

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
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Agenda Item 4

CX/NFSDU 02/4- Add...

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
Twenty-fourth Session
Berlin, Germany, 4-8 November 2002**

Government Comments

INDIA

**Proposed Draft Revised Standard for Infant Formula
(ALINORM 03/26-APPENDIX-III)**

1. SCOPE

- 1.1 As per the WHO 54.2 (2001), there is a need for emphasis on continued exclusive breastfeeding up to the age of 6 months; Infant Formula should be used as a substitute for breast milk only when it is otherwise necessary. Also, since, these standards are intended for both for normal as well as infants with special nutritional requirements, the [] need to be removed. In view of above, India would suggest that the existing clause 1.1 should be modified as under:

“1.1 This standards applies to Infant Formula in liquid or powdered form intended for use as a substitute for human milk, when necessary in cases where it is not possible to continue exclusive breastfeeding up to the age of 6 months, for meeting the normal nutritional requirements of infants. The provisions of this standard are also intended for infants with special nutritional needs, except for certain essential composition which must be modified to meet those special requirements.”

- 1.2 Since, Infant Formula cannot be equated to breast milk in terms of its composition or safety it could provide to infant, this clause needs to be modified as under:

“ The standard contains best possible compositional, quality and safety requirements to ensure a safe and nutritionally adequate product”.

- 1.3 The clause should be reworded to read as under:

“ The application of the Standard shall be in conformity with the recommendations made to countries in the International Code of Marketing of Breast-Milk Substitutes and World Health Assembly Resolutions 54.2 (2001)”.

2. DESCRIPTION

Despite the sub-title, “Product Definition” under clause 2.1, the term, “Infant formula” has not been defined anywhere in the Draft Revised Standards. The clause 2.1.1 should be modified as under to include the definition for the product, in line with the definition for Infant Formula included under the International Code of Marketing of Breast-Milk Substitutes, namely:

“ 2.1.1 Infant formula means a breast milk substitute formulated to satisfy, by itself the nutritional requirements of normal infants during the first months of life up to the introduction of appropriate complimentary feeding”.

- 2.1.2 a. The [] s should be deleted.
- b. After removal of [], the sentence should be deleted.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1.1 In the first line, for the words, “ other animals”, the words, “ buffalo or a mixture thereof” should be substituted.

3.1.2a Vitamins:

- Vitamin A - After, Vitamin A, the words, “ Retinol equivalent (RE). 1 µg RE= 3.33 IU Vitamin A should be written in ().
- Vitamin D - the Iµ unit should be changed to µg, 1 µg chloecalciferol= 40 IU
Vitamin D
- Vitamin E - Linoleic acid should be changed to polyunsaturated fatty acids
- Vitamin C - Ascorbic acid should be changed to Vitamin C
- Thiamin - Vitamin B₁ should be changed to Thiamin
- Riboflavin - Vitamin B₂ should be changed to Riboflavin
- Niacin - Niacin equivalent should be changed to Niacin
- Folic acid - Maximum level should be 11 µg based on the range of total folic acid content in human milk.
- Vitamin K- Change vitamin K₁ to Vitamin K
- Biotin - remove (Vitamin H)

3.1.2b Minerals:

- a. Chemical abbreviations may be deleted for all minerals.
- Sodium, Potassium, Calcium, Phosphorus and iodine:

The amounts per 100 Kilocalories given in the column be deleted and TDB (to be determined) may be inserted.

MAGNESIUM:

The amounts per 100 Kilocalories given in the column be deleted and NS (No Support) may be inserted.

IRON

India does not agree to the amounts proposed. A single recommendation instead of 2 levels (for cow's milk and soy proteins) is proposed for fortified cow's milk formulas and for soy-based formulas based on comments that the processes using phytases have improved the bioavailability of iron from soy. Unless this is universal, the proposed change cannot be effected due to large variations in bioavailability.

COPPER:

Minimum may be increased from 20 µg to 60 µg and the maximum proposed be deleted and TBD may be inserted.

ZINC:

India does not agree to the amounts proposed. A single recommendation instead of 2 levels (for cow's milk and soy proteins) is proposed for fortified cow's milk formulas and for soy-based formulas based on comments that the processes using phytases have improved the bioavailability of iron from soy. Unless this is universal the proposed change cannot be effected due to large variations in bioavailability.

MANGANESE:

Minimum level be decreased from 5 to 1 µg and the maximum be changed from NS to TBD based on human milk content (Mean – 1 SD)

SELENIUM:

Minimum level be decreased from 7 µg to 6 µg and the maximum be deleted and TBD is suggested.

CHOLINE:

A minimum of 7 mg is suggested instead of NSD

3.1.2.(d) **Protein**

The possibility to use sources of protein other than milk and soya should be maintained as in the current Codex Stan 72-1981. Thus the second sentence should read as

“Protein content = nitrogen content x 6.25 for soya and other protein isolates and their partial hydrolysates.”

3.1.2(e) **Fat and Fatty Acid**

- a. "Fat and Fatty Acid" may be changed to read as "Fats and Fatty Acids"
- b. Since, trans fatty acids have been implicated in impairing the metabolic conversion of linolenic and linoleic acids to DHA and AA and essential fatty acids are important in the brain, neural and retinal development of infants, especially during the first six months of life, it is suggested that for the words, " the trans fatty content shall not exceed 4% of the total fat content", the words, " the trans fatty acid level of liquid formula shall not exceed 2% and trans fatty acid level of powdered formula shall not exceed 1.5% shall be substituted.
- c. {(Docosahexaenoic Acid (DHA) and Arachadonic Acid (AA) should be added to infant formula, as a global standard .The required amounts need to be discussed}
- d. No erucic acid should be added to infant formulas.
- e. Since, Cholesterol is found in the breast milk and other milks, which is essential nutritional component for human and animal babies. it is suggested that after the existing entries, the following should be added in the end, namely,

"- no hydrogenated fats containing trans fatty acids shall be added to the product and the milk fat shall not be less than 12 percent by weight of total fat"

3.2 f **Carbohydrates:**

The type of carbohydrates like lactose, sucrose etc. need be specified. The maximum level of sucrose should be 20% of total carbohydrates and minimum level of lactose should 0.85% g/100 kJ. Lactose does appear to be specific for newborn growth. It has been shown to enhance calcium absorption and has been suggested as being critical for the prevention of rickets, in view of the relatively low calcium level in human milk. Lactose is a readily available source of galactose, which is essential for the production of galactosides, including cerebrosides.

3.2 **OPTIONAL INGREDIENTS**

- a. The existing numbering of the clause be corrected to read as "3.2.1"
In conformity to WHA 54.2 (2001), in the last line, after the words, " infant", the following shall be added in the end, namely, "up to 6 months of life".

4. **FOOD ADDITIVES:**

The clauses 4.1 relating to THICKENING AGENTS, 4.2 relating to EMULSIFIERS and 4.4. relating to ANTIOXIDANTS NEED be deleted, as thickening agents, emulsifiers and antioxidants are not needed in the preparation of infant formula.

5. CONTAMINANTS

5.2 OTHER CONTAMINANTS

For the existing clause, the following shall be substituted, namely,

"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."

6 HYGIENE

The following shall be added in the end, namely,

"Infant formula shall be free from pathogenic microorganisms and parasites."

7 PACKAGING

7.2 May be reworded as under:

"The containers including packaging materials, shall be made only of substances which are safe, food grade quality, non-toxic and suitable for their intended use"

9. LABELLING

The following shall be added in the end, namely,

" The label shall be in appropriate languages of the country in which the product is marketed."

9.1.4 since, consumer has the right to know the animal or plant source of ingredients in infant formula. This is especially important in the case of suspected allergy. Consumer may not wish to use a soy a product if they suspect its coming from genetically modified food, it is suggested that the following shall be added in the end, namely,

"A Product which contains neither milk nor any milk derivative, the source of protein, e.g., infant formula based on soya, must be mentioned".

9.1.5 The Square brackets may be removed. Health claims are not permitted under the Codex Draft Guidelines for Use of Nutrition Claims (Alinorm 97/22 appendix II). Infant formula manufacturers are increasingly using health claims that a product prevent allergic reaction, prevent spitting up, or contains nucleotides to market their products. Such claims could be used to undermine breastfeeding by creating a misleading perception that breast milk and infant formula are similar or equal. It is therefore suggested that the last sentence should be modified as under:

"No health claims, nutrient function claims or nutrient claims shall be made regarding the dietary properties of the product."

9.1.6.a. Delete first bracketed text. In the second bracketed text, the [] may be deleted and the existing may be reworded to read as under:

“Product containing less than 0.5 mg. Iron (Fe) per 100 kcal shall be labeled with a statement to the effect that when the product is given to infants over the age of 6 months their total iron requirement must be met from complementary foods that are good sources of iron”.

9.6 **ADDITIONAL LABELING REQUIREMENT:**

9.6.1 b) Remove square bracket. India does not agree with either of the two statements. The statement should be **“MOTHER’S MILK IS BEST FOOD FOR YOUR BABY”** (in caps). This is in conformity with the International Code on Marketing of the Infant Milk Substitutes, Feeding Bottles and Infant Foods.

9.6.1 e) A clear cut indication of the dangers be given on the label – like consumption of left over formula will cause infection in the baby. This clause should thus be changed to read as under:

“ a warning against the health hazards of inappropriate preparation; a warning that the product is not sterile and that the formula must be prepared just before feeding and that left-over prepared product remaining after each feeding must be discarded.”

9.6.5 Remove brackets to retain the text.

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Agenda Item 5

CX/NFSDU 02/5- Add...

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
Twenty-fourth Session
Berlin, Germany, 4-8 November 2002

Government Comments

INDIA

Proposed Draft Revised Standard for Processed Cereals Based Food for Infant and Young Children (At step 3 of the procedure) - Appendix IV

1. SCOPE

As per the WHO 54.2 (2001), there is a need for emphasis on continued exclusive breastfeeding up to the age of 6 months; Infant Formula should be used as a substitute for breast milk only when it is otherwise necessary. In view of this, India would agree to retain the second option after removing the [].

2. DESCRIPTION

The milled cereals should be not less than 75%.

2.1 Product definitions

2.1.5 Change the numbering of this clause to 2.1.4

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 ESSENTIAL COMPOSITION

3.1.1 The ingredients, 'Pasta, starchy roots (such as arrow root, yam or cassava) or starchy stems' should be deleted, as the addition of starchy roots will have a negative impact on the nutritional density and quality of cereal-based products. Allowing starchy roots and stem products as a partial or whole basis of cereal-based complementary food can potentially lower the nutritional density, especially energy, protein and some micronutrients and is therefore incompatible with adequate infant nutrition. Manufacturer could then try to raise the protein by adding amino acids, which would only address this aspect of nutritional density. Also if a product is labeled as a cereal

food it would be misleading to parents to have only 25% of the product as cereal. The degree of milling should be specified in the product description because, a large part of the nutritional benefits of cereal grains are lost when only the starchy endosperm and not the germ part of the cereal grain is included in the product. Milk may also be added in the list of ingredient. India, therefore suggests that this clause be modified to read as under:

“Dry cereal is prepared from one or more milled cereal grain such as wheat, rice, barley, oats, rye, maize, millet, sorghum and buckwheat and /or legumes (pulses) and /or sesame.”

3.2 ENERGY DENSITY

The energy density of food should not be less than 0.8 kg. calories / 1 gm. (3.3 per kJ/ 1 g.) and not per 100 gms. as given in the document. This may be corrected

3.3 PROTEIN

3.3.1 one has to assume that in many situations where animal milks are not available or not part of the local diet that cereal-based foods will be mixed with water. The refinement of the cereal-based foods should be limited to retain the maximum protein content. This also ensures that other micronutrients are retained and not lost in the milling. India therefore suggests that in the existing clause, in the end, the following should be added in the end, namely:

"The minimum content of the product protein shall be no less than 10% on a dry weight basis."

3.4 CARBOHYDRATES

3.4.1 and 3.4.2

a. In clauses 3.4.1. & 3.4.2, delete the word, “honey”

b. The sugar content should be lower. It would be preferable to lower the maximum amount permitted.

3.4.2 There appears to be a mistake in calculation of carbohydrate content (first bullet). This point has been discussed in 1999 (ALINORM 99/26,para 63) and as a result, carbohydrate level has been modified raised from 1.2g to 2.0G/100KJ. This level was mistranscribed in the draft standard and the value of 2g is given for 100 kcal and then divided by 4.18 to obtain the value per KJ. Besides, Fructose is more than twice as sweet as glucose and therefore the amount permitted should be less. Consequently the sentence should read as under:

“- The amount of added carbohydrates shall not exceed 2.0g/100 Kj or 8.4g/100kcal the amount of added fructose shall not exceed 1.2 g/100 KJ (5 g/100kcal)”

3.5 Lipids

Trans fatty acids are undesirable ingredients for infants and young children, which have been implicated in impairing the metabolic conversions of linolenic and linoleic acids to DHA and AA. It is therefore, suggested that the following should be added in the beginning of the clause, namely:

"No hydrogenated fats containing trans fatty acids shall be added to the products defined as cereal-based foods intended for infants and young children."

3.6 MINERALS

3.6.1 Retain brackets. The sodium content of complementary foods should be as low as possible. Research has shown that infants and young children may acquire a preferred taste for salty foods when fed salty foods during infancy and early childhood.

3.8 OPTIONAL INGREDIENTS

3.8.1 A standard for infant and young child foods should not allow unspecified optional ingredients. The text as it reads (" In addition to ingredients listed under 3.1, other ingredients suitable for infants who are more than four to six months of age and for young children can be used") allows the addition of any ingredients. If the phrase is to be retained then, the words, "four to six months" should be replaced to read, " six months". The "optional ingredients" permitted must be specified, meet Codex standards; have safe permissible minimum or maximum amounts and must be appropriately labelled.

3.8.3

a. Since, Cocoa can cause allergic reactions and should be introduced into the young child's diet as late as possible, at the very least after 12 months of age. It is therefore suggested that the word, "...after 9 months..." be changed to "...after 12 months..."

b. In the end, the following should be added, namely:

"Products containing cocoa must be labelled according to age of introduction".

3.9 QUALITY FACTORS

3.9.1 After the words, " All" add the words, "permissible

3.10 CONSISTENCY AND PARTICLE SIZE

3.10.1 since, bottle-feeding complementary foods is a harmful practice, which undermines breastfeeding and should be discouraged. Additionally, the introduction of cereal based foods and the progress to spoon feeding is a developmental milestone in the increasingly diversified diet of an infant, it is suggested that the [] should be deleted to include the phrase "spoon feeding".

4. **FOOD ADDITIVES**

4.4 Since, these substances can cause allergic reactions in children less than 12 months of age. Delete reference to flavours.

8. **LABELING**

The numbering of the clauses should be corrected.

8.2 Remove the end] and change the word, “language” to read as “ languages”, as many countries have more than one language.

8.3 Remove the []. In the end, add the following, namely,

"No nutrition or health claims shall be made regarding the dietary properties of the products covered by the provisions of this standard."

8.4 **DECLARATION OF NUTRITIVE VALUE**

8.4. (a) the word “kilo” is missing before “calorie”

8.6 **INFORMATION FOR UTILIZATION**

8.6.3 Delete: “if the intended age of use is below [six months].”

8.6.4

a. Remove square brackets.

b. The first sentence - change to read: The label shall indicate clearly that the age for use is after six months.

c. The second sentence - delete: "before 4 to 6 months", and insert: “not before six months”.

d. Parents should be warned that the introduction of complementary foods does not signal a need to stop breastfeeding. Breast milk continues to be the most important source of nutrition. WHO and UNICEF policy encourage mothers to breastfeed for 2 years and beyond. It is therefore suggested that the following should be added at the end, namely,

"label shall contain the following statement:

Important notice-for best child nutrition and health, breastfeeding should continue along with feeding complementary foods."

8.7 **ADDITIONAL REQUIREMENTS**

Delete [].

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Agenda Item 6

CX/NFSDU 02/6- Add...

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
Twenty-fourth Session
Berlin, Germany, 4-8 November 2002**

Government Comments

INDIA

**Proposed Draft Guidelines Vitamins and Minerals Supplement - Appendix II
(At step 3 of the procedure)**

- 3. **COMPOSITION**
- 3.2 **CONTENTS OF VITAMINS AND MINERALS**

India suggests that the second options may be retained, after removing the [].
