codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 4 **CX/NFSDU 02/4**
September 2002

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
Twenty-forth Session
Berlin, Germany, 4 - 8 November 2002

PROPOSED DRAFT REVISED STANDARD FOR INFANT FORMULA

- Comments at Step 3 of the Procedure

Comments from:

ARGENTINA
AUSTRALIA
BRAZIL
COLOMBIA
COSTA RICA
CUBA
CZECH REPUBLIC
HUNGARY
IRAN
MALAYSIA
NEW ZEALAND
NIGERIA
SLOVAK REPUBLIC
SOUTH AFRICA
TURKEY
UNITED STATES OF AMERICA

EUROPEAN COMMUNITY
ISDI - INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES
WHO - WORLD HEALTH ORGANIZATION

ARGENTINA

SCOPE

1.1 As it is presently written, the standard would be applicable to products intended both for healthy infants and for infants with special nutritional requirements. However, it is our position that formula for infants with special nutritional requirements should not be included in this standard for infant formula, but should be included in an equivalent Codex standard on foods for Special Medical Purposes. The second sentence of Section 1.1 should therefore read:

"The provisions in this standard are not intended for infants with special nutritional requirements."

Our position is based on the fact that if both types of these products were to be included in the same standard, then the compositional requirements of the standard could be inappropriate for infants with special needs. Likewise, if a specialised product is adapted to particular nutritional situations, it might be unsuitable for healthy infants and even pose a health hazard.

DESCRIPTION

2.1.2 We suggest deleting the second sentence which is redundant: "Only products that comply with the criteria laid down in the provisions of this standard would be accepted for marketing as infant formula."

We further propose to delete any remaining square brackets so that Section 2.1.2 reads as follows:

"Infant formula shall be nutritionally adequate to ensure normal growth and development when used in accordance with its directions for use to meet the nutritional requirements of infants by itself during the first months of life up to the introduction of appropriate complementary feeding."

ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1.2 (a) Protein

(i) The possibility to use sources of protein other than milk and soy should be maintained as in the current Codex Standard (Codex STAN 72-1981). Thus the second sentence should read "...nitrogen content x 6.25 for soya and **other protein isolates** and their partial hydrolysates".

Reference aminogram (Annex 1)

The proposed aminogram is not representative of human milk protein composition and is not similar to other amino acid analyses of human milk protein. We suggest to introduce an alternative aminogram which is more appropriate. The aminogram used for decades in the European Union would be an acceptable alternative, but the FAO consultation is likely to update this information.

3.1.2 (e) Fat and Fatty Acid

Trans Fatty Acids

Our position is that the trans fatty acid content of infant formula shall not exceed 5% of the total fat content and that the use of hydrogenated oils in infant formula should be prohibited. The reason is that milk fat alone can contain up to 6% trans fatty acids.

4. FOOD ADDITIVES

We would like to keep this item open for the time being.

5. CONTAMINANTS

We support the proposed text. The limits of contaminants are being established on a horizontal basis in a separate Codex Standard.

9.1 THE NAME OF THE FOOD

9.1.4 This sentence should be changed back to the original wording in Codex Standard 72-1981 to read: **"A product which contains neither milk or any milk derivative may (instead of 'shall') be labelled "contains no milk or milk products" or an equivalent phrase."**

The list of ingredients shows the composition of the product and whether it contains milk or not. It is extremely difficult to guarantee the complete absence of milk or of any milk derivative from a product. If this is to be required as in the current version, it would be necessary to establish threshold levels of permissible milk content.

9.1.5 We are of the opinion that the entire paragraph should be deleted, if foods for infants with special nutritional requirements are to be excluded from the Scope of this Standard (as suggested in our comment to the Section Scope).

However, if foods for infants with special nutritional requirements are included in the Scope of the Standard, then Section 9.1.5 must be retained and the square brackets must be deleted. It is our position that the last sentence - "No health claims shall be made regarding the dietary properties of the product." - should be deleted, as a health claim represents an essential piece of information about a product. If scientifically proven the claims should be allowed. Some legislations, for example in the European Union, permit such claims. The term "hypoallergenic formula" for example is permitted and regulated in the European Community.

In both cases, i. e. whether foods for infants with special nutritional requirements are included in the Scope of the Standard or not, we consider it appropriate to extend Section 9.1.5 by the following sentence:

"In order to provide information concerning the composition and the specific properties of foods intended to meet the nutritional requirements of infants, nutrition and health claims are permitted insofar as they are supported by relevant scientific data."

9.1.5 We support the first alternative. The square brackets should be deleted.

9.6 ADDITIONAL LABELLING REQUIREMENTS

Section **9.6.1 b)** suggests two alternatives. We support the second one, which reads:

b) The statement "Breastfeeding is the best food for your baby" or a similar statement as to the superiority of breastfeeding.

The first statement deviates from the WHO's International Code of Marketing of Breastmilk Substitutes and we therefore do not agree with it.

9.6.5 We recommend that this section should be deleted as it is redundant.

AUSTRALIA

1. SCOPE

1.1 Australia supports the inclusion of foods for special medical purposes intended for infants in the standard for infant formula as outlined in Option C from the discussion paper (CX/NFSDU 01/5-Add.1) prepared by Germany. We propose the insertion of the following which subdivides the scope into two parts and is an extract of the changes proposed under Option C except for the:

- deletion of 'partial and total' as we believe this is not necessary to include; and
- reinsertion of '**healthy**' as subdividing the scope allows for reference to 'infant formula for healthy infants' in section 1.1. Infants that have special needs are then captured by a **new** section 1.2.

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 in meeting the normal nutritional requirements of ***healthy*** *infants.*

Insertion of **new section** as proposed in Option C as follows:

1.2 The provisions in this standard are also intended for foods for special medical purposes (formulated according to the description and general principles of CODEX STAN 180-1991) for

infants except for certain compositional provisions which must be modified to meet the special nutritional requirements of the disease, disorder or medical condition for whose dietary management the food is formulated.

The existing sections 1.2 and 1.3 are re-numbered as 1.3 and 1.4 respectively.

2. DESCRIPTION

2.1 Australia supports the renaming of this section from 'Product definition' to '**Product Description**' to more accurately reflect the subject matter of the section and to be accordance with the format and content of Codex Standards as detailed in the Codex Alimentarius Commission *Procedural Manual* (12 ed)[1].

2.1.2 Australia suggests subdividing this section with the creation of a **new section 2.1.3** to incorporate foods for special medical purposes for infants. The following wording for section 2.1.2 is proposed:

*2.1.2 Infant formula **for healthy infants** shall be nutritionally adequate to ensure **normal** growth and development when used in accordance with its directions for use to meet the nutritional requirements of infants **by itself** during the first months of life up to the introduction of appropriate complementary feeding.*

The term 'normal' is included as it is already referred to in the scope (section 1.1). Australia also supports retaining 'by itself' as a means of distinguishing infant formula from other complementary foods. We do not believe that this implies that infant formula has the same nutritional value as breast milk as infant formula is aimed at being nutritionally adequate, rather than nutritionally optimal.

2.1.3 A **new section 2.1.3** for foods for special medical purposes for infants is inserted based on the **general principles of the Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991)** as follows:

2.1.3 Infant formula for infants with special nutritional requirements shall be formulated based on sound medical and nutritional principles and its use demonstrated by scientific evidence to be safe and beneficial in meeting the nutritional requirements of the infants for whom it is intended.

2.1.4 A **new section 2.1.4** is inserted to include the last sentence of the existing section 2.1.2, which was agreed to by the Committee at the 23rd Session. We propose a change in wording as indicated for simplicity and consistency of language.

*2.1.4 Only products that comply with ~~the criteria~~ **this standard** ~~laid down in the provisions of this standard~~ would be accepted for marketing as infant formula.*

2.1.5 With the insertion of 2 new sections the existing section 2.1.3 is renumbered as 2.1.5.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Comments on this section will be provided separately in response to CL 2001/47.

3.2 There is a minor error in the numbering for 3.2.1 which has been written as 4.2.1.

9. LABELLING

Australia supports as detailed in Option C (Discussion Paper CX/NFSDU 01/5-Add.1) the division of the labelling section into 2 separate sections by renaming section 9 '**Labelling of infant formula for healthy infants**' and retaining all current text except for an amendment to 9.1.5 and creating a **new section 10** for **Labelling of infant formula for special medical purposes** (see comments below).

9.1.5 Australia supports a prohibition on nutrition and health claims as provided for in Section 1.4 of the Codex Proposed Draft Guidelines for use of Health and Nutrition Claims (at Step 5) (ALINORM

[1] Guidelines for the Acceptance Procedure for Codex Standards; Format and Content of Codex Standards; (Paragraph 15) *Description, Essential Composition and Quality Factors, "These sections will define the minimum standard for the food."*

03/22 APPENDIX VII). These guidelines provide definitions (Section 2) for both health and nutrition (includes content and function) claims. Australia supports the proposed prohibition on health claims as expressed in section 9.1.5 and also, proposes extending the prohibition to include nutrition claims as defined by the above mentioned guidelines. This is supported as being consistent with the requirements of the *WHO International Code of Marketing of Breast Milk Substitute* by way of preventing the provision of information which could discourage breast feeding.

*9.1.5 No **nutrition or** health claims shall be made regarding the dietary properties of the product.*

9.1.6 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'.

9.6 ADDITIONAL LABELLING REQUIREMENTS

9.6.1b Australia suggests combining the two proposed alternatives as follows;

*b) a statement of the superiority of breastfeeding and breast milk. For example, 'Breastfeeding **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. We note that the second example '*Breast milk is the best food for your baby: it protects against diarrhoea and other illnesses'* could be construed as a health claim but recognise however, that Section 1.4 of the Codex Proposed Draft Guidelines for use of Health and Nutrition Claims (at Step 5) (ALINORM 03/22 APPENDIX VII) allows for the provision of claims in relevant standards [2].

9.6.5 Australia supports 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 Clause 9.5.2 "*The labelling of a follow-up formula shall include a statement that follow-up formula shall not be introduced before the 6 th month of life*."

10. LABELLING OF INFANT FORMULA FOR SPECIAL MEDICAL PURPOSES (NEW SECTION)

As stated above, Australia supports the insertion of a **new section 10** (as per Option C) to clearly delineate the particular labelling requirements of infant formula for special medical purposes from other infant formula. This new section would consist of the following as set out under Option C in the discussion paper:

10.1 Infant formula for special medical purposes shall be labelled in accordance with the Codex Standard for the labelling of and claims for Foods or Special Medical Purposes (Codex Stan 180-1991).

AUSTRALIA: Comments to CL 2001/47-NFSDU

Australia participated as a member of the Composition Work Group (chaired by the United States) which has made recommendations on Sections 3.1.1 and 3.1.2 of the proposed draft revised standard for infant formula. We welcome the opportunity to provide further comment as follows:

[2] 1.4 [Nutrition and] Health claims are not permitted for foods for infants and young children unless specifically provided for in relevant Codex standards.

A. GENERAL PRINCIPLES FOR ESTABLISHING MINIMUM AND MAXIMUM VALUES FOR THE ESSENTIAL COMPOSITION OF INFANT FORMULA: SECTION 3.1

2. Australia believes that this principle should include an age limit to acknowledge the introduction of complementary foods. We note that the draft general principles, circulated by the Work Group Chair in a memorandum dated September 27 2001, did make reference to 'during the first four to six months of life'. We therefore suggest that the principle be amended to reflect the wording as in the draft revised standard in section 2.1.2.

2. A nutritionally adequate infant formula product will promote normal growth and development and meet the nutritional requirements of infants when fed as a sole source of nutrition ***during the first months of life up to the introduction of appropriate complementary feeding****.*

3. To improve the accuracy of this guideline, Australia suggests including the following **bolded text**;

3. The values to be established are only for those substances that are essential ***to infant nutrition for the purposes of achieving the first and second principles above****. Optional ingredients are addressed in Section 3.2 of the standard.*

10. Australia proposes a third alternative to the options offered in the draft general principles based on the approach used in Standard 2.9.1 – Infant Formula Products of the *Australia New Zealand Food Standards Code*, i.e. set maximum amounts of essential nutrients for which there is sufficient evidence of adverse health effects at higher levels and, for all other essential nutrients, provide guideline maxima. These maxima are not mandatory but rather are intended to provide guidance to industry for implementation consistent with Good Manufacturing Practice. These guideline maxima are included as an attachment to Standard 2.9.1.

D. PROPOSED REVISIONS TO SECTION 3.1

3.1.1 Depending on the outcome of discussions regarding the inclusion of infant formula for special medical purposes in the draft infant formula standard, this section may require amendment to incorporate the formulation of special purpose infant formula from synthetic nutrients rather than those originating from animal or plant sources eg. amino acids. In this case, Australia proposes to maintain 3.1.1 and **insert an additional section 3.1.2** which would allow for the use of such synthetic nutrients.

Additionally in this new section 3.1.2, the wording should clearly allow for deviation from the prescribed compositional requirements where necessary for the formulation of infant formula for special medical purposes.

We therefore propose the insertion of the following:

3.1.2 The formulation of an infant formula may deviate from the compositional requirements of this standard only where necessary to satisfy the particular nutritional requirements of infants with metabolic, immunological, renal, hepatic or malabsorptive conditions, diseases or disorders. These products may contain synthetically derived nutrients.

3.1.2 In the text introducing the table, we assume choline has been inadvertently deleted since it is still categorised individually under (c) in the table to 3.1.2.

3.1.2 (d)(i) Protein

As in the current infant formula standard (CODEX STAN 72-1981), the possibility of infant formula containing sources of protein other than milk and soy should be maintained. Thus the second sentence should read:

Protein content = nitrogen content x 6.25 for soya protein isolates, ***other protein isolates*** *and protein partial hydrolysates.*

3.1.(B) MINERALS

Selenium

Australia supports the establishment of a minimum level for selenium but is opposed to the minimum level as recommended by the Working Group (6 µg/100kcal (1.4 µg/100kJ)) for the following reasons;

- The concentration of selenium in breast milk is influenced by geographic location and maternal diet;
- There is variation in the reported average concentration of selenium in breast milk eg. 10 to 23 µg/L[3] ;
- The minimum level proposed is based on studies of the average breast-milk concentration of selenium (18 µg/L) from mothers in the United States and Canada only; and
- Infant formula without selenium fortification have inherent selenium contents ranging from approximately 2 to 15 µg/L depending on the origin of the ingredients[4];

We support a minimum selenium level of 1.5 µg/100 kcal (0.2 µg/100 kJ) (10 µg/L) as recommended by the LSRO Report[5] , 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 not been recognised in breast fed infants.

Other Trace Nutrients

As discussed in the discussion paper (CX/NFSDU 01/5-Add.1) prepared by Germany, the current compositional provisions do not cover all indispensable nutrients that are contained in foods for special medical purposes. Therefore, if infant formula for special medical purposes are included in the infant formula standard a number of additional trace nutrients will need to be considered eg. chromium, molybdenum. We propose the following minimum and maximum values for chromium and molybdenum, which are the prescribed levels from the recently revised infant formula standard (Standard 2.9.1) in the *Australia New Zealand Food Standards Code*.

	Min/ 100kJ	Max/ 100kJ
Chromium	0.35 µg	2.0 µg
Molybdenum	0.36 µg	3.0 µg

BRAZIL

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 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.]~~

~~1.2 The standard contains compositional, quality and safety requirements to ensure a safe and nutritionally adequate product.~~

-To delete the items 1.1 and 1.2.

-We support the following draft propose presented by the Germany Delegation on CX/NFSDU 01/5-Add. November the 1st, 2001.

[3] Institute of Medicine (2000) Dietary Reference Values for Selenium.

[4] International Special Dietary Foods Industries (ISDI) comments to the Infant Formula Composition Work Group

[5] Life Sciences Research Office (1998) Assessment of Nutrient Requirements for Infant Formulas.

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

"1.2 The provisions in this stardard are also intended for foods for special medical purposes (formulated according to the description and general principles of Codex Stan 180-191) for infants except for certain compositional provisions which must be modified to meet the special nutrional requirements of the disease, disorder or medical condition for whose dietary mamagement the foods is formulated."

Justification: *The proposed draft avoids any misunderstading with the other infant formulas with specific nutritional needs. In this case, the labelling is clearer and more objetive, avoiding the misleadind of interpretation.*

- To keep the same item 1.3.

2. DESCRIPTION

2.1 PRODUCT DEFINITION

- We suggest the sequence order invertion of the items 2.1.1 e 2.1.2.

2.1.1 Infant formula, when in liquid form, may be used either directly or prepared with safe, potable, and previously boiled water before feeding according to directions for use. In powdered form it requires safe, potable, and previously boiled water for preparation.

2.1.2 ~~[~~ Infant formula shall be nutritionally ~~adequate~~ appropriate to ensure ~~[normal]~~ adequate growth and development when used in accordance with its directions for use to meet the nutritional requirements of infants by itself 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.]~~

-To exclude the square brackets of all item 2.1.2. and to substitute of the expressions "adequate" for "appropriate", and "[normal]" for "adequate" in the first line of the paragraph.

-To eliminate the 2nd phrase: "Only products that comply with the criteria laid down in the provisions of this standard would be accepted for marketing as infant formula".

3.1 ESSENTIAL COMPOSITION

3.2.1 (b) Minerals

- On the Table presented on item 3.1.2 b (minerals), invert the maximum and minimum amount per 100 kilocalories presented to Selenium and Zinc minerals.

- 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, eliminate the square brackets of the item 4.

We also suggest the inclusion, on the footnote, of bibliography references used.

3.2.1 (d) Protein

- On the item d (ii), to eliminate 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".

3.2.1 (e) Fat and Fatty Acid

On item 5, to put the word "trans" in italic, due to it must follow IUPAC rules.

3.6 SPECIFIC PROHIBITION

- We suggest the inclusion of the specific item: "The product and their components must not contain GMOs".

Justification: *The British Royal Society, in the report "Genetically modified plants for use and human health-an update", February 2002, points out special recomendations in the introduction of genetically modified foods on diet of specific and vulnerables groups such as infants, children, pregnant and lacting women. We quote as reference the Italian Government Law n.º 128/99 , which prohibits the presence of GMO in food directed to infant feeding.*

9. LABELLING

9.1 THE NAME OF THE FOOD

~~[~~ 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.~~]]~~

- To exclude all square brackets of the item 9.1.5

Justification: *The maintainance of this item keeps the coherence proposed in the Scope by the Germany Delegation.*

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

~~or~~

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

- To maintain the first item (9.1.6) without square brackets.

- To stablish a minimal value to Fe in the Table showed.

- To exclude the second proposal.

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

- The second proposal is not in accordance with the Table presented in this drafting guide.

9.6 ADDITIONAL LABELLING REQUIREMENTS

9.6.1 Labels should not discourage breastfeeding. Each container label shall have a clear, conspicuous and easily readable message which includes the following points:

a) the words "important notice" or their equivalent;

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

~~or:~~

b) ~~[~~ The statement "Breastfeeding is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breastmilk. ~~]~~

- To delete the first option of the subitem 9.6.1b

- To eliminate the square brackets of the second option of the subitem 9.6.1b, keeping the text.

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

- To delete the square brackets keeping the text.

9.6.6. Any indication required in the labelling should be made in the appropriate language of the country in which the product is sold

- To include the item 9.6.6, with the following sentence: " 9.6.6. Any indication required in the labelling should be made in the appropriate language of the country in which the product is sold".

COLOMBIA

What needs to be clarified is what the term "preparados" (preparations / infant formula) refers to or includes. The previous standard referred to "fórmulas infantiles" (infant formula). This term is somewhat clearer and more meaningful. As the English version also uses the term "formula" we may be dealing with a mistranslation. We would therefore request a revision of the Spanish text which should be amended according to the previous standard.

Scope

1. We support the inclusion of formula for infants with special nutritional requirements (food for medical purposes), including the related requirements as part of a special chapter which would yet have to be prepared.
2. Section 1.3 should provide the possibility to quote further resolutions which would supplement and/or amend the International Code of Marketing of Breast-Milk Substitutes. If such resolutions are quoted, then they should include Resolution WHA 55 (2002).
3. We accept that for these products no health claims shall be made. The only claims that may be made shall be nutrition claims.

Description

1. The statements in this section do not represent definitions. We deem it important, however, that the standard shall at least include a definition of the term "infant formula" to assist countries with the interpretation and harmonisation of the respective names.
2. It is necessary to describe the products falling into the category "preparados" (preparations / infant formula) or (if this is a mistranslation) "*fórmulas* para lactantes" (infant formula), as it seems that this involves only breast-milk substitutes, which do, however, exclude some of the additives.
3. It should be checked whether the term "agua salubre" or "safe water" has a microbiological connotation in addition to its physical and chemical connotation. The term "drinking water" makes it clear that the water involved needs to be fit for human consumption.
4. In Section 2.1.2 referring to growth and development we propose to replace the word "normal" by "appropriate".
5. As for the debate concerning the statement that infant formula should be able to meet the nutritional requirement "*by itself*", it is correct to use such wording, as the foodstuffs in question have to meet the nutritional recommendations for this population in a way similar to breast-milk. Otherwise they would not be suitable for infants.
6. To ensure compliance with World Health Assembly Resolution WHA54.2 such products should state that they meet the nutritional requirements of infants up to six months of age. If no such reference to age is made the introduction of complementary feeding might be delayed. (Section 2.1.2)

Composition

1. The wording of Section 3.1.1 needs to be revised, as it currently suggests that infant formula may be a product based on constituents of animal origin other than milk or on constituents of plant origin, even though in reality they are added ingredients. Colombia is not aware that milk from mammals other than cows is obtained for the production of said products or used as their basic ingredient.
2. As regards Section 3.1.2, we propose to take the following publication on nutrient requirements into account, which contains basic information on each individual nutrient: „Assessment of nutrient

requirements for infant formulas" (The Journal of Nutrition, Nov 98 Vol. 128 Number 11S- supplement). The publication is available at: www.faseb.org/asns/exsum.html.

Additives

1. We support a ban on the use of coloring agents in infant formula.
2. We suggest that the Working Group chaired by Switzerland consider the identification of ranges of additives corresponding to the functional characteristics for which they are added, and which respect the required minimum levels.

Labelling

1. The statement that no health claim must be made should be definitively included in Section 9.1.5.
2. In terms of contents, Section 9.1.6 is already covered by Section 9.1.5. A separate reference to iron is not necessary. The acceptable maximum level for iron is 1.5mg, according to the standard. Hence it is unclear why a specific reference on the label should be made, if only the specified levels are met. The second version of this section would result in non-compliance with the standard, as the acceptable minimum level is 0.5mg.
3. In the section "Declaration of Nutritive Value", letter a), the statement "as sold" is superfluous.
4. As the indicated values are meant for the consumers, the calorific value and the amount of nutrients contained in the product should be given in other units like "onzas" (ounces)**,** as consumers are familiar with these units and use them for food preparation.
5. As for b), we support the objection raised by Uruguay concerning the inclusion of "other ingredients" in the declaration of nutritive value, as the ingredients described need to have a nutritional connotation.
6. In Section 9.4.1 the words "best before" must be defined, i.e. the de cision must not be left to the consumer, but it is up to the manufacturer to specify certain conditions. We therefore propose the following wording: "consume not later than …date X" (specify date). Also, for greater clarification for the consumer the month must be given in letters; this aspect of labelling must not be optional.
7. As for Section 9.5.1, any direction for preparation or use must be given on the label. The statement "or on the accompanying leaflet" should be deleted. There is a possibility that potential consumers might not receive the leaflet, and the information is too important not to be listed.
8. We would definitely prefer the second version of Section 9.6., letter b), as the first does not take full account of the beneficial effects of breast-milk. Letter c) only applies to infant formula for therapeutic purposes or purposes requiring an established indication.
9. The food mentioned in Section 9.6.4. is called "alimentos complementarios" and not "suplementarios" (This comment refers to the correct Spanish term for "supplemental food", translator's note.).
10. The clarification called for in Section 9.6.5 needs to be made in the definitions contained in the standard, as it is unclear which products fall into which classifications.

COSTA RICA

1. Scope:

In Section 1.1 we suggest to replace "a los preparados para lactantes" (infant formula) by "*a las fórmulas para lactantes menores de 6 meses*" (food for infants below six months) and to change the sentence in square brackets as follows: "*This Standard shall also apply to foods for infants with special nutritional requirements, except for the modifications which are necessary to meet these special requirements and which must be in keeping with Codex Standard 180-1991.*"

We suggest to include in Section 1.3 the statement "*as well as the relevant national legislation*", as some countries have laws stipulating that breastfeeding should be promoted. In Costa Rica this is the "Ley de

Fomento a la Lactancia Materna", which is based on the International Code of Marketing of Breastmilk Substitutes. Also, we doubt that the Code (this refers to the International Code of Marketing of Breastmilk Substitutes, translator's note) is binding, as it is an international recommendation.

2. Description:

All sections shall be amended so they read as follows:

2.1.1 Infant formula is a product manufactured industrially in accordance with this CODEX Alimentarius Standard which meets the normal nutritional requirements of infants aged 0 to six months and has been formulated to suit their physiological needs until appropriate supplemental food is introduced.

2.1.2 Infant formula shall be used in accordance with directions of use. It exists in liquid or powdered form. If used in powdered form it shall be diluted with safe, potable, and previously boiled water.

2.1.3 Infant formula is so processed by physical means and so packaged as to prevent spoilage and contamination under all normal market conditions of handling, storage and distribution.

NOTE: The phrase "during the first months of life" is to be replaced by "aged 0 to six months", as it is ambiguous- In addition, there is the CODEX Standard for Follow-up Formula (CODEX STAN 156-1987, as amended in 1989).

3. Essential composition and quality factors:

In Section 3.1.1 we suggest to replace "el preparado" by "la fórmula" (Change applies to the Spanish version. Translator's note) and to amend the sentence "…based on milk of cows or other animals and/or…" as follows: "...based on milk of cows or other mammals or other constituents…"

In Section 3.1.2 we suggest to replace "el preparado" by "la fórmula" (Change applies to the Spanish version. Translator's note). The brackets shall be deleted so that the statement reads: "per 100 kilocalories or 100 kilojoules". With reference to the table specifying vitamin, minerals and choline contents we would like to comment as follows:

a) In its report "Assessment of Nutrient Requirements for Infant Formulas" the LSRO (Life Sciences Research Office of the American Society for Nutritional Sciences) Expert Panel recommends a maximum level of 150 µg of vitamin A per 100 kcal. This is in keeping with the maximum level specified by the current Standard. We would like to know what prompted the Committee to raise the maximum level for vitamin A to 180 µg per 100 kcal.

There are further deviations from the report concerning its recommendations for the minimum levels of other vitamins, and the Committee has not specified certain maximum levels where the report has recommended such values. We would like to know what the levels proposed by the Codex are based on.

With reference to vitamin E we also suggest to replace "linoleic acid" in the column "Minimum" by "polyunsaturated fatty acids".

With reference to niacin we recommend following the advice of the LSRO Expert Panel and specify a minimum level of 0.6 mg /100 kcal instead of 0.8 mg/100 kcal, the latter being based on the recommended minimum level of niacin of 550 µg/100 kcal for infant formula. The minimum level per 100 kJ would be 0.14 mg.

For folic acid we recommend replacing the minimum level of 4 µg/100 kcal by 11 µg/100 kcal. That is in keeping with the folic acid content of breast milk as mentioned in the 1998 LSRO report. In line with this recommendation the minimum level per 100 kJ would have to be changed to 2.6 µg.

b) The situation for minerals is similar to that for vitamins. We therefore would ask to clarify what reference was used.

Moreover, it is not clear from the abbreviation "N.S." whether the nutrients in question can be used in unlimited amounts or whether there is not enough information to specify maximum levels.

In the case of selenium there has been a mix-up of the values for the minimum and maximum levels. Also, the conversion of the values into kJ is incorrect.

c) For choline the current Standard specifies a minimum level of 7 mg/100 kcal, it has to be added. The above report sets a maximum level of 30 mg/100 kcal.

In Section d) Protein (i) the following wording should be added: *"The protein content is to be calculated as follows:"*; para 2 is to be corrected as follows: *"Protein content = nitrogen content * 6.25 for soya protein and protein partial hydrolysates."*

Section d) (ii) should explain the object and the purpose of the "chemical index", as currently there is only a definition and it remains unclear why it has been given. Further, it should be clarified what parameters were used to assess the result of this index. Furthermore, the aminogram in Annex 1 is not representative for breast milk. We therefore recommend to organize a consultation in order to prepare an up-dated proposal. In addition, the procedure recommended for the assessment of the quality of protein should be explained in detail or an appropriate reference should be included. In accordance with the above source the wording is to be corrected as follows: "…for calculation purposes, the concentration of methionine and cystine may be added together at the recommended ratio of 1:1." The square brackets are to be deleted, because governments are allowed to set their own regulations.

In Section d) (iii) we recommend to replace "el preparado" by "la fórmula" and to correct the sentence as follows: "... necesarias para tal efecto ..." (Changes apply to the Spanish version only. Translator's note). Also, the wording of this section is somewhat too general, as no aspects concerning the individual addition of other nitrogenous compounds are mentioned.

We recommend to correct Section e) "Fat and Fatty Acid" as follows: "... en cantidad no menor a ..." (Correction applies to the Spanish version only, Translator's note) and to delete "o sea" (or) from the statement in brackets. As for the total fat content, the LSRO report states 6.4 g/100 kcal instead of 6.5 g/100 kcal. We seek clarification as to the source of this value. The same applies to the proposed alpha-linolenic acid content (in the Spanish version (translator's note) "ácido alfa linoleico" is to be replaced by "alfa linolénico") and all other values given.

Concerning Sections f) and g) we would like to know what sources these values have been taken from, as they, too, deviate from the recommendations given by the above report.

3.2 Optional ingredients:

"Section 4.2.1" should really be "Section 3.2.1". In addition, we recommend to include a standard reference for the composition of breast milk, as the content of other optional ingredients is based on the respective levels found in breast milk.

3.3 Vitamin Compounds and Mineral Salts

In Section 3.3.1 the reference to letter d) should be deleted, as Section 3.1.2 (letter d, translator's note) refers to proteins.

4. Food Additives:

In the column "Maximum level in 100 ml" we suggest to replace the phrase "del preparado" by "de la fórmula" and the phrase "de preparados" by "de fórmula" (applies to the Spanish version only, translator's note).

In Section 4.1 "5.1.1" is to be changed to "4.1.1". Sections 5.1.1 (really 4.1.1) to 4.1.7 do not mention starch from tuber crops or pectins. We suggest to include these substances and set maximum levels for their use, as they are used in some formulas.

In Sections 4.3.1 to 4.3.9 "3.1.2 c" is to be replaced by "3.1.2 b".

We recommend that in Section 5.1 maximum levels for pesticide residues are to be set, which are in accordance with the report of the Joint Meeting on Pesticide Residues (JMPR).

In Section 6 we suggest to include items a, b and c of the current Standard, as it is much more comprehensive and clearer in this respect.

In Section 9.1.1 we suggest to replace "preparado" by "fórmula". (applies to the Spanish version only, translator's note)

Section 9.1.3 should read as follows: "If at least 90% of the protein is derived from cow's milk, the product may be labelled 'Infant Formula Based on Cow's Milk'". In view of the fact that Section 3.1.1 allows the use of milk from other mammals, it should be possible to label the product "Infant Formula based on *(name of the respective mammal)* milk".

With reference to Section 9.1.4 we suggest to list minimum levels if using the word "shall", or to replace "shall" by "may", which would make such listing optional, since the information in question is contained in the list of ingredients anyway.

In Section 9.1.5 the statement "No health claims shall be made regarding the dietary properties of the product." should be deleted, as this would depend on whether or not such claims are correct. The word "preparado" should (in the Spanish version, translator's note) be replaced by "fórmula".

Concerning Section 9.1.6 we recommend to retain the value as stipulated by the current Standard and to replace "shall (be labelled)" by "may (be labelled)". The suggested value of 0.5 mg ignores the fact that the minimum level for soy-based infant formulae has been set at 1 mg.

As for Section 9.3 we propose to keep the wording of the current Standard's Article and to change letter a) from "kilocalories (kcal) and/or kilojoules (kJ)" to "kilocalories (kcal) and kilojoules (kJ)".

Regarding Section 9.6.1 b) we recommend that the statement suggesting that breast milk protects against diarrhea be deleted. Instead the alternative statement reading "Breastfeeding is the best food for your baby…" should be kept. In para c) the term "trabajador sanitario" should be replaced by "profesional del área de salud" (applies to the Spanish version only, translator's note).

In Section 9.6.2 we recommend replacing "preparados" by "fórmulas"(applies to the Spanish version only, translator's note).

Regarding Section 9.6.4 we suggest to make the inclusion of this piece of information no longer obligatory, i. e. to change the wording as follows: "Information may appear on the label to the effect that infants…". Furthermore, "trabajador de la salud" should be replaced by "profesional del área de la salud" (applies to the Spanish version only, translator's note).

In Section 9.6.5 "preparados" should be replaced by "fórmulas" (applies to the Spanish version only, translator's note).

Literature: LSRO Report: Assessment of nutrient requirements for infant formulas. The Journal of Nutrition. Official Publication of the American Society for nutritional sciences. Supplement. Volume 128, number 11s. 1998.

CUBA

CRITERIA ABOUT SECTION 4: FOOD ADDITIVES

We maintain the former expressed criteria that the permitted additives in infant formula should be kept at the minimal necessary level based on an adequate technological justification.

We approve the current standard which does not permit the use of color additives in foods for infants and young children.

CZECH REPUBLIC

1. SCOPE

1.1 As it is presently written, the standard would be applicable to products intended both for normal healthy infants and for infants with special nutritional requirements. However it is our position that formula for unhealthy infants should not be included in this standard for infant formula, but should be included in an equivalent Codex standard on foods for Special Medical Purposes (FSMP). The second sentence should therefore read:

"The provisions in this standard are not intended for infants with special nutritional requirements."

If both types of these products were to be included here, then the compositional requirements of the standard could be inappropriate for infants with special needs. If a specialised product is adapted to particular nutritional situations, it might pose a health hazard to normal healthy infants. In addition, statements such as 'use under medical supervision' would not necessarily appear.

2.1.2 We suggest deleting the second sentence which is redundant.

After that, all the other [ ] should be deleted. 2.1 will read "*Infant formula shall be nutritionally adequate to ensure normal growth and development when used in accordance with its directions for use to meet the nutritional requirements of infants by itself during the first months of life up to the introduction of appropriate complementary feeding"*.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1.2 (d) Protein:

(i) The possibility to use sources of protein other than milk and soy should be maintained as in the current Codex STAN 72-1981. Thus the second sentence should read "...nitrogen *content x 6.25 for soya and other protein isolates and their partial hydrolysates"*.

Reference aminogram (ANNEX 1).

The proposed aminogram is not representative of human milk protein composition and is not similar to other amino acid analyses of human milk protein. An alternative aminogram should be introduced. The aminogram used for decades in the European Union would be an acceptable alternative, but the FAO consultation will likely update this information.

3.1.2 (e) Fat and Fatty Acid

Trans Fatty Acids
Our position is that the trans fatty acid content of infant formula shall not exceed 5% of the total fat content and the use of hydrogenated oils in infant formula should be prohibited. The reason is that milk fat can contain up to 6% trans fatty acids and it can be desirable to make infant formula with a fat mix containing 80% milk fat.

FOOD ADDITIVES

Further information may be provided separately, depending on the outcome of the Swiss–chaired WG.

5. CONTAMINANTS

We support the proposed text. Limits of contaminants are being established on a horizontal basis in a separate Codex Standard. These should be based on the ALARA (As Low As Reasonably Achievable) principle and on the toxicity of the different contaminants.

9.1. THE NAME OF THE FOOD

9.1.4 This sentence should be changed to the original language in the Codex Standard 72-1981 to read:*" A product which contains neither milk nor any milk derivative ~~shall~~ may be labelled contains no milk or milk products or an equivalent phrase"*.

The list of ingredients would show the composition of the product and whether it contains milk or not. It is extremely difficult to guarantee the complete absence of milk or of any milk derivative from a product. If this is to be required, it would be necessary to establish threshold levels of permissible milk content.

"[**9.1.5**...[No health claims shall be made regarding the dietary properties of the product.]]

Regarding the whole paragraph 9.1.5 which is in [ ], much will depend on whether foods for infants with special nutritional requirements are included in the Scope of the Standard. As mentioned above in Section 1.1, we strongly recommend not to include such foods in the Standard. If this is achieved, the whole paragraph 9.1.5 must be deleted.

However, if foods for infants with special nutritional requirements are included in the Scope of the Standard, then Paragraph 9.1.5 must be retained and the [ ] must be deleted. The last sentence "*No health claims shall be made regarding the dietary properties of the product*" must be deleted because a health claim will be an essential piece of information about the product. If it is justified, it should be allowed. Some legislations permit such claims, for example in Europe the claim of hypoallergenic formulae is allowed.

In all cases, i.e. whether foods for infants with special nutritional requirements are included or excluded from the Scope of the Standard we recommend to add a new paragraph 9.1.5 (or other, depending on the numbering system,) with the following wording:

"*In order to provide information concerning the composition and the specific properties of foods intended to meet the nutritional requirements of infants, nutrition and health claims are permitted insofar as they are supported by relevant scientific data*".

9.1.6 We support the first alternative, delete [ ].

9.6 ADDITIONAL LABELLING REQUIREMENTS

In **9.6.1 b)** there are two alternative proposed statements:

"b)[a statement of the superiority of breastfeeding or breastmilk, for example the statement : breastmilk is the best food for your baby, it protects against diarrhoea and other illnesses]"

or

"b)[The statement: "Breastfeeding is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breastmilk.]"

We support the second statement. The alternative language "[...it protects against diarrhoea and other illnesses]..." deviates from the WHO Code and should not be accepted.

9.6.5 We recommend to delete 9.6.5: indeed there cannot be any risk of confusion between two products, i.e. infant formula and follow-up formula, which have different names, different Codex Standards, different composition, different labelling etc.

HUNGARY

ad 2.1.2.

Square bracket should be deleted in this point. We think that the word "normal" is needed without brackets

ad 3.1.2. (d) (ii)

Square bracket should be deleted.

ad 3.2.2. (e)

In accordance with the Directive 91/321 EEC we propose the following additional criteria:

- *the lauric acid content shall not be more than 15 % of the total fat,*
- *the myristic acid content shall not be more than 15 % of the total fat,*

ad 9.6.1. (e)

We propose a modification of the second part of this point in the following way:

"formula remaining after each feeding should use only when stored as described at the label"

ad 9.6.2.

We propose to add: *"Neither the container nor"* the label shall have no picture……

ad 9.6.5.

Delete square bracket.

IRAN

2.1.2 We propose the definite age of beginning to use complementary feeding shall be introduced according to WHO recommendations.

3-1-(b) Minerals: We propose the important changes in the amounts of minerals to improve the draft based on compositions of human milk, Daily dietary minerals requirements (FAO/WHO) and Recommended Daily Allowances. They are in the following table:

Minerals	**Amounts Per 100 Kilocalories**	
	Minimum	**Maximum**
Calcium	60 mg	86 mg
Phosphorus	30 mg	38 mg
Magnesium	5 mg	10 mg
Zinc	0.5 mg	1.5 mg
Manganese	5 mg	25 mg
Copper	70 μg	100 μg
Iodine	7 μg	25 μg
Sodium	20 mg	35 mg
Potassium	80 mg	110 mg
Chloride	50 mg	100 mg
Selenium	1.5 μg	3 μg

In addition:

1 - The estimated renal solute load (ERSL) in product shall 10 - 14 (mOsm) per 100 kilocalories that like human milk and routine cow milk based formulas. ERSL is calculated as the grams of protein x 4 + the mmoles of sodium + potassium + chloride in 100 kilocalories of formula.

2 - The osmolarity is expressed as the mosmoles present in 100 kcal formula prepared at standard dilutions.

The osmolarity shall maximum 40 (mOsm) per 100 kilocalories that like human milk.

(e) Fat and fatty Acid

We propose:

1 - The product shall not contain Hydrogenated oils and crude oils.

2 - The product shall not contain linseed oil because of containing over 50 percent linolenic acid, Safflower oil because it contains over 70 percent linoleic acid, Sesame oil because of the presence of phenolic compounds, Rapeseed oil because of the presence of erucic acid, Peanut oil because it contains allergic agents and high level Arachidic Acid.

3 - Infant formula shall not contain Erucic acid according to United States legislation on low Erucic Acid Rapeseed oil (F.D.A. 1985 Title 21 c).

4 - The trans fatty acid content shall not exceed 1% of the total fat content because this is a very complex field of study and very little is known about possible negative effects of trans fatty acids upon fetal and infant growth and neurodevelopment. Until more careful research is conducted and more is known about the subtle effects of trans fatty acids, it is recommended that pregnant and nursing women limit their intake of foods containing partially hydrogenated vegetable oils, and that infants should not consume formula containing these oils.

5 - The compositions of fatty acids should like human milk according to the following table.

Fatty acids	Number of carbon	Amounts (gr/100 gr total fat)	
		Obligatory	Advisory
Capric acid	10 : 0		101 - 104
Lauric acid	12 : 0	5 - 7	
Myristic acid	14 : 0	7 - 8	
Palmitic acid	16 : 0	19 : 27	
Stearic acid	18 : 0		5 - 10
Arachidic acid	20 : 0	Maximum 0.2	
Palmitoleic acid	16 : 1		Maximum 4
Oleic acid	18 : 1	32 - 35.5	
Gaduic acid	20 : 1		0.7 - 1.1
Linoleic acid	18 : 2 (n-6)		9 - 16
Linolenic acid	18 : 3 (n-3)		0.6 - 0.9
Arachidonic acid	20 : 4 (n-6)	Maximum 0.6	
Total fatty acids with some double bond and long chain (n-3)(n-6)		Maximum 1.7	

MALAYSIA

Section 9.1.6

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.

Section 9.3 (b)

"(b) the total quantity of each vitamin, mineral,……provided the present is significant amount i.e. not less than 5% of the recommended intake".

Rationale :

i. to be in line with Codex Guidelines for Nutrition Labelling

ii. 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.

Section 9.6.5

Malaysia proposes to remove the square brackets in section 9.6.5 and adopt the text contained in the brackets.

MALAYSIA: Comments to CL 2001/47-NFSDU

VITAMIN E

Malaysia proposed Vitamin E to be expressed in major essential polyunsaturated fatty acids (linoleic acid and alpha-linolenic acid).

Rationale : To include “polyunsaturated fatty acids” is not very clear and can be misleading. In addition, other essential polyunsaturated fatty acids are present in very small amount compare to linoleic acid and alpha-linolenic acid.

NEW ZEALAND

1. SCOPE

1.1
New Zealand supports the inclusion of infant formula for special nutritional requirements as a section in the general purpose standard as outlined in Option C from the discussion paper developed by Germany (CX/NFSDU 01/5-Add 1). New Zealand believes that the scope would best reflect this position by having two parts as follows:

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

1.2 The provisions in this standard are also intended for foods for special medical purposes (formulated according to the description and general principles of Codex Stan 180-191) for infants except for certain compositional provisions which must be modified to meet the special requirements of the disease, disorder or medical condition for whose dietary management the food is formulated.

2. DESCRIPTION

New Zealand supports the text in square brackets of section 2.1.2 which is consistent with New Zealand national nutrition policy where the introduction of appropriate complementary feeding is based on signs of physiological need and readiness rather than a set age. New Zealand also supports inclusion of the word "normal" before growth.

New Zealand suggests a new section 2.1.3 which reflects the inclusion of infant foods for special medical purposes in the general purpose standard. Suggested wording is:

Foods for special medical purposes for infants are a category of foods for special dietary uses which are specially processed or formulated and presented for the dietary management of infants and may be used only under medical supervision. The formulation of foods for special medical purposes for infants should be based on sound medical and nutritional principles.

9. LABELLING

New Zealand supports the inclusion of two separate labelling components:

Section 9. Labelling of infant formula
Section 10. Labelling of foods for special medical purposes for infants.

9.1.5
New Zealand recommends removal of the bulk of the text in 9.1.5 but recommends retaining reference to the prohibition of health claims.

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

9.1.6
New Zealand does not support the text that product with not less than 0.5 mg/ Iron (Fe) be labelled as "Infant Formula with added Iron". New Zealand considers that such a statement could be taken by the consumer to refer to a superior product at times when an infant may not require the additional iron. New Zealand does not think that any such statement is required and that at the age when iron is likely to become an issue, complementary foods should also be added to the diet.

It is also noted that the proposed minimum level for Iron is 0.5 mg/100 kcal which would mean that all product would be required to label with "added iron".

9.6
b) New Zealand supports the intent of the second text in brackets:
breastfeeding is the best food for your baby or a similar statement as to the superiority of breastfeeding or breastmilk.

New Zealand recommends minor change to make the statement more accurate and would suggest a wording as follows:
Breastfeeding provides the best food for your baby.

10

New Zealand supports the addition of a section on the labelling requirements for foods for special medical purposes for infants.

10.1 Foods for special medical purposes for infants shall be labelled in accordance with the Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (Codex Stand 180-1991).

New Zealand agrees that sections 4.4 and 4.5 of Stand 180-1991 are particularly important but does not believe that rewriting these sections is required.

NEW ZEALAND: Comments to CL 2001/47-NFSDU

GENERAL PRINCIPLES

Section 3.1

Point 2 needs to include a reference to age.

A nutritionally adequate infant formula product will promote normal growth and development and meet the nutritional requirements of infants ***during the first months of life*** *when fed as a sole source of nutrition.*

Point 8 refers to the inherent variability of raw ingredients including water that may be added to infant formula. Such a principle is fraught with difficulties as the manufacturer can only control the quality and composition of water that may be used in the manufacture of infant formula but not water that may be used in preparation of the final product by the consumer.

Point 10 regarding establishing maximum levels, New Zealand supports the risk based approach that is in the first square brackets - *maximum amounts of essential nutrients should be established only for those nutrients for which there is sufficient evidence of adverse health effects at higher levels.*

New Zealand supports establishing general principles for setting upper levels based on a risk based approach however because of the vulnerability of the population group (infants) New Zealand recommends providing guidelines on maximum levels for those nutrients where there are no known adverse effects.

ESSENTIAL COMPOSITION

Section 3.1 (B)

New Zealand supports the need to consider the establishment of general principles both for deciding
(a) whether there is a need for establishing a minimum or maximum; and
(b) determining actual minimum and maximum levels.

New Zealand also supports the use of breastmilk as the reference point for establishing minimum essential nutrients. New Zealand also supports the position that bioavailability needs to be taken into account in establishing both minimum and maximum levels.

3.1.1
New Zealand recommends that reference to synthetic ingredients is required in the definition of essential composition particularly for use in the manufacture of foods for special medical purposes for infants.

3.1.2
There appears to be an error with the deletion of choline from the text.

Manganese
To be consistent with the value declared in the Min/100 kJ column should read 0.24 µg rather than .24 µg.

Selenium:
New Zealand supports the establishment of minimum levels but believes that the proposed levels are too high. The proposed minimum level of 1.4 mcg/100 kJ equates to a daily intake of approximately 31 mcg/day (based on consumption levels of 0.78 litres of formula/day. The tolerable upper limit for selenium intake for infants is 45-50 mcg/day in the USA. A minimum level of 31 mcg/day seems too close to these upper levels.

The current minimum level in the *Australia New Zealand Food Standards Code* is 0.25 mcg/100kJ (cf 1.4 mcg/100kJ proposed). We prefer a minimum selenium level of 0.2 µg/100 kJ 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 not been recognised in breast fed infants.

NIGERIA

Section 3.1.2(a) Vitamins

Vitamin A & D

We propose dual units of expression i.e. Vit A & D should be expressed in both ug and iu.

Vitamin C

We propose dual naming of Vitamin C as well as Ascorbic Acid.

SLOVAK REPUBLIC

1. SCOPE

1.1 As it is presently written, the standard would be applicable to products intended both for normal healthy infants and for infants with special nutritional requirements. However it is our position that formula for unhealthy infants should not be included in this standard for infant formula, but should be included in an equivalent Codex standard on foods for Special Medical Purposes (FSMP). The second sentence should therefore read:

"The provisions in this standard are not intended for infants with special nutritional requirements".

If both types of these products were to be included here, then the compositional requirements of the standard could be inappropriate for infants with special needs. If a specialised product is adapted to particular nutritional situations, it might pose a health hazard to normal healthy infants. In addition, statements such as 'use under medical supervision' would not necessarily appear.

2.1.2 We suggest deleting the second sentence which is redundant.

After that, all the other [ ] should be deleted. 2.1 will read *"Infant formula shall be nutritionally adequate to ensure normal growth and development when used in accordance with its directions for use to meet the nutritional requirements of infants by itself during the first months of life up to the introduction of appropriate complementary feeding".*

2. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1.2 (d) Protein:
(i) The possibility to use sources of protein other than milk and soy should be maintained as in the current Codex STAN 72-1981. Thus the second sentence read *"...nitrogen content x 6.25 for soya and other protein isolates and their partial hydrolysates".*

Reference aminogram (ANNEX 1).

The proposed aminogram is not representative of human milk protein composition and is not similar to other amino acid analyses of human milk protein. An alternative aminogram should be introduced. The aminogram used for decades in the European Union would be an acceptable alternative, but the FAO consultation will likely update this information.

3.1.2 (e) Fat and Fatty Acid

Trans Fatty Acids
Our position is that the trans fatty acid content of infant formula shall not exceed 5% of the total fat content and the use of hydrogenated oils in infant formula should be prohibited. The reason is that milk fat can contain up to 6% trans fatty acids and it can be desirable to make infant formula with a fat mix containing 80% milk fat.

4. FOOD ADDITIVES

Further information may be provided separately, depending on the outcome of the Swiss-chaired WG.

5. CONTAMINANTS

We support the proposed text. Limits of contaminants are being established on a horizontal basis in a separate Codex Standard. These should be based on the ALARA (As Low As Reasonably Achievable) principle and on the toxicity of the different contaminants.

9.1 THE NAME OF THE FOOD

9.1.4 This sentence should be changed to the original language in the Codex Standard 72-1981 to read: *"A product which contains neither milk nor any milk derivative ~~shall~~ may be labelled 'contains no milk or milk products' or an equivalent phrase".*

The list of ingredients would show the composition of the product and whether it contains milk or not. It is extremely difficult to guarantee the complete absence of milk or of any milk derivative from a product. If this is to be required, it would be necessary to establish threshold levels of permissible milk content.

"[**9.1.5**...[No health claims shall be made regarding the dietary properties of the product.]]

Regarding the whole paragraph 9.1.5 which is in [ ], much will depend on whether foods for infants with special nutritional requirements are included in the Scope of the Standard. As mentioned above in Section 1.1, we strongly recommend not to include such foods in the Standard. If this is achieved, the whole paragraph 9.1.5 must be deleted.

However, if foods for infants with special nutritional requirements are included in the Scope of the Standard, then Paragraph 9.1.5 must be retained and the [ ] must be deleted. The last sentence *"No health claims shall be made regarding the dietary properties of the product"* must be deleted because a health claim will be an essential piece of information about the product. If it is justified, it should be allowed. Some legislations permit such claims, for example in Europe the claim of hypoallergenic formulae is allowed.

In all cases, i.e. whether foods for infants with special nutritional requirements are included or excluded from the Scope of the Standard we recommend to add a new paragraph 9.1.5 (or other, depending on the numbering system,) with the following wording:

"In order to provide information concerning the composition and the specific properties of foods intended to meet the nutritional requirements of infants, nutrition and health claims are permitted insofar as they are supported by relevant scientific data".

9.1.6 We support the first alternative, delete [ ].

9.6 ADDITIONAL LABELLING REQUIREMENTS

In **9.6.1 b)** there are two alternative proposed statements:

"b) [a statement of the superiority of breastfeeding or breastmilk, for example the statement: breastmilk is the best food for your baby, it protects against diarrhoea and other illnesses]"

or

"b) [The statement: "Breastfeeding is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breastmilk.]"

We support the second statement. The alternative language "[...it protects against diarrhoea and other illnesses] ..." deviates from the WHO Code and should not be accepted.

9.6.5 We recommend to delete 9.6.5: indeed there cannot be any risk of confusion between two products, i.e. infant formula and follow-up formula, which have different names, different Codex Standards, different composition, different labelling etc.

SOUTH AFRICA

1. Scope

South Africa chooses option C and supports the wording of Germany in the discussion paper CX/NFSDU 01/5-Add 1 (November 2001):

“The provisions in this standard are also intended for foods for special medical purposes (formulated according to the description and general principles of Codex STAN 180-191) for infants except for certain compositional provisions which must be modified to meet the special nutritional requirements of the disease, disorder or medical condition for whose dietary management the foods is formulated.”

3.1 Essential composition

3.1 e South Africa proposes that Omega-3-fatty acid content of Infant Formula is at least 1% of the total fat content, similar to the average composition of mature breast milk.

9.6 Additional labelling requirements

9.6.1 (b) South Africa proposes the following wording: “Breast milk is best for infants and reduces the risk of diarrhoea and some illnesses”

9.6.5 Delete the square brackets.

TURKEY

1. SCOPE

1.1 As it is presently written, the standard would be applicable to products intended both for normal healthy infants and for infants with special nutritional requirements. However, formula for unhealthy infants should **not** be included in this standard for infant formula, but should be included in an equivalent Codex standard on foods for Special Medical Purposes (FSMP).

The second sentence should therefore read:

"The provisions in this standard are not intended for infants with special nutritional requirements."

If both types of these products were to be included here, then the compositional requirements of the standard could be inappropriate for infants with special needs. If a specialised product is adapted to particular nutritional situations, it might pose a health hazard to normal healthy infants. In addition, statements such as 'use under medical supervision' would not necessarily appear.

2.1.2 We suggest deleting the second sentence which is redundant.

After that, all the other [ ] should be deleted. 2.1 will read "*Infant formula shall be nutritionally adequate to ensure normal growth and development when used in accordance with its directions for use to meet the nutritional requirements of infants by itself during the first months of life up to the introduction of appropriate complementary feeding"*.

UNITED STATES OF AMERICA: Comments to CL 2001/47-NFSDU

GENERAL COMMENTS

General Principles
As described in more detail below, the United States recommends that the general principles for establishing minimum and maximum values for the essential composition of infant formula be identified in this standard. We have also recommended revisions to the previously proposed general principles.

Sections 3.1.2(a)- (c): Vitamins, Minerals, and Choline
We agree with the proposed revisions described in the circular letter except for two minerals that are discussed below.

Sections 3.1.2 (d)- (g): Macronutrients and Energy Content
We anticipate that we will propose recommendations for these parts of the standard following the release of a report by the Institute of Medicine of the National Academy of Sciences in September on dietary reference intakes for macronutrients.

COMMENTS ON SPECIFIC SECTIONS

3.1 ESSENTIAL COMPOSITION

3.1.2 We recommend that new language be inserted in 3.1.2 in order to address general principles for establishing minimum and maximum values for the essential composition of infant formula and refer to an appendix to this standard which would identify these general principles. The existing language in 3.1.2 would then become section 3.1.3, and subsequent sections renumbered accordingly. The new appendix to the standard would be identified as Annex 1 and the existing Annex 1 would become Annex 2.

The new language recommended for 3.1.2 is:

> "3.1.2 The establishment of minimum and maximum values in (*new)* 3.1.3 should be consistent with the general principles identified in Annex 1."

Next, we propose language for a new Annex 1 that considers the proposed general principles in CL 2001/47-NFSDU.

(new) **ANNEX 1**

General Principles for Establishing Minimum and Maximum Values for the Essential Composition of Infant Formula in (*new)* Section 3.1.3

1. The goal of establishing minimum and maximum values is to provide safe and nutritionally adequate infant formula products that meet the normal nutritional requirements of infants.
2. A nutritionally adequate infant formula product will promote normal growth and development and meet the nutritional requirements of infants when fed as a sole source of nutrition.

3. The values to be established are only for those substances that are essential to infant formula. Optional ingredients are addressed in Section 3.2 of the standard.

4. The values are based on an evaluation of the scientific evidence of the amount needed to meet the nutritional requirements of infants, and consider the composition of breast milk and human infant studies.

5. For essential nutrients, the starting point for establishing:

   a) minimum amounts is the mean level in breast milk;

   b) maximum amounts is when there is evidence of adverse health effects at higher levels.

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

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

   (b) preparation according to directions for use.

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

   (d) the inherent variability of nutrients in ingredients, and in water that may be added to the infant formula product before or after it is purchased.

   (e) overages for certain nutrients at appropriate levels to ensure that minimum levels are met throughout the expected shelf-life of the formula.

7. In establishing minimum or maximum amounts of nutrients per 100 ml (or per 100 kcal) of infant formula based on consideration of reference nutrient values expressed as units per daily intake or per kilogram of body weight, the following standard conversion factors and assumptions will be used:

   (a) The mean intake of prepared formula for infants from birth to six months of age is 750 ml per day. This is based on the following assumptions:

      (i) a representative body weight for an infant over this period would be 5 kg and a representative caloric intake would be 500 kcal per day (or 100 kcal/kg/day over the first six months); and

      (ii) prepared formulas provide about 67 kcal/100 ml.

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

[old] 3.1.2 (introductory text to the table)

We recommend the following revisions:

~~3.1.2~~ *(new)***3.1.3** Infant formula shall contain per 100 kilocalories (or 100 kilojoules) ~~of intake~~, the following minimum and maximum levels of vitamins, minerals in an available form, choline, protein, fat and fatty acid, **and** carbohydrates. ~~and energy~~. **Infant formula shall also contain when consumed according to directions for use the minimum and maximum energy content per 100 ml that is specified in (g) below.**

Rationale: We recommend deleting "of intake" in the first sentence. It does not appear necessary and may be confusing since this sentence addresses the nutrient density of infant formula (i.e., amounts per unit of energy). Also, since energy content is expressed on a different basis (i.e., per 100 ml), we recommend that the energy content provisions be addressed separately in a new sentence, and that it be clarified both in this section and in Section 3.1.3(g) that the energy values are per 100 ml *when consumed according to directions for use*.

*[old] 3.*1.2 (guidelines for presenting information in the table)

The United States recommends that the following guidelines be used in presenting information in the 3.1.2 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).

SECTION 3.1.2 (b) MINERALS

IRON

The United States has received comments that have recommended that the current maximum level for iron (1.5 mg/100 kcal) be changed to a higher level. We will further consider the recommendations and basis for establishing a maximum level prior to the upcoming Committee session.

We recommend that the last sentence of the proposed revised footnote be deleted since this is a labeling issue, and is already addressed in Section 9.1.6.

We would also like to provide the following additional reference in support of proposing a single recommendation for fortified cow's milk formulas and soy-based formulas: Hertrampf et al. Pediatrics 78:640-645, 1986).

SELENIUM

We recommend the following revisions to the proposed minimum and maximum values for selenium:

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 concentration be doubled because of the very narrow range that would be result between the minimum and maximum values.

EUROPEAN COMMUNITY

SECTION 1.1 "SCOPE"

The second sentence of this section causes concern for the reasons outlined in the discussion paper (CX/NFSDU 01/5-Add 1) prepared in 2001 by the German delegation. The options for dealing with the issue were discussed at the last session of the CCNFSDU but no conclusion was reached. The European Community would prefer foods for special medical purposes for infants to be eliminated from the Scope of the standard. The standard for foods for special medical purposes should be revised to include compositional requirements for foods for special medical purposes for infants by reference to the compositional requirements included in this standard.

SECTION 2.1.2 "PRODUCT DEFINITIONS"

The European Community believes that the first sentence of section 2.1.2 notes two requirements regarding the nutritional adequacy of infant formula. To make this clear it is proposed that "…for use to meet…" should be changed to "…for use and should meet…".

The last sentence of section 2.1.2 expresses a valid principle and the European Community supports the principle that infant formula should be the only breast milk substitute suitable to satisfy by itself the nutritional requirements of infants. However it is not appropriate to include the principle as part of the definition. This could be included in the Scope of the standard. In addition the sentence needs to be clarified. The present wording of the sentence protects the use of the description "infant formula" rather than preventing the presentation of other products as suitable for satisfying by themselves the nutritional requirements of infants. Therefore, it is proposed that the following revised sentence should be incorporated into the Scope of the standard:

> "No product other than infant formula may be marketed or otherwise represented as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first months of life.".

SECTION 3.1 "ESSENTIAL COMPOSITION" AND "ANNEX 1"

The Scientific Committee on Food (SCF) has been asked to review the compositional requirements for infant formulae. The European Community will inform the Committee of the outcome of that review when the opinion of the SCF becomes available. Meanwhile we will cooperate with the Working Group that has been established.

SECTION 3.2.2 OPTIONAL INGREDIENTS

It is important that the ingredients included in infant formula meet the nutritional requirements of infants and that this has been demonstrated. It is suggested that 3.2.2 should be changed to:

> "3.2.2 The suitability for the particular nutritional uses of infants and the safety of these nutrients shall be scientifically demonstrated.".

SECTION 3.3.1 VITAMIN COMPOUNDS AND MINERAL SALTS

The European Community have sent comments in response to CL 2002/7 NFSDU.

SECTION 4 FOOD ADDITIVES

No comments are made at this stage as this issue is under consideration by the electronic Working Group coordinated by Switzerland.

SECTION 9.1.5 THE NAME OF THE FOOD

The inclusion of the section 9.1.5 will depend on whether foods for special medical purposes are included in the standard. The European Community position is that foods for special medical purposes should not be covered by this standard and therefore the first sentence of the section should be deleted.

The European Community considers that the last sentence of section 9.1.5 is independent of the first sentence. In the absence of a definition of "health claims" within Codex, it is suggested that the proposed sentence "No health claims shall be made regarding the dietary properties of the product." should remain in square brackets, and discussions deferred until "health claims" have been defined.

SECTION 9.3 DECLARATION OF NUTRITIVE VALUE

The Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985 (Rev. 1 – 1993) suggest that information on energy value should be expressed in kJ and kcal. Therefore it is proposed that the energy declaration should be in both kJ and kcal and the first part of section 9.3 (a) should be changed to: "the amount of energy, expressed in kilojoules (kJ) and kilocalories (kcal)…".

In addition the Codex Guidelines on Nutrition Labelling suggest that the values used in nutrient declaration should be weighted average values. Therefore, it is proposed that in section 9.3 (b) "total" should be changed to "average".

Section 9.1.6 "The Name of the Food" (Iron)

Consideration of this section will depend on the outcome of discussions on Section 3.1.

SECTION 9.6 "ADDITIONAL LABELLING REQUIREMENTS"

During the discussions at the 23rd session of the CCNFSDU the European Commission proposed the second alternative wording presented in Section 9.6.1.b. Unfortunately there is an error in the proposal made and it should refer to "breastmilk" rather than "breastfeeding". Thus it is proposed that the sentence should be corrected to the following:

> "b) The statement "Breastmilk is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breastmilk."

The European Community supports the inclusion of the above revised sentence in the standard and the first option for wording under section 9.6.1.b should be deleted.

Sections 9.6.1 c) and 9.6.4 refer to "independent health worker", during discussions on the proposed draft revised standard for processed cereal-based foods for infants and young children concerns were raised about this proposed wording. For the Committee's information the European Community legislation refers to "independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care".

ISDI - INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES

1. SCOPE

Section 1.1.

CODEX Proposal:

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.]

ISDI believes infant formulas and formulas intended for infants with special nutritional requirements should be dealt with separately. Otherwise, the standard becomes too complex and confusing, and may ultimately be detrimental to the health of the infant. ISDI thus proposes to remove the sentence between brackets.

Products intended for infants with special nutritional requirements are highly specific and are designed to meet the special nutritional requirements of infants not in good health and premature infants. They 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.

The most important reason that the composition and the labelling of foods for special medical purposes (FSMPs) intended for infants should not be governed under the provisions for infant formula is that the health of infants could be compromised. A standard covering both infant formula and FSMP intended for infants would necessitate amending the current Standard by inserting many exemptions which would, in effect, result in the equivalent of a standard within a standard. The Infant Formula Standard would become long, complex and confusing. It is surely not the intention that Standards should be difficult to follow; the consequence of

such complexity could lead to errors in formulation or product labelling, which could result in a potential health risk for an infant.

The practice of having separate legislation is already established 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.

The specific factors which need to be considered if the provisions for infant FSMPs are incorporated within the Infant Formula Standard are:

- There are risks of confusion and misuse if these products fall under the Scope 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.
- Infant FSMPs have specific compositions tailored to the requirements of the particular disorder, disease or medical condition, which, most of the time, need to deviate from the provisions of the Infant Formula Standard.
- Infant FSMPs are more commonly prescribed according to the bodyweight and medical condition of the infant, not usually age. Thus some of the products are used by infants/young children up to the age of 18 months while infant formula is recommended to cover age ranges from 0 to over 4-6 months).
- They should be used under health care professional supervision.
- Infant formula or breast milk may be contraindicated for certain diseases and medical conditions.
- In the interest of safe use, specific labelling provisions need to 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. Additional additives are required to satisfy the nutritional, physical and microbiological stability of the products.

Foods for Special Medical Purposes (FSMPs) intended for infants are not breast-milk substitutes. **The sentence between square brackets in section 1.1 should be deleted**.

Section 2. DESCRIPTION

Section 2.1. Product definitions

Section 2.1.2.: ISDI agrees with the present wording and favours the deletion of the square brackets.

Section 3.1. Essential Composition

ISDI is providing its comments on this particular section in its answer to Circular Letter CL 2001/47 – NFSDU (see below).

Section 3.2. Optional ingredients

4.2.1 should read **3.2.1**

Section 3.3. Vitamin compounds and mineral salts

Section 3.3.1. ISDI is providing its comments on this particular section in its answer to Circular Letter CL 2002/7 – NFSDU (ISDI Reference 02/133).

Section 4. FOOD ADDITIVES

ISDI is part of the ad hoc working group chaired by Switzerland in charge of reviewing additives provisions in infant formula and has provided its comments on this matter to the Swiss delegation (ISDI Reference 02/081).

Section 9. LABELLING

Section 9.1. Name of the Food

The statement "*The text of the label and all other information accompanying the product shall be written in the appropriate language*." should be modified because the phrase, "*the appropriate language*," implies there is one language. In reality, there are some countries where many languages are spoken, necessitating bi- and tri-lingual labels. We suggest the phrase be changed to *"in appropriate language**(s)***" which would allow flexibility for multilingual countries, in accordance with local government or regulatory agencies.

Section 9.1.5.

CODEX Proposal:

[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]]

ISDI suggests that the proposed section 9.1.5 should be replaced by the following wording:

"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;***
- ***not undermining breastfeeding."***

It is of the utmost importance that information on the dietary properties of infant formula can be communicated as:

- ISDI is concerned that lack of appropriate information may result in improper use of foods for infants and young children, thereby endangering the health of the baby. 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). 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"*.

Finally, there is no reason to prohibit the communication of relevant information through labelling and literature if it complies with the above mentioned criteria and as long as this communication remains in line with national practices and the WHO International Code on the Marketing of Breast-milk Substitutes. It should be recalled that 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*".

THE WAY FORWARD FOR SECTION 9.1.5

Many documents originating from internationally recognised bodies emphasise that well-defined rules, enabling the use of appropriate claims, would contribute to a high level of protection of human health. They

also promote the protection of the consumer by ensuring that foods bearing nutrition, functional and health claims are labelled and advertised in an adequate and clear manner allowing consumers to make an informed choice.

Guidelines for use of nutrition and health claims are currently being developed by Codex Committee on Food Labelling (CCFL) without prejudice to the specific provisions of Codex Standards or Guidelines relating to Foods for Special Dietary Uses; ISDI is participating in these discussions[1].

Such nutrition and health claims cover all information with regard to particular characteristics of a food relating to its composition and properties. The CCFL has entrusted the responsibility for developing appropriate rules for such information to the Codex Committee on Nutrition and Food for Special Dietary Uses (CCNFSDU) which is the competent committee to carry out this work.

CCNFSDU has already commenced work on identifying appropriate criteria for health claims, including the scientific basis for establishing them (*Discussion Paper on the Scientific Criteria for Health Related Claims* prepared in April 2000 by France, Denmark, Germany and the United States of America, CX/NFSDU 00/10).

ISDI urges CCNFSDU to set provisions in the Standard for Infant Formula allowing claims that are truthful, not misleading, scientifically substantiated, and that will not undermine breast-feeding.

Section 9.3. Declaration of nutritive value.

Section 9.3(b). ISDI recommends to keep the previous wording "optional ingredient" instead of "other ingredient" and to include ***"if added"*** in order to avoid any misinterpretation. The sentence should be read:

> *"the total quantity of each vitamin, mineral, choline and any **optional** ingredient **if added** as listed in….."*

Section 9.6. Additional labelling requirements

Sections 9.6.1. and 9.6.2. : Where the wording of the sections reflects very closely that of the International Code of Marketing of Breast-milk Substitutes it is acceptable. The wording used in the Code should not be modified not even slightly.

For this reason the first wording proposed for b): "*breast-milk protects against diarrhea and other illnesses*," is not acceptable. This alternative should be deleted, as this is not scientifically proven.

Section 9.6.4.: add "of" in "*from the age **of** over 6 months*"

Section 9.6.5.: delete this sentence, which is superfluous.

ISDI : Comments to CL 2001/47-NFSDU

Changes to Section 3.1.1 to Section 3.1.2 (c) proposed by the Infant Formula Composition Work Group (IFCWG) chaired by the US delegation are described in Circular letter 2001/47. ISDI was part of this working group and agrees with its recommendations except on the following points:

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."

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[1] Alinorm 03/22 Appendix VII. The following sentence has been introduced in the Scope of the Proposed Draft Guidelines for Use of Health and Nutrition Claims:

> *"[Nutrition] and Health claims are not permitted for foods for infants and young children unless specifically provided for in relevant Codex standards".*

ISDI believes this sentence is inappropriate and should be deleted since it is a repetition of what is stated in an earlier point in the Scope (a detailed rationale can be found in ISDI position 02/172 that was sent to Codex Executive Committee in June 2002).

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

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

- Point 8

ISDI strongly opposes the statement that minimum and maximum values for the essential composition of infant formula take into account nutrients in water that may be added to infant formula after it is purchased. Although, infant formula manufacturers carefully control the water insofar as it is added **before** the purchase (i.e. liquid formula), but control of water to be added **after** the formula has been purchased can only be done by Governments.

- Point 10

ISDI supports the first option: maximum amounts of essential nutrients should be established only for those nutrients for which there is sufficient evidence of adverse effect at higher levels.

SECTION 3.1.2

SECTION 3.1.2 (a) VITAMINS

VITAMIN A

Proposed by the IFCWG :

	Min /100 kcal	Max /100 kcal	Min /100 kJ	Max /100 kJ
Vitamin A*	60 µg	180 µg	14 µg	43 µg

* expressed as retinol equivalent **(RE). 1µg RE=3.33 IU Vitamin A.**

ISDI believes specifying the conversion factor of beta carotene is important and while recognising that the precise value of this factor needs review ISDI suggests using the one described in the Codex Guidelines for Nutrition Labelling i.e. **1µg RE=6µg beta-carotene**

VITAMIN D

Proposed by the IFCWG:

	Min /100 kcal	Max /100 kcal	Min /100 kJ	Max /100 kJ
Vitamin D*	~~40 I.U. or~~ 1 µg	~~100 I.U. or~~ 2.5 µg	~~10 I.U. or~~ 0.25 µg	~~25 I.U. or~~ 0.63 µg

*** Cholecalciferol. 1 µg cholecalciferol = 40 IU Vitamin D.**

ISDI propose to use **calciferol** instead of cholecalciferol since it encompasses both Vitamin D_1 and D_2 and that Vitamin D_2 has been successfully used in infant formula for many years.

NIACIN

Proposed by the IFCWG:

	Min /100 kcal	Max /100 kcal	Min /100 kJ	Max /100 kJ
Niacin, niacin equivalents	~~0.8 mg~~ **0.6 mg**	N.S.[1]	~~0.2 mg~~ **.14 mg**	N.S.[1]

Human milk contains around 1.8 mg niacin per litre, which is equivalent to roughly 0.25 – 0.30 mg per 100 kcal. At this level, there have been no reports of niacin deficiency in breast fed infants. Therefore and as described in the 1998 LSRO report, **ISDI suggests that the minimum level of preformed niacin be set at 0.55 mg/100kcal**

FOLIC ACID

Proposed by the IFCWG:

	Min /100 kcal	Max /100 kcal	Min /100 kJ	Max /100 kJ
Folic Acid	~~4 µg~~ **11 µg**	N.S.[1]	~~1 µg~~ **2.6 µg**	N.S.[1]

ISDI wishes to **retain the current minimum level of 4 µg/100 kcal** until the outcome of the European Scientific Committee on Food re-evaluation of composition criteria of infant formula becomes available.

Rationale:

The recommendation for folate at 11 mcg/100 kcal, is taken from LSRO. LSRO recommended values that were 1 standard deviation below a mean value for breast milk folate content. However, this mean value was taken from a study in which the sample size was only 4 mothers (O'Conner et al), clearly not an adequate size to support a global recommendation.

The LSRO also cited studies showing that plasma folate levels fell in formula-fed group more than in their breast fed group. In these studies the amount of folate fed to the infants was not measured, neither in the formula used, nor in the mothers' breast milk. As the mothers were being supplemented with 100 mcg folate per day, we consider that this is an inappropriate comparison, because the milk levels were undoubtedly higher than normal.

Newer data show the total folate content of human milk is higher than previously thought. However, a substantial portion of that folate is in polyglutamic acid forms, which have reduced bioavailability compared to free folic acid. The free form is the form added to formulas.

Manufacturers generally use higher amounts of nutrients than their label claim in order to compensate for manufacturing variables and shelf life stability. If the level is mandated at 11mcg (although this needs stronger justification), the real amount added would certainly be higher.

Therefore, in light of the questionable rationale for a 300% increase in levels of folate, compared to the previous Codex recommendation, and in the absence of any indication of a need for this increase, ISDI believes that the recommendation for folate should stay at 4 mcg.

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 achieved. 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[1,2] 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 by the IFCWG:

	Min /100 kcal	Max /100 kcal	Min /100 kJ	Max /100 kJ
Sodium (~~Na~~)	20 mg	~~60 mg~~ **T.B.D.***	5 mg	15 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.

POTASSIUM AND CHLORIDE

Proposed by the IFCWG:

	Min /100 kcal	Max /100 kcal	Min /100 kJ	Max /100 kJ
Potassium (~~K~~)	60 mg	~~145 mg~~ **T.B.D.***	15 mg	~~35 mg~~ **T.B.D.***
Chloride (~~CL~~)	50 mg	~~125 mg~~ **T.B.D.***	12 mg	~~29 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

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

[2] Fomon S. J Potential renal solute load: Considerations relating to complementary feedings of breast-fed infants. Pediatrics 2000; **106** (5 suppl): 1284

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[3]. 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.

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[4]
264	477		1.8		Fomon[5]
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	

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

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

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

Cow's milk (mg/l)					
Na	**K**	**Cl**	**K/Na**	**K (Na + CI)**	**Reference**
494	1415	921	2.9	1.0	EC[6]
483	1521	1050	3.1	1.0	Fomon[7]
494	1617	1051	3.3	1.0	Souci-Fachmann[8]
505	1555		3.1		USDA[9]
455	1545		3.4		Favier[10]
460	1560	1065	3.4	1.0	Allais[11], FAO[12]
Average			3.3		

CALCIUM AND PHOSPHORUS

Proposed by the IFCWG:

	Min /100 kcal	Max /100 kcal	Min /100 kJ	Max /100 kJ
Calcium (~~Ca~~)[3]	50 mg	**N.S.**	12 mg	**N.S.**
Phosphorus ~~(P)~~[3]	25 mg	~~90 mg~~ T.B.D.*	6 mg	~~22 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.

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[13] and the UK COMA report [14].

IRON

Proposed by the IFCWG:

	Min /100 kcal	Max /100 kcal	Min /100 kJ	Max /100 kJ
Iron *~~(Fe)~~	0.5 mg	1.5 mg	0.12 mg	0.36 mg
~~Iron (Fe)~~[4]	~~1 mg~~	~~2 mg~~	~~0.25 mg~~	~~0.5 mg~~

[4] ~~In formula manufactured from soya proteins, alone or in a mixture with cow's milk protein.]~~

* These levels apply to infant formula made from cow's milk that is fortified with iron and to soy-based infant formulas *(Note: This is a preliminary recommendation. Please refer to comments below)*. If an infant formula made from cow's milk is not fortified with iron, then the labelling of the product needs to indicate that it may contain insufficient iron.

ISDI requests that a higher maximum level is set for iron:

Max iron = 2.5 mg/100 kcal

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

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

[8] Souci S.W., Fachman W., Kraut H., Food consumption and nutrition tables, WVG Ed, Stuttgart, 1981/82

[9] USDA. Composition of foods, dairy and eggs products. Agricultural Handbook 8-1. Washington D.C., 1976

[10] Favier J.C. Composition du lait de vache I. Lait de grand mélange. Cah Nutr Diet 1985;20:283-91

[11] Allais C. Science du lait. Paris : Edition Sepaic, 1984

[12] Le lait et les produits laitiers dans la nutrition humaine. Collection FAO. Alimentation et nutrition, 1998;28

[13] LSRO report pm Assessment of Nutritional Requirements for Infant Formulas 1998

[14] UK COMA report on Artificial Feeds for the Young Infant (1980)

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:

	Min /100 kcal	Max /100 kcal	Min /100 kJ	Max /100 kJ
Iodine ~~(I)~~	5 µg	~~N.S.*~~ **T.B.D.***	1.2 µg	~~N.S.*~~ **T.B.D.***

* To be determined when sufficient data are available to establish levels.

ISDI supports the proposed minimum level for iodine, but believes that the maximum level should be N.S. (Not Specified) instead of T.B.D. **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 by the IFCWG:

	Min /100 kcal	Max /100 kcal	Min /100 kJ	Max /100 kJ
Selenium (Se)	~~7 µg~~ **6 µg**	~~3 µg~~ **T.B.D.**.	~~N.S.~~[1] **1.4**	~~0,7 µg~~ **T.B.D.**

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 (2000), 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.
2. Other studies indicate significantly lower average selenium levels in mother's milk.
3. 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.
4. The EU legislation presently sets a maximum level of 3 µg/100kcal in formulas with added selenium[15,16]
5. It is questionable whether average levels found in human milk represent the minimum requirement of infants.
6. None of the members (including the US delegation) of the virtual working group have requested a minimum level of 6 microgram/100 kcal.

[15] EU Directive 91/321/EEC on infant formulae and follow on formulae

[16] SCF Opinion on the essential requirement for infant formulae and follow-on formulae, expressed in September 1993

7. 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 the draft standard or by IFCWG

		Per 100kcal		Per 100kJ	
	Units	MIN	MAX	MIN	MAX
Vitamins					
Vitamin A[a]	µg	60	180	14	43
Vitamin D[b]	µg	1	2.5	0.25	0.63
Vitamin E Expressed as alpha-tocopherol equivalent in alpha-TE	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**	**0.55**	N.S.	**0.13**	**N.S.**
Vitamin B6	µg/g protein	15 but in no case less than 35µg/100 kcal	N.S.	15 but in no case less than 9 µg/100 kcal	N.S.
Folic acid	µg	**4**	N.S.	**1**	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.
Minerals					
Sodium	mg	20	**60**	5	**15**
Potassium	mg	60	**200**	14	**48**
Chloride	mg	50	**150**	12	**36**

		Per 100kcal		Per 100kJ	
	Units	MIN	MAX	MIN	MAX
Calcium[c]	mg	50	N.S.	12	N.S.
Phosphorus[d]	mg	25	**90**	6	**22**
Magnesium	mg	5	15	1.2	3.6
Iron[e]	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.**[f]	**N.S.**	**T.B.D**[f]
Choline	mg	7	N.S.	1.7	N.S.
Carnitine	**µg**	**1.2**	**N.S.**	**0.3**	**N.S.**

[a] Expressed as retinol equivalent (RE). 1µg RE=3.33 IU Vitamin A
1µg RE=6 µg beta-carotene

[b] ~~Cholecalciferol~~ **Calciferol**. 1µg ~~cholecalciferol~~ **calciferol**=40 IU Vitamin D.

[c] The calcium to phosphorus weight to weight ratio shall not be less than 1.2 and not more than 2.2

[d] These levels apply to infant formula made from cow's milk that is fortified with iron and to soy-based infant formulas (Preliminary recommendation from the IFCWG)

[f] only if added

SECTION 3.1.2 (d) PROTEIN

♦ **PROTEIN (d) (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.

♦ **PROTEIN (d) (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**

♦ **PROTEIN (d) (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.

♦ **PROTEIN (d) (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 inalterable 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**

♦ **PROTEIN (d) (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.

(e) 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[17]).

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%[18,19]. A third study, which has just been completed[20] 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

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[17] 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.

[18] 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.

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

[20] 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

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)

	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) [21].

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%)[22,23,24,25,26,27,28,29]. There have been no studies showing impaired neural functions due even to these extreme diets.

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

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

[23] 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.

[24] 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.

[25] 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.

[26] 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.

[27] 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.

[28] 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.

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"[30].

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 %.[31]. 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

(f) CARBOHYDRATES

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

(g) 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).

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[29] 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.

[30]. 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

[31] Chen ZY,Pelletier G,Hollywood R,Ratnayake WMM.trans Fatty acids in Canadian human milk.Lipids 1995;30:15-21.

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)".

SECTION 3.3 VITAMIN COMPOUNDS AND MINERAL SALTS

ISDI has provided detailed comments to the German delegation in charge of developing a proposal for this section (ISDI ref: 02/133)

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

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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)".

2.1 Despite the subtitle "product definition", the term "infant formula" is never, in fact, explicitly defined anywhere in the draft revised standard. The following recommended text, which should come first, is an amalgam of the definition of infant formula found in the International Code (Article 3) and current language in paragraph 2.1.2:

> 2.1.1 ***Infant formula*** means a breast-milk substitute formulated industrially 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 should be accepted for marketing as infant formula.
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> 2.1.2 When in liquid form, infant formula may be used either directly or prepared with safe, and previously boiled, water before feeding according to directions for use. In powdered form, infant formula also requires safe, and previously boiled, water for its preparation. [In the context, the word "potable" appears to be redundant.]
>
> 2.1.3 [No change]

9.6.1 Where the first 9.6.1 b) is concerned, the use of the word "or" is awkward, as if there were a choice between breastfeeding or breast milk. Using Article 9.2 (b) of the International Code as 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;

The second 9.6.1 b) is no longer required. If retained, however, the words "**Breastfeeding** is the best food for your baby" should read "**Breast milk** is the best food for your baby".

9.6.1 Consistent with Article 9.2, point (c) of the International Code, the word "only" in c) should modify "on". Thus, the text 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;

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 The square brackets should be removed. The word "prevent" should replace the word "avoid".