

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

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Agenda Item 4a, 4b, 4c, 4d and 5

NFSDU/42 CRD 14

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Forty-second Session

Virtual

19 - 25 November and 1 December 2021

*Comments by India*

### Agenda Item 4a) PROPOSED DRAFT REVISED STANDARD FOR FOLLOW UP FORMULA FOR OLDER INFANTS AND DRINK/PRODUCT FOR YOUNG CHILDREN WITH ADDED NUTRIENTS OR DRINK FOR YOUNG CHILDREN: REMAINING SECTIONS (AT STEP 4)

#### Recommendation 2: Sentence in Section 3.2.1 for [name of product] for Young children

**Comments:** India agrees with the proposal to retain the sentence **[Substances shall not be added with the purpose of imparting or enhancing a sweet taste of [name of product]]** under Section 3.2.1

#### Recommendation 9: Carry-over of food additives and nutrient carriers

**Comments:** India supports Option 1

#### Rationale:

As this would ensure that section 4.3 which specifically mentions that Carry-over of a food additive from a raw material or ingredient is unacceptable for Follow-up formula.

#### Recommendation 10: Flavourings

**Comments:** India does not support the addition of flavourings in follow-up formulas for older infants and young children.

#### Rationale:

These flavourings can cause infants to develop a preference for these foods and can have a negative effect on food choices. Also, Flavours are not permitted in infant formula as per the Codex Infant Formula Standard (0 -12 month) (Codex Stan 72). In India, addition of flavourings is not allowed in formulas targeted for this age group.

#### Recommendation 12: Hygiene

**Comments:** India agrees with reference to **[the Code of Hygienic Practice for Aseptically Processed and Packaged Low-acid Foods (CXC 40- 1993) and the Code of Hygienic Practice for Low and Acidified Low-acid Canned Foods (CXC 23- 1979)]** with the modification as below:

a) Follow-up formula for older infants:

**In addition if the products are low acid, packaged aseptically or canned, such products shall also comply with** [the Code of Hygienic Practice for Aseptically Processed and Packaged Low acid Foods (CXC 40- 1993) and the Code of Hygienic Practice for Low and Acidified Low-acid Canned Foods (CXC 23- 1979)]

b) [Name of product] for young children:

**In addition if the products are low acid, packaged aseptically or canned, such products shall also comply with** [the Code of Hygienic Practice for Aseptically Processed and Packaged Lowacid Foods (CXC 40- 1993) and the Code of Hygienic Practice for Low and Acidified Low-acid Canned Foods (CXC 23- 1979)]

### Agenda 4b) Draft scope, description and labelling for drink/product for young children with added nutrients or drink for young children (at Step 7)

## SECTION B: DRINK/PRODUCT FOR YOUNG CHILDREN WITH ADDED NUTRIENTS OR DRINK FOR YOUNG CHILDREN

### SCOPE

**Comments:** India suggests inclusion of section 1.4 as follows:

**1.4** The application of this section of the standard shall conform to the recommendations made in the International Code of Marketing of Breast-milk Substitutes (1981), relevant WHO guidelines and policies as well as relevant World Health Assembly (WHA) resolutions, including the WHA resolution 69.9 (2016) and its accompanying WHO Guidance on Ending the Inappropriate Marketing of Foods for Infants and Young Children, the Global Strategy for Infant and Young Child Feeding and World Health Assembly resolution WHA 54.2 (2001).

**Rationale:**

It is essential that there is policy alignment between Codex instruments and the norms, standards, resolutions and recommendations adopted by the World Health Assembly, especially those relating to infant and young child feeding. This is essential for the protection of optimal infant and young child health and to support WHO infant and young child feeding recommendations. The decisions made at the WHA by Member States need to be imbedded into Codex standards and national legislation. Any Codex standard covering products targeted to children less than 36 months must at the very least conform to WHA Resolution 54.2 (2001) and 69.9 (2016) and accompanying guidance (2016).

The resolution WHA69.9 and Guidance on ending the inappropriate promotion of foods for infants and young children, has defined a breast milk substitute unambiguously as “A breastmilk substitute should be understood to include any milks (or products that could be used to replace milk, such as fortified soy milk), in either liquid or powdered form, that are specifically marketed for feeding infants and young children up to the age of 3 years (including follow-up formula and growing-up milks);”

Hence the marketing of “Drink for Young Children” shall come under the purview of and guided by national regulations and International Code of Marketing of Breast-milk Substitutes and subsequent relevant Health Assembly resolutions and this fact should be reflected in the Scope. Therefore, the reference regarding relevant WHO and WHA resolutions should be included, which is also in line with Codex Stan 72-1981 (Standard for infant formula and formulas for special medical purposes intended for infants)

## **2.1 Product Definition**

**Comments:** India suggests the deletion of the text in square brackets

2.1.1 Drink/product for young children with added nutrients or Drink for young children means a product manufactured for use as a liquid part of the diversified diet of young children ~~[which may contribute to the nutritional needs of young children]~~<sup>1</sup>

**Rationale:**

This gives mothers and parents an impression that these products are necessary as a contribution to the growth and development of their child.

## **9.1 The Name of the Product**

**Comments:** India reiterates that these products are breastmilk substitutes and the inclusion of “with added nutrients” at the end of “Drink/product for young children” should be removed as follows:

9.1.2 The name of the product shall be **“Drink/Product for Young Children [with Added Nutrients]”** or “Drink for Young Children” as defined in Section 2.1, or any appropriate designation indicating the true nature of the product, in accordance with national or regional usage.

**Rationale:**

- This is a health or nutrition claim, which is against World Health Assembly Resolutions prohibiting all such claims for breastmilk substitutes and foods for infants and young children.
- The text implies that these products are necessary to fulfill the nutritional needs of young children, which they are not. The World Health Assembly has declared these products as “unnecessary” and noted that health claims should not be made about them.
- WHA 69.9, that was unanimously agreed, states “...Recognizing that the Codex Alimentarius Commission is an intergovernmental body which is the principal organ of the joint FAO/WHO food standards programme and that it is the appropriate body for establishing international standards on food products, and that reviews of Codex standards and guidelines should give full consideration to WHO guidelines and recommendations, including the International Code of Marketing of Breast-milk Substitutes and relevant Health Assembly resolutions, ...’ Codex should therefore align with the WHA and no claims should be permitted on products that have globally been agreed as unnecessary.

- The committee itself has been clear that these products should not be permitted to make nutrition and health claims, which is emphasized in section 9 (Labelling).

### 9.3 Declaration of Nutritive Value

**Comments:** India supports the retention of word **[or]**

The declaration of nutrition information for the product as defined in Section 2.1 shall contain the following information which should be in the following order:

a) the amount of energy, expressed in kilocalories (kcal) and/or kilojoules (kJ), and the number of grams of protein, carbohydrate and fat per 100 g or per 100 ml of the food as sold ~~[as well as]~~ **[or]** per 100 ml of the food ready for use, when prepared according to the instructions on the label.

b) the total quantity of each vitamin, and mineral as listed in paragraph 3.1.3 of Section B and any other ingredient as listed in paragraph 3.2 of Section B per 100 g or per 100 ml of the food as sold ~~[as well as]~~ **[or]** per 100 ml of the food ready for use, when prepared according to the instructions on the label.

**Rationale:**

The food as sold and the food ready for use are different to each other.

### **Agenda 4c) Draft scope, description and labelling for follow-up formula for older infants (held at Step 7)**

#### **SCOPE**

**Comments:** India suggests inclusion of section 1.4 as follows:

**1.4** The application of this section of the standard shall conform to the recommendations made in the International Code of Marketing of Breast-milk Substitutes (1981), relevant WHO guidelines and policies as well as relevant World Health Assembly (WHA) resolutions, including the WHA resolution 69.9 (2016) and its accompanying WHO Guidance on Ending the Inappropriate Marketing of Foods for Infants and Young Children, the Global Strategy for Infant and Young Child Feeding and World Health Assembly resolution WHA 54.2 (2001).

**Rationale:**

It is essential that there is policy alignment between Codex instruments and the norms, standards, resolutions and recommendations adopted by the World Health Assembly, especially those relating to infant and young child feeding. This is essential for the protection of optimal infant and young child health and to support WHO infant and young child feeding recommendations. The decisions made at the WHA by Member States need to be imbedded into Codex standards and national legislation. Any Codex standard covering products targeted to children less than 36 months must at the very least conform to WHA Resolution 54.2 (2001) and 69.9 (2016) and accompanying guidance (2016).

The resolution WHA69.9 and Guidance on ending the inappropriate promotion of foods for infants and young children, has defined a breast milk substitute unambiguously as “A breastmilk substitute should be understood to include any milks (or products that could be used to replace milk, such as fortified soy milk), in either liquid or powdered form, that are specifically marketed for feeding infants and young children up to the age of 3 years (including follow-up formula and growing-up milks);”

Hence the marketing of “Drink for Young Children” shall come under the purview of and guided by national regulations and International Code of Marketing of Breast-milk Substitutes and subsequent relevant Health Assembly resolutions and this fact should be reflected in the Scope. Therefore, the reference regarding relevant WHO and WHA resolutions should be included, which is also in line with Codex Stan 72-1981 (Standard for infant formula and formulas for special medical purposes intended for infants).

### **Agenda 4d) Essential composition requirements for follow-up formula for older infants and drink/product for young children with added nutrients or drink for young children (held at Step 7)**

#### **SECTION A: FOLLOW-UP FORMULA FOR OLDER INFANTS**

**General Comments:** India is of the view that Follow-up Formula is not necessary and is unsuitable when used as a breast-milk replacement from six months of age onwards. The same is also observed by WHO (WHO 2013: Information concerning the use and marketing of follow-up formula).

### **3 ESSENTIAL COMPOSITION AND QUALITY FACTORS**

#### **3.1 Essential composition**

**Comments:** India supports the conclusion of EWG to retain the footnote 2.

2) For the purpose of this standard the calculation of the protein content of the final product ready for consumption should be based on  $N \times 6.25$ , unless a scientific justification is provided for the use of a different conversion factor for a particular product. The protein levels set in this standard are based on a nitrogen conversion factor of 6.25. For information the value of 6.38 is used as a specific factor appropriate for conversion of nitrogen to protein in other Codex standards for milk products.

### 3.2 Optional Ingredients

**Comments:** India suggests the correction of sentence under section 3.2.1 as follows:

3.2.1 In addition to the compositional requirements listed under 3.1.3 Section A, other ingredients or substances may be added to follow-up formula for older infants where the safety and suitability of the optional ingredient for particular nutritional purposes, at the level of use, is evaluated and demonstrated **by generally accepted scientific evidence as safe and nutritional useful by relevant convincing scientific evidence or the comparable level of evidence under the GRADE classification.**

## SECTION B: DRINK/PRODUCT FOR YOUNG CHILDREN WITH ADDED NUTRIENTS OR DRINK FOR YOUNG CHILDREN 3 ESSENTIAL COMPOSITION AND QUALITY FACTORS

### 3.1 Essential composition

**Comments:** India suggests the correction of sentence under section 3.1.1 as follows:

3.1.1 The product as defined in Section 2.1 is a product based on milk of cows or other animals or a mixture thereof and/or other ingredients which have been proven to be safe and suitable for the feeding of young children. The nutritional safety and adequacy of the product as defined in Section 2.1 shall be **scientifically demonstrated through relevant convincing scientific evidence or the comparable level of evidence under the GRADE classification**

### 3.2 Optional Ingredients

**Comments:** India suggests the correction of sentence under section 3.2.1 as follows:

3.2.1 In addition to the compositional requirements listed under 3.1.3 Section B, other ingredients or substances may be added to the product as defined in Section 2.1 where the safety and suitability of the optional ingredient for particular nutritional purposes, at the level of use, is evaluated by national and/or regional authorities and demonstrated **by generally accepted scientific evidence as safe and nutritionally useful by relevant convincing scientific evidence or the comparable level of evidence under the GRADE classification.** Optional ingredients listed in 3.2.3 Section A are also permitted.

## Agenda 5) Draft Guideline for Ready-to-use Therapeutic Foods (at Step 7)

### General Comments:

India does not support the use of RUTF as enough evidence is not available for the use of commercially manufactured RUTF for management of SAM vis-a-vis other interventions like home augmented foods. Further, in a recent trial conducted in India comparing the efficacy of RUTF (centrally produced and locally produced) with augmented energy-dense homeprepared foods (comparison group) for home based management of uncomplicated severe acute malnutrition (SAM); results showed that (i) homemade foods were as effective vis-a-vis centrally produced RUTF; (ii) 16 weeks after stopping RUTF, recovery rates dropped from 56.9% to 17.3% for locally produced RUTF and from 47.5% to 12.1% for centrally produced RUTF and not for use of these products in India.

2. India strongly supports the need for using local foods to manage the condition in accordance with the national policy. Therefore, the comments of India are limited only to the guideline formulation process for standardization of the product.

3. Further, if the use of RUTF in national/sub-national programme for the management of SAM is approved by the national authorities, these formulations should meet the relevant country specific recommendations for Essential composition as specified by the National Authorities and a footnote to this effect should be inserted under the recommendation for each Nutrient (macronutrients as well as micronutrients).

4. Also, the guidelines should include safeguards to prevent the marketing of RUTF in the open market, which increases the risk of unnecessary and inappropriate use.

### 1. PREAMBLE

**Comments:** India supports the retention of footnote<sup>1</sup> and suggests the correction of sentence under Preamble as follows:

[Children affected by severe acute malnutrition (SAM) need **adequate treatment and care including** safe, palatable foods with a high energy content and adequate amounts of vitamins, minerals and other nutrients.

Children with SAM need efficacious and timely intervention and RUTF is one of the options for the dietary management of children with uncomplicated SAM from 6-59 months **and should not undermine National nutrition recommendations and use of culturally appropriate foods. It is critical that the use of RUTF does not undermine support to sustain breastfeeding for the recommended two years or beyond or to re-establish lactation.** These guidelines should be used in accordance with technical recommendations of that are based on the relevant evidence and related Codex texts/documents by WHO, UNICEF and WFP1].

#### 4. DESCRIPTION

**Comments:** India suggests the inclusion of word 'high fat'

Ready-to-Use Therapeutic Foods (RUTF) are foods for special medical purposes and are high energy, **high fat** and contain adequate protein and other essential nutrients for the dietary management of children from 6 to 59 months with severe acute malnutrition without medical complications with appetite. These foods should be soft or crushable and should be easy for children to eat without any prior preparation.

#### 5.2 Other Ingredients

##### 5.2.1 Carbohydrates

**Comments:** India suggests the correction of sentence under section 5.2.1 as follows:

Carbohydrates are used to achieve energy requirements in balance with proteins and lipids. Plant starch, lactose, maltodextrin and sucrose are the preferred carbohydrates in RUTF. Free sugars should be limited and should not exceed **20% 10%** of total energy. Only precooked and/or gelatinized starches may be added. Glucose and fructose should not be used. Carbohydrates must adhere to the relevant Codex Alimentarius texts. Honey should not be used in RUTF due to the risk of infant botulism from *Clostridium botulinum*.

##### Rationale:

In line with WHO Guidelines for Sugar intake for adults and children (2015).

##### 5.2.2. Food Additives

**Comments:** Flavourings (artificial or natural) are not permitted. Also, genetically modified ingredients and those produced by bio-engineering are not permitted.

#### 6. NUTRITIONAL COMPOSITION AND QUALITY FACTORS

##### 6.1 Energy

**Comments:** The proposed energy density is very high and may not be required for community based feeding.

##### Rationale:

The energy requirement for catch-up growth during rehabilitation of children with SAM is based on several considerations, viz., desired composition of weight gain (Fat free mass: Fat Mass ratio of 70:30 or 50:50) and rate of catch-up growth (5-10 g/kg/day). The experience in India shows that typically 3-5 g/kg/day is achieved even with aggressive feeding of 150 Kcal/kg/day.

Further, the WHO document on feeding SAM children suggested 100-135 kcal/kg/day, which would not require such high caloric density. A community prepared food mixture can easily be prepared to provide 100-115 Kcal/kg/day to support the growth rate of 5g/kg/day.

#### 12. LABELLING

**Comments:** India suggests modification of sentence as follows:

It is recommended that the labelling of RUTF for children from 6 to 59 months with SAM be in accordance with the Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CXS 180-1991), the General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (CXS 146-1985), and Guidelines on Nutrition Labelling (CXG 2-1985) **and the International Code of Marketing of Breastmilk Substitutes and subsequent relevant WHA resolutions on labeling and claims, including the WHO Guidance on ending inappropriate marketing of foods for infants and young children**

##### 12.3 Additional Mandatory Labelling Requirements

**Comments:** India suggests modification of sentence as follows:

Provisions of section 4.4 and 4.5 of the Standard for the Labelling of and Claims for Food for Special Medical Purposes (CXS 180-1991) **and the Guidelines for Use of Nutrition and Health Claims (CXG 23-1997)** shall apply. **There should be no nutrition or health claims for these products.**

##### 12.4 The following additional statements shall appear on the label of RUTF:

**Comments:** India suggests the inclusion of the following points

- The product is not to be used for Nasogastric Tube (NG tube) administration.
- The product should be used in conjunction with breastfeeding.
- Exclusive breastfeeding is recommended for the first 6 months of life, and continued breastfeeding is recommended for up to two years or beyond.

• **The product should not be sold in open market or commercially promoted in any way.**

• **Potable drinking water must be available for children receiving this product.**

• **Product should be used strictly under medical supervision exclusively for treatment of SAM.**

#### **Instructions for use**

- The label should indicate clearly from which age the product is recommended for use. This age shall not be less than six months for any product.
- Feeding instructions shall be given; preferably accompanied by graphical presentations.
- The time within which the product should be consumed after opening should be clearly indicated.
- **Storage and packaging instructions to minimize spoilage and contamination.**