codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 6 **CX/NFSDU 03/6**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
Twenty-fifth Session
Bonn, Germany, 3- 7 November 2003

PROPOSED DRAFT REVISED STANDARD FOR INFANT FORMULA

- Comments at Step 3 of the Procedure -

Comments from:

AUSTRALIA
BRAZIL
MALAYSIA
MEXICO
NEW ZEALAND
SPAIN
UNITED STATES OF AMERICA

CRN – COUNCIL FOR RESPONSIBLE NUTRITION
ISDI – INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES
WHO – WORLD HEALTH ORGANIZATION

AUSTRALIA

1. SCOPE

Australia is a member of the Drafting Group, as coordinated by the delegation of Germany, which is investigating the possible integration or not of infant formula for special medical purposes into the draft revised standard for infant formula. Australia is contributing to this process and will await the outcome of discussions prior to providing further comment on scope.

2. DESCRIPTION

2.1 PRODUCT DEFINITION

Pending the outcome of discussions on scope, Australia considers that it is premature to decide on the inclusion or omission of 'normal' in this Section. Also we note that the Committee decision to move the second sentence of 2.1.1 to Scope (see Alinorm 03/26 para 36) has not occurred. Although following further consideration, Australia questions whether it is necessary to include this sentence.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

ESSENTIAL COMPOSITION

Comments on Section 3.1 have been provided separately in response to CL 2003/4 – NFSDU, although Australia has the following additional comments on this Section.

3.1.1 Australia suggests that the term 'suitable' does not necessarily provide consideration of safety. Australia contends that it is important for ingredients to be both suitable and safe and apply to all ingredients not just optional ingredients. Therefore on the basis of this and further comments provided on Section 3.2 (see below) concerning inclusion of 'sole source of nutrition for infants', Australia suggests the following bolded addition to Section 3.1.1:

Infant formula is a product based on milk of cows or other animals and/or other edible constituents of animal, including fish, or plant origin, and which ***is safe and suitable as the sole source of nutrition for infants****.*

3.2 OPTIONAL INGREDIENTS

In the context of the first bracket 'ingredients 'is considered the more appropriate term. Whereas for the second bracket 'substances' is preferable to 'nutrients' as it is a term that has broader application. Additionally, Australia considers that the rest of this sentence i.e. 'to ensure that the formulation is suitable as a sole source of nutrition for the infant' is better placed in Section 3.1 - Essential Composition and Quality Factors since 'optional substances' should, as the designation suggests, be optional and not necessary (i.e. essential) for an infant formula to be suitable as a sole source of nutrition for infants (see proposed text above in 3.1).

Therefore Australia supports amending 3.2.1 and suggests the following alternate shortened text:

3.2.1 In addition to the compositional requirements listed under 3.1, other ~~[nutrients/~~ingredients may be added in order to provide ~~[nutrients/~~substances ordinarily found in human milk. ~~and to ensure that the formulation is suitable as the [sole source of nutrition for the infant]~~ (moved to Section 3.1.1)**.**

Of the three options, Australia prefers inclusion of the meaning intended by 'beneficial effect' in this Section, as it is the most precise of the three terms. However even this term does not indicate the type of acceptable supporting evidence e.g. biochemical, physiological or broader health parameters. Also in the

context of optional ingredients the term 'beneficial effect' is likely to be too problematic. Therefore Australia supports the wording 'suitability' in the context of 'particular nutritional uses'. Also in accordance with our earlier comments it is proposed to replace 'nutrients' with 'substances' in Section 3.2.2 and 3.2.3 as follows:

3.2.2 The ~~usefulness/~~suitability~~/ beneficial effect~~ for the particular nutritional uses of infants and safety of these ~~nutrients~~ substances shall be scientifically demonstrated.

3.2.3 When any of these ~~nutrients~~ substances is added, the formula shall contain sufficient amounts of these ~~nutrients~~ substances to achieve the intended effect, based on levels in human milk.

LABELLING

Australia supports further consideration of the labelling section following the outcomes of discussions on scope. However, the following preliminary comments are provided for consideration.

Australia notes from the Report of the 31st session of the Codex Committee on Food Labelling (ALINORM 03/22A) that there was agreement to advance to Step 8 the Draft Guidelines for Use of Nutrition and Health Claims (para 66).

Section 1.4 of the Draft Guidelines (ALINORM 03/22A APPENDIX IV) states *nutrition and health claims shall not be permitted for foods for infants and young children except where provided for in relevant Codex standards or national legislation*. Providing the Draft Guidelines are approved/adopted by the Codex Alimentarius Commission in mid 2003, Australia supports removal of the brackets on this section. This upholds the requirements of the *WHO International Code of Marketing of Breast-Milk Substitutes* by way of preventing the provision of information which could discourage breast-feeding.

Australia recommends the deletion of this Section. The Compositional Working Group has proposed a minimum iron level of 0.5mg/100 kcal and, if adopted, all infant formula will require the addition of iron to meet the compositional requirements of the standard. Thus, it will not be necessary to differentiate infant formula with 'added iron'.

9.3 DECLARATION OF NUTRITIVE VALUE

9.3(b) Australia supports ISDI comments that propose changes to improve the clarity to this Section as shown by bolded text below. In addition we suggest removing references to 'paragraph' because they are superfluous and not consistent with terminology used elsewhere in the proposed standard.

*9.3(b) the total quantity of each vitamin, mineral, **and** choline as listed in ~~paragraph~~ 3.1.2 and any **optional** ingredient **if added** as in Section ~~listed in~~ ~~paragraph~~ 3.2 of this standard per ….*

INFORMATION FOR USE

This Section only has one paragraph and therefore does not require being separately numbered as 9.5.1.

ADDITIONAL LABELLING REQUIREMENTS

9.6.1b Australia suggests combining the two proposed alternatives with a minor bolded amendment as follows:

*b) a statement of the superiority of breastfeeding and breast milk. For example, 'Breastfeeding ~~is~~ **provides** the best food for your baby' or 'Breast milk is the best food for your baby: it protects against diarrhoea and other illnesses'.*

We believe this follows the intent of the *WHO International Code of Marketing of Breast-milk Substitutes*, which does not prescribe set wording for this statement. Combining the alternatives provides 2 examples for manufacturers, one that focuses on breastfeeding and the other on breast milk.

9.6.1d) This Section is not necessary as it is a repeat of Section 9.5

Australia proposes a minor bolded amendment to this Section as follows:

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

Australia supports the removal of the square brackets to clearly distinguish infant formula from follow-up formula. This requirement is consistent with the Codex Standard for Follow-up Formula (CODEX STAN 156-1987), which states under Section 9.5.2 "*The labelling of a follow-up formula shall include a statement that follow-up formula shall not be introduced before the 6th month of life*." In addition, we support previous comments from the WHO proposing that 'prevent' replace 'avoid' in this Section as follows:

*9.6.5 The products shall be labelled in such a way as to ~~avoid~~ **prevent** any risk of confusion between infant formula and follow-up formula.*

BRAZIL

1. SCOPE

Brazil supports the development of a single standard for infant formula. This way, the scope also must refer to infant formula for special medical purposes.

***Justification:* There are no clear differences among products. Modifications in their composition and labeling can be easily established in a single standard, avoiding possible fails of application, in case differentiated standards exist.**

2. DESCRIPTION
2.1 PRODUCT DEFINITION

2.1.1

Brazil agrees to exclude the underlined sentence of the item 2.1.1, and it does not support the permanence of this sentence in the Scope. The text would be read as follow*:*

2.1.1 Infant formula means a breast-milk substitute specially manufactured to satisfy, by itself, the [normal] nutritional requirements of infants during the first months of life up to the introduction of appropriate complementary feeding. ~~Only products that comply with the criteria laid down in the provisions of this standard would be accepted for marketing as infant formula.~~(moved to Scope)

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

[3.1 ESSENTIAL COMPOSITION

3.1.2.

(b) Mineral

- On the Table presented, on item b (Minerals), invert the maximum and minimum amount per 100 kilocalories presented to Selenium mineral.

-On the footnote of item 3, keep the phrase "The Ca:P ratio shall be not less than 1.2 and not more than [2.0]", eliminating the square brackets of the [2.0].
- On the footnote, delete the square brackets of the item 4.
- We also suggest the inclusion, on the footnote, of bibliography references used.

(d) Protein

- On item d (ii), to delete the square brackets and to keep the phrase: "The minimum value set for quality and the maximum for quantity of the protein may be modified by national authorities according to their own regulations and/or local conditions".

(e) Fat and Fatty Acid
- On the item 5, to put the word "trans" in italic, due to it must follow IUPAC rules. The text would be read as follow*:*

- the *trans* fatty acid content shall not exceed 4% of the total fat content;

3.2 OPTIONAL INGREDIENTS

3.2.1.
- In the item 3.2.1 to replace the terms: "nutrients/substances" by "nutrients/ingredients".
- To delete the square brackets. The text would be read as follow*:*

3.2.1 In addition to the compositional requirements listed under 3.1, other nutrients/ingredients may be added in order to provide nutrients/ingredients ordinarily found in human milk and to ensure that the formulation is suitable as the sole source of nutrition for the infant.

3.2.2

-To keep in the item 3.2.2., the expressions: "usefulness/suitability/beneficial effect".
- To replace: "nutritients" by "nutrients/ingredients"
- The text would be read as follow:

3.2.2 [The usefulness/suitability/beneficial effect] for the particular nutritional uses of infants and safety of these nutrients/ingredients shall be scientifically demonstrated.

3.6 SPECIFIC PROHIBITION

- To include the item with the following writing:

"The product and its components shall not have been contain GMOs".

Justification:
1) The British Royal Society, in the report "Genetically modified plants for use and human health-an update" (2002), points out special recommendations in the introduction of genetically modified foods on diet of specific and vulnerable groups such as infants, children, pregnant and lacting women.

2) The item # 49 of the Ad Hoc Codex Intergovernamental Task Force on Foods derived from Biotechnology document: "Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants, reports that:
"Attention should be paid to particular physiological characteristics and metabolic requirements of specific population groups such as infants, children, pregnant and lactating women, the elderly and those with chronic diseases or compromised immune systems".

3) The use safety of genetically modified ingredients in foods destined for infants should be evaluated in order reach a scientific consensus on the subject, reinforcing the necessity to guarantee that these components will not be used in Infant Formula elaboration.

7. PACKAGING

7.1.

To exclude the sentence in the item 7.1: "When in liquid form, the product shall be packed in hermetically sealed containers; nitrogen and carbon dioxide may be used as packing media". The text would be read as follow:

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

Justification: ***the allowed additives are already cited in item 4.5***

9. LABELING

9.1.5
- To delete all square brackets of the item 9.1.5 keeping the text.

Justification*: The Infant Formula is a product of limited use to be a breast-milk substitute.*
The Draft Guidelines for Use of Health and Nutrition Claims, which has this proposal, is at Step 5 of the Codex Committee on Food Labelling

9.1.6

-To maintain the first item (9.1.6): "Products containing not less than 0.5 mg Iron (Fe)/ 100 kilocalories shall be labeled "Infant Formula with added Iron", without square brackets, keeping the text.
- To exclude the second proposal "[Products containing less than (...) other additional sources.]"
- To establish a minimal value to iron (Fe) in the table showed.
The text would be read as follow:

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 otal iron requirements must be met from other additional sources.]~~

Justification: The iron (Fe) necessity for infants born with a normal weight is 0,55mg Fe/kg/day (FAO/WHO, 1991); or else, this minimum amount should be guaranteed in all formulas.

9.6 ADDITIONAL LABELLING REQUIREMENTS

9.6.1 (b)

- to delete the second item, keeping the first one.
- in the first item, to exclude the expression: "or breastmilk". The text would be read as follow:

b) [a statement of the superiority of breastfeeding ~~or breastmilk~~, for example the statement: Breastfeeding ~~Breastmilk~~ is the best ~~food~~ for your baby, it protects against diarrhea and other illnesses];

MALAYSIA

Paragraph 3.1.2 (e) Fat and Fatty Acid
Malaysia proposes to prohibit the use of commercially hydrogenated fats.

Rationale: The commercially hydrogenated fats may contain high level of trans fatty acids, which have been shown to be detrimental to health. As infants are very vulnerable, it is important to limit such fatty acids in infant formula.

Paragraph 9.1.6: The Name of the Food
There could be an error in the level of iron as 0.5 mg Fe is the minimum level that must be present. It is suggested that the minimum level of iron should be 1.0 mg Fe.

Paragraph 9.3: Declaration of Nutritive Value
Malaysia proposes to insert the phrase *"provided it is present in significant amount i.e. not less than 5% of NRV or of the officially recognized guidelines of the national authority"* at the end of the sentence.

This section is therefore to read:

"(b) the total quantity of each vitamin, mineral, choline as listed in paragraph 3.1.2 and any other ingredient as listed in paragraph 3.2 of this Standard per 100 grammes of the food as sold as well as per 100 milliliter of the food ready for use, when prepared according to the instructions on the label <u>provided it is present in significant amount i.e. not less than 5% of</u> <u>NRV or of the officially recognized guidelines of the national authority</u>"

Rationale: Listing of all vitamins and minerals irrespective of the amounts present in a product is not beneficial to the consumer as the amounts are of little nutritional significance.

MEXICO

After having analyzed the different proposals circulated by the Drafting Group working electronically and when analyzing the different wordings proposed for the above mentioned Draft Standard, the Mexican delegation suggests the following:

- It is necessary to establish specifications corresponding to both groups of products, that is, for normal infant formulae and for infant formulae for medical purposes. However, the specifications for the second group should be established in a rule other than that covering formulae for healthy infants, provided that in accordance with the scope of competence of the Codex the regulation of products for medical purposes does not fall within this Standard.

- Considering this, the Codex Commission should be requested to initiate the development of guidelines by a group of experts in this field, designed to support the Member States with regard to this group of products, or the Commission should assess the scope of competence for those products that are prescribed for specific pathological processes or "for medical purposes".

- Currently, the nutritional specifications contained in the Draft Standard refer to healthy or "normal" infants.

- The concept of "infants with special nutritional requirements", including that of **Infant formula for special medical purposes,** may require the establishment of a list with nutrient variables for all infant diseases (nephropathies, cardiopathies, intolerances, malnutrition, obesity etc.), because in some cases the amounts would have to be reduced or increased, e.g. for proteins, or some amino acids in particular, sodium, potassium etc., or increased for proteins, iron, folic acid, as the case may be.

Considering this, we propose the following amendments to the Draft Standard:

1 SCOPE

1.1 This standard applies to infant formula in liquid or powdered form intended for use, where necessary, as a substitute for human milk for maintaining the normal nutritional requirements of infants, including those infants with special requirements for administration.

We further suggest that a definition of "special requirements for administration" be included under the following proposal:

2. DESCRIPTION.

Infants with special requirements for administration **are those who have deglutition or suction difficulties or other physical disorders and whose caloric ingestion is equivalent to formulae for healthy infants.**

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS.
4. FOOD ADDITIVES
5. CONTAMINANTS
6. HYGIENE
7. PACKAGING
8. FILL OF CONTAINER

no changes.

9. LABELLING

9.1.1 The name of the product shall be either "Infant Formula" or "Formula for Infants **with Special Nutritional Requirements"** or any…

9.1.5 A product intended for infants with **special requirements for administration** shall be labelled to show clearly how it is to be prepared or administered.

We further propose to include consumption recommendations that could be developed while progressing with the document.

NEW ZEALAND

New Zealand is aware of the work of the working group considering the integration of infant formula for special medical purposes and awaits the deliberations of that group. The New Zealand position supports either one standard, with infant formula for special medical purposes as a section in the general standard, or two standards progressing at the same time. We are however wary of this approach slowing down progress of the infant formula standard.

Description

Further discussions on the description will depend on the outcome regarding scope.

Essential Composition

Fat and Fatty Acids
The trans fatty acid content should be raised to " should not exceed 5% of the total fat content". Milk fat can contain up to 6 % trans fatty acids and it can be desirable to manufacture infant formula with a fat mix containing 80% milk fat. Long chain polyunsaturated fatty acids should remain optional additions.

Micronutrients:
Selenium: New Zealand does not support the proposed levels for selenium. The proposed level is much higher than would be acceptable in New Zealand and much higher than levels found in breastmilk. New Zealand would support a minimum level of 0.2 µg/100kJ as recommended by the LSRO report which is based on the estimated mean minus one standard deviation value for the selenium concentration of human milk in countries where selenium deficiency has been recognised.

The current figures for selenium are incorrect with the minimum amount being higher than the maximum amount.

Ca:P: New Zealand strongly supports a maximum calcium to phosphorus ratio of 2.2.

Sodium, Potassium and Chloride: The low maxima for potassium and chloride that have been proposed deviate from those recognised by many competent authorities including the levels stated in the Australia New Zealand Food Standards Code. The balance of these solutes is key to retaining essential fluid balance and disruption of the balance will lead to either dehydration or oedema.

It is proposed that maximum sodium should be retained at 15mg/100 kJ. Potassium minimum should be 20 mg and maximum at 50 mg/100 kJ. Chloride maximum should be 35 mg/100kJ.

Iron: New Zealand questions the maximum level for iron (0.36 /100kJ) and has recently set a maximum level of 0.5 mg/100kJ.

Optional Ingredients

3.2.1 The wording in the first square bracket should be ingredient. The work substances is appropriate in the second square brackets.

3.2.2 New Zealand supports use of the word "suitability" in this sentence and the word "Nutrients" should be replaced by ingredients.

3.2.3 Replace the word "nutrients" by "ingredients".

Additives

New Zealand agrees with the alternative proposal.

Labelling

Further consideration will need to be given to the labelling section following the outcome of discussions on the scope.

Name of the Food

New Zealand supports retaining the original text of Codex standard 72-1981 because there will be minor sources of protein from other ingredients such as maltodextrin, starches , amino acids etc. This wording would be" If 90% or more of the protein is derived from whole or skim milk, as such or with minor modification, the product may be labelled "Infant Formula Based on Milk".

Under 9.1.5 reference to health claims can be removed as the Codex Committee on Food Labelling have advanced to step 8 the Draft Guidelines on Nutrition and Health Claims. IN these guidelines it states that "nutrition and health claims shall not be permitted for foods for infants and children except where provided for in national legislation"

New Zealand recommends deletion of section 9.1.6 as the minimum level of iron proposed would mean that all infant formula would have "added iron".

Declaration of Nutritive Value

The words "optional ingredient if added" should be used instead of "other ingredient" in subclause (b).

Information for Use
This section has only one paragraph and should therefore not be labelled 9.5.1.

Additional Labelling Requirements

9.6.1(b). New Zealand supports the second proposed statements but proposes that breastfeeding should be replaced with breastmilk.

9.6.1 (d) This section is not necessary and can be deleted.

9.6.5 New Zealand supports removal of the square brackets so that there is clear distinction between infant formula and follow-up formula.

SPAIN

1. Scope.

We agree with the current wording; the square brackets should be removed in order to incorporate the text in the Standard.

2.1. Product definition.
2.1.1.

In our opinion, the square brackets should be removed and the term *normal* should be retained consistent with Paragraph 1.1. of the Scope Section where it states: "in meeting the normal nutritional requirements".

3.1. Essential composition.
3.1.1.

As we have pointed out in other comments, it should be clearly defined that the constituents of plant origin do not contain gluten; consequently, we propose to replace the wording "including fish, or plant origin" with **"including fish, or plant origin not containing gluten".**

3.1.2.
b) Minerals.

- In note No. 4, the square bracket should be deleted as it is most likely a typing error.

- For **Zinc** the European Union has established a maximum amount in those formulae whose proteins originate exclusively from cow's milk, with the following values:

  Zinc: maximum 1.5 mg/100 kilocalories – 0.36 mg/100 kJ.

- **Selenium:** the maximum and minimum amounts of selenium expressed in kilocalories are mixed up, they should be: minimum 3 μg and maximum 7 μg. In addition, the minimum amount of kilojoules should be given.

c) Choline.

As there is a minimum value stated per 100 kilojoules, it should also be given per 100 kilocalories.

d) Protein – section (ii).

We support the deletion of the square brackets in the third paragraph and the adoption of the text.

3.2. Optional ingredients.
3.2.1.

We are of the opinion that in the first square brackets the term *"ingredients"*, which are those providing the nutrients, should be retained and that *"substances"* therefore be deleted from the second square brackets and *"nutrients"* be retained.

3.2.2.

As the current wording does not seem very clear to us we suggest the following text:

"The usefulness, suitability and safety of other ingredients for the particular nutritional uses of infants shall be scientifically demonstrated".

4.- Food additives.

As the *"Alternative proposal"* is similar to the original standard we repeat the comments already expressed referring to the alternative proposal.

4.1.- <u>THICKENING AGENTS</u>

4.1.1. GUAR GUM (412)

The EU´s Scientific Committee on Food (SCF) is of the opinion that the authorization of this additive is acceptable up to a level of 1 g/l in partially hydrolyzed protein-based liquid ready-to-eat formulae for healthy infants, except in the case of products intended for infants with protein intolerance.

For special medical food from birth and up to a limit of 10 g/l in liquid ready-to-eat formulae that contain protein hydrolysate and/or amino acids.

In our opinion the use of this gum should be restricted to the formulae mentioned above.

4.1.2 LOCUST BEAN GUM (410)

The SCF thinks that it should only be used in special medical food for children who suffer from nasogastric reflux; it is not necessary to give thickeners to healthy infants, because apart from having only a low energetic value they ferment in the colon and may cause abdominal pain and diarrhoea. Locust bean gum can also reduce the absorption of minerals and trace elements due to the presence of tannins and fibre as components of the gum, which would result in a delay of growth. For these reasons the use of this additive should be restricted to formulae for infants who suffer from nasogastric reflux.

4.1.6. CHEMICALLY MODIFIED STARCHES

The SCF states that the pancreatic amylase enzyme which digests the starch in children has a very low activity, and the presence of an important amount of starch (40g/day) in the diet of infants under one month causes malabsorption and fermentative diarrhoea. It also suggests that undigested starch may interact with other food ingredients in the digestive tract and hinder the development of infants. Therefore, the use of chemically modified starches is not considered acceptable neither in formulae for healthy children nor in special medical food.

4.1.7. CARRAGEENAN (407)

The SCF indicates that carrageenan is not acceptable for healthy infants due to the possible absorption by their immature intestine and the effects on their immune system which has not fully developed yet.

As regards special medical food, the SCF explains that health conditions affect the intestinal permeability, and this may be very important for the assessment of its safety.

While the revision currently undertaken is not yet finished, the SCF has no positive criterion for the acceptability of carrageenan in special medical food.

<u>EMULSIFIERS</u>

4.2.1. LECITHIN (322)

The SCF indicates that the quantity for use as an additive should be adapted to the lecithin content in breast-milk which is determined at 1 g/l.

4.5. PACKAGING GAS (Propellants). European Parliament and Council Directive 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners lays down in Article 2(3b): *"foods for infants and young children as referred to in Directive 89/398/EEC, including foods for infants and young children not in good health; these foodstuffs are subject to the provisions of Annex VI"*.

Given the fact that the gases contained in this section are additives of Annex I of the Directive 95/2, they may not be used for infant nutrition.

GENERAL COMMENTS

Irrespective of the comments provided, the Scientific Committee on Food stated in its opinion of 17 September 1998 on the applicability of the ADI for food additives to infants in the age of 0-16 weeks: "[...] direct exposure of infants to food additives [...] below the age of 16 weeks is not included in the standard toxicity test protocols. Therefore a special evaluation [...] is needed before food additives are to be accepted for use in infant formulae for infants in the age 0-16 weeks". In children toxicodynamics and toxicokinetics are different, their cells are reproducing and dividing faster, which is why there may be more severe effects.

9.- Labelling.
9.1.5.

We agree with the wording of this section, therefore the square brackets should be removed.

9.1.6.

We support the wording contained in the first paragraph as we consider it clearer and more appropriate for being a positive statement.

9.6.
9.6.1.

As we consider it more correct, we propose to replace in this paragraph *"alimentación materna"* with *"lactancia materna"* (Change applies to the Spanish version only. Translator's note).

Section b).

In accordance with the facts mentioned before we support the second option of this paragraph, which states: **"The statement 'Breastfeeding is the best food for your baby'"** or a similar statement as to the superiority of breastfeeding or breastmilk.

UNITED STATES OF AMERICA

Comments on Section 3.1 Introductory Text

3.1.2 "Infant formula [prepared ready for consumption in accordance with instructions of the manufacturer] shall contain **the following minimum and maximum levels of nutrients** per 100 kcal (or 100 kilojoules)**, and the following energy content per 100 ml.** ~~the following nutrients within the following minimum and maximum levels~~ **The general principles for establishing these levels are identified in Annex [#] of this standard.**

Comment: The proposed revision of the first sentence incorporates energy content since this is included in 3.1.2, and also attempts to simplify the language. The proposed addition of

the second sentence would refer to the general principles for establishing essential composition.

Comments on Section 3.1.2 (a-d): Energy Content, Protein, Fat and Fatty Acids, and Carbohydrates)

We are in the process of reviewing pertinent reports and considering additional input on this section, and anticipate submitting comments at a later date.

Comments on Section 3.1.2 (e-g) Table: Vitamins, Minerals, and Choline

Presentation of Table Information

We recommend that the following guidelines be used in presenting information in the table:

1. When applicable, the names in the table of essential composition are harmonized with those in the Codex Guidelines on Nutrition Labelling. Although chemical names are not identified in the table, it is recognized that they are optional for labelling purposes.

2. As a general rule, the amounts of each nutrient will be listed in the table in only one unit. Conversion factors to other units that are sometimes used by countries are identified in footnotes to this table.

3. If there is a recommendation that a minimum or maximum level be established for a nutrient, but little or no data is provided to support a specific level, the table has a notation that the value is "T.B.D" (i.e., To Be Determined). For all other nutrients without values, the table has the notation "N.S." (i.e., Not Specified).

Criteria for Removal of Brackets from Table Values

We note that at the 24th CCNFSDU session, brackets were placed around many of the values in the table, based on proposals to revise certain values. However, not all of these proposals included a scientific rationale to support the alternative value(s). We therefore recommend that the brackets be removed from all values in this table unless a scientific rationale is provided with a recommendation to change a value in order to facilitate meaningful discussion. Otherwise, we are concerned that the goal of achieving agreement based on general principles and a scientific rationale within a timely manner may not be possible.

Comments on Specific Nutrients

At this time, we concur with the values in the table in Annex II of Codex CL 2003/4- NFSDU, except where a proposed change with a scientific rationale is identified below.
We also provide comments below on certain footnotes, and may have comments on other footnotes at a later date.

Calcium and Phosphorus (footnotes).
For calcium and phosphorus, we suggest adding the following footnote:

"The calcium to phosphorus weight to weight ratio shall not be less than 1.2 and not more than 2.2."

Comment: This footnote was included in CL 2001/47-NFSDU, and we do not recall recommendations to remove it.

In addition, for phosphorus we suggest including this additional footnote:

"The availability of phosphorus in milk-based and soy-protein isolate based formulas differs considerably. All (100%) of the phosphorus in milk-based formulas is available whereas

about 70% of phosphorus is available in soy protein isolate-based formulas. Available phosphorus should serve as the basis for addition of calcium to avoid addition of nutritionally unneeded calcium to achieve a calcium/phosphorus ratio within the specified range."

Comment: The above footnote is proposed consistent with the general principle in 6(a) that bioavailability be taken into account when establishing minimum and maximum amounts.

Iron (maximum levels). We propose that the maximum value for infant formula be changed from 1.5 mg /100 kcal to a range of 2-3 mg /100 kcal. In proposing this range, we first considered the tolerable upper level of intake (UL) established by the U.S. Institute of Medicine (2001) (i.e., 40 mg/day of supplemental non-heme iron, or 8 mg/ 100 kcal for a representative infant who consumes 500 kcal per day). However, we believe that the maximum level in this Codex standard should probably be lower, because the establishment of this UL did not take into account iron's interactions with other minerals (e.g., zinc) or its oxidation potential (e.g., with unsaturated fatty acids). Rather, the Institute of Medicine's basis for setting an UL for iron was limited to gastrointestinal adverse side effects.

We further considered that whereas a maximum level of 8 mg/ 100 kcal in this standard is probably too high, a maximum level of 1.5 mg/ 100 kcal is probably too low. Regulations in the United States permit iron concentrations up to 3.0 mg/ 100 kcal (21 CFR §107.100(a)). Furthermore, iron concentrations for iron-fortified formulas in the United States reportedly range from .6 mg/ 100 kcal to 1.8 mg/ 100 kcal (Pediatrics 1999;104:119-123). Thus, we support a maximum level of 2 to 3 mg / 100 kcal based on maximum reported and permitted use in the United States, with no evidence of any problems at these levels.

Selenium (minimum and maximum levels). We propose that the maximum value be 9 mcg/100 kcal (or 2 mcg/kJ). This maximum value is based on the tolerable upper intake level of 45 mcg/d for infants 0-6 months that was established by the U.S. Institute of Medicine (2000), and the assumption that a representative caloric intake would be 500 kcal per day (as identified in our comments on general principles for setting minimum and maximum values).

We propose that the minimum value be 3 mcg/100 kcal (or .7 mcg/kJ). This minimum value is based on the average concentration of selenium in human milk of 18 mcg/L that was reported by the U.S. Institute of Medicine (2000), and the assumption that infant formula has about 67 kcal per 100 ml (as identified in our comments on general principles). Previously, we had proposed that the average concentration in human milk be doubled to derive a minimum value in order to account for lower bioavailability in infant formula, but that was without consideration of any proposed maximum levels and the tolerable upper intake level. We no longer recommend that the average human milk concentration be doubled to "correct" for bioavailability because of the very narrow range that would be result between the minimum and maximum values.

CRN – COUNCIL FOR RESPONSIBLE NUTRITION

3. Essential Composition and Quality Factors

3.1.2.C. PROTEIN.

COMMENT:

CRN recommends that the lower limit of total protein concentration be reduced after revision of current scientific data. Lower protein formulas should be used after a clinical demonstration of their adequacy,

showing that the health outcomes of infants fed formula with human milk levels of protein is similar to breast fed infants.

Estimates in 1985 by FAO/WHO for protein requirements (crude nitrogen x 6.25) were likely overestimates based on fixed protein to energy ratios in infant diets. More recently, it was recognized that the distribution of energy content of milk across the population and the distribution of protein in milk across the population were independent. The assumptions and calculations used to develop the 1985 FAO/WHO/UNU report on Energy and Protein Requirements have been reassessed (Dewey et al, 1996), resulting in a revised reduction in estimated protein requirements during infancy of 10-26%. Accounting for the new estimates are 1) better measurement of protein intake in breast-fed infants, 2) somewhat higher estimates of non-protein nitrogen (NPN) utilization from breast milk, and 3) recognition that mean protein intake may be distinct from the mean protein requirement. Lower protein requirements were corroborated by an updated factorial assessment of protein needs (Dewey et al. 1996). Maintenance nitrogen requirements were estimated in 1985 to be 120 mg N/kg/d; the revised estimates are 82-93 mg N/kg/d. Reassessment of the daily nitrogen accretion rate resulted in elimination of a 50% overage in daily nitrogen accretion rate to account for day-to-day variability in growth.

The new estimate of protein requirements for 1-2 month old infants is 2 g/kg/d. (CRN disagrees with the recent DRIs set by the US National Academy of Sciences, in which a DRI was based on the average protein concentration over the first six months of life. The concentration of protein human milk is too variable over this time for an average value to ensure an adequate level in early infancy.) The percentage reduction from earlier estimates of protein requirements, 2.25 g/kg/d, if applied to the minimum protein requirement of formulas, yields a new lower minimum of 1.6 g/100 kcal.

Improvements in dairy processing methodologies have resulted in a more finely constructed protein system that more closely mimics human milk protein patterns and essential amino acid levels. For example, the preparation of alpha-lactalbumin from whey provides formulas with tryptophan concentrations identical on a g/L basis to that in human milk, in protein-bound form, at a lower total protein concentration than in previous infant formulas.

Clinical studies involving experimental formulas with total protein levels lower than the current Codex minimum provide direct evidence that a lower protein intake is adequate for growth and development. Fomon et al. 1995 fed male infants 11 g protein/L; Fomon et al. 1999, fed infants 11.5 g/L; Lonnerdal and Chen 1990 fed diets containing different formulas containing 14.7, 13.3 and 12.2 g protein/L; in none of these studies was the growth different than breast fed reference infants.

A CRN member company has data on human milk protein from a survey of 450 human milk samples collected from women in 9 countries (US, Canada, Chile, UK, China, Philippines, Mexico, Japan, Australia). Once collated and accepted for publication, CRN can provide these data to Codex and other regulatory bodies for consideration in revision of the standards for total protein and essential amino acids.

Regarding calculations, measurement of protein on a total nitrogen basis overestimates the amount of alpha-amino acid nitrogen. This is recently recognized by both LSRO (1998) and by the Scientific Committee for Foods in the EU. It may be necessary to adjust any calculated total protein to take into account the non protein nitrogen, and it may be desirable to limit the range of non-protein nitrogen in formulas. Codex uses the same constant to calculate total protein from measured nitrogen for both intact cow's milk proteins and for protein hydrolysates. As hydrolysis increases the weight of each terminal amino acid, the proportion of the weight of the amino acid that is nitrogen is diluted. A lower value than 6.38 should be used for hydrolysates.

RECOMMENDATION:

The lower limit of total protein concentration should be reduced to 1.6g/100 kcal to reflect recent scientific data.

ESSENTIAL AMINO ACIDS

COMMENT:

Some proposed essential amino acid (EAA) levels, especially that for arginine, are misaligned with other regulatory requirements, previous literature values, other regulatory reference data and also with unpublished data by a CRN member. Human milk reference data should be based on as reliable information as possible, lest Codex set requirements that would result in necessarily different intakes of EAA in formula fed infants compared to breast fed infant. The arginine specification of 109 mg/100 kcal is much higher than the EU value (69mg/100 kcal). CRN member company data for milk from mothers in lactation days 31-60 is very similar to the EU value.

Similarly, there is little evidence that a separate requirement exists in term infants for cysteine (as opposed to a requirement for the sum of cysteine plus methionine). Arguments for utilization of formula cysteine for biosynthesis of taurine is largely moot, as formulas typically also have added taurine. It may be worth considering a specification for taurine in order to spare cysteine. Of all free amino acids in human milk, taurine is in greatest concentration. While taurine is not used in synthesis of proteins, it may have other roles. Supplementation of formula with taurine changes body nitrogen metabolism (Raiha NC et al 1996).

The proposed requirement for cysteine of 46 mg/100 kcal is nearly twice the reference value in EU regulations, and the Codex proposed methionine value of 25 mg/100 kcal is less than the EU reference of 29 mg/100 kcal. This discrepancy, together with the absence of data showing a need for a separate specification for cysteine suggest it is questionable whether there would be value to public health from setting a new cysteine specification. A CRN member cmpany unpublished data are similar to EU for methionine, and between EU and the proposed Codex value for cysteine. A CRN member company data may be useful in deliberating a new specification for the sum of cysteine plus methionine.

RECOMMENDATION:

Arginine levels should be set at 69mg/100kcal. Cysteine and Methionine values should be summed, without a separate specification for cysteine.

3.2.1.E FAT AND FATTY ACID

COMMENT:

CRN supports the fatty acid requirements proposed, and recommends Codex consider establishing a standard for minimum concentrations of docosahexaenoic acid (DHA) and arachidonic acid (AA). Evidence has continued to accumulate that indicates the health benefits to formula-fed infants of inclusion of human milk levels of DHA and AA. Authoritative bodies, most recently the Child Health Foundation (Koletzko, et al. 2001), have recommended that DHA and AA as a percentage of total fat be included to formulas for term infants at 0.35% AA and 0.2% DHA.

RECOMMENDATION:

DHA and AA should be added in balance to each other, and inclusion of eicosapentaeoic acid (EPA) should be limited to not exceed human milk EPA.

9.1 The Name of the Food

9.1.5. [9.1.5 A product intended for infants with special nutritional requirements shall be labelled to show clearly the special requirement for which the formula is to be used and the dietary property or properties on which this is based. [No health claims shall be made regarding the dietary properties of the product.]]

COMMENT:

Currently the Scope of the proposed draft continues to cover both healthy infants and infants with special nutritional requirements. To avoid a public health and safety issue, information about the product must be made available and must supply all relevant details about the proper use of the product. The lack of appropriate information about the product may result in inappropriate use of the product. Nutrition and

health claims, being true statements/information regarding the dietary properties of the foods are the only direct way of providing direct information to carers.

RECOMMENDATION:

Remove first set of brackets to retain wording. Maintain second set of brackets around the health claim statement.

We appreciate the opportunity to comment on this CODEX draft from an industry perspective. We hope to achieve a CODEX standard that fulfils the primary objective to provide a safe and nutritious food for infants.

REFERENCES

Dewey K.et al. 1996 Eur.J. Clin. Nutr. 50 Suppl S119-47
Fomon et al. 1995 Am. J. Clin. Nutr, 62:35
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Raiha NC et al 1996 Acta Ped.. 85(12):1403-7.
Koletzko, B et al. 2001,Acta Ped. 90: 460-464

ISDI – INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES

ISDI PROPOSAL	JUSTIFICATION
1. SCOPE **1.1.** This standard applies to infant formula in liquid form or powdered form intended for use, where necessary, as a substitute for human milk in meeting the normal nutritional requirements of infants. [~~The provisions in this standard are also intended for infants with special nutritional requirements, except for certain provisions which must be modified to meet those special requirements~~.]	**The second sentence in square brackets should be deleted. Infant formulas and formulas intended for infants with special nutritional requirements should be dealt with separately.** As demonstrated by the simulation made by the German delegation, a standard encompassing both types of formulas (Draft A) would be complex, confusing and leading to misunderstanding and misinterpretation. This may ultimately be detrimental to the health of the infant. Below some examples of the disadvantages having one single standard: • Infant FSMPs are designed, for example, to be used for the dietary management of infants suffering from a particular disease or medical condition like phenylketonuria, galactosemia, malabsorption, allergies, inborn errors of metabolism. Their composition is therefore very specific and most of the time deviates from the provisions of the Infant Formula Standard. • Due to their specific composition, some products may present a health hazard if used by persons (infants) for which they are not intended. Similarly, infant formula or even breast milk may be contraindicated for infants suffering from

	certain diseases such as phenylketonuria. • They are usually prescribed according to the bodyweight and medical condition of the infant, not age. They can be used up to the age of 18 months while infant formula is recommended to cover age ranges from 0 to over 4-6 months). • Specific labelling provisions must be applied to these products. Information about the product must be made available and must supply all relevant details on its proper use. This information will necessarily include a reference to the health status of the infants. • Specific additives are required to maintain the quality and stability of infant FSMPs, as they are often formulated from ingredients not routinely found in infant formula at high levels e.g. medium chain triglyceride fats, fatty acids, maltodextrin, amino acids. Stability of the product must be maintained throughout shelf-life as well as on reconstitution; stability on reconstitution must be guaranteed not only within a feeding bottle, but often the feed will be administered via nasogastric tube and thus must be stable during hanging time. The practice of having separate legislation already exists e.g. in Europe, these formulas are regulated with a Directive on Foods for Special Medical Purposes (1999/21/EC). An equivalent Standard at Codex level is under consideration to cover these specific formulas. Finally from a law enforcement point of view, surveillance would be easier with 2 separate standards.
2. DESCRIPTION **2.1.1 Product definitions** Infant formula means a breast-milk substitute specially manufactured to satisfy, by itself, the ~~[~~ normal ~~]~~ nutritional requirements of infants during the first months of life up to the introduction of appropriate complementary feeding. ~~Only products that comply with the criteria laid down in the provision of this standard would be accepted for marketing as infant formula. (moved to Scope)~~	Remove the square brackets. This standard should apply only to products intended for infants in good health. The last sentence should be deleted, it is unnecessary.
3.1. Essential Composition	ISDI has provided comments to the working group led by Germany and the USA (03/095).
3.2 OPTIONAL INGREDIENTS **3.2.1** In addition to the compositional requirements listed under 3.1, other ~~[~~nutrients/ingredients~~]~~ may be added in order to provide ~~[~~nutrients/substances~~]~~ ordinarily found in human milk and to ensure that the formulation is suitable as the sole source of nutrition for the infant. **3.2.2** ~~[~~The ~~usefulness/~~suitability~~/beneficial effect]~~ for	The word "**ingredient**", is appropriate and is in line with the title of the section The word "**substances**" is appropriate as there are components of milk (oligosaccharides, peptides, immune factors etc) which are not nutrients, but which are important for infant health. The "**suitability** for the particular nutritional uses" is

the particular nutritional uses of infants and safety of these ~~nutrients~~ **ingredients** shall be scientifically demonstrated. **3.2.3** When any of these ~~nutrients~~ **ingredients** is added, the formula shall contain sufficient amounts of these ~~nutrients~~ **ingredients** to achieve the intended effect, based on levels in human milk.	in itself a beneficial effect. The word "nutrients" should be substituted by the word "ingredients" for consistency with 3.2.1. The word "nutrients" should be substituted by the word "ingredients" for consistency with 3.2.1.
3.3. Vitamin compounds and mineral salts	ISDI has provided its comments on this particular section in its answer to Circular Letter CL 2002/7 – NFSDU (ISDI Ref 02/133).
4. FOOD ADDITIVES	ISDI has provided comments to Switzerland leading the working group on this matter (03/163)
9. LABELLING **9.1.3** If cow's milk is the ~~only~~ **main** source of protein, the product may be labelled "Infant Formula Based on Cow's Milk" ~~**9.1.5.** [A product intended for infants with special nutritional requirements shall be labelled to show clearly the special requirement for which the formula is to be used and the dietary property or properties on which this is based.~~ ~~[No health claims shall be made regarding the dietary properties of the product]]~~ **In order to provide information concerning the composition and the specific properties of infant formula, nutrition and health claims are permitted insofar as they are** **- truthful;** **- not misleading;** **- scientifically substantiated and** **- not undermining breastfeeding.**	Many other components may contain some protein, such as starches, maltodextrins. Therefore ISDI suggests changing the word "only" to "main". The sentence in square brackets should be deleted, there is no need for such a paragraph if the standard covers only formulas intended for healthy infants. The sentence in square brackets should be deleted and replaced by the suggested wording in bold. It is of the utmost importance that information on the dietary properties of infant formula can be communicated as: • **The lack of appropriate information on these adapted foods may orient the parent to choosing non-adapted and inappropriate foods for their infants and young children. Nutrition and health claims, being true statements/information regarding the dietary properties of the foods provide important information to parents.** • **Some countries already allow certain health and nutrition claims in labelling of formulas and weaning foods intended for healthy infants.** • **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 (Codex General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses)[1].** Finally, there is no reason to prohibit the communication of relevant information through

[1] This section states that these foods may not be "*described or presented in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding their character in any respect*".

	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. The aim of the Code on the Marketing of Breast-milk Substitutes is to "*contribute to the provision of safe and adequate nutrition for infants, by the protection and promotion of breastfeeding, and* ***by ensuring the proper use of breast milk substitutes, when these are necessary, on the basis of adequate information*** *and through appropriate marketing and distribution*".
9.3. Declaration of nutritive value. (b) the total quantity of each vitamin, mineral, choline and any ~~other~~ **optional** ingredient **if added** as listed in paragraph 3.2 of this standard per 100 grammes of the food as sold as well as per 100 mililiter of the food ready for use, when prepared according to the instructions on the label.	Using the wording "optional ingredient" is in line with section 3.2. Including "if added" avoids misinterpretation.
9.5. Information for use 9.5.1 Directions as to the **appropriate** preparation and use of the food, and its storage and keeping after the container has been opened shall appear on the label or on the accompanying leaflet.	The word "appropriate" should be added for sake of clarity.
9.6. Additional labelling requirements **9.6.1. b)** ~~[a statement of the superiority of breastfeeding or breast milk, for example the statement: Breast milk is the best food for your baby , it protects against diarrhea]~~ ~~or:~~ ~~[The statement "Breastfeeding is the best food~~ (sic) ~~for your baby", or a similar statement as to the superiority of breastfeeding or breast milk]~~ **a statement of the superiority of breastfeeding**.	The first wording proposed for b) is not acceptable from a scientific point of view, and it may be unduly alarming to mothers who are not able to breastfeed. Moreover, it deviates from the wording of the International Code of Marketing of Breast-milk Substitutes. ISDI suggests using the wording from the Article 9.2 of the Code: "*a statement of the superiority of breastfeeding"*. If this is not accepted, ISDI prefers the second choice for section b).
9.6.1. d) ~~instructions for appropriate preparation~~	This is redundant with section 9.5.1 and should be deleted
9.6.4.and in any case from the age **of** ~~over~~ six months	
9.6.5. ~~[The product shall be labelled in such a way as to avoid any risk of confusion between infants formula and follow-up formula]~~	This sentence is superfluous and should be deleted

GENERAL PRINCIPLES for establishing minimum and maximum values for the essential composition on infant formula: Section 3.1

Point 6.c) and 6.d)

As already acknowledged by several country delegates during the last session of CCNFSDU and as reported in CL 2003/4, "the obligation to take into account the contribution of the water used to the total nutrient content of the product ready for consumption was considered to be unworkable". Infant formula manufacturers carefully control the water insofar as it is added **before** the purchase (i.e. liquid formula), but cannot have a complete control of the water to be added **after** the formula has been purchased.

More over, point 6c) and point 6d) address the same matter of ingredient variability, ISDI therefore suggests to combine these two points and suggest the following:

ISDI proposal replace 6c) and 6d) by:
~~6.c) total levels of a nutrient in infant formula, taking into account both naturally occurring nutrients in the ingredients and added nutrients~~
~~[6.d) the inherent variability in ingredients **[**and in water**]** that may be added to the infant formula product before or after it is purchased]~~

6.c) total levels of a nutrient in infant formula, taking into account both naturally occurring nutrients and their variability in the ingredients and added nutrients.

SECTION 3.1.1

PRESENT CODEX PROPOSAL
"Infant formula is a product based on milk of cows or other animals and/or other edible constituents of animal, including fish, or plant origin, which have been proved to be suitable for infant feeding."

ISDI proposal:
3.1.1 "Infant formula is a product based on milk of cows or other animals and/or other edible **ingredients** which have been proved to be suitable for infant feeding."

ISDI is of the opinion that all dietary resources should be permitted in the manufacture of infant formula providing that safety and nutritional quality is guaranteed. In particular, infant formula can be based on milks of different origins depending on the resources of the countries where the product is manufactured. For example milk from buffalo, goats and other animals is also suitable for infant feeding. Other nutritious sources from vegetables could also be used.

A large choice in the source of ingredients is of the utmost importance for the following reasons:
- Infant formula should be manufactured according to local nutritional resources provided that the quality criteria defined in the Standard are respected.
- Infant formula should answer to cultural and/or religious habits (e.g. vegans, vegetarians...)
- Some infants are allergic to certain ingredients and alternatives should be permitted
- Some ingredients may be chemically synthesised
- Flexibility allows innovation

SECTION 3.1.2

PRESENT CODEX PROPOSAL
*"Infant formula [**prepared ready for consumption in accordance with instructions of the manufacturer**] shall contain per 100kcal (or 100 kilojoules) the **following nutrients within the following minimum and maximum levels**:"*

Although mentioned in other sections of the standard, it should be made clear that formula should be prepared using safe and suitable water ISDI therefore suggested the following wording:

ISDI proposal:
3.1.2 "Infant formula [prepared ready for consumption **with safe and suitable water**, in accordance with instructions of the manufacturer] shall contain per 100kcal (or 100 kilojoules) the following nutrients within the following minimum and maximum levels:"

a) ENERGY CONTENT

PRESENT CODEX PROPOSAL
The energy content of the product shall not be less than 60 kcal/100 ml (250 kJ/100 ml) and not more than 75 kcal/ 100 ml (315 kJ/100 ml).

ISDI supports the proposed levels. However, for the sake of clarity, ISDI suggests the following wording: "The energy content of the product as prepared **according to manufacturer's instructions** shall not be less than 60 kcal/100 ml (250 kJ/100 ml) and not more than 75 kcal/ 100 ml (315 kJ/100 ml)".

b) PROTEIN

♦ **b) (i) Para 1**

PRESENT CODEX PROPOSAL
Protein content = nitrogen content x 6.38 for cow's milk proteins and protein partial hydrolysates.

Protein content = nitrogen content x 6.25 for soya protein isolates and protein partial hydrolysates

ISDI Proposal
"Protein content = nitrogen content x 6.38 for cow's milk proteins and **their** partial hydrolysates.
Protein content = nitrogen content x 6.25 for **other** proteins and their partial hydrolysates"

The Standard defines the coefficients of conversion for only two types of protein (cow milk and soya extracts). In addition, comments received from various delegations show that there are some divergent opinions on the factors to be used, Germany for instance, proposes to apply only one factor for all kinds of proteins.
The "default" factor 6.25 is used by nutritionists for the conversion of nitrogen content to protein and is based on the assumption that a protein contains 16 g of (protein) nitrogen. Real proteins have nitrogen contents which are near, above, or below this value of 16g N/100g.

The nitrogen content of the total **milk protein** is about 15.8% (thus the factor would be 6.33), pure alfa-s1 casein has 15.74% N (factor = 6.35). Thus, the traditional factor of 6.38 for milk protein is close to reality: 6.25 would be far from the reality.

Isolated **soy protein**, due to its high content in nitrogen rich (N) arginine, has about 17.5% N (thus factor 5.7). Numerous proteins from vegetable source will have factors between 5 and 6.

Today we have the necessary amino acid data to establish the corresponding factors for a large number of food proteins. If we were to be purely scientific, the appropriate factors for each kind of food protein could be used, however, there would be inevitably many factors, not one or two, and this add much complication.
Saying that N * 6.25 = protein is a "default definition" simplifies many procedures even though if it may not be completely accurate.

Therefore ISDI suggests to keep the first sentence as such for cow's milk proteins and their partial hydrolysates and to modify the 2nd sentence to apply it to all protein sources.

♦ **b) (i) Para 2**

PRESENT CODEX PROPOSAL
The "chemical index" shall mean the lowest of the ratios between the quantity of each essential amino acid of the test protein and the quantity of each corresponding amino acid of the reference protein (breast milk, as defined in Annex 1).

This sentence is meaningless since chemical index is not mentioned again at any other point in this Standard, and should be deleted here. The relevant reference is the comparison to the breast milk as mentioned under section (d)(ii). **ISDI proposes to delete this paragraph**

♦ **b) (ii) Para 2**

PRESENT CODEX PROPOSAL
For an equal energy value, the formula must contain an available quantity each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast milk, as defined in Annex 1); nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together.

ISDI proposal:
"For an equal energy value, the formula must contain an available quantity **of** each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast milk, as defined in Annex 1); nevertheless, for calculation purposes, the concentrations of methionine and cystine may be added together**, as well as phenylalanine and tyrosine."**

Regarding metabolic pathways of amino acids, tyrosine can be derived from phenylalanine and thus, these two amino acids should be added together as are methionine and cystine. For healthy infants these metabolic pathways are interdependent.

♦ **b) (ii) Para 3**

PRESENT CODEX PROPOSAL
[The minimum value set for quality and the maximum for quantity of the protein may be modified by national authorities according to their own regulations and/or local conditions.]

For nutritional safety purposes, it is important that unalterable minimum criteria be set regarding protein quality. Moreover, this sentence has the potential to be a barrier to trade in contradiction with the Codex aims. **ISDI proposes to delete the sentence**

♦ **b) (iii) Para 1**

PRESENT CODEX PROPOSAL
Isolated amino acids may be added to Infant Formula only to improve its nutritional value for infants. Essential amino acids may be added to improve protein quality, only in amounts necessary for that purpose. Only natural L forms of amino acids shall be used.

ISDI suggests **deleting the word "*natural*"** in "*Only natural L forms of amino acids shall be used*" since L-forms are the natural forms.

c) FAT AND FATTY ACIDS

♦ PRESENT CODEX PROPOSAL
The product shall contain:
- linoleic acid (in the form of glycerides) at a level of not less than 300 mg/100 kcal (or 70mg/100 kJ) and not more than 1200 mg/100 kcal (285 mg/100 kJ);

ISDI proposal:

"Linoleic acid	300mg/100kcal - N.S.	70mg/100kJ - N.S."

ISDI does not see any need to set a maximum level for linoleic acid in infant formula. The proposed level is based on the European directive but is not in agreement with the LSRO report of the American Society for Nutritional Sciences. Limits for linoleic acid have been based on the average levels found in human milk and on suggestions that high levels of linoleic acid may suppress long chain polyunsaturated (LCP) fatty acid synthesis. The results of a study in rats challenge this

concept. No suppressing effect of high dietary linoleic acid levels was found on the biosynthesis of docosahexaenoic acid (DHA) from linolenic acid using high-precision mass spectrometry tracer methods (Sheaff et al., 1995[2]).

There are no safety concerns regarding high levels of linoleic acid. If a maximum level should be set, those proposed by the LSRO should be adopted.

♦ PRESENT CODEX PROPOSAL
- the linoleic/alpha-linolenic acid ratio shall not be less than 5 nor greater than 15;

ISDI proposal, for consistency with the proposed figures for minima (300/50=6):
"- the linoleic/alpha-linolenic acid ratio shall not be less than **6** nor greater than **16**;"

♦ PRESENT CODEX PROPOSAL
- the trans fatty acid content shall not exceed 4% of the total fat content;

ISDI proposal
"- the trans fatty acid content shall not exceed **5**% of the total fat content; and the use of partially hydrogenated oils in infant formula is prohibited"

The limit of 4% in the proposed draft revised standard is identical to the limit in the Commission Directive 91/321/EEC on infant formulae and follow-on formulae. It is based on the opinion expressed by the European Scientific Committee for Food (SCF) expressed on 17 September 1993. In this opinion the SCF

> *"… considered that the trans fatty acid content of formulae should be as low as practically feasible. .... Apart from partially hydrogenated fat, the major source for trans fatty acids in infant formulae is cow's milk fat, which may contain about 2 to 5 % of trans fatty acids. Cow's milk fat is only used in fat blends in European formulae and, since it does not exceed 80% of total fat, an upper limit of trans fatty acid content of 4% of total fat can be set without limiting the current use of cow's milk fat in formula. This latter value is also similar to the average trans fatty acid content in mature human milk in Europe."*

The SCF opinion was based on the literature available at that time. But since then more reliable methods for analysis of trans fatty acids have been developed and have shown that:

1. Cow's milk fat often contains naturally more than 5% *trans* fatty acids

Two publications have reported *trans* fatty acid levels in cow's milk above 5 % and up to 6.5%[3,4]. A third study, which has just been completed[5] analysed the bi-monthly variation in *trans* isomer levels in whole milk powders produced in Brazil, Denmark, Indonesia and the Netherlands over a twelve month period in 1996/1997. Results showed that seasonal variation is very high and that, depending on the season and presumably on what they are eating, genetically similar animals generate milk with widely differing *trans* content. These results are summarised in table 2 below:

***Table 2**: Trans* fatty acids in whole milk powder (g/100 g total fatty acids)

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[2] Sheaff RC, Su HM, Keswick LA, et al: Conversion of a-linolenate to dososahexaenoate is not depressed by high dietary levels of linoleate in young rats: tracer evidence using high precision mass spectrometry. *J Lipid Res* 1995;36:998-1008.

[3] Wolf RL, Bayard CC, Fabien RJ. Evaluation of sequential methods for the determination of butterfat fatty acid composition with emphasis on *trans*-18-1 acids. Application to the study of seasonal variations in French butters. JAOCS 1995; 72:1471-83.

[4] Henninger M, Ulberth F. *Trans* fatty acid content of bovine milk fat. Milchwissenshaft 1994; 49:555-58.

[5] Dionisi F, Golay PA, Fay L.B. Influence of milk fat presence on the determination of *trans* fatty acids in fats used for infant formula. Analytica Chimica 21914 (2002) 1-13

	Denmark	Netherlands	Brazil	Indonesia
Jan/Feb	3.25	3.61	5.26	5.25
Mar/Apr	3.29	3.30	5.15	5.80
May/Jun	3.70	5.23	4.54	5.86
Jul/Aug	4.25	5.64	3.26	5.45
Sep/Oct	4.39	5.50	3.79	5.27
Nov/Dec	3.57	3.29	5.81	5.58

Most of these *trans* fatty acids (about 80 %) were *trans* oleic acid. *Trans* linoleic and *trans* linolenic acid were present only at low levels: milk fat is not a major source of these essential fatty acids.

A regulation limiting *trans* fatty acids to 4% automatically limits the use of milk fat in infant formulations even though it is a good source of lipid for this purpose. Agricultural policies around the world support milk production in recognition of the nutritional importance of milk, but use of the fat, will be restricted.

Similar to the reasoning of the SCF who sets the European guidelines at 4% based on formula containing milk fat at 80%, it would be reasonable to set the maximum permitted *trans* fatty acid content in infant formula at 5%, now that we know that milks contain higher total levels of trans fat than had been previously thought.

2. Specific Effects of Trans Fatty Isomers

It is well known that the body has all the mechanisms for handling *trans* fatty acids – in fact *trans* fatty acids are a natural metabolite of normal lipid metabolism. Evidence is growing that different *trans* fatty acid isomers have different effects on metabolism. The *trans* fatty acid known as conjugated linoleic acid (CLA), for example has been implicated in anti cancer effects. More recent evidence has shown that dietary vaccenic acid (the *trans* isomer of 18:1) which is found in cow's milk can be converted into CLA by mice (Santora, 2000) [6].

3. There is no solid evidence of detrimental effect of *trans* fatty acids in development.

In the past, some delegations have stated that *trans* fatty acids may be incorporated into brain and retina and alter optimal physiological function, without, unfortunately referencing such statement. A thorough review of the scientific literature on this point carried out by ISDI did not reveal the source either. In fact, to the contrary, studies in animals (these kinds of studies cannot be carried out in human infants) have shown that even when *trans* fatty acid are fed at unrealistically high levels (up to 36% of calories which is equivalent to 5-12 times the average human intake) very little *trans* fatty acid is incorporated into the brain and retinal tissues (0.0-0.5%)[7,8,9,10,11,12,13,14]. There have been no studies showing impaired neural functions due even to these extreme diets.

[6] Santora JE, Palmquist DL and Roehrig KL 2000 *Trans* vaccenic acid is desaturated to conjugated linoleic acid in mice. J Nutr 130:208-215

[7] Adlof RO, Emken EA. Distribution of hexadecenoic, octadecenoic and octadecadienoic acid isomers in human tissue lipids. Lipids 1986;21(9):543-7.

[8] Beyers EC, Emken EA. Metabolites of cis,trans, and trans,cis isomers of linoleic acid in mice and incorporation into tissue lipids. Biochim Biophys Acta 1991;1082(3):275-84.

[9] Grandgirard A, Bourre JM, Julliard F, et al. Incorporation of trans long-chain n-3 polyunsaturated fatty acids in rat brain structures and retina. Lipids 1994;29(4):251-8.

[10] Jones GP, Birkett A, Sanigorski A, et al. Effect of feeding quandong (Santalum acuminatum) oil to rats on tissue lipids, hepatic cytochrome P-450 and tissue histology. Food Chem Toxicol 1994;32(6):521-5.

[11] Opstvedt J, Pettersen J, Mork SJ. Trans fatty acids. 1. Growth, fertility, organ weights and nerve histology and conduction velocity in sows and offspring. Lipids 1988;23(7):713-9.

[12] Pettersen J, Opstvedt J. Trans fatty acids. 3. Fatty acid composition of the brain and other organs in the newborn piglet. Lipids 1989;24(7):616-24.

[13] Pettersen J, Opstvedt J. trans fatty acids. 5. Fatty acid composition of lipids of the brain and other organs in suckling piglets. Lipids 1992;27(10):761-9.

[14] Pettersen J, Opstvedt J. Trans fatty acids. 2. Fatty acid composition of the brain and other organs in the mature female pig. Lipids 1988;23(7):720-6.

There is some evidence, particularly in tissue and cell cultures that *trans* fatty acid inhibit the enzymatic conversions to long chain polyunsaturated fatty acids. However it appears that this interaction is most relevant when essential fatty acid intake is low.
An Expert Panel composed of well-recognized specialists in the field of lipid nutrition in infants concluded: "Existing data have not established a causal relation between *trans* fatty acid intake and changes in early development"[15].

4. Human milk fat contains up to 17% *trans* fatty acids

A review of the literature on total *trans* fatty acids in human milk showed a range from 1.3 % in a group of 38 Spanish women to 7.2 for a group of 198 Canadian women, with a lowest value of 0.1 % and a highest value of 17 %.[16]. These levels are considerably higher than those originally considered by the European Scientific Committee for Food.

5. Conclusion

Limiting *trans* fatty acid levels in infant formula to 4% total fatty acids will unnecessarily restrict the use of cow's milk lipid. Human milk fat contains up to 17% *trans* fatty acid, and no negative effects of *trans* fatty acid on metabolism nor on development have been established as long as sufficient essential fatty acids are available. It therefore seems that a level of *trans* fatty acid for infant formula of 5% should not raise any concerns for health. This will also allow a reasonable use of milk fat in infant formula.

Finally, ISDI suggests prohibiting the use of partially hydrogenated oils in infant formula because of their high level of trans fatty acids.

♦ **Other comments on fats: LCPUFA**

Mandatory minimum levels of docosahexaenoic acid (DHA) and arachidonic acid (AA) in infant formula have been proposed by some delegations. These fatty acids are found in human milk and are postulated to be important in neural and visual tissue structure and function. When included in formula fed to infants, levels of AA and DHA will increase in red blood cells and plasma, however it is not known if increases occur in neural tissues (brain or retina). Many studies have been carried out looking for effects of feeding AA and DHA on neural or visual development. Some studies do show a positive effect, where others were unable to measure such an effect.

ISDI supports the optional addition of LCPUFA at limits set in the European Directive, which are not exceeding:

1% of the total fatty acids content for ω –3-LCP
2% of the total fatty acids content for ω –6-LCP

d) CARBOHYDRATES

ISDI suggests to change the heading of this section into **"DIGESTIBLE CARBOHYDRATES"** and agrees with the proposed level on carbohydrates.

SECTION 3.1.2

SECTION 3.1.2 (a) VITAMINS

NIACIN
Proposed in CL 2003/4

	Min /100 kcal	Max /100 kcal	Min /100 kJ	Max /100 kJ
Niacin	**[0.6] mg**	N.S.[1]	**[0.14] mg**	N.S.[1]

[15]. Carlson SE,Clandinin MT,Cook HW,Emken EA,Filer LJ. *trans* Fatty acids: infant and foetal development. Am J Clin Nutr 1997;66:717S-736S
[16] Chen ZY,Pelletier G,Hollywood R,Ratnayake WMM.*trans* Fatty acids in Canadian human milk.Lipids 1995;30:15-21.

For sake of clarity, ISDI wishes that the following footnote is added "**as preformed niacin**"

FOLIC ACID
Proposed in CL 2003/4

	Min /100 kcal	Max /100 kcal	Min /100 kJ	Max /100 kJ
Folic Acid	**[11] µg**	N.S.	**(2.6] µg**	N.S.

ISDI is aware certain recent recommendations indicate that a minimum level higher than the level of 4 µg/100kcal (originally in the standard) would be required. ISDI is currently reviewing these recommendations and will bring a proposal forward for the second round of comments for the Electronic Working Group on Compositional Criteria of Infant Formula mid-May.

SECTION 3.1.2(b) MINERALS

In Circular letter 2001/47 it is suggested to delay the setting of maximum levels for Na, K, Cl and P until the FAO and WHO Expert consultation on Energy and Protein requirements in Human Nutrition is completed. This recommendation is based on the fact that the level of protein should be taken into consideration when setting maximum levels for minerals in infant formula in order to have a control on the potential renal solute load (PRSL) of the formula as fed.

ISDI believes there is no need for delaying the setting of maximum levels for Na, K, Cl and P and requests that maximum levels for these minerals are discussed along with the other provisions of this section.

Rationale:
Fomon and Zeigler[17,18] have found that when an infant is in good health and consuming a predominantly liquid diet *ad libitum*, the renal concentrating ability of nearly all infants is sufficient to maintain a water balance even if the feeding provides a PRSL as high as that of cows' milk. It is only infants suffering from acute febrile illness, or who have a decreased renal concentrating ability or are being fed energy-dense formula that are at risk from not maintaining the correct water balance if the formula has a high RSL or PRSL.

Calculations described in the Annex to this document show that unless a very high maximum level of protein is set in this Standard for infant formula, the maximum levels proposed for minerals should ensure that formula remain below the PRSL upper limit of 35 mOsm/100 kcal suggested by Fomon and Zeigler[1]. In addition epidemiological evidence suggests that risk of hypertonic dehydration starts only when the PRSL reaches higher than 39mOsm/100kcal.

SODIUM
Proposed in CL 2003/4

	Min /100 kcal	Max /100 kcal	Min /100 kJ	Max /100 kJ
Sodium	20 mg	**T.B.D.**	5 mg	**T.B.D.**

*To be determined after maximum protein levels are proposed.

ISDI supports the maximum level of sodium set in previous Codex standard:
Max sodium = 60 mg/100kcal.

[17] Fomon S. J and Zeigler EE. Renal solute load and potential renal solute load in infancy. *J Paediatr*. 1999; **134**: 11-4.
[18] Fomon S. J Potential renal solute load: Considerations relating to complementary feedings of breast-fed infants. Pediatrics 2000; **106** (5 suppl): 1284

POTASSIUM AND CHLORIDE
Proposed in CL 2003/4

	Min /100 kcal	Max /100 kcal	Min /100 kJ	Max /100 kJ
Potassium	[60] mg	**T.B.D.**	[15] mg	**T.B.D.**
Chloride	50 mg	**T.B.D.**	12 mg	**T.B.D.**

* To be determined after maximum protein levels are proposed.

ISDI agrees with the minimum levels proposed, and suggests maintaining the maximum level adopted in the current Codex Standard for potassium and chloride i.e.:
Max Potassium = 200 mg/100 kcal
Max Chloride = 150 mg/100 kcal

Rationale:
Potassium is the major solute of intracellular water, whereas sodium and chloride are the major solutes of extracellular water. These solutes are essential for controlling the size of the water compartments of the body and the movement of water among them. Movement of the body's water is thus dependent on the absorption and secretion of these ions[19]. Disruption of the physiological balance between intracellular K and extracellular Na + Cl will lead to either dehydration or oedema.
Water enters the gastrointestinal tract in the form of food, saliva, gastric and pancreatic juices, and bile. Although the quantities of sodium, potassium and chloride delivered by the gastrointestinal secretions greatly exceed the dietary intakes, the electrolyte balance in the formula may affect physiological balance.

The low maxima for potassium and chloride, which have been proposed, deviate from the recommendations of several authorities including the U.S. Infant Formula Act (IFA), the Canadian requirements, as well as the previous Codex infant formula standard. In these recommendations, the electrolytes have maxima of 200 mg/100 kcal for potassium and 150 mg/100 kcal for chloride.

Argentina (CX/NFSDU 00/6) and the USA (CCNFSDU meeting 2000, CRD 18) have both suggested that the proposals for maximum levels for potassium and chloride are unnecessarily low. These low levels may not even be achievable whereas higher levels have never presented any concerns for safety.

The K/Na ratio in cows' milk is remarkably constant at 3.3, and similar to that in human milk (average 3.1, range 2.5-3.9) as shown in the table 1 below. This implies that there may be a physiological ratio between those two electrolytes, optimised to maintain water balance across membranes

Since the sodium maximum has been set at 60 mg/100 kcal in the current standard, the potassium maximum should be at least 60 x 3.1 = 186 mg per 100 kcal, which we suggest to round up to 200 mg, as K/Na ratio often exceeds 3.1 in human milk.

For these reasons, ISDI recommends keeping the same ratio between sodium and potassium as in human milk.

[19] Fomon SJ. Sodium, chloride and potassium. In : Nutrition of Normal Infants. Fomon SJ Ed., Mestoy 1993, pp. 219-232.

Table 1: **Sodium, Potassium, Chloride in human milk and cow's milk**

Human milk (mg/l)					
Na	**K**	**Cl**	**K/Na**	**K (Na + CI)**	**Reference**
227	527		2.3		Fomon[20]
264	477		1.8		Fomon[21]
184	470		2.6		Fomon[5]
175	464		2.7		Fomon[5]
166	460		2.8		Fomon[5]
134	430		3.2		Fomon[5]
151	465	421	3.1	0.8	Fomon[5]
121	426	410	3.5	0.8	Fomon[5]
126	406	419	3.2	0.7	Fomon[5]
113	443		3.9		Fomon[5]
84	443		5.3		Fomon[5]
162	507	366	3.1	1.0	Fomon[5]
Average			3.1	0.8	
Cow's milk (mg/l)					
Na	**K**	**Cl**	**K/Na**	**K (Na + CI)**	**Reference**
494	1415	921	2.9	1.0	EC[22]
483	1521	1050	3.1	1.0	Fomon[23]
494	1617	1051	3.3	1.0	Souci-Fachmann[24]
505	1555		3.1		USDA[25]
455	1545		3.4		Favier[26]
460	1560	1065	3.4	1.0	Allais[27], FAO[28]
Average			3.3		

CALCIUM AND PHOSPHORUS
Proposed in CL 2003/4

	Min /100 kcal	Max /100 kcal	Min /100 kJ	Max /100 kJ
Calcium	[50] mg	**[N.S.]**	[12] mg	**[N.S.]**
Phosphorus	[25] mg	T.B.D.	[6] mg	T.B.D.

3 The ~~Ca:P~~ calcium to phosphorus weight to weight ratio shall not be less than 1.2 and not more than 2.2. ~~[2.0].~~

* To be determined after maximum protein levels are proposed.

ISDI supports the maximum level of phosphorus set in previous Codex standard:
Max phosphorus = 90 mg/100kcal.

[20] Fomon SJ. Sodium, chloride and potassium. In: Nutrition of Normal Infants. Fomon SJ Ed, Mestoy 1993, 219-232.
[21] Fomon S. J and Zeigler EE. Renal solute load and potential renal solute load in infancy. *J Paediatr*. 1999; **134**: 11-4.
[22] European Commission Directive 91/321/EEC on infant formulae and follow-on formulae
[23] Fomon S. J and Zeigler EE. Renal solute load and potential renal solute load in infancy. J Paediatr. 1999; 134: 11-4.
[24] Souci S.W., Fachman W., Kraut H., Food consumption and nutrition tables, WVG Ed, Stuttgart, 1981/82
[25] USDA. Composition of foods, dairy and eggs products. Agricultural Handbook 8-1. Washington D.C., 1976
[26] Favier J.C. Composition du lait de vache I. Lait de grand mélange. Cah Nutr Diet 1985;20:283-91
[27] Allais C. Science du lait. Paris : Edition Sepaic, 1984
[28] Le lait et les produits laitiers dans la nutrition humaine. Collection FAO. Alimentation et nutrition, 1998;28

High levels of phosphorus in infant formula are undesirable. For this reasons a maximum level of phosphorus is recommended by both the US LSRO report[29] and the UK COMA report [30].

IRON
Proposed in CL 2003/4

	Min /100 kcal	Max /100 kcal	Min /100 kJ	Max /100 kJ
Iron	(0.5] mg	[1.5] mg	[0.12] mg	[0.36] mg

ISDI requests that a higher maximum level is set for iron:
Max iron = 2.5 mg/100 kcal

Rationale:
The EU directive specifies a maximum iron level of 1.5 mg/100kcal for formula with **added** iron and the LSRO recommendation for a maximum iron content is somewhat higher at 1.65 mg/100kcal. These maximum levels are rather low if they apply to countries where major iron deficiencies are encountered. Iron deficiency has several long-lasting repercussions on health, in particular, it can lead to long-term irreversible functional changes in behaviour and cognition. The current US Infant Formula Act has a maximum for iron of 3.0mg/100 kcal and the AAP-CON recommendation (1993) suggests a maximum level of 2.5 mg /100kcal). ISDI supports this latter level.

IODINE
Proposed in CL 2003/4

	Min /100 kcal	Max /100 kcal	Min /100 kJ	Max /100 kJ
Iodine	[5] µg	**[T.B.D.]**	[1.2] µg	**[T.B.D.]**

ISDI is aware certain recent recommendations indicate that a minimum level higher than the level of 4 µg/100kcal (originally in the standard) would be required. ISDI is currently reviewing these recommendations and will bring a proposal forward for the second round of comments for the Electronic Working Group on Compositional Criteria of Infant Formula mid-May.

Regarding the maximum level, ISDI believes that it should be N.S. (Not Specified) instead of T.B.D. (To Be Determined). **Indeed, ISDI notes that it is very difficult to propose a maximum limit since the iodine content of cow's milk is not constant and depends on seasons and hygienic or agricultural techniques**.

SELENIUM
Proposed in CL 2003/4

	Min /100 kcal	Max /100 kcal	Min /100 kJ	Max /100 kJ
Selenium	**[6] µg**	**T.B.D**.******	**[1.4] µg**	**T.B.D.********

****** when added

ISDI opposes the setting of a minimum level of selenium and suggests the following:
Min selenium = N.S.

Rationale:
The proposed minimum level of 6 mcg/100 kcal would be, according the US Institute of Medicine (IOM, 2000) [31]., the average level found in human milk. ISDI would like to express the following objections to this proposed minimum:

1. Selenium levels of human milk are under the influence of the selenium content of the mother's diet.

[29] Life Sciences Research Office. 1998. Assessment of Nutrient Requirements for Infant Formulas. Bethesda, Maryland: Life Sciences Research Office, American Society for Nutritional Sciences.
[30] UK COMA report on Artificial Feeds for the Young Infant (1980)
[31] Institute of Medicine. 2000. Dietary Reference Intakes for Vitamin C, Vitamin E, Selenium, and Carotenoids. Washington, DC: National Academy Press.

2. The IOM report indicates that, based on the average level of selenium found in human milk of mothers in the US and Canada, the acceptable intake (AI) of 0-6 months old infants is 15 microgram/day. Assuming an intake of 500 kcal/day, this would result in an AI of 15:5 = 3 microgram/100 kcal. Assuming a bioavailability of only 50% of selenium added as inorganic salts to infant formulae as compared to mother's milk, the level of 6 microgram/100 kcal is obtained. However, this denies the presence of organic selenium already present in the other ingredients used in infant formulae, such as the protein source (soy protein isolate may contain significant amounts of selenium);
3. Other studies indicate significantly lower average selenium levels in mother's milk[28].
4. There are no indications of selenium deficiencies in infants fed normal infant formula for which no minimum level has been set in legislation as it is the case in the European Union.
5. The EU legislation presently sets a maximum level of 3 µg/100kcal in formulas with added selenium[32,33]
6. It is questionable whether average levels found in human milk represent the minimum requirement of infants.
7. The majority of the ad hoc working group members did not agree with this minimum level of 6 µg/100 kcal.
8. The bioavailability and the metabolism and efficacy of selenium in the diet strongly depends on its chemical (organic versus inorganic) form. As a result, it would be more prudent to set a maximum level only.

For these reasons, ISDI strongly opposes setting a minimum level of selenium in infant formula.

Finally, due to its toxicity, ISDI suggests setting a maximum level for selenium, **if added**.

OTHER COMMENTS

➢ *L-CARNITINE*

L-Carnitine is not listed as compulsory nutritional substance in infant formula. However, ISDI suggests its addition as its presence depends on the raw materials used to manufacture the formula. ISDI proposes to use the level determined in the EU Directive 91/321/EEC.

ISDI proposal:		
Carnitine	1.2 mcg/100kcal - NS	0.3 mcg/100kJ - N.S.
With the appropriate footnote: "if added"		

➢ *CONVERSION FACTORS*

Although ISDI is aware conversion factors should be reviewed, it suggests, in the meantime using the following:

1 IU vitamin A = 0.3 mcg retinol
1 mcg RE = 1 mcg all-trans retinol = 6 mcg all-trans ß-carotene = 3.33 IU vitamin A
1 IU vitamin D = 25 ng (0.025 mcg) cholecalciferol = 25 ng ergocalciferol

RECAPITULATION

In bold: ISDI's opinion when diverging from the proposal in CL 2003/4

[32] EU Directive 91/321/EEC on infant formulae and follow on formulae
[33] SCF Opinion on the essential requirement for infant formulae and follow-on formulae, expressed in September 1993

		Per 100kcal		Per 100kJ	
	Units	MIN	MAX	MIN	MAX
e) Vitamins					
Vitamin A*	µg	60	180	14	43
Vitamin D**	µg	1	2.5	0.25	0.63
Vitamin E***	mg/g	0.5	[N.S.]	0.1	[N.S.]
Vitamin C****	mg	[8]	N.S.	[1.9]	N.S.
Thiamin	µg	[40]	N.S.	[10]	N.S.
Riboflavin	µg	[60]	N.S.	[14]	N.S.
Niacin***	mg	[0.6]	N.S.	[0.14]	**N.S.**
Vitamin B6	µg/g protein	[15/g protein] but in no case less than 35µg/100 kcal	N.S.	[15/g protein] but in no case less than 9µg/100 kcal	N.S.
Folic acid	µg	[11]	N.S.	[2.6]	N.S.
Pantothenic acid	µg	[300]	N.S.	[70]	N.S.
Vitamin B12	µg	0.10	N.S.	0.025	N.S.
Vitamin K	µg	4	N.S.	1	N.S.
Biotin	µg	[1.5]	N.S.	[0.4]	N.S.
f) Minerals					
Sodium	mg	20	**60**	5	**15**
Potassium	mg	[60]	**200**	[14]	**48**
Chloride	mg	50	**150**	12	**36**
Calcium[c]	mg	[50]	[N.S.]	[12]	N.S.
Phosphorus	mg	[25]	**90**	[6]	**22**
Magnesium	mg	[5]	[N.S.]	[1.2]	3.6
Iron	mg	[0.5]	**2.5**	[0.12]	**0.6**
Iodine	µg	[5]	**N.S.**	[1.2]	**N.S.**
Copper*******	µg	[60]	T.B.D	[14]	T.B.D.
Zinc	mg	0.5	T.B.D.	0.12	T.B.D.
Manganese	µg	[1]	T.B.D.	[0.24]	T.B.D.
Selenium******	µg	**N.S.**	**T.B.D.**	**N.S.**	**T.B.D.**
Choline	mg	7	N.S.	1.7	N.S.
Carnitine	**µg**	**1.2**	**N.S.**	**0.3**	**N.S.**

* Expressed as retinol equivalent (RE). 1µg RE=3.33 IU Vitamin A, **1µg RE=6 µg beta-carotene**

** Calciferol. 1µg Vitamin D (calciferol) =40 IU

*** alpha tocopherol equivalent

**** expressed as ascorbic acid

***** **as preformed niacin**

****** The calcium to phosphorus weight to weight ratio shall not be less than 1.2 and not more than 2.2

******* [Adjustments may be needed in these levels for infant formula products made in regions with a high content of copper in the water supply]

******** [~~when~~ **if** added]

MINERALS IN MILK AND RELATIONSHIP TO RENAL SOLUTE LOAD (RSL) AND PROTEIN RENAL SOLUTE LOAD (PRSL)

The levels of sodium, potassium and chloride in cows' milk are given on page 6 and protein and phosphorus levels are: Protein in whole cows' milk: 32.9mg/l

Phosphorus in whole cows' milk: 93mg/l[1]

Phosphorus in skimmed milk protein: 28g/g[2]

Formula used for the calculation for PRSL[1]: **PRSL = N/28 + Na + Cl + K + Pa**

where a is available P. In the case of cows' milk-based formula it is assumed that all phosphorus will be available whereas with soya protein based, it is assumed that two-thirds of the phosphorus will be available.

If the maximum levels permitted for protein and other minerals in various regulatory requirements is taken into consideration:

Product/standard	units	Protein g	Sodium Mg	potassium mg	chloride mg	phosphorus mg
current Codex Standard[3]	100kcal	3	60	200	150	-
LSRO[4]	100kcal	3.4	50	160	160	70
EC[2]	100kcal	3	60	145	125	90
ISDI recommendations	100kcal	3	60	200	150	90

Then the impact on the renal solute load using the 1998 Fomon conversion factor -(protein x 5.7 = urea mOsml/l- and using a value of 67kcal/100ml of feed

Fomon values[1]	Protein g/l	urea mOsm/l	sodium mmol/l	Potassium Mmol/l	chloride mmol/l	phosphorus mmol/l	**PRSL** **mOsm/l**	**MOsm/ 100kcal**
Human milk	10	57	7	11	13	5	**93**	**14**
whole cows' milk	32.9	188	21	39	30	30	**308**	**46**
Max ISDI levels	19.8	113	17	27	38	19	**214**	**34**
LSRO levels[4]	22.4	128	14	27	30	15	**214.2**	**32**
EC levels[2]	19.8	113	17	25	24	19	**197.3**	**30**

Thus even in a scenario where all calculated values are at the presently accepted maximum levels, the potential renal solute load would always be lower than the maximum of 35mOsm/100kcal upper limit for infant formula proposed by Fomon[1].

[1] Fomon S. J and Zeigler EE. Renal solute load and potential renal solute load in infancy. J Paediatr. 1999; 134: 11-4.

[2] European Commission Directive 91/321/EEC on infant formulae and follow-on formulae

[3] Codex Standard for infant formula (CODEX STAN 72-1981)

[4] Assessment of nutrient requirements for infant formulas, Life Science Research Office, 1998

WHO – WORLD HEALTH ORGANZATION

1.1 In the first line of this paragraph, consistent with international usage, e.g. the International Code of Marketing of Breast-milk Substitutes and the draft revised standard for cereal-based foods for infants and young children, it would be preferable to say "… for use, *when* necessary" in place of "… for use, *where* necessary".

1.3 The more usual formulation would read "recommendations *made* to countries *in* the International Code … and World Health Assembly resolution WHA54.2 (2001)" in place of "recommendations **given** to countries **under** the International Code … and **the** World Health Assembly resolution WHA54.2 (2001)".

However, the reference to resolution WHA54.2 could usefully be replaced with a reference to the Global Strategy for Infant and Young Child Feeding the resolution WHA55.25 by which it was formally endorsed. Moreover, resolution WHA55.25 also includes a specific mention of the Codex Alimentarius Commission:

> *REQUESTS the Codex Alimentarius Commission to continue to give full consideration, within the framework of its operational mandate, to action it might take to improve quality standards of processed foods for infants and young children and to promote their safe and proper use at an appropriate age, including through adequate labelling, consistent with the policy of WHO, in particular the International Code of Marketing of Breast-milk Substitutes, resolution WHA54.2, and other relevant resolutions of the Health Assembly;*

Note: This text is provided for information; it is not intended for inclusion in the draft revised standard. The recommended revised text would thus read (new text in italics):

> 1.3 The application of *this* Standard should take into account the recommendations *made* to countries in the International Code of Marketing of Breast-milk Substitutes *(1981), the Global Strategy for Infant and Young Child Feeding and World Health Assembly resolution WHA55.25 (2002).*

2.1.1 As to the proposed definition of "infant formula", during the Committee's discussion at its 24th session some delegations expressed concern over two points:

- whether to retain the word "normal" before the words "nutritional requirements", and
- the imprecision/ambiguity of the words "during the first months of life".

The words "normal" and "during the first months of life" could be deleted with no loss of either clarity or accuracy. Indeed, the language would be crisper and more to the point, in addition to being consistent with circumstances, which is to say that there has been *no change* concerning the recommended age of introduction of complementary foods for formula-fed children.

Whereas the Health Assembly, following a systematic review of the relevant scientific and epidemiological literature in 2000–2001, pronounced on the optimal duration of exclusive *breastfeeding*, the Assembly said nothing about the optimal duration of exclusive *formula* feeding. The recommended revised text would thus read:

> 2.1.1 Infant formula means a breast-milk substitute specially manufactured to satisfy, by itself, the nutritional requirements of infants up to the introduction of appropriate complementary feeding.

9.6.1 Where the first 9.6.1 b) is concerned, the use of the word "or" is awkward, as if somehow there were a choice between breastfeeding or breast milk. Using Article 9.2 (b) of the International Code as a model, the text here could simply read:

> b) a statement of the superiority of breastfeeding, for example: Breast milk is the best food for your baby; it protects against diarrhoea and other illnesses;

In paragraph 9.6.1 b), the words "**Breastfeeding** is the best food for your baby" should logically read "**Breast milk** is the best food for your baby".

Consistent with Article 9.2, point (c), of the International Code, the word "only" in c) should modify the word "on". Thus, paragraph 9.6.1 c) of the draft revised standard should read:

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

The Committee's discussion during its 24th session suggests that there are at least two meanings where the term "independent health worker" is concerned:

- Health workers whose professional judgement is not affected by any considerations other than the best nutritional and health interests of the babies under their responsibility.
- Health workers who are not part of a governmental institution engaged in health care for mothers and children.

However, having already declared that "health workers should encourage and protect breastfeeding" (article 7.1), the International Code does not use the word "independent", referring only to a "a statement that the product should be used only on the advice of a health worker as to the need for its use and the proper method of use" (article 9.2 (c)).

9.6.4 To be consistent with usual terminology, e.g. the International Code, "supplemental" in this paragraph should be "complementary", and the words "from the age **over** six months" should presumably read "from the age **of** six months".

9.6.5 To promote brand identity and consumer fidelity, it is not unusual for manufacturers to use very similar labels on infant formula and follow-up formula. However, this practice only increases the risk of the misuse of products, especially given the price difference between the two, i.e. in principle, infant formula is more expensive than follow-up formula. The square brackets should therefore be removed. The word "prevent" should replace the word "avoid".

Foods for special medical purposes

The discussion during the Committee's 24th session demonstrated a lack of consensus on whether to maintain a single standard for infant formula, including foods for special medical purposes intended for infants, or whether foods for special medical purposes should be included in a separate new standard.

For purely practical reasons, it might be easier to have two standards, which would also promote awareness of the major differences in intended use of the respective products. Moreover, the labelling provisions and restrictions for one group of products can be quite different for the other, e.g. absence of protection and promotion of breastfeeding in those rare situations where no milk should be given to infants with special medical problems.

In either case, i.e. one standard or two, there should be a clear and consistent use of the terms:

- "infant formula" as defined in the present draft revised Codex standard, and
- "foods for special medical purposes intended for infants".

However, irrespective of the final decision in this regard, both products are breast-milk substitutes and consequently both fall within the scope of the International Code of Marketing of Breast-milk Substitutes.