produced or imported infant formulas. The results show a wide range of vitamin and mineral levels occasionally way above the manufactures label claims and the maximum/'Guidance upper levels' recommended in this draft of the codex.

In regard to these levels we agree with the ESPGHAN statement ^[1] in their medical position paper that "infant formula should only contain components in such amounts that serve the nutritional purpose or to provide another benefit. The inclusion of unnecessary components, or unnecessary amounts of components, may put a burden on the metabolic and other physiologic functions of the infant."

2. **In section "a) Protein" Footnote 2** (in square brackets)

Israel: Propose to remove the square brackets and keep the conversion factor of 6.25

3. **In section "b) Lipids" Footnote 5 (in square brackets)** "The content of trans fatty acids shall not be higher than [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."

Israel: Supports the maximum value of 3% for trans fatty acids, or lower.

4. **In section "d) Vitamins" Vitamin A (µg RE)**

[1] JPGN 41:584–599, 2005

Per 100 kcal	
Min	Max
60	180

Israeli Comments: Israel is concerned of the use of high vitamin-A levels recommended in some comments. The use of a maximum of 180 µg RE vitamin-A or a higher values, such as 225 µg RE, as proposed in the previews codex for infant formula, will provide a daily quantity of 900 or 1125 µg RE vitamin-A respectively (calculated based on a reference infant with a weight of 5 kg consuming infant formula with an energy content of 500 Kcal per day). This content of vitamin-A is above the USA DRI's^[2] upper limit of 600 µg RE . In addition, we in Israel, as is advised in other countries, recommend a supplementation of vitamin A+D drops containing 330 µg RE per day. All this will bring the amount of vitamin-A to a 1230 µg RE or higher per day.

5. Carrageenan

Israel noted that Carrageenan is included in the provisional list of accepted food additives for infant formulae in this current draft of the Codex standard for an infant formula.

We agree, with the statement of ESPGHAN^[3] in their medical position paper, that Carrageenan is not recommended. It appears inadvisable to use Carrageenan in infant formulae intended for feeding young infants, including those in the category of food for special medical purposes.

MEXICO -1-

- We suggest deleting the square brackets from the footnotes under 3.1.3 a).
- It had been agreed to maintain the square brackets under 3.1.4 until a more detailed review has been carried out.
- We suggest deleting the square brackets from the footnote under 3.1.5 b). We further suggest transferring the footnote under the carbohydrate table of paragraph c), which is surrounded by square brackets, to Appendix IV (B). In the table regarding vitamin C, the square brackets should be deleted and the value given should be a guidance level. The iron value under 3.1.5 e) should be a guidance upper level and not a maximum value. We suggest that the value indicated in the table regarding sodium be a maximum level instead of a guidance upper level.

We suggest deleting the words surrounded by square brackets in the headline of 3.2 so that it reads "Optional ingredients".

Mexico recommends deleting the square brackets from the sentence under 9.1.6.

We suggest deleting the square brackets from 9.5.

Regarding 9.6.6 it had been agreed that nutrition and health claims could be made provided that they were supported by scientific evidence and in conformity with the respective national legislation.

MEXICO -2-

- We suggest adding saccharose in 3.2.3 in case it is necessary.
- Mexico will wait for the proposal of Switzerland in order to analyze the additional additives in Section A.

PHILIPPINES

[2] www.nap.edu

[3] JPGN 41:584-599, 2005

SECTION A: INFANT FORMULA

1. SCOPE

The Philippines recommends the modification of the sentence under item 1.3, thus deleting “product other than” and the phrase “during the first months of life” as follows:

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.~~

Rationale: This proposal is in accordance with Section 11 of Rule V of Revised Implementing Rules and Regulations of Executive Order No. 51 Otherwise known as the Philippine “Milk Code,” no advertising, promotions, sponsorship, or marketing materials and activities for breastmilk substitutes intended for infants and young children up to twenty-four (24) months, shall be allowed...as well as related products within the scope of the code.

2. DESCRIPTION

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Essential Composition

We support the deletion of the square brackets and its content and modify the sentence under footnote ²⁾ and adding the words “**milk and protein**” on superscript ³⁾ as follows:

a) Protein

²⁾ ~~{For the purpose of this standard, the calculation of the protein content 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 nitrogen source.} The protein levels set in this standard are based on a nitrogen conversion factor of 6.25. The amino acid profile of the formula should comply with the reference human milk amino acid profile. The protein content should be determined as total N x 6.25.~~

³⁾ ~~{Infant formula based on non-hydrolysed cow’s milk protein containing less than 2 g protein/100 kcal and infant formula based on hydrolysed milk protein containing less than 2.25 g protein/100 kcal should be clinically evaluated.}~~

Rationale: safety and nutritional efficacy of infant formula requires:

- compliance with the reference human milk amino acid profile
- a validated safe minimum protein level which at the lower end is substantiated with clinical data demonstrating adequate growth

Further, the conditions defined in footnote 2 and 3 fulfill the specific safety and nutritional efficacy criteria for protein when applied to infant formula.

We support the retention of the sentence and deletion of the square brackets in the last sentence of 3.1.4 under protein as shown below:

~~{unless the methionine to cystine or the phenylalanine to tyrosine ratio are outside the range of 0.7-1.5:1}~~

b) Lipids

We support the deletion of the square brackets in superscript ⁵⁾ enclosing total fatty acids and 3% leaving the sentence as is as shown below:

Total fat ⁵⁾ (g)

Commercially hydrogenated oils and fats shall not be used in infant formula.

⁵⁾ Lauric and myristic acids are constituents of fats, but combined should not exceed 20% of total fatty acids. The content of trans fatty acids shall not be higher than 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 formula.

c) Carbohydrates

We support the deletion of the square brackets in superscript ⁶⁾ enclosing the sentence on sucrose and leaving the sentence as is as shown below:

Unless needed, sucrose ~~unless needed~~, and the addition of fructose ~~particularly~~ should be avoided in infant formula, because of potential life-threatening symptoms in young infants with unrecognized hereditary fructose intolerance.

Rationale: in fructose-intolerant people, ingestion of fructose and sucrose produces complicated chemical changes that cannot be corrected because of the absence of the enzyme aldolase B. Ingestion of fructose causes profound hypoglycemia and progressive liver damage. The body is unable to convert its energy storage materials, glycogen, into glucose. Subsequently, the blood sugar falls. In addition, blocks in the metabolic pathway of fructose processing will cause a build-up of substances that damage the liver.

The Philippines suggests to increase the maximum limit of nucleotides to 16 mg/100 kcal.

Rationale:

- In a publication in 1995, it became clear that the total amount of nucleotides in breastmilk, which included both free nucleotides and nucleotides in other forms, averaged ~72 mg/L (9.25 mg/100 kcal) and ranged as high as ~110 mg/L (~16 mg/100 kcal) (leach, 1995).

- Several additional clinical studies of nucleotides in infant formulas at concentrations higher than 5 mg/100 kcal are available and results of these studies support a recommendation for a maximum level of 16 mg/100 kcal for total added nucleotides. These studies have not reported occurrence of adverse effects in infants fed formulas containing total added nucleotides at or above 72 mg/L, including one study with soy formula with nucleotides of about 300 mg/L (~45 mg/100 kcal).

- The Life Sciences Research Office (LSRO)-American Society for Nutritional Sciences' in its *Assessment of Nutrient Requirements for Infant Formulas* recommended a maximum content of nucleotides and nucleotide precursors in infant formula of 16 mg/100 kcal, a value similar to the upper limit reported for human milk. The Expert Panel of said assessment specified that the maximum level of free nucleotides, including available nucleosides and nucleic acids (DNA and RNA) that serve as nucleotide precursors be limited to the amount and composition present in human milk and not exceed 20% of the total nonprotein nitrogen supplied in infant formula, and a maximum total level of 16 mg/100 kcal.

- "The levels of 16 mg/100 kcal of total nucleotides has been added to some infant formulas for more than a decade and there is also a long history of apparently safe use of soy formulas with nucleotides level well above the 5 mg/100 kcal proposed by IEG." (USFDA)

d) Vitamins & e) Minerals

On nutrients (per 100 kcal), Our position is based on the country's Recommended Energy and Nutrient Intakes (RENI 2002 also known as RDA), FAO/WHO and other references cited in the rationale.

Nutrients (Per 100 kcal)

Vitamins/ Minerals	Philippine Position	Minimum	Maximum	Rationale
Vitamin A	Increase	60	180 205	The USFNB (IOM-FNB, 2001) has

(ug) RE	maximum limit from 180 to 205 ug			established the tolerable upper intake levels (UL) for infants (0-12 mos.) at 600 ug of preformed Vitamin A per day, thus, 205 ug is within the safe limit. (Reference: Phil. RENI 2002)
Riboflavin (ug)	Increase maximum limit from 400 to 405 ug	80	400 405	<p>For Filipino infants less than 6 mos., the reported mean volume of milk consumed is 0.75L/day (FNRI-DOST, 1989). With a reported riboflavin concentration of 0.35 mg/L in breastmilk (IOM-FNB, 1998), the adequate intake (AI) of riboflavin is computed as follows:</p> $0.75L \times 0.35 \text{ mg/L} = 0.26 \text{ mg} \sim 0.3 \text{ mg/day}$ <p>For infants 6 to <12 months, the recommended intake may be extrapolated from the AI of younger infants or from breastmilk and weaning food, or from extrapolation of adult requirement. The estimated average milk volume consumed by this age group is reported to be 0.6 L/day (FAO/WHO, 2002; FNRI-DOST, 1989) and the corresponding riboflavin intake from milk is 0.21 mg/day.</p> <p>Further, there have been no reports of toxicity of riboflavin either in humans or in animals. This is probably because the absorption of riboflavin is a saturable process, meaning that it cannot rise beyond a certain level. The maximal absorptive capacity for riboflavin, is about 20 mg/day (Guthrie and Picciano, 1995). Intakes in excess of this amount are excreted in the urine.</p> <p>(Reference: Phil. RENI, 2002)</p>
Iron (mg) (formula based on cow's milk protein and protein hydrolysate)	Strongly propose a single level of iron for all infant formulas	0.45 0.5	2.0 2.5	<p>The maximum levels are low if apply to countries where iron deficiency is a public health problem. The AAP-CON recommendation (1993) is therefore more appropriate.</p> <p>Although a level of 0.3 mg/100 kcal seemed to fulfill conditions during the first six months of life, it has been considered prudent to provide a higher level of iron fortification to prevent the risk of</p>
Iron (formula based on soy protein)				

isolate)				<p>iron deficiency anemia. Therefore the minimum level of 0.5 mg/100 kcal has been selected.</p> <p>Iron absorption is lowered by the presence of phytic acid in soya-based formula. However, this reduction largely depends on the phytic acid level and the vitamin C to iron ratio of formula. Most formula have a vitamin C to iron ratio favoring good iron absorption.</p> <p>Based on the recent scientific evidence and on the minor differences in iron levels between milk and soya-based proposed formulas, we strongly propose one standard with a minimum iron level of 0.5 mg/100 kcal and a maximum iron at 2.5 mg/100 kcal. The proposed values complies with the proposed draft levels as well as with the nutritional requirements for iron.</p> <p>Further, the UL for iron of infants below 12 months is 40 mg/day which is still far beyond the propose maximum limit of 2.5 mg. (Reference: IOM-FNB, 2001)</p>
Iodine (ug)	Increase maximum limit from 50 to 75 ug	10	50- 75	<p>The National Nutrition Survey-Food and Nutrition Research Institute (NNS-FNRI, 2003) reported a prevalence rate of iodine deficiency disorders (IDD) among pregnant (18%) and lactating (23.7%) women whose Urinary Iodine Excretion (UIE) is below 50 ug/L. The joint FAO/WHO Expert consultation noted that there are wide variations in the iodine content of breastmilk as a function of maternal iodine intake. The consultation cited a study which indicated that iodine balance is achieved at an intake of 90 ug/day. Further, the average urinary iodine deficient infant was normalized with a daily dose of 90 ug/day given for several months (FAO/WHO, 2002).</p> <p>On the basis of this consideration, a revision has been proposed for the earlier WHO, UNICEF and the</p>

				International Council for the Control of Iodine Deficiency Disorders (ICCIDD) recommendations of 50-90 ug/day for children 0-12 mos (FAO/WHO, 2002). The 2002 Philippine RDA Committee adopts this value as the RNI for Filipino infants 0-12 mos. (Reference: Phil. RENI, 2002)
Phosphorus (formula based on cow's milk protein and protein hydrolysate) Phosphorus (formula based on soy protein isolate)	Single standard for both cow's (milk protein and protein hydrolysate) and soy (protein isolate formula) with a minimum level of 25 and maximum level at 100 mg/100 kcal	25	90 100	The proposed range covers the nutritional requirements at lower and upper end of all infant formulas.
Potassium	Increase maximum limit from 160 to 200 mg	60	160 200	<ul style="list-style-type: none"> - Potassium is the major solute of intracellular water, whereas sodium and chloride are the major solutes of extracellular water. - The potassium to sodium ratio in human milk is remarkably constant at 3.1, and similar to that in cow's milk. This implies that there is a physiological ratio between these two electrolytes. - Since the sodium maximum level is set at 60 mg/100 kcal, the potassium maximum level should be at least around 186. As the human milk potassium to sodium ratio often exceeds 3.1, a maximum level of 200 mg/100 kcal seem appropriate for infant formulas. - U.S. Infant Formula Act, the Canadian requirements, as well as the current Codex Standard on Infant Formula have maximum levels of 200 mg/100 kcal.
Copper	Increase maximum limit from 80 to 100ug	35	80 100	<p>The American Academy of Pediatrics has recommended that infant formula provide 60ug/100kcal. By following this recommendation, a typical formula-fed infant from birth to 6 months of age receiving 700kcal/day would consume approximately 0.4 mg/day.</p> <p>Further, FAO/WHO Expert Committee concluded that no</p>

				deleterious effects can be expected in humans whose copper intake is 0.5 mg/kg body weight per day (FAO/WHO, 1971). (Reference: Phil. RENI 2002)
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3.2 Optional Ingredients

We support the deletion of the square brackets and the phrase inside it and retain the sentence as is as, and deleting the statement with underline under 3.2.1. Thus, shows the following:

3.2 Optional ~~for non-mandatory~~ 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.~~

Rationale:

The term “optional” is clear that it is not required or mandatory to be part of the standard unless desired to be added.

Regarding 3.2.1, breastmilk contains incomparable ingredients. It also contains non-nutritional components that may promote health, growth, and development (which benefits cannot be similar to infant formula, more so providing benefits which may be similar to outcomes of populations of breastfed babies) such as antimicrobial factors, digestive enzymes, hormones, anti-inflammatory factors and growth modulators.

Optional Ingredients	Philippine Position	Minimum	Maximum	Rationale
Docosahexaenoic acid (DHA)	Increase the maximum limit from 0.5 to 1.0	0	0.5 1.0	<p>Clinical studies have evaluated DHA supplementation in the range of 0.5 to 1.0, no adverse effects were reported for the studied range.</p> <p>The WHO/FAO expert consultation “Fats and Oils in Human Nutrition, 1994” states that “for term infants the provision per kilogram body weight should amount to 40 mg of ARA and its associated n-6 fatty acids and 20 mg of DHA.” Therefore increasing the DHA level to 1% of FA will be in line with these recommendations.</p>

We support the deletion of the square brackets in [3.2.4] and leave the sentence as is.

4.6 Carry-Over of Food Additives

We support the deletion of the square brackets in letter (b) of 4.6, as shown below:

(b) ~~[-of the carrier substances mentioned in the Advisory List of Vitamin Compounds for Use in Foods for Infants and Children within the limits of the maximum levels stipulated in that List.]~~

Rationale:

We acknowledge that CCFAC is currently considering the establishment of a new additive functional class for nutrient carriers. However, we believe that the list of nutrient carriers should remain as is at the end of the advisory list of mineral salts and vitamin compounds for the use in foods for infants and young children. As this list is currently under revision by CCNFSDU we consider that this list of nutrient carriers should also be reviewed.

9. Labeling

9.1 The Name of the Food

9.1.6:

We support retaining option 2, thus deleting its square brackets under 9.1.6, as follows:

~~[Products containing less than 0.5 mg iron (Fe)/100 kcal shall be labeled with a statement to the effect that when the product is given to infants over the age of four months, their total iron requirements must be met from other additional sources.]~~

Rationale:

Option 2 statement clarified that iron needs is increasing due to iron requirements of growing infants which could be sourced not only from milk products but also from other complementary food which must be given beyond 6 months of age. Further, there is Iron Deficiency Anemia (IDA) problem in the Philippines. Thus, we stressed the need for iron supplements from other sources or through the introduction of complementary iron rich food to infants from 6 months onwards.

9.3 Declaration of Nutritive Value

We propose to delete the word “other” in 9.3 (b) and add “optional ingredients if added” as follows:

(b) the total quantity of each vitamin, mineral, choline as listed in paragraph 3.1.2 and any ~~other optional~~ **optional ingredients if added** 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.

Rationale:

Adding the word “optional” instead of “other” is in line with Section 3.2. Including the words “if added” supports the word optional, thus avoiding misinterpretation.

9.5 Information for Use

We propose to modify the sentence in item 9.5 and deleting the square brackets and the phrase inside 9.5.1 and 9.5.2. Further, adding a sentence in 9.5.4 (in bold letters) as shown below:

~~[Products in liquid form may be used either directly or prepared with safe water and previously boiled water before feeding according to directions for use. Products in powder form also require safe and previously boiled water for preparation.~~

All products should be used according to the instructions for use. Products in powder form and concentrated liquids should be prepared with safe and previously boiled water before feeding. Ready to use liquid formula may be used directly according to the instructions for use.

9.5.1 Adequate directions for the appropriate preparation 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 ~~{or and in the accompanying leaflet if used}~~.

9.5.2 Adequate directions regarding the storage of the product after the container has been opened shall appear on the label. ~~{or and in the accompanying leaflet }~~.

9.5.4 The directions should be accompanied by a warning about the health hazards of inappropriate preparation **or unnecessary or improper use of infant formula including information that powdered infant formula may contain pathogenic microorganisms and must be prepared and used appropriately.** }

Rationale:

Instructions for use must be clear. Infant formula in powdered form is given emphasis since it is widely used than the liquid form.

In paragraphs 9.5.1 and 9.5.2 the square brackets and the phrase inside them are deleted since the printing of adequate directions must be in the label itself to avoid detachment (as in the accompanying leaflet) of important information to the product and avoid added cost to the manufacturer (due to additional printing). The added phrase in 9.5.4 is recommended in accordance with the Philippines' Implementing Rules and Regulations (IRR) of Executive Order (EO) 51, specifically Section 26, letter f of Rule VII.

9.6 Additional Labeling Requirements

We propose to add in letter b of 9.6.1, a statement that there is no substitute for breastmilk as follows:

b) The statement "Breastmilk is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breastmilk, **and a statement that there is no substitute for breastmilk.**

We proposed to add in 9.6.2 the phrase "**or graphics**" after **no pictures** and **nor any other picture** respectively thus, the sentence would appear:

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

Rationale:

Pictures and graphics pose subliminal message.

9.6.3:

We propose to add "**close to breastmilk**" after "humanized" and "maternalized," thus, the sentence would appear:

9.6.3 The terms "humanized," "maternalized," "**close to breastmilk**" or other similar terms shall not be used.

Rationale:

The purpose is to be in accordance with the country's national legislation particularly stipulated in the IRR of EO 51 and IAC guidelines of breastmilk substitutes.

9.6.4:

We propose to change the word "**supplemental**" into "**complementary**," thus the sentence would appear:

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

Rationale:

The proposed change of the term **supplemental** to **complementary** is to be consistent with the country's national nutritional guidelines. The term **complementary** is more appropriate to be used since it connotes that mother's milk is complete to meet the nutritional needs of infants from 0-6 months, while the term **supplemental** connotes that a support food is needed because the breastmilk is inadequate.

9.6.6

We support the deletion of the square brackets and all information inside the 9.6.6. Rather we proposed to adopt the existing statement in the Codex Guidelines for use of Health and Nutrition Claims under the item 1.4 of Scope of CAC/GL 23 written as follows:

"Nutrition and health claims shall not be permitted for foods for infants and young children except where specifically provided for in relevant codex standards or national legislation."

Rationale: The purpose is to be consistent with the existing codex guidelines on health and nutrition claims and likewise be in accordance with the country's national legislation.

4. FOOD ADDITIVES

Section 4.2 Emulsifiers

We suggest to include INS 472e (diacetyltartaric acid and fatty acid esters of glycerol-GMP)

Rationale:

This will ensure product quality. It also retains homogeneity of liquid products and liquid reconstituted product especially in formulas where whole proteins are not used. Works better in combination with additive 322 (lecithins) and 471 (mono-anddiglycerides). Has a GRAS status in the US.

Section 4.4 Antioxidants

We suggest to add INS 309 (gamma-tocopherol) and INS 308 (delta-tocopherol) in the list at the amount of 1 mg in all types of infant formula singly or in combination.

Rationale:

They prevent the oxidation of vulnerable fatty acids. Alone or in combination to stabilize preparations containing fats and vitamins. Synergistic effect with additives 304 (L-Ascorbyl palmitate). They are used as natural antioxidants and are much more effective in preventing oxidation of vulnerable fatty acids than alpha tocopherol.

Section 4.5 Packing gas

We suggest to retain nitrogen gas.

Rationale:

Other listed gases need safety evaluation prior to inclusion in the list.

Annex 1

We suggest to delete the square brackets in Annex 1 above the essential and semi-essential amino acids in breastmilk and include this part as reference part, thus appear as follows:

{ Annex 1 }

Essential and semi-essential amino acids in breastmilk

ANNEX II

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

We support the deletion of the square brackets starting from the second sentence in # 4, thus we suggest to retain the entire paragraph in # 4 as is without the square brackets.

AGENDA ITEM 4 (b) DRAFT REVISED STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS

1. DESCRIPTION

2.1. Product definition

We recommend to change the phrase “**Infant Formula**” to “**Formulas for Special Medical Purposes Intended for Infants**” in the beginning of the sentence for Section B to be in line with its title. Thus, the sentence would be as follows:

2.1.2 **Formulas for Special Medical Purposes Intended for Infants** is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold.

3. Essential Composition and Quality Factors

3.3 Vitamin Compounds and Mineral Salts

See Section A 3.3

We support the adoption of Section A 3.3, however, adding the phrase: “**unless restricted due to the disorder, disease or medical condition of the infants,**” thus, appear the sentence as follows:

Vitamins and minerals added in accordance with Section 3.1.3 (d and e) and 3.2.1 should be selected from the Advisory Lists of Mineral Salts and Vitamin Compounds for use in Foods for Infants and Children (CAC/GL 10-1979). **Unless restricted due to the disorder, disease or medical condition of the infants.**

Rationale:

The added phrase is self-explanatory.

4. Food Additives

We support the deletion of the square brackets in food additives here in Section B 4 and reiterate our position in Section A under Food Additives to be the same with Section B. (see comments to Section A 4 for reference).

A. Advisory List of Mineral Salts and Trace Elements for Use in Foods for Special Dietary Uses Intended for Use by Infants and Young Children

We support the deletion of the square brackets of the following mineral salts and trace elements: calcium sulphate, cupric carbonate, cupric citrate, and UMP (uridine 5-monophosphate). Other mineral salts and trace elements in square brackets with purity requirements by CAC, FCC, JECFA, and other internationally recognized institutions are likewise supported. Mineral salts and trace elements without purity requirements except those identified in the first sentence of this paragraph are not supported.

UNITED STATES OF AMERICA

I. GENERAL COMMENTS

We support the concept of Section B for formulas for special medical purposes intended for infants. We also support the approach that the items in Section A serve as the model for Section B with modifications as needed for Section B.

II. SPECIFIC COMMENTS

2. DESCRIPTION

2.1.1 Formula for Special Medical Purposes Intended for Infants means a substitute for human milk or infant formula that complies with Section 2, Description of the Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991) and is specially manufactured to satisfy, by itself, the special nutritional requirements of infants with specific disorders, diseases or medical conditions during the first months of life up to the introduction of appropriate complementary feeding. **These products are to be used under the continuous direction and monitoring of a physician.**

Comment: We propose addition of the sentence shown above to the description of Formula for Special Medical Purposes Intended for Infants.

Rationale: For clarity and completeness of the description of Formulas for Special Medical Purposes Intended for Infants, it is important to draw attention to the need for these products to be used as a part of medical care.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1.3 The energy content and nutrient composition of Formula for Special Medical Purposes Intended for Infants shall be based on the requirements for infant formula as given in Sections A 3.1.2 and A 3.1.3, except for the compositional provisions which must be modified to meet the special nutrition requirements deriving from disease(s), disorder(s), or medical conditions(s), for whose dietary management the product is specially formulated, labeled and presented.

Comment: Although all of Section A3.1 is in square brackets, we anticipate that many of the nutrients in Part A may be taken out of square brackets at the 28th Session of CCNFSDU, thereby providing an opportunity for consideration of levels for these nutrients for Part B. Formulas for special medical purposes intended for infants differ substantially from routine infant formulas and from one other. Therefore, all references to Part A must be done with careful consideration.

3.2 Optional Ingredients

3.2.1 In addition to the compositional requirements listed 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 for the infant and for the dietary management of his/her disease, disorder or medical condition.

Comment: We recommend that the content of Section 3.2 (Optional Ingredients) be established in Part A before considering this section in Part B.

4. FOOD ADDITIVES

Comment: The Delegation of Switzerland is preparing a revised list of food additives for the standard, taking into account proposals made by CCFAC on this section for the draft revised standard for Processed Cereal Based Foods for Infants and Young Children and comments submitted to the 27th Session (ALINORM 06/29/26 para 109). We have not yet received a revised list from the Delegation of Switzerland, but anticipate having comments on it at the upcoming CCNFSDU session.

The United States believes it is necessary for the CCNFSDU to establish working principles for establishing

food additive provisions to guide a transparent decision-making process for the Committee and to facilitate progress on the food additive provisions of the standard. We expect to re-propose working principles for the Committee's consideration at its 28th Session.

We also note that the Codex Alimentarius Commission decided to defer consideration of adoption of food additive provisions in the GSFA for two infant formula categories (13.1.1 and 13.1.2), pending finalization of the draft standard for infant formula and submission of the additive sections for endorsement by CCFAC (ALINORM 06/29/41, para 49).

9. LABELLING

Comment: We anticipate that labels for formulas for special medical purposes intended for infants will need to be adapted according to the specific nature of these formulas. Provisions of the Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991) will need to be incorporated, as appropriate, to reflect the medical purpose of these products.

In addition to the requirements under the Codex General Standard for Labelling of Prepackaged foods (CODEX STAN 1-1985 (Rev. 1-1991)) the following specific provisions apply:

9.1 The Name of the Food

Comment: Part A includes several provisions under 9.1. However, in ALINORM 05/28/26 and ALINORM 06/29/26, the Part B draft includes only the provision regarding the name of the product, shown as renumbered 9.1.2 below. We do not recall discussion that all of the provisions from A9.1 should not be included in B9.1 and recommend inclusion of 9.1.1, 9.1.2, 9.1.3, 9.1.4, and 9.1.5, as shown below.

A9.1.1 The text of the label and all other information accompanying the product shall be written in the appropriate language(s).

Comment: We recommend addition of A9.1.1. to Part B.

Rationale: We recommend this addition to keep the Labelling Section of Part B parallel to the corresponding section in Part A. Section 9.1.1 from Part A shown above is applicable to Part B.

[9.1.4 2 The name of the product shall be "Formula for Special Medical Purposes Intended for Infants" or any appropriate designation indicating the true nature of the product, in accordance with national usage.]

Comment: The content of this section is consistent with the content of A9.1.2. and renumbering as 9.1.2 is parallel with the numbering in Part A.

[9.1.3 **Labels for** Formula for Special Medical Purposes Intended for Infants in which the essential characteristics involves a specific modification of the content or nature of the proteins, fats or carbohydrates shall bear a description of this modification and information on the **protein**, amino acid, fatty acid or carbohydrate profile, when necessary.]

Comment: We recommend the wording for 9.1.3 specify that this information be on the labels.

Rationale: This information is critical for correct use of these types of products and needs to be stated on the label.

Comment: Protein should be included in the list of modifications to be described, as the modification in protein may not be captured by including information only on the amino acid profile.

[A9.1.4 If cow's milk is the only source of protein, the product may be labelled "~~Infant Formula~~ **Formula for Special Medical Purposes Intended for Infants** Based on Cow's Milk".]

A9.1.5 A product which contains neither milk or any milk derivative shall be labelled "contains no milk or milk products" or an equivalent phrase.

Comment: These provisions from Section A (A9.1.4 and 9.1.5) are not in square brackets and are applicable to Section B. We propose their addition, with the correct product name, as shown above.

9.5 Information for Use

See Section A9.5, **including 9.5.1, 9.5.2, 9.5.3, and 9.5.4.**

Comment: For greater clarity, we suggest the above edit.

Rationale: Some of the provisions from CODEX STAN 180-1991 pertain to use of formulas for special medical purposes intended for infants and should be included in B.9.5 as well as the provisions from Section A9.5. To avoid confusion and provide for consistent and parallel numbering in Section B9.5, reference should be made to the subsections of Section A9.5.

[9.5.5 Formula for Special Medical Purposes Intended for Infants shall be labelled with the information as specified in Sections 4.4.1, 4.4.2, 4.4.3, 4.4.4, 4.5.1, and 4.5.6 of CODEX STAN 180-1991.]

Comment: We recommend addition of 9.5.5 with reference to pertinent information in CODEX STAN 180-1991.

Rationale: Sections 4.4.1, 4.4.2, 4.4.3, 4.4.4, 4.5.1, and 4.5.6 of CODEX STAN 180-1991 contain information pertaining to the use of formula for special medical purposes intended for infants.

9.6 Additional Labelling Requirements

~~[9.6.1 Formula for Special Medical Purposes Intended for Infants shall be labeled with the additional information specified in Sections 4.4.1, 4.4.3, 4.4.4, 4.5.1, and 4.5.5 of CODEX STAN 180-1991.~~

Information specified in Sections 4.5.2, 4.5.3, and 4.5.5 of CODEX STAN 180-1991 shall be included on the label or provided separately from the package.]

Comment: We suggest listing of information for use in Section 9.5.5, as shown above and listing of additional information that does not pertain to use of the product in this section.

9.6.2 A prominent statement indicating that the product is intended as the sole source of nutrition shall appear on the label.

~~[9.6.3 In addition, the information specified in Sections 4.5.2, 4.5.3 and 4.5.6 of CODEX STAN 180-1991 shall be included on the label or be provided separately from the package.]~~

Comment: Information in Section 9.6.3 has been incorporated into Sections 9.5.1 and 9.6.1 as shown above.

~~9.6.43 Labels and information provided separately from the package should not discourage breastfeeding, unless breastfeeding is contraindicated on medical grounds for the disease(s), disorder(s) or medical condition(s) for which the product is intended.~~

~~9.6.54 The product shall be labelled in such a way as to avoid any confusion between formula for special medical purposes intended for infants, infant formula and follow-up formula.]~~

Comment: These sections should be renumbered if Sections 9.5 and 9.6 are reorganized as suggested. We also suggest removal of square brackets on these sections.

10. METHODS OF ANALYSIS AND SAMPLING:

Comment: We note that the methods of analysis and sampling for infant formulas in Part A should also apply to Part B when the square brackets are removed from A.10.

VIETNAM

This standard is composed of two sections: section A covering infant formula for normal, healthy infants and section B covering infant formulae for special medical purposes (FSMP), i.e. formulae for infants with special nutritional needs due to their specific physiological status.

Section A: Infant formula:

The revision of this standard was maintained at step 6 (see Report Appendix IV(A)) of the Codex procedure.

The revised draft will be forwarded for adoption to the Codex Commission early July 2006.

Although many revisions are acceptable, three major issues are still highly debated and require your attention:

- Essential composition:

The recommendations of the International Expert Group (coordinated by ESPGHAN (Prof. Koletzko)) were the basis for discussion and enabled to make considerable progress. However, several issues are still open and will be discussed within an electronic Working Group, chaired by Germany (Prof. H. Przyrembel).

Agreed items:

All items are acceptable.

- General principles for establishing min. and max. values

Maximum levels will be set using a science-based risk assessment approach.

Upper guidance value will be set in absence of scientific data based on an established history of safe use.

- Lipids & Carbohydrates.

Openstanding items (in brackets):

- Essential composition & Optional ingredients:

Item	Codex proposal	Issue	Our comment
<u>Essential composition</u>			
Protein	Protein-nitrogen <u>conversion factor</u> of 6.25, unless justification for other factor	Some delegations insist on 6.38 for milk protein	<u>Agree</u> with Codex proposal
	<u>Min. level</u> at 1.8 g/100 kcal for <u>milk protein</u> with clinical testing if <ul style="list-style-type: none"> – <2.0 g/100 kcal for intact milk protein – <2.25 g/100 kcal for hydrolysed milk protein <u>Min. level</u> at 2.25 g/100 kcal for soy protein isolate	EU needs to validate with Member States	<u>Agree</u> with Codex proposal
	<u>No addition of Cys and Met</u> for calculation purposes unless ratio between 0.7 – 1.5:1	US & ISDI oppose to this criterium and will provide data to e-WG on safe history of use aiming removal of this criterium	<u>Do not agree</u> with Codex proposal Scientific justification was provided earlier to markets

Vitamins & Minerals	No agreement on max. and/or upper guidance levels	US & ISDI propose <u>upper guidance value</u> based on history of safe use and will provide data to e-WG in order to establish appropriate upper level ISDI Report is finalised by March 10 and send to chair of e-WG	<u>Support</u> ISDI report, which will be send to markets next week..
Optional ingredients			
Nucleotides	Max. level of addition at 5 mg/100 kcal	Several delegation opposed and request a level of 16 mg/100 kcal	<u>Agree</u> with Codex proposal
LCPUFA	Mandatory addition of ARA when DHA is added	ISDI requests authorisation of DHA addition only based on recent scientific evidence	<u>Do not agree</u> with Codex proposal Scientific justification was provided earlier to markets

- Additives:

The delegation of Switzerland will prepare a revised list of additives for consideration by the next meeting.

- Nutrition and health claims:

No discussion on this section. Noteworthy, several delegations do not support claims.

The sentence [No [nutrition and] health claims shall be made regarding the dietary properties of the product.] was retained in [].

Section B: FSMP:

The revision of this standard was advanced to step 5 (see Report Appendix IV(B)) of the Codex procedure and is acceptable.

The following issues were agreed upon:

- WHO Code and FSMP:

Upon a lengthy discussion, consensus was achieved that the Code does not apply in its entirety to FSMP. Therefore the sentence in §1.4 reads "The application of this section of the standard should take into account, as appropriate for the product to which the section and the special needs of the infants for whom they are intended".

- Product definition:

Agreement that FSMP can substitute breast-milk or infant formula.

- Compositional criteria:

Compositional criteria are pending on the progress of section A taking into account that for FSMP.

- Additives:

The delegation of Switzerland will prepare a revised list of additives for consideration at the next meeting.

ISDI - International Special Dietary Foods Industries

General comment:

ISDI would like to propose the cross references in the Section B to be removed and replaced by the entire text.

Rationale:

It would simplify the reading of the document and reduce risks of confusion/errors where the practical aspects of the Standard will be implemented, and will impact on consumers i.e. the labelling information.

Proposed text	ISDI comments and justification
<p>1. Scope 1.1 This section of the standard applies to Formula for Special Medical Purposes Intended for Infants in liquid or powdered form intended for use, where necessary, as a substitute for human milk <u>or infant formula</u> in meeting the special nutritional requirements deriving from the disorder, disease or medical condition for whose dietary management the product has been formulated.</p>	ISDI supports the proposed wording.
<p>1.4 The application of this section of the Standard should take into account, <u>as far as appropriate for the products to which this section applies and the special needs of the infants for whom they are intended,</u> 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).</p>	ISDI supports the proposed wording.
<p>2. DESCRIPTION 2.1 Product definition 2.1.1 Formula for Special Medical Purposes Intended for Infants <u>means a substitute for human milk or infant formula</u> that complies with Section 2, Description, of the Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991) and is specially manufactured to satisfy, by itself, the special nutritional requirements of infants with specific disorders, diseases or medical conditions during the first months of life up to the introduction of appropriate complementary feeding.</p>	ISDI supports the proposed wording.
<p>3.1 Essential Composition 3.1.1 Formula for Special Medical Purposes Intended for Infants is a product based on ingredients of <u>animal, plant and/or synthetic origin</u> suitable for human consumption. All ingredients and food additives shall be gluten-free.</p>	ISDI supports the proposed wording. However, ISDI would like to remind that Essential Composition in Section A is not final yet and therefore adjustments may need to be done in the future.
<p>3.1.2 The composition of Formula for Special Medical Purposes Intended for Infants should be based on sound medical and nutritional principles</p>	<u>Delete</u> part of the second sentence <u>Rationale:</u> it is redundant.

<p>and Their use should have been demonstrated by scientific evidence, to be safe, and beneficial in meeting the nutritional requirements of infants for whom they are intended.</p>	
<p>4. Food Additives see Section A 4. The following additional food additives are permitted in the preparation of Formula for Special Medical Purposes Intended for Infants (to be filled in).</p>	<p>ISDI detailed comments have been previously provided to the delegation of Switzerland in charge of the revision of this section.</p> <p><u>Rationale</u>: see annex</p>
<p>9.5 Information for Use see section A 9.5 {Products in liquid form may be used either directly or prepared with safe water and previously boiled water before feeding according to directions for use. Products in powder form also require safe and previously boiled water for preparation. All products should be used according to instructions for use. Products in powder form and concentrated liquids should be prepared with safe and previously boiled water before feeding. Ready for consumption liquid formula may be used directly according to instructions for use.</p>	<p><u>Reword</u> and change the order of the sentence.</p> <p><u>Rationale</u>: adds clarity and powdered formula are the most commonly used type of formula around the world.</p>
<p>9.6 Additional Labelling Requirements 9.6.1 Formula for Special Medical Purposes Intended for Infants shall be labelled with the additional information as specified in Sections 4.4.1, 4.4.3, 4.4.4, and 4.5.1 and 4.5.5 of CODEX STAN 180-1991.</p>	<p><u>Delete</u> the cross reference to section 4.5.5. <u>Add</u> “and”</p> <p><u>Rationale</u>: it is redundant with section 4.5.3. which section 9.6.3. refers to.</p>

ANNEX

Comments on Food Additives for FSMPs
(Section 4. Food Additives)

These comments are based on CX/NFSDU 05/27/6-ADD.1 the Proposed List of Food Additives for the Codex Draft Revised Standard For Infant Formula and Formulas for Special Medical Purposes Intended for Infants Prepared By the Swiss Electronic Working Group and ALN 06/29/26.

We support the additives proposed by the Swiss Electronic Working Group for Section A and the additional additives the Working Group as proposed for Section B, with the following comments:

Part 1: Additives listed in Appendix IV(A) where ISDI requests a different level for FSMPs (Section B) that the one proposed in Section A.

	INS NO.			Maximum level in 100 mL of the “ready for consumption” product	Technological Justification
4.1	<i>Thickening Agents</i>				
4.1.2	410	Carob bean gum (Locust bean gum)		0.1 g in all types of infant formula REQUESTED at 0.5 g /100ml	Non caloric thickening agent. Emulsion stabiliser, adjustment of viscosity. Used in some anti regurgitating formulas. If a lower level is used, the solution separates very quickly in phases. Carob bean floats to the upper level of the solution very quickly, so a minimum viscosity is needed to prevent this phenomenon. This can be obtained only by minimum concentrations from 0.4g/100ml.
	472e	Diacetyltartaric and fatty acid of		REQUESTED at GMP	Retains homogeneity of liquid products and

		esters of glycerol			liquid reconstituted powder especially in formulas where whole proteins are not used. Has a high HLB, works better in combination with additive 322 and 471. Has a GRAS status in the US
	308	Gamma-tocopherol		REQUESTED at 1 mg in all types of infant formula singly or in combination	Alone or in combination to stabilise preparations containing fats and vitamins. Synergistic effect with additives 304 and 305. They are used as natural antioxidants and are much more effective in preventing oxidation of vulnerable fatty acids than alpha tocopherol.
	309	Delta-tocopherol			

Part 2: Additives not listed in Appendix IV(A) that ISDI requests for FSMPs (Section B) in addition to those proposed in Section A.

	INS no.			Maximum level in 1kg or 1l of the product	Technological Justification
		<i>Thickening agents</i>			
	401	Sodium alginate		<p style="text-align: center;">1g/l</p> <p>From four months onwards in special food products with adapted composition, required for metabolic disorders and for general tube feeding</p>	Used in some liquid formula containing fibre. When used in combination with additive 412, 401, 410, 415, the hydrocolloids in the mix prevent the separation of fibre in the liquid feed. It is important during the sterilisation process that the room temperature viscosity of the product is reduced otherwise the sterilisation effect will be impaired. At the same time, the same viscosity and gelling effect must be thermoreversible in order to hold the fibres together during feeding. Single hydrocolloids do not have the necessary effect and there are no other protein free additives available for this type of application.

	410	Carob bean gum (Locust bean gum)		10 g/l From birth onwards in products for reduction of gastro-oesophageal reflux	Non caloric thickening agent. Emulsion stabiliser, adjustment of viscosity. Used in some anti regurgitating formulas. If a lower level is used, the solution separates very quickly in phases. Carob bean floats to the upper level of the solution very quickly, so a minimum viscosity is needed to prevent this phenomenon.
	412	Guar gum		10 g/l From birth onwards in products in liquid formulae containing hydrolysed proteins, peptides or amino- acids.	Minimises and delays physical separation of the product, fat separation and fat globule coalescence. Guar gum is an excellent water binder, it does not form gel, which is an advantage in liquid products, it is cold water soluble and will not modify the thickening effect obtained by carrageenan.
	415	Xanthan gum		1.2 g/l From birth onwards for use in products based on amino acids or peptides for use with patients who have problems with impairment of the gastro- intestinal tract, protein mal-absorption or inborn errors of metabolism.	Thickening for semi solid preparation. Optimum viscosity is achieved when used in conjunction with other thickening agents.
	440	Pectins		10 g/l From birth onwards in products used in case of gastro-intestinal disorders.	Used a gelling agent in place of gelatine. Particularly efficient in presence of fruits and in acidic preparations. Thickening for semi solid preparation. Optimum viscosity is achieved when used in conjunction with other thickening agents.
	466	Sodium carboxymethyl cellulose		10 g/l or kg From birth onwards in products for the dietary management of metabolic disorders.	Better thickening, gel formation, solvation and a less "sandy" product is obtained with additive 466 compared to pectine. It disperses easily in water forming colloidal solutions; it can therefore be used as a suspending agent, an emulsifying agent and in the preparation of gels. Furthermore, it improves dispersion of other agents. Its technological functions are hardly influenced by temperature and metal salts have little effect on its viscosity.

	472c	Citric and fatty acid esters of glycerol		7.5 g/kg for formulae sold as powder 9 g/l for formulae sold as liquid	Has an HLB value of 10-12, is one of the most effective emulsifiers of oil in water emulsions. Produces a stable, milky white emulsion, giving the final product (usually products with superior stability, taste and organoleptic properties. Positive opinion on such usage has been expressed by the European Scientific Committee for Food in June 1997 and September 2002)
	1450	Starch sodium octenyl succinate		20 g/l From birth onwards	Viscosity and stability properties that native starch tend to lose when processed

		<i>Emulsifier</i>			
	471	Mono- and diglycerides of fatty acids		5 g/l From birth onwards in specialised diets, particularly those devoid of proteins	Natural stabiliser that retains homogeneity of liquid products and liquid reconstituted powder. Because it has an intermediate hydrophilic/lipophilic balance (HLB) value, it is suitable for emulsifying products containing fats which require intermediate HLB emulsifiers. It is a robust substance in that it can withstand harsh processing conditions, such as spray drying and UHT processing. This property has been beneficial for the development of ready-to-feed UHT liquid products providing complete nutrition. It is also used extensively for emulsifying fat and carbohydrate components. Its resistance to ionic interactions make it suitable for use in products containing mineral and trace elements such as nutritionally complete products.