CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 2, 4b, 5, 6, 7, 8, 9, 11 and 12 **NFSDU/40 CRD 25**

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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 the African Union

Item 2

Matters for action

Issue 1: CCEXEC75 request that CCNFSDU consider a prioritization mechanism to better manage its work (**Para 15**).

Comment: African Union supports the recommendation on developing this mechanism. We propose that a working group be established to develop a working draft document for the mechanism.

Rationale: As the number of new work for this committee increases, there is need to have established criteria which will be used by the committee to make objective decision on the work to be prioritized at any given time within the constraints of time and other resources.

Issue 2: CCMAS39 request for clarification on the provision for Vitamin D in which CXS 72-1981 specifies Vitamin D3 while the Advisory lists of nutrient compounds for use in foods for special dietary uses intended for infants and young children (CXG 10-1979) indicates the source of Vitamin D as Vitamin D2 and Vitamin D3 (**Para 17**).

Comment: African Union supports the requirement of Vitamin D to be maintained as Vitamin D3 in CXS 72-1981

Rationale: Vitamin D3 from animal source has higher potency compared to Vitamin D2 from plant sources. Given the population in question (infants), it is important that they are provided with nutrients of relatively high potency. In addition, Vitamin D3 is more efficacious in raising plasma vitamin D concentration than D2 and therefore will be more beneficial to infants.

Issue 3: CCFA50 recommendation that CCNFSDU consider the revocation of the following provisions, taking into consideration the lack of JECFA specifications: potassium hydrogen malate (INS 351(i)), potassium malate (INS 351(ii)), monosodium tartrate (INS 335(i)), monopotassium tartrate (INS 336(i)), dipotassium tartrate (INS 336(ii)) in the Standard for Processed Cereal-Based Foods for Infants and Young Children (CXS 74-1981). (**Para 19**).

Comment: African Union supports CCFA recommendation to revoke the food additives

Rationale: Use of food additives in foods for infants and young children should be reduced to the minimum extent possible**.** They should only be used where there is an indispensable technological justification and where JECFA has fully evaluated their safety as well as published their specifications. With the lack of specifications, the food additives should be revoked.

Item 4b

Background of review of the standard

At the 39th Session, the meeting agreed to continue work on the revision of the Standard for Follow-up Formula and to forward the essential composition requirements for older infants and young children agreed at the 39th and previous sessions to Step 5 for adoption by CAC41. An electronic working group chaired by New Zealand, co-chaired by Indonesia and France was established to:

a) finalize the labelling requirements for follow up formula for older infants

b) finalize the labelling requirements for [name of product] for young children

c) consider options for the structure of the standard/standards;

d) develop a proposal for the scope sections for both follow-up formula for older infants and [name of product] for young children; and

e) finalize the product definitions contained within section 2.1 for both follow-up formula for older infants and [name of product] for young children and finalise the name of the product for young children.

The eWG discussed the follow–up formula standard and developed a preamble and 19 recommendations to be considered by the 40th Session of CCNFSDU. African Union has discussed both the preamble and the recommendations and provides comments as follows:

Issue: Preamble: That CCNFSDU to discuss the preamble of the standard

Comment: African Union supports the idea of having a preamble to this standard. We propose the preamble be amended to read as indicated below:

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 or supported***]~~ *by member states* ~~*[***may also***]~~ ***should*** *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] for Young Children (12 to 36 months of age). It does not apply to products covered by the Codex Standard for Infant Formula (CXS 72 – 1981).

Rationale: The preamble should provide strong recommendation to users of the standard to consider and apply the International Code of marketing of BMS as well as the accompanying WHA resolutions.

In the first paragraph of the preamble, it is important to introduce the word '**promote**' so as to be consistent with the spirit and intent of the Code of protecting, promoting and supporting breast feeding. We support deletion of the word '**necessary**' and adopt the word '**appropriate**'. This will be consistent with the understanding that the products are not nutritionally essential rather their use only occurs where appropriate.

In the second paragraph, we propose deletion of the words '**as appropriate**' so that it becomes necessary to take into consideration the recommendations of the Code. We support maintaining both '**endorsed** and **supported**' so as to take care of both scenarios and replace '**may be'** with '**should**' to make it a strong recommendation.

Issue: Recommendation 1, 2 and 3: That CCNFSDU agree to the following text for of the Scope (for follow-up formula for older infants):

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

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

1.3 Only products that comply with the criteria laid down in the provisions of this section of this Standard ~~*[***should /***~~ ***shall***~~*]*~~ *be presented as Follow-up Formula for Older Infants*

Comment: African Union Supports the proposed scope for follow-up formula for older infants

Rationale: The proposed scope is in compliance with the procedural manual of ensuring that a scope should be precise, specific and that it does not introduce ambiguity to the standard. In addition, guidance regarding referencing to WHO/WHA and other documents has been provided by CCEXEC75. Placing the reference to WHA in the preamble will ensure WHO/WHA recommendations and resolutions have the same importance as when placed in the scope of the standard.

Issue: Recommendation 4, 5 and 6: That CCNFSDU agree to the following text for of the Scope for [name of product] for young children):

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.

Comment: African Union Supports the proposed scope for name of product] for young children

Rationale: The proposed scope is in compliance with the procedural manual of ensuring that a scope should be precise, specific and that it does not introduce ambiguity to the standard. In addition, guidance regarding referencing to WHO/WHA and other documents has been provided by CCEXEC75. Placing the reference to WHA in the preamble will ensure WHO/WHA recommendations and resolutions have the same importance as when placed in the scope of the standard.

Issue: Recommendation 7: That CCNFSDU agree to the following definition for follow-up formula for older infants:

*~~[~~**Follow-up formula for older infants** means a product, ~~**specially**~~ 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.~~]~~*

Comment: African Union Supports the adoption of the definition as presented.

Rationale: The definition lays emphasis that the products are breast milk substitutes in line with spirit and intent of the Code and deletion of the word '**specially**' eliminates any significance given to the products that may create the impression of a special product whereas they have deemed to be unnecessary by WHA resolutions WHA 39.28 and WHA 69.9.

Issue: Recommendation 8: That CCNFSDU agree to the following definition for [name of product] for young children:

[Name of product] for young children** means a product **~~specially [formulated and]~~** manufactured for use **~~[as a breast-milk substitute],~~** as a liquid part of the **~~[progressively]~~** ~~[~~diversified~~]~~ diet of young children **[in order to contribute to the nutritional needs of young children] ~~[when nutrient intakes may not be adequate to meet nutritional requirements].~~

Comment: African Union proposes the definition to be amended to refer the products as breast milk substitute as follows:

*[**Name of product**] **for young children** means a product **~~specially [formulated and~~**] manufactured for use **~~[~~as a breast-milk substitute~~],~~** as a liquid part of the ~~[progressively]~~ ~~[~~diversified~~]~~ diet of young children [**in order to contribute to the nutritional needs of young children**] **~~[when nutrient intakes may not be adequate to meet nutritional requirements]~~**.*

Rationale: According to WHA resolution 69/7 addendum 1, any products manufactured targeting infants and young children from 6 to 36 months are treated as BMS. As result, the words, '***as a breast-milk substitute'*** should not be deleted from the definition.

Issue: Recommendation 9: That CCNFSDU agree to the following text for introductory paragraph to the Labelling Section for follow-up formula for older infants:

*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.]~~"***

Comment: African Union supports the proposed deletion in the provided text:

Rationale: Clause 1.4 of the *Guidelines for Use of Nutrition and Health Claims (CXG 23-1997),* clearly prohibits use of nutrition claims in products intended for infants and young children. Therefore, the statement is not necessary in the current draft standard. This will also ensure that committee makes reference to existing Codex Standards as guided by the procedural manual to avoid unnecessary conflicts of Codex Standards.

Issue: Recommendation 10: That CCNFSDU agree to the text on Additional Labelling Requirements for follow-up formula for older infants:

Comment: African Union supports adoption of the text as drafted for clause 9.6 in its entirety.

'[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 ~~[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.]]~~'

Rationale: The clause as drafted will ensure that breast feeding is protected and promoted given the statements required by the clause. In addition, clause 9.6.4 will eliminate the confusion of the products especially in populations who are not able to read and write and would heavily rely on features such as colour or shape. This will reduce chances of cross-promotion of related products.

Issue: Recommendation 11: That CCNFSDU agree to the following text for introductory paragraph to the Labelling Section for [Name of product] for young children:

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.~~

Comment: African Union supports the proposed deletion

Rationale: Clause 1.4 of the *Guidelines for Use of Nutrition and Health Claims (CXG 23-1997),* clearly prohibits use of nutrition claims in products intended for infants and young children. Therefore, the statement is not necessary in the current draft standard. This will also ensure that committee makes reference to existing Codex Standards as guided by the procedural manual to avoid unnecessary conflicts of Codex Standards.

Issue: Recommendation 12: That CCNFSDU agree to the name of product section 9.1 for [Name of product] for Young Children

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.

Comment: African Union supports the proposed clause 9.1 in its entirety:

Rationale: The clause emphasizes the proper naming of the products in relation to the source of protein in the product and thus giving the true nature of the product. This will assist consumers make informed decision in relation to the source of protein contained in the product.

Issue: Recommendation 13: That CCNFSDU agree to text on the List of Ingredients

Comment: African Union supports the proposed clause 9.2 in its entirety:

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~~ class~~es~~ 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~~]~~.

Rationale: The opening statement of 9.2.1 indicates '**a complete list of ingredients**' and thus, no need for the statement '**including optional ingredients**' as they are already part of the complete list. In addition, clause 9.2.2 obligates that the specific name of food additives be declared and provides as an option, the labelling related to INS numbers and class names of the food additives. Most consumers are not in a position to understand INS and class names of food additives, therefore making it mandatory to indicate the name of food additive used will be beneficial to the consumers.

Issue: Recommendation 14: That CCNFSDU agree to the following text for the Declaration of Nutritive Value for [name of product] for young children

Comment: African Union supports the proposed clause 9.3

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~~] [or]~~ 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~~] [or]~~ 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.

Rationale: The clause makes it mandatory to declare both the amount of energy as well as vitamins and minerals in both per 100 grams as well as per 100 millilitres of a ready to use products after reconstitution as well as per serving size. This information will provide proper guidance to consumers on how to use the products to achieve the intended benefits.

Issue: Recommendation 15: That CCNFSDU agree to the following text for date marking and storage instruction for [name of product] for young children

Comment: African Union supports the proposed clause 9.4

9.4 Date Marking and Storage Instructions

*9.4.1 (i) The "**Best Before Date" or "Best Quality Before Date**" shall be declared by the day, month and year except that for products with a shelf-life of more than three months, ~~[~~at least~~]~~ the month and year ~~[~~shall be declared~~]~~. ~~[~~The day and year shall be declared by uncoded numbers with the year to be denoted by 2 or 4 digits, and the month shall be declared by letters or characters or numbers. Where only numbers are used to declare the date or where the year is expressed as only two digits, the competent authority should determine whether to require the sequence of the day, month, year, be given by appropriate abbreviations accompanying the date mark (e.g. DD/MM/YYYY or 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.

Rationale: The recently reviewed *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985) requires that dates be declared as "Best Before Date" or "Best Quality Before Date" and therefore this standard will be consistent with the published Codex texts.

Issue: Recommendation 16: That CCNFSDU agree to the following text for instruction for use for [name of product] for young children

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 c~~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~~ Hygiene 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.]*

Comment: African Union supports the proposed clause 9.5 in its entirety:

Rationale: The clause provides sufficient instruction related to use and storage of the products. In particular, it mentions that the information should also carry **graphics instructions** in order to communicate effectively to all consumers. The word 'Good Hygienic Practice' in clause 9.5.1 should read as 'Good Hygiene Practice' in line to the current understanding of the term.

Issue: Recommendation 17: That CCNFSDU agree to the following text for additional labelling [name of product] for young children

Comment: African Union supports the proposed clause 9.6 in its entirety as well as opening of the square brackets:

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****].*

Rationale: The statement in 9.6.1 is necessary to contribute to addressing inappropriate marketing of the products. The statement in 9.6.2 will eliminate confusion among the products as well as cross promotion of the products.

Issue: Recommendation 18: That CCNFSDU consider the following Name of Product (for young children) and further discuss the inclusion of 'formulated' within this name:

*[**Formulated**] drink for young children*

Comment: African Union do not support inclusion of the term '**Formulated**' to the name of the product.

Rationale: We propose a prefix that denotes the major food matrix of the products describing the true nature of the product be placed before the words, 'drink for young children' e.g. if based on milk, '***Milk-based drink for young children***'

Issue: Recommendation 19: That CCNFSDU agree to further discuss the structure of the standard(s) at the Committee meeting, noting the preference of the eWG for either one standard with two parts or two separate standards.

Comment: African Union supports the standard developed as one standard with two parts.

Rationale: Based on previous consensus within the committee, there was general agreement that these two products are related and have a point of differentiation at 12 months of age where the nutrient requirements of young children change. It will also be more convenient to implement one standard by both the government and industry.

Item 5

Background of Ready to Use Therapeutic Foods

The work on RUTF was adopted by the 37th Session of CCNFSDU where an eWG co-chaired by South Africa, Uganda and Senegal was established to develop either a standard or a guideline for RUTF. During the 38th Session, the committee discussed and agreed to develop a guideline as opposed to a standard, which would provide guidance mainly to encourage the use of locally available foods in the production of RUTF. In addition, the session agreed on the general structure of the guidelines. At the end of the 39th session an eWG co-chaired by the 3 countries was established to develop a draft guideline for discussion in step 3 during the 40th Session. The eWG made 22 recommendations touching on the various clauses of the guidelines.

Issue: Recommendation 1: That CCNFSDU agree to preamble of the standard

Children affected by severe acute malnutrition (SAM) need safe, palatable foods with a high energy content and adequate amounts of 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. Although 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. 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 WFP[1]. 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.

Comment: African Union supports the preamble

Rationale: The preamble provides the rationale of the standard and gives the important reference materials that must be used together with the guidelines in formulating RUTF products.

Issue: Recommendation 2: That CCNFSDU agree to the text for vitamins and minerals section

[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 and minerals 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 (CXG 10-1979). Examples of vitamin and mineral forms 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.]

Comment: African Union proposes that the words, 'appendix 4 of.' be introduced before the reference to the WHO document so as to read, ' *appendix 4 of WHO Management of severe malnutrition: A manual for physicians and other senior health workers (1999*)'. We also propose the opening of brackets of the last sentence of paragraph 2

Rationale: From the advice of CCEXEC75, the proper format for referencing documents external to Codex is to refer to the specific area of the text and not the whole document.

The opening of square brackets will ensure that appropriate compensation of potency of the various nutrients is considered during the formulation.

Issue: Recommendation 3: That CCNFSDU agree to the text on available Carbohydrates section

Comment: African Union proposes the text to read as follows:

'Available Carbohydrates[2] 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.'

Rationale: The guidelines should make specific reference to Codex texts where they exist.

Issue: Recommendation 4: It is recommended that:

4.1 CCNFSDU take note and agree with the proposed list of food additives (Table 1) and their technological justification that are currently used in RUTF.

4.2 CCNFSDU agree that the electronic working group recommend a proposed list of food additives to the Committee for consideration on their technological justification.

Comment: African Union does not support the adoption of this recommendation and the accompanying table 1

Rationale: A review of the proposed food additives against the General Standards for Food Additives (GSFA) indicates that most of the food additives are approved for use in complementary foods and some are approved for either Formulae for special medical purposes for infants (FC 13.1.3) or for dietary products (FC 13.3). The CCNFSDU must first consult the CCFA (as the competent Codex committee for food additives) for approval of the list of food additives before adopting them. The committee should refer the matter to CCFA on how to proceed with these provisions.

Issue: Recommendation 5: That CCNFSDU agree to the use of other matrices in RUTF formulation as by making reference to section 3 of CXS 180

Comment: African Union supports the reference to the text

Rationale: The requirement in this reference will promote the use of locally available raw materials in the formulation and manufacture of RUTF. This will ensure that the children being managed for SAM upon recovery will access the foods and thus ensure a sustainable management program.

Issue: Recommendation 6: That CCNFSDU agree to the proposed text on energy and the energy values

Comment: African Union supports the energy density value as proposed

Rationale: The proposed energy density value per 100g is sufficient to manage SAM. It is similar to those published by the Joint UNICEF/WHO statement on the management of SAM

Issue: Recommendation 7: That CCNFSDU agree not to set the minimum and maximum/GUL values for carbohydrates

Comment: African Union supports the recommendation not to set the level for carbohydrates

Rationale: This will allow flexibility in the amount of carbohydrates used. Further, the guidelines provide specific guidance for protein and fats and thus leave carbohydrates to provide the remaining energy density.

Issue: Recommendation 8: That CCNFSDU agree to proposed protein values in RUTF.

Comment: African Union supports the recommendation for protein of providing 10 – 12 % of energy from protein

Rationale: This level of protein will ensure that the potential of ammonia accumulation is reduced in this population whose metabolism is already compromised.

Issue: Recommendation 9: That CCNFSDU agree to keep the statement "at least 50% of protein is provided by milk products" in square brackets until there is further guidance from FAO on determining protein quality using PDCAAS.

Comment: African Union supports the recommendation to keep the text in square bracket.

Rationale: The product should be developed based on comparison of protein quality without necessarily tying the product to a specific source of protein which may not be readily available. It is therefore necessary to wait for the guidance of FAO on the method of comparing quality of protein before a final decision is made.

Issue: Recommendation 10: That CCNFSDU agree to the proposed text on fats/lipids and the proposed minimum and maximum fats/lipids as 'Lipids should provide 45% to 60% of the total energy'.

Comment: African Union supports the recommendation of the level of lipids.

Rationale: The product is formulated to be energy dense. Using lipids at this level will allow for this objective to be achieved in lower amounts compared to the source being from either protein or carbohydrates. This will ensure that children attain the daily energy requirements despite consuming small amounts due to reduced appetite.

Issue: Recommendation 11: That CCNFSDU agree to retain the linoleic acid and alpha-linolenic acid values as stipulated in the 2007 Joint Statement in the current RUTF.

Comment: African Union supports the recommendation to retain the levels

Rationale: In addition to providing high energy density from lipids, it is important to have the essential fatty acids included in the products because of their role in normal functioning of the body including supporting recovery and development of cognitive abilities.

Issue: Recommendation 12: That CCNFSDU agree to the minimum, maximum and associated footnote for vitamin A.

Comment: African Union supports adoption of the maximum level of 1.2 mg RE/100g (0.22 mg/ RE/100kcal and 220 µg RE/100kcal) and the accompanying note

Rationale: The proposed level is less likely to predispose the children to the risk of toxicity associated with high consumption of Vitamin A. In addition, the higher level provides overages to account for losses during production given the narrow range provided (0.8 – 1.2 mg RE/100g).

Issue: Recommendation 13: That CCNFSDU agree to the minimum, maximum/GUL and associated footnote for vitamin D.

Comment: African Union supports adoption of the maximum level of 20 µg/100 g (3.6 µg100 kcal) together with foot note 3. The recommended form of vitamin D should be D3.

Rationale: The range provided (15 – 20 µg/100 g) is sufficient to enable manufacturers to formulate their products in a manner that will achieve the levels inclusive of possible overages. The maximum limit is also consistent with levels recommended in the Joint WHO/UNICEF statement. Vitamin D3 from animal source has higher potency compared to Vitamin D2 from plant sources. Given the population in question (children with SAM), it is important that they are provided with nutrients of relatively high potency. In addition, Vitamin D3 is more efficacious in raising plasma vitamin D concentration than D2 and therefore will be more beneficial to children with SAM.

Issue: Recommendation 14: That CCNFSDU agree to the minimum and associated footnote for vitamin E.

Comment: African Union supports adoption of the minimum level of 20 mg/100 g (4 mg α-TE /100 kcal) together with foot note 4. Vitamin E toxicity is unlikely and thus there is no need to establish an upper limit for the same.

Rationale: Vitamin E is an important antioxidant in the body and thus there is the need to set a minimum that will provide benefits to the consumers.

Issue: Recommendation 15: That CCNFSDU agree to the following recommendations for vitamin K, vitamin B1, vitamin B2, vitamin C, vitamin B6, vitamin B12, folic acid, niacin, pantothenic acid and biotin for RUTF.

Comment: African Union supports the adoption of the proposed levels for these nutrients.

Rationale: The levels are derived from WHO/UNICEF joint statement which has been the basis of most of the RUTF in the market and whose use had the desired positive results to the children and thus there is no need to review them at this stage.

Issue: Recommendation 16: That CCNFSDU agree to the recommended levels for sodium, potassium, calcium, phosphorus, magnesium, iron, zinc, copper, selenium and iodine for RUTF.

Comment: African Union supports the adoption of the proposed levels for these nutrients. However, for calcium, phosphorus and magnesium, African Union supports maximum level of 600 mg/100 g, 600 mg/100 g and 140 mg/100 g for the minerals respectively. African Union seeks clarification on the source of the alternative maximum levels of calcium (785 mg/100 g), phosphorus (785 mg/100 g) and magnesium (235 mg/100 g).

Rationale: The levels supported by African Union are based on WHO/UNICEF Joint statement.

Issue: Recommendation 17: That CCNFSDU consider that the current formulation of RUTF, as well as the proposed nutrients as stipulated in the 2007 Joint Statement be the basis for RUTF formulation, unless there is scientific evidence on any additional nutrients that has been demonstrated to be safe and beneficial in meeting the nutritional requirements of SAM children.

Comment: African Union supports this recommendation.

Rationale: The recommended levels in the 2007 Joint Statement has been implemented over time with convincing results[1,2] (Bhuta Z. A et.al. Evidence based intervention for improving maternal and child nutrition: *What can be done and at what cost*. Lancet 2013 Vol 3, 382:452-77[i].). However, where new levels are proposed based on sound scientific evidence may be adopted.

Issue: Recommendation 18: That CCNFSDU agree to the proposed text of " Processing Technologies" section of the Guidelines.

Comment: African Union supports this recommendation.

Rationale: The recommended text provides guidelines for the process of production of the RUTF but provides opportunities for introducing new technologies/methodologies thus the clause does not stifle technology and innovation.

Issue: Recommendation 19: That CCNFSDU agree to the proposed draft text for "good manufacturing practices and good hygiene practices".

Comment: African Union supports this recommendation.

[1] Bhuta Z. A et.al (2013). Evidence based intervention for improving maternal and child nutrition: *What can be done and at what cost*. Lancet Vol 3, 382:452-77

[2] Brown, K. H. et al (2009). Management of children with acute malnutrition in resource-poor settings Nat. Rev. Endocrinol. 5, 597–603; doi:10.1038/nrendo.2009.194

Rationale: The proposed text makes normative reference to Codex standards related to hygiene and thus it is consistent with the Codex procedural manual which requires committees to make reference where codex texts exist.

Issue: Recommendation 20: That CCNFSDU agrees to the proposed text for "the methods of analysis and sampling" section of the guidelines.

Comment: African Union proposes this text to be amended to read as:

It is recommended that methods of analysis and sampling of RUTF be in accordance with the Recommended Methods of Analysis and Sampling (CXS 234-1999), ~~General Standard for Contaminants and Toxins in Food and Feed (CXS 193-1995), The Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods (CXG 21-1997), Code of Hygienic Practice for Low Moisture Foods (CXC 75-2015), and other relevant Codex Alimentarius texts. When needed, specific methods of analysis should be developed in accordance with appropriate Guidelines on Measurement Uncertainty (CXG 54-2004), Protocol for the Design, Conduct and Interpretation of Method Performance Studies (CXG 64-1995), and Harmonized IUPAC.~~

In addition, new clauses on contaminants and pesticide residue limits should be introduced to make reference to Codex Standard CXS 193-1995 and levels established by Codex Alimentarius Commission for pesticide residue.

Rationale: The clause should only make reference to the *Codex methods of analysis and Sampling* (CXS 234-1999).

Issue: Recommendation 21: That CCNFSDU agrees to the proposed text for "packaging" section of the guidelines.

Comment: African Union supports this recommendation.

Rationale: The proposed text is comprehensive to address packaging of the products and is consistent with similar clauses in other existing Codex Standards.

Issue: Recommendation 22: That CCNFSDU agree with the proposed draft text for the "labelling" section of the guidelines

Comment: African Union proposes to amend the first bullet of additional mandatory labelling by replacing 'medical ' with 'health worker' so as to read as indicated below. With this amendment African Union supports the adoption of the text on labelling.

"*USE UNDER ~~MEDICAL~~ HEALTH WORKER SUPERVISION" shall appear on the label in bold letters in an area separated from the written, printed, or graphic information*.'

Rationale: The proposed text comprehensively addresses the labelling aspects and in particular makes reference to Codex labelling standards. The proposed amendment is consistent with current practice where the products are used under the supervision of other health workers.

Item 6

Background of biofortification definition

At the 36th session, the committee agreed to initiate work with a view of developing a common definition of biofortification. During the 37th Session, Zimbabwe and South Africa accepted to chair and co-chair an electronic working group to develop a discussion paper and a proposal for the definition. During the 39th Session, the chairs introduced the paper and noted that the eWG had focused on further development of the five criteria to assist in guiding the drafting of the definition. The Committee noted that a number of aspects in the definition needed further consideration, as well as the questions on where the definition would be placed and how it should be used. Following this discussion the committee recommended further work to be carried out with regard to the proposed draft definition. The Committee agreed to re-establish the eWG, led by Zimbabwe and South Africa, to further develop the proposed draft definition for Biofortification. The ToRs were to:

a) Refine the draft definition;

b) Explore other alternative terms to biofortification and

c) Consider the request from CAC38 on how the definition would be used and where it would be best placed.

The eWG developed 5 recommendations for CCNFSDU40.

Issue: Recommendation 1: That CCNFSDU agree to the proposed draft definition for biofortification and its accompanying footnotes

Comment: Africa Union supports the proposed text

Rationale: The definition as proposed offers a common understanding of the term and allows countries to determine the process that may be used in nutrient enrichment. The proposed definition of biofortification makes the process distinct from other forms of nutrient enrichment such as conventional food fortification. The definition encompasses all the agreed criteria.

Issue: Recommendation 2: That CCNFSDU agree to the use of the term "biofortification" in the proposed draft definition.

Comment: African Union supports the use of the term 'biofortification'

Rationale: The term biofortification has been extensively used over the years and has several definitions including one by WHO and there is therefore the need to harmonize both the definition and the use of the term. Changing the term at this particular time to an alternative term will introduce confusion and ambiguity not only to Codex but in other areas where the term has been used.

Issue: Recommendation 3: That CCNFSDU discusses the placement of the definition for biofortification with CCFL after the finalization of the development of the definition.

Comment: African Union proposes that the committee should not discuss placement of the definition unless such a request is received from CCFL.

Rationale: The request to the committee by CCFL was to develop a definition for biofortification (REP 13/FL Para 127). Therefore, the committee should limit its work to this request.

Issue: Recommendation 4: CCNFSDU agree that the proposed areas of use for the biofortification definition should not be stipulated if the definition will be placed in the Codex Procedure Manual.

Comment: African Union supports the adoption with amendment as indicated below

'*CCNFSDU agree that the proposed areas of use for the biofortification definition should not be stipulated. ~~if the definition will be placed in the Codex Procedure Manual.~~*'

Rationale: As indicated in recommendation 3, the placement of the definition was not part of the request to the committee (REP 13/FL Para 127).

Issue: Recommendation 5: That CCNFSDU agree that CCFL discusses the distinction between biofortified and nonbiofortified foods once a definition for biofortification has been adopted

Comment: African Union supports the adoption of the recommendation

Rationale: CCFL had requested for a definition from CCNFSDU and therefore it is only procedural for this committee to report back to CCFL after which the CCFL will decide where to place the definition if they had not done so at the time they were requesting for the definition.

Item 7

Background

The new work on NRV-NCD for omega-3 fatty acids (EPA and DHA) was agreed at the 36th session of the CCNFSDU and approved by CAC38 in 2015. CCNFSDU's 38th session in 2016 considered the need to obtain additional scientific advice through JEMNU or NUGAG, and it was noted that NUGAG was already in the process of scoping a review on PUFAs associations with human health. It was agreed that the Committee continued to work on the NRV once NUGAG report would be available. Following the 11th meeting of NUGAG in 2017, two abridged versions of NUGAG reports on polyunsaturated fatty acids were shared with the eWG, and the co-chairs initiated eWG discussion of the documents and collected members' opinions. No consensus was reached at the following 39th CCNFSDU as delegations were of the view that: the systematic reviews conducted by NUGAG for the PUFA guideline development by NUGAG were: very comprehensive, but had been presented late to the EWG and more time would be needed to consider them; and risk assessors should consider the systematic NUGAG reviews rather than CCNFSDU delegates who were mostly risk managers. Subsequently, the terms of reference of the re-established electronic working group on NRV-NCD for EPA/DHA among other to complete the assessment of the most current scientific evidence as presented in the NUGAG systematic reviews taking into consideration further advice from FAO/WHO.

Issue: Discussion of proposed draft NRV-NCD for EPA and DHA long chain omega-3 fatty acids

Comment: African Union proposes suspension of discussion by CCNFSDU until FAO/WHO responds to the request of the committee.

Rationale: WHO had raised reservation on the PURE studies. Therefore, the response by WHO/FAO on the request by the eWG as outlined in the ToR of the committee is critical for the progress of this work. The committee should therefore wait for the response before proceeding with the work.

Item 8

Issue: Discussion paper on Trans fatty acids to include a level of 1 g per 100g of fat

It is proposed 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).

Comment: African Union supports the adoption of 1g per 100g, however it should not be linked to low saturated fats

Rationale: Trans fatty acids have a negative health effect in terms of Cardio Vascular Diseases (CVDs) and thus in helping consumers make informed decision and protect them from false claims the level as proposed will go a long way in to achieve the objective. However, linking the claim to that of low saturated fats does not add any more benefit and they should be used independently.

Item 9

Issue: The need to proceed with work on establishing NRVs for older infants and young children

Comment: African Union supports the approval of the work in this areas. However, the eWG should identify the relevant codex Strategic goal for 2014/19 that is supporting this work. Further the eWG should revise the proposed timelines to reflect the actual progress of work. The referred Codex strategic objectives were those in the previous Strategic Plan and the timeline is not accurate.

Rationale: There is need to establish NRVs for infants 6 – 12 months and young children 12 – 36 months given the increase of products targeting this age group. The NRVs will also assist governments in their nutrition programs for these age groups.

Item 11

Issue: Establishment of a standard or guidelines for probiotics

Comment: African Union supports discussion on probiotics and in particular with a view to developing guidelines for the use of probiotics rather than a standard. The discussion should also determine whether CCNFSDU is competent enough to handle the issue or whether the committee would recommend establishment of an Adhoc committee to develop the guidelines

Rationale: The subject of probiotics is an emerging area with gaps related to their need, effect and even their safety as well as the type and dosage that gives an intended benefit. However, their use has increased over time thus requiring attention.

Item 12

Issue: Guidelines to establish nutritional profiles.

Comment: African Union supports work to commence on the development of guidelines to establish nutritional profiles.

Rationale: The guideline seeks to provide guidance on front of pack labelling concept. Currently this concept is not harmonized at the international level. Developing a Codex guideline on nutritional profiles will offer guidance to national authorities in developing relevant legislation and regulations.