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-Add. 2**
November 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:

- **CHINA**
- **CUBA (E, F, S)**
- **IBFAN - International Baby Food Action Network**

CHINA

2. DESCRIPTION

We suggest that 2.1.2. [and to satisfy by itself the nutritional requirements of infants during the first four to six months of life] be modified as [and to satisfy by itself the nutritional requirements of infants during the first six months of life].

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

We suggest that use both I.U. and mg or μg for Vitamin A and Vitamin E in 3.1.2 (a) Vitamins.

We propose not to change the amounts of Potassium, Chloride and Phosphorus in 3.1.2 (b) **Minerals** from the current standard.

The Minimum level of Selenium (Se) in 3.1.2 (b) **Minerals** should be N.S.

We believe that the maximum value of Ca:P ratio should be 2.2 in the footnotes of 3.1.2., based on the concept that the Ca:P ratio should be close to that of human breast milk. According to Barltrop and Hillier (1974) the Ca:P ratio of human breast milk ranges from 2.0 to 2.5 (Acta Paediatr Scand).

We suggest that the square brackets in 3.1.2 (d) Protein (ii) [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 removed.

We suggest that "- trans fatty acid content shall not exceed 4% of the total fat content;" in 3.1.2 (e) **Fat and Fatty Acid** be deleted. The reason is that there is no agreed analytical method for trans fatty acid, and it is difficult for laboratories in developing countries to measure trans fatty acids in infant formula.

We suggest that "The product shall contain carbohydrates at a level of not less than 7 g/100 kcal (1.7 g/100 kJ) and not more than 14 g/100 kcal (3.4 g/100 kJ)" in 3.1.2 (f) Carbohydrates be deleted.

4. FOOD ADDITIVES

We suggest that some natural fruit extracts which are already permitted in the CODEX STANDARD FOR FOLLOW-UP FORMULA, CODEX STAN 156-1987 (amended 1989) should be added in the list.

9. LABELING

We suggest that the square brackets in 9.1.4 [may] be removed.

We suggest that [No health claims shall be made regarding the dietary properties of the product.] in 9.1.5 be deleted.

We suggest that all the contents in 9.1.6 [Products containing not less than 0.5 mg Iron (Fe)/ 100 kilocalories shall be labeled "Infant Formula with added Iron"]. or [Products containing less than 0.5mg Iron (Fe)/ 100 kcal shall be labeled with a statement to the effect that when the product is given to infants over the age of four months, their total iron requirements must be met from other additional sources] be removed.

We suggest that the sentence "it protects against diarrhoea and other illnesses" in 9.6.1 b) be removed.

We suggest that the square brackets in 9.6.4 [over six months of age] be removed.

We suggest that the square brackets in 9.6.5 [The products shall be labeled in such a way as to avoid any risk of confusion between infant formula and follow-up formula] be removed.

CUBA (E, F, S)

In our opinion, the square brackets in **"SCOPE"**, item 1.3, should be deleted.

In **"PRODUCT DEFINITIONS"**, item 2.1.2, the square brackets should be deleted. The content matches current practice in our country.

In **"LABELLING"**, in our opinion the square brackets around or in 9.14, 9.15 and 9.16 should be deleted.

Nous considérons que dans le **CHAMP D'APPLICATION**, il faut supprimer les crochets à la section 1.3.

Supprimer les crochets à la section 2.1.2, "**DEFINITIONS DU PRODUIT**". Le contenu va dans le sens de la pratique dans notre pays.

Dans **ETIQUETAGE**, nous considérons qu'il faut supprimer les crochets aux sections 9.1.4, 9.1.5 et 9.1.6.

Consideramos que se deben eliminar los corchetes en **ÁMBITOS DE APLICACIÓN** en el 1.3.

Eliminar corchetes en 2.1.2 "**DEFINICIÓN DEL PRODUCTO**". Esto corresponde con la práctica actual en nuestro país.

En **ETIQUETADO** consideramos que se deben eliminar los corchetes en 9.14, 9.15 y 9.16.

IBFAN - INTERNATIONAL BABY FOOD ACTION NETWORK

The revised draft of the Standard on Infant Formula is a great improvement over the original standard. It is an important step forward in the protection of infant health. The following comments reflect suggestions that could be made to further improve the revised draft.

1. SCOPE

1.1 **delete**: "healthy"; **remove square brackets** from the phrase, "The provision in this standard are intended for infants with special nutritional requirements, except for certain provisions which must be modified to meet those special requirements.

"An international standard must protect 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 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.

Remove the text in square brackets "to date"

Remove the square brackets on footnote [25].

Add to footnote 25: "WHA 54.2 2001".

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. 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

3.1.2 Harmonize naming of vitamins (vitamin and then chemical name in parenthesis).

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

3.1.2(e) Fat and Fatty Acid

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 formulas shall not exceed 1.5%."

The 4% of the draft Standard is higher that 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 linoleic acids to DHA and AA. Also trans fatty acids may compromise the optimal growth and development of neural, brain and retinal tissue.

no erucic acid

Docosahexanoic acid (DHA) and arachadonic acid (AA) should be added to infant formulas.

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 0.85g/100kJ.

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 above compositional requirements are in conformity with the European Council Directive on infant formulae and follow-on formulae.

4. FOOD ADDITIVES

4.1; 4.2; 4.3; 4.4. Delete the section in square brackets

4.5 Carry-over of Food Additives.

Retain “No food additives shall be present as a result of carry-over from raw materials and other ingredients. Delete the remainder of this section.

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 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 standard should have a stated maximum level for pesticides and not vague phrases as in the present text, “pesticides…are reduced to the maximum extent possible”.

However there are 200 known pesticides 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. Therefore a maximum level of cumulative pesticide load should be defined based on independent scientific data.

5.2 Delete current text and change 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. Therefore ideally infant formula should be totally free from all contaminants, including residues of hormones and antibiotics. As hazardous levels for these substances for babies and young children are not known, it is impossible to determine permissible levels that do not present a health hazard for this group.

6. HYGIENE

6.1 Reword to read: 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 1 1969, Rev.3, 1997), and other relevant Codex texts such as Codes of Hygienic 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.

6.2 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"

9. LABELLING

The revised standard has improved the section on labelling to provide greater protection of infant health. The following changes are recommended to further improve the Standard.

9.1.4 Remove the square brackets and change "may" to "must". Reword to read: "A product which contains neither cow's milk or any cow's milk derivative must be labelled 'contains no cow's milk or cow's 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 in the case of suspected allergy. Parents may also wish to not use a soy product if they suspect its source to be from genetically modified plants and/or are concerned about the levels of phytoestrogens.

9.1.5 Remove the square brackets and change the last sentence to read: "No health claims, shall be made regarding the dietary properties of the products covered by this product".

Infant formula manufacturers are increasingly using health claims to market their products. Such claims could be used to undermine breastfeeding by creating a misleading perception that breastmilk and infant formula are equal. In general, claims are used to idealize the product rather than inform the consumer. This form of idealization is contrary to the International Code and therefore should not be permitted. The Proposed Draft Guidelines for Nutrition and Health Claims (Alinorm 01/22 Appendix VIII) recommend that no health claims be made for infant formulas and foods for foods for young children

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

9.6.1 Remove brackets

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

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

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".

The label must have graphics so that mothers who cannot read have a better chance of mixing the formula correctly.

9.6.4 Remove brackets and retain text.

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.