

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
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ORGANIZATION



JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 4 (a)

CX/NFSDU 06/28/4

July 2006

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES 28th Session

Chiang Mai, Thailand, 30 October - 3 November 2006

DRAFT REVISED STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS: SECTION A DRAFT REVISED STANDARD FOR INFANT FORMULA

- Comments at Step 6 of the Procedure -

Comments from:

ARGENTINA

AUSTRALIA

BOLIVIA

CHINA

COSTA RICA

INDIA

NORWAY

PERU

UNITED STATES OF AMERICA

AIDGUM – International Association for the Development of Natural Gums

ENCA – European Network of Childbirth Associations

IDF - International Dairy Federation

ILCA - International Lactation Consultants Association

ISDI - International Special Dietary Foods Industries

ARGENTINA

2. DESCRIPTION

2.1 Product Definition

2.1.2

Argentina believes it is appropriate to delete the term “*cualesquiera*” from the Spanish version as it is not the correct translation of its counterpart in English.

The paragraph should be redrafted as follows:

“El preparado para lactantes se elabora exclusivamente por medios físicos y se envasa de manera que se evite su alteración y contaminación en cualesquiera condiciones normales de manipulación, almacenamiento y distribución en el país en que se vende el producto.”

4. FOOD ADDITIVES

4.1 Thickening Agents

Argentina suggests that these additives be deleted from the table as their use is not justified in food for healthy children.

Bibliography:

-Scientific Committee for Food (SCF), The European Commission, 106th Meeting of the SCF on 21 March 97.

-Aggett PJ, Agostoni C, Goulet O, Hernell O, Koletzko B, Lafeber HI, Michaelsen KF, Milla P, Rigo J, Weaver LT. Antireflux or Antiregurgitation Milk Products for Infants and Young Children: A Commentary by the ESPGHAN Committee on Nutrition. *J Pediatr Gastroenterol Nutr* 2002; 34: 496-8.

4.3 pH-Adjusting Agents

Argentina suggests that the following items of the table of food additives be corrected:

In 4.3.12 and 4.3.14 (column “**Maximum level in 100 mL of the ready-to-drink product**”), the phrase “Limited by GMP and within the limits for sodium and potassium in Section 3.1.2(c) in all types of infant formula” should be redrafted as follows: “Limited by GMP and within the limits for sodium, potassium **and phosphorus** in Section 3.1.2(c)”, as the maximum levels established in 3.2.1 (c) in order to avoid potentially deleterious effects and distortions in the calcium/phosphorus relation.

4.6 Carry-over of Food Additives

Argentina believes that the brackets in part b) should be deleted from this item, as it is reasonable to consider that removal of such compounds is difficult.

Argentina also believes that it would be appropriate to limit the table of additives as it concerns food to be consumed by infants.

9.1 The Name of the Food

9.1.6

Argentina believes it is appropriate to consider the second option of iron declaration in this item:

[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.]

We also suggest that this second alternative should be mandatory as we consider it necessary and more appropriate given its emphasis on the importance of meeting the need for iron, which may cause not only anemia but also alterations in cognitive development if there are deficiencies at this age.

9.5 Information for Use

Argentina suggests that the word “salubre” in the Spanish version be replaced by “potable”, which is the appropriate translation into Spanish.

Further, Argentina supports the deletion of the brackets as all mandatory declaration information should be included in the label rather than in a brochure, which generally comes separately.

9.5.1 and 9.5.2

Argentina supports the deletion of the bracketed phrases in both items as mandatory declaration information shall be included in the label rather than in a brochure, which generally comes separately. If necessary, label information may be duplicated in the brochure.

9.6 Additional Labelling Requirements

9.6.6

Argentina suggests that the brackets in this item be deleted as this food should not contain nutrition legends or health claims to promote sales. Paediatricians should indicate whether an infant formula should be consumed and which.

AUSTRALIA

Australia has confined its comments to matters that are not currently under consideration by other working groups (i.e. Sections 3.1 and 4).

Paragraph 9.3 (b)

Australia proposes that the words ‘other ingredient’ in this section be replaced by ‘optional ingredient’ to maintain terminology that is consistent with our similar preference for the title of Section 3.2, as submitted to the Working Group on the Composition of Infant Formula.

Paragraph 9.5

Australia supports the intention of the introductory paragraph for Section 9.5. However, we are of the view that the wording should be changed to the following text, so that it is more precise on the grouping of liquid products according to their method of 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 to use liquid formula may be used directly according to instructions for use.’

Paragraphs 9.5.1 and 9.5.2

Australia does not support the text in square brackets for Sections 9.5.1 and 9.5.2 (i.e. ‘...or the accompanying leaflet’), and therefore requests the deletion of this text. The directions for use and for storage after opening are critical to the safe use of infant formulas, and should be shown on the label and accompany the container at all times.

Paragraph 9.6.6

Paragraph 9.6.6 is not necessary in the context of the generic prohibition of nutrition and health claims on foods for infants and young children unless otherwise permitted in a Codex Standard (Paragraph 1.4 in the Codex *Guidelines for Use of Nutrition and Health Claims*). Paragraph 9.6.6 should be deleted, as the introduction to Section 9 states that its provisions are *in addition* to Codex general labelling requirements.

However, Australia supports a reference in Section A of the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants to the generic prohibition (unless specifically permitted) on nutrition and health claims on foods for infants and young children. We propose that such a reference be made in the introductory paragraph to Section 9, and suggest the new text: *These requirements include a prohibition on the labelling of nutrition and health claims unless specifically provided for in relevant Codex standards.*

The introduction would then read:

“The requirements of the Codex General Standard for the Labelling of Pre-packaged Foods (CODEX STAN 1-1985 (Rev. 1-1991), the Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985 (Rev.1-1993), and the Guidelines for Use of Nutrition and Health Claims apply to infant formula and formulas for special medical purposes intended for infants. These requirements include a prohibition on the labelling of nutrition and health claims unless specifically provided for in relevant Codex standards.”

In addition to these requirements, the following specific provisions also apply:”

BOLIVIA

SECTION A: INFANT FORMULA

General comments

Bolivia believes it is important for future revisions of this document and other documents to adhere to a logical order of revision. In our opinion the comments regarding Section A of this document should be circulated first and the comments regarding Section B, which is dependent on Section A, should be issued afterwards.

We are further of the opinion that, to maintain the legibility of the Standard, all the wording of Section A that applies to Section B as well should be quoted in detail in both texts.

Comments regarding translation

Bolivia would like to draw the attention of the Secretariat of the Committee to some translation errors in the Spanish version which change the meaning of the Standard

In the title, the word "Preparados" should be replaced with "Formulas" which is the correct translation of the word "*Formula*".

In 1.1 the wording "las necesidades nutricionales" should be modified to read "los requerimientos nutricionales" in accordance with the wording of the original English version "The nutritional requirements".

The wording of 9.2.1 should be reviewed completely as the Spanish version is not consistent with the English original.

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.

Justification

Bolivia asks to delete the word "normal", as it causes confusion regarding the question of what is or is not a normal infant.

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 [six] months of life.

Justification

Bolivia asks to add a clarification that these formulas are intended for infants younger than six months in line with the World Health Assembly resolutions to which reference is made in this document. This would correspond to the definition of the document. Without such clarification users of the Standard might understand that this document applies to formulas for infants aged from 0 to 12 months.

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 and World Health Assembly resolutions WHA54.2 (2001) [WHA 55.25 y 58.32] [and relevant WHA resolutions].

Justification

Bolivia asks to add a reference to the World Health Assembly resolutions relating to the production of infant formula, as these resolutions are regarded to be the general international framework for the marketing of these products.

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 [six] months of life up to the introduction of appropriate complementary feeding.

Justification

As it is understood that - IF NECESSARY - this product will be the sole source of nutrition when medically indicated, it is not necessary to point this out in the definition.

The comment regarding the wording "six months" is equivalent to the comment made regarding 1.3.

2.2 Other definitions

The term *infant* means a person not more than 12 months of age. [Young infant means a child aged 0 to 6 months and older infant means a child aged 6 to 12 months.]

Justification

This suggestion complements the one above, and the purpose is to make it absolutely clear that this Standard refers to infants aged from 0 to 6 months.

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.}

Justification

Bolivia agrees with the second proposal as the first one may lead to confusion in labelling.

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

Justification

Bolivia asks again to address the issue of nutrition and health claims regarding the dietary properties of the product in this Section. Moving it to "Additional Labelling Requirements" might give the impression that this information may or may not be included on the label.

Bolivia believes it is important to comply with the provisions of the Standard CAC/GL23 "Guidelines for Use of Nutrition and Health Claims" according to which:

"1.4 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."

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.

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 any]**.

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]** in the accompanying leaflet **[if any]**.

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.}

Justification

Bolivia agrees with the general wording of 9.5 Information for Use, which should always be included in the label. As far as the use of a leaflet is concerned, we believe that at the moment there is a wide range of products worldwide which are marketed without any leaflet and where all the information required for the consumer is indicated on the label. Therefore it should be indicated in 9.5.1 that the information for use shall always appear on the label as well as in the leaflet, if any.

CHINA

ALINORM 06/29/26, Appendix IV (A)	JUSTIFICATION
SECTION A: INFANT FORMULA	A :
[3.1 ESSENTIAL COMPOSITION	
a) PROTEIN	
<p>3.1.3 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.]</p>	Delete brackets and keep the text.
<p>3) [Infant formulae bases on non-hydrolysed cows' milk protein containing less than 2 g prtotein/100 kcal and infant formula based on hydrolysed protein containing less than 2.25 g protein/ 100 kcal should be clinically evaluated.]</p> <p>3.1.4 [unless the methionine to cysteine or the phenylalanine to tyrosine ratio <u>are</u> outside the range of 0.7-1.5:1].</p>	<p>Keep brackets.</p> <p>Delete both brackets and text</p> <p>Reason:</p> <p>Formulas based on unmodified milk protein have a methionine to cystine ratio of about 3 and would be limited by this criterion. While Casein-predominant infant formula, prepared from unmodified cow's milk protein, it have been used for many years on the market make up a considerable part of the infant formula. Its long historical use has demonstrated the adequate supports to the growth during early life.</p>
<p>3.1.5</p> <p>5) ...20% of [total fatty acids]. ...</p> <p>... not be higher than [3%] of total fatty acids. ...</p> <p>... The acceptance of up to [3%]of trans fatty acids ...</p>	<p>Keep brackets</p> <p>Support IDF suggestion of 5%</p> <p>Support IDF suggestion of 5%</p>

<p>C)Total carbohydrates</p> <p>6) ... [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.]</p>	<p>Delete the brackets and change the text to the following:</p> <p>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.</p> <p><u>Reason</u></p> <ul style="list-style-type: none"> - There is no scientific evidence that the consumption of sweeter formulae would lead to greater weight gain. - There is no proof that the consumption of sweeter formulas would promote a preference for sugar in later life. <p>Sucrose is an available superior quality source of carbohydrates.</p>
* (Vitamin C, phosphorous)	Do not find the interpretation on asterisk (*)
d) Vitamins	No objection on the guidance upper level (GULs).
e) Minerals and Trace elements	
Iron (formula based on cows' milk protein and protein hydrolysate)(mg)	Suggest establishing a single level of iron for all infant formulas with the minimum at 0.5 mg/100 kcal and the maximum at 2.5 mg/100 kcal. A minimum 0.5 mg/100 kcal is appropriate to fulfill iron requirements of infants during the first six months of life. Although a level of 0.3 mg/100 kcal seemed to fulfill iron requirements of infants in optimal environmental 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 iron deficiency anemia. Therefore the minimum level of 0.5 mg/100 kcal has been selected.
Iron ((formula based on soy protein isolate)(mg)	Suggest establishing a single level of iron for all infant formulas with the minimum at 0.5 mg/100 kcal and the maximum at 2.5 mg/100 kcal.
Calcium (mg)	Agree.
Phosphorus (formula based on cows' milk protein and protein hydrolysate) (mg)	A single level of phosphorus is favoured with the minimum at 25 mg/100 kcal and the maximum at 100 mg/100 kcal, including formulas based on cows' milk protein and protein hydrolysate and formula based on soy protein isolate.
Ratio Calcium/Phosphorus	High levels of phosphorus in infant formula are undesirable. We support max. Ca/P ratio of 2.2. This value is physiological and is regularly found in the breast milk.
Chloride (mg)	Agree.
Potassium (mg)	The maximum level of 200 mg/100 kcal for potassium in current Codex Standard (72-1981) is safe to infant, and is technologically necessary for the production of hydrolysed formula, and should be kept.

	<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 cows' milk. This implies that there is a physiological ratio between those two electrolytes. - Since in this standard, 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.
Manganese (ug)	<p>A minimum of 1 µg/100 kcal is justified.</p> <p>Suggest a maximum at 100µg/100 kcal.</p>
Iodine (ug)	<p>A minimum of 1 µg/100 kcal is justified.</p> <p>In agreement with maximum of 50µg/100 kcal.</p>
Copper (ug)	<p>A minimum of 20 mg/100 kcal and A minimum of 100 mg/100 kcal are justified.</p>
Zinc (mg)	<p>Propose a level of zinc for all infant formulas with the minimum at 0.5 mg/100 kcal and the maximum at 2.4 mg/100 kcal.</p>
Choline	<p>Agree.</p>
3.2 Optional [or non-mandatory] ingredients	<p>Delete both brackets and the text</p>
3.2.1 or to provide other benefits that are similar to outcomes of populations of breastfed babies.	<p>Agree</p>
Total [added] nucleotides mg	<p>Delete the brackets and suggest the min at N.S. and the max. limits at 16.0 mg/100 kcal</p>
Cytidine 5'-monophosphate(CMP) mg	<p>Suggest the min at N.S. and the max. limit at 6.5 mg/100 kcal</p>
Uridine 5'-monophosphate(UMP) mg	<p>Suggest the min at N.S. and the max. limit at 3.7 mg /100 kcal</p>
Adenosine 5'-monophosphate(AMP) mg	<p>Suggest the min at N.S. and the max. limit at 3.0 mg/100 kcal</p>
Guanosine 5'-monophosphate(GMP)	<p>Suggest the min at N.S. and the max. limit at 3.5 mg/100 kcal</p>
Inosine 5'-monophosphate(IMP) mg	<p>Suggest the min at N.S. and the max. limit at 1.0 mg/100 kcal</p>
Docosahexaenoic acid ¹⁵⁾ (% of fatty acids) 0.5	<p>Propose to use % of total fat.</p> <p>Propose to use the min at N.S. and the max limit at 1.0 of total fatty acids</p>

3.2.3 15) ARA	Propose to use the min at N.S. and the max limit at 1.0 of total fatty acids
[3.2.4]	Keep brackets
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.]	Delete brackets and change the text as follows: (b) of the carrier substances mentioned in the Advisory List of Vitamin <u>and Mineral Compounds</u> for use in Foods for Infants and Children within the limits of the maximum levels stipulated in that List. Reason: Both lists of vitamin and mineral compounds should be included.
9.1.6 [Products containing not less than 0.5 mg Iron (Fe)/ 100 kilocalories shall be labeled “ Infant Formula with added Iron”] Or [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.]	Delete this section, because it is not necessary now that a min. level for iron has been required for all infant formulas.
9.5 Information for Use [Products in liquid form may be used either directly or prepared ... by a warning about the health hazard of inappropriate preparation.]	Delete brackets and keep text
9.6.6 [No [nutrition and] health claims shall be made regarding the dietary properties of the product.]	Delete the whole article and the article number. Rationale: It is necessary to provide nutrition and/or health claim of some ingredients used in the foods for the sake of the consumer’s right of knowing. Change text to the following: Nutrition and health claims shall be permitted for the products covered by this standard, where they have been demonstrated beyond doubt in rigorous studies with adequate scientific standards, and the evidence has been accepted by an independent scientific body reviewing the data. Reason: – All claims that are scientifically substantiated, with the substantiation validated through independent scientific review, should be allowed. – There is no nutrition-based rationale for placing a

	<p>severe restriction on claims for these products. These claims should be allowed as long as they are scientifically substantiated and are expressed in a manner that is understood by and is not misleading to the parent or caregiver.</p> <ul style="list-style-type: none">- Claims on products for infants and young children can provide parents and caregivers with important information about the composition and properties of a product that is specially designed for this age category. There is no justification for denying them information that is based on scientific substantiation.
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COSTA RICA

Discussed text	Position	Justification
<p>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.]</p>	<p>We suggest keeping the sentence and deleting the square brackets.</p>	
<p>9.1 The Name of the Food 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].</p>	<p>We suggest deleting this section, considering that a minimum iron content will be established for infant formula that will cover the iron requirements from birth to weaning age.</p>	<p>These statements may be confusing, as the wording "Infant Formula with added Iron" on the label could be interpreted as meaning that other formula which are not labelled with such a statement are insufficient to satisfy an infant's requirements.</p> <p>The minimum levels of iron which are established in the Standard have to be sufficient and suitable for feeding infants at least up to the age of six months.</p>
<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. 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]. 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.]</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.</p> <p>The information on the preparation of the product should always appear directly on the label.</p>

9.6 Additional Labelling	We suggest rewording the sentence in	The proposed sentence would
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<p>Requirements 9.6.6 [No [nutrition and] health claims shall be made regarding the dietary properties of the product.]</p>	<p>square brackets in accordance with the modification which has been agreed for section 8.1.1 of the Draft Revised Standard for 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>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 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 CCFSDU so that the use of a similar sentence would be consistent with an agreement reached previously.</p>
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INDIA

1. Scope:

1.1 India, reiterates its stand that the standard for infant formula and formulas for special medical purposes is covered by the provisions of the international code of marketing of breastmilk substitutes and subsequent WHA Resolutions which clearly emphasize the need to protect, promote and support exclusive breastfeeding for the first six months of life. The World Health Assembly Resolutions 54.2 (2001) and 55.25 (2002) and the adoption of Global Strategy on Infant and Young Child Feeding have already set the pace for standards for infant formula and for cereal based foods for infants and young children.

In the light of above, it is necessary to replace the words ‘where necessary’ with the following clause in the sentence at 1.1:-

“When it is not possible to exclusively breastfeed the infant for the first six months of life”.

Also delete the word ‘normal’ from the sentence at 1.1.

1.3 The word “six” may be added in the last sentence of para, between the words “first months” to read as “first six months” and delete the word “healthy”also.

1.4 Replace the words “should take into account” with the words “shall be in conformity with”. Add “WHA Resolution 55.25 (2002)” also and make the word “Resolution” as “Resolutions”, to read:

“The application of the Standard shall be in conformity with the recommendations given to countries under the International Code of Marketing of Breast-Milk Substitutes, the Global Strategy for Infant and Young Child Feeding, World Health Assembly Resolution 54.2(2001), WHA Resolution 55.25(2002) and subsequent relevant resolutions of the WHA”.

2. Description

2.1 Product definition

2.1.1 The word “six” may be added between the words “first months” and replace the word “upto the introduction of appropriate complementary feeding” by the following words:

“when it is not possible to exclusively breastfeed”

The clause may be reworded as under:

“Infant formula means a breastmilk substitute especially manufactured to satisfy, by itself, the nutritional requirements of infants during the first six months of life, when it is not possible to exclusively breastfeed”.

2.1.2 Delete the words “is so processed by physical means only” and replace with “must be processed” and add photodegradation, to read as under:

“Infant formula must be so processed and packaged as to prevent spoilage, photodegradation, 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

3.1 Essential Composition

3.1.3

a) Protein

2. The conversion factor 6.25 could be used for infant formula using various/mixed sources of protein. But this factor is scientifically incorrect for the product using only milk/milk products or only soy as protein source.

For milk/milk products a factor of 6.38 has been very well established (Table 1: References 1 – 11) and employed internationally in various Codex, AOAC, ISO and IDF standards (Table 1: references 12 – 40).

Using a factor of 6.25 for milk/milk products would unjustifiably make milk products based infant formula more expensive and hence uncompetitive, and would wrongly and grossly underestimate protein level in infant formula based on only milk and milk products as protein source. Therefore for infant formula with protein source of only milk/milk products, a factor of 6.38 should be used.

In contrast to the above, the factor 6.25 would highly overestimate the protein provided by the infant formula using only soy as protein source, as the scientifically established factor for soy is 5.71 (see Table 2: references 1-8). Hence using 6.25 for only-soy based product would result in actually much lesser protein in the product than declared/estimated. We therefore recommend that for infant formula deriving protein only from soy, a conversion factor of 5.71 should be used.

Our recommendations are also in line with FAO/WHO recommendations (Table 1 - reference 4 and Table 2 – reference 7) regarding the use of a specific nitrogen conversion factor when a specific factor is known.

Internationally, factor of **N x 6.38** is permitted for milk Protein. For the products (Infant formula or Formula for Special Medical Purposes) with milk proteins (solely or more than 90% milk proteins) the factor of **N X 6.38** should be allowed.

India proposes to keep the following items

Protein content = nitrogen content X 6.38 for hydrolysates of cows' milk protein

or

Protein content = nitrogen content X 6.25 hydrolysates of cows' milk protein and of soy or vegetable protein.

Or

Protein content = nitrogen content X 5.71 hydrolysates of soy only.

India supports nitrogen conversion factor of 6.25 only for estimating protein from mixed sources. Since India is producing infant formula based exclusively on cows' milk, India wants 6.38 factor when the source of protein is only milk/milk products in infant formula.

b) Lipids

Milk fat should not be less than 12% by weight of total fat since cholesterol, which is found in milk fat, is essential for human babies.

(c) Carbohydrates

Starches are not present in human milk. Infants under the age of six months do not have the enzymatic capacity to digest starches. Therefore starches should not be permitted for infant formulas promoted for use by infants less than six months of age.

3.2 Optional (or non-mandatory) Ingredients:

3.2.1

Concern

If these ingredients are optional then there is no point to refer these in the standard, as this gives a chance to claim/define infant formula similar to breast milk.

Inputs

No nutrition or health claims or comparative claims may be made for these infant formulas having optional ingredients.

3.5 Purity Requirements

The line “ free from chemical and microbial contamination as far as possible” may be added to the text

Change to read:

“All ingredients shall be clean and free from chemical and microbial contamination as far as possible, of good quality, safe and suitable for ingestion by infants. They shall conform to optimal quality requirements, such as colour, flavour and odour”.

4. Food Additives**4.1 Thickening agents.**

4.1.1 to 4.1.6

Infants do not need dietary fiber from nutritional angle. Further the addition of thickening agents may chelate micronutrients making them unavailable, thus resulting in micronutrients deficiency, which may affect growth and cognitive function.

So thickening agents should not be added to infant formula.

4.1.7 Carrageenan

4.1 It has adverse effect on the gut causing ulceration of cecum of both rats and guinea pigs when it was added to their diets. Hence its safety is doubtful in the case of human beings.

4.2 It is desirable to exclude emulsifiers in infant formula

4.3 pH Adjusting Agents.

It is desirable to exclude all the phosphates containing additives in the infant formulae as it upsets the calcium phosphate ratio, which has adverse effect on bone metabolism.

Phosphoric acid and its salts should not be permitted as pH adjusting agents.

4.4 Antioxidants

The total intake should not exceed the RDA.

4.5 Packaging gas (Propellants)

The relative risk/benefit of gases other than Nitrogen need safety evaluation. It is preferable to use nitrogen gas of food grade quality.

4.6 Carry-over of Food Additives

There is no need to keep sentences at (a) & (b) and hence the square brackets alongwith the bracketed text may be deleted.

The sentence may now read as:

“No food additives shall be present as a result of carry-over from raw materials and other ingredients”.

5. Contaminants**5.1 Pesticide Residues**

The existing para may be replaced by the following text:-

“The product shall be free from residues of hormones, antibiotics, N-nitrosamines, nitrates, heavy metals, mycotoxins, as determined by agreed analysis, and free from other contaminants, especially pharmacologically active substances such as phyto-estrogens”.

6. Hygiene

6.2 After the existing sentence, the following text may be added;

“and shall be free from pathogenic microorganisms, parasites and any other hazardous or deleterious substances”.

9. Labeling**9.1. The name of the Food**

9.1.6 The square brackets may be removed from the first option and “0.5 mg” changed to “1.5 mg.” in the sentence.

Delete the second option.

9.6 Additional Labelling Requirements

9.6.1.b The following statement may be inserted after the words ‘a similar statement’ like

“Breast milk is the best food for your baby, breastfeeding benefits both baby and mother”.

9.6.4 The age of six months for introduction of complementary foods as per WHA Resolution 54.2 (2001) may be included in the sentence instead of appropriate age.

The sentence may be reworded as under:

“Information shall appear on the label to the effect that infant should receive complementary foods in addition to the formula, from the age of six months for their specific growth and development needs”.

9.6.6 Both the square brackets may be deleted.

ANNEXURE

Table 1: Some references on scientifically analyzed samples of dairy protein sources

Ref No.	References : scientific publications, analytical data, international standards	Product Name/Class	Nitrogen Conversion Factor (NCF)	% N in Protein
1	Hammarsten, O. (1883) Z. physiol. Chem. 7, 227	Raw Milk	6,38	15,67
2	Jones, D.B. (1941) United States Department of Agriculture, Circular No. 183. (Original version 1931).	Milk	6,38	15,67
3	Adrian et al, la science alimentaire de A à Z, Editions Lavoisier, 1995	Milk and milk products	6,38	15,70
4	FAO/WHO (2003) FAO food and nutrition paper 77, Rome, ISSN 02544725	Milk	6,38	15,67
5	van Boekel M.A.J.S. and B. Ribadeau Dumas (1987) Neth. Milk Dairy J. 41, 281-284	Rennet whey	6,41 with carbohydrate	15,59
6	Karman A.H. and van Boekel M.A.J.S. (1986) Neth. Milk Dairy J. 40, 315-336	Rennet whey	6,45 with carbohydrate	15,5
7	Leatherhead Food Research Association. Analytical Methods Manual. 1996. Nitrogen (or Total Protein) Content by Kjeldahl.	Milk and dairy products	6,38	15,67
8	J Adler-Nissen. Enzymic Hydrolysis of food proteins. Elsevier Applied Science. (1988) 15-17	Whey protein concentrate Casein	6,38 6,38	15,67 15,67
9	Boisen, S. Bech-Andersen, S. and Eggum B.O. (1987) Acta Agric.Scand. 37, 299-304	Skim Milk Powder	6,91*** No Amides	14,47
10	Pijanowski, E. Zarys chemii i technologii mleczarstwa, T.1, PWRiL, Warszawa 1980:72	Milk Protein	6,38	15,67
11	Campbell, J.R., Marshall, R.T. Podstawy produkcji mleka spozywczego i jego przetworów, PWN, Warszawa, 1982:486	Milk Protein	6,39	15,65
12	Codex Stan A15 – 1995 Rev. 1 – 2003	Whey powders	6,38	15,67
13	Codex Stan A18 – 1995 Rev. 1 – 2001	Edible Casein products	6,38	15,67
14	Codex Stan A3 – 1971 Rev. 1 – 1999	evaporated milks	6,38	15,67
15	Codex Stan A4 – 1971 Rev. 1 – 1999	sweetened condensed milks	6,38	15,67
16	Codex Stan A5 – A10	Milk powder	6,38	15,67
17	Codex Stan 243 – 2003	Fermented milks	6,38	15,67
18	ISO 8968 -1 IDF20-1 Milk. Determination of	Milk	6,38	15,67

	nitrogen content. Kjeldahl Method			
19	AOAC 991.23	Milk	6,38	15,67
20	ISO IDF25. Processed cheese products. Protein Determination	Processed Cheese	6,38	15,67
21	AOAC 920.123	Cheese	6,38	15,67
22	AOAC 920.105	Liquid milks	6,38	15,67
23	AOAC 930.29	Dried milk	6,38	15,67
24	AOAC 920.115	Sweetened condensed milks	6,38	15,67
25	AOAC 945.48	Evaporated milk	6,38	15,67
26	AOAC 939.02 (TNx2xNCF)1.07	Milk Chocolate Flavored	6,38	15,67
27	IDF 92. Caseins and Caseinates. Determination of protein content	Caseins and caseinates	6,38	15,67
28	AOAC 920.109	Cream	6,38	15,67
29	AOAC 930.06	Ice Cream and Frozen Desserts	6,38	15,67
30	AOAC 986.25	Infant Formulae	6,38	15,67
31	Codex Stan 234 – 1999 Codex Recommended Methods of Analysis and Sampling	Whey Powder	6,38	15,67
32	Codex Stan 1-1985 (Rev. 1-1991, amended in 1999,2001,2003 and 2005) Codex General Standard for the Labelling of Prepackaged Foods	Milk	6,38	15,67
33	AOAC 927.03	Casein In Fluid Milk	6,38	15,67
34	AOAC 925.24	Albumin	6,38	15,67
35	AOAC 941.06	Casein in Malted and Chocolate Milk	6,38	15,67
36	AOAC 998.05	Non Casein Nitrogen	6,38	15,67
37	AOAC 998.06	Non Casein Nitrogen	6,38	15,67
38	AOAC 998.07	Non Casein Nitrogen	6,38	15,67
39	AOAC 991.21	Non Protein Nitrogen	6,38	15,67
40	ISO 8968-5 IDF 20-5. Milk — Determination of nitrogen content — Part 5:Determination of protein-nitrogen content	Protein Nitrogen	6,38	15,67

Note: *** Calculated from amino acid data

ANNEXURE

Table 2. Some references on scientifically analyzed samples of soy protein source

Ref No.	References : scientific publication, analytical data, international standard	Product Name/Class	Nitrogen Conversion Factor (NCF)	% N in Protein
1	De Rham, O. (1982) Lebensm. Wiss. Technol. 15, 226-231.	Soy Isolate Soy (Glycine max)	5,6-5,8*** 5,75-5,8***	17,54 17,24
2	Boisen, S. Bech-Andersen, S. and Eggum B.O. (1987) Acta Agric.Scand. 37, 299-304	Soy Meal	5,65*** With Amides	17,70
3	Mosse, J. (1990) J. Agric. Food Chem. 38, 18-24.	Soy (Glycine max)	5,38-5,67***	18.18
4	Jones, D.B. (1941) United States Department of Agriculture, Circular No. 183. (Original version 1931).	Soy (Glycine max)	5,71	17,51
5	FAO/WHO (2003) FAO food and nutrition paper 77, Rome, ISSN 02544725	Soy (Glycine max)	5,71	17,51
6	Leatherhead Food Research Association. Analytical Methods Manual. 1996. Nitrogen (or Total Protein) Content by Kjeldahl.	Soy (Glycine max)	5,71	17,51
7	FAO/WHO (1970) FAO Nutritional Study 24, Rome	Soy (Glycine max) Soy Flour Soy Products	5,71 5,71 5,71	17,51 17,51 17,51
8	AOAC 945.39	Soy Flour	5,70	17,54

NORWAY**3. Essential composition and quality factors**

Comments related to the essential composition and quality factors are made in the electronic working group.

9. Labelling

9.1.6 The discussion on composition has to be finalized before discussing this paragraph.

9.2.1 To make the sentence more legible, insert a full stop after the words “added minerals” and “respectively”. Delete “added” in front of minerals. The sentence will be as follows; **“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, respectively. Within these groups the vitamins and minerals don’t need to be listed in descending order of proportion.”**

9.3 (b) It seems like the paragraph referred to in this point (3.1.2) has become paragraph 3.1.3. There are more substances than vitamins, minerals and choline listed in this paragraph. It is also necessary to specify the reference to paragraph 3.2, which should be paragraph 3.2.3. Paragraph 9.3 (b) are suggested changed to; **“the total quantity of each substance listed in paragraph 3.1.3 and any other ingredient as listed in paragraph 3.2.3 of this standard, per 100 grams 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.”**

9.5 Keep the sentence, but delete the word “water” after safe in the first sentence. The paragraph will be as follows; **“Products in liquid form may be used either directly or prepared with safe and previously boiled water before feeding according to directions of use. Products in powder form also require safe and previously boiled water for preparation.”**

9.5.1 Delete the words in square brackets “or in the accompanying leaflet” and keep the rest of the sentence. To make sure that this information is available for the consumer it should be printed on the packaging. An accompanying leaflet may easily disappear and the information will be lost.

9.5.2 Delete the words in square brackets “or in the accompanying leaflet” and keep the rest of the sentence. The rationale is the same as stated above, cf. paragraph 9.5.1.

9.5.3 Keep the sentence.

9.5.4 Inappropriate use can also cause an unwanted effect. Therefore add the word use at the end of the sentence. The sentence will be as follows; **“The directions should be accompanied by a warning about the health hazards of inappropriate preparation and use”.**

9.6.6 Norway agrees that no nutrition and health claims shall be made on these products. We are aware of the fact that nutrition and health claims on products marketed to children are regulated in the Guidelines for Use of Nutrition and Health Claims (CAC/GL-23-1997, Rev. 1-2004). However, Norway believes that the proposed text should be included in this standard to point out the importance of not having nutrition and health claims on products intended for infants. Norway therefore supports deleting both square brackets around the text in point 9.6.6.

PERU

Peru agrees with the wording of the Draft Standard.

UNITED STATES OF AMERICA

We previously submitted comments to the Delegation of Germany on Section 3 (Essential Composition and Quality Factors) of this Draft Revised Standard in response to CL 2005/53-NFSDU.

The partial and preliminary comments below focus on text still in brackets in ALINORM 06/29/26, Appendix IVA.

4. FOOD ADDITIVES

The United States appreciates the offer of the Delegation of Switzerland at the last CCNFSDU session to prepare a revised list of additives, 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 last session (ALINORM 06/29/26 para 109). We plan to provide comments on the revised list of additives prepared by the Swiss Delegation.

The United States continues to believe 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.

4.6 Carry-over of Food Additives

No food additives shall be present as a result of carry-over from raw materials and other ingredients with the exception:

(a) of the food additives listed under Sections 4.1 to 4.4 of this standard within the limits of the maximum levels stipulated in this standard; and

(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.]

Comment: The electronic work group (EWG) coordinated by the Swiss Delegation did not amend section 4.6 in its September 2005 report (CX/NFSDU 05/27/6—Add.1) and requested that CCNFSDU examine this issue carefully at its November 2005 Session. Because of time limitations, CCNFSDU was not able to consider this issue at the November 2005 meeting. In response to the request from the EWG, we suggest that the CCNFSDU consider incorporation of the text recommended by CCFAC for the processed cereal-based foods standard into the standard for infant formula (Section A), with appropriate editing as proposed below for reference to the infant formula standard and correction of the title of the Advisory List when it is finalized.

“Only the food additives listed in this Section or in the Codex [Advisory List of Vitamin Compounds for Use in Foods for Infants and Children (CAC/GL 10-1979)] may be present in the foods described in section 2.1 of this Standard, as a result of carry-over from a raw material or other ingredient (including food additive) used to produce the food, subject to the following conditions:

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

b) The food into which the food additive is carried over does not contain the food additive in greater quantity than would be introduced by the use of the raw materials or ingredients under good manufacturing practice, consistent with the provisions on carry-over in the Preamble of the General Standard for Food Additives (CAC/STAN 192-1995, Rev. 5 (2004)).

The following food additives are acceptable for use in the preparation of ~~processed cereal based foods for infants and young children~~ **infant formula**, as described in Section 2.1 of this Standard (in 100 g ml of product, ready for consumption prepared following manufacturer's instructions, unless otherwise indicated)."

Rationale: The language recommended by CCFAC for carry-over of food additives in the processed cereal based foods standard is appropriate for the infant formula standard as well.

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 Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985 (Rev. 1-1993) and the Guidelines for Use of Nutrition and Health Claims the following specific provisions apply:

9.1 The Name of the Food

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.]

Comment: Iron levels in the infant formula standard remain to be established. Appropriate label information should be discussed after the iron levels are established.

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 requires safe and previously boiled water for preparation. **Directions for preparation and handling should be in accordance with Good Hygienic Practices.**

Comment: A statement should be added to Section 9.5 to incorporate reference to recent recommendations about use of good hygienic practices in preparation and handling of infant formula. These include the FAO/WHO Expert Consultation, the European Food Safety Authority report (2004), and the Codex Committee on Food Hygiene meeting report (2005).

Editorial Comment: Delete the word water from the first sentence for clarity.

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, e.g., that powdered formula should be fed immediately after its reconstitution, and that all formula (whether ready-to-feed or reconstituted from powder or liquid concentrate) remaining in the bottle after feeding should be discarded,~~ shall appear on the label [~~or in the accompanying leaflet~~].

Comment: We recommend addition of detail to include information about appropriate preparation, storage, and disposal of the product as shown above.

Rationale: The safe use of infant formula depends on correct preparation, storage, and disposal of the product.

Comment: We recommend deleting the language in 9.5.1 that would allow information to be contained only in a leaflet that would accompany the product.

Rationale: This information should be on the label, which is affixed to the can or container. An accompanying leaflet can easily become separated from the product.

~~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].~~

Comment: If Section 9.5.1 is edited as shown above, we suggest that Section 9.5.2 be deleted.

Rationale: Section 9.5.2 does not add anything not already covered in Section 9.5.1, as edited above.

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

Comment: The square brackets should be removed from Section 9.5.3. If Section 9.5.2 is deleted, Section 9.5.3 should be renumbered to 9.5.2.

9.5.4 The directions should be accompanied by a warning about the health hazards of inappropriate preparation.]

Comment: The square brackets should be removed from Section 9.5.4. If Section 9.5.2 is deleted, Section 9.5.4 should be renumbered to 9.5.3.

9.6 Additional Labelling Requirements

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

Comment: The United States notes that the Guidelines for Use of Nutrition and Health Claims that were adopted at the 27th session of the Codex Alimentarius Commission (ALINORM 04/27/41, para 51) contain the following provision:

1.4 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.

Thus, the bracketed text as written in 9.6.6 is inconsistent with Section 1.4 which at a minimum provides for nutrition and health claims permitted by national legislation.

Because of this contradiction, we recommend that the current language in 9.6.6 be deleted. We note that the Committee could use the opportunity provided by the language in Section 1.4 to allow further discussion about claims on infant formula that may further the Codex

goal of protecting consumer health in addition to encouraging fair international trade in food.

10. METHODS OF ANALYSIS AND SAMPLING

See Revised Table attached.

Comment: Table 10 remains to be updated for the draft revised infant formula standard, Section A. The following table incorporates AOAC methods that are current and applicable for use with infant formula.

Attachment

10. METHODS OF ANALYSIS AND SAMPLING

Analyte	Method	United States Comments on Methods
Dietary fibre, total	AOAC 991.43	Current method
Iodine (milk-based formula)	AOAC 992.24	Current method
Pantothenic acid	AOAC 992.07	Current method
Pantothen-ic acid	<i>The Analyst 89 (1964)(1) 3-6,232</i>	This is an old method (US Department of Agriculture. Agriculture Handbook 97 (1965)) that should not be used.
Vitamin A	AOAC 974.29	This is an old colorimetric method. Methods AOAC 992.04 or AOAC 992.06 should be used.
Vitamin A (retinol)	AOAC 992.04	Current method
Vitamin A (retinol)	AOAC 992.06	Current method
Vitamin A / carotenes	AOAC 942.15	Method 942.15 is a method for titratable acidity in fruit products. It is not suitable as a method for Vitamin A/carotenes.
Vitamin K	AOAC 992.27	Current method
Vitamin D (D ₃ , milk based infant formula)	AOAC 992.26	Current method
Vitamin E	AOAC 971.30	This is a colorimetric method dating from 1971 that should not be used.
Vitamin E - milk-based formula	AOAC 992.03	Current method
Vitamin B12	AOAC 952.20	This is an old method (1952) that should not be used. Newer and more appropriate method is listed in next row of table.
Vitamin B12	AOAC 986.23	Current method
Vitamin B6	AOAC 961.15	This is an old method (1961) that should not be used. Newer and more appropriate method is listed in next row of table.
Vitamin B6	AOAC 985.32	Current method

Analyte	Method	United States Comments on Methods
Vitamin C	AOAC 967.22 AOAC 967.21	This titrimetric method is applicable only to vitamin preparations and should not be used with infant formulas. See next row of table for appropriate method.
Vitamin C	AOAC 985.33	Current method
Determination of Choline	AOAC 999.14	Current method
Determination of Vitamin K	AOAC 999.15	Current method
Detection of Irradiated foods	Codex general methods	
Determination of Lead	Codex general methods	
Calcium	AOAC 984.27	Current method
Chloride	AOAC986.26	Current method
Carbohydrates	method described in CAC/VOL IX Ed 1, Part III	
Crude protein	Method described in CAC/VOL IX Ed 1, Part III	
Fat	CAC/RM 55-1976	
Fatty Acids	AOAC 996.06	Current method and suitable for nB6 and B3 long-chain fatty acids
Fill of containers	CAC/RM 46-1972	
Folic acid	AOAC 944.12	This is an old method (1944) that should not be used. Newer and more appropriate method is listed in next row of table.
Folic acid	AOAC 992.05.	Current method
Linoleate (glycerides)	AOAC 922.06 AOAC 969.33 AOAC 963.22 AOAC 979.19	AOAC 922.06, AOAC 963.22, and AOAC 979.19 are older chromatographic and spectrophotometric methods that should not be used AOAC 969.33 is a method for preparation of methyl esters and

Analyte	Method	United States Comments on Methods
		not an analysis of fatty acids.
Linoleic acid	AOAC 992.25	Current method
Loss of drying	AOAC 934.01 AOAC 925.23	
Nicotinamide (non-milk) Nicotimamide (milk-based)	AOAC 961.14 AOAC 944.13	These are old methods (1961 and 1944) that should not be used. Newer and more appropriate method is listed in next row of table
Niacin and nicotinamide	AOAC 985.34	Current method
Phosphorus	AOAC 986.24	Current method
Protein efficiency ratio (PER)	AOAC 960.48	Current method . Rat bioassay
Riboflavin	AOAC 970.65	This is an old method (1970) that should not be used. Newer and more appropriate method is listed in next row of table
Riboflavin	AOAC 985.31	Current method
Selenium	AOAC	Current method. If selenium is a required ingredient in infant formulas, an analytical method for measuring it must be available.
Sodium and potassium	ISO 8070 IDF 119A	These are old methods (1987) that should not be used. Newer and more appropriate method is listed in row below
Sodium and potassium	AOAC 984.27	Current method
Thiamine	AOAC 942.23	This is an old method (1942) that should not be used. Newer and more appropriate method is listed in next row of table
Thiamin	AOAC 986.27	Current method
Total dietary fibre	AOAC 985.29	Current method

AIDGUM – International Association for the Development of Natural Gums

4. FOOD ADDITIVES - The following additives are permitted for Infant Formulas.

	INS no.		Maximum Level	Technological Justification
4.1		Emulsifier		
4.1.1	414	Gum Arabic (Acacia)	1,5 g / 100 g.	Stabilizer, retains homogeneity.

	INS no.		Maximum Level	Technological Justification
4.7		Thickeners		
4.7.3	414	Gum Arabic (Acacia)	GMP	Thickening agent and emulsion stabilizer For fruit coating to prevent fruit from sticking together Also used as an ingredient of nutrient forms

ENCA – European Network of Childbirth Associations

Section A: Draft revised standard for Infant formula

1. SCOPE

1.1 Delete the word “normal” to be in line with the product definition in 2.1.1.

1.3 delete the words “normal healthy” as they have no definition in Codex Alimentarius nor in WHO. The Scope of section B further defines the conditions of infants needing the products of section B, as both sections are to be read together this defines that section A covers all the other infants

1.4 Delete brackets and **reword** to read:

The application of the Standard **shall be in conformity with** the recommendations given to countries under the International Code of Marketing of Breast-Milk Substitutes (1981) the Global Strategy for Infant and Young Child Feeding and World Health Assembly Resolution 54.2 (2001) and WHA Resolution 55.25 (2002).

Reinsert the WHA resolution 55.25 This is in line with the request of the Commission (report Alinorm 04/41 para 83) and the request of the Executive Committee (report Alinorm 01/4, paras 38-39)

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

COMMENTS TO THIS SECTION HAS BEEN SENT AS REQUESTED TO THE DELEGATION OF GERMANY

5. CONTAMINANTS

5.1 Reword to read:

"The product shall be prepared with special care under good manufacturing practices, so that residues of those pesticides which may be required in the production, storage and processing of the raw materials or the finished food ingredient do not remain, or if technically unavoidable, **do not exceed a maximum level of 0.01 mg/kg for each substance in the product as sold.**"

This is in accordance with the European legislation

5.2 Delete current text and **reword** to read: "The product shall be free from residues of hormones, antibiotics, N-nitrosamines, nitrates, heavy metals, mycotoxins, as determined by agreed analysis, and free from other contaminants, especially pharmacologically active substances such as phytoestrogens."

Infant formula is the sole food for infants for the first six months of life and should be free from all contaminants, including residues of hormones and antibiotics.

6. HYGIENE

6.1 Replace "it is recommended" by "shall be "prepared

Stating that the product shall be manufactured in accordance with these Codes of practice is stronger than a recommendation that the product be made in accordance with them.

6.2 Reword to read: "The product **shall** comply with any microbiological criteria established in accordance with the principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997; and shall be free from pathogenic microorganisms, parasites and any other poisonous or deleterious substances"

6.3 Add this new paragraph

The consumers should be informed that this is not a sterile product and that preparation shortly before feeding and discarding of left-over is needed to prevent multiplication of germs present in the product (cf. Joint FAO/WHO workshop on *Enterobacter sakazakii* and other microorganisms in powdered infant formula)

Therefore the labelling section needs a special chapter on this.

9. LABELLING

9.1 The name of the food

Add the following text: The name of the food should not be, or contain, anything which indicates or may be understood by the purchaser to be a claim of any kind or to imply a health advantage.

For example:

A milk called "Humana" deviates attention from the fact that it is infant formula for artificial feeding **HA** or **Hypollergenic** added to the name are a claim and not part of the name.

9.5. Information to use

Delete the square brackets from 9.5 and retain text

After the FAO/ WHO Workshop on *Enterobacter Sakazakii* and other microorganisms in powdered infant formula, special concern should be given to recommend adequate preparation instruction for powdered infant formula as for example "use of boiling water or by heating reconstituted formula" This is a quote from the executive summary of the mentioned workshop.

9.5.1. It is important to give consumers a rationale why prepared formula should not be stored

Add this sentence at the end:

Discard leftovers because of possible contamination of the product during manufacturing or preparation with pathogen germs which grow in the prepared product and can cause illness in the baby. Be aware that this product as sold is not sterile.

9.5.1 and 9.5.2 Delete square brackets and text, as caregivers shall have the information on the product itself to guarantee that they are available to be read by occasional care givers to assure correct preparation, storage and handling.

9.6. Additional labelling requirements

9.6.4 Reword to read:

Information shall appear on the label to the effect that infants should receive **complementary** food in addition to **infant** formula from the age **over six months onward as advised by an independent health worker to satisfy their specific growth and development needs.**

9.6.6 Delete square brackets and retain the text to read:

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

Health claims are increasingly used by Infant formula manufacturers to market their products. They undermine breastfeeding and create a misleading perception that breastmilk and infant formula are similar or equal. In general, claims are used to idealize the product rather than to inform the consumer. This form of idealization is contrary to the International Code and therefore should not be permitted.

Example: currently claims for infant formula with LCPUFA are made by manufacturers to make health professionals and parents believe that this sort of formula enhances intellectual outcome or the view.

ISDI says in CX/NFSDU 03/6 page 27 on LCPUFA “however it is not known if increases occur in neural tissues. Some studies do show a positive effect, where others were unable to measure such effect.

This example shows clearly how claims are based on inconclusive scientific evidence. The main aim seems to achieve marketing advantages by misleading consumers.

IDF - International Dairy Federation

1. Introduction

The 27th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU), 21-25 November 2005 was not able to find a consensus on the question of nitrogen conversion factor pertaining to the calculation of protein contents in infant formula as defined in the Section 3: Essential Composition and Quality Factors. It was decided to retain the respective footnote 2* in square brackets (ref. Codex ALINORM 06/29/26, para 80 – 83, para. 106 and Appendix IV/A).

*) Wording of the footnote:

“[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.”

2. Scientific justification for the use of specific nitrogen protein conversion factors (NCFs)

CCNFSDU had requested Codex members and observers to provide scientific justification for the use of specific protein factors before 15 February 2006. (CL 2005/53-NFSDU)

In response to this invitation, the IDF undertook a comprehensive review of the scientific literature on nitrogen conversion factors. It has been submitted to the delegation of Germany and has been published under the title “Comprehensive review of scientific literature pertaining to nitrogen protein conversion factors “ in April 2006. The publication (ref. Bulletin of the IDF no. 405/2006) is available for free download from the IDF Internet homepage: <http://www.fil-idf.org/content/default.asp?PageID=381>

The IDF review identified the following conversion factors (NCFs) for the two sources of protein as specified for infant formulae:

milk proteins: 6,34 to 6,38

soy proteins: 5,7 to 5,8

The published scientific data provide a wealth of evidence and justification for the use of different NCFs for milk protein and soy protein. IDF was not able to find any scientific data justifying the use of a single NCF of 6,25 for milk protein and soy protein.

3. Knowledge on primary structure of milk proteins and soy proteins and application in infant formula

3.1 Nitrogen conversion factors for the various milk proteins

The complete primary structure of the main milk proteins is known and internationally recognized (Farrell et al., 2004). This knowledge enabled Karman and van Boekel (1986) and later van Boekel and Ribadeau-Dumas (1987) to determine, with a high degree of precision, the NCFs for most protein fractions occurring in milk (99.5 %) (see Table 1 of the Appendix).

The NCFs obtained by taking into account the known sequences of all the individual proteins with their lateral groups and their proportions in milk are as follows:

- **6.36 for natural milk protein**, a value that is very close to the historically used value of 6.38 (Hammarsten, 1883);
- **6.36 for casein** (isoelectric casein is the casein being effectively used for this type of formula)
- **6.41 for whey protein** (most of the whey protein in infant formulas is whey proteins derived from renneted milk).

Accordingly, the NCFs that must be used for protein fractions of milk-based infant formulae are 6.36 for the casein part and 6.41 for the whey protein part.

3.2. Nitrogen conversion factors for milk-based infant formula

On the basis of the figures of Table 1 of the Appendix the NCFs for milk-based infant formulae were calculated for different whey protein to casein proportions that are used in infant formula. These respective calculated values can be found in Table 2 of the Appendix.

The results clearly show that regardless of the relative proportions of whey proteins and casein in milk-based infant formula the nitrogen conversion factor remains close to the value of 6.38.

In conclusion, the scientific knowledge about the primary structure of milk proteins (Table 1 of the Appendix) as well as data on milk proteins used in infant formula (Table 2 of the Appendix) justifies the use of the internationally recognized NCF of 6.38 for milk protein for infant formulae.

3.3 Nitrogen conversion factors for soy-based infant formula

Soy (*Glycine max*) proteins, mostly globulins, are distinguished according to their sedimentation coefficients into globulins 7 S (or β conglycinin), globulins 11 S (or glycinin) and globulins 2S. Globulins 7S and 11S account both for more than 80 to 90% of total protein content. The ratio 11 S/7 S varies between 0.5 and 1.7, according to the cultivars (Utsumi, 1992).

The first NCF proposed for soy proteins was 5.71 (Jones, 1931). It was calculated from the nitrogen determinations performed by Osborne and Campbell (1898) on soy protein extracts. Then, for no known scientific reason other than a theoretical 15 % nitrogen content in all protein sources, the value of 6.25 was agreed for all vegetable proteins and applied for soy proteins. This occurred despite the fact that ever since 1946, this value was considered too high, in view of the studies performed on soy isolates (Smiley and Smith, 1946, Smith and Circle, 1972, Mossé, 1990, Sosulski and Imafidon, 1990). Tkachuk (1969) suggested the NCF of 5.69 for total proteins contained in defatted unhulled soybean flour. Mossé (1990) determined a NCF of 5.52 ± 0.02 from the amino acid profiles of 6 samples of soy protein powders.

From the described sequences of the main soy protein fractions (Utsumi, 1992), Lorient (2006, unpublished work)¹ calculated the different NCFs detailed in Table 3 of the Appendix.

Given the variability of the relative proportions between Glycinin (11S) and β -conglycinin (7S), 0.5 to 1.7 (Utsumi, 1992) in the cultivars, it is not easy to calculate a mean NCF but the calculated values of Table 3 of the Appendix lie in a very narrow range. One can therefore consider that the NCFs in all soy cultivars vary between 5.56 and 5.66 leading to a mean value of 5.61.

However, the value of 5.61 does not take into account the covalently bound side groups. According to Utsumi et al. (1997), the three subunits of the β -conglycinin (7S) are glycosylated (Koshiyama, 1969) as well as the hemagglutinin component (Lis et al., 1966) which amounts to 3 % of soy flour (Liener and Rose, 1953). Thus, taking into account the glycosylated part of 7S, the glycosylation of hemagglutinin and the various 7S/11S ratio the calculated NCFs for the different soy cultivars are varying between 5,69 and 5,79 (see Table 4 of the Appendix).

The calculated values for soy protein in Table 3 and Table 4 of the Appendix confirm the figure given in the literature (5,71) also taking into account the slight variability depending on the cultivar. The use of a NCF of 6.25 for soy proteins is not scientifically justified. It leads to an overestimation of protein content of between 8 and 10 %.

3.4 Technological processes applied to milk proteins and the evolution of the nitrogen conversion factor

IDF would like to clarify a misperception that may have arisen from the statement of the Observer of ESPGHAN as contained in Codex ALINORM 06/29/26, para. 82.

Milk-based infant formulas are prepared by using milk, casein, and whey protein as raw materials. New formulations may also include milk and/or whey protein concentrates or isolates obtained by various separation technologies based on either steric size exclusion of milk and whey proteins (membrane ultrafiltration or gel filtration chromatography) or electro-chemical charge of proteins (membrane nanofiltration, electro-dialysis and ion exchange resins).

It must be pointed out that the whey protein concentrates (WPC) or whey protein isolates (WPI) obtained through industrial separation processes are not enriched in Non-Protein Nitrogen (NPN) as has been erroneously stated by Koletzko et al. (2005), according to Maubois (INRA, France, 2006)². Indeed, the NPN-

¹ Pr. Denis Lorient, Emeritus Professor of Food Chemistry at the Ecole Nationale Supérieure de Biologie Appliquée à la Nutrition et à l'Alimentation (ENSBANA), University of Burgundy, Dijon, France

² Dr. Jean-Louis Maubois, Research Director INRA Rennes, National Dairy Research Laboratory, Institut National de Recherche Agronomique (INRA), Rennes, France

constituting molecules have a very low molecular weight of less than 500 Da according to Wolfschoon-Pombo and Klostermeyer, 1981 and Alais, 1984 and they cannot be retained by the ultrafiltration (UF) membranes of which the molecular cut-off is around 5 000 to 20 000 Da. The NPN-constituting molecules are also excluded by the gel permeation resins and separated by the ion exchange resins used in the chromatographical processes. According to Hoppe and Higgins (1992), the NPN losses with all the demineralization processes (electrodialysis, ion exchange, membrane nanofiltration) represent between 25 to 30 % of the initial whey NPN.

Moreover, it has been demonstrated that there are little losses in whey low molecular weight proteins (about 0.02 % according Hargrove et al., 1976) such as α -lactalbumin (Delaney, 1976; Boer and Robertsen, 1983). Thus, most of the WPC and WPI have a lower NPN content than the dairy product from which they are originated. The NPN-constituting molecules are characterized by NCFs of 7.36 for the κ -caseinomacropptide to 3.60 for the milk NPN fraction (Karman and van Boekel, 1986). The low content of NPN leads in all the dairy raw materials used for infant formulas (demineralised whey, whey protein concentrates, whey protein isolates, etc) to a balanced variation of the value of the NCF according to the specific separation process which always remains between 6.30 and 6.45 for rennet whey proteins and acid whey proteins according to the findings of Karman and van Boeckel (1986).

Some infant formulae for special medical purposes contain enzymatic hydrolysates. It is obvious that for total-hydrolysed infant formula the conversion factor is meaningless since there will be no protein left.

4. Conclusions

- The published scientific data on milk protein, including the knowledge about the primary sequence of milk proteins, demonstrate that the nitrogen conversion factor of 6,38 for milk protein is justified in case of either total milk protein or milk protein used in infant formula.
- According to scientific data, the appropriate nitrogen conversion factor for soy protein would be 5,71.
- The technological processes applied to the milk proteins used in the manufacturing of milk-based infant formula induce a decrease of NPN content and they have no decreasing effect on the nitrogen conversion factor for milk protein.
- The proposed introduction of a single arbitrary nitrogen conversion factor (NCF) of 6,25 for all protein sources in the Codex Standard for Infant Formula cannot be justified on the basis of the available scientific data. Such a factor does not take into account the enormous research work of the past 50 years aiming at improving the knowledge about proteins as essential nutrients for human beings as well as their differences in terms of amino acid composition and their specific nutritional quality.
- A single arbitrary nitrogen conversion factor (NCF) of 6,25 would result in an underestimation by about 2% of the actual protein content in milk-based infant formula and a serious overestimation of the content of soy by approximately 9% in soy-based infant formula.

5. IDF recommendations to CCNFSDU

Codex should take into account the published scientific data regarding different sources of protein with recognized different protein conversion factors.

The scientifically established nitrogen protein conversion factors for milk protein of 6,38 and for soy protein of 5,71 should be applied in the Codex Standard for Infant Formula according to the established recommendation on use of a specific nitrogen protein conversion factor when such a specific factor is known (FAO 1970) and (FAO 2003).

The NCF of 6.38 for milk protein is recognized and used in all Codex Standards for milk and milk products as well as in all international methods of analysis. It is also applied in regional and national legislation all over the world. The recently held seventh session of the Codex Committee on Milk and Milk Product has reinforced the validity of the NCF of 6,38 for milk protein and highlighted the need for a consistent application of the conversion factor for the calculation of milk protein content throughout Codex. (CODEX ALINORM 06/29/11, para. 17)

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Appendix

Table 1 : Nitrogen conversion Factors of various milk proteins, according to van Boekel and Ribadeau-Dumas (1987)

Product / protein	NCF (with carbohydrates)	% of each protein / total protein in milk
α 1- casein	6.36	30.3%
α 2- casein	6.29	7.9%
β - casein	6.37	28.2%
κ -casein	6.35	10%
γ -casein	6.34	2.4%
β - Lactoglobulin	6.29	9.7%
α - Lactalbumin	6.25	3.6%
Serum albumin	6.07	1.2%
Proteoses peptones	6.55	0.9%
Immunoglobulins	6.20	2.4%
Milk	6.36	
Isoelectric (Acid) casein	6.36	
Rennet whey proteins	6.41	

Note : Proteins are defined as a sequence (determined by the organism's genom) of amino-acids bound by covalent bounds (primary structure) and to which carbohydrate groups can be also attached by covalent bounds. These side groups are constituting parts of the protein, not only because they are covalently bound to the amino-acid chain but also for their technological, nutritional and physiological functions.

Table 2 : Nitrogen conversion factors for different formulations of milk infant formulas currently available, using values of Table 1, calculated by Jean-Louis Maubois (INRA France) for different formulations of milk infant formulae (2006, unpublished work)

Proportion in infant formula Whey protein (6,41) / isoelectric casein (6,36)	Conversion factor for the infant formula
20 / 80	6,370
30 / 70	6,375
50 / 50	6,385
60 / 40	6,390

(Calculation example: 60/40 whey/casein formula : $(60 \times 6.41 + 40 \times 6.36) / 100 = 6.39$)

Table 3: Nitrogen conversion factors for soy protein calculated on the base on knowledge of primary structure (Utsumi, 1992) for different fractions of soy proteins calculated by Lorient (2006, unpublished work)

Product / protein	NCF
β - conglycinin (α') (7S)	5.58
β - conglycinin (α) (7S)	5.65
β - conglycinin (β) (7S)	5.66
Glycinins (mean value of the 5 subunits) (11S)	5.56

Table 4 : Nitrogen conversion factors of different soy cultivars taking into account the glycosylated part of 7S and the glycosylation of hemagglutinin (Utsumi et al., 1997, Koshiyama,1969, Lis et al., 1966) calculated by Lorient (2006, unpublished work)

Ratio 11 S / 7 S	NCF
0,5	5,79
1	5,73
1,5	5,69

ILCA - International Lactation Consultants Association

Section A: Draft revised standard for Infant formula

1.1 delete the word “normal” *to repeat the wording of the product definition in 2.1.1. as Infant formula is not the biological norm of the nutritional requirements of infants*

1.3 delete the words “normal healthy” *as they have no definition in Codex Alimentarius nor in WHO.*

1.4 Reword to read: “The application of the Standard **shall be in conformity with** the recommendations given to countries under the International Code of Marketing of Breast-Milk Substitutes (1981) the Global Strategy for and Young Child Feeding and World Health Assembly Resolution 54.2 (2001) **and WHA Resolution 55.25 (2002).** “

6.1 Replace “it is recommended” by “shall be “prepared
Stating that the product shall be manufactured in accordance with these Codes of practice is stronger than a recommendation that the product be made in accordance with them.

6.3 Add this new paragraph: “The consumers should be informed that this is not a sterile product and that preparation shortly before feeding and discarding of left-over is needed to prevent multiplication of germs present in the product”

Infant Joint FAO/WHO workshop on Enterobacter sakazakii and other microorganisms in powdered infant formula)Therefor the labelling section needs a special chapter on this: the label of each container has to have a clear, conspicuous and easy readable and understandable message printed on it.

9.1 The name of the food

Add the following text: “The name of the food should not be, or contain, anything which indicates or may be understood by the purchaser to be a claim of any kind or to imply a health advantage.”

For example:

A milk called “Humana” deviates attention from the fact that it is infant formula for artificial feeding.

HA or Hypoallergenic added to the name are a claim and not part of the name.

9.5. Information to use

Delete the square brackets from 9.5 and retain text

After the FAO/ WHO Workshop on Enterobacter Sakazakii and other microorganisms in powdered infant formula, special concern should be given to recommend adequate preparation instruction for powdered infant formula as for example “use of boiling water or by heating reconstituted formula” This is a quote from the executive summary of the mentioned workshop.

9.5.1. Delete “or on the accompanying leaflet” or change to “**and** in the accompanying leaflet” *as the danger that the information to use is not available to all caregivers if it comes only on a separate leaflet is great.*

Add this sentence at the end: “Discard leftovers because of possible contamination of the product during manufacturing or preparation with pathogen germs which grow in the prepared product and can cause illness in the baby. Be aware that this product as sold is not sterile.”

It is important to give consumers a rationale why prepared formula should not be stored

9.5.2 Delete “or on the accompanying leaflet” or change to “**and** in the accompanying leaflet” *as the danger that the information to use is not available to all caregivers if it comes only on a separate leaflet is great.*

9.6. Additional labelling requirements

9.6.5 Reword to read:

“Information shall appear on the label to the effect that infants should receive **complementary** food in addition to **infant** formula from the age **over six months onward as advised by an independent health worker to satisfy their specific growth and development needs.**”

9.6.7 Delete square brackets and retain the text to read:

“No nutrition and health claims shall be made regarding the dietary properties of the product.”

Health claims are increasingly used by Infant formula manufacturers to market their products. They undermine breastfeeding and create a misleading perception that breastmilk and infant formula are similar or equal. In general, claims are used to idealize the product rather than to inform the consumer. This form of idealization is contrary to the International Code and therefore should not be permitted.

ISDI - International Special Dietary Foods Industries

ISDI PROPOSAL	JUSTIFICATION
<p>4. FOOD ADDITIVES</p> <p>The following additives are permitted in the preparation of Infant Formula, as described in Section 1 of this Standard, and with the restrictions stated below:</p> <p>Only the food additives listed in this Section or the Codex Advisory List of Vitamin Compounds for Use in Foods for Infants and Children (CAC/GL 10-1979) may be present in the foods described in Section 2.1 of this Standard, as a result of carry-over from a raw material or other ingredient (including food additive) used to produce the food, subject to following conditions:</p> <p>a) The amount of the food additive in the raw materials or other ingredients (including food additives) does not exceed the maximum level specified; and</p> <p>b) The food into which the food additive is carried-over does not contain the food additive in greater quantity than would be introduced by the use of the raw materials or ingredients under good manufacturing practice, consistent with the provisions on carry-over in the Preamble of the General Standard for Food Additives (CAC/STAN 192-1995, Rev. 5 (2004)).</p> <p>The following additives are acceptable for use in the preparation of Infant Formula, as described in Section 2.1 of this Standard (in 100 mL of product, ready for consumption prepared following manufacturer’s instructions, unless otherwise indicated).</p>	<p><u>Replace</u> the current text by the text in bold.</p> <p><u>Rational</u>: adds clarity and allows consistency with the wording agreed in 2005 for the Draft Revised Standard for Processed Cereal-based Foods for Infants and Young Children.</p>

<p>INS 410: Carob bean gum (locust bean gum) 0.1g 0.5g in all type of formula</p>	<p><u>Change</u> the level of INS 410</p> <p><u>Rational</u>: 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.</p>
<p>4.6 Carry-over of Food Additives No food additives shall be present as a result of carry-over from raw materials and other ingredients with the exception: (a) of the food additives listed under Sections 4.1 to 4.4 of this standard within the limits of the maximum levels stipulated in this standard; and (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.}</p>	<p><u>Delete</u> []</p> <p><u>Rational</u>: while acknowledging that CCFAC is currently considering establishing a new additive functional class for nutrient carriers, ISDI believes that the list of nutrient carriers should remain where it is currently i.e. at the end of the advisory list of mineral salts and vitamin compounds for the use in foods for infants and young children currently under revision by CCNFSDU. ISDI believes that this list of nutrient carriers should also be reviewed.</p>
<p>9.1.6 {Products containing not less than 0.5 mg Iron (Fe) /100 kilocalories shall be labelled “Infant formula with added iron”}</p> <p>Or</p> <p>{Products containing less than 0.5 mg Iron (Fe) /100 kilocalories 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 additional sources.}</p>	<p><u>Retain</u> option 2</p> <p><u>Rational</u>: the wording in option 2 is more relevant for caregivers.</p>
<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 [...] hazards of inappropriate preparation.}</p> <p>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>Rational</u>: adds clarity and powdered formula are the most commonly used type of formula around the world.</p>
<p>9.5.1 Adequate directions for the appropriate preparation and use of the product to minimize microbiological risks, including its storage and disposal after preparation, i.e. e.g. that powdered formula should be fed immediately after its reconstitution, and that formula remaining in the bottle after feeding should be discarded, shall</p>	<p><u>Amend</u> the square brackets to “[and in the accompanying leaflet if available.]”</p> <p><u>Rational</u>: this information should appear on the label as there is a risk that the mother/carer may lose an accompanying leaflet if this is the only source of this information.</p>

appear on the label for in the accompanying leaflet and in the accompanying leaflet if available.	
9.5.2 Adequate directions regarding the storage of the product after the container has been opened shall appear on the label for in the accompanying leaflet and in the accompanying leaflet if available.	<p><u>Amend</u> the square brackets to “[and in the accompanying leaflet if available.]”</p> <p><u>Rational</u>: this information should appear on the label as there is a risk that the mother/carer may lose an accompanying leaflet if this is the only source of this information.</p>
9.5.4 The directions should be accompanied by a warning about the health hazards of inappropriate preparation.]	<u>Delete</u> the bracket
<p>9.6.6 [No [nutrition and] health claims shall be made regarding the dietary properties of the product]</p> <p>Nutrition and health claims shall be permitted for foods for infants where they have been demonstrated in rigorous studies with adequate scientific standards.</p> <p>Taking into account paragraph 1.4 of the Guidelines for Use of Nutrition and Health Claims, nutrition and health 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><u>Reword</u> into a positive statement</p> <p><u>Rational</u>: ISDI proposed wording is in support of the wording proposed by Switzerland (Alinorm 05/28/26 para 83). It is of the utmost importance that information on the dietary properties of infant formula can be communicated as:</p> <ul style="list-style-type: none"> • Claims explain the specific nutritional characteristics of the different formula • Claims do not interfere with a mother’s decision to breast feed. Prohibiting claims on these products cannot be justified by public health grounds. • Providing factual, science-based nutrition information on labelling protects the health of the formula-fed infants by differentiating the composition of formula from less nutritious alternatives. • Some countries already allow certain health and nutrition claims on infant formula. • Provisions ensuring that claims for foods for special dietary uses are appropriately used, have already been detailed in Section 3.1 of Codex STAN 146-1985. <p>Finally, there is no reason to prohibit the communication of relevant information through labelling and literature if it complies with the above mentioned criteria and as long as this communication remains in line with national practices and the WHO International Code on the Marketing of Breast-milk Substitutes.</p> <p>For the <u>detailed justification</u>, see the Annex.</p>

Annex

Justification to support the permission of Nutrition and Health Claims for Infant Formulae

Given the importance that the communication of health claims have in terms of providing information to parents and health care professionals on the proper use of breast milk substitutes, and also to provide an incentive for scientific research around infant and child nutrition, it is very important that specific provisions are discussed and included in the Codex Standard for Infant Formula.

As currently worded, the prohibition is in conflict with 3.2.1 and 3.2.2 regarding optional ingredients, because the mere statement of inclusion of an optimal ingredient, except within the ingredients declaration panel, or its amount would be prohibited.

Notably the definition of health claims in the Codex Food Labelling Guidelines includes 2.2.1 *Nutrient Function Claims* – a nutrition claim that describes the physiological role of the nutrient in growth, development and normal functions of the body. Statements about the role of nutrients in growth and development in the context of feeding of infants provide point-of-use nutrition education for mothers. Similarly, 2.1.2 *Nutrient Comparative claims* help mothers to understand the nutritional limitations of other milks, such as cows' or goats' milk, and educate mothers to the nutritional shortcomings of other milks and to differentiate among various formulas.

If 9.6.6 were accepted, as is, any description of a role of nutrient in infant development would be banned regardless of the level of scientific evidence behind the statement. Infant formula labelling is an important source of nutrition information and education to consumers. Manufacturers rely on labelling statements to identify recent science-based changes in composition – changes supported by clinical evidence.

The proposed wording has the advantage that product labels are reviewed on a country by country basis already, and thus, the scrutiny of claims is at the appropriate level.

It is troublesome that CCFL accepted guidelines prohibiting all types of health claims without consideration of type of claim or extent of supportive information. (prohibition of health claims is under discussion in the EU, current Australian regulation prevents nutrition and health claims). It also is troublesome that the prohibition of nutrition and health claims was decided without input from the users of the information namely, mothers who purchase formula, and health care professionals who advise mothers on the use of formula. The United States, which has the most experience with and most comprehensive regulations on health claims, does not prohibit health claims on infant formula (and in the U.S. health claims refer only to the subset of Codex health claims that relate nutrients to disease risk.

Importantly, health claims (of the type typically appearing in the labelling of infant formula) are consistent with WHO and are important to support scientific innovation. Article 4 of the WHO Code for the Marketing of Breast milk Substitutes states, “Governments should have the responsibility to ensure that objective and consistent information is provided on infant and young child feeding for use by families and those involved in the field of infant and young child nutrition.” Nutrition and health claims are science-based objective, consistent information.

Article 7.2 states, “Information provided by manufacturers and distributors to health professionals regarding products within the scope of this Code should be restricted to scientific and factual matters,” exactly the type of information represented by health claims.

Article 9.4 of the Code states, “The label of the food products within the scope of this Code should also state all of the following points: (a) the ingredients used; (b) the composition/analysis of the product.” As written, clause 9.1.5 would prohibit factual information about the composition of the product.

WHA resolution 54.2 does not resolve to prohibit health claims, but does ask that the Code be taken into consideration in dealing with health claims. It calls on all sectors of society, including commercial enterprises, to “contribute to improved nutrition for infants and young children by every possible means at their disposal.” “Every possible means” clearly must include the description of nutritional

components in infant formula, especially components that have been shown clinically to contribute to improved nutrition of infants.

“The WHO Report of an Expert Consultation, The Optimal Duration of Exclusive Breastfeeding, March 28-30, 2001 states, “The expert consultation recognized that some mothers will be unable to, or choose not to, follow this recommendation (to breastfeed); they should be supported to optimize their infants’ nutrition.” Health claims encourage optimized nutrition for babies not breastfed.

Understanding the Codex Alimentarius states, “In the best traditions of the Food and Agriculture Organization (FAO) and the World Health Organization (WHO), as part of its persistent endeavors to develop the Codex Alimentarius the Commission has encouraged food-related scientific and technological research as well as discussion.” Health claims foster scientific research.

The Scientific Committee of Food (2003) recommended, “modifications to an infant formula or a follow-on formula beyond the established standards should be based on and justified by defining an expected benefit (nutritional, functional, technological, or others).” Thus, the medical and scientific communities expect manufacturers to demonstrate and communicate benefits related to innovations, precisely the type of information that the prohibition of health claims would prevent.

Finally, it must be remembered that the purpose of Codex is to protect the health of consumers and ensure fair practices in the food trade (Annex 1). Fair practices in food trade should include nutrition and health claims to allow manufacturers of foods to describe their products fully and allow consumers to be protected from inferior products. Fair practices, for infants who are not breastfed for whatever reason, should ensure that formulas that have been designed and shown through scientific studies to have special attributes can be identified for those attributes.

As stated in 1.2 of the scope of the Standard, “No product other than infant formula may be marketed or otherwise represented as suitable for satisfying by itself the nutritional requirements of normal health infants during the first months of life.” Only infant formula can meet the nutritional needs of infants who are not breastfed. There are many organizations committed to protecting breastfeeding; only the Codex standard exists to protect the health of formula fed infants. The standard is not intended to assist in public health campaigns to promote breastfeeding; it is designed to protect the nutritional status and health of infants who are not breastfed.