ICS 67.230

# DRAFT EAST AFRICAN STANDARD

Follow-up formula for older infants and products for young children — Specification — Part 1: Follow-up formula for older infants

# **EAST AFRICAN COMMUNITY**

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## **Foreword**

Development of the East African Standards has been necessitated by the need for harmonizing requirements governing quality of products and services in the East African Community. It is envisaged that through harmonized standardization, trade barriers that are encountered when goods and services are exchanged within the Community will be removed.

The Community has established an East African Standards Committee (EASC) mandated to develop and issue East African Standards (EAS). The Committee is composed of representatives of the National Standards Bodies in Partner States, together with the representatives from the public and private sector organizations in the community.

East African Standards are developed through Technical Committees that are representative of key stakeholders including government, academia, consumer groups, private sector and other interested parties. Draft East African Standards are circulated to stakeholders through the National Standards Bodies in the Partner States. The comments received are discussed and incorporated before finalization of standards, in accordance with the Principles and procedures for development of East African Standards, XXXXXX.

East African Standards are subject to review, to keep pace with technological advances. Users of the East African Standards are therefore expected to ensure that they always have the latest versions of the standards they are implementing.

The committee responsible for this document is Technical Committee EASC/TC 018, *Nutrition and Foods for Special Dietary Uses*.

Attention is drawn to the possibility that some of the elements of this document may be subject of patent rights. EAC shall not be held responsible for identifying any or all such patent rights.

DEAS 1237 consists of the following parts, under the general title *Follow-up formula for older infants and products for young children*—Specification:

- Part 1: Follow-up formula for older infants
- Part 2: Products for young children with added nutrients



## Introduction

The application of this standard should be consistent with national/regional health and nutrition policies and relevant national/regional legislation and take into account the recommendations made in the International Code of Marketing of Breast-milk Substitutes (WHO, 1981), as per the national/regional context.

Relevant World Health Organization (WHO) guidelines and policies and World Health Assembly (WHA) resolutions were considered in the development of this standard and may provide further guidance to countries.

Follow-up formulas are mainly produced to be used as a liquid part during complementary feeding for infants and young children. This standard is developed in two parts based on the nutritional requirements of targeted age with Part 1 formulated in a manner to provide sufficient nutrient for infants up to 12 months while part 2 targets nutrition needs for children up to 36 months. This standard will therefore ensure the products provides nutrients necessary for optimal growth of the infants and young children as well as ensure fair trade of the products.

The application of this standard should be consistent with national/regional health and nutrition policies and relevant national/regional legislation and take into account the recommendations made in the International Code of Marketing of Breast-milk Substitutes (WHO, 1981), as per the national context.

Existing relevant World Health Organization (WHO) guidelines, policies and World Health Assembly (WHA) resolutions were considered in the development of this standard and may provide further guidance to countries on the regulation and use of the products. Current or updated WHA resolution should also be taken in to account during implementation of these standards



# Follow-up formula for older infants and products for young children — Specification — Part 1: Follow-up formula for older infants

## 1 Scope

This Draft East African Standard specifies requirements, sampling and test methods for follow up formula in liquid or powdered form intended for older infants.

## 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

AOAC 999.11, Lead, Cadmium, Copper, Iron, and Zinc in foods — Atomic absorption Spectrophotometry after dry ashing

CXC 23, Code of Hygienic Practice for Low and Acidified Low Acid Canned Foods

CXC 40, Code of Hygienic Practice for Aseptically Processed and Packaged Low-Acid Foods

CXC 66, Code of Hygienic Practice for Powdered Formulae for Infants and Young Children

CXG 10, Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses intended for Infants and Young Children

CXG 21, Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods

CXG 50, General Guidelines on Sampling

CXS 192, General Standard for Food Additives

EAS 38, Labelling of pre-packaged foods — General requirements

ISO 14501, Milk and milk powder — Determination of aflatoxin M1 content — Clean-up by immunoaffinity chromatography and determination by high-performance liquid chromatography

## 3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

ISO Online browsing platform: available at <a href="http://www.iso.org/obp">http://www.iso.org/obp</a>

#### 3.1

## follow-up formula for older infants

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.

Note to Entry: Follow-up formula for older infants shall be processed by physical means only and shall be packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold.

#### 3.2

#### older infant

a person from the age of 6 months and not more than 12 months of age.

#### 3.3

#### **Guidance upper level (GUL)**

are for nutrients without sufficient information for a science-based risk assessment. These levels are values derived on the basis of meeting nutritional requirements of older infants and an established history of apparent safe use. They may be adjusted based on relevant scientific or technological progress. The purpose of the GULs is to provide guidance to manufacturers and they should not be interpreted as goal values.

#### 3.4

### food grade packaging material

packaging material, made of substances which are safe and suitable for their intended use, and which will not impart any toxic substance or undesirable odour or flavour to the product.

## 4 Requirements

## 4.1 Essential ingredients

- **4.1.1** Follow-up formula for older infants is a product based on milk of cows, sheep, goat, buffalo, camel or a mixture thereof and/or other ingredients which have been proven to be safe and suitable for the feeding of older infants. The nutritional safety and adequacy of follow-up formula for older infants shall be scientifically demonstrated to support growth and development of older infants.
- **4.1.2** Vitamin compounds and mineral salts shall be used in accordance CXG 10.

## 4.2 Optional ingredients

- **4.2.1** In addition to the compositional requirements listed under clause 4.4.1.3, 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.
- **4.2.2** When any of these ingredients or substances is added, the formula shall contain sufficient amounts to achieve the intended effect, taking into account levels in human milk.
- **4.2.3** The following substances may be added, in which case their content per 100 kcal (100 kJ) in the follow-up formula for older infants ready for consumption shall not exceed the levels listed below.

#### a) Taurine

| Unit        | Minimum | Maximum | GUL |
|-------------|---------|---------|-----|
| mg/100 kcal | -       | 12      | -   |
| mg/100 kJ   | -       | 2.9     | -   |

## b) Total nucleotides

If used it shall not exceed 3.4 mg/100ml (5 mg/100kcal)

## c) Docosahexaenoic acid (DHA)<sup>20)</sup>

| Unit        | Minimum | Maximum | GUL |  |
|-------------|---------|---------|-----|--|
| mg/100 kcal | -       | -       | 30  |  |
| mg/100 kJ   | -       | -       | 7   |  |

<sup>&</sup>lt;sup>20)</sup> If docosahexaenoic acid (22:6 n-3) is added to follow-up formula for older infants, a minimum level of 20 mg/100 kcal (4.8 mg/100 kJ) should be reached, and arachidonic acid (20:4 n-6) contents should reach at least the same concentration as DHA. The content of eicosapentaenoic acid (20:5 n-3), which can occur in sources of LC-PUFA, should not exceed the content of docosahexaenoic acid.

### d) Choline

| Unit        | Minimum | Maximum | GUL |
|-------------|---------|---------|-----|
| mg/100 kcal | -       |         | 50  |
| mg/100 kJ   | -       | -       | 12  |

## e) Myo-inositol

| Unit        | Minimum   | Maximum | GUL |
|-------------|-----------|---------|-----|
| mg/100 kcal |           | -       | 40  |
| mg/100 kJ   | <b>/-</b> | -       | 10  |

## f) L-carnitine

If used it shall not be less than 7.5 µmol/100 kcal

## g) (+) lactic acid-producing cultures

Only L (+) lactic acid-producing cultures may be used for the purpose of producing acidified follow-up formula for older infants.

## 4.3 General requirements

- **4.3.1** All ingredients shall be clean, of good quality, safe and suitable for ingestion by older infants. They shall conform with their normal quality requirements, such as colour, flavour and odour.
- **4.3.2** When prepared according to the directions of use, the product shall be free of lumps and of large, coarse particles.

## 4.4 Specific prohibitions

- **4.4.1** The product and its components shall not have been treated by ionizing radiation.
- **4.4.2** The other prohibitions are stated under the clause on food additives.

## 4.5 Specific requirements

- **4.5.1** Follow up formula for older infants shall contain per 100 ml not less than 60 kcal (251 kJ) and not more than 70 kcal (293 kJ) of energy.
- **4.5.2** Follow-up formula for older infants prepared ready for consumption shall contain per 100 kcal (100 kJ) the following nutrients with the following minimum and maximum or guidance upper levels (GULs) as appropriate:

# a) Protein<sup>1), 2), 3)</sup>

| Unit       | Minimum                | Maximum | GUL |
|------------|------------------------|---------|-----|
| g/100 kcal | 1.84), 5)              | 3.0     |     |
| g/100 kJ   | 0.43 <sup>4), 5)</sup> | 0.72    | -   |

- <sup>1)</sup> For the purpose of this standard the calculation of the protein content of the final product ready for consumption should be based on N x 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.
- <sup>2)</sup> For an equal energy value the formula must contain an available quantity of each essential and semiessential amino acid at least equal to that contained in the reference protein (breastmilk as defined in Annex I of the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants [CXS 72-1981]);<sup>3</sup> nevertheless for calculation purposes the concentrations of tyrosine and phenylalanine may be added together and the concentrations of methionine and cysteine may be added together.
- <sup>3)</sup> Isolated amino acids may be added to follow-up formula for older infants only to improve its nutritional value for infants. Essential and semi-essential amino acids may be added to improve protein quality, only in amounts necessary for that purpose. Only L-forms of amino acids shall be used.
- <sup>4)</sup> The minimum value applies to cows' and goats' milk protein. For follow-up formula for older infants based on non-cows' or non-goats' milk protein, other minimum values may need to be applied. For follow-up formula for older infants based on soy protein isolate, a minimum value of 2.25 g/100 kcal (0.54 g/100 kJ) applies.
- <sup>5)</sup> A lower minimum protein level between 1.6 g/100 kcal and 1.8 g/100 kcal (0.38 g/100 kJ and 0.43 g/100 kJ) in follow-up formula for older infants based on non-hydrolysed milk protein can be accepted. Such follow-up formula and follow-up formula for older infants based on hydrolysed protein should be evaluated for their safety and suitability and assessed by a competent national and/or regional authority based on clinical evidence.

#### b) Lipids

# (i) Total fat<sup>6), 7)</sup>

| Unit       | Minimum | Maximum | GUL |
|------------|---------|---------|-----|
| g/100 kcal | 4.4     | 6.0     | •   |

| g/100 kJ | 1.1 | 1.4 | - |
|----------|-----|-----|---|
| •        |     |     |   |

<sup>&</sup>lt;sup>6)</sup> Partially hydrogenated oils and fats shall not be used in follow-up formula for older infants.

### (ii) Linoleic acid

| Unit        | Minimum | Maximum | GUL  |
|-------------|---------|---------|------|
| mg/100 kcal | 300     | -       | 1400 |
| mg/100 kJ   | 72      | -       | 335  |

## (iii) α-Linolenic acid

| Unit                       | Minimum | Maximum | GUL |
|----------------------------|---------|---------|-----|
| mg/100 kcal                | 50      | N.S.*   | -   |
| mg/100 kJ                  | 12      | N.S.    | •   |
| N.S. * means not specified |         |         |     |

## (iv) Ratio linoleic acid/ α-linolenic acid

| Min. |   | Max. |
|------|---|------|
| 5:1  | X | 15:1 |

### c) Carbohydrates

# (i) Available carbohydrates<sup>8)</sup>

| Unit       | Minimum | Maximum | GUL |
|------------|---------|---------|-----|
| g/100 kcal | 9.0     | 14.0    | -   |
| g/100 kJ   | 2.2     | 3.3     | -   |

<sup>&</sup>lt;sup>8)</sup> Lactose and glucose polymers should be the preferred carbohydrates in follow-up formula for older infants based on milk protein and hydrolysed protein. Only precooked and/or gelatinized starches gluten-free by nature may be added. Sucrose and/or fructose should not be added, unless needed as a carbohydrate source, and provided the sum of these does not exceed 20 percent of available carbohydrates

### d) Vitamins

### (i) Vitamin A

| Unit | Minimum | Maximum | GUL |
|------|---------|---------|-----|
|      |         |         |     |

<sup>&</sup>lt;sup>7)</sup> Lauric acid and myristic acid are constituents of fats, but combined shall not exceed 20 percent of total fatty acids. The content of trans fatty acids shall not exceed 3 percent of total fatty acids. Trans fatty acids are endogenous components of milk fat. The acceptance of up to 3 percent of trans fatty acids is intended to allow for the use of milk fat in follow-up formula for older infants. The erucic acid content shall not exceed 1 percent of total fatty acids. The total content of phospholipids should not exceed 300 mg/100 kcal (72 mg/100 kJ).

| μg RE <sup>9)</sup> /100 kcal | 75 | 180 | - |
|-------------------------------|----|-----|---|
| μg RE <sup>9)</sup> /100 kJ   | 18 | 43  | - |

<sup>&</sup>lt;sup>9)</sup> Expressed as retinol equivalents (RE).

1  $\mu$ g RE = 3.33 IU vitamin A = 1  $\mu$ g all-trans retinol. Retinol contents shall be provided by preformed retinol, while any contents of carotenoids should not be included in the calculation and declaration of vitamin A activity.

## (ii) Vitamin D

| Unit                        | Minimum | Maximum | GUL | V |  |
|-----------------------------|---------|---------|-----|---|--|
| μg <sup>10)</sup> /100 kcal | 1.0     | 3.0     | ·   |   |  |
| μg <sup>10)</sup> /100 kJ   | 0.24    | 0.72    | 7   |   |  |

<sup>&</sup>lt;sup>10)</sup> Calciferol. 1 μg calciferol = 40 IU vitamin D.

## (iii) Vitamin E (alpha-tocopherol)

| Unit                             | Minimum             | Maximum | GUL |
|----------------------------------|---------------------|---------|-----|
| mg α-TE <sup>11)</sup> /100 kcal | 0.5 <sup>12)</sup>  | -       | 5   |
| mg α-TE <sup>11)</sup> /100 kJ   | 0.12 <sup>12)</sup> |         | 1.2 |

<sup>&</sup>lt;sup>11)</sup> 1 mg  $\alpha$ -TE (alpha-tocopherol equivalents) = 1 mg d- $\alpha$ -tocopherol.

## (iv) Vitamin K

| Unit        | Minimum | Maximum | GUL |
|-------------|---------|---------|-----|
| μg/100 kcal | 4       | -       | 27  |
| μg/100 kJ   | 0.96    | -       | 6   |

## (v) Vitamin B1 (Thiamine)

| Unit        | Minimum | Maximum | GUL |
|-------------|---------|---------|-----|
| μg/100 kcal | 60      | -       | 300 |
| μg/100 kJ   | 14      | -       | 72  |

## (vi) Vitamin B2 (Riboflavin)

| Unit        | Minimum | Maximum | GUL |
|-------------|---------|---------|-----|
| μg/100 kcal | 80      | -       | 500 |

<sup>&</sup>lt;sup>12)</sup> Vitamin E shall be at least 0.5 mg α-TE per g PUFA, using the following factors of equivalence to adapt the minimal vitamin E content to the number of fatty acid double bonds in the formula: 0.5 mg α-TE/g linoleic acid (18:2 n-6); 0.75 α-TE/g α-linolenic acid (18:3 n-3); 1.0 mg α-TE/g arachidonic acid (20:4 n-6); 1.25 mg α-TE/g eicosapentaenoic acid (20:5 n-3); 1.5 mg α-TE/g docosahexaenoic acid (22:6 n-3).

| μg/100 kJ | 19 | - | 120 |
|-----------|----|---|-----|
| 1 3       |    |   | -   |

# (vii)Vitamin B3 (Niacin<sup>13)</sup>)

| Unit        | Minimum | Maximum | GUL  |
|-------------|---------|---------|------|
| μg/100 kcal | 300     | -       | 1500 |
| μg/100 kJ   | 72      | -       | 359  |

<sup>13)</sup> Niacin refers to preformed niacin

## (viii) Vitamin B6 (Pyrodoxine)

| Unit        | Minimum | Maximum | GUL |
|-------------|---------|---------|-----|
| μg/100 kcal | 35      | -       | 175 |
| μg/100 kJ   | 8       | -       | 42  |

## (ix) Vitamin B12 (Cobalamine)

| Unit        | Minimum | Maximum | Y | GUL  |
|-------------|---------|---------|---|------|
| μg/100 kcal | 0.1     |         |   | 1.5  |
| μg/100 kJ   | 0.02    | -       |   | 0.36 |

## (x) Vitamin B5 (Pantothenic acid)

| Unit        | Minimum | Maximum | GUL  |
|-------------|---------|---------|------|
| μg/100 kcal | 400     | -       | 2000 |
| μg/100 kJ   | 96      | -       | 478  |

## (xi) Vitamin B9 (Folic acid)

| Unit        | Minimum | Maximum | GUL |
|-------------|---------|---------|-----|
| μg/100 kcal | 10      | -       | 50  |
| μg/100 kJ   | 2.4     | -       | 12  |

# (xii)Vitamin C<sup>14)</sup> (Ascorbic acid)

| Unit        | Minimum | Maximum | GUL   |
|-------------|---------|---------|-------|
| mg/100 kcal | 10      | -       | 7015) |
| mg/100 kJ   | 2.4     | -       | 1715) |

<sup>&</sup>lt;sup>14)</sup> Expressed as L-ascorbic acid.

<sup>&</sup>lt;sup>15)</sup> This GUL has been set to account for possible high losses over shelf-life in liquid products; for powdered products lower upper levels should be aimed for

## (xiii) Vitamin B7 (Biotin)

| Unit        | Minimum | Maximum | GUL |
|-------------|---------|---------|-----|
| μg/100 kcal | 1.5     | -       | 10  |
| μg/100 kJ   | 0.36    | -       | 2.4 |

## e) Minerals and trace elements

## (i) Iron<sup>16)</sup>

| Unit        | Minimum | Maximum | GUL        |  |
|-------------|---------|---------|------------|--|
| mg/100 kcal | 1.0     | 2.0     |            |  |
| mg/100 kJ   | 0.24    | 0.48    | <b>/</b> - |  |

 $<sup>^{16)}</sup>$  For follow-up formula for older infants based on soy protein isolate a minimum value of 1.5 mg/100 kcal (0.36 mg/100 kJ) and maximum of 2.5 mg/100 kcal (0.6 mg/100 kJ) applies.

## (ii) Calcium

| Unit        | Minimum | Maximum | GUL |
|-------------|---------|---------|-----|
| mg/100 kcal | 50      |         | 180 |
| mg/100 kJ   | 12      |         | 43  |

## (iii) Phosphorus

| Unit        | Minimum | Maximum | GUL                |
|-------------|---------|---------|--------------------|
| mg/100 kcal | 25      | -       | 100 <sup>17)</sup> |
| mg/100 kJ   | 6       | -       | 24 <sup>17)</sup>  |

<sup>&</sup>lt;sup>17)</sup> This GUL should accommodate higher needs with follow-up formula for older infants based on soy protein isolate.

## (iv) Ratio calcium/phosphorus

| Min. | Max. |
|------|------|
| 1:1  | 2:1  |

## (v) Magnesium

| Unit        | Minimum | Maximum | GUL |
|-------------|---------|---------|-----|
| mg/100 kcal | 5       | -       | 15  |
| mg/100 kJ   | 1.2     | -       | 3.6 |

# (vi) Sodium

| Unit        | Minimum | Maximum | GUL |
|-------------|---------|---------|-----|
| mg/100 kcal | 20      | 60      | -   |
| mg/100 kJ   | 4.8     | 14      | -   |

# (vii)Chloride

| Unit        | Minimum | Maximum | GUL |  |
|-------------|---------|---------|-----|--|
| mg/100 kcal | 50      | 160     | -   |  |
| mg/100 kJ   | 12      | 38      |     |  |

# (viii) Potassium

| Unit        | Minimum | Maximum | GUL |
|-------------|---------|---------|-----|
| mg/100 kcal | 60      | 180     | •   |
| mg/100 kJ   | 14      | 43      | -   |

# (ix) Manganese

| Unit       | Minimum | Maximum | GUL |
|------------|---------|---------|-----|
| μg/100 kca | 1.0     |         | 100 |
| μg/100 kJ  | 0.24    |         | 24  |

# (x) lodine

| Unit        | Minimum | Maximum | GUL |
|-------------|---------|---------|-----|
| μg/100 kcal | 10      | -       | 60  |
| μg/100 kJ   | 2.4     | -       | 14  |

# (xi) Selenium

| Unit        | Minimum | Maximum | GUL |
|-------------|---------|---------|-----|
| μg/100 kcal | 2       | -       | 9   |
| μg/100 kJ   | 0.48    | -       | 2.2 |

# (xii)Copper<sup>18)</sup>

| Unit        | Minimum | Maximum | GUL |
|-------------|---------|---------|-----|
| μg/100 kcal | 35      | -       | 120 |
| μg/100 kJ   | 8       | -       | 29  |

<sup>18)</sup> Adjustment may be needed in these levels for follow-up formula for older infants made in regions with a high content of copper in the water supply.

## (xiii) Zinc<sup>19)</sup>

| Unit        | Minimum | Maximum | GUL  |
|-------------|---------|---------|------|
| mg/100 kcal | 0.5     | -       | 1.5  |
| mg/100 kJ   | 0.12    | -       | 0.36 |

<sup>&</sup>lt;sup>19)</sup> For follow-up formula for older infants based on soy protein isolate a minimum value of 0.75 mg/100 kcal (0.18 mg/100 kJ) applies.

## 5 Food additives

#### 5.1 General

Food Additives (Acidity regulators, antioxidants, emulsifiers, packaging gases and thickeners) when used shall be in accordance with Table 1 and Table 2 of CXS 192 in food category 13.1.2 (Follow-up formulae

## 5.2 Flavourings

Flavourings shall not be used in this product.

## 5.3 Carry-over principle

Only the food additives listed in food category 13.1.2 (Follow-up formulae) of CXS 192 or in the CXG 10-1979 may be present in the foods defined in clause 3.1 of this standard, as a result of carry-over from a raw material or other ingredient (including food additive) used to produce the food, subject to the following conditions:

- a) the amount of the food additive in the raw materials or other ingredients (including food additives) does not exceed the maximum level specified; and
- b) the food into which the food additive is carried over does not contain the food additive in greater quantity than would be introduced by the use of the raw materials or ingredients under good manufacturing practice, consistent with the provisions on carry-over in the preamble of the CXS 192.

### 6 Hygiene

- **6.1** Follow-up formula for older infants shall be prepared and handled in accordance with EAS 39 and other relevant Codex texts such as CXC 66 and in the case of liquid formula that has been commercially sterilized should also consider CXC 40 and CXC 23. The products should also comply with any microbiological criteria established in CXG 21
- **6.2** Follow up formula for older infants shall not exceed microbiological limits given in Table 2 when tested in accordance with test methods specified therein.

Table 2 — Microbiological limits for follow up formula for older infants

| S/N   | Microorganism                  | Limit            | Test method   |
|---|--------------------------------|------------------|---------------|
| 1.  | Enterobacteriaceae, CFU/g      | <10 <sup>a</sup> | ISO 21528 - 2 |
| 2.  | Salmonella spp in 25 g         | Absent           | ISO 6579-1    |
| 3.  | Staphylococcus aureus, CFU/g   | <10 <sup>a</sup> | ISO 6888-1    |
| 4.  | Bacillus cereus, CFU/g, max.   | 50               | ISO 7932      |
| 5.  | Yeasts and moulds, CFU/g, max. | 10 <sup>2</sup>  | ISO 21527-2   |
| <sup>a</sup> less than 10 CFU/g means that it is not detectable in that sample hence may commonly be referred to as "absent". |                                |                  |               |

### 7 Contaminants

#### 7.1 Pesticide residues

The products covered by this standard shall comply with the maximum residue limits for pesticides established by the Codex Alimentarius Commission.

### 7.2 Other contaminants

- **7.2.1** The products covered by this standard shall comply with the maximum levels of the General Standard for Contaminants and Toxins in Food and Feed (CXS 193)
- **7.2.2** Follow-up formula for older infants shall comply with the maximum limits for contaminants specified in Table 3, when tested in accordance with test methods therein.

Table 3— Maximum limits for contaminants in Follow-up formula for older infants

| S/N  | Contaminant         | •  | Maximum limit | Test method   |
|------|---------------------|--|---------------|---------------|
| i.   | Lead, mg/kg         |  | 0.01          | AOAC 999.11   |
| ii.  | Aflatoxin M1, μg/kg |  | 0.5           | ISO 14501     |
| iii. | Melamine, mg/kg     | Solid<br>(powdered<br>follow up<br>formula | 1.0           | AOAC 2016.015 |
| •    |                     | Liquid<br>follow up<br>formula             | 0.15          |               |

## 8 Packaging

Follow-up formula for older infants shall be packaged in food grade packaging materials which do not have adverse effects on the composition of the product including its nutritional value, properties and appearance.

## 9 Labelling

#### 9.1 General

The requirements of the EAS 38, EAS 803, 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

In addition to the requirements of EAS 38, each unit shall be legibly and indelibly labelled with the information in 9.2 to 9.7.

## 9.2 Name of the product

- **9.2.1** The text of the label and all other information accompanying the product shall be written in the acceptable languages as per EAS 38.
- **9.2.2** The name of the product shall be "Follow-up formula for older infants",
- 9.2.3 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.
- **9.2.4** A product which contains neither milk nor any milk derivative shall be labelled "contains no milk or milk products" or an equivalent phrase.

## 9.3 List of ingredients

- **9.3.1** 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.
- **9.3.2** The specific name shall be declared for ingredients of animal or plant origin and for food additives. In addition, appropriate functional classes for food additives shall be included on the label. The food additives INS number may also be optionally declared.

## 9.4 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 clause 4.4.1.3 of Section A and any other ingredient as listed in clause 4.4.2 of Section A 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; and
- c) in addition, the declaration of nutrients in a) and b) per 100 kcal or per 100 kJ is permitted.
- d) The presence of available carbohydrates shall be declared on the label as "carbohydrates". The type of carbohydrate shall be declared, and this declaration shall follow immediately the declaration of the total carbohydrate content in the following format:

"Carbohydrate ... g, of which sugars ... g".

This may be followed by the following: "x" ... g, where "x" represents the specific name of any other carbohydrate constituent.

## 9.5 Date marking and storage instructions

- 9.5.1 The date marking and storage instructions shall be in accordance with Section 4.7 of the CXS 1.
- **9.5.2** Where practicable, storage instructions shall be in close proximity to the date marking.

### 9.6 Information for use

- **9.6.1** 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.
- **9.6.2** Adequate directions for the appropriate preparation 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.
- 9.6.3 The label shall carry clear graphic instructions illustrating the method of preparation of the product.
- **9.6.4** The directions should be accompanied by a warning about the health hazards of inappropriate preparation, storage and use.
- **9.6.5** Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label.
- **9.6.6** 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.

## 9.7 Additional labelling requirements

- **9.7.1** Where there is national regulation related to infant and young children nutrition, the specified requirements therein apply. In addition, the requirements given in 9.7.2 to 9.7.6 shall apply
- **9.7.2** 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) the statement "breastfeeding is recommended up to two years and beyond";
- d) 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.
- e) the statement "The use of this product should not lead to cessation of continued breastfeeding".
- **9.7.3** The label shall have no pictures of infants, young children and women nor any other picture, text, or representation that might:
  - a) idealize the use of follow-up formula for older infants;
  - b) suggest use for infants under the age of 6 months (including references to milestones and stages);
  - c) recommend or promote bottle feeding;
  - d) undermine or discourage breastfeeding; or that makes a comparison to breastmilk, or suggests that the product is similar, equivalent to or superior to breastmilk;
  - e) 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.
- **9.7.4** The terms "humanized", "maternalized", or other similar terms shall not be used.
- **9.7.5** Follow-up formula for older infants shall be distinctly labelled in such a way as to avoid any risk of confusion with infant formula, drink for young children with added nutrients or product for young children with added nutrients or drink for young children or product for young children, and formula for special medical purposes intended for infants, in particular as to the text, images and colours used, to enable consumers to make a clear distinction between them.
- **9.7.6** The labelling of follow-up formula for older infants shall not refer to Infant formula, drink for young children with added nutrients or product for young children with added nutrients or drink for young children or product for young children, or formula for special medical purposes intended for infants, including numbers, text, statements, or images of these products.

## 10 Sampling

Sampling shall be done in accordance with CXG 50.

# **Bibliography**

- [1] CXS 156-1987 Standard for follow-up formula for older infants and product for young children
- [2] World Health Organization (WHO). 1981. International Code of Marketing of Breast-Milk Substitutes. <a href="https://www.who.int/publications/i/item/9241541601">https://www.who.int/publications/i/item/9241541601</a>



