codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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

Agenda Item 5 **CX/NFSDU 01/5**
September 2001

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
Twenty-third Session
Berlin, Germany, 26-30 November 2001

PROPOSED DRAFT REVISED STANDARD FOR INFANT FORMULA

- Comments at Step 4 of the Procedure -

Comments from:

GERMANY
JAPAN
MALAYSIA
MEXICO
NEW ZEALAND
POLAND
SPAIN

ISDI - International Special Dietary Foods Industries

GERMANY

ad 1. SCOPE

1.1. Proposal: *"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 2nd sentence in square brackets should be deleted.

Justification: In our opinion the statement that these products meet the normal nutritional requirements of healthy infants just as human milk is sufficient to characterize the products. The word "healthy" may be deleted since the "normal" nutritional requirements of infants refer to healthy infants. At the same time the nutrition of (sick) infants with special nutritional requirements mentioned in square brackets may be deleted since these are not to be regulated by this Standard.

1.3 Proposal: The current text should be replaced by "*In addition to the requirements mentioned in 1.2 special labelling provisions in accordance with the International Code of Marketing of Breast-milk Substitutes are made to ensure proper use of these products and to prevent detrimental effects on breastfeeding"*.

Justification: In the present Standard the labelling requirements have to comply with the International Code of Marketing of Breast-milk Substitutes **(Article 9)**.

All other requirements of the Code cannot be enforced by a Standard.

ad 2. DESCRIPTION

2.1.2 : The sentence should be divided into two parts rewording the part of the sentence in square brackets. Then the second sentence should read as follows: *"Given as a sole food instead of breast milk it must provide for the nutritional requirements of infants during the first four to six months of life"*.

Justification: Thus it would be avoided to attribute a higher nutritional value to infant formula than to human milk since the former is described as substitute for food, and at the same time it is requested that when it is consumed as the sole food it has to satisfy the need for all kinds of nutrient.

ad 3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1.2 Proposal: *"Infant formula **ready for consumption** 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 acids and carbohydrates"*.

Amendments: "Fatty acids" should be used in the plural and the word "energy" should be deleted from the enumeration. The data included in the tables refer to the ready-to-eat form of the product.

3.1.2a and b: We hold the view that it is not necessary to stipulate maximum values for vitamins, except for **vitamin A** and **D**. A survey of German infant formula shows that vitamins are added in quantities of not more than three times the minimum value

We can agree to the additional stipulating of a protein-related minimum content of **vitamin B_6**.

The maximum amount for **sodium** related to 100 kJ ought to be 14 mg instead of 15 mg, in accordance with the EU Directive.

The minimum and maximum amounts for iron indicated in the table refer to infant formula, which is to be labelled as enriched with iron.

The minimum amount of 7 µg for **selenium** related to 100 kcal was caused by a mistake.

We would approve of the amendments to the regulations concerning **copper** and **manganese** (Determination of a maximum value). In our opinion no minimum amount for **fluoride** should be stipulated since usually its content in the ready-to-eat form of the product is determined by the fluoride content of the water used. We would approve a maximum amount for fluoride being stipulated.

3.1.2 c We consent to a minimum amount of 7 mg/100 kcal and/or 1.7 mg/100 kJ.

3.1.2 d The **quality of the protein** used **should** be determined **on the basis of the amino acid score** and the **quality of the finished product on the basis of the existing request that - related to energy - the food has to provide at least the same amounts of all indispensable and conditionally indispensable amino acids as those contained in human milk.**

Our proposal: *"The amino acid score shall mean the lowest of the ratios between the quantity of each indispensable [and conditionally] indispensable amino acid of the protein and the quantity of each corresponding amino acid of the reference protein (breast milk protein, as defined in Annex 1)*

Justification: "amino acid score" and "indispensable amino acid" are the correct terms.

Then the following text would have to be inserted into **section 3.1.2 d ii**: *"The amino acid score of the protein/protein mixture shall not be less than 1 [0.9]".*

Justification: Thus the quality of the protein used would be regulated irrespective of the subsequent request which, however, would have to be changed.

Proposal: *"For an equal energy value, the formula must contain at least the same quantity of each indispensable and conditionally indispensable amino acid as that provided by the reference (human milk, as defined in Annex 1)".* In our opinion the second part of the paragraph dealing with methionine and cystine should be deleted. The subsequent paragraph in square brackets should be deleted as well.

Justification: Linguistic streamlining. It should not be admissible to consider **methionine** and **cystine** as substances which can replace each other completely. Small infants have a minimum need for both of them.

In our opinion there is no nutritional necessity for deviating from the indicated requirements as to quantity and quality of the protein.

Appendix I, however, would have to be changed (see below).

3.1.2 e This paragraph should be rearranged:

- fat contents
- linoleic acid contents
- alpha-linolenic acid contents
- linoleic/alpha-linolenic acid ratio
- trans fatty acids
- erucic acid content

3.1.2 f When calculating the energy value on the basis of the required **carbohydrate** contents it is remarkable that they are incompatible with stipulated minimum and maximum contents for fat. The minimum content of carbohydrates thus has to be raised to 8g/100kcal, the maximum content has to be reduced to 13 g/100 kcal.

Examples of calculation based on the current prerequisites: 7 g carbohydrates and 3 g protein/100 kcal would require 6.7 g fat/100 kcal, however, only 6.5 g fat/100 kcal are permitted.

14 g carbohydrates and 1.8 g protein/100 kcal would, at most, allow a fat content of 4.0 g/100 kcal whereas 4.4 g/100 kcal are stipulated at present.

Moreover the carbohydrates should be declared as **"digestible"** since the quantitative limits only refer to digestible carbohydrates.

Infant formula should be **gluten-free**.

3.1.2 g Proposal: This paragraph stipulating the limits for the energy content ought to precede section 3.1.2 with the contents of which it has nothing to do. It should be referred to as number 3.1.2. **The current sections 3.1.2 a to f would then become 3.1.3 a to f.**

Accordingly the sections 3.2.1 and 3.3.1 would have to refer to 3.1.3 a and b (not c) and/or 3.1.3 a and b (not c and d).

3.2 Proposal: *In addition to the vitamins and minerals listed under 3.1.3 (a) and (b) other nutrients may be added when required and in conformity with national regulations in order to provide other nutrients ordinarily found in human milk".*

Justification: The request that infant formula has to be suitable as a sole food source for small infants has already been included **in section 2.1.2** and does not have to be repeated. Otherwise it would be assumed that the prerequisites hitherto are not sufficient to comply with this request.

ad 4. Additives:

The list should be revised pursuant to the proposal of the Netherlands (CX/NFSDU 00/6 - Add. 1) and pursuant to the General Standard for Food Additives. The list of the Netherlands also mentions flavours and enzymes in its heading which we cannot accept. However, the list submitted does neither contain flavours nor enzymes.

Another criticism of the list in CX/NFSDU 00/6 - Add. 1 from our part concerns the use in products which are not regulated in the present Standard (foods for special medical purposes and complementary food).

We can agree to all thickeners suggested for infant formula except for **carrageen**.

The same also applies to the enlarged list of emulsifiers. In our opinion **lecithine** should be restricted to 1 g/L in the ready-to-eat form of the product and should be specified as phosphatidylcholine.

ad 9. Labelling

9.1.4 The square brackets around the whole section and around "may" should be deleted.

9.1.5 This section should be left in square brackets until it has been decided whether this Standard or parts of it shall also be applied to foods for special medical purposes.

Our proposal for 9.1.5*: "Information on special compositional properties of the product may be given on the label. This information is restricted to the absence or presence of lactose, saccharose and iron and to the whey/casein ratio in formula based on cow´s milk protein".* **Or***: "Only claims on compositional properties of an infant formula are permitted".*

Justification: This objective information may influence the choice of the product. In this context it is not a matter of health claims. **Health claims** as they have been and are defined in the Guidelines for Use of Nutrition Claims should not be permitted for infant formula.

9.1.6 After our proposal for 9.1.5 has been made, the first alternative can be deleted. The second alternative should be maintained without square brackets.

9.6.1 b: We support the text without square brackets and the deletion of the square brackets and their contents.

9.6.4 We support the deletion of the square brackets and a change of the wording as follows: *"Information that infants over six months of age should receive complementary foods (Beikost) in addition to infant formula or follow-up formula shall appear on the label".*

9.6.5 This section should be deleted since according to the labelling stipulated in sections 9.1.1 and 9.6 a confusion with follow-up formula seems to be ruled out.

Annex 1 Our proposal

Indispensable and conditionally indispensable amino acids in breast milk

For the purpose of this standard the indispensable and conditionally indispensable amino acids are the following

	expressed in g/100 g crude protein	**expressed in mg/100 kcal**
arginine	5,1	92
cystine	2,1	38
histidine	2,6	47
isoleucine	4,6	83
leucine	9,3	167
lysine	6,6	119
methionine	1,1	20
phenylalanine	3,6	65
threonine	4,3	77
tryptophane	1,7	31
tyrosine	4,0	72
valine	5,5	99

Justification

The amino acid pattern which, further to a proposal from Canada in 1998, replaced the original amino acid pattern, is, as far as histidine, isoleucine, leucine, lysine, threonine, tryptophane and valine are concerned, based on the values of FAO/WHO/UNU (1985: Energy and Protein Requirements, WHO Technical Report Series No. 724), indicated in g amino acids per 100 g crude protein (total nitrogen content x 6.25). These values, although being derived from the data referring to a protein content of 1.64 g protein per 100 ml, were converted into a crude protein content of 1.8 g /100 kcal (the minimum protein content in the present Standard) and indicated as mg/100 kcal. Since the individual values for methionine and cystine and for phenylalanine and tyrosine were missing in these lists (respectively indicated as a sum of both values) and also a value for arginine, the data of Sarwar et al. (J. AOAC Int. 79(1996)498-502) were added for arginine, cystine, methionine, phenylalanine and tyrosine. These values, however, refer to transitory milk (5^{th} to 10^{th} day postpartum) with a relatively high crude protein content of 1.5 g/100 ml and they have been indicated in g/100 g "true protein" resulting from the total amount of anhydrous amino acids measured and constituting 85 % of the crude protein content. Therefore we have converted the **data of Sarwar et al. (1996) for arginine, cystine, methionine, phenylalanine and tyrosine to the crude protein content** (N x 6.25) and replaced them in the table.

JAPAN

Section 3.1.2

Table of vitamins and minerals

(1) "Niacin, niacin equivalents" should be "Niacin". We propose to be modified as follows:

	Amounts per 100 kilocalories		Amounts per 100 kJ	
	Minimum	Maximum	Minimum	Maximum
(a) Vitamins				

Niacin	0.25 mg	N.S.	0.06 mg	N.S

(2) Vitamin K_1 should be modified as "Vitamin K" or "Vitamin K_1, and/or K_2"

(3) In upper limit of the Ca:P ratio, brackets (e.g. [2.0]) should be removed:
"The Ca/P ratio shall be not less than 1.2 and not more, than 2.0."

Reasons for the proposal:

(1) Japan considered that the conversion ratio of tryptophan to niacin in infant is very low level compared to adult.

(2) In breast milk vitamin K is composed of K_1 and K_2, and vitamin K_2 accounts for nearly 20 % of vitamin K.
Therefore the products containing vitamin K_1 and K_2 are preferred.
In Japan the products containing vitamin K_2 are marketed.

(3) The contents of Ca and P in infant formula are much higher than those in breast milk. It is important that the contents of P and Ca should be reduced by optimizing the balance between the two, so Japan supports the Ca/P ratio in the bracket.

(e) Fat and fatty acid

The provisions that the trans fatty acid shall not exceed 4 % of the total fat content should be discussed based on risk analysis.

Reasons for the proposal:

According the data obtained from the laboratory in Japan, which have been determined trans fatty acids contents in various types of refined oil by the AOAC method, many of them exceed 4 % of the total fat (Table 1).
Japan thinks that the risk analysis on the content of trans fatty acid have not been discussed yet, therefor the prudential discussion is needed.

Table 1

	Content of trans fatty acid
Soybean oil	3.9 %
Palm olein oil	3.9 %
Palm kernel oil	4.3 %
Coconut oil	4.8 %
Canola oil	4.8 %
MCT	4.7 %

Section 4.4

We propose adding L-ascorbyl stearate as follows.

4.4.3 L-Ascorbyl stearate 1 mg in all types of infant formula

Reasons for the proposal:

L-ascorbyl stearate is listed in Table 1 of Draft Codex General Standard for Food Additives, in preparation by Codex Committee on Food Additives and Contaminants.

The draft standard of its use (max. level 50 mg/kg (at step 6)) is proposed in food group for infant formula (Food Cat. No. 13.1).

And the Japanese Ministry of Health , Labor and Welfare allows the use of not only L-ascorbyl palmitate, but also L-ascorbyl stearate, as food additives in infant formula.

Section 9.1.6

Japan thinks that the labelling of adding iron should be generally voluntary.

Reasons for the proposal:

Labelling of adding iron is needed for all products fit for the proposed draft standard.

ANNEX 1 Essential and semi-essential amino acids in breast milk

In determining the amino acid composition as NRV, it should be considered which secretion period of breast milk is appropriate to be referred, and then the amino acid composition of the breast milk of the specified period should be reviewed.

In the point of view Japan thinks the discussion is insufficient.

Reasons for the proposal:

The protein content in colostrum is the highest and it becomes lower day by day even after 1 month after delivery. The amino acid content also varies in parallel.

Therefore, to specify the secretion period of breast milk is important in determining NRV of amino acid composition.

Japan thinks that a part of data as a reference for NRV is based on the transitional milk on the 5th to 10th days of delivery from 12 mothers.

Investigations are conducted for determining the amino acid composition of the breast milk collected from several thousand mothers are published. These surveys are also conducted in consideration of secretion period, region, season, and background of breast milk such as mother's health and baby's development conditions.

The value of the investigations are shown in Table 2 below.

Table 2

(mg/100kcal)

	ALINORM 99/26	CX/NFSDU 98/7 ANNEX 1	Yonekubo et al. 21 days - less than 3 months	Itoda et al. 16-60 days
Arginine	107	69	65.3	66.2
Cystine	44	24	34.8	45.1
Histidine	47	45	43.5	46.8
Isoleucine	83	72	110.3	96.3
Leucine	167	156	195.9	183.4
Lysine	119	122	123.4	125.6
Methionine	23	29	27.6	26.2
Phenylalanine	75	62	71.1	71.4
Threonine	77	80	78.4	88.1
Tryptophan	31	30	36.3	29.4
Tyrosine	85	59	72.6	75.5
Valine	99	80	107.4	88.0

Notes: Yonekubo et al. (21 days to less than 3 months): J. Japanese Soc. Nutr. Food Sci. (1989) 42, 194.
Itoda et al. (16 to 60 days on average): Japanese P. Pediatric Gastroenterology and Nutrition (1991) 5, 209.

MALAYSIA

Section 1 Scope

Section 1.3

Malaysia proposes to remove the square brackets in section 1.3 and adopt the text contained in the brackets and to add the statement "……..*as well as relevant National Codes*" after the word "*to date….*".

This section is to read :

The application of the Standard should take into account the recommendations given to countries under the International Code of Marketing of Breast-milk Substitutes and relevant World Health Assembly Resolutions as well as relevant National Codes.

Section 2.1 Product Definition

Section 2.1.2

Malaysia proposes to delete the square brackets and adopt the text in the brackets.

This section is to read :

Infant formula shall be nutritionally adequate to promote normal growth and development when used in accordance with its directions for use and to satisfy by itself the nutritional requirements of infants during the first four to six months of life.

Section 3.1 Essential Composition

Section 3.1.2 d(ii)

Malaysia proposes to delete the text in square brackets in section 3.1.2d (ii), i.e 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.

Section 3.1.2 e

Malaysia would like to propose the reduction of the level of trans-fatty acids in the Proposed Draft to not exceeding 1% of the total fat content. The level of trans fatty acids in infant formula should be kept to the minimum as these fatty acids have been proven to be detrimental to human health.

Section 9.1 The name of the food

Section 9.1.4

Malaysia proposes to replace the word "may" in the square bracket with "shall" and delete all the square brackets in section 9.1.4 so as not to mislead the consumers.

This section is to read :

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

Section 9.1.5

Malaysia proposes to delete the square brackets and adopt the text in the brackets. However, to allow for certain specially formulated infant formula products to be clearly identified and thereby assisting the consumer in the choice of such products, Malaysia proposes to add a sentence to the end of the section.

The section is now to read :

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.

For products that are specially processed or formulated to satisfy well recognized and particular dietary requirements known to exist as a result of a physical or physiological conditions or specific disease or disorder or both, a statement giving the physical or physiological condition may be given on the label.

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.

Section 9.3 Declaration of nutritive value

In section (b) the words "when added" should be inserted in the first line after the words "optional ingredients".

Section 9.6 Additional Labelling Requirements

Section 9.6.1

Malaysia proposes to delete the square brackets and adopt the text in the brackets, except the phrase:

i) 9.6.1 (b) : "it protects against diarrhoea and other illnesses", to be in line with the International Code of Marketing of Breast Milk Substitutes by WHO.

ii) 9.6.1.(c) :The word "independent" before the word "…health worker".

This section is therefore to read :

Label should not discourage breast feeding. Each container label shall have a clear, conspicuous and easily readable message which includes the following points : a) the word "important notice" or their equivalent; b) a statement of the superiority of breast-feeding or : the statement : Breast milk is the best food for your baby; c) a statement that the product should only be used on advice of a health worker as to the need for its use and the proper method of use; d) instructions for appropriate preparation; and e) a warning against the health hazards of inappropriate preparation.

Section 9.6.4

Malaysia proposes to remove the square brackets in section 9.6.4 and adopt the text contained in the brackets.

This section is to read :

Information that infants over six months of age should receive supplemental foods in addition to the formula shall appear on the label.

Section 9.6.5

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

This section is to read :

The products shall be labeled in such a way as to avoid any risk of confusion between infant formula and follow-up formula.

MEXICO

1. SCOPE

1.1 The text should be amended follows: "This standard applies to infant formula in liquid or powdered form intended for use as a substitute for human milk in meeting the normal nutritional requirements of healthy infants whenever breast-feeding by the mother does not take place for justified reasons."

We propose deleting the text in square brackets in Paragraph 1.1 stating that the provisions in this standard are intended for infants with special nutritional requirements, since the specifications laid down in Paragraph 3.1 regarding the "essential composition" are aimed at healthy infants. If necessary, the particular cases for which this special composition applies should be considered.

2. DESCRIPTION

We request that the term ***"infant formula"*** be defined. In doing so, the WHO's International Code of Marketing of Breast-Milk Substitutes must be taken into account. However, consideration must also be paid to the fact that "substitute for human milk" is also defined in the aforementioned code, and that Paragraph 3.1.1 contains a description of the product. Mexico is of the opinion that Paragraphs 2.1.1, 2.1.2 and 2.1.3 are not product definitions but instead regulations or specifications regarding the product.

2.1.2 We propose that the square brackets in this paragraph be deleted and that the wording be changed as follows: "The products must by themselves satisfy the nutritional requirements of infants during the first six months of life."

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1.1 We propose deleting *"including fish"* since the usage of fish is already implied by "edible constituents of animal" and thus need not be emphasised by the above reference. Moreover, the word *"adecuados"* should be replaced by *"aptos"* (Translator's note: This amendment only applies to the Spanish version).

3.1.2 We propose deleting the brackets in "(or 100 kilojoules)" so that the text reads *"per 100 kcal or 100 kJ"*.

The square brackets around the table in Paragraph 3.1.2 should be deleted.

3.1.2 Paragraph d) ii) third paragraph. The square brackets should be deleted and the statement that the quantity of protein may be modified should be retained.

We propose deleting the square brackets around the footnotes to the table and retaining the wording of the notes.

In Paragraph 3.4, the term "Lactante de corta edad" (young infants) should (in the Spanish version) be replaced by "Lactante" (infants).

In Paragraph 3.5 we propose replacing "Purity requirements" by "Quality requirements".

In Paragraph 4 we propose deleting the square brackets and retaining the additives suggested.

In the fourth item of Paragraph e), we propose (Translator's note: In the Spanish version) replacing "á-Linoléico" (alpha-linoleic acid) by "á-Linolénico" (alpha-linolenic acid), as this is the form in which linolenic acid occurs.

9. LABELLING

We propose deleting the square brackets around Paragraph 9.1.4, retaining the wording, and replacing the word "may" by "must", so that stating on the label that the product is free of milk and milk products is not optional.

We propose deleting the first paragraph of Paragraph 9.1.5, which refers to products for infants with special nutritional requirements, and removing the square brackets surrounding the second paragraph, so that this provision applies to "products for healthy infants".

We propose deleting Paragraph 9.1.6. This paragraph states that products containing not less than 0.5 mg iron are to be labelled "Infant Formula with added Iron", even though this is the minimum amount required to correspond to the iron content of breastmilk. The second paragraph allows the possibility of even lower iron content.

Paragraph 9.5.1 should say ”on the label ***and*** on the ... leaflet” so that the preparation directions are given in both cases and the option of choosing one or the other is not granted, especially for products only coming with an accompanying leaflet.

In Paragraph 9.6.1, the square brackets should be deleted and the wording ”Or: the statement: Breastmilk is the best food for your baby, it protects against diarrhea and other illnesses” should be retained.

Paragraph 9.6.2 should be divided as of ”The label may have...”, and the provision contained in the following section should be made binding by the following wording: ”The label must have graphics....”

We propose deleting the square brackets in Paragraphs 9.6.4 and 9.6.5 and retaining the statements that infants over six months of age should receive supplemental foods, and that a distinction is to be drawn on the label between infant formula and follow-up formula.

In addition, the group believes the following editorial changes need to be made in the Spanish version to ensure its correct interpretation. The specific changes have all been emphasised in bold type:

1.1 We propose replacing ”Igualmente sirve de norma para” (The provisions in this standard are intended for...) by ”Igualmente aplica a” (It also applies to...).

2.1.1 We propose deleting ”Salubre” (Translator’s note: ”healthy ”, used here in the sense of ”safe”) and retaining ”agua potable” (potable water) so that the paragraph reads as follows:

2.1.1 El preparado para lactantes, cuando se halla en forma líquida, puede usarse directamente o bien diluirse con **agua potabl**e, hervida previamente a la administración, según cada caso. La forma en polvo, necesita ser disuelta en **agua potable** hervida previamente. (Infant formula, when in liquid form, may be used either directly or diluted with **potable**, previously boiled water before feeding, as appropriate. In powdered form it requires **potable**, previously boiled water for preparation.)

2.1.2 El preparado para lactantes, deberá ser nutricionalmente adecuado para **asegurar** el crecimiento y desarrollo **normal** cuando se emplee de acuerdo con **las respectivas** instrucciones de uso **y así,** satisfacer por sí sólo las necesidades **nutricias** de los lactantes durante sus primeros cuatro a seis meses de vida. (Infant formula shall be nutritionally adequate to **ensure** normal growth and development when used in accordance with its **relevant** directions for use **and hence** to satisfy by itself the nutritional requirements of infants during the first four to six months of life.)

2.1.3 El preparado para lactante se elabora y se envasa **de tal manera que se evite su alteración y contaminación** en condiciones normales **de manipulación, almacenamiento y** distribución. (**Infant formula is to be** processed and packaged **such** that under normal conditions of **transport, storage** and distribution **its spoilage and contamination are ruled out**.)

2.2.1 **Por lactante**s, se entienden los niños **menores** de doce mese de edad. (The term ***infant*** means a person **under** 12 months of age.)

3.1.2 El preparado para lactantes, debe **estar constituido de tal manera que por cada** 100 kilocalorías o cada 100 kilojulios **ingeribles,** contenga las siguientes cantidades mínimas y **máximas de energía alimentaria, proteína, lípidos, hidratos de carbono, vitaminas y minerales de adecuada biodisponibilidad;** (Infant formula **must be made** such that it contains per 100 **metabolisable** kilocalories or per 100 **metabolisable** kilojoules the following minimum and **maximum levels of energy, protein, lipids, carbohydrates, vitamins and minerals of adequate bioavailability:)**

4 Paragraph e, fifth item: el contenido de **ácidos grasos** trans no debe superar el 4% del contenido total de grasa; (the **trans fatty acid** content [Translator’s note: In the Spanish text ”trans fatty acids” appears in the plural] shall not exceed 4% of the total fat content;)

4 Paragraph f – the term ”carbohidratos” is to be replaced by ”hidratos de carbono” (Translator’s note: Both mean ”carbohydrates”) while ”nutriente” should be replaced by ”nutrimentos” (Translator’s note: Both mean nutrients).

3.5 Todos los ingredientes estarán limpios, serán de buena calidad e inocuos **y tolerados** por los lactantes. Se ajustarán a los requisitos normales de calidad tales como color, olor y sabor. (All ingredients shall be clean, of good quality, safe and **digestible** by infants. They shall conform with their normal quality requirements, such as colour, flavour and odour.)

5.1 El producto deberá prepararse con especial cuidado, mediante buenas prácticas de fabricación, a fin de eliminar totalmente los residuos de plaguicidas **que haya requerido la producción**, almacenamiento o elaboración de las materias primas o del producto final, o si ello es técnicamente imposible, de eliminar la mayor cantidad posible **de dichos residuos**. (Translator's note: This amendment only applies to the Spanish version.)

7.2 Los recipientes, incluidos los materiales, **solo serán fabricados con** sustancias inocuas y adecuadas para el uso ... (Translator's note: This amendment only applies to the Spanish version.)

9.1 We propose replacing the term "Idioma" by "lenguaje" (Translator's note: Both mean "language").

9.3 Paragraph b) – The statement "...Además, se permitirá ...", (In addition ... is permitted) is to be augmented as follows:

Además, en el caso de nutrimentos específicos se permitirá.... (In the case of special nutrients, in addition ... is permitted....)

9.4.1 We propose replacing "mediante" by "señalando", so that it reads: "Consumir preferentemente antes del"), **señalando** el día, el mes ..." (Translator's note: This amendment only applies to the Spanish version.)

9.6.1 We propose changing the end of the paragraph as follows: "... y e) advertencias acerca de los riesgos para la salud que pueden derivar de una preparación **inadecuada y de** que deberá **desecharse** todo sobrante **del preparado."** (Translator's note: This amendment only applies to the Spanish version.)

NEW ZEALAND

Section 1.1 - New Zealand does not support the coverage of infant formulas for special medical conditions under the general standard for infant formula, as per the square bracketed text.

Section 2.1.2 - New Zealand supports the inclusion of wording in square brackets that infant formula shall satisfy the nutritional needs of the infant for the first four to six months of life. This is consistent with national nutrition guidelines and recommendations in New Zealand.

Section 3 - New Zealand supports the operation of a working group (para 70 of Alinorm 01/26) to consider the essential compositional factors, including the values for amino acid content of infant formula, and the expression thereof in relation to energy or protein.

Section 3.1.2 - New Zealand questions whether there should be an upper limit given ti niacin, given the United States' new upper limits. We note that there may be a mistake in the figures given for selenium, as the maximum figure is lower than the minimum. We also suggest that the figures for choline be reviewed, as there is no minimum value stated per 100 kilocalories, while there is a maximum value per 100 kilojoules. Finally, in clause (e), we query whether DHA can be optional.

Section 9.1.4 - New Zealand supports inclusion of the square-bracketed text.

Section 9.1.5 - New Zealand does not support addressing special purpose formula within the general standard.

Section 9.1.6 - The issue of added iron labelling is complex, as the scope of the Standard is for infants aged up to 12 months of age, even though some infants may change to follow-on formula at six months. It is therefore difficult to prescribe a blanket statement on iron that is accurate across all age groups. Neither of the proposed statements in section 9.1.6 is acceptable to New Zealand, as all infant formula must contain

more than 0.5 mg of iron per 100 kilocalories, according to the table in section 3. We recommend development of a statement that provides the correct information to caregivers that the iron content of follow-on formula is superior to cow's milk. Finally, New Zealand does not support added iron statements on infant formula that is not follow-on formula.

POLAND

p 4. We accept only – 4.1.1. Guar Gum – 1 g/l,
4.1.2 Locust bean gum – 1 g/l,
4.1.7 Carrageenan – 0,3 g/l

If more than one of the substances above mentioned is added to a foodstuff, the maximum level established for that foodstuff for each of those substances is lowered with that relative part as is present of the other substances together in the foodstuff.

4.2.1 Lecithin – 1 g/l,
4.2.3 Mono- and diglycerides – 4 g/l,
4.3.9 Potassium citrate,
4.3.10 L(+)Lactid acid – quantum satis,
4.3.12 Citric acid – q.s.,
4.4.1 Mixed tocopherols concentrate – 10 mg/l
4.4.2 L-Ascorbyl palmitate – 10 mg/l.

We do not agree to use for infant formula –

4.1.6 Hydroxypropyl starch,
4.3.2 Sodium hydrogen carbonate,
4.3.5 Potassium hydrogen carbonate.

p.5. According to our food legislation maximum limits of heavy metals for infant formula should be no more than:

Pb	0.10 mg/kg,	
Cd	0.01 mg/kg,	
Hg	0.005 mg/kg,	
As	0.10 mg/kg,	
Zn	35.00 mg/kg	/except products enriched zinc compounds/,
Sn	10,00 mg/kg.	

SPAIN

Re Section 1. Scope

- As we agree with the content of the wording in brackets in Section 1.1, we propose that the brackets be removed.
- We believe the passage "... and relevant World Health Assembly Resolutions [to date]" to be unnecessary and propose that it be deleted.

Re Section 2. Description

- In Section 2.1.1, "... safe, potable, and previously boiled water" should be replaced by "... potable water".

- As we agree with the content of the wording in brackets in Section 2.1.2, we propose that the brackets be removed.

Re Section 3. Essential composition and quality factors

- In the table, the following **zinc values**:

"	Amounts per 100 kilocalories		Amounts per 100 kilojoules	
	Minimum	Maximum	Minimum	Maximum
Zinc (Zn)	0.5 mg	N.S.	0.12 mg	N.S."

should be replaced by the following:

"	Amounts per 100 kilocalories		Amounts per 100 kilojoules	
	Minimum	Maximum	Minimum	Maximum
Zinc (Zn)	0.5 mg	1.5 mg	0.12 mg	0.36 mg"

- - Moreover, in the table the following choline values:

"	Amounts per 100 kilocalories		Amounts per 100 kilojoules	
	Minimum	Maximum	Minimum	Maximum
Choline	N.S.	N.S.	1.7 mg	N.S."

should be replaced by the following:

"	Amounts per 100 kilocalories		Amounts per 100 kilojoules	
	Minimum	Maximum	Minimum	Maximum
Choline	7 mg	N.S.	1.7 mg	N.S."

Under "Protein", we propose deleting the final paragraph (in brackets) of Section ii), as in our opinion this could lead to technical obstacles in the international foodstuffs trade.

Re Section 4. Food additives

Section 4.1 Thickening agents

- In the column headed "Maximum level in 100 ml of the ready-to-drink product", we propose **replacing** the text "0.1 g in all types of infant formula" for the additive guar gum by **"0.1 in all liquid products which contain partially hydrolyzed proteins"**.
- We propose **deleting locust bean gum as an additive.**
- **The usage of chemically modified starches is not technically justified.** There is a choice of other thickening agents. In addition, starches containing phosphorus could affect the calcium–phosphorus ratio.
- We propose **deleting carrageenan** since its usage as a thickening agent in formula for healthy infants is not justified.

Section 4.2 Emulsifiers

- We propose **reducing the maximum of lecithin from "0.5 g" to "0.1 g".**

Re Section 9. Labelling

- We propose amending the wording of Section 9.1 as follows:

"The text on the label and all other information accompanying the product shall be written in the language of the country where the product is circulated."

- - To avoid confusion, we propose amending the wording of Section 9.1.1 as follows:

"The product is to be labelled 'infant formula'."

- Section 9.1.6 should in our opinion be deleted, since according to the table in Section 3.1.2 no products may be sold on the market which contain less than 0.5 mg iron/100 kcal.
- In Section 9.3, letter a) "... in kilocalories (kcal) and/or kilojoules (kJ) ..." in the first line should be replaced by "... in kilocalories (kcal) and kilojoules (kJ) ...".
- In Section 9.6.1 we propose deleting **"it protects against diarrhea and other illnesses"** (in lines 4 and 5 of the Spanish version), which could lead to misunderstandings.
- As we agree with the content of the wording in brackets in Section 9.6.4, we propose that the brackets be removed.
- As we agree with the content of the wording in brackets in Section 9.6.5, we propose that the brackets be removed.

Annex I

We propose replacing the table as follows:

ESSENTIAL AND SEMI-ESSENTIAL AMINO ACIDS IN BREAST MILK

The following essential and semi-essential amino acids in breast milk (listed in mg per 100 kJ and 100 kcal) are of importance for this standard:

	per 100 kJ	per 100 kcal
Arginine	16	69
Cystine	6	24
Histidine	11	45
Isoleucine	17	72
Leucine	37	156
Lysine	29	122
Methionine	7	29
Phenylalanine	15	62
Threonine	19	80
Tryptophane	7	30
Tyrosine	14	59
Valine	19	80

ISDI - INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES

1. SCOPE

Section: 1.1.
The second sentence of this paragraph should be modified as it covers formulae intended for infants not in good health who have special nutritional requirements. In the European legislation these formulae are regulated by a directive on Foods for Special Medical Purposes (1999/21/EC). An equivalent Standard at Codex level is under consideration and will cover these specific formulae.

Products intended for infants not in good health are highly specific and are designed for the dietary management of infants suffering from a particular disease (e.g. infant suffering of phenylketonuria, galactosemia, malabsorption, allergies, inborn errors of metabolism etc). The composition and the labelling of such products cannot be governed by provisions for infant formula for several reasons:

- These special products cover age ranges from 0 to over 4-6 months (e.g. up to 18 months)
- They should be used under professional health care supervision

- They have specific compositions which most of the time cannot meet provisions of Infant Formula Standard
- Due to their specific composition, some products may present a health hazard if used by persons for which they are not intended
- Infant formulae or breastmilk may be contraindicated for certain diseases
- Specific labelling provisions should be applied to these products.
- There are risks of confusion and misuse if these products fall under the scope of the infant formula Standard.

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: 1.2. No comments

Section 1.3.
The current wording was proposed by the Canadian delegation as a compromise but many delegations continued to disagree with the inclusion of the reference to the WHA resolutions. ISDI **strongly** supports the reference to the International Code of Marketing of Breast-milk Substitutes but requests **the deletion** of the mention of the WHA resolutions.

The WHA resolutions are impracticable because they refer to several Declarations, Summits, and Recommendations of other meetings dating back to 1979. This information is potentially vast in its implications and has not been presented to Codex in a transparent manner. Thus it has not been possible for all stakeholders to evaluate its potential impacts. In contrast, the Code has been universally discussed in detail, accepted and implemented over a period of 20 years.

The WHA resolutions are also written in language that is frequently vague and open to multiple interpretations, thus they will not well serve the interests of Codex.
They tend to be in the form of 'urging' Member States to take action to implement them. We believe that national governments should make the decision on how to implement them as appropriate to the social and legislative framework of each country.

Section 2. DESCRIPTION
Section 2.1: Product definitions
Section 2.1.1: No comments

Section 2.1.2.
ISDI agrees with the present wording and favours the deletion of the square brackets. There is wide spread international scientific consensus that breast-milk alone is sufficient to feed healthy infants during the first 4 – 6 months. For this reason WHO has recommended in 1995 (Weekly Epidemiological Record No 17) "*that infants should be fed exclusively on breast-milk from birth to 4 – 6 months of age; that is, they should be given no other liquids or solids than breast milk*". As defined in the section "Scope" of this Standard, infant formulae are intended for use, when necessary, as a substitute for human milk in meeting the normal nutritional requirements of healthy infants. Consequently, infant formula must fulfil the same nutritional requirements as breast-milk and in particular it must satisfy by itself the nutritional requirements of the healthy infant during the first four to six months of life.

Section 3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

Section 3.1. ESSENTIAL COMPOSITION
It should be stressed that these proposals are intended only for infant formulae for ***healthy*** infants. Formula intended for non-healthy infants requires adaptation of its composition in order to meet specific dietary needs.

These adaptations are not considered in the following remarks. Formula for non-healthy should be excluded from this Standard

Present Codex proposal

3.1.1 Infant formula is a product based on milk of cows or other animals and/or other edible constituents of animal, including fish, or plant origin, 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 formulae 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 local nutritional resources provided that the quality criteria defined in the Standard are respected.
- Infant formulae should answer to cultural and/or religious habits (e.g. vegans, vegetarians...)
- Some infants are allergic to certain ingredients and alternatives should be proposed
- Flexibility allows innovation

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.

Present Codex proposal

3.1.2 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, carbohydrates and energy:

ISDI proposes to delete the words "and energy" as the amounts are proposed per 100 kcal. A recapitulation is tabled for vitamins and minerals at the end of this section.

VITAMINS

The names of the vitamins should be consistent with the provisions set in the Codex labelling. Names should be harmonised accordingly.

Maximum levels for vitamins should be set only for vitamins A and D. These are the only vitamins for which there may be safety concerns.

Present Codex proposal

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

The previous Standard expressed the quantity of vitamin A in IU, while in the current draft it is in µg of retinol equivalents. ISDI agrees with the proposal of Japan to express the quantity of vitamin A in both units, i.e. in IU and in µg retinol equivalents, in the same way as for vitamin D which is expressed in IU and µg calciferol equivalent.

ISDI favours the adoption of 180 µg RE /100 kcal (600 IU) as maximum level. This level is recommended by the European Scientific Committee on Foods and endorsed by the European Directive 91/321/EEC.

ISDI proposal: to add IU

Vitamin A: Min: 60 µg/100kcal –	**Max: 180 µg/100kcal**	**Min: 14 µg/100kJ –**	**Max: 43 µg/100kJ**
Min: 200 IU/100kcal –	**Max: 600 IU/100kcal**	**Min: 48 IU/100kJ –**	**Max 143 IU/100kJ**

Present Codex proposal
Niacin*[1] *Min: 0.8 mg/100kcal // Max: N.S. Min: 0.2 mg/100kJ // Max: N.S.
(expressed as niacin equivalents)

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 ISDI proposed that infant formula should include as minimum 0.5 mg/100kcal preformed niacin as suggested by the LSRO report**.

Biotin (Vitamin H) ***1.5 µg100kcal // N.S.*** ***0.4 µg100kJ // N.S.***
As mentioned above, the names of the vitamins should be consistent with the provisions set in the Codex labelling. **Therefore, ISDI proposes to delete the wording "vitamin H" and to retain only the wording "biotin".**

Present Codex proposal
Potassium (K) ***Min: 60 mg // Max: 145mg 100kcal*** ***Min:15 mg // Max: 35 mg 100kJ***
Chloride (CI) ***Min: 50 mg / Max: 125 mg 100kcal*** ***Min: 12 mg // Max: 29 mg 100kJ***

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 (Fomon 1993). 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 K/Na ratio in cow's 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 below. This implies that there may be a physiological ratio between those two electrolytes, optimised to maintain water balance across membranes.

Sodium, Potassium, Chloride in human milk and cow's milk[1]					
Human milk (mg/l)					
Na	**K**	**Cl**	**K/Na**	**K (Na + CI)**	**Reference**
227	527		2.3		Fomon
264	477		1.8		Fomon
184	470		2.6		Fomon
175	464		2.7		Fomon
166	460		2.8		Fomon
134	430		3.2		Fomon
151	465	421	3.1	0.8	Fomon
121	426	410	3.5	0.8	Fomon
126	406	419	3.2	0.7	Fomon
113	443		3.9		Fomon

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

84	443		5.3		Fomon
162	507	366	3.1	1.0	Fomon
Average			3.1	0.8	
Cow's milk (mg/l)					
494	1617	1051	3.3	1.0	Souci-Fachmann
505	1555		3.1		USDA
455	1545		3.4		Favier
460	1560	1065	3.4	1.0	Allais
Average			3.3		

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 feasible to achieve whereas higher levels have never presented any concerns for safety.

For these reasons then, ISDI recommends keeping the same ratio between sodium and potassium as in human milk. Since the sodium maximum has been set at 60 mg/100 kcal, 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.

ISDI also suggests maintaining the maximum level adopted in the previous CODEX Standard for chloride of 150 mg /100kcal.

ISDI proposal:

Potassium (K)	**Min: 60 mg/100kcal Max: 200 mg/100kcal**	**Min: 14 mg/100kJ Max: 48 mg/100kJ**
Chloride (Cl)	**Min: 50 mg/100kcal Max: 150 mg/100kcal**	**Min: 12 mg/100kJ Max: 36 mg/100kJ**

Present Codex proposal

Calcium (Ca)	***50 mg/100kcal // N.S.***	***12 mg/100kJ // N.S.***
Phosphorus (P)	***25 mg/100kcal // 90 mg/100kcal***	***6 mg/100kJ // 22 mg/100kJ***

Ratio Ca/P: Footnote 3

ISDI favours the increase of the maximum level of the Ca: P ratio to 2.2. This level was requested by the French, Brazilian and Swiss delegations in the preparation of the revision of this Standard (CX/NFSDU 96/8-Part II) and included in the original draft. This request was reiterated in the comments of Argentina and China for the session 2000.

The French delegation provided in their submission the following scientific justification: "A certain number of arguments suggest that the upper limit for the Ca/P ratio could be increased to 2.2 (instead of 2). In breast milk the Ca/P is often higher than 2 with a standard deviation of about 20 %. (See Acta Paediatr Scand 1974; 63:347-50; Med Nutr 1993;29:183-71).

The Swiss delegation provided a technical justification as follows: "The current footnote sets the maximum Ca: P ratio at 2.0. When this norm was agreed upon, products with a low phosphorus content did not exist yet. A number of low P infant formulas are currently marketed in several countries all over the world. They provide advantages in comparison with the traditional formulae with higher phosphorus content. There is, however, a risk that these products exceed the Ca: P ratio of 2.0. We therefore propose to raise maximum

allowed Ca: P ratio to 2.2. This value is safe and physiological. As a matter of fact, this value and even higher values are regularly found in breast milk."

Comments made by Germany are very pertinent and should be considered. "The reduction of the maximum amount of the calcium-phosphorus quotient should refer to the **molar** Ca: P ratio as indicated in the original". The molecular weight of Ca and P is 40 and 31 respectively, so the molar ratio = 2 becomes 2x [40:31] = 2.2 (weight/weight). This request is also supported and clearly expressed in the UK recommendations[2].

ISDI requests that the upper limit for the Ca: P ratio is set at 2.2 (weight/weight ratio) as originally requested by the French, Brazilian, Swiss, Chinese, Argentinean and German delegations. **ISDI prefers to retain the weight/weight ratio calculation as a reference as it is simplest.**

Present Codex proposal

Iron (Fe) (cow milk based formulae)	***0.5 mg/100kcal // 1.5 mg /100kcal***	***0.12 mg/100kJ // 0.36 mg/100kJ***
Iron (Fe) (soy based formulae)	***1 mg/100kcal // 2 mg /100kcal***	***0.25 mg/100kJ // 0.5 mg//100kJ***

ISDI supports the Delegation of the USA in recommending that the range of levels for iron be the same for milk and soy formulae, and further, that the range be enlarged. Indeed, the important factor is the bioavailability of the iron in the soy-based formula, which was previously diminished due to the presence of phytates in soy isolates. However, processes using phytases have now improved the bioavailability of iron from soy.

The EU directive 91/321/EEC specified a minimum iron level as 0.5 mg/100kcal and ISDI supports this minimum level of 0.5mg/100kcal. Although the LSRO recommended a low 0.2 mg/100kcal, there were within LSRO, dissenting opinions and ISDI agrees that this level is too low.

The EU directive specifies a maximum iron level of 1.5 mg/100kcal for formulae 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 and 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 the AAP-CON recommendation (1993) suggest a maximum level of 2.5 mg /100kcal). ISDI supports this latter level.

The ISDI proposal for all formulae with added iron is:

Iron (Fe) Min[1]: 0.5 mg/100kcal //Max: 2.5 mg /100kcal Min: 0.12 mg/100kJ // Max: 0.6 mg/100kJ

Footnote [1]: If the product should be used after 4-6 months of age, the minimum level of iron should be 1mg/kcal or infants should receive iron supplements.

Present Codex proposal

Copper (Cu) Max: 20 µg/100kcal // Min: 80 µg/100kcal Max: 4.8 µg/100kJ // Min: 19 µg/100kJ

As mentioned by the USA, maximum level for copper is too low. Levels proposed correspond to the mean daily copper intake of breastfed infants and does not take into account potential differences in bioavailability of copper in breast milk and infant formulas

From a regulatory affairs standpoint, the EU Directive is out of line with other bodies such as Codex Alimentarius and the FDA Infant Formulae Act and the LSRO Report, which are:

---

[2] Report on Health and social subjects. 41, Dietary reference values for food energy and nutrients for the United Kingdom.

	Copper µg/100kcal
EU Directive 91/321/EEC	20-80
Codex Alimentarius	minimum 60 maximum not specified
US IFA	minimum 60 maximum not specified
LSRO	60-160
ESPGHAN for low birth weight	90-120

Although the level currently permitted in the EU Directive is within the range found in breast milk from European women, it is lower than that recorded in the human milk of some women in the US. The levels recorded in breast milk are given in the attached table. In addition there is some evidence that the bioavailability of copper in infant formula is lower than in human milk[3] and is also influenced by other nutrients in the diet [4,5]. The UK Department of Health report[6] (1991) assumed an absorptive efficiency for copper from infant formula of 50% and Loennerdal (1998)[7] quoted the mean retention of copper as being 52% for copper fortified infant formulae.

The LSRO Report concluded in its recommendations for the level of copper in infant formula that the maximum level of 160µg/100kcal is significantly lower than have been associated with copper-associated liver disease.

In addition the present maximum level of copper is also incompatible with the ESPG(H)AN recommendation for the copper level for low birth weight infants which is 90-120µg/100kcal. Thus up to the weight of 2.5kg the infant should have a minimum of 90µg/100kcal, but once over 2.5kg, this has to drop to a maximum of 60µg/100kcal.

The original EC Scientific Committee for Food report in 1983, expressed concerns over technological problems related to the oxidation of fatty acids if the copper fortification maximum was set too high. Since this time the manufacture of infant formula has become more advanced and there have been no problems with oxidation of fatty acids including the more vulnerable long-chain fatty acids added to both term and low birth weight formulae. It should be noted that in the case of the latter the minimum copper level to meet the ESPG(H)AN recommendation is 90µg/100kcal that is above the maximum permitted for term formula (see above). Despite this there have been no reports of oxidation due to the level of copper present.

---

3 Johnson, PE. and Canfield, W.K. Stable copper and zinc absorption in free-living infants fed breast milk or formulas J Trace Elem. Exp. Med. 1989; 2: 285-295.

4 Loennerdal, B. Dietary factors affecting trace element bioavailability from human milk, cow's milk and infant formulas. Prog. Food Sci. 1985; 9: 35-62.

5 Loennerdal, B. Effects of milk and milk components on calcium, magnesium, and trace element absorption during infancy. Physiol. Rev 1997: 77: 643-669.

6 UK Department of Health Report No 41 Dietary Reference Values of Food Energy and Nutrients for the United Kingdom HMSO 1991 171-173.

7 Loennerdal, B Copper nutrition during infancy and childhood. Am. J. Clin. Nutr 1998; 67 (suppl) 1046S-1653S.

The copper content recorded in Human milk for Term infants

Reference:	Year	Geographical Location	Time post-partum	Copper as µg/100kcal
Information quoted in official recommendations				
EC SCF report (Casey *et al* 1989)[8]	1993			33
ESPGAN	1987			90 - 120
UK COMA	1980	UK		56
LSRO	1998	US		20- 70 mean 33
Other references				
Jochum *et al*[9]	1995	Germany	4 months	44
Ohtake *et al*[10]	1993	Japan	15 - 84 days	47±19
			85 - 201 days	31±13
Butte *et al*[11]	1987	USA	2 months	51±11
			3.months	45±10
			4.months	43±11
Casey *et al*[12]	1985	USA	25 - 31days	66±6
Casey *et al*[13]	1989	USA		29 - 57
Fransson *et al*[14]	1984	USA	2 - 4.months	52±42
Fransson *et al*[15]	1983	USA	0.5 - 12months	18 - 81

ISDI is the opinion that no maximum value should be set for copper as no adverse effects have been reported. Recent studies (Jochum et al[3], 1995; Schlesinger[16] et al., 1992) have found no adverse effects on

8 Casey, C.E. Neville, M.C. and Hambidge, K.M. Studies in human Lactation: Secretion of zinc, copper and manganese in human milk. *Am. J. Clin. Nutr*. 1989; 49: 773-785.

9 Jochum, F. Fuchs, A Cser A., Menzel, H. and Lombek, I. Trace mineral status of full-term infants fed human milk-based formula or partially hydrolysed whey protein formula. *Analyst* 1995; 120: 905-909.

10 Ohtake, M. and Tamura, T Changes in zinc and copper concentrations in breast milk and blood of Japanese women during lactation J. Nutr. Sci. Vitaminol. 1993 39: 189-200.

11 Butte, N.T., Garza, C., Smith, E.O., Wills, C. and Nicols B.L Macro- and trace- mineral intakes of exclusively breast-fed infants. *Am. J. Clin. Nutr*. 1987 45: 42-48.

12 Casey, C.E., Hambidge, K.M. and Neville, M.C. Studies in human lactation: zinc, copper, manganese and chromium in human milk in the first month of lactation. *Am. J. Clin. Nutr*. 1985; 41: 1193-1200.

13 Casey, C.E. Neville, M.C. and Hambidge, K.M. Studies in human Lactation: Secretion of zinc, copper and manganese in human milk. *Am. J. Clin. Nutr*. 1989; 49: 773-785.

14 Fransson, G. and Loennerdal B. Iron, copper, zinc, and magnesium in human milk fat. *Am. J. Clin*. 1984 39 185-189.

15 Fransson, G. and Loennerdal B. Distribution of trace and minerals in human and cows' milk *Pediatric Res*. 1983 17 912-915.

16 Schlesinger L, Arevalo M, Arredo S, et al. Effect of a zinc-fortified formula on immunocompetence and growth of malnourished infants. Am J Clin Nutr 1992:56:491-8.

copper status with feeding formulas with zinc to copper ratios of 63/1 and 47.5/1, respectively. In a survey of the levels of minerals in infant formulas, the mean copper content was found to be 110 ± 32 µg/100 kcal[17]. Acute dietary copper toxicity has not been reported in infants.

If a maximum level should be set, ISDI suggests a level of at least 160µg/100 kcal as reported by the US Life Science Research Office (LSRO) in September 1998.

ISDI proposal:

Copper (Cu) Min: 20 µg/100kcal Max: N.S. // Min: 4.8 µg /100kJ Max: N.S. **If a maximum level should be set: at least 160µg/100 kcal (39 µg/100kJ)**

Present Codex proposal

Zinc (Zn)	***0.5 mg/100kcal //N.S.***	***0.12 mg/100kJ // N.S***
(cow milk based formulae)		
Zinc (Zn)	***0.75 mg/100kcal //2.4 mg/100kcal***	***0.18 mg/100kJ // 0.6 mg/100kJ***
(soy based formulae)		

As recommended by the USA, ISDI supports that levels for zinc be the same for milk and soy based formulas. The same reasoning as outlined above for iron sustains this proposal. Limits should be set to cover all types of formulae.

ISDI proposal:

Zinc (Zn)	**Min: 0.5 mg/100kcal Max: N.S.**	**Min: 0.12 mg/100kJ Max: N.S**

Present Codex proposal

Manganese (Mn)	***5 µg/100kcal // N.S.***	***1.2 µg/100kJ // N.S.***

ISDI supports the minima for manganese as this is the quantity found in breast milk.
No new reported data suggest that a maximum be established for manganese in infant formula. No limit is set by the EU Directive 91/321/EEC. **Thus, ISDI recommends endorsing the European position and that no limit should be set for manganese**. If minima should be set it should concern only formula with added manganese, as there are naturally great fluctuations of manganese in raw materials.

Present Codex proposal

Selenium (Se)	***NS // 3 µg/100kcal***	***N.S. // 0.7 µg/100kJ***

ISDI supports the absence of a minimum requirement for selenium. Although there is clear evidence for the essentiality of selenium for infants, no evidence of Se deficiency has ever been observed in formula-fed infants. Infant formulas without Se fortification have inherent Se contents ranging from approximately 2 to 15 µg Se/l depending on the origin of the ingredients.

Nevertheless the addition of selenium may be desirable in some cases and should be permitted. For this reason the European Directive 91/321/EEC was recently amended by Directive 96/4/EC to allow the addition of selenium.

Regarding the maximum level, the European Scientific Committee for Foods recommended in 1993 a maximum level of 3µg/100 kcal, however, based on more recent data, the US LSRO recommendation (September 1998) proposes a maximum level of 5µg/100 kcal. Levander (1989)[18] states that human milk

[17] Hamill TW, Young ER, Eitenmiller RR, et al: Ca, P, Mg, Zn, Cu, Mn, Na, K and Cl contents of infant formulas manufactured in the United States. J Food Comp Analysis 1989;2:132-9.

[18] Levander OA. Upper limit of selenium in infant formulas. J Nutr 1989;119:1869-73.

collected in South Dakota, a high Se area, has been reported to contain 60 µg Se/l (or 8.8 µg Se/100 kcal). Selenium toxicity or any adverse effect of high intakes of selenium has never been reported in human milk-fed nor in formula fed infants. The USA as well as Canada support the introduction of a higher limit. The US delegation has stressed that a level of 5µg/100 kcal is at the upper limit of selenium levels in human milk and is far less per unit body weight than the intake associated with development of selenosis in adults.

In conclusion ISDI requests that no minima be set for selenium, and that only when selenium has been added the maximum be set at 5.0µg /100 kcal.

ISDI would like to stress that maximum for selenium should be set **only when this nutrient is added** to the infant formulae (supported by Germany, Argentina, China and the EU directive)

ISDI proposal:

Selenium (Se)	**Min: NS**	**Max: 5.0 µg/100kcal**	**Min: NS Max: 1.2 µg/100kJ**
With the appropriate footnote: "if added"			

Present Codex proposal

Choline	***7.1 mg/100kcal // NS //***	***1.7 µg/100kJ // N.S.***

ISDI supports the minimum level (7.1mg/100kcal) proposed by the Standard regarding choline although no requirements are set in the EU directive. This is in agreement with the LSRO recommendations.

Carnitine

Carnitine is not listed as compulsory nutritional substance in infant formulae. 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	**Min: 1.2 µg/100kcal**	**Max: NS**	**Min: 0.3 µg/100kJ**	**Max: N.S.**

Conversion factors

Finally, it is suggested to have the following conversion factors:

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

Recapitulation

		Per 100kcal		Per 100kJ	
	Units	MIN	MAX	MIN	MAX
Vitamins					
Vitamin A Expressed as retinol equivalent	**µg** **IU**	**60** **200**	**180** **600**	**14** **48**	**43** **143**
Vitamin D	**µg** **IU**	1 40	2.5 100	0.25 10	0.63 25
Vitamin E Expressed as alpha-tocopherol equivalent in alpha-TE	mg/g	0.5[1]	N.S.[2]	0.1[1]	N.S.[2]
Vitamin C	mg	8	N.S.[2]	1.9	N.S.[2]
Vitamin B1	µg	40	N.S.[2]	10	N.S.[2]

Vitamin B2	µg	60	N.S.[2]	14	N.S.[2]
Niacin	**mg**	**0.5**	**N.S.**[2]	**0.12**	N.S.[2]
Vitamin B6	µg/g protein	15[3]	N.S.[2]	**3.6**[3]	N.S.[2]
Folic acid	µg	4	N.S.[2]	1	N.S.[2]
Pantothenic acid	µg	300	N.S.[2]	70	N.S.[2]
Vitamin B12	µg	0.10	N.S.[2]	0.025	N.S.[2]
Vitamin K1	µg	4	N.S.[2]	1	N.S.[2]
Biotin	**µg**	**1.5**	**N.S.**[2]	**0.4**	**N.S.**[2]
Minerals					
Sodium	mg	20	60	5	15
Potassium (K)	**mg**	**60**	**200**	**14**	**48**
Chloride (Cl)	**mg**	**50**	**150**	**12**	**36**
Calcium (Ca)[4]	**mg**	**50**	**N.S.**[2]	**12**	**N.S**[2]**.**
Phosphorus (P)[4]	**mg**	**25**	**90**	**6**	**22**
Magnesium (Mg)	mg	5	15	1.2	3.6
Iron (Fe)[5]	**mg**	**0.5**	**2.5**	**0.12**	**0.6**
Iodine (I)	µg	5	NS	1.2	NS
Copper (Cu)	**µg**	**20**	**N.S.**[6]	**4.8**	**N.S.**[6]
Zinc (Zn)	**mg**	**0.5**	**N.S.**[2]	**0.12**	**N.S**[2]**.**
Manganese (Mn)[7]	**µg**	**5**	**N.S.**[2]	**1.2**	**N.S**[2]**.**
Selenium (Se)	**µg**	**N.S.**	**5**[7]	**N.S.**	**1.2**[7]
Choline	mg	7.1	N.S.[2]	1.7	N.S.[2]
Carnitine	**µg**	**1.2**	**N.S.**[2]	**0.3**	**N.S.**[2]

[1]: per g polyunsaturated fatty acids, but in no case less than 0.5mg/100kcal (or 0.1mg/100kJ)
[2]: N.S.: Not specified
[3]: In no case less than 35µg/100kcal (8.4 µg/100kJ)
[4]: Ca/P (w/w) ratio shall be not less than 1.2 and not more than 2.2
[5]: If the product should be used after 4-6months of age, the minimum level of iron should be 1mg/100kcal or infants should receive iron supplements.
[6]: If a maximum level should be set: at least 160µg/100 kcal (39 µg/100kJ)
[7]: Only if added

Section (d): <u>PROTEIN</u>

(i) Present Codex 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 soya protein isolates and their partial hydrolysates

Coefficients of conversion

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.

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. The proposed wording is the following

ISDI Proposal

Protein
(i) **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**

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 and should be deleted. This criterion is now obsolete. The relevant reference is the comparison to the breast milk as mentioned under section (d)(ii).

ISDI proposal: to delete this paragraph

Present Codex proposal

(ii) The product shall contain protein at a level of not less than 1.8 g/100 kcal (0.45 g/100 kJ) and not more than 3 g/100 kcal (0.7 g/100 kJ).

ISDI has no comment regarding the total quantity of protein.

Present Codex proposal

(iii) 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.

This sentence is essential regarding the determination of the quality of the protein. The statement "the formula must contain an available quantity of each essential amino acid…" requires that every acid must meet the criteria. The sentence should read: " available quantity OF each essential..."

Moreover, 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.

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 concentration of methionine and cystine may be added together, as well as phenylalanine and tyrosine

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.]

This sentence must be deleted. 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 proposal: deletion of the sentence

Present Codex proposal
(iii) 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.

No comments

Section (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 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 in part on the average levels found in human milk and suggestions that high levels of linoleic acid may suppress long chain polyunsaturated (LCP) fatty acid synthesis. The results of one recent study 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[19]).

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.

ISDI proposal:

Linoleic acid	**Min: 300mg/100kcal**	**Max: N.S.**	**Min: 70mg/100kJ**	**Max: N.S.**

Present Codex proposal
- fat at a level not less than 4.4 g/100 kcal (1.05 g/100 kJ) and not more than 6.5 g/100 kcal (1.5 g/100 kJ);
- the alpha-linolenic acid content shall not be less than 50 mg/100 kcal (12 mg/100 kJ);
- the linoleic/alpha-linolenic acid ratio shall not be less than 5 nor greater than 15;

ISDI agrees with the limits proposed for alpha-linolenic acid. Regarding the ratio (5 to 15), ISDI suggests for consistency with the proposed figures for minima (300/50=6) changing it into 6 to 16.

Present Codex proposal
The trans fatty acid content shall not exceed 4% of the total fat content;

Section 3.1.2(e) of the proposed draft revised standard for infant formula requires that **the *trans* fatty acid content shall not exceed 4% of the total fat content.** ISDI believes that this value is too low and proposes that the maximum *trans* fatty acid level be set at 5% of the total fat content, for the following reasons.

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 Scientific

[19] 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.

Committee for Food (SCF) of the European Commission 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 recent publications have reported *trans* fatty acid levels in cow's milk above 5 % and up to 6.5%[20] [21]. A third study, which has just been completed[22] analysed the bi-monthly variation in *trans* isomer levels in whole milk powders produced in Brazil, Denmark, Indonesia and the Netherlands over a twelve month period in 1996/1997. Results showed that seasonal variation is very high and that, depending on the season and presumably on what they are eating, genetically similar animals generate milk with widely differing *trans* content. These results are summarised in the following table:

Trans fatty acids in whole milk powder
(g/100 g total fatty acids)[11]

	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 (about 80 %) of these *trans* fatty acids 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 set 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 formulae at 5%, now that we know that milks contain higher total levels of trans fat than had been previously thought.

---

[20] 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.

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

[22] Dionisi F, Golay PA. Occurrence of trans fatty acids in milk fat with special emphasis to trans-octadecadienoic and trans octadecatrienoic acids. Submitted for publication.

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 tfa 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) [23].

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

IBFAN, ENCA and India have stated that *trans* fatty acids may be incorporated into brain and retina and alter optimal physiological function. IBFAN unfortunately did not reference this 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 tFA are fed at unrealistically high levels (up to 36% of calories which is equivalent to 5-12 times the average human intake) very little tFA is incorporated into the brain and retinal tissues (0.0-0.5%)[3-10] . There have been no studies showing impaired neural functions due even to these extreme diets.

There is some evidence, particularly in tissue and cell cultures that tfa 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 (Carlson 97 review)

An Expert Panel composed of well-recognized specialists in the field of lipid nutrition in infants concluded that "Existing data have not established a causal relation between *trans* fatty acid intake and changes in early development"[24].

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 %.[25]. These levels are considerably higher than those originally considered by the European Scientific Committee for Food.

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% tfa, and no negative effects of tfa on metabolism nor on development have been established as long as sufficient essential fatty acids are available. It therefore seems that a level of tFA 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.

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

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

---

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

[24] Carlson SE,Clandinin MT,Cook HW,Emken EA,Filer LJ. trans Fatty acids:infant and fetal development.Am J Clin Nutr 1997;66:717S-736S.

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

Present Codex proposal
The erucic acid content shall not exceed 1% of the total fat content;
ISDI supports this maximum level for erucic acid. This is in agreement with the European Directive.

Other considerations regarding comments on fats received by the Codex Committee

LCPUFA
Mandatory minimum levels of docosahexaenoic acid (DHA) and arachidonic acid (AA) in infant formula have been proposed by ENCA and by India. 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. In conclusion, mandating addition of these fatty acids to infant formula is premature, although their inclusion should be permissible.

Peanut oil
ENCA proposes that peanut oil should not be allowed for reasons of allergy. However there is no evidence that peanut oil, if it is well refined without any protein residues, brings on allergy.

Cholesterol
India proposes that cholesterol be added to infant formula based on results from studies on cholesterol supplemented rats showing lower plasma cholesterol levels in later life. There have been many studies of this sort carried out in rats, pigs, and simians but they have had contradictory results and conclusions are difficult to secure. Retrospective studies have been carried out on human early feeding patterns in light of present cardiovascular disease. Here too, conflicting results have been obtained, and there are probably further covariates (e.g. apoE phenotype, lifelong cholesterol intake) which need to be considered (Berger et al 2000)[26].

CARBOHYDRATES
Present Codex proposal
The product shall contain carbohydrates at a level of not less than 7 g/100kcal (1.7 g/100 kJ) and not more than 14 g/100kcal (3.4 g/100 kJ).

ISDI agrees with the proposed level on carbohydrates.

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

ISDI proposal:
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 3.2 OPTIONAL INGREDIENTS: No comment

[26] Berger A, Fleith, M, and Crozier G. 2000 Nutritional Implications of replacing bovine milk fat with vegetable oil in infant formulas J. Ped Gastroenterol and Nutr Vol 30:115-130

Section 3.3 VITAMIN COMPOUNDS AND MINERAL SALTS:

Section 3.3.1. No comment. The Advisory List of Mineral Salts and Vitamin Compounds for use in Foods for infants and young children (CAC/GL 10-1979 is under revision in a separate document

Section 3.4. CONSISTENCY AND PARTICLE SIZE: no comment

Section 3.5. PURITY REQUIREMENTS: no comment

Section 3.6. SPECIFIC PROHIBITION: no comment

Section 4. FOOD ADDITIVES

This part is under revision in a separate document. The inventory was prepared by the Dutch delegation but was not discussed last year. ISDI has already sent its comments to the Dutch delegation. ISDI underlines that the General Standard on Food Additives level is under discussion and suggests for simplification that this Section only refers to the provisions of GSFA for infant formula.

Sections 5 to 8: no comment

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.

Sections 9.1.1 to 9.1.3: No comment

Section 9.1.4 ISDI support the deletion of the square brackets

Section 9.1.5 The proposed statement, "No health claims shall be made regarding the dietary properties of the product" should be deleted. The restrictions of Section 5.2.4 of Codex STAN 146-1985 (Codex General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Use) are sufficient to prevent inappropriate claims

Section 9.1.6. **No comment**

Section 9.2. List of ingredients

Section 9.3. DECLARATION OF NUTRITIVE VALUE.

Section 9.3(b). ISDI recommends to include **"if added"** after optional ingredients 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 9.5 INFORMATION FOR USE

Sections 9.6.1. and 9.6.2 ISDI agrees with these two sections and believes that the square brackets should be removed. The wording of the sections reflect very closely those of the International Code of Marketing of Breast-milk Substitutes. The wording used in the Code should not be modified not even slightly. For this reason the alternative wording after b): "breast-milk protects against diarrhea and other illnesses," is not acceptable. This alternative should be deleted, as this is not scientifically proven.

Section 9.6.3: No comment

Section 9.6.4.: ISDI strongly supports the modification of the wording between square brackets. Thus "*over six months of age*" should be replaced by "***from 4 to 6 months***". This is totally in line with the recommendation by the WHO published in 1995 of which we quote:

"The World Health Organization recommends that infants should be fed exclusively on breast milk from birth to 4 to 6 months of age; that is, they should be given no other liquids or solids than breast milk, or even water, during this period. Given the worldwide variation in growth velocity, an age range is an essential element of this feeding recommendation. Mean growth Z-scores are indeed observed to begin falling at different points within this 4-to-6-month range in breast-fed infants from different populations worldwide. WHO and its partners are in the process of refining the definition of "optimal" growth, as measured by accepted functional indicators of infant health and well-being.

After this initial 4-to-6-month period of exclusive breast-feeding, children should continue to be breast-fed for up to 2 years of age or beyond, while receiving nutritionally adequate and safe complementary foods. Starting complementary feeding too early or too late are ***both*** *undesirable. Ideally, the decision when precisely to begin will be made by a mother, in consultation with her health worker, based on her infant's specific growth and development needs."*

Section 9.6.5. ISDI suggests deleting this sentence, which is superfluous.

ANNEX 1

ESSENTIAL AND SEMI-ESSENTIAL AMINO ACIDS IN BREAST MILK
For the purpose of this Standard the essential and semi-essential amino acids in breast milk, expressed in mg per 100 kJ and 100 kcal, are the following:

Regarding the reference protein, ISDI remarks that the important factor is the real intake of each amino acid. The quantity of protein may vary from 1.8 to 3g/100kcal. The need for a certain amount of amino acid should be ensured and for this reason the expression of the aminogram should be per 100kcal and not per gram of crude protein as proposed by certain delegations.

There are several different proposals regarding the aminogram of breast milk to be used as reference. ISDI is of the opinion that an international reference is needed rather than a reference based on a single survey as it is the case of the aminogram proposed by Canada derived from a single study by made by Sarwar *et al,* 1996[27].

The Sarwar aminogram is significantly different from much of the published literature on the composition of human milk. It is also quite different from the one currently in use in the EU. In particular for several amino acids considerably higher levels are reported: For several reasons the Sarwar aminogram is not acceptable:

- The study focussed mainly on the comparison between preterm and term milk.

[27] Sarwar, G, Darling P, Ujhe, M, Botting H, and Pencharz, PB 1996 J AOAC International Vol 79 (2) pp498-502.27

- These milks were measured at 5–10 days post partum a period characterising "transition" milk rather than "mature" milk. This is reflected by the high protein content of the milk reported in this study of 14 g per litre, instead of the usual 10 - 12 g / litre, in which the so-called non protein nitrogen is included.
- Only 12 mothers were included in the survey, a very small number of subjects to use as a basis for an international standard.
- Mothers from only one country, with presumably similar diet and lifestyle were studied.
- Protein of transition milk is known to differ from mature milk qualitatively as well as quantitatively. This is reflected in the Sarwar aminogram by its deviation in amounts of several amino acids e.g. Arginine +55 %, Cystine +83 % and Tyrosine +44 %.
- In the scientific literature several studies have reported the amino acid composition of breast milk. The values in these studies, when calculated in the same way as the Sarwar study, i.e. amino-acyl residues as a percentage of total amino acids, give the following ranges:
  Arginine: 3.1 – 4.5 % vs. 5.97 in the Sarwar study.
  Cystine: 1.5 – 2.4 % vs. 2.45 in the Sarwar study.
  The values found in the Sarwar study are not in conformity with the values reported until now in the literature.

Adoption of this aminogram will have serious consequences. It will necessitate the modification of all currently sold infant formulae because they will not contain enough arginine. In order to increase the arginine level either the protein content has to be increased, which is contrary to current paediatric recommendations, or arginine as free amino acid has to be added, which is very costly or in many developing countries not possible, and carries its own risks. In addition this will contribute to increased osmotic load. In addition it should be remembered that arginine is not even an essential amino acid, but is synthesised in the body from ornithine and aspartate. In fact, in all studies looking at the effect of various protein quality and quantity in infant formulae, in which arginine content was well below that of the Canadian proposal, no significant differences in plasma arginine levels were found in comparison with breast-fed infants.

For all these reasons we believe that the Sarwar aminogram is not an appropriate reference for an international standard. This position is supported by the delegations of Japan, Germany, Spain and Argentina.

ISDI proposes that **the reference aminogram of the European Directive 91/321/EEC is adopted as a reference in this Standard. This aminogram is based on the FAO consultation and has a long history of safe use.**