

CODEx ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
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World Health
Organization

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Agenda Item 4b

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Original language only

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

Fortieth Session

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26 – 30 November 2018

REVIEW OF THE STANDARD FOR FOLLOW-UP FORMULA: SCOPE, PRODUCT DEFINITION AND LABELLING

Replies to comments at Step 3 to CL 2018/63-NFSDU

Comments of Kenya and Lao Peoples Democratic Republic

KENYA

Recommendation 1: That CCNFSDU agree to the following text for Section 1.1 of the Scope (for follow-up formula for older infants): “1.1 *This section of the Standard applies to Follow-up Formula for Older Infants, as defined in Section 2.1, in liquid or powdered form.*”

Comment: We support the statement for clause 1.1 as presented.

Justification: The statement is clear and precise for the intended product.

Recommendation 2: That CCNFSDU agree to the following text for Section 1.2 of the Scope (for follow-up formula for older infants): “1.2 *This section of the Standard contains compositional, quality, safety, [labelling and analytical] requirements for Follow-up Formula for Older Infants.*”

Comment: Kenya supports adoption of the text as proposed including the opening up of the square brackets.

Justification: The proposed revision includes in the body of the standard both provision of labelling as well as prescribing the methods of analysis for the various parameters for both quality and compositional requirements.

Recommendation 3: That CCNFSDU agree to the following text for Section 1.3 of the Scope (for follow-up formula for older infants): “1.3 *Only products that comply with the criteria laid down in the provisions of this section of this Standard [should / shall] be presented as Follow-up Formula for Older Infants*”

Comment: We support the use of the word “Shall” in place of “Should”

Justification: The use of “shall” only obligates the products complying with standard to be classified as follow-up formula. Use of “should” presents a strong recommendation which may not be legally binding.

Recommendations 4, 5 & 6: They recommendation relates to scope of products yet to be named targeting young children from the age of 12 months

Comment: We support similar wordings as provided for recommendations 1,2 and 3

Justification: Same reasons as recommendation 1,2 &3.

Recommendations 7: That CCNFSDU agree to the following definition for follow-up formula for older infants: “**Follow-up formula for older infants** means a product, **specially** manufactured for use **as a substitute for breast-milk**, as a liquid part of a progressively diversified diet for older infants when complementary feeding is introduced.”

Comment: We support the text including the deletion and adoption of the bold text so as to read, “*Follow-up formula for older infants means a product, manufactured for use as a substitute for breast-milk, as a liquid part of a progressively diversified diet for older infants when complementary feeding is introduced.*”

Justification: The use of the term ‘specially’ portrays the product as unique or having enhanced advantages and thus has potential to mislead the users in believing the product has advantages. This may negate the aim of protecting breastfeeding. In addition, given that the product is intended to be used during

complementary feeding, it is likely that it may partially or whole replace breast milk and thus qualifies to be a breastmilk substitute.

Recommendations 8: That CCNFSDU agree to the following definition for [name of product] for young children, and make a decision on whether to retain or delete the text contained within [] : **“[Name of product] for young children means a product specially ~~formulated and~~ manufactured for use ~~as a breast-milk substitute~~, as a liquid part of the ~~[progressively]~~ [diversified] diet of young children ~~[in order to contribute to the nutritional needs of young children] ~~[when nutrient intakes may not be adequate to meet nutritional requirements]~~”.~~**

Comment: We support the text to read as, *“[Name of product] for young children means a product manufactured for use as a breast-milk substitute as a liquid part of the diversified diet of young children [in order to contribute to the nutritional needs of young children”*

Justification: According to national law on Breast Milk Substitutes, follow-up formulas and all foods for infants and young children up to the age of 24 months are classified as breastmilk substitute.

Recommendations 9: That CCNFSDU agree to the following text for introductory paragraph to the Labelling Section for follow-up formula for older infants: *“The requirements of the Codex 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 follow-up formula for older infants. ~~[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.]”~~*

Comment: We support deletion of the bold text

Justification: The provision of the bold text are already included in the referenced text in the clause.

Recommendations 10, 11, 12, 13, 14, 15 & 17

Comment: We support the proposed text

Justification: The text in 9.6 adds clarity for the additional labelling requirements while the introductory statement eliminates unnecessary statements as they are already captured in the standards.

Recommendations 16 information for use

Comment: We support the proposed text with the following slight editorial improvement in sub clause 9.5.2 and 9.5.4 as indicated below in bold

“9.5.2 Adequate directions for the appropriate preparations and use of the product, including its storage and disposal after preparation, i.e. ~~that~~ formula [product] remaining after feeding should be discarded, shall appear on the label.”

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

Justification: To improve the language of the text.

Preamble

We propose the preamble to read as follows:

*The Codex Alimentarius Commission acknowledges the need to {protect, **promote** and support ~~/recognize~~} breastfeeding as an unequalled way of providing ideal food for the healthy growth and development of infants. At the same time Codex acknowledges that numerous formulae have been produced, intended for use, where ~~necessary~~ / appropriate}, as a substitute for human milk in meeting the normal nutritional requirements of infants provided they are prepared 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 and these products should not 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 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 that have been ~~[endorsed or supported]~~ by member states ~~[may also]~~ **should** 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).

LAO PEOPLES DEMOCRATIC REPUBLIC

STRUCTURE OF THE STANDARD

The view of the Lao PDR is that because these products are conceptually similar; serve as a liquid part of the diversified diet of older infants and young children during the complementary feeding period; and are commonly used and marketed to replace breast milk feedings, they should be part of the same standard.

Further justification for one Standard with two parts is as follows:

1. Lao PDR recognizes that milks intended for the 12-36 month age group are not necessary for child diets but have been widely marketed as breast milk substitutes for the older child and should be addressed in concert as such.
2. There can be merit in distinguishing the sometimes-necessary products (infant formula), which have their own standard, from these unnecessary products (follow-up formula), which should have their own standard.
3. Precedent has been set for having a single standard with sub-divisions, as seen in STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS CODEX STAN 72 – 1981.

Thus, Lao PDR supports one standard for follow-up formula (CODEX STANDARD FOR FOLLOW-UP FORMULA CODEX STAN 156-1987) divided into 2 categories; Section A: 6-12 months, and Section B: 12-36 months.

[NAME OF PRODUCT] FOR YOUNG CHILDREN

This issue as discussed in the document submitted by the Electronic Working Group proposes the name 'formulated drink for young children'. Lao PDR strongly opposes the use of the word 'formulated' in the name of this product as it confers a scientific basis for the product and further infers health benefits, while in reality and globally accepted, the product is not medically necessary. The Lao PDR position is based on our support for the designation of these milks as breastmilk substitutes (per WHA 69.9) and application of the International Code of Marketing of Breast-milk Substitutes prohibitions on any promotion and idealisation of these products. Any term used to refer to these products must be neutral and confer no perceived health benefits. Additionally, Lao PDR is concerned by the growing evidence that "follow-on" formula is quite often confused as equivalent in composition to infant formula but that use for that purpose is dangerous and harmful for infants and thus care must be taken to avoid conflating the two products in the perception of consumers. Lao PDR supports the term "drink for young children".

PREAMBLE

Lao PDR supports the explicit reference to the contents of relevant WHA Resolutions, including WHA Resolution 69.9 in the Preamble and/or individual Scope text of the 2 categories.

SECTION A: FOLLOW-UP FORMULA FOR OLDER INFANTS

9.6 Additional Labelling Requirements

- 9.6.1** Lao PDR believes that the text of 9.6.1 could be simplified to a single compulsory message rather than including a number of points, some which allow for ambiguity. We recommend 9.6.1 to read: "IMPORTANT NOTICE: Breastmilk is best for your baby. Infants should be exclusively breastfed for the first 6 months of life and continue to be breastfed to two years of age or beyond. This product should only be used on the advice of a health care worker."
- 9.6.2** Lao PDR recommends that the term 'older infant' be added to the opening sentence so that it reads 'The label shall have no pictures of infants, older infants and women nor any other picture, text or representation that might:..' This addition is necessary to make the text relevant to the standard / age category under discussion. The infant formula standard only refers to infants as that is the age category for which infant formula is intended and for whom one does not want its use idealised. Therefore, this product must refer to both infants and older infants for whom the product use should not be idealised.
- 9.6.4** Lao PDR believes the text should read '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, through the use of different colour schemes, designs, names, slogans and mascots other than company name and logo. Cross promotion between products is not permitted.' This statement provides sufficient clarity and is in line with the WHO Guidance on ending the inappropriate promotion of foods for infants and young children.

SECTION B: [NAME OF PRODUCT] FOR YOUNG CHILDREN

2. DESCRIPTION

2.1 Product definition

2.1.1 Lao PDR does NOT support the text as proposed. Lao PDR believes the definition should read: '[Name of product] for young children means a product manufactured for use as a breast-milk substitute, as a liquid part of the diversified diet of young children.'

The justification for this opinion is that any product used towards the liquid part of the diversified diet of a child up to age 2 and beyond will displace breastmilk, especially when the product is a milk type product (whether from animal or plant origin) and this must be made clear in the definition. We recognize the findings of the WHO Guidance on Ending Inappropriate Promotion of Foods for Infants and Young Children (2016), WHA 69.9 and the International Code of Breastmilk substitutes for this rationale. The standard must be aligned with WHA 69.9 and accompanying guidance.