

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
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World Health
Organization

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Agenda Item 4c and 5a

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

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Comments by IBFAN

AGENDA ITEM 4C)

IBFAN thanks the chair and the co-chairs for their work on the revision of the proposed draft revised Standard for Follow-up Formula (CXS 156-187) at Step 6. We are pleased to provide the following submission. Our specific comments are in red.

SECTION B: FOLLOW-UP FORMULA FOR YOUNG CHILDREN

1 SCOPE

- 1.1 This section of the Standard applies to [name of the product], for young children as defined in Section 2.1, in liquid or powdered form.
- 1.2 This section of the Standard contains compositional, quality, safety, use, labelling and analytical and sampling requirements for [name of the product] for young children.
- 1.3 Only products that comply with the criteria laid down in the provisions of this section of this Standard shall be presented as [name of the product] for young children.

ADD:

- 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 WHA54.2 (2001).

2 DESCRIPTION

2.1 Product Definition

- 2.1.1 [Name of the product] for young children means a product, manufactured for use as a breast-milk, substitute as a liquid part of the diet of young children [in order to contribute to the nutritional intake of young children].
- 2.1.2 [Name of the product] for young children is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal recommended conditions of handling, use, storage and distribution in the country where the product is sold.

2.2 Other Definitions

- 2.2.1 The term young child means a person from the age of 12 months up to the age of three years (36 months).

9. LABELLING

The requirements of the General Standard for the Labelling of Pre-packaged Foods (CXS 1-1985), the Guidelines on Nutrition Labelling (CXG 2-1985) and the Guidelines for Use of Nutrition and Health Claims (CXG 23-1997) apply to [name of the product] for young children. These requirements include a prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation.

9.1 The Name of the Product

9.1.1 The text of the label and all other information accompanying the product shall be written in the appropriate language(s).

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

9.1.3 The sources of protein in the product shall be clearly shown on the label.

- a) If [name of animal] milk is the only source of protein[*], the product may be labelled '**[name of the product] for young children** based on [name of animal] milk [protein]'
- b) If [name of plant] is the only source of protein[*], the product may be labelled '**[name of the product] for young children** based on [name of plant] [protein]'
- c) **If [name of animal] milk and [name of plant] are the sources of protein[*], the product may be labelled 'Follow-up Formula for Older Infants Based on [name of animal] milk protein and [name of plant] protein' or '[name of the product] for young children based on [name of plant] protein and [name of animal] milk protein'.**

* For clarity, addition of individual amino acids where needed to improve protein quality does not preclude use of the above labelling options.

9.1.4 A product which contains neither milk nor any milk derivative **shall** be labelled "contains no milk or milk products" or an equivalent phrase.

9.2 List of Ingredients

9.2.1 A complete list of **all** ingredients shall be declared on the label in descending order of proportion except that in the case of added vitamins and minerals, these ingredients may be arranged as separate groups for vitamins and minerals. Within these groups the vitamins and minerals need not be listed in descending order of proportion.

9.2.2 The specific name shall be declared for ingredients of animal or plant origin and for food additives. **In addition, appropriate functional classes for these ingredients and additives may be included on the label. The food additives INS number may also be optionally declared the INS number.**

9.3 Declaration of Nutritive Value

The declaration of nutrition information ~~{for follow-up formula for older infants}~~ 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** 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 A and any other ingredient as listed in paragraph 3.2 of Section A per 100 g or per 100 ml of the food as sold **as well as** per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.
- c) In addition, the declaration of nutrients in a) and b) per 100 kilocalories (or per 100 kilojoules) is permitted.

9.4 Date Marking and Storage Instructions

9.4.1 ~~(i) The "Best Before Date" or "Best Quality Before Date" shall be declared by the day, month and year except that for products with a shelf-life of more than three months, [at least] the month and year [shall be declared] [The day and year shall be declared by uncoded numbers with the year to be denoted by 2 or 4 digits, and the month shall be declared by letters or characters or numbers. Where only numbers are used to declare the date or where the year is expressed as only two digits, the competent authority should determine whether to require the sequence of the day, month, year, be given by appropriate abbreviations accompanying the date mark (e.g. DD/MM/YYYY or YYYY/DD/MM).]~~

~~(ii) In the case of products requiring a declaration of month and year only, the date shall be introduced by the words "Best before end insert date; or "Best Quality before end insert date].~~

The date marking and storage instructions shall be in accordance with section 4.7.1 of the General Standard for the Labelling of Prepackaged Foods.

4.7.1 If not otherwise determined in an individual Codex standard, the following date marking shall apply, unless clause 4.7.1 (vii) applies:

(i) When a food must be consumed before a certain date to ensure its safety and quality the "Use-by Date" or "Expiration Date" shall be declared.

(ii) Where a "Use-by Date" or "Expiration Date" is not required, the "Best-Before Date" or "Best Quality Before Date" shall be declared.

IBFAN considers that the use of "Best Before Date" or "Best Quality Before Date" is not appropriate for follow-up formulas for older infants. The CXS 1-1985 states that when a food must be consumed before a certain date to ensure its **safety and quality** "Use-by Date" or "Expiration Date" should be used. IBFAN considers that a follow-up formula should not be consumed after the expiration date, since there is no guarantee of the compliance with the required nutritional content of the standard, nor its microbiological and other quality and safety requirements. Since follow-up formula is intended for older infants from 6 to 12 months these precautions must be in place for this vulnerable population

~~9.4.2 In addition to the date, any special conditions for the storage of the food shall be indicated if [where they are required to support the integrity of the food and, where] the validity of the date depends thereon.~~

Where practicable, storage instructions shall be in close proximity to the date marking.

9.5 Information for use

9.5.1 ~~Ready to use products in liquid form **should** be used directly. Concentrated liquid products must be prepared with potable water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. Products in powdered form must contain a statement that the product is not sterile and preparation instructions must include that the product be reconstituted with safe water at 70 degrees centigrade according to the (WHO/FAO (2007) guidelines, "Safe preparation, storage and handling of powdered infant formula (http://apps.who.int/iris/bitstream/handle/10665/43659/978924_1595414_eng.pdf?sequence=1)~~

and WHA resolutions WHA 58.32 (2005) and 61.20 (2008) as well as the Codex Alimentarius 'Code of hygienic practice for powdered formulae for infants and young children (2008), which provides relevant recommendations for the labeling of powdered infant formula and follow-up formula.

~~Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.~~

9.5.2 Adequate directions for the appropriate preparations and use of the product, including its storage and disposal after preparation, i.e. that {product} remaining after feeding should be discarded, shall appear on the label.

9.5.3 The label shall carry clear graphic instructions illustrating the method of preparation of the product.

9.5.4 ~~The directions should be accompanied by a warning and about the health hazards of inappropriate preparation, storage and use.~~

9.5.5 Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label.

9.5.6 The label of [name of the product] for young children shall include a statement that the product **is not suitable for infants under the age of 12 months**, and **may** be used as part of a diversified diet..

9.6 Additional Labelling Requirements

9.6.1 Labels should not discourage breastfeeding,

Each container label shall have a clear, conspicuous and easily readable message which includes the following points:

a) the words "important notice" or their equivalent;

b) the statement "Breastmilk is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breastmilk;

c) a statement that the product should only be used on advice of an **independent** health worker as to the need for its use **including that the product is not suitable for infants under the age of 12 months** and the proper method of use.

(d) the statement; 'The use of this product must not replace breast-milk and lead to cessation of continued breastfeeding'.

9.6.2 The label **shall have no pictures of infants, young children and women nor any other picture, text or representation**, including pictures of feeding bottles, that could undermine or discourage breastfeeding.

9.6.2.1 idealize the used of **[name of the product] for young children**;

9.6.2.2 suggest use for infants under the age of 12 months (including references to milestones and stages);

9.6.2.3 recommend or promote bottle feeding;

9.6.2.4 undermine or discourage breastfeeding, that makes a comparison to breast-milk, or suggests that the product is similar, equivalent to or superior to breast-milk;

9.6.2.5 convey an endorsement or anything that may be construed as an endorsement by a professional or any other body, unless this has been specifically approved by relevant national ~~or regional~~ regulatory authorities.

9.6.3 The terms "humanized", "maternalized" or other similar terms that compare the product to breastmilk shall not be used.

9.6.4 Products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, (name of product) for young children, and formula for special medical purposes, in particular as to the text, images and colours used, to enable consumers to make a clear distinction between them. Cross promotion between product categories is not permitted on the labelling of the product.

In summary IBFAN notes that the commonly used marketing strategy of cross-branding of products with infant formula through labelling and advertisements is a threat to breastfeeding and infant and child health. This marketing strategy is misleading and confusing and clearly designed to circumvent national regulations that cover the marketing of products for infants and young children. Cross branding on formulas and other products for infants and young children over 6 months increases the risk of infants being fed with inappropriate products that do not meet their nutritional needs. *"The practice of cross-promotion of breast-milk substitutes must be curbed."* (WHO/UNICEF INFORMATION NOTE - Cross-promotion of infant formula and toddler milks, WHO, 2018)

IBFAN comments on the Preamble to Sections A and B of the Standard for Follow-up Formula

PREAMBLE – Remove brackets as indicated.

The Codex Alimentarius Commission acknowledges the need to **protect and support** ~~–recognize~~ **exclusive breastfeeding for the first six months of life and sustained breastfeeding to two years or beyond** ~~breast-feeding~~ as an unequalled way of providing ~~ideal~~ the **normal/optimal** food for the healthy growth and development of infants **and young children**. At the same time Codex acknowledges that numerous formulae have been produced, intended for use, ~~where~~ ~~necessary~~ ~~/~~ ~~appropriate~~, as a substitute for **human-milk breastfeeding** in meeting the ~~normal~~ nutritional requirements of infants ~~provided they are~~ when prepared **as directed**, under hygienic conditions and given in adequate amounts. In addition, various products have also been produced intended specifically for young children as they progress to a more diversified diet of family foods. Although **classified as breastmilk substitutes, these products are NOT necessary to meet the nutritional requirements of young children and their marketing should not undermine discourage** breastfeeding.

The production, distribution, sale and use of follow-up formula for older infants and ~~[name of product]~~ for young children should be consistent with national health and nutrition policies and relevant national/regional legislation, **and conform to take into account, [as appropriate,]** the recommendations made in the International Code of Marketing of Breast-milk Substitute (1981) and the Global Strategy for Infant and Young Child Feeding. 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**, that **has** ~~have~~ been **endorsed and supported** by member states **shall also** ~~[may also]~~ provide guidance to countries in this context.

This Standard is divided into two sections. Section A refers to Follow-up Formula for Older Infants (6 to 12 months of age), and Section B deals with ~~[Name of Product]~~ for Young Children (12 to 36 months of age). It does not apply to products covered by the Codex Standard for Infant Formula (CXS 72 – 1981).

AGENDA ITEM 5A)**General Comments:**

Since older infants and young children suffering from SAM have compromised capacity to digest and absorb solid foods, it is critical that breastfeeding or the provision of donor breastmilk be the primary intervention for rehabilitation. Breastfeeding and the provision of human milk provides the gut healing proteins, enzymes, peptides and the numerous oligosaccharides as well as critical immunological, protective constituents to promote healing of damaged tissue, eliminate accompanying infections and rehabilitate growth.

RUTFs can be introduced after 6 months as a complementary food while breastfeeding is continued and supported to promote growth for older infants and young children suffering from growth faltering as a result of SAM.

IBFAN is of the opinion that flavourings of any kind should not be permitted, and that additives and any ingredients used for foods for malnourished children, should only be permitted following strict independent scrutiny regarding safety and necessity. Any evidence regarding the efficacy of the product should meet WHO's definition of scientific substantiation: 'Relevant convincing / generally accepted scientific evidence or the comparable level of evidence under the GRADE classification'. The evidence should cover resource implications, sustainability, social and economic risks, how outcomes were measured and risk of bias.

This is a very vulnerable population and ingredients should only be present for the purpose of rendering the food safe, nutritious and appropriate, not for technical purposes.

On no account should RUTF be placed on the open market or promoted in any way.

It must also be born in mind that access to nutritious and appropriate foods is just one aspect of a full package of treatments and care that are required for sustained rehabilitation of malnourished children and the prevention of recurrence.

Recommendation 1:

IBFAN does not agree with either Option 1 or 2.

IBFAN is of the opinion that it is important to distinguish between healthy older infants and young children and those who are compromised resulting from SAM and to take into account the possible increased vulnerability to food processing additives.

IBFAN is of the opinion that only those to ensure the microbial safety of the product should be used.

Recommendation 2:

IBFAN agrees that the CCFNSDU consults the CCFA, however the caveats regarding the uniqueness of the health compromised population must be taken into account.

Recommendation 3:

IBFAN does not agree with the proposed text for "carry-over and carriers".

IBFAN is of the opinion that it is important to distinguish between healthy older infants and young children and those who are compromised resulting from SAM. Their increased vulnerability to food processing additives must be taken into account and only those additives that help ensure the microbial safety of the product should be used.

Recommendation 4:

IBFAN agrees with the proposed protein values of the Guidelines for RUTF.

Recommendation 5:

IBFAN agrees with the proposed text on Processing Technologies in RUTF Guidelines.

IBFAN notes that "validated microbial reduction treatments" to inactivate microbial pathogens must take into account the impact on SAM populations and ensure their safety.