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DRAFT EAST AFRICAN STANDARD

Follow-up formula for older infants and products for young children — Specification — Part 2: Products for young children with added nutrients

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 2: Products for young children with added nutrients

1 Scope

This Draft East African Standard specifies requirements, sampling and test methods for products for young children with added nutrients in liquid or powdered form intended for young children.

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.

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*

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 http://www.iso.org/obp

3.1
product for young children with added nutrients
a product manufactured for use as a liquid part of the diversified diet of young children.

Note to entry: products for young children with added nutrients 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
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.

3.3
young child
a person from the age of more than 12 months up to the age of 3 years (36 months)

4 Requirements

4.1 Raw Material

4.1.1 Product for young children with added nutrients a is a product based on milk of cows or other animals or a mixture thereof and/or other ingredients which have been proven to be safe and suitable for the feeding of young children. The nutritional safety and adequacy of the product shall be scientifically demonstrated to support growth and development of young children.

4.1.2 When prepared ready for consumption, in accordance with the instructions of the manufacturer, the products shall contain per 100 ml not less than 60 kcal (251 kJ) and not more than 70 kcal (293 kJ) of energy.

4.1.3 Product for young children with added nutrients prepared ready for consumption shall contain per 100 kcal (100 kJ) the following nutrients with the following minimum and maximum or GULs, as appropriate.

a) protein[1,2]

Unit	Minimum	Maximum	GUL
g/100kcal	1.8	-	-
g/100kJ	0.43	-	-

[1)] 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.

[2)] Protein Digestibility Corrected Amino Acid Score (PDCAAS) is the preferred method to determine protein quality. However, Protein Efficiency Ratio (PER) can continue to be used. Digestible Indispensable Amino Acid Store (DIAAS) could also be considered should it be recognized by FAO in the future. When determined using PDCAAS methodology, appropriate digestibility values and the reference amino acid pattern (see Table 5 of the Report of the FAO Expert Working Group: Protein quality assessment in follow-up formula for young children and ready to use therapeutic food), the PDCAAS shall be not less than 0.9. In formulations with lower scores the quality and/or quantity of protein should be adjusted to achieve the desired value. Detail on how to calculate the PDCAAS is listed in the Report of the FAO Expert Working Group: Protein quality assessment in follow-up formula for young children and ready to use therapeutic food. When determined by PER methodology, the protein quality shall not be less than 85 percent of that of casein

b) Lipids[3)]

i) Total fat

Unit	Minimum	Maximum	GUL
g/100kcal	3.5	-	-
g/100kJ	0.84	-	-

[3)] Partially hydrogenated oils and fats shall not be used in the product as defined in Section 2.1

ii) α-Linolenic acid

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

iii) Linoleic acid

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

c) Carbohydrates

i) Available carbohydrates [4), 5)]

Unit	Minimum	Maximum	GUL
g/100kcal	-	12.5	-
g/100kJ	-	3.0	-

[4)] Lactose should be the preferred carbohydrate in the product as defined in Section 2.1 based on milk protein. For products based on non-milk protein, carbohydrate sources that have no contribution to sweet taste should be preferred and in no case be sweeter than lactose.

[5)] Mono- and disaccharides, other than lactose, should not exceed 2.5 g/100 kcal (0.60 g/100 kJ). National and/or regional authorities may limit this level to 1.25 g/100 kcal (0.30 g/100 kJ). Sucrose and/or fructose should not be added.

[6)] For the product as defined in Section 2.1 with a protein level below 3.0 g/100 kcal a maximum level of available carbohydrates up to 14 g/100 kcal (3.3 g/100 kJ) may be permitted by competent national and/or regional authorities.

d) Vitamins

i) Vitamin A

Unit	Minimum	Maximum	GUL
µg RE[7)] /100 kcal	60	180	-
µg RE[7)] /100 kJ	14	43	-

[7)] expressed as RE.

1 µg RE = 3.33 IU vitamin A = 1 µg 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[8)]

Unit	Minimum	Maximum	GUL
µg[9)] /100 kcal	1.5	4.5	-
µg[9)] /100 kJ	0.36	1.1	-

[8)] Competent national and/or regional authorities may deviate from the conditions as appropriate for the nutritional needs of their population.

[9)] Calciferol. 1 µg calciferol = 40 IU vitamin D.

iii) Vitamin B2 (Riboflavin)

Unit	Minimum	Maximum	GUL
µg /100 kcal	80	-	650
µg /100 kJ	19	-	155

iv) Vitamin B12(Cobalamin)

Unit	Minimum	Maximum	GUL
µg /100 kcal	0.1	-	2.0
µg/100 kJ	0.02	-	0.48

v) Vitamin C (Ascorbic acid)[10)]

Unit	Minimum	Maximum	GUL

mg /100 kcal	10	-	70
mg /100 kJ	2.4	-	17

[10)] expressed as L-ascorbic acid.

e) Minerals and trace elements

i) Iron[11)]

Unit	Minimum	Maximum	GUL
mg /100 kcal	1.0	3.0	-
mg /100 kJ	0.24	0.72	-

[11)] For the product as defined in Section 2.1 based on soy protein isolate a minimum value of 1.5 mg/100 kcal (0.36 mg/100 kJ) applies.

ii) Calcium

Unit	Minimum	Maximum	GUL
mg /100 kcal	90	-	280
mg /100 kJ	22	-	67

iii) Zinc

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

iv) Sodium chloride should not be added to the product for young children with added nutrients

4.2 Optional ingredients

4.2.1 Ingredients shall not be added with the purpose of imparting or enhancing a sweet taste of the products for young children with added nutrients. In addition to the compositional requirements listed under clause 4.1, other ingredients or substances may be added to products for young children with added nutrients 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.

4.2.3 The following substances may be added, in which case their content per 100 kcal (100 kJ) in the products for young children with added nutrients 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)[20)]

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

[20)] 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	-	-	10

f) L-carnitine

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

g) L (+) 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 Purity requirements

4.3.1 General

All ingredients shall be clean, of good quality, safe and suitable for ingestion by young children. They shall conform with their normal quality requirements, such as colour, flavour and odour.

4.3.2 Vitamin compounds and mineral salts

Vitamin compounds and mineral salts used shall be selected from the Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children (CXG 10-1979).

4.3.3 Consistency and particle size

When prepared according to the directions of use, the product shall be free of lumps and of large, coarse particles.

4.3.4 Specific prohibitions

The product and its components shall not have been treated by ionizing radiation.

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

The flavourings used in products covered by this standard should comply with the Guidelines for the Use of Flavourings (CXG 66-2008). Only the following flavouring may be used.

Name of flavouring	**Maximum use level**
Natural Fruit Extracts	GMP
Vanilla Extracts	GMP
Ethyl Vanillin	50mg/kg
Vanillin	50mg/kg

5.3 Carry-over principle

Only the food additives listed in food category 13.1.2 (Follow-up formula) of the General Standard for Food Additives (CXS 192-1995) or in the Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children (CXG 10-1979) may be present in the products for young children with added nutrients, 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 General Standard for Food Additives (CXS 192-1995).

6 Contaminants

6.1 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 193-1995).

6.2 The products for young children with added nutrients shall comply with the maximum residue limits for pesticides established by the Codex Alimentarius Commission.

7. Hygiene

7.1 Products for young children with added nutrients 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.

7.2 Products for young children with added nutrients shall not exceed microbiological limits given in Table 2 when tested in accordance with test methods specified therein.

Table 2 — Microbiological limits

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

8 Labelling

8.1 General

8.1.1 The requirements of the EAS 38, EAS 803, apply to products for young children with added nutrients. These requirements include a prohibition on the use of nutrition and health claims for foods for young children

8.1.2 In addition to the requirements of EAS 38, each unit shall be legibly and indelibly labelled with the information in 8.2 to 8.7.

8.2 Name of the product

8.2.1 The text of the label and all other information accompanying the product shall be written in the acceptable languages as per EAS 38.

8.2.2 The name of the product shall be “products for young children with added nutrients”, “drink for young children with added nutrients” or “drink for young children or product for young children”

8.2.3 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 ‘products for young children with added nutrients based on (name of animal) milk protein’.

b) If (name of plant) is the only source of protein*, the product may be labelled ‘products for young children with added nutrients 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 ‘products for young children with added nutrients based on [name of animal] milk protein and (name of plant) protein’ or ‘products for young children with added nutrients 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.

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

8.3 List of ingredients

8.3.1 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.

8.3.2 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.

8.4 Declaration of nutritive value

a) The declaration of nutrition information for products for young children with added nutrients shall contain the following information which should be in the following order:

b) 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;

c) the total quantity of each vitamin and mineral and any other ingredient shall be 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

d) in addition, the declaration of nutrients in a) and b) per 100 kcal or per 100 kJ is permitted.

e) 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 after 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.

8.5 Date marking and storage instructions

8.5.1 The date marking and storage instructions shall be in accordance with EAS 38.

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

8.6 Information for use

8.6.1 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.

8.6.2 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.

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

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

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

8.6.6 The label of products for young children with added nutrients shall include a statement that the product shall not be introduced before 12 months of age, is not to be used as a sole source of nutrients and that young children should receive complementary foods in addition to the product.

8.7 Additional labelling requirements

8.7.1 Where there is national regulation related to infant and young children nutrition, the specified requirements therein apply. In addition, the requirements given in 8.7.2 to 8.7.6 shall apply

8.7.2 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 the 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”.

8.7.3 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 products for young children with added nutrients;

b) suggest use for infants under the age of 12 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.

8.7.4 The terms “humanized”, “maternalized”, or other similar terms shall not be used.

8.7.5 products for young children with added nutrients shall be distinctly labelled in such a way as to avoid any risk of confusion with infant formula, follow up formula 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.

8.7.6 The labelling of products for young children with added nutrients shall not refer to Infant formula, follow up formula, and formula for special medical purposes intended for infants, including numbers, text, statements, or images of these products.

9 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. https://www.who.int/publications/i/item/9241541601