codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 6 **CX/NFSDU 00/6**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
Twenty-second Session
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PROPOSED DRAFT REVISED STANDARD FOR INFANT FORMULA (CODEX STAN 72-1981) – Comments at Step 3 of the Procedure -

Comments from:

ARGENTINA
JAPAN
KOREA, REPUBLIC OF
POLAND
SPAIN

ENCA - EUROPEAN NETWORK OF CHILDBIRTH ASSOCIATIONS
EUROPEAN COMMISSION
IBFAN - INTERNATIONAL BABY FOOD ACTION NETWORK
ISDI - INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES

ARGENTINA

Section 1: Scope: We suggest only referring to the Code of Marketing of Breast-milk Substitutes and deleting any reference to the World Health Assembly Resolutions (11 altogether) as their text is not directly related to the work of the Codex. These documents refer mainly to health policies and do not help clarify the scope of this standard.

Section 2.1. - Product Definitions: We suggest that the square brackets in paragraph 2.1.2. be removed for the same reasons explained with regard to the draft for cereals.

Section 3.1. - Essential Composition:

- Paragraph 3.1.2.(a), (b) and (c), is entirely between square brackets.

We accept most of the table, with the following reservations:

- Potassium: The proposed range is 60 to 145 mg/100 kcal, which are the EU values. The present standard has a range of 80 to 200 mg/100 kcal. We agree with the reduction of the minimum amount but do not see any reason to reduce the maximum.
- Chloride: The proposed range is 50 to 125 mg/100 kcal, which are the EU levels. The present standard has a range of 55 to 150 mg/100 kcal. We propose maintaining the amounts specified in the present standard.
- Phosphorus: The proposed range of 25 to 90 rng/100 kcal corresponds to the EU levels. The present standard does not set any maximum. Although we do not see any need, should a maximum value be specified, we believe this should be higher than the proposed amount: given the maximum amount of protein suggested (3 g of proteins), the average phosphorus content from the milk alone will be 93 mg on average.
- Selenium: The proposal is only acceptable if the maximum only applies to formulae with added selenium, as in the case of the EU.
- Ca:P ratio: We believe that the maximum value of this ratio should be 2.2, as in the earlier document (which was amended at the last meeting in Berlin and placed between square brackets). The scientific and technical reasons for this were given in 1996 by the delegations of Switzerland and France.

- Paragraph 3.1.2.(d) Protein: The last sentence of paragraph 3.1.2(d)(ii), is in square brackets. We suggest that this sentence be removed as it could constitute a trade barrier.

Section 9.1. Name of the Food: We suggest that the square brackets in paragraph 9.1.4. be removed. With regard to paragraph 9.1.5, we wish to clarify that in the case of formula for infants with special nutritional requirements, certain claims regarding the dietary properties of the product will have to be allowed, for example in the case of hypo-allergenic formula for premature babies, on condition that these are not misleading and are scientifically justified.

We believe that paragraph 9.1.6. should be deleted as it was agreed that iron supplementation was obligatory (see paragraph 3.1.2.(b) of the draft text).

Section 9.3. - Declaration of Nutritive Value: Subparagraph (b) should specify that any added vitamins, minerals, choline and optional ingredients should be listed.

Section 9.5. - Information for Use: We suggest that the wording between square brackets in paragraph 9.5.2. be replaced by: "after four to six months of age" to mirror the WHO recommendation.

Section 9.6. - Additional Labelling Requirements: We suggest that the square brackets embracing paragraphs 9.6. 1. and 9.6.2. be deleted as they reflect the WHO Code. However, we do not agree with the alternative statement proposed in subclause 9.6.1a) in square brackets [breast milk is the best food for your baby, it protects against diarrhoea and other illnesses] as it deviates from the text of the WHO Code.

Annex 1: In our opinion, the amino acid composition of breast milk was represented more accurately in the previous version of the draft. This composition corresponded to that given in the relevant EU Directive. We therefore propose that the previous version of the draft be applied.

JAPAN

Section 3.1.2: Proposals on the table of vitamins and minerals

(1) The expression of the quantity of vitamin A in I.U.: The expression in I.U. should also be approved.

(2) Niacin equivalents: The expression of niacin alone is sufficient.

(3) Vitamin K_1 should be modified as follows:

"Vitamin K" or "Vitamin K_1, and/or K_2"

(4) Upper limit of the Ca:P ratio: Brackets (e.g. [2.0]) should be removed, namely:

The Ca/P ratio shall be not less than 1.2 and not more, than 2.0.

Reasons for the proposal:

(1) As the expression of the quantity of vitamin A in I.U. is more easily understood by consumers and will cause no problem in converting β-carotene into vitamin A, the use of the I.U. expression should also continue to be allowed.

(2) It has been pointed out that, in respect of niacine, tryptophan in protein should be accounted for. However, as the quality of protein to be used for infant formula is specified in a separate section, the tryptophan content should not differ significantly. The specification of the niacin content alone is, therefore, more reasonable.

(3) Vitamin K contained in milk is composed of K_1 and K_2, rather than K_1 alone. Cow's milk fat contains more K_2 than K_1. In human milk, vitamin K_2 accounts for nearly 20% of all vitamin K.

Current infant formula products (at least those termed "adapted products") use a large quantity of vegetable oil, and vitamin K which originates from the vegetable oil is vitamin K_1. In view of this, in order to intake the minimum amount of vitamin K described in the CODEX Standard, the use of vitamin K_2, which achieves a more similar vitamin K component pattern to that of human milk, is desirable.

In Japan, 2 mg of vitamin K_2 in a syrup form is given orally three times: at birth, one week after birth, and one month after birth, in order to prevent hemorrhagic diseases of newborns, especially intracranial hemorrhage. The safety of vitamin K_2 has thus been confirmed.

Natto (fermented soybeans) is regularly taken in Japanese meals. Bacillus natto's ability to produce vitamin K is strong and the vitamin K of such microbial production is mainly

vitamin K_2. Therefore, vitamin K_2 produced by fermentation processes is approved as a natural additive in Japan.

As infant formula intended for infants with allergic disease uses no soybean oil, whose vitamin K_1 content is high, to avoid soybean allergy, it uses vitamin K_2, which is approved as a natural additive, in Japan.

(4) The contents of Ca and P in infant formula are much higher than those in breast milk. As P places a high metabolic load on infants, much effort has been made to reduce the load. On the other hand, as Ca impedes the digestion and absorption of fat, increasing the Ca content to an unnecessarily high level may reduce the amount of available energy to be taken, which is not desirable. Therefore, both P and Ca should be reduced by optimizing the balance between the two, and increasing the Ca/P ratio itself does not improve the infant formula.

Section 3.1.2: Proposal on fats and linoleic acid

(1) Content of trans fatty acid: The provisions for trans fatty acid should be deleted. The amount of trans fatty acid should be re-examined after clarifying the problems associated with the analysis methods.

Reasons for the proposal:

According to the data obtained from NOF Corporation's Food Laboratory, which measures various types of refined oil using the AOAC method (namely according to Japan's Standard Oil and Fat Analysis Method), the total trans fatty acid content of 4 % is not realistic. Insufficient verification of the measurement methods may cause serious confusion.

	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 9.1.5: What does [No health claims shall be made regarding the dietary properties of the product.] specifically mean?

Section 9.1.6: This section should be deleted.

Reasons for the proposal:

In Japan iron has long been added to infant formula. Writing "Infant Formula with Added Iron" on the label may lead to misunderstanding that other necessary ingredients are not added. This is wholly unjustifiable.

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

We propose to examine, first of all, which secretion period of breast milk should be referred to in determining the amino acid composition as NRV. Thereafter. the amino acid composition of the breast milk of the specified period should be reviewed.

Japan proposes the following NRVs indicated in Table 1.

Reasons for the proposal:

Large differences in the amino acid composition of breast milk, which is referred to as NRV to be used for evaluating nutritional values of products, between this and previously proposed Standards, markedly increases our distrust.

The protein content in colostrum is the highest and it becomes increasingly low day by day even after 1 month after delivery. The expression of protein content per energy shows the same pattern. The amino acid content also varies in parallel. Therefore, which secretion period of breast milk should be referred to for amino acid composition as NRV should be investigated.

The previously proposed CODEX values show no data source, as pointed out by various countries, and no ground for the proposed CODEX values.

The values proposed by Canada use the amino acid patterns reported by Sarwar et al. (1996) and FAO/WHO/UNU (1985) as reference values. The values of His, Ile, Leu, Lys, Thr, Trp and Val were the values of breast milk reported by Sarwar et al., while the values of Cys, Met, Phe, Tyr and Arg are based on the amino acid pattern reported by the FAO/WHO/UNU (1985).

The FAO/WHO/UNU (1985) data use the average of the data from four references, all of which are old data reported in 1954-1985, and were obtained from small samples. The values of breast milk reported by Sarwar et al. are based on the transitional milk on the 5th to 10th days of delivery from 12 mothers who had full-term delivery at an institution in Toronto. These specific data should not be used as a reference for NRV.

Moreover, that the samples were of transitional milk is in itself a problem.

In Japan, Yonekubo et al. (Meiji Milk) and Itoda et al. (Snow Brand) determined the amino acid composition of the breast milk collected from several thousand mothers throughout Japan. This survey is satisfactory in that the breast milk was sampled by limiting factors affecting the components of breast milk, such as mother's health and baby's developmental conditions and that the composition was determined by secretion period, region or season.

It is evident, without referring to these data, that the amino acid content in breast milk is the highest in colostrum, and begins to decline thereafter. The course of decline is seen when expressed in energy. Therefore, the value of amino acid in breast milk to be used as a reference value in the evaluation of nutritional values of infant formula should be determined by taking into account the value of normal milk at 16 days to less than 3 months after parturition, which contains adequate amino acids (protein) to be fed to infants. In view of these, we propose the value established as shown in Table 1 below (lower value of breast milk analysis by Yonekubo et al. and Itoda et al.).

Table 1

(mg/100kcal)

	New Codex (99/26)	Old Codex (97/26)	Yonekubo et al. (Meiji Milk) 21 days - less than 3 months	Itoda et al. (Snow Brand) 16-60 days	Japan (draft)
Arginine	107	69	65.3	66.2	65
Cystine	44	23	34.8	45.1	35
Histidine	47	45	43.5	46.8	44
Isoleucine	83	72	110.3	96.3	96
Leucine	167	156	195.9	183.4	183
Lysine	119	122	123.4	125.6	123
Methionine	23	29	27.6	26.2	26
Phenylalanine	75	62	71.1	71.4	71
Threonine	77	80	78.4	88.1	78
Tryptophan	31	30	36.3	29.4	29
Tyrosine	85	59	72.6	75.5	73
Valine	99	80	107.4	88.0	88

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.

Japan (draft): The lower value of the amino acid content among the above data was adopted.

1.3: [and relevant World Health Assembly Resolutions] is not necessary.

2.1.2: We have no comments on the discussion about the first four to six months of life.

3.1.2 (d) (ii): Square brackets should be removed in view of the importance of the description in the brackets.

5.2: We consider that the wording "be free from" is impossible with available analytical techniques.

9.1.4: We have no comments.

9.1.5: The sentence in square brackets is not necessary.

9.1.6: This section should be deleted.

9.6.1: The sentence [or: the statement: Breast milk ... other illnesses] in the inner brackets should be deleted.

KOREA, REPUBLIC OF

3. Essential composition and quality factors

In 3.1.2 (e) Fat and fatty acids

- there is possibility that so many kinds of trans fatty acids derived from unsaturated fatty acids and it is still difficult to determine exactly to ensure quality control.

  a) 'the trans fatty acids content shall not exceed 4 % of the total fat content' to be removed, and 'fats or oils hydrogenated shall not be used as lipids source for infant formula' is preferably placed somewhere instead.

In 3.1.2. (f) Carbohydrates

- request this section to be reviewed for the composition of sugars of carbohydrate, there seems to be necessary lactose content should be ensured to somewhat percentage of total carbohydrates since the nutrient composition of this product is intended to be similar to that of breast milk, and a suggestion be added to this section as following:

  a) *lactose content shall not be less than 50 % of the total carbohydrates.*

In 3.4 Consistency and particle size

- materials for teat can be various and can be suggested as:

  a) When prepared according to the label directions for use, the product shall be free of lumps and of large coarse particles and suitable for being fed through *an appropriate artificial teat* (instead of a soft rubber or plastic teat).

In 9.4 Date marking and storage instructions

- a suggestion and reasons for adjustment of the sentence is shown in the section of Cereal based food for infant and young children, 8.4 Date marking and storage instructions.

In 9.6 Additional labeling requirements

- in this article, it seems to be complicate to do so, and only instruction for appropriate preparation will be enough, thereafter

  a) the last sentence 'and e) a warning against the health hazards of inappropriate preparation' to be removed.

POLAND

point 3.1. – the content of iodine (I) should be limited also to the maximum level,

point 4.4. – the content of antioxidants should be given as "singly or in combination".

According to the Polish draft food legislation the permitted level of heavy metals should be for the milk products for infant and young children:

- Pb – no more than – 0.1 mg/kg
- Cd – no more than – 0.01 mg/kg
- Hg – no more than – 0.05 mg/kg
- As – no more than – 0.1 mg/kg
- Zn – no more than – 35.0 mg/kg.

SPAIN

Section 1. Scope

We suggest that Subsection 1.3. be deleted on the grounds that no reference should be made to future World Health Assembly resolutions whose content is unknown.

Section 2. Description

We suggest that the square brackets in paragraph 2.1.2. be deleted.

Section 3. Essential Composition and Quality Factors

- In paragraph 3.1.2., first line, "... contain 100 kilocalories ...", should read "... contain per 100 kilocalories ..." (Translator's Note: English text already reads "... per 100 kilocalories ...")
- In the table, the values for zinc, which presently read:

"	Amounts per 100 kilocalories		Amounts per 100 kJ	
	minimum	maximum	minimum	maximum
Zinc (Zn)	0.5 mg	1. 5 mg[1]	0. 12 mg	0. 6 mg[1]"

Should read:

"	Amounts per 100 kilocalories		Amounts per 100 kJ	
	minimum	maximum	minimum	maximum
Zinc (Zn)	0.5 mg	1.5 mg	0. 12 mg	0.36 mg"

- The table should specify the values for choline
- In paragraph d) Protein, the first two subparagraphs should be substituted as follows:

  "Protein content = nitrogen content *x* 6.38 for cow's milk proteins.

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

- We suggest deleting the content of the last subparagraph of indent (ii) of the paragraph on "Protein", which appears in square brackets, as it could give rise to technical barriers to the international trade of foods.

Section 4. Food Additives

Subsection 4. 1. - Thickening Agents.

Envisaging the use of chemically modified starches is not technically justified. Other thickening agents are proposed and, besides, these forms of starch with phosphorus could upset Ca : P equilibrium.

Subsection 4.2. - Emulsifiers.

There should be a note stating the reduction in the proportional share of lecithin or mono- and diglycerides.

Section 5. Contaminants

The wording "practically free from other contaminants" in Subsection 5.2 is not acceptable as it does not provide the necessary juridical or practical basis for official food control or guarantee the movement of goods. Concrete figures should therefore be included for pesticides, heavy metals and other contaminants.

Section 9. Labelling

- To ensure that the information is correct and not misleading to the consumer, Subsection 9.1.3. should be redrafted as follows:

  "9.1.3. If the protein is derived entirely from cow's milk, the product shall be labelled "milk for infants".

- We suggest that paragraph 9.1.6. be deleted as products with less than 0.5 mg iron/ 100 kcal cannot be marketed, as specified in the table in paragraph 3.1.2.

- In Subparagraph 9.3(a), first line, "... expressed in kilocalories (kcal) and/or kilojoules should read "... expressed in kilocalories (kcal) and kilojoules .....

- The square brackets in Paragraph 9.5.2. should be removed and the content reworded to "over four to six months of age".

- The content of the square brackets in Paragraph 9.6. 1. should be removed as it could mislead the consumer.

Annex I

We propose the table given in Annex I to Document CX/NSFDU 98/7 which reads as follows:

ESSENTIAL AND SEMI-ESSENTIAL AMINOACIDS IN BREAST MILK

For the purpose of this Standard, the essential and semi-essential aminoacids in breast milk, expressed in mg per 100 kJ and 100 kcal, are the following:

	per 100 kJ	per 100 kcal
Arginine	16	69
Cystine	6	24
Histidine	11	45
Isoleucine	17	72

	per 100 kJ	per 100 kcal
Leucine	37	156
Lysine	29	122
Methionine	7	29
Phenylalanine	15	62
Threonine	19	80
Tryptophan	7	30
Tyrosine	14	59
Valine	19	80

ENCA - EUROPEAN NETWORK OF CHILDBIRTH ASSOCIATIONS

1. Scope

Reference to the International Code must stay in the scope. The harmonisation of international regulatory documents facilitates their implantation through national legislation.

1.3. Delete the brackets around relevant WHA resolution because they give clarification to the international code.

The European directive dealing with formula (91/321/CEE) refers to the aims and principles of the Code and allows member states to follow the international code in the legislation of marketing and information.

Rephrase 1.3. to read. The application of the standard shall follow the recommendation given to countries under the International Code ...

2. Description

2.1.2 *Delete* the reference to any age because it suggest an earlier introduction of complementary foods than may be necessary.

3. Composition

3.1.2. (f) *Change the Reading to* ***"fat and fatty acids"***

Change to read **"the trans fatty acid content shall not exceed 2 % of the total fat amount."**

This reduction is important because trans fatty acids has been shown to impair the metabolism.

Peanut oil (arachis) should not be allowed to be added because it trigger a lot of allergies. Long chain fatty acids as DHA and AA which have shown to enhance the neural development and which are present in breastmilk should be added.

5.1. Pesticides residues

Infant formula should be free of pesticides residues and ideally should be produced without the involvement of pesticides in the productions, storage or processing process.

5.2 Other contaminants

delete the word "**practically**"

9. Labelling

The labelling requirements should not be weakened. Some changes would further improve the protection of the consumer.

9.1.5 "***Delete the brackets*** **no health claims, shall be made regarding the dietary properties of this product"**

and add **"no nutrient content claims or no nutrient and add no function claims**

Reason: These claim are used to promote these products.

9.6.1. This section is very important. It must not be weakened. Square brackets should be deleted.

9.6.2. and *c) add* **"independent"** before health-worker

e) *add* that **"leftover formula should be discarded."**

9.6.2. change "may have graphics" to **"must have"**

9.6.4. add a paragraph saying **"The products should be labelled to avoid confusion between infant formula and follow-on formula."**

This labelling requirement is also in the European Council Directive intended for export to third countries.

EUROPEAN COMMISSION

1. Section 1.1. "Scope"

The second sentence of this section causes concern for the following reasons:

a) It proposes to make the provision of the standard applicable to products intended for infants with special nutritional requirements, meaning foods for special medical purposes.

However the definition of foods for particular nutritional uses in general refers to foods "... which ... satisfy particular dietary requirements ...". The risk of confusion is evident.

b) There will be confusion as to whether the standard in infant formulae or the standard on foods for special medical purposes will be applicable to products for special medical purposes intended for infants.

If the standard on infant formulae were to apply then statements such as

- use under medical supervision;

- the product poses a health hazard if used by persons for which is not intended

- for the dietary management of (disease, disorder);

- concerning contra-indications

which are foreseen by the Codex Standard on foods for special medical purposes will not be included on the labelling.

c) If the standard on infant formulae were to apply there would be some provisions that would be inappropriate for products for special medical purposes for infants. For example in those cases where breast milk is contra-indicated (e.g. galactosemia, phenylketonuria) a statement as to the superiority of breast-feeding would be contrary to medical advice and undermine the confidence of those responsible for feeding these infants towards such medical advice.

For the above reasons formulae for special medical purposes intended for infants should be covered by the standard on foods for special medical purposes and not by the standard on infant formulae. The latter should be amended to state that, where this is not contrary to the requirements dictated by the intended use, foods for special medical purposes intended specifically for infants shall comply with the relevant compositional requirements laid down in the Codex Standard for infant formulae and its subsequent revisions.

2. Section 1.3. "Scope"

The reference to relevant World Health Assembly Resolutions is not acceptable. The text in square brackets should be deleted.

3. Section 2.1.2.

The text in the square brackets is the essential part of the definition and should be retained as such. Other products, which are not complete formulae, may promote normal growth and development but are not able to sustain them alone and are not infant formulae.

4. Section 3.1.2.b. "Minerals"

The maximum for Zinc per 100 U should be 0.36 mg instead of 0.6 mg.

5. Section 4. "Additives".

Will collaborate with relevant Working Group.

6. Section 9.1.5. "Health claims"

The proposed sentence on claims, in square brackets, is not acceptable and should be deleted.

7. Section 9.1.6. "Iron"

The two paragraphs under consideration do not have to be alternatives; both could be retained. However, the first alternative should be facultative i.e. instead of "... shall be labelled ... " it should read "... may be labelled".

If a choice must be made, then the second alternative is preferable.

8. Section 9.5.2.

The text in square brackets should read "over four to six months of age".

9. Section 9.6.1. and 9.6.2. "Labelling"

The square brackets should be deleted.

10. Section 9.6.1.b. "Labelling"

The proposed alternative statement in square brackets is not acceptable.

11. Annex 1

There are reservations about the new figures in the Annex and the implications for the composition of currently available products.

IBFAN - INTERNATIONAL BABY FOOD ACTION NETWORK

The revised draft of the Standard on Infant Formula is a great improvement of the current Standard. It is an important step forward in the protection of infant health. The following suggestions could improve the revised draft further.

* = the most important proposed changes

* 1. SCOPE

1.1 Delete "healthy"

An international standard should apply to all infants. Deleting reference to "healthy" in this sentence is necessary considering the next sentence which reads "The provisions of this standard are also intended for infants with special nutritional requirements, except for certain provisions which must be modified to meet those special requirements."

1.3 Remove square brackets. Reword to read "The application of the Standard **shall be in conformity with the** recommendations given to countries under the International Code of Marketing of Breast-milk Substitutes and relevant World Health Assembly resolutions."

Reference to the International Code is needed in the Standard. It is the universally accepted basis which governs the marketing of infant formula and as such should be reflected in the Codex Standard. WHO encourages governments to implement the International Code through legislation, regulation and other appropriate measures, and the harmonization of these two documents would facilitate this process. The above revised wording is similar to that of the European Commission Directive on infant formulae and follow-on formulae.

*2. Description

2.1.2 delete text in square brackets

The amended text is simpler and clearer.

3. Essential Composition and Quality factors

3.2.4 Harmonize naming of vitamins (vitamin and then chemical name in parentheses)

Generally the revised draft standard proposes adequate content requirements with the following exceptions:

3.1.2 (e) Fat and Fatty Acid(sic)

Add "s" to fatty acid.

Change to read: **-the trans fatty acid level of liquid formula shall not exceed 2 % and the trans fatty acid level of powdered formula shall not exceed 1.5 %.**

The 4 % in the draft standard is higher than the current average levels of these undesirable fatty acids in North American infant formulas. Trans fatty acids have been implicated in impairing the metabolic conversion of linolenic and linleic acids to DHA and AA. They may be incorporated into the developing brain and retinal tissue and alter optimal physiological function.

-no erucic acid.

(Docosahexaenoic acid (DHA and arachadonic acid (AA) should be added to infant formula. The required amounts need to be discussed.)

(f) Carbohydrates

Add: **Maximum level of sucrose should be 20% of total carbohydrate content.**
Minimum level of lactose should be 0.85 g/100 kJ

Lactose is the natural sugar found in breast milk; therefore, the lactose content in infant formula should be maximalized. The sucrose (cristalized common sugar) level should be limited. These composition requirements are in conformity with the European Council Directive on infant formulae and follow-on-formulae.

4. Food Additives

4.1 Delete the section in square brackets.

There is no need for thickening agents, emulsifiers and antioxidants in the preparation of infant formula.

5. Contaminants

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

This standard should have a stated maximum level for pesticides and not vague phrases such as the present text "pesticides ... are reduced to the maximum extent possible". However there are 200 known pesticides found in baby foods. By stating the maximum allowed level for each pesticide the cumulative pesticide load is unclear and may present a health hazard to babies and young children.

5.2 Remove square brackets, delete "practically", and change to read: "The product shall be free from residues of hormones, antibiotics, **N-nitrosamines, nitrates, heavy metals, mycotoxins**, as determined by means of agreed analysis, and free from other contaminants, especially pharmacologically active substances."

Infant formula, the sole food source of infant for the first 6 months of life should be free from all contaminants, not only residues of hormones and antibiotics. Ideally infant formula should be totally free from such contaminants.

6. Hygiene

6.1 Reword to read: **"The product covered by the provisions of this standard shall be prepared and handled in accordance with the appropriate sections of the Recommended International Code of Practice-General Principles of Food Hygiene (CAC/RCP 11969, Rev. 3, 1997), and the Recommended International Code of Hygiene Practice for Foods for Infants and Children (CAC/RCP 21-1979)."**

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

6.3 (a) Reword to read: **"shall be free from pathogenic microorganisms"**

6.3 (b) Reword to read: **"shall be free from parasites"**

Add: **6.3 (d) "shall not contain any other poisonous or deleterius substances in amounts which may be a hazard to health."**

*9. Labelling

The revision of the standard improved the section on labelling to provide greater protection of infant health. We advocate that no changes be made to weaken this section. The following changes would further improve the standard:

9.1.4 Remove square brackets and change "may" to "must". Reword to read: "A product which contains neither milk or any milk derivative **must** be labelled "contains no milk or milk product" **and must state the source of the protein content, i.e. 'Infant Formula Based on Soya'.**"

Parents have the right to know the animal or plant source of the ingredients in infant formula. This is especially important in the case of suspected allergy. Parents also may not wish to use a soy product if they suspect its coming from genetically manipulated plants.

*9.1.5 Remove square brackets and change the last sentence to read: "No health claims, **nutrient function claims or nutrient content claims** shall be made regarding the dietary properties of this product."

Infant formula manufacturers are increasingly using health claims to promote their products. Such claims could be used to undermine breastfeeding by creating a misleading perception that breastmilk and infant formula are equal. For example, current labels claim that products prevent allergic reactions, prevent spitting up, or contain nucleotides. Health claims are not allowed in the Codex Draft Guidelines for Use of Nutrition Claims (Alinorm 97/22 appendix II). In any event the sentence regarding health claims must not be deleted.

9.1.6 Delete first bracketted text. Retain second bracketted text and reword to read: "Products containing less than 0.5 mg Iron (Fe)/100 kcal shall be labelled with a statement to the effect than when the product is given to infants over the age of **six months**, their total iron requirements must be met from **local complementary foods that are good sources of iron.**"

The above text is a warning to parents that they should try to increase their infant's iron intake from the age of six months by feeding with high iron complementary foods.

Section 9.6.1 is an important addition to the original standard. It essentially adds the labelling section of the International Code to the Codex Standard. It must not be weakened. The following changes would improve it.

9.6.1 and 9.6.2 Remove square brackets.

9.6.1 Regarding the two alternative text suggestioned for (a) **"Breastfeeding helps protect your child against diarrhea and other illnesses"** is a good compromise.

It is both the act of breastfeeding and breast milk which are protective.

In section (c) of the same paragraph insert the word "independent" to read "'(c) a statement that the product should only be used on the advice of an **independent** health worker as to the need for the use and the proper method for use;"

Pharmacists are commonly being referred to as "health workers". Because pharmacists sell the infant formula they are not independent of commercial influences.

In section (e) change to read. "(e) a warning against the health hazards of inappropriate preparation **and a statement that leftover formula should be discarded.**"

Bacteria and viruses will grow in leftover formula. It then becomes a source of infection for the infant.

9.6.2 Change to read. "The label shall have no pictures of infants nor any other picture or text which idealizes **artificial feeding**. The label **must carry clear** graphic **instructions** illustrating the method of preparation of the product.

These changes strengthen the text on graphics. The text now says "may have graphics" showing the method of preparation. The labels must have these graphics so that mothers who cannot read have a better chance of mixing the formula correctly.

9.6.3 Change to read: "The terms 'humanized, 'maternalized' or **any** other **comparison to human milk shall not be used on the label or information accompanying the product.**"

Labels and accompanying information should not give the impression to consumers that the product is as good as breast milk for infants

***** Add. **9.6.4 "The products shall be labelled in such a way as to avoid any risk of confusion between infant formula and follow-on formula".**

Many brands currently show very little difference between the labels of these two very different products. Young infants can become very ill if fed follow-on formula. These products are usually cheaper so mothers are tempted to buy them. This labelling requirement is also found in the "European Council Directive on infant formulae and follow-on-formulae intended for export to third countries".

ISDI - INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES

1. SCOPE

1.1.

The second sentence of this paragraph should be modified as this covers formulae intended for infant not in good health (special nutritional requirements). In the European legislation these formulae are classified as Foods for Special Medical Purposes. An equivalent Standard at Codex level should be developed soon.
Products intended for infants not in good health are highly specific and are designed for the dietary management for infants suffering from a particular disease (e.g. infant suffering of phenylketonuria, of galactosemia, malabsorbtion, allergies, inborn error of metabolism etc..). The composition and the labelling of such products cannot be governed by provisions for infant formula for several reasons:

- These products covers age range from 0 to over 4-6 months (e.g. up to 18 months)
- They should be used under health care supervision
- They have specific compositions which most of the time cannot meet provisions of Infant Formula Standard
- Due to specific composition, some products may pose health care hazard if used by persons for which is not intended
- Infant formulae or breastmilk may be contraindicated for certain diseases
- Specific labelling provisions should be applied to these products.
- There are important risks of confusion and misuse if these products are under the scope of the infant formula Standard.

For these reasons Foods for Special Medical Purposes (FSMPs) intended for infants should be regulated by the same rules established for FSMPs for adults in the future Standard. ISDI proposes to amend the present wording of the section 1.1 of the Infant Formula Standard on the understanding that deviations from the labelling as well as from the compositional parameters should be permitted for infants with special nutritional requirements. However, its should be stated that as soon as the FSMPs Standard is drafted, FSMPs for infants should be transferred from infant formula Standard into the FSMPs Standard.

1.3. The current wording was proposed by the Canadian delegation as a compromise and found acceptable by many delegations except the reference to the WHA resolutions. Thus, ISDI 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 not under the control of the CCNFSDU and consequently this Committee should not endorse future resolutions which may not be in agreement with or of relevance to this Standard.

Furthermore, as reminded in the discussion of the Standard on General Principles, ISDI would like to stress that Standards should be established **only** on a scientific basis.

2. DESCRIPTION

2.1.2. ISDI agreed with the present wording and favours the deletion of the square brackets. There is a wide spread international scientific consensus that breast-milk alone is sufficient to feed 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 infant during the first four to six months of life.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1. ESSENTIAL COMPOSITION

Vitamins and minerals – ISDI agrees with the proposed table for vitamins and minerals with the exception of the following:

Vitamin A -- The previous Standard expressed the quantity of vitamin A in I.U., while in the current draft it is in µg of retinol equivalents. ISDI proposes to express the quantity of vitamin A in both units, i.e. in I.U. and in µg retinol equivalents, in the same way as for vitamin D it is expressed in I.U. and µg. calciferol equivalent.

Additionally, there is no toxicological reason for the relatively low maximum for vitamin A (retinol equivalents/RE) of 180µg RE (600 I.U)/100 kcal. The U.S. Infant Formula Act allows a maximum of 225µg RE (750 I.U)/100 kcal, which applies only to preformed vitamin A). ISDI favours the adoption of 225µg RE /100 kcal as maximum level as recommended by the Infant Formulae Act.

Potassium/ Chloride -- The proposed maximum values for potassium and chloride are too restrictive. They are unnecessary from a safety standpoint and in some instances difficult or even impossible to meet.

U.S. Infant Formula Act (IFA) and Canadian requirements, as well as the previous Codex infant formula standard, for these electrolytes have maxima of 200 mg/100 kcal for potassium and 150 mg/100 kcal for chloride. Electrolytes were found to have other important functions in formulas, the IFA ranges were considered adequate to meet the needs for a wide range of infant formulas. The industry's experience suggests that this is the case. Additionally, further restrictions such as those proposed in the draft Codex Standard could limit the development of new formula or result in poorly stabilised products or undesirable acid-base balance for infants.

The total mEq of anions must balance the total mEq of cations to have electroneutrality. Sodium and potassium are the primary cations in formulas. Calcium will combine with phosphate to give an insoluble salt and would be chelated with citrate if there were inadequate phosphate to bind it.

Chloride is the major anion, but citrate is present in all infant formulas as an easily metabolised organic anion. Much of the citrate is chelated with calcium and magnesium, but these soluble complexes carry a negative charge. Since calcium and magnesium tend to destabilise proteins, it is important that the activities of these ions be kept low.

Proteins and some amino acids carry net charges at the usual pH of infant formulas, 6.5 to 7.0. Most proteins are net anions in this pH range. Other anions such as sulphate are present at lower levels.

The balance of sodium, potassium, chloride and citrate ions is a primary determinant of the pH of an infant formula. If the product is too acid, it will not be possible to make a stable feeding and if too alkaline, it will result in damage to protein and other nutrients.

The electrolytes also have important functions in acid-base balance of the infant. Excretion of sodium or potassium represents a loss of permanent base unless the ions are accompanied by an equimolar amount of chloride. Loss of chloride without sodium or potassium is a net loss of permanent acid and can lead to alkalosis.

An infant formula should have a net excess of permanent base. The metabolism of sulphur amino acids to sulphate produces permanent acid that must be excreted. The deposition of calcium and phosphate in bone and teeth also results in acid that must be excreted.

Subsequently, ISDI recommends that previous maximum levels for potassium and chloride (200 and 150 mg /100 kcal respectively) as adopted in the previous Infant Formula Standard (CODEX STAN 75-1981) be kept as such.

Phosphorus – ISDI is of the opinion that there is no need for setting a maximum for phosphorus as there is a maximum limit fixed by the Ca/P ratio. A maximum level for phosphorus may be misinterpreted.

Iron -- The proposed maxima for iron are too low. The current US Infant Formula Act has a maximum for iron of 3.0 mg/ 100 kcal and ISDI fully supports this maximum level taking into account that iron deficiency is one of the major health problem in the world.

Iodine – ISDI supports the present proposed values which are in accordance with the European Infant Formulae Directive 91/321/EEC.

Copper – 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*[1]*.,* 1995; Schlesinger[2] *et al.,* 1992) have found no adverse effects on 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 (Hamill *et al.*, 1989[3]). 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.

Zinc - First line, the maximum level for zinc should be read 0.36 mg /100 kJ

Manganese -- 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 maximum limit be set for manganese. However, if an upper limit is set, it should be no less than 50µg / 100 kcal **added** manganese. The US LSRO (September 1998) recommends a maximum level of 100µg/100 kcal.

Selenium – ISDI supports the absence of a minimum requirement for selenium. Although there is clear evidence for the essentiality of selenium for infants, infant formula manufacturers' experience does not indicate a need for a selenium minimum. No evidence of Se deficiency had been observed in formula-fed infants. Infant formulas without Se fortification have inherent Se contents ranging from approximately 2 to 15 µg Se/l. Nevertheless the addition of selenium may be desirable in some cases. 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)[4] states that human milk 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 other adverse effects of high intakes of selenium has not been reported in human milk-fed infants in the US. Similarly no selenium toxicity or other adverse effects of high intakes of selenium have been reported in formula fed infants.

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[1] Jochum F, Fuchs A, Cser A, et al. Trace mineral status of full-term infants fed human milk, milk-based formula or partially hydrolysed whey protein formula. *Analyst* 1995;120:905-9.

[2] 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.

[3] 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.

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

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

ISDI would like to stress that maxima for selenium and manganese should be set **only when these nutrients are added** to the infant formulae.

In addition, ISDI would suggest that the conversion factor between kJ and kcal should be kept closer to the value 4.18 when appropriate.

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. 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.*" During the last session the value of 2.2 has been questioned and was replaced by the value of 2.0 in square brackets. ISDI requests that the upper limit for the Ca: P ratio is set at 2.2 as originally requested by the French, Brazilian and Swiss delegations. This request is also supported and clearly expressed in the UK recommendations[5].

3.1.2.(d) PROTEIN

3.1.2.(d)ii. ISDI would recommend that the sentence bracketed 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*." be deleted This statement goes against Codex' goal of creating unified standards and will constitute an important barrier to trade.

3.1.2.(e). Fat and Fatty Acid

In the title, an "s" should be added to fatty acid to read Fatty Acids.

Section on linoleic acid. Upper limits for linoleic acid have been set based in part on the average levels human milk and suggestions that high levels of linoleic acid may suppress long chain polyunsaturated (LCP) fatty acid synthesis and subsequent prostaglandin formation. The results of one recent study challenge this concept. No suppressive effects of high dietary linoleic acid levels were found on the biosynthesis of docosahexanoic acid (DHA) from linolenic acid using

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

high-precision mass spectrometry tracer methods (Sheaff *et al.*, 1995[6]). Additionally, the results of multigeneration studies with rodents (Bourre *et al.*, 1989[7]) and formula-feeding studies with neonatal piglets (Arbuckle *et al*, 1994[8]) showed that the tissue accretion of the long-chain derivatives of linoleic acid and linolenic acid is dependent on dietary amounts, less so on their ratios. In these studies, the levels of DHA in retinal and synaptosomal membranes were little affected by the dietary quantity of linoleic acid if linolenic acid was provided at a minimum of 0.7% of energy (0.078 g/100 kcal).

If an upper limit is set, ISDI suggests a level of 2.24g linoleic acid/100 kcal which is accordance with the US LSRO recommendation (September 1998). This is supported by data regarding the maximum levels of linoleic acid reported in human milk (in excess of 42% total fatty acids, Insull and Ahrens, 1959[9]; Insull *et al.*, 1959[10]) plus an additional 20% for variability. These levels are known to vary considerably depending on the diet of the lactating woman (Insull *et al.*, 1959[9]; Sanders, 1992;[11] Innis, 1992[12]; Koletzko, 1992[13]).

In addition, ISDI would recommend a linoleic/α-linolenic acid ratio from 5 to 20.

3.2 OPTIONAL INGREDIENTS

3.2.1 There is a typing error, 0 should be deleted in the word "infan0t".

3.3 VITAMIN COMPOUNDS AND MINERAL SALTS

3.3.1. The reference to "Sections 3.1.2(a,b,c,d)" should be "Sections 3.1.2(a,b,c)" as there is no section "d".

In addition, ISDI strongly favours the revision of the Advisory List of Mineral Salts and Vitamin Compounds for use in Foods for infants and young children (CAC/GL 10-1979). This

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[6] 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.

[7] Bourre JM, François M, Youyou A, et al: The effects of dietary a-linolenic acid on the composition of nerve membranes, enzymatic activity, amplitude of electrophysiological parameters, resistance to poisons and performance of learning tasks in rats. *J Nutr* 1989;119:1880-2.

[8] Arbuckle LK, MacKinnon MJ, Innis SM: Formula 18:2(n-6) and 18:3(n-3) content and ratio influence long-chain polyunsaturated fatty acids in the developing piglet liver and central nervous system. *J Nutr* 1994;124:289-98.

[9] Insull W, Ahrens EH: The fatty acids of human milk from mothers on diets taken ad libitum. *Biochem J* 1959;72:27-33.

[10] Insull W, Hirsch J, James T, Ahrens EH: The fatty acids of human milk. II. alterations produced by manipulation of caloric balance and exchange of dietary fats. *J Clin Invest* 1959;443-50.

[11] Sanders TAB, Reddy S: The influence of a vegetarian diet on the fatty acid composition of human milk and the essential fatty acid status of the infant. *J Pediatr* 1992;120:S71-7.

[12] Innis SM. Human milk and formula fatty acids. *J Pediatr* 1992:120:S56-61.

[13] Koletzko B, Thiel I, Abiodun PO: The fatty acid composition of human milk in Europe and Africa. *J Pediatr* 1992;120:S62-70.

task has been mentioned in the "summary status of work" (p18). ISDI has already forwarded a list of substances (attached to this document) which are presently missing and is ready to collaborate in the revision of this list.

4. FOOD ADDITIVES

The revision of the list of food additives has been officially decided during the last Codex session. It will be undertaken simultaneously with the revision of the list of the Standard for processed cereal-based foods for infants and young children ISDI supports this revision and suggests adding additives already evaluated by scientific bodies such as the European Scientific Committee on foods. This committee has already evaluated the technological needs and the nutritional safety of several additives that are needed in the manufacture of infant formulae intended for healthy infants as well as for infants not in good health.

9. LABELLING

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.

9.1.4 ISDI support the deletion of the square brackets

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 are sufficient to prevent inappropriate claims

9.1.6 This section regarding iron content is no more relevant and should be deleted. A common iron minimum has been set for all infant formulae.

9.3. DECLARATION OF NUTRITIVE VALUE.

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….."*

9.5 INFORMATION FOR USE

9.5.2. 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."*

9.6 ADDITIONAL LABELLING REQUIREMENTS

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.

ANNEX 1

The annex contains the reference amino acid composition (aminogram) for breast-milk. The original draft revised standard contained the aminogram of the EU Directive. At last year meeting of CCNFSDU in Berlin it was replaced by one derived from a study by Sarwar, as proposed by the Canadian delegation. The Sarwar aminogram is significantly different from the one currently in use in the EU. In particular for three amino acids considerably higher levels are reported: Arginine +55 %, Cystine +83 % and Tyrosine +44 %, as shown in the table.

For several reasons the Sarwar aminogram is not acceptable:

- The study focussed mainly on the cystine and tyrosine content and the comparison between preterm and term milk. It should be noted, however, that the study measured "transition milk" (5 – 10 days post partum) instead of "mature milk. This is reflected in the unusual 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.
- The amino acid values are reported as amino acyl residues, which gives a 10 % higher value when compared with amino acids.
- The Canadian proposal did not take into account the presence of so-called Non Protein Nitrogen, which is about 25 % of the total nitrogen in breast milk. They simply calculated amino acyl content per 100 g protein x 1.08 %.
- 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 at all in conformity with the values reported until now in the literature.

Adoption of the new 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. But it should be remembered that arginine is not even an

essential amino acid, but is in the body synthesised from lysine. This is reflected by the fact that 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 non appropriate and should be replaced by the original EU aminogram.

	mg/100 kcal		Alinorm 99/26 vs EC Directive
	EC Directive	Alinorm 99/26	
ARG	69	107	**155%**
CYS	24	44	**183%**
HIS	45	47	104%
ILE	72	83	115%
LEU	156	167	107%
LYS	122	119	98%
MET	29	23	79%
PHE	62	75	121%
THR	80	77	96%
TRY	30	31	103%
TYR	59	85	**144%**
VAL	80	99	124%