CODEX ALIMENTARIUS COMMISSION



Food and Agriculture Organization of the United Nations



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REVIEW OF THE STANDARD FOR FOLLOW-UP FORMULA (CXS 156-1987): DRAFT SCOPE, DESCRIPTION AND LABELLING FOR FOLLOW-UP FORMULA FOR OLDER INFANTS

(REP19/NFSDU, Appendix III)

Note: CCFL45 endorsed the labelling sections 9.1 to 9.63 with amendments to 9.2.2, 9.3 and 9.4.1 (i) and (ii) and 9.4.2. With regard to 9.6.4, the Committee endorsed the first sentence and agreed to return the last sentence on cross-promotion for further consideration by CCNFSDU (REP19/FL, para. 28)

The changes proposed by CCFL is presented in strikethrough / bold underlined font

(for comment at Step 6 through <u>CL 2019/77-NFSDU</u>)

SECTION A: FOLLOW-UP FORMULA FOR OLDER INFANTS

1 SCOPE

- 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.
- 1.2 This section of the Standard contains compositional, quality, safety, labelling, analytical and sampling requirements 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 shall be presented as Follow-up Formula for Older Infants.

2 DESCRIPTION

2.1 Product Definition

- 2.1.1 **Follow-up formula for older infants** means a product, manufactured for use as a breastmilk**substitute**, as a liquid part of a diet for older infants when progressively diversified complementary feeding is introduced.
- 2.1.2 Follow-up formula for older infants is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold.

2.2 Other Definitions

- 2.2.1 The term **infant** means a person of not more than 12 months of age.
- 2.2.2 The term **older infant** means a person from the age of 6 months and not more than 12 months of age

9. LABELLING

The requirements of the *General Standard for the Labelling of Prepackaged 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 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 Follow-up Formula for Older Infants as defined in Section 2.1, or any appropriate designation indicating the true nature of the product, in accordance with national [or 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 'Follow-up Formula for Older Infants Based on [name of animal] milk [protein].

- b) If [name of plant] is the only source of protein[*], the product may be labelled 'Follow-up Formula for Older Infants 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 'Follow-up Formula for Older Infants 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 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.

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 grams <u>g</u> or per 100 millilitres <u>ml</u> of the food as sold [as well as] [or] per 100 millilitres <u>ml</u> 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 grams <u>g</u> or per 100 millilitres <u>ml</u> of the food as sold as well as per 100 millilitres <u>ml</u> 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 (<u>kcal)</u> (or per 100 kilojoules <u>kJ</u>)) 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 YYY/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.

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 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 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 follow-up formula for older infants shall include a statement that the product shall not be introduced before 6 months of age, is not to be used as a sole source of nutrition] and that older infants should receive complementary foods in addition to the product.

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 "Breast-milk is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breast-milk;

c) a statement that the product should only be used on advice of a health worker as to the need for its use and the proper method of use.

d) the statement; 'The use of this product should not 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 that might:
 - 9.6.2.1 idealize the use of follow-up formula for older infants;
 - **9.6.2.2** suggest use for infants under the age of 6 months (including references to milestones and stages);
 - 9.6.2.3 recommend or promote bottle feeding;
 - **9.6.2.4** undermine or discourage breastfeeding; or 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 shall not be used.

9.6.4 Products shall be distinctly 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 [label/labelling] of the product.