CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 7 **NFSDU/39 CRD/10**

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

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PROPOSED DRAFT GUIDELINES FOR READY-TO-USE THERAPEUTIC FOODS

Comments of the European Union, Nigeria and African Union

EUROPEAN UNION

European Union competence

European Union vote

General comments

The European Union (EU) would like to thank South Africa, Senegal and Uganda for their work on document CX/NFSDU 17/39/7.

The EU is pleased that the comments it provided in the eWG were taken into account in the document. As explained in previous occasions, the EU supports the work on these guidelines on ready-to-use therapeutic foods (RUTF). Its main concern was to make sure that no doubts exists in the guidelines on the status of RUTF as food for special medical purposes, covered by CODEX Standard 180-1991, and that the language used in the guidelines follows the one used in the Standard on food for special medical purposes. The EU considers that the text proposed by the Chairs adequately addresses the EU concerns so far.

Specific comments on the recommendations

Recommendation 1 (Preamble)

The EU is pleased that the reference to RUTF in the preamble is now consistent with the product definition, in particular as regards the reference to the status of RUTF as food for special medical purposes.

At the same time, however the EU proposes the first paragraph of the draft preamble to be deleted because the Code of Ethics for International Trade in Food including Concessional and Food Aid Transactions should be implemented and followed in any case and in connection with all work of Codex Alimentarius, not only with regard to RUTF. If still deemed necessary by the Committee, a reference to the Code of Ethics could be included in the last paragraph of the preamble, beginning with *"These guidelines should be used in accordance with… "*

In addition, the EU is of the opinion that the Preamble may not be the right place to elaborate on possible strategies to prevent SAM and would therefore suggest removing the first three sentences of the third paragraph. However, the EU proposes to insert the following text to emphasize the role and function of RUTF within nutritional interventions to combat malnutrition: "*RUTF is not regarded as a substitute for best nutritional practices or normal household food, but as one option for the dietary management that should only be used within the community-based management of uncomplicated severe acute malnutrition in children, in accordance with international standards for such care and in conjunction with essential primary health care."*

Altogether, the following changes are proposed:

> ~~*The major objectives of the work of the Codex Alimentarius Commission are to protect the health of the consumer and ensure fair practices in the trade in food through the elaboration and harmonization of definitions and requirements for food. In order to realize this objective CAC developed a Code of Ethics for International Trade in Food including Concessional and Food Aid Transactions (CAC/RCP 20-1979) embodying the principles of sound consumer protection. The objective of this code is to establish standards of ethical conduct for all those engaged in international trade in food or for those responsible*~~

~~*for regulating food and thereby protecting the health of the consumers and promoting fair trade practices. It is within this context that all those engaging in the international trade in food with specific reference to Ready-To-Use Therapeutic Foods (RUTF) commit themselves to the provisions of the code.*~~

~~*Investing in prevention of SAM through sustainable measures and interventions is crucial. Such interventions could include the improvement of access to high quality food and safe water through improving water and sanitation systems, improved access to health care, and the effective promotion of exclusive breastfeeding for the first six months of a child´s life combined with continued breastfeeding up to 24 months and beyond.* *Thus, preventive programmes have an immense job to do in the context of poverty, and in the meantime children who already are suffering from SAM need to receive appropriate treatment.*~~ ***RUTF is not regarded as a substitute for best nutritional practices or normal household food, but as one option for the dietary management that should only be used within the community-based management of uncomplicated SAM in children, in accordance with international standards for such care and in conjunction with essential primary health care.***

Recommendation 2 (Description)

The EU is satisfied that the text clearly refers to the fact that the products are food for special medical purposes and speaks of "dietary management" of severe acute malnutrition (instead of "treatment") to ensure consistency with the language used in Codex Standard 180-1991 on foods for special medical purposes. At the same time, however, the EU proposes a minor redrafting to the description of RUTF as follows:

Ready to Use Therapeutic Foods (RUTF) are high energy, fortified, ready to eat foods for special medical purposes for the dietary management of children from 6 to 59 months with severe acute malnutrition without medical complications and **with appetite**. These foods should be soft or crushable and should be easy for children to eat without any prior preparation.

The proposed modification would be in line with the criteria of the Joint Statement on community-based management of severe acute malnutrition (2007) and the update on the management of severe acute malnutrition in infants and children made by WHO in 2013. The idea of children having appetite is mentioned along both documents.

Recommendation 3 (Raw Materials and Ingredients)

The EU can agree with the proposed text. However, as already noted in previous occasions, the EU is not in a position to comment in detail on specific compositional requirements of RUTF, as these products are not on the EU market and there is no specific advice from the European Food Safety Authority on them.

The EU remains convinced that the composition of RUTF should primarily be based on relevant WHO documents (and their future modifications) and on the advice of UNICEF, WHO and the World Food Program as well as NGOs with extensive experience in the field.

The EU is pleased that the reference to Section 3 of the Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991] is fully consistent with the language used in STAN 180-1991. This ensures a higher level of consumer protection, as it requires that not only the ingredients, taken one by one, but also the overall formulation of RUTF complies with Section 3 of STAN 180-1991.

Recommendation 4 (Milk and dairy products)

The EU can agree with the proposed text. However, as already noted in previous occasions, the EU is not in a position to comment in detail on specific compositional requirements of RUTF, as these products are not on the EU market and there is no specific advice from the European Food Safety Authority on them.

The EU remains convinced that the composition of RUTF should primarily be based on relevant WHO documents (and their future modifications) and on the advice of UNICEF, WHO and the World Food Program as well as NGOs with extensive experience in the field.

Recommendation 5 (Legumes and Pulses)

See comments on recommendation 4.

Recommendation 6 (Fats and Oils)

See comments on recommendation 4.

Recommendation 7 (Cereals)

See comments on recommendation 4.

Recommendation 8 (Vitamins and Minerals)

See comment on recommendation 4.

Recommendation 9 (Available carbohydrates)

With regard to recommendation 9.1 the EU would like to ask for clarification as to why the wording "energy density" at the beginning of the paragraph was removed. From the draft text as proposed now, it could be understood that available carbohydrates are only added for improving the palatability, while available carbohydrates can also serve as a source of energy.

With regard to the Chairs` proposal to prohibit the addition of fructose and high fructose corn syrup to RUTF, the EU understands that the energy production from substrates such as galactose and fructose is slower than normal in children with severe acute malnutrition and would therefore support that fructose (or galactose) not be added as sources of energy to foods for malnourished children. However, the EU is not aware of any negative effects of small amounts of fructose added for palatability reasons, especially since RUTF is intended to be consumed only for a short period of time (several weeks). Furthermore, the EU assumes that high fructose corn syrup would not be used in RUTF because it is a liquid and would therefore increase the water content of such products.

With regard to the inclusion of a footnote on the acceptable available carbohydrates, the EU would like to add maltodextrin to the list of as follows:

[Sucrose, vegetable starch, **maltodextrin**, glucose, glucose syrup should be the preferred carbohydrates in RUTF. Fructose and corn syrup as ingredients should be avoided in RUTF, because of potential adverse effects in SAM children. Only precooked and/or gelatinised starches gluten -free by nature may be added]

With regard to the question on whether or not an acceptable limit of available carbohydrates should be included in the guidelines, the EU is of the opinion that currently no limit of available carbohydrates should be included in the guidelines, taking into consideration that there are many questions arising, e.g. with respect to the acceptability and efficacy of feeding RUTF with less sugar and the technological possibilities of replacing sugar. With respect to sugars that are added only for improving the palatability of RUTF, the EU suggest to include the sentence *"Any carbohydrate added for sweetness should be used sparingly."* in the text which would be in line with the Guidelines on Formulated Complementary Foods for Older Infants and Young Children.

Recommendation 10 (Food additives)

The EU can support the recommendation.

The EU considers the proposed stepwise approach as pragmatic and appropriate.

As regards the text in section '5.2.2 Food Additives and Flavours' the EU has the following observations:

The title of the section should be amended to '5.2.2 Food Additives'. The Codex definition of a food additive includes "flavourings" as well (see the definition in the Procedural Manual, 25th edition, page 23). Moreover, the term "flavour" is not appropriate since it refers to the characteristics/ properties of a substance, whilst a substance imparting the flavour is called "flavouring" (see the Guidelines for the Use of Flavourings, CAC/GL 66-2008).

In addition, the EU recommends amending the text in the brackets to "[This section will contain a list of food additives or make a reference to the General Standard for Food Additives (CODEX STAN 192-1995)]".

The EU understands that the final goal would be to include the reference to the GSFA. However, both options (i.e. (i) to list the individual additives and (ii) reference to the GSFA) are in line with the Codex procedures. The Committee should keep flexibility in case the individual additives would need to be listed as an intermediate solution before the provisions are introduced in an appropriate food category of the GSFA.

Recommendation 11 (The Use of other Matrices in RUTF Formulation)

The EU can support the recommendation.

The EU is pleased with new wording proposed by the Chairs, as it ensures legal clarity and, at the same time, addresses the concerns of the eWG Members related to "new formulations".

Recommendation 12 (Energy and Energy values)

See comment on recommendation 4.

Recommendation 13 (Minimum and maximum values for protein)

The EU can support the recommendation.

Recommendation 14 (Protein quality)

The EU considers that quality of protein is important in this context and strongly supports keeping 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.

Recommendation 15 (Lipids/Fats)

The EU would like to ask for clarification as to how the Chairs of the eWG have calculated the minimum level for linoleic acid of 576.9 mg/100 kcal and for alpha linolenic acid of 57.69 mg/100 kcal. The EU considers that the values proposed here are not compatible with other specifications of the document. If the minimum for n-6 fatty acids is 3% of the total energy (as explained in the 2007 Joint Statement), it corresponds to 3 kcal /100 kcal coming from n-6 fatty acid. This is equivalent to **333 mg/100 kcal**, considering that 1g of lipids corresponds to 9 kcal.

The same problem applies to alpha linolenic acid (ALA), therefore the minimum level of ALA should be **33.33 mg/100kcal** instead of 57.69mg/100kcal.

In light of this, the text should read as follows:

“[Incorporation of fats and/or oils in RUTF serves to increase the energy density and the amount of essential

fatty acids. At least 45% to 60% of energy derived from fat is desirable. The level of linoleic acid should not be less than ~~576.9~~ **333 mg** per 100 kcal when used in the production of RUTF and should ensure a ratio between linoleic acid and alpha-linolenic acid of between 5:1 and 15:1.]

Fats/Lipids should provide 45%-60% of the total energy.

Unit	Minimum	Maximum	GUL
g/100g	26	37	-
g/100kcal	5	6.7	-“

Recommendation 16 (Essential Fatty Acids values)

The EU would like to ask for clarification as to how the Chairs of the eWG have calculated the minimum level for linoleic acid of 576.9 mg/100 kcal and for alpha linolenic acid of 57.69 mg/100 kcal. The EU considers that the values proposed here are not compatible with other specifications of document. If the minimum for n-6 fatty acids is 3% of the total energy (as explained in the 2007 Joint Statement), it corresponds to 3 kcal /100 kcal coming from n-6 fatty acid. This is equivalent to 333 mg/100 kcal, considering that 1g of lipids corresponds to 9 kcal.

The same problem applies to alpha linolenic acid (ALA), therefore the minimum level of ALA should be 33.33 mg/100kcal instead of 57.69mg/100kcal.

In light of this, the recommendation should read as follows:

Essential Fatty acids values

Linoleic Acid = 3-10% of total energy

[The level of linoleic acid should not be less than ~~576.9~~ **333 mg** per 100 kcal]

Alpha-linolenic acid = 0.3- 2.5% of total energy

[The level of alpha -linolenic acid should not be less than ~~57.69~~ **33 mg** per 100 kcal]”

Recommendation 17 (Vitamin A)

The EU supports the minimum and maximum values proposed by the Chairs for vitamin A, however, the EU proposes the term "trans" to be replaced either by **all-trans-retinol** or **retinol** in line with recent scientific opinion of EFSA on Dietary Reference Values for vitamin A

Recommendation 18 (Vitamin D)

While the EU supports the minimum and maximum values proposed by the Chairs for vitamin D, it considers that there is no need, in conformity with vitamin A, to establish a GUL for vitamin D.

As regards the footnote proposed by the Chairs, the EU suggests a minor redrafting to the wording so that the footnote would read as follows: "**1 µg vitamin D = 40 IU**". This wording would acknowledge that fact that both vitamin D2 and vitamin D3 may be used in RUTF formulation.

Recommendation 19 (Vitamin E)

See comment on recommendation 4.

Recommendation 20 (Recommendations for vitamin K, B1, B2, C, B6, B12 folic acid, niacin, pantothenic acid and biotin)

See comment on recommendation 4.

Recommendation 21 (Recommendations for sodium, potassium, calcium, phosphorus, magnesium, iron, zinc, copper, selenium and iodine)

As to the proposals for higher maximum values for calcium, phosphorus, and magnesium the EU agrees that higher levels of those nutrients might be warranted in products with alternative formulations, by way of example when milk powder is (partly) replaced by other ingredients. However, noting that in recent scientific advice on the composition of infant and follow-on formulae (EFSA 2014) and on Dietary Reference Values for phosphorus (EFSA 2015) certain molar ratios of calcium-to-phosphorus have been considered, the basis for the proposed maximum value for phosphorus of 785 mg/100g is unclear.

In addition, the EU would like to add a statement indicating that the addition of sodium is not permitted. It could be added in paragraph 5.1.5.

Recommendation 23 (Contaminants)

The EU agrees with the recommendation.

Recommendation 24 (Technologies for and Effect for Processing)

The EU can agree with the proposed recommendation.

Recommendation 25 (Good manufacturing and Good hygiene practices)

No comment.

Recommendation 26 (Methods of Analysis and Sampling)

No comment.

Recommendation 27 (Packaging)

The EU can agree with the proposed recommendation.

Recommendation 28 (Labelling)

As noted in previous occasions, the EU considers that the labelling section should, where possible, cross-refer to relevant existing CODEX texts. In this context, the EU welcomes the removal of sub-section on "declaration of nutritive value" since it is already outlined in the Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991). The EU also agrees with the Chairs` proposal to remove the references to Codex General Standard for the Labelling of Pre-packaged Foods (CODEX STAN 1-1985) and the Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997) to avoid unnecessary duplication.

As regards the additional labelling requirements, the EU would kindly like to reiterate its request for more information on the rationale for the inclusion of the statements on breastfeeding in the guidelines. The EU does not have problems with the content of the statements, but wonders whether their inclusion is really necessary, taking into account that the 2007 Joint Statement by the WHO, WFP, UNSCN and UNICEF "Community-Based Management of Severe Acute Malnutrition", while recognising the essential contribution of exclusive breastfeeding for the first six months of a child's life to prevent severe acute malnutrition, also notes that treatment is needed for those children who already are suffering from severe acute malnutrition. In addition the EU would propose the deletion of the words "parenteral" and "rectal" in order to make sure that the labelling of the products, which are usually distributed in very small packs, is clearly legible. It seems that

there is no problem of parenteral or rectal use and it is not usually required. In addition, these products are used under medical supervision and are not placed on the market to be bought directly by the final consumer.

As regards the proposed text on the instructions for use, the EU proposes the following redrafting to the wording taking into account possible innovation and product development in the future:

The text **~~"The product should be consumed within 24 hours after opening]~~** should be replaced by the following wording: **"The time within which the product should be consumed after opening should be clearly indicated".**

NIGERIA

Recommendation 1:

Nigeria proposes the preamble be amended and rearranged as indicated in the highlights below:

The major objectives of the work of the Codex Alimentarius Commission are to protect the health of the consumer and ensure fair practices in the trade in food through the elaboration and harmonization of definitions and requirements for food. In order to realize this objective CAC developed a Code of Ethics for International Trade in Food including Concessional and Food Aid Transactions (CAC/RCP 20-1979) embodying the principles of sound consumer protection. ***The objective of this code is to establish standards of ethical conduct for all those engaged in international trade in food or for those responsible for regulating food and thereby protecting the health of the consumers and promoting fair trade practices.*** *It is within this context that all those engaging in the international trade in food with specific reference to Ready-To-Use Therapeutic Foods (RUTF) commit themselves to the provisions of the code.*

Rationale: The deletion (as indicated with strike through) was proposed to avoid repetition, since the same information is in subsequent paragraphs and that the information is elaborated in the referenced text of CAC/RCP 20-1979.

Recommendation 2:

Nigeria supports the inclusion of the proposed text in description of RUTF with few editorial amendments as presented below:

Ready to Use Therapeutic Foods (RUTF) are high-energy, fortified, ready-to-eat foods for special medical purposes for the dietary management of children from 6 to 59 months with severe acute malnutrition without medical complications. These foods **~~should~~** ***are*** soft or crushable and **~~should be~~** easy for children to eat without any prior preparation.

Rationale: It is a definition and thus it should not provide requirement rather provide a clear definition of the product.

Recommendation 5:

Nigeria supports the adoption of the proposed text with addition of soybean, edible shea-nut and Bambara-nut as indicated.

Rationale: Soybean, edible shea-nut and Bambara-nut are used in most countries and thus it is important to include it in the list.

Recommendation 23:

The aflatoxin limit should make reference to national or regional legislation/regulation

Rationale: Aflatoxin contamination of food is a major public health concern in Africa and given that these guidelines are promoting the use of local foods in production of RUTF, there is need to provide for the maximum level of aflatoxin. In the absence of such limit in Codex Stan 193-1995, a phrase, “the maximum level of aflatoxin should comply with those limit set by the national or regional competent body” should be introduced.

Recommendation 24:

Nigeria supports the proposed text with modification on the last paragraph where it gives irradiation as an acceptable form of non-thermal method of eliminating microorganism.

“..Commonly used microbial reduction treatments that could be applied to RUTF or their raw materials include both thermal (e.g. roasting, steam treatment followed by a drying step) and non-thermal (e.g. ***~~irradiation~~****, antimicrobial fumigation) control measures. [Guidelines for the Validation of Food Safety Control*

Measures (CAC/GL 69-2008) and Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM) (CAC/GL 63-2007) should be adhered to]"

Rationale: Ionising irradiation is not allowed for treatment of products (such infant formula) to be consumed by infants and young children (Clause 3.7 of CODEX STAN 72-1981) and thus it should be deleted.

Recommendation 28: Labelling

Nigeria propose deletion of the statement, "A statement indicating whether the product is or is not intended as the sole source of nutrition" under mandatory labeling requirement. Additionally we propose open up of other square brackets related to the product being used within 24 hours and that related to exclusive breast feeding.

Rationale: In normal use of RUTF, it is used along with other foods and thus this statement serves no purpose in the guidelines. In regard to the brackets suggested for opening we fully support their content as they will ensure hygiene related to keeping opened products for long as well as promoting and protecting breastfeeding practices.

AFRICAN UNION

African Union thanks South Africa, Uganda, and Senegal for co-chairing work on the proposed draft guideline for ready-to-use therapeutic foods.

Issue - Recommendation 1: That CCNFSDU agree to the draft text for the preamble as drafted in the recommendation

Comment: African Union proposes that the preamble be amended and rearranged as indicated below:

The major objectives of the work of the Codex Alimentarius Commission are to protect the health of the consumer and ensure fair practices in the trade in food through the elaboration and harmonization of definitions and requirements for food. In order to realize this objective CAC developed a Code of Ethics for International Trade in Food including Concessional and Food Aid Transactions (CAC/RCP 20-1979) embodying the principles of sound consumer protection. ~~***The objective of this code is to establish standards of ethical conduct for all those engaged in international trade in food or for those responsible for regulating food and thereby protecting the health of the consumers and promoting fair trade practices.***~~ *It is within this context that all those engaging in the international trade in food with specific reference to Ready-To-Use Therapeutic Foods (RUTF) commit themselves to the provisions of the code.*

Children affected by severe acute malnutrition (SAM) need safe, palatable foods with a high energy content and adequate ***and bioavailable*** *amounts of vitamins, minerals and other critical nutrients. Children with SAM need timely treatment and RUTF is a critical part of the treatment…….*

Rationale: In the first paragraph, the deletion (as indicated with strike through) was proposed to avoid repetition since the same information is in subsequent paragraphs and that the information is elaborated in the referenced text of CAC/RCP 20-1979.

Issue - Recommendation 3: That CCNFSDU consider the proposed opening text on "Raw Materials and Ingredients" section of the proposed Guidelines on RUTF as follows:

RUTF are made of powdered or ground ingredients embedded in a lipid-rich matrix [e.g. paste and biscuit], resulting in an energy and nutrient-dense food. The following raw materials, many of which can be sourced locally, are suitable ingredients for the production of RUTF under the specified conditions given below. The formulation of RUTF shall comply with Section 3 of the Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991.

Comment: African Union supports the proposed text

Rationale: The text emphasizes the importance of sourcing the raw materials locally from the available foods of the community/country.

Issue - Recommendation 5: That CCNFSDU agree to the proposed text on legumes and pulses as follows:

Legumes and pulses, such as ***soybean*** *lentils, chickpeas, cowpeas, beans, peanut, sesame and other types of legumes and pulses must comply with the Standard for Peanuts (CODEX STAN 200-1995), Code of Hygienic Practice for Groundnuts (Peanuts) (CAC/RCP 22- 1979) and the Code of Hygienic Practices for Low-Moisture Foods (CAC/RCP 75-2015), and other relevant Codex Alimentarius text when used in the manufacturing of RUTF. Legumes and pulses must be appropriately processed to reduce, as much as possible, the anti-nutritional factors normally present, such as phytate, lectins (haemagglutenins), trypsin and chymotrypsin inhibitors.*

Comment: **African Union** supports the proposed text with addition of soybean as indicated

Rationale: Soybean is used in most countries and thus it is important to include it in the list.

Issue - Recommendation 6: That CCNFSDU agree to the proposed text on fats and oils and a statement that prohibit the use of partially hydrogenated fats and oils in RUTF.

Fats and oils used in the manufacturing of RUTF must comply with the relevant Codex Alimentarius texts. Fats and oils are incorporated as technologically feasible for the purpose of achieving the energy density and providing essential fatty acids. Care must be taken to avoid oxidized fat which will adversely affect nutrition, flavour and shelf life. Partially Hydrogenated fats and oils should not be used in RUTF.

Comment: **African Union** supports the proposed text

Rationale: This is necessary to safeguard the health of consumers from consuming fats and oils that may pose adverse health effect considering the vulnerable nature of the consumer group to which RUTF applies.

Issue Recommendation 7: That CCNFSDU agree to the proposed text on the use of cereals in RUTF formulation as follows:

All milled cereals suitable for human consumption may be used provided that they are processed in such a way that the fibre content is reduced, when necessary, and that the effects of anti-nutritional factors such as phytates, tannins or other phenolic materials, lectins, trypsin, and chymotrypsin inhibitors which can lower the protein quality and digestibility, amino acid bioavailability and mineral absorption are removed or reduced, whilst retaining maximum nutrient value.

Comment and rationale: **African Union** supports the proposed text as it provides guidance on the quality of milled cereals to be used.

Issue Recommendation 9:

9.1 *That CCNFSDU agree to the proposed text on addition of available carbohydrates into RUTF formulation, and a statement that prohibit the use of honey in RUTF.*

The palatability of the RUTF can be increased by the addition of appropriate 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.

9.2 *That CCNFSDU agree to the inclusion of a footnote on the acceptable available carbohydrates in RUTF formulation and consider the proposed text for the footnote as follows:*

[1][Sucrose, vegetable starch, glucose, glucose syrup] should be the preferred carbohydrates in RUTF. Fructose and high fructose corn syrup as ingredients should be avoided in RUTF, because of potential adverse effects in SAM children. Only precooked and/or gelatinised starches gluten-free by nature may be added].

9.3 *That CCNFSDU consider whether the acceptable limit of available carbohydrates should be included in the guidelines.*

Comment: **African Union** supports the proposed text.

Rationale: Honey has been associated with *Clostridium botulinum* contamination and thus its prohibition in RUTF is welcomed. With regard to the footnote, we propose opening the square brackets. As much as vegetable starch is best due to it being complex carbohydrates, the use of mono and di-saccharides poses no health risk to the children at this age whose glycemic index may also be low.

Issue - Recommendation 10: That CCNFSDU agree to the following proposed stepwise approach to address the use of food additives in RUTF formulation:

a. *The eWG compile a list of food additives currently used by the industry in the manufacturing of RUTF that include their technological rationale and function and approximate use levels.*

b. *The eWG compare the food additives currently used in RUTF to food additives approved for use in existing Codex texts aimed at infants and young children to determine whether the food additives in RUTF have already been evaluated in infants and young children.*

c. *The eWG recommend a proposed list of food additives for CCNFSDU to confirm the technological need.*

d. *Once CCNFSDU confirms the technological need, CCNFSDU could forward a list of food additives used in RUTF to CCFA for their consideration on safety aspects, and also request input from CCFA on the appropriate food category assignment, as well as guidance on appropriate procedural steps to be followed.*

Comment: **African Union** supports the proposed and support the recommendation to refer food additives issues to CCFA for guidance.

Issue - Recommendation 12: That CCNFSDU agree to the proposed text on energy and the energy values as follows:

Energy

The energy density of the formulated RUTF should be at least ~~5.2 to 5.5 Kcal per g~~ ***520 to 550 kcal per 100 gram****. The energy density of the RUTF can be achieved during manufacturing by the addition of energy containing ingredients (i.e. fats and oils and/or digestible carbohydrates) and/or processing the basic raw materials and ingredients as indicated in the Section on "Technologies for and effects of processing.*

Comment: **African Union** supports the proposed text with amendment

Rationale: To make it consistent with the table which qualifies the energy per 100 g of the product.

Issue - Recommendation 13:

That CCNFSDU agree not to set the minimum and maximum/GUL values for carbohydrates.

Comment: We support the proposed recommendation as the requirements are already taken care of by the provision of minimum and maximum energy requirements.

Issue - Recommendation 14: 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.

["at least 50% of protein is provided by milk products"]

Comment: **African Union** supports the proposed text.

Rationale: The guidance from FAO will be important in determining the percentage of protein from milk in the products.

Issue - Recommendation 16: That CCNFSDU agrees to retain the linoleic acid and alpha-linolenic acid values as stipulated in the 2007 Joint Statement in the current RUTF nutritional composition as follows:

Essential Fatty acids values

Linoleic Acid = 3-10% of total energy

[The level of linoleic acid should not be less than 576.9 mg per 100 kcal]

Alpha- linolenic acid = 0.3-2.5% of total energy

[The level of alpha-linolenic acid should not be less than 57.69 mg per 100 kcal]

Comment: **African Union** supports the proposed text and opening the of the square brackets

Rationale: It provides guidance which will ensure high quality fat is used during production of the product especially related to the essential fatty acids.

Issue - Recommendation 17: That CCNFSDU agree to the minimum, maximum and associated footnote for vitamin A

Comment: **African Union** supports the minimum as proposed and recommend the higher upper limit of 1.2

Rationale: Children who are SAM have a very low level of vitamin A and thus higher level of Vitamin A in RUTF will improve their nutritional status.

Issue - Recommendation 19: That CCNFSDU agree to the minimum and associated footnote for vitamin E

Comment: **African Union** supports the proposed text

Rationale: The guideline provides a conversion factor to α-TE which is the most important form of Vitamin E.

Issue - Recommendation 20: 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 proposed nutrients and level. AU proposes that the table be editorially improved such that all vitamin Bs are grouped together i.e.by moving Vitamin C to the end of the vitamin list.

Rationale: For ease of referencing and reading.

Issue - Recommendation 21: That CCNFSDU agree to the following recommendations for sodium, potassium, calcium, phosphorus, magnesium, iron, zinc, copper, selenium and iodine for RUTF

Comment: **African Union** supports the proposed nutrients and levels

Rationale: The nutrient levels will achieve the intended objective of improving the nutritional status of the target population.

Issue - Recommendation 22: 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 the joint statement

Rationale: The joint statement is an acceptable scientific basis that may be used in the formulation of the RUTF.

Issue Recommendation 23: Draft text on Contaminants

[It is recommended that the products covered by the provisions of these guidelines comply with the General Standard for Contaminants and Toxins in Food and Feed (CODEX STAN 193-1995), Maximum Residue Limits (MRLs) and Risk Management Recommendations (RMRs) for Residues of Veterinary Drugs in Foods (CAC/MRL 2-2015) and Codex Maximum Residue Limits for Pesticides.

Other Contaminants

The product should not contain contaminants or other undesirable substances (e.g. biologically active substances, metal fragments) in amounts which may represent a risk to the health of children. The product covered by the provisions of these Guidelines shall comply with those maximum residue limits and maximum levels established by the Codex Alimentarius Commission. ~~A maximum of 10 ppb (µg/kg) for aflatoxin is allowed in the RUTF products~~.]

Comment: The aflatoxin limit should make reference to national or regional legislation/regulation

Rationale: Aflatoxin contamination of food is a major public health concern in Africa and given that these guidelines are promoting the use of local foods in production of RUTF, there is need to provide for the maximum level of aflatoxin. In the absence of such limit in Codex Stan 193-1995, a statement, 'the maximum level of aflatoxin should be comply with those limit set by the national or regional competent body' should be introduced.

Issue - Recommendation 24: That CCNFSDU agree to the proposed text of "Technologies for and effect for processing" section of the Guidelines

Comment: **African Union** supports the proposed text except on the last paragraph where it gives irradiation as an acceptable form of non-thermal method of eliminating microorganism.

*"..Commonly used microbial reduction treatments that could be applied to RUTF or their raw materials include both thermal (e.g. roasting, steam treatment followed by a drying step) and non-thermal (e.g. **~~irradiation~~**, antimicrobial fumigation) control measures. [Guidelines for the Validation of Food Safety Control Measures (CAC/GL 69-2008) and Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM) (CAC/GL 63-2007) should be adhered to]"*

Rationale: Ionising irradiation is not allowed for treatment of products (such infant formula) to be consumed by infants and young children (Clause 3.7 of CODEX STAN 72-1981) and thus the provision should be deleted.

Issue Recommendation 26: That CCNFSDU agrees to the proposed text for "the methods of analysis and sampling" section of the guidelines as follows:

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

Comment: **African Union** supports the proposed text

Issue - Recommendation 27: That CCNFSDU agrees to the proposed text for "packaging" section of the guidelines as follows:

It is recommended that RUTF be packaged in such a way to safeguard the hygienic and other qualities including nutritional properties of the food for the duration of its defined shelf-life. The packaging materials shall be made only of substances which are safe and suitable for their intended uses. Where the Codex Alimentarius Commission has established a standard for any such substance used as packaging materials, that standard shall apply.

Comment: **African Union** supports the proposed text

Rationale: The recommendation emphasizes the need to ensure the safety of the RUTF throughout the shelf life.