

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Item 5, 7

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

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Comments of Sierra Leone

Agenda Item 5

Recommendation 1:

Criterion 1: Source Organism

All potential source organisms ((e.g. animal, plant, fungi, yeasts, bacteria) [and/or] food may be Biofortified*

*Biofortification does not include conventional fortification covered by CAC/GL 9/1987.

Sierra Leone supports the proposed text as it clearly define the term 'source organism'.

Recommendation 2:

Criterion 2: Nutrient and Related Substance to allow for all nutrients and related substances.

Sierra Leone supports the proposed text which is wide enough to accommodate all possible inclusion in biofortification.

Recommendation 3:

Criterion 3: Outcome Measurable increased nutrient and related substance content [and/or] bioavailability

Sierra Leone supports the proposed text which takes into account the nutrient content and their bioavailability. This is key in ensuring the food or products achieve the intended benefits to the consumers.

Recommendation 4: That CCNFSDU agree with the proposed text and the associated footnote for **Criterion 4. Intended Purpose**

The nutrient or related substance is added in an amount sufficient for the intended purpose*

*Paragraph 3.1.1. of the Principles for the Addition of Essential Nutrients to Foods (CAC/GL 9-1987).

Sierra Leone supports the proposed text as this assures consumer of the intended use which is to increase the nutritional value of the product

Recommendation 5: That the Committee consider whether the text which reference the footnote should be included as part of the proposed definition for Biofortification. **Criterion 5: Methods**

Methods* of Production

* To be determined by the competent National/Regional authority]

Sierra Leone supports the proposed text to allows countries to determine the methods of production based on their policies and legislations.

Recommendation 6: That CCNFSDU consider the proposed draft definition for Biofortification and associated footnotes for discussion.

"Biofortification is the process whereby any nutrients¹ or related substances² of all potential source organisms (e.g. animal, plant, fungi, yeasts, bacteria)of/[and] foods are increased by a measurable level [and/or] become more bioavailable³ for the intended purposes⁴.The process applies to any method of production⁵ [and excludes conventional fortification⁶]"

Sierra Leone support the proposed text including the opening of the square bracket

“Biofortification is the process whereby any nutrients¹ or related substances² of all potential source organisms (e.g. animal, plant, fungi, yeasts, bacteria) [or/[and] foods are increased by a measurable level [and/or] become more bioavailable³ for the intended purposes⁴. The process applies to any method of production⁵ [and excludes conventional fortification⁶]”

Sierra Leone believe that the current definition together with the footnotes has taken care of critical components related to the nutrient content, its bioavailability of resultant products as well as recognizing different countries regulation/legislations and policies.

Agenda Item 7

Sierra Leone commended the work of the electronic working group (eWG) co-chaired by South Africa, Uganda and Senegal that was established to develop either a standard or guideline for the RUTF. One of the objectives was to 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.

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

Sierra Leone proposes 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. 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. RUTF are high energy, fortified, ready-to-eat foods for special medical purposes suitable for the dietary management of children with SAM. RUTF are primarily intended for children with uncomplicated SAM from 6-59 months. Although RUTF are 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.*

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. These guidelines should therefore be used in accordance with the 2007 Joint statement of the UN agencies on Community-based management of severe acute malnutrition⁵, relevant WHO Child Growth Standards⁶, WHO guidelines in the management of Severe Acute Malnutrition in infants and children⁷, the Global Strategy for Infant and Young Child Feeding⁸, the International Code of Marketing of Breastmilk Substitutes⁹ and subsequent relevant WHA Resolutions on infant and young child feeding.

These guidelines have been prepared for the purpose of providing an agreed upon approach to the requirements which underpin the production of, and the labelling and claims for, 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 in this area.

These guidelines should be used in accordance with the 2007 Joint statement of the UN agencies on Community-based management of severe acute malnutrition⁵, relevant WHO Child Growth Standards⁶, WHO guidelines in the management of Severe Acute Malnutrition in infants and children⁷, the Global Strategy for Infant and Young Child Feeding⁸, the International Code of Marketing of Breastmilk Substitutes⁹ and subsequent relevant WHA Resolutions on infant and young child feeding.

The guidelines are also intended for use as an instrument designed to avoid or reduce 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 can also be used, if applicable, by governments in case of international trade disputes. Governments and other users should ensure adequate provisions are made for competent technical experts for the appropriate use of these guidelines.

Rationale: In the first paragraph, the deletion 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. The introductory sentence of the third paragraph, which is describing prevention rather than treatment, is proposed for deletion (as indicated with strike through) as it is in contrary to the intention of the guidelines which emphasizes on treatment. The rest of sentences of paragraph 3 are moved to paragraph 5 to improve on the logical flow of the guidelines

Recommendation 2: That CCNFSDU agree to the proposed text for 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. These foods **are** soft or crushable and easy for children to eat without any prior preparation.*

Severe Acute Malnutrition is defined by weight for height (or length) less than -3 Z-score of the median WHO growth standards, or by mid upper arm circumference (MUAC) <11.5 cm, or by the presence of bilateral oedema.

Sierra Leone support proposed definitions with the slight modification as highlighted which provides a clear definition of the product.

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).

Sierra Leone accepts the proposed text as it emphasizes the importance of sourcing the raw materials locally from the available foods of the community/country.

Recommendation 4: That CCNFSDU agree to the proposed text for the "Milk and other dairy products" section as follows:

Milk and other dairy products used in the manufacturing of RUTF must comply with the *Standard for Milk*

Powders and Cream Powder (CODEX STAN 207-1999) and the Standard for Whey Powders (CODEX STAN 289-1995), and other guidelines and Codes of Practice recommended by Codex Alimentarius Commission which are relevant to these products. Relevant codes of practice include the Code of Hygienic Practice for Milk and Milk Products (CAC/RCP 57-2004) and the Code of Hygienic Practices for Low-Moisture Foods (CAC/RCP 75-2015).

Sierra Leone support the proposed text as is making reference to codex standards for the raw material.

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 (haemagglutinins), trypsin and chymotrypsin inhibitors.*

Sierra Leone accept the proposed text with addition of soybean as indicated thus it is important to include it in the list.

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.

Sierra Leone support the proposed text which is guiding on the safety and quality of fat to be used in the manufacture of the RUTF given that it will be consumed by a vulnerable population.

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.

Sierra Leone support the proposed text as this provides guidance on the quality of milled cereals to be used.

Recommendation 8:

8.1 That CCNFSDU consider specifying forms of minerals salts and trace elements to be used in RUTF formulation, which will not alter the acid-base metabolism of SAM children.

8.2 That CCNFSDU agree to the proposed text on vitamins and minerals as follows.

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* (CAC/GL 10-1979).

Sierra Leone support the proposed text as this provides reference to published Codex standards for use in preparing the RUTF.

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.

Sierra Leone supports the proposed text and prohibits the use of honey in RUTF. With regard to the food note, Sierra Leone proposes opening the 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.

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.*

Sierra Leone supports the proposed text which is in accordance with the codex procedural manual of referring issues to the competent Codex committee for adoption.

Recommendation 11: That CCNFSDU agree to the proposed text which reference Section 3 of the CODEX STAN 180-1991 on the use of other matrices in RUTF formulations as follows:

RUTF may be manufactured with formulations different from the one laid down in these guidelines provided that these formulations comply with Section 3 of the Standard for Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991).

Sierra Leone supports the proposed text making a normative reference to Codex standard.

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.*

Sierra Leone proposed text with the slight change the table which qualifies the energy per 100 g of the product.

Recommendation 13:

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

Sierra Leone supports the proposed text as it takes care of the provision of minimum and maximum energy requirements.

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"]

Sierra Leone supports the proposed text as the guidance from FAO will be important in determining the percentage of protein from milk in the products.

Recommendation 15: That CCNFSDU agree to the proposed text on fats/lipids and the proposed minimum and maximum fats/lipids values 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 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.*

Sierra Leone support the proposed text with amended as indicated because it is already mentioned in previous recommendation on energy requirement while the part of 40 - 60 % is further down the recommendation.

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]

Sierra Leone support the proposed text and opening the of the square brackets which will ensure high quality fat is used during production of the product especially related to the essential fatty acids.

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

Sierra Leone support 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 in RUTF will improve their nutritional status.

Issue Recommendation 18: That CCNFSDU agree to the minimum, maximum/GUL and associated footnote for vitamin D

Comment: We support the minimum and propose the lower proposed level of maximum (20 µg/100 g)

Rationale: Children suffering from SAM in developing countries will still be exposed to sunlight and thus they will be able to synthesis Vitamin D.

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

Sierra Leone support the proposed text as the guideline provides a conversion factor to α-TE which is the most important form of Vitamin E.

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

Sierra Leone supports the proposed nutrients and level. Sierra Leone proposed 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

Sierra Leone supports the proposed nutrients and levels this will achieve the intended objective of improving the nutritional status of the target population.

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.

Sierra Leone support the joint statement

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

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.]

Sierra Leone: 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.

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

Sierra Leone 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 it should be deleted

Recommendation 25: That CCNFSDU agree to the proposed draft text for "good manufacturing practices and good hygiene practices"

Sierra Leone support the proposed text as it makes reference to relevant existing Codex Standards

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).

Sierra Leone support the proposed text as it makes reference to relevant Codex Standards

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.

Sierra Leone support the proposed text as the recommendation emphasizes the need to ensure the safety of the RUTF throughout the shelf life.

Recommendation 28: Labelling

Sierra Leone 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.