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CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 7 **CX/NFSDU 17/39/7-Add.1**

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

Thirty-ninth Session

Berlin, Germany

4 – 8 December 2017

Proposed Draft Guidelines for Ready-To-Use Therapeutic Foods

Comments at Step 3 (Replies to CL 2017/78-NFSDU)

Comments of Albania, Brazil, Canada, Colombia, Costa Rica, Egypt, India, Paraguay, Philippines, Helen Keller International (HKI), United States of America, Federation of European Specialty Food Ingredients Industries (EU Specialty Food Ingredients), International Baby Food Action Network (IBFAN), International Council on Amino Acid Science (ICAAS), International Dairy Federation (IDF/FIL), International Organization of the Flavor Industry (IOFI), International Special Dietary Foods Industries (ISDI), Médecins Sans Frontières International MSF (MSF) and United Nations Children's Fund (UNICEF)

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2017/78-NFSDU issued in September 2017. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific paragraphs.

Explanatory notes on the appendix

2. The comments submitted through the OCS are, hereby attached as **Annex** and are presented in table format.

ANNEX

Comments on the Proposed Draft Guidelines for Ready-To-Use Therapeutic Foods

GENERAL COMMENT	MEMBER/ OBSERVER
ok. *Category : EDITORIAL*	**Albania**
Brazil appreciates the work done by South Africa, Senegal and Uganda and thanks for the opportunity to present the following comments about the proposed draft guideline for Ready-to-Use Therapeutic Foods. The products marketed as RUTF are not available on Brazil market. Thus, Brazil will kindly provide general comments on key aspects of the proposed draft guideline without detailing on specific compositional requirements of RUTF. Initially, we would like to point out that it is very useful when the document presents a contextualization of the theme, the history of the discussion and the consolidation of the eWG comments. We believe that it facilitates the analysis and the proposal of suggestions. *Category : SUBSTANTIVE*	**Brazil**
Canada thanks South Africa, Senegal and Uganda for chairing the eWG and preparing the proposed draft guidelines for the use Ready-to-Use Therapeutic Foods (RUTF) in the management of severe acute malnutrition (SAM), for consideration by the Committee. Canada supports the Proposed Draft Guidelines for RUTF, as per Appendix 1. Canada generally supports the 28 recommendations and has provided comments for some of the recommendations in the following text. 1. Canada notes some inconsistencies in the draft guideline on how certain words are represented. For example, the hyphens between the words Ready-to-Use Therapeutic Foods are varied throughout the document: “Ready-To-Use” and “Ready to Use” are both used in the document. Consistency should be applied throughout the document. 2. Canada also notes the inconsistent use of capital letters while referencing Codes of Practices, and notes that consistency should be applied throughout the document. 3. Canada suggests removing the words “shall” and replacing with “should”, throughout the document. *Category : EDITORIAL*	**Canada**
Colombia would like to note that its comments are based on the Spanish version of Codex CX/NFSDU 17/39/7. *Category : EDITORIAL*	**Colombia**
Costa Rica thanks South Africa, Senegal and Uganda for their work in coordinating the electronic working group and for	**Costa Rica**

preparing the document CX/NFSDU 17/39/7 PROPOSED DRAFT GUIDELINES FOR READY-TO-USE THERAPEUTIC FOODS. It would also like to reiterate its gratitude for being able to submit specific comments on this topic, as detailed in the following recommendations. Costa Rica supports the preamble proposed in Recommendation 1. Costa Rica supports the proposed text for the description of the RUTF in Recommendation 2. Costa Rica supports the proposed introductory text in Recommendation 3. Costa Rica supports the proposed text in Recommendation 4. Costa Rica supports the proposed text in Recommendation 5. Costa Rica supports the proposed text in Recommendation 6.	
Egypt approves the "PROPOSED DRAFT GUIDELINES FOR READY TO USE THERAPEUTIC FOODS (RUTF)" as presented to be submitted at step 3 *Category : TECHNICAL*	**Egypt**
India does not support the use of RUTF as enough evidence is not available for the use of commercially manufactured RUTF for management of SAM vis-a-vis other interventions. Further, in a recent trial conducted in India comparing the efficacy of RUTF (centrally produced and locally produced) with augmented energy-dense home-prepared foods (comparison group) for home based management of uncomplicated severe acute malnutrition (SAM); results showed that (i) homemade foods were as effective vis-a-vis as centrally produced RUTF; (ii) 16 weeks after stopping RUTF, recovery rates dropped from 56.9% to 17.3% for locally produced RUTF and from 47.5% to 12.1% for centrally produced RUTF and not for use of these products in India. India strongly supports the need for using local foods to manage the condition in accordance with the national policy. Therefore, the comments of India are limited only to the guideline formulation process for standardization of the product. *Category : SUBSTANTIVE*	**India**
We agree on the continuity of the works *Category : TECHNICAL*	**Paraguay**
The Philippines supports the Proposed Draft Guidelines on Ready to Use Foods. The proposed guidelines are consistent with the previous submitted Philippine positions on ready to use foods based on generally accepted scientific evidence. Specific Comments	**Philippines**

Preamble To be consistent with section 3 of the CODEX STAN 180-1991, the proposed guidelines should include in the Preamble or add in General Principles the following statements which reads as follows: "The formulation of ready to use foods should be based on sound medical and nutritional principles. Their use should have been demonstrated, by scientific evidence, to be safe and beneficial in meeting the nutritional requirements of the persons for whom they are intended". The Philippines supports the adoption of the use of formulation of foods for special medical purposes and their qualifications since RUTF is considered as food for special medical purposes intended for the dietary management of severe acute malnutrition. It is important to include the above paragraph to clarify that the formulation of RUTF should have medical and nutritional basis and be clinically proven to be safe and beneficial for intended users. The findings of Oakely et al (2010) emphasized that clinical evidence should be considered before recommending any changes to the formulation of RUTF. Section 5. SUITABLE RAW MATERIAL AND INGREDIENTS For Section 5, the Philippines proposes to add “Suitable” before Raw Materials and Ingredients to be consistent with other previously issued Codex Standards such as the Codex Standards for Complementary Foods. Section 5.1.1 Milk and Dairy Products The current text might restrict future technological developments for dairy ingredients therefore we would like the provision to reference the milk and milk product standards. We would therefore support the following amendment to the text: 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 Codex milk and milk products standards as well as 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). Section 5.1.2 Legumes and Pulses It is critical to state the use of local foods and to take into account local food consumption patterns in the basic composition of RUTF for cost-effective and safe ingredients in combinations that meet international specifications. .This is consistent with the decision in the 37th CCNFSDU Session. Osendarp et al (2015) identified locally adapted formulations to include commodities such as chickpea, sesame, soybean, maize, and sorghum in East Africa ; soy and whey permeate in Malawi rice-lentils or chickpeas in Bangladesh, Pakistan, and Ethiopia; and almonds in Afghanistan. This basic composition was also identified in a scientific review (Wagh and Deore, 2014). Section 5.1.3 Fats and Oils	

We support retention of the bracketed statement with minor revision : The composition of fats and oils should allow for product that flows during processing to have a desirable consistency (e.g. semi solid) and ensures physical stability throughout the supply chain. We believe that it is necessary to indicate this rationale. The Philippines supports the prohibition of partially Hydrogenated fats and oils in RUTF due to adverse effects of trans fatty acids in later life. The deleterious effects of trans fat intake on risks of diet related non-communicable diseases have been well demonstrated in several studies and reviews (Kiage et al, 2013, Teegala et al 2009, Atthia-Skihiri et al 2009). 5.2.2 Food Additives and Flavours We propose to add the statement “Where possible, no food additives shall be added. However, if technologically justified, only Food Additives and Flavours appropriate for 6-59 months older infants and children and their prescribed limits in reference to the General Standard for Food Additives (Codex Stan 192-1995) shall be permitted. Section 5.2.1 Available Carbohydrates We support deletion of the bracket and retention of the statements “Sucrose, vegetable starch, 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 children with severe acute malnutrition. Only pre-cooked and/or gelatinised starches gluten-free by nature may be added. Addition of fructose can cause fructose intolerance (Latulippe and Scoog, 2011). Consumption of beverages with high fructose corn syrup demonstrated a-dose dependent increases in circulating lipid/lipoprotein risk factors for CVD and uric acid within 2 week increase (Stanhope et al, 2015). It is important to identify the basic composition of ready to use foods including other ingredients and the use of other forms of RUTF formulation 6. Nutritional Composition and Quality Factors. 6.1 Energy The Philippines supports the proposed 5.2-5.5 kcal per gram of RUTF formulation. This is consistent with the energy content of currently available lipid based RUTF. 6.2 Proteins We are in agreement to include “at least 50% of protein provided by milk products” in the essential composition of ready to use foods to ensure protein sufficiency. Alternatively, protein content should at least be 10-12% of total energy of RUTF. This is consistent with the identified nutrient levels of RUTF based on WHO Guideline Update on the Management of Severe Acute Malnutrition in Infants and Children. Studies that have directly compared RUTF which contain at least 50% of the protein from milk dairy vs other forms of RUTF have shown that they are more effective in the dietary management of children ages 6 to 59 months with SAM (Oakely, et. al., 2010, Irena and co-workers, 2015, Bahwere et al., 2016, Bahwere et al., 2014).	

6.3 Fats We support the retention of the bracketed statement “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 lipid content is in line with the nutritional composition of RUTF indicated in the Community Based Management of Severe Acute Malnutrition – 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. We also propose that it will be relevant to wait for the WHO Scientific Review on the effectiveness of RUTF in considering the minimum and maximum levels of selected nutrients for RUTF. The Philippines is in agreement with the review of the nutritional composition for RUTF consistent with the current scienific evidence including the WHO Recommendations (WHO, 2007, WHO, 2012) and to also consider the conversion factors of International Standard Units. According to Oakley et al (2010) considering the critical clinical status of children with SAM, any change in the composition of RUTF should be evaluated in a clinical trial before they are used on a widespread basis. 8.3 Toasting We are in agreement to retain the bracketed statement “The use of appropriate enzymes may be considered to decrease anti-nutrients in ingredients” to ensure maximum retention of nutrients. The use of enzyme to reduce anti-nutritional factors in soybeans, which can be of benefit in enhancing the nutritional quality of cereal-legume gruels was demonstrated in a scientific study (Nigerian Food Science and Technology, 2015). We also recommend to include “The use of processing methods such as soaking, combination of cooking and fermentation may reduce anti-nutritional factors and enhance nutritional quality of foods. 8.5 Other Processing Technologies We support deletion of the brackets and retention of the statement “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”. 9. MANUFACTURING PRACTICES AND GOOD HYGIENE PRACTICES We propose to add, “the product should comply with the Recommended International Code of Hygienic Practice for Foods for Infants and Children of the Codex Alimentarius Standard CAC/RCP 21-1979.” to be more specific rather than stating “other relevant Codex text. 11. Packaging We propose to amend the statement to “The packaging materials shall be made only of substances which are safe and suitable for their intended uses. It should also be of a sturdy export quality to provide protection of the goods for carriage by air, sea, and/or road to the final destination (including remote locations under adverse climatic conditions) (DOH and	

UNICEF Philippines, 2015). Where the Codex Alimentarius Commission has established a standard for any such substance used as packaging materials, that standard shall apply." 12. Labeling We support that the labeling of RUTF for children from 6 to 59 months be in accordance with the Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-991), the General Standard for the Labelling of and Claims for Pre-packaged Foods for Special Dietary Uses (CODEX STAN 146-1985 and Guidelines on Nutrition Labelling (CAC/GL 2- 1985) since these are the specific relevant labelling guidelines of this type of product. The Philippines supports the proposed mandatory labelling requirements which are consistent with the labelling of Foods for Special Medical Purposes (CODEX STAN 180-1991) including the retention of the statement "Exclusive breastfeeding is recommended for the first 6 months of life, and complementary feeding from six months onwards with continued breastfeeding up to 24 months and beyond." This statement is very important to ensure that use of RUTF will not undermine breast feeding. This statement complies with the International Code of Marketing Breastmilk Substitute and our local regulations (Executive Order 51 s. 1986 or the National Code of Marketing of Breastmilk Substitutes, Breastmilk Supplements, and related products, penalizing violations thereof, and for other purposes, and its revised Implementing rules and Regulations, 2006). Nutritional Composition Vitamin A We support minimum 0.8 mg and maximum 1.1 mg/100 g based on the recommendation on RUTF (WHO 2013). Vitamin D We support minimum 15 ug and maximum 20 ug/100 g based on the recommendation on RUTF (WHO 2013). We also support a GUL of 30. Calcium We support minimum 300 mg and maximum 600/100 g mg based on the recommendation on RUTF (WHO 2013) Phosphorus We support minimum 300 mg and maximum 600 mg/100 g based on the recommendation on RUTF (WHO 2013) Magnesium We support minimum 80 mg and maximum 140 mg/100 g based on the recommendation on RUTF (WHO 2013)	

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General Comments The United States thanks South Africa, Senegal, and Uganda for co-chairing the eWG and preparing this report. In general, the U.S. supports the eWG recommendations for the proposed draft guideline for ready-to-use therapeutic foods and offers some general comments on the eWG recommendations. RUTF are made of ingredients that are part of a normal diet and are intended for community based management of severe acute malnutrition (SAM) in children . Thus, the United States views RUTF as foods for special dietary use (FSDU), rather than foods for special medical purposes (FSMP) because dietary management of SAM can be achieved by modification of the normal diet and can be eaten safely at home by a malnourished child with no medical complications and guided by appetite .	**USA**

The United States views the purpose of this Guideline to provide globally applicable technical information for RUTF production for Member countries and facilitate international relief efforts where needed. In line with this view, the United States views trade and policy issues (advertising, marketing, sale, and promotion) to be outside the scope of the CCNFSDU. WHO expert-derived technical documents can provide important background information supporting Codex texts. However, Codex texts which have trade implications should not make the content of a referenced WHO document legally binding for Members. The United States notes that WHO is conducting a review of lipid based nutrient supplements which will review RUSF and RUTF for treatment of moderate and severe malnutrition and suggests the Committee consider this technical document during the development of this Guideline. The United States notes that humanitarian and development agencies, including the United Nations World Food Program (WFP), the United Nations Children Fund (UNICEF) and the U.S. Agency for International Development (USAID) have been jointly reviewing the evidence for the harmonization of specifications for ready to eat foods, including RUTF and RUSF. Additionally, there are other efforts revising the science and the development of a combined protocol for the treatment of severe and moderate acute malnutrition that would improve the coverage, quality, cost-effectiveness and continuity of care, such as research being carried out by the International Rescue Committee and Action Against Hunger | ACF-USA (http://www.ennonline.net/fex/53/thecompasstudy). *Category : SUBSTANTIVE*	
Specific Comments Recommendation 1 – Preamble The preamble should provide context for a technical guideline for RUTF, thus the United States suggests that it address issues directly relevant to the technical guideline for RUTF rather than elaborate on existing Codex texts or documents that can referenced. We offer the following suggestions to sharpen the focus on science and risk based principles in drafting this guideline: 1. Delete the first paragraph and cite references for the objectives of Codex Alimentarius (Codex Procedural Manual) and CAC/RCP 20-1979 in the last paragraph. The Guideline should focus on technical aspects of RUTF and refer to existing Codex texts where advice exists. 2. In the second paragraph, omit the term ‘for special medical purposes’ because dietary management of SAM can be achieved by modification of the normal diet thus does not meet the definition of a food for special medical purposes. The United States supports the concept that RUTF can be prescribed according to weight thus may be used by other age groups.	**USA**

3. Delete the third paragraph as the interventions discussed do not include RUTF do not provide information on technical aspects of manufacturing RUTF. 4. In the fourth paragraph, the United States suggests: • inclusion of a general statement such as “Expert-derived technical recommendations may be relevant to Codex texts when they contribute transparent and rigorous scientific assessment of relevant scientific evidence“ and cite the several expert-derived recommendations such as those listed as well as the 2016 FAO/WHO microbial risk assessment report in a footnote; • that the “Global Strategy for Infant and Young Child Feeding, the International Code and subsequent and relevant WHA resolutions” be deleted or bracketed as specific WHA resolutions are not specifically referenced; • dispute clauses are generally not included in Codex texts thus the United States suggests this text be deleted. The United States suggests: Children affected by severe acute malnutrition (SAM) need safe, palatable foods with a high energy content and adequate amounts of vitamins, and minerals and other critical nutrients. Children with SAM need timely treatment and RUTF [are] a critical part of that treatment. RUTF are high energy, fortified, ready-to-eat foods suitable for the [community-based] dietary management of children with SAM. RUTF are primarily intended for children [with SAM without medical complications]. Although RUTFs are given to other age groups with various forms of malnutrition at the implementation level, the primary focus for this guideline is children with SAM from 6-59 months. Since RUTF are [nutritionally balanced products] prescribed according to weight, National Authorities may decide to include the provision of RUTF in their national protocols for use by other age groups by [adjusting dosage by weight]. These guidelines should be used in accordance with expert-derived technical recommendations1 that are based on transparent and rigorous scientific review of relevant evidence and relevant Codex texts2. These guidelines provide requirements for the production and labelling of Ready-to-use therapeutic foods. The Guidelines are intended to facilitate the harmonization of requirements for RUTF products at the international level and may [aid] provide assistance to governments wishing to establish national regulations in this area. 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 RUTFs. Governments and other users should consult with competent technical experts for the appropriate use of these guidelines. Footnote 1 - 2007 Joint Statement of the UN Agencies ; 2013 WHO document on Updates on the Management of Severe Acute Malnutrition in infants and children ; [2016 FAO/WHO microbial risk assessment report (FAO/WHO Microbial safety of	

lipid-based ready-to-use foods for management of moderate acute malnutrition and severe acute malnutrition]; Footnote 2 - Code of Ethics for International Trade in Food including Concessional and Food Aid Transactions (CAC/RCP 20-1979). Recommendation 2 – Description The United States does not support describing RUTF as a food for special medical purposes (FSMP) because it does not meet the Codex definition of a FSMP and suggests the Committee further discuss this issue as defining RUTF as a FMSP runs counter to the goal of community-based management of SAM. The United States queries whether the intended program goals to treat SAM with community-based management can be achieved with FSMP that can only be used under medical supervision as stated in Codex Stan 180-1991. This limitation not only can hamper the programmatic aspect of RUTF but also will make it more expensive. The Standard for the Labelling of and Claims for Foods for Special Medical Purposes (Codex Stan 180-1991) describe foods for special medical purposes as foods that "…are intended for the exclusive or partial feeding of patients with limited or impaired capacity to take, digest, absorb or metabolize ordinary foodstuffs or certain nutrients contained therein, or who have other special medically-determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet, by other foods for special dietary uses, or by a combination of the two." Because RUTF is used in a community-based setting and identified for children with malnutrition without medical complications, that have the capacity to eat ordinary food, and whose dietary management can be achieved by modifying the normal diet, the United States views RUTF as a food for special dietary use, not a food for special medical purposes. With regard to the definition for SAM, the United States suggests citing the reference for the definition in a footnote (e.g. 2009 WHO Child Growth Standards and the identification of severe acute malnutrition. The United States suggests: Ready to Use Therapeutic Foods (RUTF) are high-energy, fortified, ready-to-eat foods for special medical purposes [used] for the [community-based] dietary management of children from 6 to 59 months with severe acute malnutrition without medical complications. These foods should be soft or crushable and should be easy for children to eat without any prior preparation. (Severe Acute Malnutrition) is defined as weight for height (or length) less than –3 Z-score of the median WHO growth standards, or mid upper arm circumference (MUAC) <115 cm, or the presence of bilateral oedema. Recommendation 3 – Raw Materials and Ingredients	

The United States suggests the Committee further discuss the reference to Section 3 of CODEX STAN 180-1991 in this Guideline due to the EWG's diverging views on this matter. The United States does not support referencing Section 3 as RUTF does not meet the definition of Foods for Special Medical Purposes. Categorization of RUTF as Foods for Special Medical Purposes could consequently lead to negatively impacting the ability of donor countries to provide food assistance in emergency relief situations. The United States, however, supports inclusion of text that addresses the concept that use of raw materials and ingredients "should be demonstrated, by scientific evidence, to be safe and beneficial in meeting the nutritional requirements of the persons for whom they are intended." The United States suggests: 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. [Their use should have been demonstrated, by scientific evidence, to be safe and beneficial in meeting the nutritional requirements of the persons for whom they are intended.] Recommendation 4 - Milk and other Dairy Products The United States supports the proposed text as it cites relevant Codex texts. Recommendation 5 – Legumes and Pulses The United States supports the proposed text as it references relevant Codex texts. Recommendation 6 – Fat and Oils The United States supports the proposed text, however notes that the body of scientific evidence supports the relationship between industrially produced trans fat and risk for coronary heart disease. The United States acknowledges that quantifying 'a significant amount' may be challenging thus suggests an edit that recognizes that PHOs are the major dietary source of industrially-produced trans fat in processed food. The United States also suggests an edit as fat oxidation is less a concern for the manufacturing of RUTF. The more relevant concern is the texture and ability of the paste to flow during processing and ensuring physical stability of the paste through the supply chain; rather than fat oxidation. The United States suggests: Fats and oils used in the manufacturing of RUTF products 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. [The composition of fats and oils should allow for a product that flows during processing and ensures physical and chemical stability throughout the supply chain.]	

Partially Hydrogenated fats and oils[, the major dietary source of industrially-produced trans fat in processed food,] should not be used in RUTF products. Recommendation 7 - Cereals The United States supports the amended text below for improved readability. The United States suggests: All milled cereals suitable for human consumption may be used provided that [their processing reduces] fibre content, 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. Recommendation 8 – Vitamins and Minerals The United States supports the proposed text in 8.2 and prefers to provide information on specific forms of mineral salts and trace elements for children with SAM in a footnote citing the appropriate reference containing that information. Recommendation 9 – Other ingredients (digestible, available carbohydrates) The United States supports proposed text in 9.1; however, notes that while carbohydrates are used to improve palatability, they are also a source of energy and acknowledges that the Committee may wish to focus on its function to improve palatability. For 9.2, the United States prefers the footnote be omitted and suggests further discussion of the strength of evidence to support the exclusion of fructose and high fructose corn syrup in RUTF for children with SAM. The United States notes that the WHO Guideline for Sugars intake for adults and children state “These recommendations do not apply to individuals in need of therapeutic diets, including for the management of severe and moderate acute malnutrition. In addition, the references (Malik, 2015 and Hu 2010) cited to support the proposed footnote present epidemiological studies on sugar-sweetened beverages, not sugar and high fructose corn syrup conducted largely in adults. As simple sugars are being added to RUTF to increase palatability and contribute calories for short term management of SAM, the United States does not agree that the literature cited supports limiting the type of simple sugar allowed if they meet the intended purposes. For 9.3, the United States queries the rationale for including an acceptable limit of available carbohydrate if it is not viewed as a source of energy. Recommendation 10 – Food Additives and Flavours The United States supports discussion of this proposed approach and suggests starting with a list of known list of	

ingredients and additives and consider how to best allow for innovation.

Recommendation 11 – Use of other Matrices in RUTF formulation
The United States view is that RUTF do not meet the definition of Foods for Special Medical Purposes and notes the diverging views of the EWG thus suggests that the Committee further discuss this issue. For this reason, the United States suggests the following edits rather than the reference to Section 3 of the Standard for Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991) as we view RUTF as a food for special dietary uses for use in community based management of SAM.

The United States suggests:
RUTF formulations manufactured with ingredients other than those specified in this guideline [should be proven to suitable and safe for their intended purpose. Use of other ingredients should be demonstrated by scientific evidence, to be safe and beneficial in meeting the nutritional requirements of the persons for whom they are intended.]

Recommendation 12 - Energy from Macronutrients
The United States Supports the proposed text and notes that digestible carbohydrate is not defined in Codex texts and suggests 'available carbohydrate' be used to be consistent the Guidelines for Nutrition Labelling (CAC/GL 2-1985).

Recommendation 13 – Min Max/GUL for total available Carbohydrates
The United States Supports the chairs' recommendation.

Recommendation 13 - Min Max/GUL for Protein
The United States supports the chairs' recommendation and queries if 2.5 and 2.9 are the intended min and max for g/100 kcal. (Min per 100kcal= 12.8x100/520 =2.5; Max per 100kcal= 16.2x100/550 = 2.9)

Recommendation 14 - Protein quality
The United States supports the chairs' recommendation. While milk protein provides higher bioavailability of key micronutrients that encourage linear growth and cognitive development such as Ca, P, Mg and Vitamin D (Hess et al., 2015), the United States also recognizes that other local and culturally acceptable protein sources may be appropriate (provided that scientific evidence supports comparable effectiveness with RUTF formulations containing protein from milk products). Including a measure of protein quality that is internationally standardized and validated in collaborative studies such as PDCAAS in this Guideline may assist in providing flexibility with the statement in brackets.

Recommendation 15 – Min Max/GUL for Fats/lipids
The United States supports the proposed text and notes that these levels allow for proper flow in processing of RUTF and

ensures physical stability.

Recommendation 16 – Essential fatty acids
The United States queries the basis for the absolute values of linoleic acid and alpha-linolenic acid per 100 kcal and suggests the conversion be explained in text for clarity.

Recommendation 17 – Vitamin A
The United States prefers 1.1 mg RE/100g and corresponding values expressed per 100 kcal as the maximum. 1.1 mg RE/100g is the estimated minimum content when the product contains the highest level possible at t0 (release time at manufacturer), and considering the RUTF maximum at 24 months shelf life, stored at 30C or under. With most products consumed well before their best-before date, vitamin A content when consumed is expected to be within this RUTF range most of the time.
The United States notes that the Guidelines on Nutrition Labelling provide vitamin equivalents for Vitamin A of RAE and RE thus suggests that both RAE and RE and their conversions be provided.

Recommendation 18 – Vitamin D
The United States supports the proposed recommendation and does not oppose the proposed maximums as these ranges are wide enough to be technologically feasible and assist manufacturers in compliance. The minimum levels of Vitamin D are in alignment with current WHO and IOM recommendations.
The United States notes that forms of vitamin D listed in the GL 10-1979 are ergocalciferol and cholecalciferol thus the Guideline may not need to specify the forms if GL 10-1979 is referenced.

Recommendation 19 – Vitamin E
The United States supports the proposed recommendation. The United States is not aware of evidence to suggest an appropriate maximum level.

Recommendation 20 – Vitamins K, B1, B2, C, B6, B12, folic acid, niacin, PA, and biotin
The United States supports the proposed recommendations. Scientific evidence has shown that RUTF formulations containing these amounts of nutrients are safe and beneficial in the community based management of SAM.

Recommendation 21 –Minerals (sodium, potassium, calcium, phosphorus, magnesium)
The United States supports the proposed recommendations. Scientific evidence has shown that RUTF formulations containing these amounts of nutrients are safe and beneficial in the community based management of SAM.

The United States supports the higher maximum amounts for calcium, phosphorus, and magnesium to allow for catch-up

bone growth and flexibility in designing single premix formulas for consistent levels of calcium in the finished product. Recommendation 22 – Additional Nutrients The United States supports the proposed recommendation provided that RUTF formulations containing additional nutrients are shown be safe and beneficial in meeting the nutritional requirements of children with SAM. Recommendation 23 – Contaminants The United States supports the chairs' proposed recommendations to further discuss the approach to contaminants in RUTF and leave the draft text in brackets until further decisions are made by the Committee. The United States suggests inclusion of 'older infants' in "Other contaminants" to reflect the 6 - 59 month age range. 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 [older infants and] 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. Recommendation 24 – Technologies for and effect of processing The United States supports the proposed recommendation as it addresses the array of available technologies used in the production of RUTF. Recommendation 25 – Good manufacturing practices and hygiene practices The United States supports the proposed recommendation as this text addresses technologies used in RUTF production and suggests the following edit for consistency when referencing Codex texts: [These practices should be in accordance with the] [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].	

Recommendation 26 - Methods of analysis and sampling The United States supports the proposed recommendation. The cited Codex texts are relevant to this section. The United States suggests that the Harmonized IUPAC Guidelines as be referenced in a footnote. ….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 [Guidelines]. Recommendation 27 – Packaging The United States supports the proposed recommendation as it addresses the safety, quality, and suitability for the intended use. Recommendation 28 - Labelling The United States supports further discussion of the proposed Codex texts to inform the labelling provisions for RUTF. The United States prefers omitting the Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991), as we do not view RUTF as a food for special medical purposes. In line with this view, the United States suggests keeping the “Declaration of Nutritive Value” and then referencing the General Standard for the Labelling of and Claims for Pre-packaged Foods for Special Dietary Uses (CODEX STAN 146-1985) to be consistent with the other headers present in this section. Regarding the “Additional Mandatory Labelling Requirements” section, the United States supports further discussion of the approach to determine the mandatory statements that should be included in the labelling requirements for RUTF. The United States is not opposed to providing additional information on labelling, however, queries if the proposed text (except for the second bullet point), implicitly describes a product that is not suitable for community based management of SAM (i.e. foods that can be eaten safely at home by a malnourished child with no medical complications and guided by appetite). Such labeling is inconsistent with the use of the product and difficult to comply with in community settings. The United States notes that some sections like the List of Ingredients refers to a Codex text while other sections are deleted such as the Declaration of Nutritive Value or text from another Codex text is provided as in Additional Mandatory Labelling requirements. The United States suggests internal consistency within the standard may be helpful for users. The United States supports the Chairs view that statements regarding breastfeeding and breastmilk substitutes while important, are out of scope in a technical guideline for RUTF and notes that other Codex Committees may be more appropriate to determine how to address such statements. *Category : SUBSTANTIVE*	

IBFAN wishes to thank South Africa, Senegal and Uganda for their work on this agenda item and their leadership of the Electronic Working Group. General Comments: • IBFAN is of the opinion that current scientific evidence does not support the wide spread use of RUTF products compared to the use of culturally appropriate energy dense family foods for the community management of SAM or MAM and the support of sustained breastfeeding. • National Authorities should ensure that any decisions to provide food products are based on sound independent evidence. Such evidence should meet WHO's definition of scientific substantiation: 'Relevant convincing / generally accepted scientific evidence or the comparable level of evidence under the GRADE classification'. The evidence should cover the effectiveness of RUTF as a treatment food, resource implications, sustainability, social and economic risks, how outcomes were measured and risk of bias. (See IBFAN's review of literature in the IBFAN Brief on the Use of RUTF). • Access to nutritious and appropriate foods is just one aspect of a full package of treatments and care that are required for sustained rehabilitation of malnourished children and the prevention of recurrence. The protection and support of breastfeeding and culturally appropriate complementary feeding must be a fundamental and an essential component of a rehabilitation package. Other critical components must include: nutrition education; the treatment of infections; support for maternal care; the strengthening of health systems; the prevention of early child bearing; literacy and the improvement of water supply, sanitation and hygiene. • The widespread use of RUTF products has and continues to trigger diversion of public funds away from support for sustainable solutions such as breastfeeding and locally sourced, culturally appropriate, bio-diverse family foods. • To safeguard against needless and inappropriate use of these products IBFAN is of the opinion that these products should not be on the open market. The marketing and trade of RUTF products introduces a commercial element that increases the risk of unnecessary and inappropriate use. During the 2015 CCNFSDU session, the Chair suggested that conditions relating to marketing could not be addressed by Codex (Para 82, REP16/NFSDU). This issue needs to be clarified and addressed urgently. • Products that are intended for infant and young child feeding and are legally available on the open market require stringent marketing restrictions in order to protect breastfeeding, complementary feeding and child health from commercial influence. For this reason the marketing of breastmilk substitutes and related products are all covered by the International Code of Marketing and subsequent relevant WHA Resolutions. The Codex Standard covering Formulas for Special Medical	**International Baby Food Action Network**

Purposes (FSMP)(CODEX STAN 72 – 1981) is an inadequate safeguard for vulnerable children. Indeed the adoption of the Standard has led to increased promotion and, growth in the FSMP market, with subsequent inappropriate use. RUTF are intended for therapeutic use only and although the International Code and WHA resolutions provide some important safeguards, extra safeguards are needed to prevent misuse. • Since Codex Guidelines are voluntary instruments for the safety aspects to be effective, they must be implemented into national law. Codex texts dealing with food safety are already integrated into the regulatory mechanisms of many countries. National authorities can use these to improve the safety of products (eg. Codex Code of Practice for Low-Moisture Foods (CAC/RCP 75-2015). • Importantly, this Codex Guideline is being developed through a process which is not adequately safeguarded from conflicts of interest. Undue influence from manufacturers and distributors, their associations and the organizations funded by them is likely to subvert the public health purpose. It will lead to increased global trade of a single commodity and its widespread use at the expense of sustainable solutions. Manufacturers and distributors might also put pressure on governments to accept imports of products that may not be needed or wanted. • To facilitate sound decision making on this important topic, the support to the process being pursued in the CCNFSDU, needs to include more robust evidence of the validity of using RUTF in community management of SAM. Lack of such evidence and concern about the marketing and misuse of these products was among the reasons UNICEF's proposal was rejected in the 35th CCNFSDU session in Bali. The situation has not changed and there continues to be a serious lack of such evidence. IBFAN does not see the need for creating a Codex instrument for products that are intended for therapeutic use in the management of SAM. Increased marketing will lead to increased use of these products and the replacement of locally sourced, culturally appropriate and bio-diverse foods. If there is to be a Codex instrument relating to RUTF it must have adequate safeguards to mitigate the risks of needless use and misuse. Recommendation 1 Preamble The preamble is improved from previous versions, referring to the need for prevention and several important safeguards. However it still fails to address key concerns. 1. Para 1 While it is true that one of the objectives of Codex is to protect health, and that the Code of Ethics contains important safeguards, the preamble fails to mention that another evident aim of Codex is to facilitate global trade. The last Paragraph of the Preamble is an admission of this purpose and states: 'These guidelines can also be used, if applicable, by	

governments in case of international trade disputes.'
2. The Preamble rightly mentions the importance of the International Code and Resolutions and the Codex Code of Ethics in International Trade in Food including Concessional and Food Aid. It fails to include a specific statement that the products must not be placed on the market and not promoted in any way. This is essential.
3. Para 2 claims that RUTF are a critical part of the treatment of SAM – this ignores the use of energy dense local family foods and promotes a single product based solution.

Rationale: As mentioned above, products intended for infant and young child feeding and that are legally allowed to be on open sale, require stringent marketing restrictions in order to protect breastfeeding, complementary feeding and child health from commercial influence. Since 1981 the WHO has recommended that the marketing of all such products are covered by the International Code of Marketing of Breastmilk Substitutes and subsequent relevant WHA Resolutions, and not should not be promoted. The Code and Resolutions are also highlighted in the Codex Code of Ethics.

RUTF are a different matter in that they are intended for therapeutic use only. In view of the risks of misuse they should not be on open sale in retail outlets. For this reason the International Code and Resolutions, while important safeguards, do not provide sufficient safeguards. The Codex Standard covering Formulas for Special Medical Purposes (FSMP) (CODEX STAN 72 – 1981) is also inadequate. Although FSMPs are intended for use only in very specific conditions, the existing controls are far from adequate and inappropriate marketing of these products has continued regardless with widespread misuse use of these products.

Rather than make an unqualified claim that RUTF is a 'critical part of treatment' of SAM, the Preamble must acknowledge that current scientific evidence does not demonstrate that RUTF products are better than culturally appropriate energy dense family foods for the community management of SAM and the support of sustained breastfeeding. National Authorities must base any decisions to provide food products on sound independent evidence that meets WHO's definition of scientific substantiation. 'Relevant convincing / generally accepted scientific evidence or the comparable

Investing in prevention of SAM through sustainable measures and interventions is crucial. In addition to access to nutritious and appropriate foods, a full package of treatment and care is required for sustained rehabilitation of malnourished children and the prevention of recurrence. These include effective promotion and support of exclusive breastfeeding for the first six months of a child´s life combined with continued breastfeeding to 24 months and beyond; nutrition education; the treatment of infections; support for maternal care; prevention of early child bearing; the strengthening of health systems; the improvement of water and sanitation systems; and improved access to health care. 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.

The Statement in Para 2 of the Preamble should be altered as follows: "Children with SAM need timely and appropriate treatment DELETE: and RUTF is a critical part of the treatment. RUTF are high energy, fortified, ready-to-eat foods for special medical purposes suitable for that can – if considered appropriate and under strict conditions – be used for the dietary management of children with SAM. INSERT: Energy dense home-prepared family foods are as effective as RUTF for the treatment of uncomplicated 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." IBFAN RATIONALE: The statement as proposed in the Preamble is misleading. The attached briefing includes evidence that energy dense home-prepared family foods can be as effective as RUTF for the treatment of uncomplicated SAM. The use of RUTF is a market driven intervention, which can provide energy with added nutrients, however it is only one option, that is costly, not culturally appropriate, not community based, not bio-diverse, encourages dependency on imported products and is not sustainable. The second part of Para 4 should be changed as follows: "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 DELETE and claims for, INSERT: OF RUTF. The guidelines are intended to DELETE: 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. DELETE: 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. ADD: Governments DELETE: and other users should have a duty to ensure that adequate provisions are made for competent technical experts for the appropriate use of these guidelines. National Governments must be free to ban the import of RUTF and safeguard their national nutrition policies. ADD: These Guidelines are not intended to provide program recommendations for the treatment and management of SAM	

and national authorities should develop programs that are appropriate to their cultural, economic and social needs that are based on sound independent scientific evidence. RUTF products should not be promoted in any manner nor sold in the open market. Recommendation 6 Fats and Oils ADD: The addition of fats and oils must be in accordance with the recommended limit of less than 30% of total energy as set by the WHO Fact Sheet No. 394. http://www. WHO.int/mediacentre/factsheets/fs394/en/ Recommendation 8 Vitamins and Minerals It should be noted that the scope proposes that the Guidelines can be applicable for children from 6 to 59 months, while the Advisory Lists of Nutrient Compounds for use in Foods for Special Dietary Uses Intended for Infants and Young Children (CAC/GL 10-1979) is intended for older infants and young children 0 to 36 months. Recommendation 9 Available carbohydrates The palatability of the RUTF can be increased by the addition of appropriate available carbohydrates. The addition of added sugars to not exceed the WHO recommendation of 5% of total energy. Remove the brackets and add: NOT be used. [Sucrose, vegetable starch, glucose, glucose syrup] should be the preferred carbohydrates in RUTF. Fructose and high fructose corn syrup as ingredients should NOT be used in RUTF, because of potential adverse effects in SAM children. Only precooked and/or gelatinised starches gluten-free by nature may be added]. Recommendation 10 Food Additives and Flavours IBFAN is of the opinion that additives and flavours are an added health risk to children with SAM compromised with gut damage and in a food that is fortified with industrial nutrients. Moreover food additives and flavours are used for cosmetic purposes. Therefore IBFAN does not agree that food additives and flavours should be used as ingredients for RUTF.	

Recommendation 11 "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)." IBFAN COMMENT: If such variety of formulation is envisaged the question must be raised: why is a global Guideline necessary? Why make a claim about the benefits of harmonisation? If it is agreed that a Guideline is necessary – it is essential that it does not subvert the "UN Strategy to build capacity within countries to produce RUTF" or undermine national nutrition strategies. Section 3 of the FSMP Standard does not help. It is ambiguous and does not provide an adequate safeguard for the protection of vulnerable children. For example it refers loosely to unqualified 'scientific evidence' and its only marketing safeguard is a prohibition of advertising to the general public. This leaves the door open for the many other more subtle forms of promotion, such as sponsorship, advertising to health professionals, health and nutrition claims, fundraising appeals, press releases, donations etc. The EU Commission has recognized that its weak FSMP legislation has been exploited by the baby food industry and that claims and marketing of FSMPs for infants and young children have been misleading and have led to growth in the market and widespread inappropriate use. EU legislation that will come into force in 2020 will ban health and nutritional claims for FSMPs. Can products that are not produced according to these guidelines be labelled as RUTF? IBFAN does not agree that any formulation can be used for the treatment of SAM. If RUTF is considered necessary – National Governments have a duty to ensure that the formulation is culturally appropriate, safe and adequate. See attached briefing for the documented evidence showing that formulation with other ingredients resulted in reduced effectiveness in the treatment of SAM. Recommendation 12 Energy Add: The energy density of the formulated RUTF should be at least 5.2 - to 5.5 kcal per 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 in amounts that do not exceed the WHO recommendations for added fats and free sugars) and/or processing	

the basic raw materials and ingredients as indicated in the Section on "Technologies for and effects of processing. IBFAN is of the opinion that the energy density of 5.2 – 5.5 kcal/g should have a solid scientific basis. Recommendation 14 The recommendation of 50% of protein provided by milk products needs to be evidence based. Such a high level of cow's milk proteins may aggravate compromised ability to digest non-breastmilk proteins. Recommendation 27 IBFAN proposes that the package size should be researched to determine: a) the risk of contamination of opened and stored packages b) the possibility of overfeeding the product and the risk of reducing breastmilk intake. Recommendation 28 IBFAN recommends the additional labelling provisions: A clear statement on the label: This product is not to be sold on the open market. Nutrition, health and convenience claims are not permitted for RUTF products. There should be no idealised pictures or text To be used under medical supervision by an independent qualified health care worker. IBFAN Rationale: why has the reference to: Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997) been deleted? This contains the essential safeguard in Para 1.4 Nutrition and health claims shall not be permitted for foods for infants and young children except where specifically provided for in relevant Codex standards or national legislation. *Category : SUBSTANTIVE*	
ICAAS comment on Agenda Item 7: Proposed Draft guidelines for Ready-to-use Therapeutic Foods (RUTF).	**International Council on Amino Acid Science**

International Council on Amino Acid Science (ICAAS) was proud to be involved in the RUTF eWG. The below comment relates to the section 8.1.3.1 (protein quality) of the proposed Draft Guidelines. Background: During the 2nd consultation (June 2017), the Chairs requested the eWG Members whether they would support the proposal that the statement “50% of protein sources from milk products” be kept in square bracket until there is guidance from FAO. At the end of the 2nd consultation, the Chairs noted widespread support by Members to keep the statement in square brackets until there is FAO guidance on the determination of protein quality. Comment: Since then, a peer-reviewed paper has been published (American Journal of Clinical Nutrition 2017 Aug 16. doi: 10.3945/ajcn.117.156653). The clinical trial described in the above paper demonstrated that “soya, maize, and sorghum-RUTF enriched with essential amino acids” was: 1. as efficacious as the standard “peanut and milk-based RUTF” in the treatment of severe acute malnutrition in children. 2. better than the standard “peanut and milk-based RUTF” in correcting iron deficiency anemia. Conclusion: ICAAS believes that the above paper is relevant to the discussion on section 8.1.3.1 (protein quality) and it supports a complete removal of the restrictive stipulation to have milk protein providing 50% of protein sources in RUTF. In addition to clinical efficacy, it is important to note that a local cereal-based RUTF (such as above mentioned soya, maize and sorghum-based RUTF) would substantially lower costs, foster local production, reduce sugar intake and have a much better environmental/sustainability impact. The product in question has been in development for over ten years and has involved considerable investment by several stakeholders including Irish Aid, Prana Foundation, Japan International Cooperation Agency (JICA) and the Global Innovation Fund. *Category : TECHNICAL*	

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
1. PREAMBLE / paragraph 1	
~~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.~~ The provisions of these Guidelines are intended to provide an agreed approach to the requirements which underpin production of, and the labelling and claims for, Ready-to-use therapeutic foods. The Guidelines are intended to facilitate the harmonization of requirements for RUTF products at the international level and may provide assistance to governments wishing to establish national regulations in this area. 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 RUTFs. These Guidelines can also be used, if applicable, by	**Brazil** Brazil is of the opinion that the preamble should be condensed in order to objectively describe the appropriate use of the RUTF products and how the guideline should be used. Therefore, we would like to suggest some amendments in the draft text in order to align with other Codex texts: - The 1st paragraph could be deleted and the reference to the CAC/RCP 20-1979 included in the last paragraph. We understand that the information given by the 1st paragraph is covered by CAC/RCP 20-1979. The objectives of Codex are not mentioned, in general, in specific guidelines or standards. - Part of the last paragraph could be moved to the beginning of the preamble as it states the purpose of the guidelines. - The sentences 'Children with SAM need timely treatment and RUTF is a critical part of the treatment', 'safe, palatable foods with a high energy content and adequate amounts of vitamins, minerals and other critical nutrients' and 'primarily' should be deleted as the use of the RUTF should not be prioritized and it does not replace nor breastfeeding or adequate and healthy food with respect to the specificities of the target population. - The full reference of the International Code of Marketing of Breast-milk Substitutes should be included in the last paragraph as well as the WHA Resolutions 63.23 and 69.9 - Ending inappropriate promotion of foods for infants and young children. WHA 63.23 urged Member States to end inappropriate promotion of food for infants and young children, and to ensure that nutrition and health claims shall not be permitted for foods for infants and young children, except where specifically provided for in relevant Codex Alimentarius standards or national legislation. WHA 69.9 recognizes the role of the Codex Alimentarius Commission and requests that reviews of Codex Standards and Guidelines should give full consideration to WHO guidelines and recommendations, including the International Code of Marketing of Breast-milk Substitutes and relevant WHA resolutions. Thus, we suggest the following amendments: *Category : SUBSTANTIVE*

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
governments in case of international trade disputes. Governments and other users should be provided with the technical competent technical experts needed for good use of these guidelines.	
~~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.~~ The first paragraph shall be removed.	**MSF** MSF thinks that the following paragraph " 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. 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." is not relevant for this codex standard. *Category : EDITORIAL*
1. PREAMBLE / paragraph 2	
Children affected by severe acute malnutrition (SAM) need ~~safe, palatable foods with a high energy content and~~ adequate ~~amounts of vitamins, minerals and other critical nutrients. Children with SAM need timely~~ treatment and ~~RUTF is a critical part of the treatment~~care. RUTF are high energy, fortified, ready-to-eat foods for special medical purposes suitable for the dietary management of children with SAM. RUTF	**Brazil** *Category : SUBSTANTIVE*

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
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.	
Children affected by severe acute malnutrition (SAM) need safe, palatable foods with a high energy content and adequate 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.	**Canada** Canada supports the draft text proposed in Recommendation 1. Canada notes that the definition of RUTF is provided in the description (Section 4) and therefore may not be required in the Preamble. Canada therefore suggests removing the sentence providing a definition of RUTF in the second paragraph of the preamble *Category : EDITORIAL*

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
Children affected by ~~severe acute malnutrition (SAM)~~ undernourishment/undernutrition need safe, palatable foods with a high energy content and adequate 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.	**Colombia** Colombia supports the proposed text. However, it proposes that the term “desnutrición” in Spanish (“undernourishment”/”undernutrition”) be used in place of “malnutrición” (“malnutrition”) throughout the document, taking into account that the World Health Organisation recognises malnutrition as deficiencies, excesses or imbalances in a person’s intake of energy and/or nutrients; the term “malnutrition” covers two broad groups or conditions. One is undernourishment/undernutrition, which includes four situations: low height for one’s age, low weight for one’s height, low weight for one’s age and deficiencies or shortages of micronutrients. The other is being overweight, being obese and having non-communicable diseases related to food (such as coronary heart disease, heart attacks, diabetes and cancer). *Category : TECHNICAL*
Children affected by severe acute malnutrition (SAM) need safe, palatable foods with a high energy content and adequate 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~~	**India** 1. “Other critical nutrients” needs to be defined. A vague statement may be misused by the manufacturers for unsubstantiated health claims by including necessary ingredients 2. The statement “RUTF is a critical part of the treatment” may be deleted as many countries do not use these products for treating SAM for the want of adequate scientific evidence in their favor. 3. The statement “Since RUTF is prescribed according to weight, National Authorities may decide to include the provision of RUTF in their national protocols for use by other age groups” may be deleted as enough scientific evidence is not available to recommend their use in age groups beyond the age of 5 years. Moreover, the use of RUTF by other age-groups is not under the scope of these guidelines. *Category : SUBSTANTIVE*

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
~~of RUTF in their national protocols for use by other age groups.~~	
Children affected by severe acute malnutrition (SAM) need safe, palatable foods with a high energy content and adequate 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~~,~~ ,high fat. high sugar, 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.	**India** *Category : TECHNICAL*
Children affected by severe acute malnutrition (SAM) need safe, palatable foods with a high energy content and adequate 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~~ may be given to other age groups with various forms of malnutrition at the implementation level, the primary focus for these	**MSF** *Category : TECHNICAL*

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
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.~~ which RUTF was initially designed.	
1. PREAMBLE / paragraph 3	
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~~.~~, with the proper introduction of complementary feeding. 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.	**Colombia** Colombia proposes that the following text be included in paragraph 3: “with the proper introduction of complementary feeding”. *Category : TECHNICAL*
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 followed by age-appropriate complementary feeding (where possible using locally available foods) 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	**India** *Category : TECHNICAL*

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
meantime children who already are suffering from SAM need to receive appropriate treatment.	
1. PREAMBLE / paragraph 4	
These guidelines should therefore be used in accordance with the 2007 Joint statement of the UN agencies on Community-based management of severe acute malnutrition[1], relevant WHO Child Growth Standards[2], WHO guidelines in the management of Severe Acute Malnutrition in infants and children[3], the Global Strategy for Infant and Young Child Feeding[4], the International Code of Marketing of Breastmilk Substitutes[5] Code of Marketing of Breast-milk substitutes, Ending inappropriate promotion of foods for infants and young children (WHA 63.23 and WHA 69.9) and subsequent relevant WHA Resolutions on infant and young child ~~feeding~~feeding and the Code of Ethics for International Trade in Food including Concessional and Food Aid Transactions (CAC/RCP 20-1979). ~~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. 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~~	**Brazil** *Category : SUBSTANTIVE*

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
~~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.~~	
These guidelines should therefore be used in accordance with the 2007 Joint statement of the UN agencies on Community-based management of severe acute malnutrition[1], relevant WHO Child Growth Standards[2], WHO guidelines in the management of Severe Acute Malnutrition in infants and children[3], the Global Strategy for Infant and Young Child Feeding[4], the International Code of Marketing of Breastmilk Substitutes[5] and subsequent relevant WHA Resolutions on infant and young child ~~feeding~~feeding and the WHO Guidance on ending inappropriate marketing of foods for infants and young children. 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. 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	**India** *Category : SUBSTANTIVE*

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
the appropriate use of these guidelines.However, the guidelines are not intended for providing any programmatic recommendations for the use of RUTF in national/sub-national programme for the management of SAM and national authorities may take appropriate decisions to use alternatives like augmented home prepared foods. National Authorities should ensure that any decisions to provide food products are based on sound independent evidence and such evidence should meet WHO's definition of scientific substantiation, i.e., 'Relevant convincing / generally accepted scientificevidence or the comparable level of evidence underthe GRADE classification.' The evidence should cover resource implications, sustainability, social and economic risks, how outcomes were measured and risk of bias	
These guidelines should therefore be used in accordance with the last update of the 2007 Joint statement of the UN agencies on Community-based management of severe acute malnutrition[1], relevant WHO Child Growth Standards[2], WHO guidelines in the management of Severe Acute Malnutrition in infants and children[3], the Global Strategy for Infant and Young Child Feeding[4], the International Code of Marketing of Breastmilk Substitutes[5] 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	**MSF** *Category : EDITORIAL*

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
governments wishing to establish national regulations in this area. 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.	
3. Scope	
The provisions of these guidelines apply to Ready to Use Therapeutic Foods designed for children from age 6 to 59 months with severe acute malnutrition. Ready-to-Use Supplementary Foods (RUSF), micronutrient supplements[6], processed cereal based foods[7], formulated complementary foods for older infants and young children[8], canned baby foods[9] are not covered by these guidelines.	**MSF** *Category : EDITORIAL*
4. Description	
4.1 Ready to Use Therapeutic Foods (RUTF) are high-energy, fortified, ready-to-eat foods for special medical purposes for the dietary management of ~~children~~ children, specially infants from 6 to 59 ~~months~~ months, with severe acute malnutrition without medical complications. These foods should be soft or crushable and should be easy for children to eat without any prior preparation.	**Brazil** Given that RUTFs are given to other age groups with various forms of malnutrition at the implementation level, but the focus is children from 6 to 59 months with severe acute malnutrition without medical complications, Brazil suggests the following text: *Category : SUBSTANTIVE*

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
4.1 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 be soft or crushable and should be easy for children to eat without any prior preparation.	**Colombia** Colombia supports the proposed description, but it recommends and believes that it is essential that the term “enriquecido/fortificado” (“enriched/fortified”) (numeral 4.1) be left in the Spanish version of CX/NFSDU 17/39/7, as the English version of the text has “fortified” and the translation in Spanish is “enriquecido” (“enriched”). It is important to Colombia that the Spanish version says “enriquecido/fortificado” (“enriched/fortified”). *Category : TECHNICAL*
4.1 Ready to Use Therapeutic Foods (RUTF) are high-energy, high fats, high sugar, 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 be soft or crushable and should be easy for children to eat without any prior ~~preparation~~preparation and the availability of safe drinking water must be ensured prior to administering RUTF to children..	**India** *Category : TECHNICAL*
4.1 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~~complications **and with appetite**. These foods should be soft or crushable and should be easy for children to eat without any prior preparation.	**International Special Dietary Food Industries** ISDI supports the proposed text for 4.1 Ready to Use Therapeutic Foods (RUTF) with the following modification: 4.1 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. Justification: 2 reference documents emphasize on the necessity for malnourished child to have appetite to be given RUTF.

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
	1. The joint statement 2007 Community-based management of severe acute malnutrition, page 4 (http://www.who.int/nutrition/publications/severemalnutrition/9789280641479/en/): When there are no medical complications, a malnourished child with appetite, if aged six months or more, can be given a standard dose of RUTF adjusted to their weight. 2. Update on the management of severe acute malnutrition in infants and children, WHO, 2013 (http://apps.who.int/iris/bitstream/10665/95584/1/9789241506328_eng.pdf) : appetite is a concept mentioned through all the document, and specifically in pages 3-4-5: Criteria for inpatient or outpatient care 1.3 Children who are identified as having severe acute malnutrition should first be assessed with a full clinical examination to confirm whether they have medical complications and whether they have an appetite. Children who have appetite (pass the appetite test) and are clinically well and alert should be treated as outpatients. Children who have medical complications, severe oedema (+++), or poor appetite (fail the appetite test), or present with one or more Integrated Management of Childhood Illness (IMCI) danger signs should be treated as inpatients (strong recommendation, low quality evidence). 5. Therapeutic feeding approaches in the management of severe acute malnutrition in children who are 6–59 months of age 5.1 Children with severe acute malnutrition who present with either acute or persistent diarrhoea, can be given ready-to-use therapeutic food in the same way as children without diarrhoea, whether they are being managed as inpatients or outpatients (strong recommendation, very low quality evidence). 5.2 In inpatient settings, where ready-to-use therapeutic food is provided as the therapeutic food in the rehabilitation phase (following F-75 in the stabilization phase) Once children are stabilized, have appetite and reduced oedema and are therefore ready to move into the rehabilitation phase, they should transition from F-75 to ready-to-use therapeutic food over 2–3 days, as tolerated. The recommended energy intake during this period is 100–135 kcal/kg/day. *Category : TECHNICAL*

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
4.1 Ready to Use Therapeutic Foods (RUTF) are high-energy, fortified, ready-to-eat foods for special medical purposes designed for the dietary management of children from 6 to 59 months with severe acute malnutrition without medical complications. These foods should be soft or crushable and should be easy for children to eat without any prior preparation.	**MSF** *Category : EDITORIAL*
5. Raw Materials and Ingredients	
5. RAW MATERIALS AND INGREDIENTS	**Brazil** With regard to the use of other matrices for RUTF formulation, Brazil agrees that section 3 of the CODEX STAN 180-1991 may be used as a reference for further discussion. We are of the opinion that the guidelines should allow the use of other ingredients provided that there is scientific evidence to support the effective delivery of the nutritional requirements for the target group. Therefore, the proposed guideline should allow the use of other matrices and ingredients that are locally available, and not only those listed in the draft. *Category : SUBSTANTIVE*
5. RAW MATERIALS AND INGREDIENTS	**Colombia** Colombia supports the proposed text. *Category : TECHNICAL*
RUTF are made of powdered or ground ingredients embedded in a lipid-rich matrix [e.g. paste ~~and~~ or 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).	**Canada** Canada supports the draft text proposed in Recommendation 3. Canada notes a minor editorial comment: *Category : EDITORIAL*

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
5.1.1 ~~Milk and other Dairy Products~~Animal source foods	**Brazil** As previously commented, we suggest replacing “Milk and other Dairy Products” for “Animal Source Foods” in order to allow the extent of use of locally available ingredients and to align with CAC/GL 8-1991. Animal source foods such as meat, fish, poultry, eggs, milk and milk products are nutrient dense and good sources of high quality proteins and micronutrients. Hence, Brazil suggests the following text: *Category : SUBSTANTIVE*
5.1.1 Milk and other Dairy Products	**Colombia** Colombia supports the proposed text. *Category : TECHNICAL*
~~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).~~Animal source foods, such as meat, fish, poultry, eggs and milks and other dairy products, must comply with the relevant Codex Alimentarius texts when used in the manufacturing of RUTF.	**Brazil** *Category : SUBSTANTIVE*
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 /relevant Standard	**India** Any ingredient used in the manufacture of RUTF must comply with the relevant Standard formulated by Competent National Authority. *Category : TECHNICAL*

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
formulated by Competent National Authority 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).	
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 Codex Milk and Milk Products standards as well as** 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).	**IDF/FIL** The IDF feels the current text might restrict future technological developments for dairy ingredients therefore we would like the provision to reference the milk and milk product standards. We would therefore support the following amendment to the text: 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 Codex milk and milk products standards as well as 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). *Category : SUBSTANTIVE*
5.1.2 Legumes and ~~Pulses~~Seeds	**Canada** Canada notes that pulses are the grain seeds of legumes, and thus do not need to be specified in addition to legumes. However, Canada notes that sesame are not legumes and are therefore not captured under the section title. Canada suggests revising the title of this section to “Legumes and Seeds” *Category : SUBSTANTIVE*
5.1.2 Legumes and Pulses	**Colombia** Colombia supports the proposed text. *Category : TECHNICAL*
Legumes and pulses, such as lentils, chickpeas,	**India** Any ingredient used in the manufacture of RUTF must comply with the relevant Standard

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
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 or relevant Standard formulated by Competent National Authority when used in the manufacturing of RUTF.	formulated by Competent National Authority . Further, Peanuts and Sesame are oilseeds and not pulses and legumes. *Category : TECHNICAL*
Legumes and pulses, such as lentils, chickpeas, cowpeas, beans, peanut, sesame and other types of legumes and pulses must comply ~~with the~~ **with appropriate Codex standards such as 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.	**International Special Dietary Food Industries** ISDI supports the proposed text for 5.1.2 Legumes and Pulses with the following modifications: Legumes and pulses, such as lentils, chickpeas, cowpeas, beans, peanut, sesame and other types of legumes and pulses must comply with appropriate Codex standards such as 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. ISDI suggests reintroducing the following sentence, as per recommendation 5 of the last proposed draft 2017 eWG Consultation Paper 2 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. *Category : TECHNICAL*
5.1.3 Fats and Oils	**Colombia** Colombia supports the proposed text. *Category : TECHNICAL*
Fats and oils used in the manufacturing of RUTF must comply with the relevant Codex Alimentarius ~~texts~~texts	**India** 1. Any ingredient used in the manufacture of RUTF must comply with the relevant Standard

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
or relevant Standard formulated by Competent National Authority. Fats and oils are incorporated (within the permissble limits as per WHO recommendations) as technologically feasible for the purpose of achieving the energy density and providing essential fatty ~~acids~~acids (keeping negative health implications of high fat intake in view). Care must be taken to avoid oxidized fat which will adversely affect nutrition, flavour and shelf life. [The composition of fats and oils should allow for a product that flows during processing and ensures physical stability throughout the supply chain.	formulated by Competent National Authority. 2. WHO recommends that total fat should not exceed 30% of total energy intake. A product deriving high energy from fats is not scientifically sound and is abnormal composition for a diet. Accordingly, the guidelines should not aim to permit using fats "as much as technologically feasible" but rather keep negative health implications of high fat intake in view. 3. Further, oil and the associated energy could be incorporated in the form of oil seeds like groundnuts and sesame, rather than oil per se. Use of physically refined oils or virgin oils wherever possible could be a good option to avoid the contaminants that arise from oil refining. Saturated fats like butter or palm and coconut oil may also be incorporated as these medium chain fatty acids impart good health and wellness. *Category : TECHNICAL*
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. [The composition of fats and oils should allow for a product that flows during processing and ensures physical stability throughout the supply chain.]	**UNICEF** *Category : EDITORIAL*
Partially Hydrogenated fats and oils should not be used in RUTF.	**IDF/FIL** IDF is supportive of the proposal to restrict industrial TFA within the guidelines for ready-to use therapeutic foods through use of the clause 'Partially hydrogenated oils and fats shall not be used in RUTF products". We consider this approach to be in line with global public health, expert bodies and regulators goals in limiting TFA intakes through restriction of intakes of industrially produced TFA. *Category : SUBSTANTIVE*

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
5.1.4 Cereals	**Colombia** Colombia supports the proposed text. *Category : TECHNICAL*
5.1.4 Cereals	**EU Specialty Food Ingredients** We believe the use of the wordings “when necessary” in the first sentence is not self-explanatory and raise interpretation questions. What is meant by this? Is there a maximum limit in fibers not to be exceeded and if exceeded, then the milled cereals should be further processed to reduce this fiber content? *Category : TECHNICAL*
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~~ . 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~~ should be removed or reduced, whilst retaining maximum nutrient value.	**Canada** Canada agrees with the proposed text in Recommendation 7, but notes that this section is a run-on sentence. Canada proposes the following editorial changes *Category : EDITORIAL*
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.	**International Special Dietary Food Industries** ISDI supports the proposed text for 5.1.4 Cereals with the following modifications: 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 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. The “effects of” should be deleted to align with 5.1.2 Legumes and Pulses reintroduced sentence.

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
	Category : EDITORIAL
5.1.5 Vitamins and Minerals	**Brazil** Brazil is of the opinion that the Committee should discuss if the criteria and requirements mentioned in the following paragraph and excluded from this version of the document are already covered by CAC/GL 10-1979. It is also important to consider if there are studies and methodologies to verify if these requirements are met. 'Vitamin and mineral forms used must be soluble and easily absorbed by patients with SAM. The added minerals should be water-soluble and should not form insoluble components when mixed together. The product should have a mineral composition that will not alter the acid base metabolism of children with severe acute malnutrition.' *Category : SUBSTANTIVE*
5.1.5 Vitamins and Minerals	**Colombia** Colombia supports the two proposals. *Category : TECHNICAL*
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).	**India** This needs discussion as the scope of the proposed products is 0-59 months. Referred advisory list is for infants and young children *Category : TECHNICAL*
All added vitamins and minerals must be in accordance with the principles of *Advisory Lists of Nutrient Compounds for use in Foods for Special Dietary Uses Intended for Infants and Young Children* (CAC/GL 10-1979).	**UNICEF** Many minerals listed in CAC/GL 1979 are not adapted for children with SAM. Children with SAM have a reduced gastric acidity and are unable to dissolve minerals which are usually dissolved in acids in the stomach. Some forms of minerals included in CAC/GL 1979 are not soluble at high stomach pH and there is a risk they will be poorly absorbed by a malnourished child. Secondly, some mineral forms and their combinations may lead to complications such as metabolic acidosis, as malnourished children are less capable of excreting excess acids due to their deficient state. Therefore UNICEF proposes that the forms of the minerals are specified within the RUTF guideline for each mineral nutrient

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
	Category : TECHNICAL
5.2.1 Available Carbohydrates[1]	**Brazil** Brazil is of the opinion that the quantity of free sugars used in RUTF should be restricted in light of the WHO (1) recommendations. It is important to take into account the WHO (2015) recommendation to reduce the intake of free sugars to less than 10% of energy and conditionally recommended a further reduction to less than 5% of energy for both adults and children. Furthermore, it is important to note that high levels of free sugars may not be appropriated to SAM, considering potential undesirable effects such as hyperglycaemia, hyperinsulinemia and osmotic diarrhoea. (1) WHO. Guideline: Sugars intake for adults and children. Geneva: World Health Organization; 2015. *Category : SUBSTANTIVE*
5.2.1 Available Carbohydrates[1]	**EU Specialty Food Ingredients** We think the term “available” is confusing. We prefer the term which was used in the previous consultation “digestible” as this is more commonly used. We note that the list of preferred carbohydrates remains in brackets. We don’t understand why maltodextrin is not included when glucose syrup and starch are. The different between these 3 ingredients is the DE value and maltodextrin is a DE value between starch and glucose syrup. In addition, maltodextrin is well digested and does not contain fructose. We don’t understand the wording “vegetable starch”. Starch usually comes from cereals, legumes or potatoes. The wording “plant starch” would be more appropriate but “starch” without further qualification is fully understandable. We don’t understand why “Only precooked and/or gelatinised starches gluten-free by nature may be added”. Gluten is not considered as an issue in children with SAM. RUTFs are not intended for infants for whom gluten should be avoided but for children from 6 to 59 months where this restriction is not scientifically necessary. *Category : SUBSTANTIVE*
5.2.1 ~~Available~~ Carbohydrates[1]	**International Special Dietary Food Industries**

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
	Category : TECHNICAL
The palatability of the RUTF can be increased by the addition of ~~appropriate~~ available carbohydrates.	**International Special Dietary Food Industries** *Category : TECHNICAL*
Available carbohydrates must adhere to the relevant Codex Alimentarius ~~texts.~~texts and should not exceed WHO recommendations on maximum intake of free sugars in diet	**India** WHO recommends that intake of free sugars should be limited to less than 10% of total energy intake. Therefore, in pursuit to increase the energy density and palatability of RUTF by addition of digestible carbohydrates, health implications of high sugar intake must be kept in view in addition to adherence to relevant Codex Alimentarius texts. *Category : TECHNICAL*
~~Available carbohydrates~~ Carbohydrates must adhere to the relevant Codex Alimentarius texts.	**International Special Dietary Food Industries** ISDI supports the proposed text for 5.2.1 Available Carbohydrates with the following modifications: 5.2.1 Carbohydrates1 The palatability of the RUTF can be increased by the addition of appropriate carbohydrates. 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. Justification: ISDI seeks further clarification on the appropriateness of the term “available carbohydrates”, because the term is not consistently used throughout Codex text as shown below. IF/iFSMP standard: CODEX STAN 72 – 1981 COMPOSITION Total carbohydrates*) Unit Minimum Maximum GUL g/100 kcal 9.0 14.0 -

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
	g/100 kJ 2.2 3.3 - *) Lactose and glucose polymers should be the preferred carbohydrates in formula based on cows' milk protein and hydrolysed protein. Only precooked and/or gelatinised starches gluten-free by nature may be added to Infant Formula up to 30% of total carbohydrates and up to 2 g/100 ml. Guidelines on nutrition labelling: CAC/GL 2-1985 (Rev. 1 - 1993) 1. Sugars means all mono-saccharides and di-saccharides present in food. 2. Listing of nutrients: The amounts of protein, available carbohydrate (i.e., carbohydrate excluding dietary fibre) and fat; 3. The presence of available carbohydrates should be declared on the label as "carbohydrates". Where the type of carbohydrate is declared, this declaration should follow immediately the declaration of the total carbohydrate content in the following format: "Carbohydrate... g, of which sugars... g". This may be followed by the following: "x"... g where "x" represents the specific name of any other carbohydrate constituent. FUF standard: CODEX STAN 156 – 1987 Carbohydrates: The product shall contain nutritionally available carbohydrates suitable for the feeding of the older infant and the young child in such quantities as to adjust the product to the energy density in accordance with the requirements set out in Section 3.1. PROCESSED CEREAL-BASED FOODS standard: CODEX STAN 074-1981, REV. 1-2006 NUTRIENT CONTENT CARBOHYDRATES: 3.4.1 If sucrose, fructose, glucose, glucose syrup or honey are added to products mentioned in CANNED BABY FOODS standard: CODEX STAN 73-1981 DECLARATION: The declaration of nutrition information shall contain the following information which should be in the following order: The amount of energy, expressed in Calories (Kcal) and/or kilojoules (kJ), and the number of grammes of protein, carbohydrate and fat per 100 grammes of the food as sold as well as per specified quantity of the food as suggested for consumption; *Category : TECHNICAL*
Honey should not be used in RUTF due to the risk of	**Colombia**

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
infant botulism from *Clostridium botulinum.*	Colombia supports the three proposals and proposes that the name of the micro-organism be written in italics in the Spanish version of CX/NFSDU 17/39/7. *Category : TRANSLATION*
[1][Sucrose, vegetable starch, 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~~ undernourishment'/'undernutrition' children. Only precooked and/or gelatinised starches gluten-free by nature may be added].	**Colombia** *Category : TECHNICAL*
[1][Sucrose, vegetable starch, 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].	**Colombia** Colombia supports the decision not to establish minimum or maximum values or NSR for carbohydrates. *Category : TECHNICAL*
[1][Sucrose, vegetable starch, glucose, glucose syrup] should be the preferred carbohydrates in RUTF. Fructose and corn syrup as ingredients should not be ~~avoided~~ used in RUTF, because of potential adverse effects in SAM children. Only precooked and/or gelatinised starches gluten-free by nature may be added].	**India** *Category : TECHNICAL*
[1][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].	**International Special Dietary Food Industries** ISDI supports the proposed text with the following modifications: 1[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]. *Category : TECHNICAL*

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
5.2.2 Food Additives and Flavours	**Colombia** Colombia supports the proposed text. *Category : TECHNICAL*
[This section will make reference to the *General Standard for Food Additives* (CODEX STAN 192-1995)].	**India** India is of opinion that foods for older infants and young children should not include food additives and flavors. These are primarily for aesthetic and cosmetic purposes and expose the vulnerable gut of a child suffering from SAM to unnecessary chemicals, many of which have detrimental effects and can prolong rehabilitation. Exposing infants to unnecessary chemicals at such an early age adds to the lifelong chemical burden. Examples of detrimental effects of some of the additives currently being used are as follows: Benzoates: In a report from Thailand, Sodium benzoate has been reported to be mutagenic and cytotoxic which may have serious health implications. Use of this additive, therefore may be dangerous for the health of children. Carmine: Cochineal carmine, or simply carmine (E120), is a red colouring that is obtained from the dried bodies of the female insect Dactylopiuscoccus Costa (the cochineal insect). A number of cases of an IgE-mediated hypersensitivity due to carmine following ingestion have been reported which requires due diligence before allowing this additive in RUTF. US FDA requires carmine to be identified by name on the food label due to the risk of potential allergic reaction. Polysorbates: Polysorbate 80 can cause severe nonimmunologic anaphylactoid reactions and therefore its' use as an additive requires due diligence *Category : SUBSTANTIVE*
[This section will make reference to the *General Standard for Food Additives* (CODEX STAN ~~192-1995)]~~ 192-1995) and the *Guidelines for the Use of Flavourings* (CAC/GL 66-2008)].	**IOFI** *Category : EDITORIAL*
5.3 The Use of other Matrices in RUTF formulation	**Colombia** Colombia supports the proposed text. *Category : TECHNICAL*

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
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).	**India** Any decisions regarding the composition of these products must be based on evidence that meets WHO's definition of scientific substantiation: "Relevant convincing / generally accepted scientific evidence or the comparable level of evidence under the GRADE classification'. Moreover, the Codex STAN 180-1991, in the para on General Principles states, "formulation of foods for special medical purposes should be based on sound medical and nutritional principles. Their use should have been demonstrated, by scientific evidence, to be safe and beneficial in meeting the nutritional requirements of the persons for whom they are intended."Availablescientific evidence suggests that effectiveness of RUTF formulations using ingredients other than milk powder as a protein source like soya is sub-optimal. While considering new formulation with other ingredients in accordance with the general principles mentioned in the Standard for Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991) several scientific studies have reported that use of formulation with other ingredients are less effective in terms of recovery rates in comparison to standard, pea-nut and milk (25%) based formulation (see below). • An equivalence non-blinded cluster randomized controlled trial from Zambia has found that the effectiveness of a milk-free soy-maize-sorghum-based RUTF (SMS-RUTF) with 25% milk content in standard peanut-based RUTF (P-RUTF) in treatment of children with SAM is not equal, recovery rates being lower in children who received SMS-RUTF. • A randomized, double blind, clinical, quasi-effectiveness trial from Malawi has concluded that treating children with SAM with 10% milk (plus Soy) RUTF is less effective compared with treatment with the standard 25% milk RUTF. Recovery among children receiving 25% milk RUTF was greater than children receiving 10% milk RUTF, 64% compared with 57% after 4 wk, and 84% compared with 81% after 8 wk (P< 0.001). Children receiving 25% milk RUTF also had higher rates of weight and height gain compared with children receiving 10% milk RUTF. *Category : SUBSTANTIVE*
The energy density of the formulated RUTF should be at least 5.2 - to 5.5 kcal per gram. The energy density of ~~the~~ RUTF can be achieved during manufacturing by the addition of energy containing ingredients (i.e. fats	**Canada** Canada agrees with Recommendation 12, and proposes the following editorial changes *Category : EDITORIAL*

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
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~~8.	
The energy density of the formulated RUTF should be at least 5.2 - to 5.5 kcal per 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.	**Colombia** Colombia supports the proposed text and energy values. *Category : TECHNICAL*
The energy density of the formulated RUTF should be at least 5.2 - to 5.5 kcal per 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.	**India** This is empirical and hence needs more discussion before finalising a value. Also, additional energy required will depend on the amount of breastmilk the older infant and young child is receiving. Further, WHO recommends that intake of free sugars should be limited to less than 10% of total energy intake. Therefore, in pursuit to increase the energy density and palatability of RUTF, digestible carbohydrates should keep health implications of high sugar intake in view in addition to relevant Codex Alimentarius texts. *Category : TECHNICAL*
The energy density of the formulated RUTF should be ~~at least~~ between 5.2 - to 5.5 kcal per 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.	**International Special Dietary Food Industries** ISDI supports the proposed text in 6.1 Energy with the following modifications: The energy density of the formulated RUTF should be between 5.2 - to 5.5 kcal per 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.

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
	Category : EDITORIAL
6. Nutritional Comopsition and Quality Factors	
6.2 Proteins	**Brazil** Brazil notes that some members indicated that the wording “50% of protein sources from milk products” should not be removed since there is no scientific evidence of products with other protein source other than milk that have been demonstrated to be efficient for the management of SAM children. However, we think that other sources of high quality protein could also be considered. Dietary protein quality should be based on the latest available methods as recommended by FAO (PDCAAS or DIAAS). Hence, we agree with the proposal to keep the wording “50% of protein sources from milk products” in square bracket until there is guidance from FAO. It is important to note that other approaches based on the quality of the protein (and not only on the source) is used in other relevant Codex Standards, such as CODEX STAN 72-1981. *Category : SUBSTANTIVE*
["at least 50% of protein is provided by milk products"]	**Canada** Canada notes that it would be desirable to allow for formulations without a minimum of 50% of protein from milk products but it is not clear that there is enough information at this time to set guidelines for such products. Canada therefore agrees with the proposal not to remove the square brackets from “50% of protein sources from milk products” until there is clearer guidance from FAO on protein quality. *Category : TECHNICAL*
["at least 50% of protein is provided by milk products"]	**Colombia** Colombia supports keeping the statement. *Category : TECHNICAL*
["at least 50% of protein is provided by milk products"]	**HKI** 6.2 Proteins: While likely beneficial, the minimum dairy protein requirement is not based on scientific evidence, but rather on “best guesses”. In addition, unless backed by evidence, setting such a high level of protein from milk products is unnecessarily restrictive - it undermines/does not support ongoing product innovation i.e the development of alternative

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
	RUTF recipes using other high quality protein sources that may have similar impact on both anthropometric and functional recovery; and which could ultimately decrease the high cost of RUTF. (Note Bahwere et al have recently conducted a nonblinded, 3-arm, parallel-group, simple randomized controlled trial that enrolled Malawian children with severe acute malnutrition. It showed that an amino acid–enriched milk-free soya, maize, and sorghum (FSMS)–RUTF and an amino acid–enriched low milk, soya, maize, and sorghum (MSMS)–RUTF containing 9.3% milk were as efficacious as the standard peanut and milk based RUTF in terms of recovery rates and length of stay. (Am J Clin Nutr, 2017)). Finally, we believe that the quality of protein based on PDCAAS/DIAAS, in addition to the source, should be prioritized. *Category : TECHNICAL*
~~["at~~ "at least 50% of protein is provided by milk ~~products"]~~products"	**IDF/FIL** IDF strongly disagrees that the statement “at least 50% of protein is provided by milk products” should be kept in square brackets. Globally, it is estimated that as a result of undernutrition, 155 million children are stunted and 7.7% of children are wasted. This is a global, critical public health emergency. Severe acute malnutrition contributes to about 45% of deaths in children under age 5 (WHO, 2016). Therefore, the RUTF Guideline will greatly impact the lives and mortality of those suffering from severe acute malnutrition. The mandate is for safe, efficacious RUTF products. There are numerous studies showing that dairy ingredients are effective in RUTF used in the treatment and recovery of severe acute malnutrition and there is no scientific evidence showing the need to remove milk from RUTF. In the scientific literature, to date, there are no published studies showing that plant and pulse-based RUTF are superior to dairy-containing RUTF. We believe milk should remain the principal ingredient for these products, at least until such a time that valid, sound evidence shows an equivalent protein source is available which

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
	meets the amino acid, micronutrient, and macronutrient needs of malnourished children, and which is as at least as effective in enabling the long-term recovery from severe acute malnutrition. Studies that have directly compared RUTF which contain at least 50% of the protein from milk dairy vs other forms of RUTF have shown they are more effective in the dietary management of children ages 6 to 59 months with SAM. • Overall findings from four studies indicate that RUTF containing lower amounts of dairy ingredient, i.e., dairy protein replaced with non-dairy protein sources, are not as effective for the treatment of SAM. However, replacing skim milk powder with another dairy protein source (whey) can be equally effective. o Oakley et al., (2010) conducted a randomized, double-blind clinical study comparing the efficacy of a RUTF containing 10% milk supplemented with soy vs. a RUTF with 25% milk, with care taken to balance both macro- and micro-nutrients.7 Results showed consumption of the 25% milk RUTF formulation resulted in a significantly better rate of recovery and growth rate. Rates of weight, height, and MUAC gain were also higher with the 25% Milk RUTF. o Irena and co-workers (2015) tested the hypothesis that a milk-free RUTF made with soy, maize and sorghum would have equivalent effects as RUTF containing 25% milk on recovery rates.8 They found that the milk-containing RUTF produced significantly better rates of weight gain and recovery vs. the non-milk RUTF; recovery was particularly improved among children less than 2 years o Bahwere et al., (2016) compared the efficacy of a milk-free RUTF made with soy, maize and sorghum (SMS-RUTF) with a standard peanut based RUTF containing 25 percent milk. The study found that SMS-RUTF was not inferior to the peanut based milk RUTF for recovery rate, weight gain and length of stay in children greater than 24 months of age. However, in children 6 to 24 months of age, recovery rate with SMS-RUTF supplementation was inferior to the peanut based milk RUTF. In this study there was no clinically relevant catch up height for age during treatment and no significant differences in linear growth. In fact, the severity of stunting in children ages 6 to 23 months at enrolment slightly increased. Further data showed an inferior response to the milk-free RUTF in children aged less than two years.

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
	o Bahwere et al., (2014) compared the effects of RUTF containing whey protein (WPC34) vs a RUTF containing dried skimmed milk (DSM).10 Overall results indicated that RUTF containing whey is equally effective as an RUTF containing dry skim milk Both the use of dairy protein and milk minerals allow the use of poorer-quality protein sources to be used; therefore, it does not stifle innovation – it encourages it. Mandating that 50% of the protein in RUTF allows use of different dairy protein sources which provide formulation flexibility to lower costs. It also fosters innovation for the remaining 50% of the protein where beans, pulses, and other locally available protein sources can be considered and tested among this group. Dairy ingredients can be used in variable combinations to meet local preferences, lower cost and achieve excellent acceptability. The use of locally-available ingredients also lower costs. • A linear programming tool for modeling new RUTF formulations has been developed and tested (Ryan et al., 2014). These researchers used this tool to demonstrate that through the use of linear programming, low-cost, optimized country-specific, alternative RUTF products for SAM recovery could be developed.11 The products contained a variety of dairy ingredients (milk powder, acid whey, whey protein concentrate 34 percent and whey protein concentrate 80 percent), and demonstrated how dairy ingredients can be used in variable combinations to meet local preferences, lower cost and achieve excellent acceptability. The use of locally-available ingredients also lower costs. • Weber et al., (2016) used linear programming to formulate and produce RUTF using local ingredients for testing in Ethiopia, Ghana, Pakistan and India.12 Products were then tested for acceptability in 50 children from each country with MAM due to ethical reasons of conducting an acceptability trial with children with SAM. The RUTF produced all included dairy proteins other than milk and were compared to standard peanut-based RUTF containing milk. Ingredient costs of the formulations were about 60% of standard RUTF. RUTF products were consumed and preferred equally as well as standard RUTF in Ethiopia, Ghana and India. In Pakistan, while the products were equally consumed, mothers perceived the children preferred the standard peanut based RUTF made with milk. The products will undergo further testing prior to being used in equivalency trials. • Equivalency trials are now underway in some of the countries using the new formulated products.

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
	A recommendation change such as "removing all milk-sourced products from all RUTF formulations" should require a large body of evidence. A recently published study by Bahwere and others claims that RUTF without milk is efficacious in the treatment of severe acute malnutrition in children aged 6–23 and 24–59 months (Bahwere et al., 2017). Effectiveness trials should be held to prove that such a change would actually work in real-life settings, rather than in tightly controlled, feeding observational settings, such as the ones conducted in this particular study. It should also be noted that in this study, the researchers used a commercialized amino acid matrix in the RUTF formulation which would impact the results. Furthermore, although the authors of this study suggest “cost-savings” by removing all dairy products, no actual cost-effectiveness analyses was conducted. References: • Oakley E, Reinking J, Sandige H, et al. A ready-to-use therapeutic food containing 10% milk is less effective than one with 25% milk in the treatment of severely malnourished children. J. Nutr. Dec 2010;140(12):2248-2252. • Irena AH, Bahwere P, Owino VO, et al. Comparison of the effectiveness of a milk-free soy-maize-sorghum-based ready-to-use therapeutic food to standard ready-to-use therapeutic food with 25% milk in nutrition management of severely acutely malnourished Zambian children: an equivalence non-blinded cluster randomised controlled trial. Maternal & child nutrition. Dec 2015;11 Suppl 4:105-119. • Bahwere P, Balaluka B, Wells JC, et al. Cereals and pulse-based ready-to-use therapeutic food as an alternative to the standard milk- and peanut paste-based formulation for treating severe acute malnutrition: a noninferiority, individually randomized controlled efficacy clinical trial. Am. J. Clin. Nutr. Apr 2016;103(4):1145-1161. • Bahwere P, Banda T, Sadler K, et al. Effectiveness of milk whey protein-based ready-to-use therapeutic food in treatment of severe acute malnutrition in Malawian under-5 children: a randomised, double-blind, controlled non-inferiority clinical trial. Maternal & child nutrition. Jul 2014;10(3):436-451. • Bahwere P, Akomo P, Mwale M, et al. Soya, maize, and sorghum-based ready-to-use

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
	therapeutic with amino acid is as efficacious as the standard milk and peanut paste-based formulation for the treatment of severe acute malnutition in children: A noninferiority individually randomized controlled efficacy clinical trial in Malawi. Am. J. Clin. Nutr. Aug 2017 published ahead of print • Ryan KN, Adams KP, Vosti SA, Ordiz MI, Cimo ED, Manary MJ. A comprehensive linear programming tool to optimize formulations of ready-to-use therapeutic foods: an application to Ethiopia. Am. J. Clin. Nutr. Dec 2014;100(6):1551-1558. • Weber JM, Ryan KN, Tandon R, et al. Acceptability of locally produced ready-to-use therapeutic foods in Ethiopia, Ghana, Pakistan and India. Maternal & child nutrition. Jan 18 2016. • UNICEF, WHO, World Bank Group. 2017. Joint malnutrition estimates. https://data.unicef.org/wp-content/uploads/2017/06/JME-2017_brochure_June-25.pdf. *Category : SUBSTANTIVE*
["at least 50% of protein is provided by milk products"] Protein should provide 10%-12% of the total energy.	**International Special Dietary Food Industries** ISDI supports the proposed text in 6.2 Protein with the following modifications: ["at least 50% of protein is provided by milk products"] ISDI suggests reintroducing the following sentence, as per recommendation 13 of the last proposed draft 2017 eWG Consultation Paper 2 RUTF: Available Protein should provide 10%-12% of the total energy. Justification: ISDI seeks further clarification on the appropriateness of the term “available protein”, because the term is not generally used in CODEX text. The following standards for example make use of the term “protein”: - IF/iFSMP standard: CODEX STAN 72 – 1981 - FUF standard: CODEX STAN 156 – 1987 - Guidelines on nutrition labelling: CAC/GL 2-1985 (Rev. 1 - 1993) *Category : TECHNICAL*
["at least 50% of protein is provided by milk products"]	**UNICEF** UNICEF supports the inclusion of a PDCASS score to define the quality of the protein in

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
	RUTF. This value should reflect an RUTF made with 50% protein provided by milk products *Category : TECHNICAL*
6.3 Fat	**Colombia** Colombia supports keeping the values for essential fatty acids. *Category : TECHNICAL*
6.3 Fat	**EU Specialty Food Ingredients** We note that the complete paragraph on fats remains in square brackets. We have a comment related to the wording for the expression of the energy from fats. It should be written either as “At least 45% of energy derived from fat is desirable” or “45% to 60% of energy derived from fat is desirable”. When using a range, it does not make sense to say “at least”. We firmly believe, as expressed in our previous comments, that children suffering from SAM would benefit if adequate PUFAs (LA and ALA) could be added as part of the fat content, as well as LC-PUFA (DHA and ARA) and should receive at least the same level recommended for healthy children. This is not the case with the current wording which only mentions a minimum for linoleic acid as well as a ratio between linoleic and alpha-linolenic acids, worded as follows: “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”. We are unsure about the meaning of the sentence on LA and ALA which indicates “when used in the production of RUTF”. This seems to indicate that the minimum LA level as well as the ratio range is optional. We question the addition of “when used in the production of RUTF” in the sentence and respectfully request removal of this unnecessary and potentially confusing phrase. Furthermore, the proposed minimum value of 576.9 mg/100 kcal for LA with the proposed range for the ratio between LA:ALA means that ALA would be between 38.46 and 115.38 mg/100 kcal. In order to achieve the appropriate minimum level of DHA the ratio of LA:ALA should be no higher than 10:1. We believe the minimum level of ALA for RUTF should not be set below the value established by all other RASB for healthy children (see table below). It is therefore respectfully requested that RUTF be made to harmonize with existing and emerging standards for healthy children. There is little if no justification for denying SAM

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
	children the same access to a minimum threshold for key fatty acids as healthy children. Given that the Chairs have also opted not to propose a minimum level addition of DHA to RUTF, the level of ALA becomes even more important. While a poor precursor DHA production in vivo, ALA does to a very limited degree act to support blood DHA levels. If ALA levels in RUTF are already below that needed to prevent ALA deficiency, the opportunity for in vivo DHA production will be practically eliminated. In addition and, as explained in our contribution to CP2, recent studies on SAM children clearly indicate the need for LC-PUFAs. In particular, Babirekere-Iriso et al. (2016) recently concluded "Thus, the current recommended therapeutic feeds for rehabilitating children with SAM are not able to correct their whole-blood LCPUFA compromised status. Although there were significant increases in n-6 LCPUFA values during treatment, the decreases in n-3 LCPUFA and AA proportions from admission to discharge pose particular concern, as AA and DHA play important functional roles in the brain, retina and immune system." "…formulations with higher n-3 PUFA contents to decrease n-6:n-3 ratio and preformed LCPUFA may need to be considered in therapeutic diets for children with SAM."(preformed LCPUFA being DHA and AA). Consistent with the above observation, results from a randomized controlled trial of SAM children in Kenya indicates the necessity of adding DHA to RUTF (Jones et al., 2015). Specifically, children treated with traditional RUTF were found to have declining DHA levels during and after treatment compared to those supplemented also with fish oil capsules. These results led the authors to conclude, "PUFA requirements of children with SAM are not met by current formulations of RUTF, or by an RUTF with elevated short-chain n-3 PUFA without additional preformed long-chain n-3 PUFA". (Jones et al., 2015). A level of at least 20 mg DHA/100 kcal (suggested GUL - 50 mg DHA/100 kcal), and an equal amount of ARA, should also be added to RUTF. This level would be expected meet adequate intake levels indicated for healthy children 6-24 months (EFSA, 2010; EFSA, 2014). If defining a minimum level of these critical nutrients is beyond the expertise of this eWG, we respectfully request that optional addition language for DHA and ARA from the current infant formula standard be considered for LC-PUFA in the RUTF guidelines. Recommended ALA Minimums from RASBs vs RUTF eWG Proposal

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
	Codex Stan 156-1987 (Follow-up formula, revision in progress, values proposed in 2015 working group consultations) - Recommended ALA Minimum Level: 50 mg/100 kcal (0.5% E) EFSA, 2014. (Essential composition of infant and follow-on formula) - Recommended ALA Minimum Level: 50 mg/100 kcal (0.5% E) FAO/WHO Expert Consultation, 2010. FAO, 2010. Fats and Fatty Acids in Human Nutrition. FAO Food and Nutrition Paper 91. ISSN 0254-4725 - Recommended ALA Minimum Level: 6-24 mo AI 0.4-0.6% E European Food Safety Authority, 2010. Scientific Opinion on Dietary Reference Values for fats, including saturated fatty acids, polyunsaturated fatty acids, monounsaturated fatty acids, trans fatty acids, and cholesterol. EFSA Journal 2010; 8:1461. http://www.efsa.europa.eu/en/scdocs/doc/1461.pdf - Recommended ALA Minimum Level: 0.5 % E Agence Français de Sécurité Sanitaire des Aliments, 2006/2010 AFSSA Opinion Regarding the Update of the Recommended Dietary Intake for Fatty Acids. AFSSA-opinion 2006-SA-0359. Published in 2010. - Recommended ALA Minimum Level: 6-12 months: 0.45% E 1 to 3 years: 0.45% E 3 to 9 years: 1.0% E References: Babirekere-Iriso et al. Changes in whole-blood PUFA and their predictors during recovery from severe acute malnutrition. British Journal of Nutrition (2016), 115, 1730–1739.

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
	EFSA Panel on Dietetic Products, Nutrition, and Allergies (NDA); Scientific Opinion on Dietary Reference Values for fats, including saturated fatty acids, polyunsaturated fatty acids, monounsaturated fatty acids, trans fatty acids, and cholesterol. EFSA Journal 2010; 8(3):1461. EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2014. Scientific Opinion on the essential composition of infant and follow-on formulae. EFSA Journal 2014;12(7):3760. *Category : SUBSTANTIVE*
6.3 ~~Fat~~Lipids	**International Special Dietary Food Industries** *Category : EDITORIAL*
[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.	**Colombia** Colombia supports the proposed text in square brackets. *Category : TECHNICAL*
~~[Incorporation of fats and/or oils in RUTF serves to increase the energy density and the amount of essential fatty acids. At least~~ Lipids should provide 45% to 60% of ~~energy derived from fat is desirable.~~ the total energy.	**International Special Dietary Food Industries** ISDI suggests the following modification for 6.3 Fat section: 6.3 Lipids Lipids should provide 45% to 60% of the total energy. Justification: The deleted part has already been provided in section 5.1.3. The proposed working is similar to the one in section 6.2, hence more appropriate. *Category : EDITORIAL*
The level of linoleic acid should not be less than 576.9 mg per 100 kcal when used in the production of RUTF	**India** WHO recommends that total fat should not exceed 30% of total energy intake. A product

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
and should ensure a ratio between linoleic acid and alpha-linolenic acid of between 5:1 and 15:1.]	deriving high energy from fats is not scientifically sound and is abnormal composition for a diet. Accordingly, the guidelines should not aim to permit using fats as much as technologically feasible but rather keep negative health implications of high fat intake in view. However, if WHO advice of keeping fat level below 30% is not observed, the label should include text saying that "This is a high fat product." *Category : TECHNICAL*
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~~ RUTF. The level of linoleic acid should ensure a ratio between linoleic acid and alpha-linolenic acid of between 5:1 and 15:1.~~]~~	**International Special Dietary Food Industries** ISDI suggests the following modification for 6.3 Fat section: The level of linoleic acid should not be less than 333 mg per 100 kcal when used in the production of RUTF. The level of linoleic acid should ensure a ratio between linoleic acid and alpha-linolenic acid of between 5:1 and 15:1.] Justification: 1.According to the recommendation 16 of the last proposed draft 2017 eWG Consultation Paper 2 RUTF, the text should include the range for linoleic acid and alpha linoleic acid, which comply with the joint statement: 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] ISDI believes that mathematically the given value is not compatible with the specification given in the range as a minimum: - Being given that minimum is 3 kcal/100kcal - Being given that 1g of lipid □9 kcal - 3 kcal □ 0.333g = 333 mg Therefore, the minimum should be 333 mg/100kcal. Alpha- linolenic acid = 0.3-2.5% of total energy

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
	[The level of alpha-linolenic acid should not be less than 57.69 mg per 100 kcal] ISDI believes that mathematically this value is not compatible with the specification given in the range as a minimum: - Being given that minimum is 0.3 kcal/100kcal - Being given that 1g of lipid □9 kcal - 0.3 kcal □ 0.0333g = 33 mg Then the minimum should be 33 mg/100kcal. ISDI believes that the following proposed statement needs further discussion, as has not appeared in the joint statement before, has not been indicated in the conclusion of the recommendation 16 of the last proposed draft 2017 eWG Consultation Paper 2 RUTF, and is not supported by scientific evidences for the treatment of severe acute malnutrition. 3. The level of linoleic acid should ensure a ratio between linoleic acid and alpha-linolenic acid of between 5:1 and 15:1.] *Category : TECHNICAL*
7. Contaminants	
7. CONTAMINANTS	**EU Specialty Food Ingredients** The proposed text refers to “maximum residue limits and maximum levels established by the Codex Alimentarius Commission” without further referencing the appropriate Codex documents. *Category : TECHNICAL*
7. CONTAMINANTS	**International Special Dietary Food Industries** ISDI believes that between section 6.3 Fat and 7. CONTAMINANTS there should be a Vitamins and Minerals section with the following proposed text: Please see Annex “Nutrition Composition for RUTF”. *Category : EDITORIAL*
[It is recommended that the products covered by the provisions of these guidelines and the ingredients used in such products comply with the *General Standard for Contaminants and Toxins in Food and Feed* (CODEX	**Canada** Canada agrees with the proposed draft text in this section, including the removal of the aflatoxin maximum. Canada proposes the following revisions *Category : SUBSTANTIVE*

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
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~~.~~ Future consideration may also be given to determining if all of the contaminant MLs in the General Standard for Contaminants and Toxins in Food and Feed are applicable to children with a pre-existing condition such as SAM	
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.~~]	**Colombia** Colombia supports the proposal not to include the maximum level of aflatoxins of 10 ppb in the draft text of the Guidelines until agreement is reached regarding the best approach for managing the contaminants present in the RUTF. *Category : TECHNICAL*
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.~~]	**India** The maximum level of permissible Aflatoxin RUTF should be 5 ppb (µg/kg). In a report by UNICEF (2013-14), of all the samples tested, 99.5% had Aflatoxin < 5ppb µg/kg. Therefore, there is no need to provide a bigger window for this harmful contaminant. *Category : TECHNICAL*
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	**International Special Dietary Food Industries** ISDI supports the proposed text in section 7. CONTAMINANTS with the following modifications:

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
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.~~] [A maximum of 10 ppb (µg/kg) for aflatoxin is allowed in the RUTF products].	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]. Justification: WHO has already worked on the provision of instructions for the maximum allowance level of aflatoxin in the RUTF. 1. The WHO joint statement 2007 (http://www.who.int/nutrition/publications/severemalnutrition/9789280641479/en/). The body of the statement it is mentioned: “Update 2011. The Joint Statement has been updated to reflect the revised MUAC cut-off of 115 mm on pages 2 and 3. The maximum aflatoxin level has been revised to 10 parts per billion on page 6.” 2.The 2 presentations from UNICEF mention information regarding afladoxin. - Presentation 1 (http://www.who.int/nutrition/publications/severemalnutrition/9789280641479/en/): On page 12, the UNICEF specifications are given: 10 mcg per kg max - 10 parts per billion - 10 ppb. - Presentation 2 (https://www.unicef.org/supply/files/6a_Peter_Svarrer_Jakobsen_UNICEF_aflatoxin_results.pdf): UNICEF presents an overview of the quality of RUTF purchased in 2013-2014 regarding aflatoxin. *Category : TECHNICAL*

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
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.~~]	**UNICEF** There has been no investigation of the risks of known contaminants within RUTF for SAM children, specifically in reference to the contaminants to be controlled within RUTF. Further guidance on these issues is needed to ensure the Codex Guideline for RUTF makes recommendations as to how best to protect the target group of RUTF, with specific reference to contaminants such as mycotoxins, including but not limited to aflatoxins. *Category : TECHNICAL*
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~~ products' starting materials 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.~~]	**UNICEF** *Category : TECHNICAL*
8. Technologies for and Effect for Processing	
8. PROCESSING TECHNOLOGIES ~~FOR AND EFFECT FOR PROCESSING~~	**Canada** Canada notes that the title of this section, "Technologies for and effect for processing" is not clear. Canada suggests “Processing Technologies” for the title. *Category : EDITORIAL*
8. TECHNOLOGIES FOR AND EFFECT FOR PROCESSING In addition to the practices described below, Good Hygiene Practices (General principles of food hygiene CAC/RCP 1-1969) should be implemented to avoid	**International Special Dietary Food Industries** Under the title 8. TECHNOLOGIES FOR AND EFFECT FOR PROCESSING ISDI suggests adding the following sentence: In addition to the practices described below, Good Hygiene Practices (General principles of food hygiene CAC/RCP 1-1969) should be implemented to avoid cross contamination during the packing and storage of raw materials.

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
cross contamination during the packing and storage of raw materials.	Justification: According to the recommendation 4 of the last proposed draft 2017 eWG Consultation Paper 2 RUTF, this sentence should be added. *Category : EDITORIAL*
8.1 Preliminary Treatment of Raw Materials	**Colombia** Colombia generally supports the proposed text, but it recommends adding the following clarification for the roasting stage: “The use of appropriate enzymes may reduce the antinutrients in ingredients (see CAC/GL 8-1991).” *Category : TECHNICAL*
8.3 Toasting	**EU Specialty Food Ingredients** We support the addition in square brackets of appropriate enzymes. Enzymes such as phytase can substantially reduce anti-nutritional factors such as phytates. *Category : TECHNICAL*
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]	**International Special Dietary Food Industries** ISDI supports the proposed text in 8. TECHNOLOGIES FOR AND EFFECT FOR PROCESSING with the following modification: 8.5 Other Processing Technologies, para. 2: 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. 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] Justification: Irradiation as a non-thermal control measure is not authorized in foods for infants and young children according to CODEX STAN 74.

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
	Category : TECHNICAL
9. Manufacturing Practices and Good Hygiene Practices	
9. MANUFACTURING PRACTICES AND GOOD HYGIENE PRACTICES	**Colombia** Colombia supports the preliminary draft text. *Category : TECHNICAL*
The ingredients and final product should be prepared, packed and held under sanitary conditions and should comply with relevant Codex texts.	**Canada** Canada agrees with the text in this section but notes a minor editorial comment; a period is missing at the end of the final sentence. *Category : EDITORIAL*
11. Packaging	
11. PACKAGING	**Colombia** Colombia supports the proposed text. *Category : TECHNICAL*
12. Labelling	
12. LABELLING	**Colombia** Colombia supports the proposed text. *Category : TECHNICAL*
It is recommended that the labelling of RUTF for children from 6 to 59 months be in accordance with the *Standard for the Labelling of and Claims for Foods for Special Medical Purposes* (CODEX STAN 180-991), ~~*Codex General Standard for the Labelling of Pre-packaged Foods* (CODEX STAN 1-1985)~~, the *General Standard for the Labelling of and Claims for Pre-packaged Foods for Special Dietary Uses* (CODEX STAN 146-1985), ~~*Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997)~~ and *Guidelines on Nutrition Labelling* (CAC/GL 2- 1985).	**India** In addition to the standards and guidelines mentioned in the text below, the following text may be added at the end: “and the International Code of Marketing of Breast milk Substitutes and subsequent relevant WHA resolutions on labeling and claims, including the WHO Guidance on ending inappropriate marketing of foods for infants and young children.” *Category : SUBSTANTIVE*
~~**Declaration of Nutritive Value**~~	**Brazil** Brazil would like to ask for clarification about the reason why the section ‘Declaration of

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
	Nutritive Value' has been deleted from the document. *Category : SUBSTANTIVE*
~~**Declaration of Nutritive Value**~~	**India** Declaration of nutritive value is essential on the package of RUTF. *Category : SUBSTANTIVE*
Additional Mandatory Labelling Requirements	**Brazil** Brazil suggests the following amendments: *Category : SUBSTANTIVE*
"USE ONLY UNDER MEDICAL SUPERVISION" shall appear on the label in bold letters in an area separated from the written, printed, or graphic information.	**Brazil** *Category : SUBSTANTIVE*
"For the dietary management of severe acute ~~malnutrition"~~ malnutrition under medical supervision " shall appear on the label.	**India** *Category : TECHNICAL*
The product is not to be used for ~~parenteral, rectal or~~ Nasogastric Tube (NG tube) administration.	**International Special Dietary Food Industries** ISDI supports the proposed text in Additional Mandatory Labelling Requirements with the following modifications: • The product is not to be used for Nasogastric Tube (NG tube) administration. Justification: No other type of food mentions such purposes for the product use, as well as there is no evidence on the potential use of RUTF for parenteral or rectal administration. *Category : TECHNICAL*
A statement indicating whether the product is or is not intended as the sole source of nutrition. However, national authorities can take a decision based on the national legislations according to national needs. • A statement indicating that RUTF are high-fat and high-sugar products.	**India** *Category : TECHNICAL*

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
A statement indicating that RUTF are not breastmilk substitutes and shall not be presented as such.	**Canada** Canada supports retaining the statements on breastfeeding on the label of RUTF. Canada notes that despite referencing the Code of Marketing of Breast-milk Substitutes and other WHA resolutions in the Preamble, it is important to require these statements on the label of RUTF to prevent RUTF from replacing breastfeeding. *Category : SUBSTANTIVE*
A statement indicating: [Exclusive breastfeeding is recommended for the first 6 months of life, and continued breastfeeding is recommended for at least 24 months.] • A statement indicating that RUTF is only for medical purposes, and it is not allowed the marketing for the public in general.	**Brazil** *Category : SUBSTANTIVE*
[Exclusive breastfeeding is recommended for the first 6 months of life, and continued breastfeeding is recommended for at least 24 months.]	**India** This should be retained. *Category : TECHNICAL*
The time in which the product should be consumed ~~within 24 hours~~ after ~~opening~~opening should be clearly indicated.	**International Special Dietary Food Industries** ISDI supports the proposed text in Additional Mandatory Labelling Requirements with the following modifications: Instructions for use • The label should indicate clearly from which age the product is recommended for use. This age shall not be less than six months for any product. • Feeding instructions shall be given; preferably accompanied by graphical presentations. • The time in which the product should be consumed after opening should be clearly indicated. Justification: The reason for this is that it allows different packaging formats and product types.

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
	Suggested re-wording allows different packaging formats and product types. *Category : TECHNICAL*
Annex	
ANNEX	**EU Specialty Food Ingredients** Units are missing in the nutritional composition for RUTFs. Vitamin D: we are in favour of setting a GUL rather than a maximum level. EFSA in its 2012 opinion on setting the Tolerable Upper Intake Level (UL) for vitamin D proposed a UL of 50 µg/day for children aged 1-10. Therefore, we believe a GUL at 30 µg/100 g is appropriate for RUTFs. Should a maximum value be retained instead of a GUL, for stability reason, it's important to have the larger range so we would, in this case, favour 22 µg/100 g. Vitamin E units: there is a typo. It should read "DL-alpha-tocopherol" and not di-alpha-tocopherol" Calcium: we note that the maximum value remains in square brackets. We support the value of 785 mg. Magnesium: we support 140 mg as the UL, which is a long term safe dose, for infants aged 7-11 months is set at 80 mg (EFSA, 2015 - http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2015.4186/epdf). For children from 1 to 3, the UL is increase to 170 mg/d and then further increased to 250 mg/d from 3 to 10 years. As the target population of RUTFs covers 6 to 59 months, we believe the maximum value should not be too high. Copper: we note that the values for copper were chosen as 1.4 mg for the minimum value and 1.8 mg for the maximum value. We believe these values are too high compared to the needs of the population. EFSA in 2015 (http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2015.4253/epdf) set an Average Intake

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
	(AI) of 0.4 mg/d for infants from 7 to 11 months, a value of 0.7 mg/d for children from 1 to 3 and 1 mg/d for 3 to 10 years of age. Therefore, we wonder why the value of 1.4 mg/d was chosen for the minimum and believe this is too high. Regarding the maximum level, SCF (predecessor of EFSA) issued an opinion in 2003 (http://www.efsa.europa.eu/sites/default/files/efsa_rep/blobserver_assets/ndatolerableuil.pdf) and set an UL for 1 to 3 years of age at 1 mg/d and for 4 to 6 at 2 mg/d. SCF did not set an UL for infants from 6 to 12 months. Based on SCF opinion, we believe setting an UL at 1.8 mg/d is too high. *Category : SUBSTANTIVE*
Table: Nutritional Composition for RUTF	**Colombia** Colombia supports the proposed protein values. *Category : TECHNICAL*
Table: Nutritional Composition for RUTF	**International Special Dietary Food Industries** ISDI recommends that the unit of measurements be added to Table: Nutritional Composition for RUTF *Category : EDITORIAL*
Energy	**Colombia** Colombia supports the proposed text and energy values. *Category : TECHNICAL*
Protein	**International Special Dietary Food Industries** 1. ISDI does not support the proposed Protein minimum limit of 12.8 g protein/100 g and value of 2.3. Justification: This value is to be compatible with the recommendation which is “protein should provide 10 to 12 % of total energy”. - If 1 g protein provides 4 kcal and - The minimum energy is 520 kcal /100g - 10% of 520 = 52 kcal

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
	- 52 kcal/4 kcal/g = 13 g The minimum is then 13 g protein/100g. The exact minimum value is 2.36, rounded to 2.4 g/100 g. 2.ISDI does not support the proposed Protein maximum limit of 16.2 g protein/100 g and value of 3.1 g/100 g. Justification: This value is to be compatible with the recommendation which is “protein should provide 10 to 12 % of total energy” - If 1 g protein provides4 kcal and - The maximum energy is 550 kcal /100g - 12% of 550 = 66 kcal - 66 kcal/4 kcal/g = 16.5 g The maximum is then 16.5 g protein/100g. The exact maximum value is 3.17, rounded to 3.2 g/ 100g. ISDI suggests the following: Protein Minimum Maximum GUL 13 g /100 g 16.5 g /100 g - 2.4 3.2 - *Category : TECHNICAL*
~~12.8~~13 g/ 100 g	**International Special Dietary Food Industries** *Category : TECHNICAL*
16.~~2~~5 g /100 g	**International Special Dietary Food Industries** *Category : TECHNICAL*
2.~~3~~4	**International Special Dietary Food Industries** *Category : TECHNICAL*

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
3.~~1~~2	**International Special Dietary Food Industries** *Category : TECHNICAL*
Vitamin A	**Colombia** Colombia supports a maximum of 1,1 for vitamin A. *Category : TECHNICAL*
Vitamin A	**India** Proposed levels of Vitamin A are very high. The RDA for Indian Children from 6 months to 6 years is 350 to 400 mcg (ICMR, 2010).Vitamin A values should not exceed these levels as high levels can cause serious adverse effects. *Category : TECHNICAL*
~~[1~~1.~~1] OR [1.2]~~1	**Canada** Canada supports the lower vitamin A maximum value of 1.1 mg RE/100g as it aligns with the recommendations in the Community-based management of severe acute malnutrition. 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. Geneva: World Health Organization; 2007. *Category : TECHNICAL*
~~[0~~0.~~2] OR [0.22]~~2	**Canada** Canada supports the lower vitamin A maximum value as it aligns with the recommendations in the Community-based management of severe acute malnutrition. 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. Geneva: World Health Organization; 2007. *Category : TECHNICAL*
~~[200] OR [220]~~200	**Canada** Canada supports the lower vitamin A maximum value as it aligns with the recommendations in the Community-based management of severe acute malnutrition. 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. Geneva: World Health Organization; 2007. *Category : TECHNICAL*

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
Vitamin D	**Colombia** Colombia supports a maximum of 20 and the GUL of 30 mcg/100 g for vitamin D. *Category : TECHNICAL*
Vitamin D	**Colombia** Colombia supports the retention of the proposed values for vitamin K, vitamin B1, vitamin B2, vitamin C, vitamin B6, vitamin B12, folic acid, niacin and pantothenic acid. *Category : TECHNICAL*
Vitamin D	**India** Proposed maximum levels of Vitamin D are very high. Recommended Dietary Allowance (RDA) for Vitamin D for Indians is 10 mcg. Maximum Vitamin D values should not exceed these levels as high levels can cause serious adverse effects. *Category : TECHNICAL*
~~[20] OR [22]~~20	**Canada** Canada supports the vitamin D maximum of 20 µg/100 g as it aligns with the recommendations in the Community-based management of severe acute malnutrition. 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. Geneva: World Health Organization; 2007. *Category : TECHNICAL*
~~[20] OR~~ [22]	**International Special Dietary Food Industries** ISDI agrees with the proposed minimum of 15 mcg/100g if the maximum accepted limit is [22]. *Category : TECHNICAL*
[20] OR ~~[22]~~[22] UNICEF support 22mcg	**UNICEF** *Category : TECHNICAL*
~~[3~~3.~~6] OR [4]~~6	**Canada** Canada supports the vitamin D maximum of 20 µg/100 g as it aligns with the recommendations in the Community-based management of severe acute malnutrition. 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. Geneva: World Health Organization; 2007. *Category : TECHNICAL*

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
[3] 1 µg cholecalciferol = 40 IU vitamin D According to the conclusion of the paragraph 9.2 of the last proposed draft 2017 eWG Consultation Paper 2 RUTF, "The Chairs also recommend that although the two forms of vitamin D allowed in RUTF formulation, namely cholecalciferol (D3) and ergocalciferol (D2), are already specified in CAC/GL 10-1979, such forms should still be specified in the nutritional composition section to provide further guidance to member states".	**International Special Dietary Food Industries** ISDI agrees with the note 3 1 µg cholecalciferol = 40 IU vitamin D with respect to the following clarification required here: According to the conclusion of the paragraph 9.2 of the last proposed draft 2017 eWG Consultation Paper 2 RUTF, "The Chairs also recommend that although the two forms of vitamin D allowed in RUTF formulation, namely cholecalciferol (D3) and ergocalciferol (D2), are already specified in CAC/GL 10-1979, such forms should still be specified in the nutritional composition section to provide further guidance to member states". *Category : EDITORIAL*
Vitamin E	**Colombia** Colombia supports the minimum value for vitamin E. *Category : TECHNICAL*
Vitamin E	**India** the proposed minimum level of Vitamin E is high as compared to the Recommended Dietary Allowance (RDAs) for Vitamin E. Vitamin E values should not exceed these levels as high levels can cause serious adverse effects. *Category : TECHNICAL*
[4]1 mg RRR-α-tocopherol =2.00 mg *all-rac*-α-tocopherol ~~(di-~~ (dl- α-tocopherol)	**UNICEF** *Category : EDITORIAL*
Vitamin B2	**India** The proposed minimum values for Vitamin B2 are very high for children. The RDA of Vitamin B2 for Indian Children is 0.4 – 0.8 mg/day. Vitamin B2 values should not exceed these levels. *Category : TECHNICAL*
Vitamin C	**India** The proposed values for Vitamin C are high for children. Recommended Dietary Allowances for Indian, ICMR, 2010, are 25-40 mg. Vitamin C values should not exceed these levels.

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
	Category : TECHNICAL
Vitamin B12	**India** The proposed minimum value for Vitamin B12 is high for children between 0-8 years. The RDA for Indian Children is 0.2 - 1.0 mcg. Vitamin B12 values should not exceed these levels. *Category : TECHNICAL*
Folic Acid	**India** The proposed minimum value for Folic Acid is high for children between 0-3 years. The RDA for Indian Children is 25-100 mcg. Folic Acid values should not exceed these levels. *Category : TECHNICAL*
Sodium	**India** Sodium level should be much less than 290 mg/100g. For sodium (sodium chloride), the adverse effect concerned does not have a defined threshold, but is a continual graded response such that risk increases with increasing intake. Therefore, it is important to keep it to minimum. *Category : TECHNICAL*
Sodium	**International Special Dietary Food Industries** ISDI believes that no Sodium should be added in the RUTF formulation. There will be some sodium naturally present in the raw materials used. *Category : EDITORIAL*
1,~~400~~600 mg/100 g	**International Special Dietary Food Industries** ISDI does not support the proposed Potassium maximum limit value of 1,400 mg/100 g and suggests to increase the limit to 1,600 mg/100 g. Justification: The extend range to 1600 mg/100 g takes into account the technical feasibility based on raw materials variability. *Category : TECHNICAL*
Calcium	**Colombia** Colombia supports the adoption of the minimum values for the maximum of the nutrients

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
	calcium, phosphorous and magnesium. *Category : TECHNICAL*
Calcium	**India** Maximum value should be 600 mg/100g *Category : TECHNICAL*
~~[600] or [785]~~600	**Canada** Canada supports the lower proposed maximum levels for calcium, phosphorus and magnesium as they align with the recommendations in the Community-based management of severe acute malnutrition. A joint statement by the World Health Organization, the World Food Programme, the United Nations System Standing *Category : TECHNICAL*
~~[600] or~~ [785]	**International Special Dietary Food Industries** ISDI agrees with the proposed minimum of 300 mcg/100g if the maximum accepted limit is [785]. *Category : TECHNICAL*
[600] or ~~[785]~~[785] UNICEF supports 600mg	**UNICEF** *Category : TECHNICAL*
~~[109] or [143]~~109	**Canada** Canada supports the lower proposed maximum levels for calcium, phosphorus and magnesium as they align with the recommendations in the Community-based management of severe acute malnutrition. A joint statement by the World Health Organization, the World Food Programme, the United Nations System Standing *Category : TECHNICAL*
Phosphorus	**India** Maximum value should be 600 mg/100g *Category : TECHNICAL*
~~[600] or [785]~~600	**Canada** Canada supports the lower proposed maximum levels for calcium, phosphorus and magnesium as they align with the recommendations in the Community-based management of severe acute malnutrition. A joint statement by the World Health Organization, the World Food Programme, the United Nations System Standing

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
	Category : TECHNICAL
[600] or ~~[785]~~[785] UNICEF supports 600mg	**UNICEF** *Category : TECHNICAL*
~~[109] or [143]~~109	**Canada** Canada supports the lower proposed maximum levels for calcium, phosphorus and magnesium as they align with the recommendations in the Community-based management of severe acute malnutrition. A joint statement by the World Health Organization, the World Food Programme, the United Nations System Standing *Category : TECHNICAL*
Magnesium	**India** Maximum value should be 140 mg/100g *Category : TECHNICAL*
~~[140] or [235]~~140	**Canada** Canada supports the lower proposed maximum levels for calcium, phosphorus and magnesium as they align with the recommendations in the Community-based management of severe acute malnutrition. A joint statement by the World Health Organization, the World Food Programme, the United Nations System Standing *Category : TECHNICAL*
[140] or ~~[235]~~[235] UNICEF supports 140mg	**UNICEF** *Category : TECHNICAL*
~~[26] or [43]~~26	**Canada** Canada supports the lower proposed maximum levels for calcium, phosphorus and magnesium as they align with the recommendations in the Community-based management of severe acute malnutrition. A joint statement by the World Health Organization, the World Food Programme, the United Nations System Standing *Category : TECHNICAL*
Zinc	**India** The proposed values are higher than the RDA. The Recommended Dietary Allowance of Zinc for Indian children (1-6 yrs) is 5-7 mg/day (ICMR, 2010) *Category : TECHNICAL*
~~1.8~~2 mg/ 100 g	**International Special Dietary Food Industries**

SPECIFIC COMMENTS	
Section / paragraph	**Member/Observer/rationale**
	ISDI does not support the proposed maximum limit value of 1,8 mg/100 g and suggests to increase the limit to 2 mg/100 g. Justification: The extend range to 2 mg/100 g takes into account the technical feasibility based on raw materials variability. *Category : TECHNICAL*
~~140~~160 µg/100 g	**International Special Dietary Food Industries** ISDI does not support the proposed maximum limit value of 140 µg/100 g and suggests to increase the limit to 160 µg/100 g. Justification: The extend range to 160 µg/100 g takes into account the technical feasibility based on raw materials variability. *Category : TECHNICAL*