codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 4 **CX/NFSDU 02/4-Add. 1**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

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

PROPOSED DRAFT REVISED STANDARD FOR INFANT FORMULA

- Comments at Step 3 of the Procedure

Comments from:

CUBA
ENCA - EUROPEAN NETWORK OF CHILDBIRTH ASSOCIATIONS

CUBA

II Recommendations

A. General Principles for establishing minimum and maximum values for the essential composition of infant formula

We agree with the ten proposed general principles. We support the first nine principles exactly as they are; as for principle No 10 we prefer the first version: Maximum amounts of essential nutrients should be established only for those nutrients for which there is sufficient evidence of adverse health effects at higher levels.

B. Additional considerations for general principles.

Minimum levels

We agree that a consideration in determining whether there is a need for a minimum level is whether a nutrient has been shown to be essential and that a possible starting point for establishing a minimum level might be the composition of breastmilk. We note that in establishing minimum levels, the general principles might also take into account the criteria of bioavailability.

Maximum levels

We share the view that a consideration in determining whether there is a need for a maximum level is whether a nutrient has been shown to result in adverse health effects at higher levels.

We think that the Committee may wish to address the need for additional general principles for maximum levels.

C. Additional considerations in presenting the information in the Section 3.1.2 table

We agree with the three additional rules mentioned in this section.

D. Proposed revisions to 3.1., Section 3.1.2

We propose to delete the word "energy" at the end of this section.

Vitamin A

We agree with the recommendation to provide a conversion factor in a footnote.

Vitamin D

As in the case of vitamin A, we agree with the proposal to show the conversion factor in a footnote.

Vitamin E

We support the replacement of "linoleic acid" by "polyunsaturated fatty acids".

We accept the proposals concerning the names for vitamin C, thiamin, riboflavin, niacin and biotin.

Folic acid

We agree with the proposed increase of the minimum value for folic acid to 11 µg /100 kcal.

Section 3.1 (B) Minerals.

Sodium, potassium, chloride, phosphorus and calcium.

We agree with the proposed deletion of the chemical abbreviations. In view of the reference to breast milk, we agree with an increase in the calcium/phosphorus ratio to 2.2.

We agree that as long as there is no scientific evidence to justify a change, maximum levels for calcium should be shown as "N.S.".

Concerning the above minerals we share the view that maximum values shall be shown as "T.B.D." until such time as the Committee can take into consideration recommendations for maximum protein levels (i. e. after the FAO/WHO Expert consultation on Energy and Protein requirements in Human Nutrition).

Magnesium

- The chemical abbreviation is to be deleted.
- We agree with the proposed change of maximum levels to "N.S.".

Iron

- The chemical abbreviation is to be deleted.
- We agree with the view that maximum levels for iron are absolutely necessary because of iron's inhibition of the absorption of zinc and copper.

Iodine

- We agree with the deletion of the chemical abbreviation.
- We agree with the proposed establishment of maximum levels because of the potential risk for excessive intakes to occur as a result of iodine contamination. Therefore, such levels should be shown as "T.B.D." until sufficient data are available to establish levels.

Copper

- The chemical abbreviation is to be deleted.
- We agree with the proposal to increase minimum levels to 60 µg and to show maximum levels as "T.B.D." until sufficient data are available to establish levels.

Zinc

- The chemical abbreviation is to be deleted.
- We support the proposal to show the maximum value as "T.B.D." until sufficient data are available to establish such levels.

Manganese

- The chemical abbreviation is to be deleted.
- We agree with the proposal to reduce the minimum level to 1 µg and to show the maximum level as "T.B.D." until sufficient data are available to establish such levels.

Selenium

- The chemical abbreviation is to be deleted.
- We support the establishment of a minimum level because selenium is an essential nutrient and agree with the proposed value of 6 µg/100 kcal which takes the selenium concentration of breastmilk into account.

The maximum level should be shown as "T.B.D." until sufficient data are available to establish such levels.

Choline

- We support the proposed minimum value (7 mg), as choline is considered an essential nutrient. The value takes into account the concentration found in breastmilk.

ENCA - EUROPEAN NETWORK OF CHILDBIRTH ASSOCIATIONS

1. SCOPE

1.1 **Remove square brackets** from the phrase **and add** highlighted word:

The provisions in this standard are also intended for infants with special nutritional requirements, except for certain ***compositional*** provisions which must be modified to meet those special requirements.

> *An international standard must protect all infants. Some compositional flexibility of the proposed draft standard can deal with any adjustment in ingredients to accommodate the needs of infants requiring dietary modifications by keeping the overall protection of this very young consumers through the other provisions of the standard.*

1.2 **Add** to read:

The standard contains compositional, quality and safety requirements to ensure "**as best possible**" a safe and nutritionally adequate product.

> *Infant formulas cannot be declared to be 100% safe or nutritionally adequate as they are only a replacement for breast milk. To accurately describe these products, the phrase **as best possible** is needed to qualify the statement.*

1.3 **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 World Health Assembly Resolutions 54.2 (2001).

2. DESCRIPTION

2.1.2 Delete the word [normal] as it is not clearly defined.

2.1.2 should read:

"Infant formula shall be nutritionally adequate to ensure growth and development when used in accordance with its directions for use. *FULLSTOP Delete rest of sentence.*

Retain the sentence: Only products that comply with...

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1.2(e) Fat and Fatty Acid

Add "s" to fatty acid, to read" Fat and Fatty Acids"

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

Trans fatty acids have been implicated in impairing the metabolic conversion of linolenic and linoleic acids to DHA and AA. Essential fatty acids are important in the brain, neural and retinal development of infants especially during the first six months of life.

- No erucic acid should be added to infant formulas.
- No peanut oil should be added because they can still contain substances which can trigger a peanut allergy
- DHA and AA should be added to all infant formulas as a global standard should give the best intellectual development potential to all infants.

(f) Carbohydrates

Lactose is the natural sugar found in breastmilk, therefore the lactose content in infant formula should be as optimal as possible. The addition of other sugars such as sucrose or starches should be restricted.

The carbohydrate content should not be fixed in gram/100 kcal but related to their relative sweetness compared to lactose in breastmilk.

3.2 Optional ingredients

3.2.3 ***Add:*** *Optional ingredients are mentioned in the ingredients list and give no right to make claims or use them in any promotional way to undermine breastfeeding.*

4. FOOD ADDITIVES

There is no need for thickening agents, emulsifiers and antioxidants in the preparation of infant formula with the exception of some special formulas where they may be necessary for product properties .

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 and processing of the raw materials or the finished food ingredient do not remain, or if technically unavoidable, **do not exceed a maximum level of 0.01 mg/kg for each substance in the product as sold** ."

This is in accordance with the European legislation.

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

Infant formula is the sole food for infants for the first six months of life and should be free from all contaminants, including residues of hormones and antibiotics. As hazardous levels for these substances are not known the current text linking permissible levels amounts which do not present a health hazard is impossible. Ideally infant formula should be totally free from such contaminants.

6. HYGIENE

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

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

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

6.3 **Add** this new paragraph.

The consumers should be informed that this is not a sterile product and that preparation shortly before feeding and discarding of left-over is needed to prevent multiplication of germs present in the product (cf. recent Enterobacter deaths in the US and in BELGIUM).

9. LABELLING

9.1 **Add** *"s" to language* **to read** *" languages" to reflect the linguistic situation in many countries.*

9.1.4 **Add** the following: and must state the source of the protein content, i.e. Infant Formula Based on Soya".

Consumers have the right to know the animal or plant source of the ingredients in infant formula.

9.1.5 **Remove** the square brackets from the last sentence and **read**:

"No health claims, shall be made regarding the dietary properties of the products."

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

9.6.1 b) **Remove** brackets around the first option and **keep** the text as proposed. Delete second option.

The advantages of breastmilk and breastfeeding for infants are proved by epidemiological research. The American Academy of Pediatrics has acknowledged them in their statement. Breastfeeding and the Use of Human Milk Pediatrics Vol 100 No 6 December 9. Since then more research have been published and reviewed that prove the superiority of breastfeeding.

9.6.1.e) It is important to give consumers a rational why prepared formula should not be stored.

Add this part of the sentence at the end: because of possible contamination of the product during manufacturing or preparation with pathogen germs which grow in the prepared product and can cause illness in the baby.

9.6.2 **Change** to read: "The label shall have no pictures of infants and women nor any other picture or text which idealizes artificial feeding. The label **must** have graphics illustrating the method of preparation of the product and methods of feeding **in accordance with the global strategy on infant and young child feeding**".

This is in accordance with the resolution accepted at the World Health Assembly in May 2002.

The label must have graphics so that mothers who cannot read have a better understanding.

9.6.4 Reword to read:

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

9.6.5 **Remove** brackets to **retain** the text.

Many brands currently show little difference between the labels of these two very different products. Young infants can become very ill if fed follow-up formula. These products are usually cheaper so mothers are tempted to buy them rather than routine formula.

This labelling requirement is also included in the European Council Directive on infant formulae and follow-on formulae.