

18 October 2019

Review of the Standard for Follow-up Formula (CXS 156-1987): Proposed draft product definition and labelling for [product] for young children¹

ISDI (CRD) comments on CCNFSDU41 Agenda Item 4c): Proposed draft product definition and labelling for [product] for young children at STEP 4

Background

ISDI would like to take the opportunity to submit its comments on REP19/NFSDU Appendix IV. ISDI notes that CCNFSDU40 did not have a chance to discuss the scope, definition and labelling of [name of product] for young children in detail. The Committee briefly discussed the definition but taking into account the lack of consensus and limited time at the plenary, the Chair postponed the discussion to CCNFSDU41. ISDI notes that the draft text is held at step 4 since CCNFSDU40.

PROPOSED DRAFT REVISED STANDARD FOR FOLLOW-UP FORMULA (CXS 156-1987)

SECTION B: [NAME OF PRODUCT] FOR YOUNG CHILDREN

2 DESCRIPTION

2.1 Product Definition

2.1.1 **[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]~~**.

ISDI Comment

ISDI supports the following definition (clean copy): *[Name of product] for young children means a product manufactured for use as a liquid part of the diversified diet of young children in order to contribute to the nutritional needs of young children.*

ISDI proposal (clean copy)

2 DESCRIPTION

2.1 Product Definition

2.1.1 [Name of product] for young children means a product manufactured for use as a liquid part of the diversified diet of young children in order to contribute to the nutritional needs of young children.

ISDI welcomes the deletion of "as a breast milk substitute" in the sentence and finds it appropriate the product in the Standard is not defined as a 'breast milk substitute'.

ISDI reiterates that the revised Standard for Follow-up formula prescribes compositional requirements for [Name of product] for young children. Its composition is not the same as Infant formula or follow-up formula for older infants and it does not constitute the sole source of nutrition. The composition of [name of product] for young children

¹ For the background information, please refer to REP19/NFSDU Appendix IV.

means that they cannot be considered as Breast Milk Substitutes as they do not provide the full suite of nutrients provided by breast milk.

The revised Standard for [name of product] for young children lays down mandatory requirements for only 8 micronutrients (Vitamin C, A, D, B2, B12, Iron, Calcium, Zinc). In comparison, the current Infant Formula Standard lays down mandatory requirements for 22 micronutrients. There are also differences between both products in terms of the mandatory requirements for macronutrients.

[Name of product] for young children are formulated to be consumed as a complement (supplementary) to the daily diet, not to replace breast milk nor to discourage consumption of family foods. They are often used in conjunction with continued breastfeeding similarly to other complementary foods. They are also used as a partial or complete replacement for cow's milk or in place of other beverages that are often inappropriate like sugar sweetened beverages (sodas, sweetened tea etc.) or micronutrient fortified beverages intended for adults.

Due to the diet pattern of young children the electronic working group in charge of the revised criteria for [name of product] for young children at Codex level concluded these products could not be classified as Breast milk Substitutes (eWG on FUF 2018).

Therefore, it would be factually incorrect to define [name of product] for young children as a 'breast milk substitute'.

In fact, such terminology:

- would introduce risk as it could lead parents/caregivers to believe that these products are a suitable replacement for breast-milk. This could result in serious adverse health consequences if these products were mistakenly used as a sole source of nutrition (e.g. 0-6 months).
- would contravene the general principles of labelling 'Prepackaged food shall not be described or presented on any label or in any labelling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect' (Ref: Section 3.1 CODEX STAN 1-1985; Labelling of Prepackaged Foods).

9.5 Information for use

- 9.5.1** [Ready to use] products in liquid form **should** ~~may~~ be used ~~either~~ directly, ~~or in the case of~~ concentrated liquid products [and powdered 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 powder form should be reconstituted with water that is safe or has been rendered safe by previous boiling for preparation.]~~ 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 formula ~~[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. ~~[Pictures of feeding bottles are not permitted on labels of (name of product) for young children.]~~
- 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 product] for young children shall include a statement that the product shall not be introduced before 12 months of age and should be used as part of a ~~[diversified]~~ ~~[balanced]~~ diet.]

ISDI Comment

ISDI generally supports the content of paragraph 9.5. However, ISDI suggests to slightly modify 9.5.3, to read (clean copy): *The label shall carry clear instructions illustrating the method of preparation. Use of graphics is permitted and encouraged for multi-step instructions.*

ISDI recommends that the section 9.5.6. is re-worded to capture text in section 9.6. (Additional Labelling Requirements) of the current Standard to read as follows (clean copy): *9.5.6 The label of [name of product] for young children shall include a statement that the product shall not be introduced before 12 months of age and is*

not a breast milk substitute. It should be used as part of a diversified diet and not suitable as a sole source of nutrition.

ISDI highlights that section 9.6 (*Additional Labelling Requirements*) of the current Codex Standard for Follow-up Formula states “*The products covered by this Standard are not breast-milk substitutes and shall not be presented as such*”. This wording is not captured under revised section 9.6 and ISDI proposes that its intent is now captured under 9.5.6 to ensure appropriate use.

There was a strong support within the eWG that [name of product] for young children are not breast milk substitutes. [Name of product] for young children contains a limited number of essential nutrients. It can only be used as part of a diversified diet of a young child.

This additional wording is proposed to clarify the role of [name of product] for young children in the diet.

The revised Standard for Follow-up formula lays down compositional requirements for [Name of product] for young children. It is critical to point out that its composition is not the same as Infant formula (sole source of nutrition) OR breast milk. For example, the revised Standard for [Name of product] for young children lays down mandatory requirements for only 8 micronutrients (Vitamin C, A, D, B2, B12, Iron, Calcium, Zinc). In comparison, the current Infant formula Standard lays down mandatory requirements for 22 micronutrients. There are also differences between products in terms of the mandatory requirements for macronutrients.

This additional wording: “*and is not a breast milk substitute. It should be used as part of a diversified diet and not suitable as a sole source of nutrition*” also ensures that:

- Parents/caregivers are provided with clear and accurate information on feeding.
- There is no contravention to the general principles of labelling ‘*Prepackaged food shall not be described or presented on any label or in any labelling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect*’ (Section 3.1 CODEX STAN 1-1985; Labelling of Prepackaged Foods).

ISDI proposal (clean copy)

9.5 Information for use

- 9.5.1** Ready to use products in liquid form should be used directly. Concentrated liquid products and powdered 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. 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 instructions illustrating the method of preparation. Use of graphics is permitted and encouraged for multi-step instructions.
- 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 product] for young children shall include a statement that the product shall not be introduced before 12 months of age and is not a breast milk substitute. It should be used as part of a diversified diet and not suitable as a sole source of nutrition.