

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Item 4a, 4b, 5, 6, 8, 9, 10 and CRD 3

NFSDU/40 CRD 14

Original language only

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

Fortieth Session

Berlin, Germany

26 – 30 November 2018

Comments of Thailand

ITEM 4A

SECTION A: FOLLOW-UP FORMULA FOR OLDER INFANTS

3 ESSENTIAL COMPOSITION AND QUALITY FACTORS

a) Protein

Footnote 6)

- We propose to remove the Footnote 6 as follows;

~~“(6) A lower minimum protein level between 1.6 and 1.8 g/100 kcal (0.38 and 0.43 g/100 kJ) in follow up formula based on non-hydrolysed milk protein can be accepted. Such follow up formula and follow up formula 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.”~~

Docosahexaenoic acid

Footnote 21)

- We agree to revise the minimum level of docosahexaenoic acid as proposed in order to prevent technological difficulties in the production process.

SECTION B: [NAME OF PRODUCT] FOR YOUNG CHILDREN

3 ESSENTIAL COMPOSITION AND QUALITY FACTORS

c) Carbohydrates

Available carbohydrates 4)

Footnote 4)

- From our view, carbohydrates used in this product should be lactose derived from milk. Sucrose and/or fructose should not be added.
- Moreover, we would like to propose that if carbohydrates other than lactose are added in the product, those carbohydrates' sweetness should be equal or less than lactose or their Dextrose Equivalent (DE) should be in the range between 5-20 such as oligosaccharide, glucose polymer and maltodextrin.
- The additional text proposed by the EWG should not be included in the footnote.
- The section should then read as follows;

~~“(4) [Lactose should be the preferred carbohydrates in [name of product] based on milk protein. For products not based on milk protein, carbohydrate sources (like starch) that have no contribution to the sweet taste should be preferred.~~

~~Sucrose and/or fructose should not be added in [name of product]. If carbohydrates, other than lactose are added in [name of product], those carbohydrates' sweetness should be equal or less than lactose or their Dextrose Equivalent (DE) should be 5-20 such as oligosaccharide, glucose polymer and maltodextrin~~

~~Mono and disaccharides, other than lactose, either added as ingredients, or constituents of ingredients and/or increased above the amount contributed by the ingredients by some other means, should not exceed 2.5 g/100kcal (0.60 g/100kJ) of available carbohydrate. National and/or regional authorities may limit this level to 1.25 g/100 kcal (0.30 g/100 kJ). Sucrose and/or fructose or other carbohydrates contributing to the sweet taste of [name of product] should not be added, unless needed as a carbohydrate source. Other noncarbohydrate ingredients should not be added with the purpose of imparting or enhancing a sweet taste.”~~

[Vitamin D3⁹⁾

- We propose to replace “Vitamin D3” with “Vitamin D” to preserve the consistency with the section A of standard for follow up formula and standard for infant formula.
- We agree with the proposal to include Vitamin D with the minimum level of 1.5 µg /100 kcal and maximum level of 4.5 µg /100 kcal.

- And, we would like to propose to remove the square bracket in Footnote 9).
- The section should then read as follows;

“~~Vitamin D₃~~”

Unit	Minimum	Maximum	GUL
µg ¹⁰⁾ /100 kcal	{1.5}	{4.5}	-
µg ¹⁰⁾ /100 kJ	{0.36 }	{1.08}	-

{9) Competent national and/or regional authorities may deviate from the conditions as appropriate for the nutritional needs of their population.}

10) Calciferol. 1 µg calciferol = 40 IU vitamin D.”

ITEM 4B

General Comments

Name of Product for Young Children

- For clarity, we proposed to avoid using the word “Follow-up” in the product name. Also, we would like to propose appropriate product name as “Formula for Infants”, “Formula for Older Infants” and “Formula for Young Children”.
- The name of product “Formula for Young Children” should be used instead of “~~Formulated~~ drink for young children”. Since, the word ‘drink’ couldn’t distinguish this drink from other beverages distributed in the market such as water, fruit juice and alcoholic beverage.
- So, the name of product should read:

“~~Formulated~~ drink Formula for young children”

Structure of the standard(s)

- We would like to propose that the document should be separated to two standards including: the Standard for Follow-up Formula for Older Infants and the Standard for Follow-up Formula for Young Children in order to be clear and easy for document usability in practice.

Specific Comments

- Our comments for specific sections of the document (CX/NFSDU 18/40/5) are as follows:

Appendix II

- Proposed Draft Revised Standard for Follow-Up Formula (CODEX STAN 156-1987)

[PREAMBLE]

- We agree with the proposed text with our recommendation to include the word “promote” in the first sentence 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 / supported by member states may also 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] Formula for Young Children (12 to 36 months of age). It does not apply to products covered by the Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72 — 1981 CXS 72-1981).”

SECTION A: FOLLOW-UP FORMULA FOR OLDER INFANTS

2 [SCOPE

- We agree with the proposed text with the inclusion of the text “labelling and analytical” in 2.2. For 2.3, “shall” should be used in the provision, rather than “should”. So, the scope should read:

“2.1 This section of the Standard applies to Follow-up Formula for Older Infants, as defined in Section 2.1, in liquid or powdered form.

2.2 This section of the Standard contains compositional, quality, safety, ~~labelling and analytical~~ requirements for Follow-up Formula for Older Infants.

2.3 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.”

3 DESCRIPTION

3.1 Product Definition

- We agree with the proposed text with our recommendation to insert the word “formulated and”, meanwhile “as a substitute for breast-milk” should be deleted.
- For clarity and safety concern, it is important to note that Follow up formula isn't suitable for babies under 6 months.
- The provision should then read:

“3.1.1 Follow-up formula for older infants means a product, **specialy formulated and** 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.”

9. [LABELLING]

- We agree with the proposed text with our recommendation to delete the last sentence.

“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.~~”

9.4 Date Marking and Storage Instructions

- For reasons of safety and quality of these product and align the date marking and storage instructions for follow-up formula for older infants with the work on date marking finalised by the Codex Committee on Food Labelling (CCFL), we proposed that the term “Use-by Date” or “Expiration Date” should be used in this provision, rather than “Best Before Date” or Best Quality Before Date”. And, we agree with the proposed text that should read:

“9.4 Date Marking and Storage Instructions

9.4.1 (i) The ~~“Best Before Date” or “Best Quality Before Date”~~ **“Use-by Date” or “Expiration 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 YYYY/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>”.~~

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~~ the validity of the date depends thereon.

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

9.6 Additional Labelling Requirements

- We agree with the proposed text as follows:

“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 an ~~an [independent]~~ health worker as to the need for its use ~~[including any exception to the age of introduction of 6 months]~~ and the proper method of use.

~~(d) the statement: 'The use of this product must not replace breast milk and lead to cessation of continued breastfeeding'.~~

~~9.6.2 The label shall have no pictures of infants and women nor any other picture[,] or text[,] which idealizes the use of follow-up formula. The label shall have no pictures, images, text or other~~ representation that might:

~~9.6.2.1 idealize the used 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, that makes a comparison to breast milk, or suggests that the product is nearly~~ 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, regional or international regulatory authorities.]~~

~~9.6.3 The terms "humanized", "maternalized" or other similar terms shall not be used. [In addition, the product should not be compared to breast milk].~~

~~9.6.4 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[, and to enable consumers to make a clear distinction between them, in particular as to the text, images and colours used.]]~~

SECTION B: [NAME OF PRODUCT] FOR YOUNG CHILDREN

1 | SCOPE

- We agree with the proposed text with the inclusion of the text "labelling and analytical" in 2.2. For 2.3, "shall" should be used in the provision, rather than "should". So, the scope should read:

"1.1 This section of the Standard applies to [name of product] for young children, as defined in Section 2.1, in liquid or powdered form.

1.2 This section of the Standard contains compositional, quality, safety, ~~[labelling and analytical]~~ requirements for [name of product] for young children.

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 [name of product] for young children."

2 DESCRIPTION

2.1 Product Definition

- We agree with the proposed text with our recommendation to retain the word "formulated and", meanwhile "as a breast-milk substitute" should be deleted.

- It is important to note that FUF product should be used as part of the overall foods to meet nutritional requirements for young children; however, the FUF is not the breastmilk substitutes.

- The provision should then read:

"2.1.1 [Name of product] for young children means a product ~~as a breast-milk substitute~~ **especially [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]."~~

9. LABELLING

- We agree with the proposed text, meanwhile, standard for [Name of Product] for Young Children (aged 12-36 months) covers a product to be used as part of the overall foods to meet nutritional requirements.

- However, it is necessary to establish the NRV-R for Young Children and strongly proposes that this work shall be carried out by the Joint FAO/WHO Expert Meetings on Nutrition (JEMNU), the scientific advice mechanism (JEMNU) with high credibility and acceptance from all parties concerned.

- The provision should then read:

“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 [Name of Product] for Young Children. **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.**”

9.1 The Name of the Product

- We agree with proposed text, to use the term ‘may’ in Section 9.1.5 instead of ‘shall’.

“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 [Name of Product] for Young Children 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 ‘[Name of Product] for Young Children Based on [name of animal] milk [protein]’.

b) If [name of plant] is the only source of protein^[*], the product may be labelled ‘[Name of Product] for Young Children Based on [name of plant] [protein]’.

c) if [name of animal] milk and [name of plant] are the sources of proteins*, the product may be labelled ‘[Name of Product] for Young Children Based on [name of animal] milk protein and [name of plant] protein’ or ‘[Name of Product] for Young Children 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.]

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

9.2 List of Ingredients

- We agree with the proposed text as follows:

“9.2 List of Ingredients

9.2.1 A complete list of ingredients ~~[including optional 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 names for these ingredients and additives may be included on the label. [The food additives INS number may also be optionally declared the INS number.]**”

9.3 Declaration of Nutritive Value

- We agree with the proposed text as follows:

“9.3 Declaration of Nutritive Value

The declaration of nutrition information for [name of product] for young children 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 or per 100 millilitres of the food as sold ~~as well as~~ per per 100 millilitres 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 B and any other ingredient as listed in paragraph 3.2 of Section B per 100 grams or per 100 millilitres of the food as sold ~~as well as~~ per per 100 millilitres 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 [serving size and/or per] 100 kilocalories (or per 100 kilojoules) is permitted.”

9.4 Date Marking and Storage Instructions

- For reasons of safety and quality of these product and align the date marking and storage instructions for follow-up formula for older infants with the work on date marking finalised by the Codex Committee on Food Labelling (CCFL), we

proposed that the term “Use-by Date” or “Expiration Date” should be used in this provision, rather than “Best Before Date” or “Best Quality Before Date”. And, we agree with the proposed text that should read:

“9.4 Date Marking and Storage Instructions

9.4.1 (i) The ~~“Best Before Date” or “Best Quality Before Date”~~ **“Use-by Date” or “Expiration 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 YYYY/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>”.~~

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

- We agree with the proposed text as follows:

“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 e~~ 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.”

9.6 Additional Labelling Requirements

- We agree with the proposed text as follows:

“9.6 Additional Labelling Requirements

9.6.1 The label of [name of product] for young children shall have no image, text or representation ~~, including pictures of feeding bottles,~~ that could undermine or discourage breastfeeding or which idealises the use of [name of product] for young children. The terms ‘humanized’, ‘maternalized’ or other similar terms must not be used on the label.]

~~9.6.2~~ 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[, and to enable consumers to make a clear distinction between them, in particular as to the text, images and colours used].”

ITEM 5

General comments

- We agree with the document in principle.

Specific comments

- Our comments for specific sections of the document are as follows:

- Appendix 1

-1. PREAMBLE

- We agree on the proposed text with additional amendments as follows;

“Children affected by severe acute malnutrition (SAM) need safe, palatable foods with a high energy content and adequate amounts of [protein](#), vitamins, minerals and other nutrients. ~~Children with SAM need efficacious and timely treatment and RUTF is part of the care.~~ RUTF are primarily intended for children with uncomplicated SAM from 6-59 months [of age](#). ~~Although~~ [However](#), RUTF may be given to other age groups with various forms of malnutrition at the implementation level, ~~the primary focus for these guidelines is children with SAM from 6-59 months. Since RUTF are prescribed according to weight,~~ National Authorities may decide to include the provision of RUTF in their national protocols for use by other age groups.

~~These guidelines provide guidance for the production and labelling of RUTF.~~ The guidelines are intended to facilitate the harmonization of requirements for RUTF at the international level and may provide assistance to governments wishing to establish national regulations [for the production and labelling of RUTF](#). ~~The guidelines are also intended for use as an instrument designed to avoid or remove difficulties which may be created by diverging legal, administrative and technical approaches to RUTF and by varying definitions and nutrient compositions of RUTF.~~ These guidelines should be used in accordance with technical recommendations of the relevant evidence and related Codex texts/documents by WHO, UNICEF and WFP1. ~~Governments and other users should ensure adequate provisions are made for competent technical experts for the appropriate use of these guidelines.~~

1) A Joint Statement by the World Health Organization, the World Food Programme, the United Nations System Standing Committee on Nutrition and the United Nations Children’s Fund. 2007. Community-Based Management of Severe Acute Malnutrition; A Joint Statement by the World Health Organization and the United Nations Children’s Fund. 2009. Child growth standards and the identification of severe acute malnutrition in infants and children, Geneva: World Health Organization; World Health Organisation. 2013. Guideline: Updates on the management of severe acute malnutrition in infants and children, Geneva: World Health Organization; World Health Organisation. 2003. Global Strategy for Infant and Young Child Feeding, Geneva: World Health Organization; World Health Organisation. 1981. International code of marketing of breast-milk substitutes, Geneva: World Health Organization and subsequent relevant WHA Resolutions on infant and young child feeding; Code of Ethics for International Trade in Food including Concessional and Food Aid Transactions (CXC 20-1979); Food and Agriculture Organisation and World Health Organisation. 2016. FAO/WHO Microbial safety of lipid-based ready-to-use foods for management of moderate acute malnutrition and severe acute malnutrition, Rome: Food and Agriculture Organisation.”

-5. SUITABLE RAW MATERIALS AND INGREDIENTS

-5.1 Basic Raw Materials and Ingredients

-5.1.5 Vitamins and Minerals

- We propose inserting the three reference documents as follows;

“[Vitamin and mineral forms used must be soluble and easily absorbed by patients with SAM. Children with SAM have low or absent gastric acid which means that they should not be given inorganic salts of minerals that are insoluble or requiring an acid gastric environment for absorption, in order to avoid metabolic acidosis. It is important that RUTF should have a mineral composition that leads to a moderate excess of non-metabolisable base. The non-metabolizable base can be approximated by the formula: estimated absorbed millimoles (sodium + potassium + calcium + magnesium) - (phosphorus + chloride.)

All added vitamins must be in accordance with the Advisory Lists of Nutrient Compounds for use in Foods for Special Dietary Uses Intended for Infants and Young Children (CAC/GL 10-1979). Examples of minerals for RUTF formulation can be found in the WHO Management of severe malnutrition: A manual for physicians and other senior health workers (1999). [The amount of vitamins and minerals added to achieve the target level must be adjusted based on the chemical form and scientific evidence showing adequate stability and bioavailability in the finished product.]

[Joint Statement on Community-Based Management of Severe Acute Malnutrition by the World Health Organization, the World Food Programme, the United Nations System Standing Committee on Nutrition and the United Nations Children’s Fund, 2007](#)

[WHO. Child growth standards and the identification of severe acute malnutrition in infants and children, 2006; A Joint Statement by the World Health Organization and the United Nations Children’s Fund; Geneva: World Health Organization; 2009](#)

[WHO. Guideline: Updates on the management of severe acute malnutrition in infants and children. Geneva: World Health Organization; 2013](#)”

-5.2 Other Ingredients

-5.2.1 Available Carbohydrates⁶

- We note that RUTF has been used as the therapeutic foods for children with severe acute malnutrition in short period and it does not cause children to addict with sweet taste. With this in mind, we propose deleting the last sentence;

“The palatability of the RUTF can be increased by the addition of available carbohydrates. Available carbohydrates must adhere to the relevant Codex Alimentarius texts.

Honey should not be used in RUTF due to the risk of infant botulism from *Clostridium botulinum*.

- 6) Sucrose, plant starch, maltodextrin, should be the preferred carbohydrates in RUTF. Fructose, glucose and corn syrup as ingredients should be avoided in RUTF, because of potential adverse effects in SAM children]. Only precooked and/or gelatinized starches ~~[gluten free]~~ by nature may be added. ~~“Any carbohydrate added for sweetness should be used sparingly.”~~

-5.2.2 Food Additives and Flavours

- From our views, RUTF as food additive should be used as necessary considering the technological justification. We further view that the specific list for RUTF should be developed in the future. However, in the meantime, we suggest that the lowest value of additives under Food Category 13.1 and 13.2 should be selected.

~~“This section will make reference to the General Standard for Food Additives (CODEX STAN 192-1995). In order to facilitate the guidelines setting process, food additive under Food Category 13.1 and 13.2 should be selected to be used as necessary in the RUTF.”~~

- 6. NUTRITIONAL COMPOSITION AND QUALITY FACTORS

-6.2 Proteins

- In general, we agree with the texts proposed by eWG. Considering scientific information and quality of protein, we additionally view that “the source of protein other than milk” should come from the protein sources that are locally available, for example legumes or cereals, in certain countries. With this in mind, we would propose the additional texts to read;

“Protein should provide 10% - 12% of the total energy. ~~at least 50% of protein is provided by milk products~~ by other protein sources from legumes or cereals”

-8. PROCESSING TECHNOLOGIES

-8.3 Toasting

- We propose to remove the last bullet as follows;

~~“The use of appropriate enzymes may be considered to decrease anti-nutrients in ingredients.”~~

- 12. LABELLING

- For reason of clarity of pre-packaged food labelling, we propose to retain “CODEX STAN 1-1985” to read;

“It is recommended that the labelling of RUTF for children from 6 to 59 months be in accordance with the Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CXS 180-991), Codex General Standard for the Labelling of Pre-packaged Foods (CODEX STAN 1-1985), ~~the General Standard for the Labelling of and Claims for Pre-packaged Foods for Special Dietary Uses (CXS 146-1985)~~, Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997) and Guidelines on Nutrition Labelling (CXG 2- 1985).”

- Additional Mandatory Labelling Requirements

- It is important to note that RUTF has been used as the therapeutic foods for children with severe acute malnutrition in short period; however, the RUTF is not the breastmilk substitutes. With the reason, we propose to remove the 6th and 7th

“Additional Mandatory Labelling Requirements

The following statements shall appear on the label of RUTF:

- "USE UNDER MEDICAL SUPERVISION" shall appear on the label in bold letters in an area separated from the written, printed, or graphic information.
- "For the dietary management of severe acute malnutrition" shall appear on the label.

- A prominent warning statement consisting of an explanatory statement in bold letters indicating that RUTF are for special medical purposes and may pose a health hazard when consumed by individuals who do not have the disease(s), disorder(s) or medical condition(s) for which the food is intended.
- The product is not to be used for parenteral, rectal or Nasogastric Tube (NG tube) administration.
- A statement indicating whether the product is or is not intended as the sole source of nutrition.
- ~~A statement indicating that RUTF are not breastmilk substitutes and shall not be presented as such.~~
- ~~[Exclusive breastfeeding is recommended for the first 6 months of life, and continued breastfeeding is recommended for at least 24 months.]~~

-ANNEX

-Table: Nutritional Composition for RUTF

- Considering safety concern, adverse effect and nutrition need, we propose the levels of vitamin A, vitamin D, calcium, phosphorus and magnesium as follows;

vitamin A

Unit	Minimum	Maximum	GUL
mg RE/100g	0.8	[1.1] OR [1.2]	-
mg/ RE/100kcal	0.15	[0.2] OR [0.22]	-
² µg RE/100kcal	150	[200] OR [220]	-

² 1µg RE = 3.33 IU Vitamin A = 1 µg 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.

vitamin D

Unit	Minimum	Maximum	GUL
³ µg/100 g	15	[20] OR [22]	[30]
³ µg/100 kcal	2.7	[3.6] OR [4]	-

³1 µg cholecalciferol = 40 IU vitamin D

Calcium

Unit	Minimum	Maximum	GUL
mg/100 g	300	[600] or [785]	-
mg/100 kcal	58	[100] or [143]	-

Phosphorus

Unit	Minimum	Maximum	GUL
mg/100 g	300	[600] or [785]	-
mg/100 kcal	58	[100] or [143]	-

Magnesium

Unit	Minimum	Maximum	GUL
mg/100 g	80	[140] or [235]	-
mg/100 kcal	15.4	[26] or [43]	-

ITEM 6

“Biofortification”

first sentence

- The word “of essential nutrient (s)” should be added

Footnote 1

- For clarity, we considered CCFL to use the term “bio” with alternative terms namely: agri-fortification, agro-fortification or nutri-fortification.
- In addition, we requested CCFL to consider the definition of biofortification on how it would be used and where to be placed.

Footnote 2

- We would like to ensure that the process definition excludes direct addition of essential nutrients to food or any Genetic Modifications.

Footnote 3

- We would like to proposed the replacement of “Conventional addition to food is covered by” with “Refer to”.
- Therefore, the definition of “Biofortification” should read:

“Biofortification¹ is any process² other than conventional addition of essential nutrient (s) to food³ whereby nutrient⁴ content is increased or become more bioavailable in all potential food sources⁵ for the intended nutritional purposes⁶.

1) Some Member governments may prefer to use an equivalent term.

2) Process to be determined by the competent national/regional authority.

3) ~~Conventional addition to food is covered by~~ Refer to the General principles for the addition of essential nutrients to foods (CXG 9-1987).

4) Nutrient is defined by the Guidelines on nutrition labelling (CXG 2-1985).

5) e.g. animal, plant, fungi, yeasts, bacteria

6) Nutritional purpose:

- preventing/reducing the risk of, or correcting, a demonstrated deficiency in the population;
- reducing the risk of, or correcting, inadequate nutritional status or intakes in the population;
- meeting requirements and/or recommended intakes of one or more nutrients;
- maintaining or improving health; and/or
- maintaining or improving the nutritional quality of food.”

ITEM 8

Proposal for conditions for a “free” of Trans Fatty Acids (TFAs) claim

We would like to confirm our previous comments supporting the Canada’s proposal on the definition for the claim of TFA free as follows:

1. We agree with the proposal that an entry for a claim of “free” of TFAs be inserted between Saturated Fat and Cholesterol within the Table of conditions for nutrient content claims in the Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997).
2. And, we agree with the proposal for the claim for free of TFAs that the food should contain no more than 1 g per 100 g of fat and must meet the conditions set for “low” in saturated fats are as follows: 1.5 g saturated fat per 100 g (solids), 0.75 g saturated fat per 100 mL (liquids) and 10% of energy of saturated fat.
3. From our view, these trans fats occur naturally in milk and milk products. So, proposal for the claim for free of TFAs should exclude milk and milk products.
4. We propose to consider valid analytical methods for measuring the proposed TFA level in all foods.
5. On a basis of general principle, the selected method should be practical, even though new proposed methods are more accurate, precise and reliable than current endorsed methods, since the proposed methods may require additional cost and capacity development for developing countries,

So, when the proposed method are endorsed as type II meanwhile the current endorsed methods are still effective and reliable, it is proposed that CCMAS should retain the current methods as alternative method (type III).

ITEM 9

General comments

In principle, Thailand agrees to continue the work on NRV-R for Older Infants and Young Children. Since, there are information, i.e. nutrients and value, for consumers.

We propose that this work be carried out by the Joint FAO/WHO Expert Meetings on Nutrition (JEMNU), the scientific advice mechanism (JEMNU) with high credibility and acceptance from all parties concerned.

ITEM 10

General comments

We have general comments on handling of new food additives those already evaluated by JECFA, but for which technological justification has not yet been confirmed by CCNFSDU (i.e. xanthan gum, pectin, etc.) as follows:

CCNFSDU should consider the need of technological justification for food additives intended for use in its commodity standards prior to the inclusion into the priority list for JECFA safety evaluation. While CCFA consider other factors on the use of food additives.

After scientific advices on the food additives was made by JECFA and informed to CCNFSDU through CCFA, CCNFSDU should accept and recognize the advice that should be taken into account and used in elaborating proposals or provisions to be included in CCNFSDU standards or GSFA, i.e. their safety for use in the product at the specified levels.

CRD 3

General Comments

1. We agree that methods of analysis for nutrients in the standard should be reviewed from time to time once there are new analytical methodologies to keep them updated and submitted to CCMAS for technical review, typing, endorsement.

2. On a basis of general principle, the method selected should be practical, even though new proposed methods are more accurate, precise and reliable than current endorsed methods, since the proposed methods may require greater capacity building and cost for developing countries,

So, when the proposed method are endorsed as type II meanwhile the current endorsed methods are still effective and reliable, it is proposed that CCMAS should retain the current methods as alternative method (type III).

Specific Comments

- We agree with an analytical method for 9 Minerals and Trace Elements (AOAC 2015.06 / ISO 21424 | IDF 243) (shown in TABLE 4.) And, this method should be submitted to CCMAS for technical review, typing, endorsement and inclusion in the Recommended Methods of Analysis and Sampling (CODEX STAN 234-1999).
- Meanwhile, the methods (AOAC 984.27 ICP emission spectroscopy) meet the specifications in CXS 72-1981 and fit for purpose, we proposed to retain the methods as alternative method (type III).