

# CODEx ALIMENTARIUS COMMISSION



Food and Agriculture  
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**Agenda item 5** **CX/NFSDU 18/40/6-Add.1**

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

Fortieth Session

Berlin, Germany, 26 - 30 November 2018

### Proposed Draft Guideline for Ready-to-Use Therapeutic Foods Replies to CL 2018/64-NFSDU

*Comments of Argentina, Brazil, Colombia, Ecuador, India, Jamaica, Japan, Malawi, Norway, Sri Lanka,  
EU Speciality Food Ingredients, HKI, ICAAS, IBFAN, IACFO, IDF, ISDI, MSF, UNICEF*

#### Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2018/64-NFSDU issued October 2018. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific sections.

#### Explanatory notes on the appendix

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

GENERAL COMMENT	MEMBER / OBSERVER
Colombia supports the proposed text and suggests mentioning the most efficient chemical form for each of the vitamins and minerals that are part of the RUTF.	Colombia
We support the proposed guideline. It's detailed with the right nutrient requirement to treat SAM.	Ghana
Any decisions regarding the suitability and appropriate composition of RUTF must be based on relevant and convincing evidence of efficacy, that is free from commercial influence.	International Association of Consumer Food Organizations
<p>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 and MAM and the support of sustained breastfeeding.</p> <p>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, and how outcomes were measured and risk of bias. (See IBFAN's review of literature in the IBFAN Brief on the Use of RUTF).</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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. Similarly, these safeguards are needed for products intended for this vulnerable population. RUTFs intended for therapeutic use only and although the International Code and WHA resolutions provide some important safeguards, extra safeguards are needed to prevent misuse.</p> <p>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).</p> <p>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 continues.</p> <p>The scope of RUTF has been limited in the recent management of SAM children of Rohingya refugees in Bangladesh. Mothers and caretakers successfully managed SAM children with their own home-prepared foods, which they use for home foods. These children improved within two months, completely gaining to 0 Z score of WH after feeding. The ingredients were rice powder, soya oil, sugar and egg. The cost is nominal 25-30 cents per day. Ingredients were supplied and mothers were shown how to cook in their camp house. Every family</p>	International Baby Food Action Network

had cooking facilities. The intervention was followed with a two-month observation period without supply of ingredients but alongside continued advice on family feeds.	
IUFoST supports the concept of these guidelines for special food products used to meet dietary requirements of children with severe malnutrition. With regard to the name, consideration should be given to the need for the word "therapeutic" since this could cause legal problems in some countries. Therapeutic implies treatment of diseases, which could make such products drugs under laws in many countries.	<b>IUFOST</b>
Microbiological and Chemical Contaminant Criteria	<b>UNICEF</b> UNICEF will provide a report to share at the physical working group meeting reviewing contaminant risks. UNICEF notes that it is convention to refer to primary codex texts for microbial and contaminant specification criteria. While respecting this convention, allows for efficient updating of codex texts, we find that partners and suppliers appreciate the ease of having specific criteria listed in the one reference document.

**SPECIFIC COMMENTS****PREAMBLE (Recommendation 1)**

Argentina agrees with this preamble

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

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

**Argentina****Brazil**

Brazil would like to suggest some amendments in the proposed text. We are of the opinion that the text should not emphasize the use of RUTF because the focus should be on foods locally available. Brazil also suggests including in the footnote the full reference of 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:

1) Joint Statement on Community-Based Management of

	<p>Severe Acute Malnutrition by the World Health Organization, the World Food Programme, the United Nations System Standing Committee on Nutrition and the United Nations Children's Fund, 2007; WHO. Child growth standards and the identification of severe acute malnutrition in infants and children, 2006; A Joint Statement by the World Health Organization and the United Nations Children's Fund; Geneva: World Health Organization; 2009; WHO. Guideline: Updates on the management of severe acute malnutrition in infants and children. Geneva: World Health Organization; 2013; WHO. Global Strategy for Infant and Young Child Feeding. Geneva: World Health Organization; 2003; WHO. International code of marketing of breast-milk substitutes. Geneva: World Health Organization; 1981, WHA Resolutions 63.23 and 69.9 - Ending inappropriate promotion of foods for infants and young children, and subsequent relevant WHA Resolutions on infant and young child feeding; Code of Ethics for International Trade in Food including Concessional and Food Aid Transactions (CAC/RCP 20-1979; 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; 2016.</p>
<p>Children affected by severe acute malnutrition (SAM) need safe, palatable foods with a high energy content and adequate amounts of vitamins, minerals and other nutrients. Children with SAM need efficacious and timely treatment and RUTF is part of the care. RUTF are primarily intended for children with uncomplicated SAM from 6-59 months. Although RUTF may be given to other age groups with various forms of malnutrition at the implementation level, the primary focus for these guidelines is children with SAM from 6-59 months. Since RUTF are prescribed according to weight, National Authorities may decide to include the provision of RUTF in their national protocols for use by other age <del>groups</del> <u>groups and other forms of malnutrition such as moderate acute malnutrition.</u></p> <p>Children affected by severe acute malnutrition (SAM) need safe, palatable foods with a high energy content and adequate amounts of vitamins, minerals and other nutrients. Children with SAM need efficacious and timely treatment and RUTF is part of the care. RUTF are primarily intended for children with uncomplicated SAM from 6-59 months. Although RUTF may be given to other age groups with various forms of malnutrition at the implementation level, the primary focus for these guidelines is children with SAM from 6-59 months. Since RUTF are prescribed according to weight, National Authorities may decide to include the provision of RUTF in their national protocols for use by other age <del>groups</del> <u>groups and other forms of malnutrition such as moderate acute malnutrition.</u></p>	<p><b>Colombia</b></p> <p>Bearing in mind that in Colombia as in other countries FTLC is used for the treatment of moderate acute malnutrition (&lt;-2 SD) and severe acute malnutrition (&lt;-3 SD), we recommend the following adjustment in the preamble.</p> <p>Bearing in mind that in Colombia as in other countries FTLC is used for the treatment of moderate acute malnutrition (&lt;-2 SD) and severe acute malnutrition (&lt;-3 SD), we recommend the following adjustment in the preamble.</p>
<p>Having guidelines for ready-to-consume therapeutic foods will allow countries to manufacture these products so that they are suitable for the treatment of acute malnutrition in children aged 6 to 59 months. However, it is essential to have parameters so that the products that are manufactured meet the intended purpose. It is also important to emphasise that this food in no way replaces breast milk and, therefore, the messages that are included on the labels of these products should indicate the importance of continuing to provide breast milk to ensure a better response. In addition, it should be noted that these foods can be manufactured from local foods with a high nutritional value as</p>	<p><b>Ecuador</b></p>

<p>well as from culturally accepted local foods.</p> <p>Purpose of the guidelines</p> <p>We agree with the planned guidelines. This type of product is aimed at young children; therefore, the specifications for these products must be strict to ensure the safety of the children.</p>	
<p><del>Older infants and</del> Children affected by severe acute malnutrition (SAM) need safe, palatable foods with a high energy content and adequate amounts of vitamins, minerals and other nutrients. Children with SAM <del>need efficacious and need</del> timely treatment and RUTF <del>is part of the care. RUTF are primarily is</del> intended for children with uncomplicated SAM from 6-59 months. <del>Although RUTF may be given. Other options include augmented home prepared foods. It is important to other age groups with various forms of malnutrition at the implementation levels sustain breastfeeding and homemade, the primary focus for these guidelines is children with SAM from 6-59 months culturally acceptable complementary foods. Since RUTF-It is absolutely necessary that RUTFs are prescribed according to weight, National Authorities may decide to include the provision of RUTF in their national protocols used only under Medical Supervision for use by other children in the age groups- group of 6 – 59 months.</del></p> <p>These guidelines provide guidance for the production and labelling of RUTF. The guidelines are intended to facilitate the harmonization <u>and standardization</u> of requirements <u>production of</u> for RUTF at the international level and may provide assistance to governments wishing to establish national <u>regulations as per their policy</u> regulations. The guidelines are also intended for use as an instrument designed to avoid or remove difficulties which may be created by diverging legal, administrative and technical approaches to RUTF and by varying definitions and nutrient compositions of <u>RUTFRUTF products</u>. These guidelines should be used in accordance with technical recommendations of the relevant <del>evidence and evidence</del> related Codex texts/documents by WHO, UNICEF and WFP<sup>41</sup> <u>and relevant National regulations of the implementing Nation</u>. Governments and other users should ensure adequate provisions are made for competent technical experts for the appropriate use of these guidelines. <u>so that these products are used only to treat SAM under strict medical supervision and to avoid general use of them.</u></p> <p><sup>1)</sup> A Joint Statement by the World Health Organization, the World Food Programme, the United Nations System Standing Committee on Nutrition and the United Nations Children's Fund. 2007. <i>Community-Based Management of Severe Acute Malnutrition</i>; A Joint Statement by the World Health Organization and the United Nations Children's Fund. 2009. <i>Child growth standards and the identification of severe acute malnutrition in infants and children</i>, Geneva: World Health Organization; World Health Organisation. 2013. <i>Guideline: Updates on the management of severe acute malnutrition in infants and children</i>, Geneva: World Health Organization; World Health Organisation. 2003. <i>Global Strategy for Infant and Young Child Feeding</i>, Geneva: World Health Organization; World Health Organisation. 1981. <i>International code of marketing of breast-milk substitutes</i>, Geneva: World Health Organization and subsequent relevant WHA Resolutions on infant and young child <u>feedingfeeding and the WHO Guidance on ending inappropriate marketing of foods for infant and young children</u>; <i>Code of Ethics for International Trade in Food including Concessional and Food Aid Transactions</i> (CXC 20-1979); Food and Agriculture Organisation and World Health Organisation. 2016. <i>FAO/WHO Microbial safety of lipid-based ready-to-use foods for management of moderate acute malnutrition and severe acute malnutrition</i>, Rome: Food and Agriculture Organisation.</p>	<p><b>India</b></p> <ol style="list-style-type: none"> <li>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 like home augmented foods. 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.</li> <li>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.</li> <li>Further, if the use of RUTF in national/sub-national programme for the management of SAM is approved by the national authorities, these formulations should meet the relevant country specific recommendations for Essential composition as specified by the National Authorities and a footnote to this effect should be inserted under the recommendation for each Nutrient (macronutrients as well as micronutrients).</li> </ol> <ol style="list-style-type: none"> <li>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.</li> <li>Reference for the relevant WHA resolutions needs to be given in the footnote.</li> <li>*Other Nutrients needs to be specified.</li> <li>Additional suggested changes have been highlighted</li> </ol>

<p>Children affected by severe acute malnutrition (SAM) need safe, palatable foods with a high energy content and adequate amounts of <u>protein</u>, vitamins, minerals and other nutrients. Children with SAM need efficacious and timely treatment and RUTF is part of the care. RUTF are primarily intended for children with uncomplicated SAM from 6-59 months. Although RUTF may be given to other age groups with various forms of malnutrition at the implementation level, the primary focus for these guidelines is children with SAM from 6-59 months. Since RUTF are prescribed according to weight, National Authorities may decide to include the provision of RUTF in their national protocols for use by other age groups.</p>	<p>at appropriate place in the text of the preamble.</p> <p><b>Sri Lanka</b></p>
<p>To provide guidance on technical and nutritional aspects of the production of Ready to Use Therapeutic Foods for children from the age of 6 to 59 months <del>with severe acute malnutrition</del> <u>with uncomplicated severe acute malnutrition</u>, including</p>	<p><b>HKI</b></p> <p>From the preamble above ("RUTF are primarily intended for children with uncomplicated SAM from 6-59 months") we understood that RUTF was meant for dietary management of severe acute malnutrition with no medical complications as per the 2007 Joint statement. Yet the purpose of the guidelines does not mention the term "uncomplicated" SAM. To be consistent HKI suggests consideration of following phrasing: "To provide guidance on technical and nutritional aspects of the production of Ready to Use Therapeutic Foods for children from the age of 6 to 59 months with uncomplicated severe acute malnutrition, including..."</p>
<p>Children affected by severe acute malnutrition (SAM) need safe, palatable foods with a high energy content and adequate amounts of vitamins, minerals and other nutrients. Children with SAM need efficacious and timely treatment and RUTF is part of the care. RUTF are primarily intended for children with uncomplicated SAM from 6-59 months. Although RUTF may be given to other age groups with various forms of malnutrition at the implementation level, the primary focus for these guidelines is children with SAM from 6-59 months. <del>Since RUTF are prescribed according to weight</del>, National Authorities may decide to include the provision of RUTF in their national protocols for use by other age groups.</p> <p><sup>1)</sup> A Joint Statement by the World Health Organization, the World Food Programme, the United Nations System Standing Committee on Nutrition and the United Nations Children's Fund. 2007. <i>Community-Based Management of Severe Acute Malnutrition</i>; A Joint Statement by the World Health Organization and the United Nations Children's Fund. 2009. <i>Child growth standards and the identification of severe acute malnutrition in infants and children</i>, Geneva: World Health Organization; World Health Organisation. 2013. <i>Guideline: Updates on the management of severe acute malnutrition in infants and children</i>, Geneva: World Health Organization; World Health Organisation. 2003. <del><i>Global Strategy for Infant and Young Child Feeding</i>, Geneva: World Health Organization; World Health Organisation. 1981; <i>International code of marketing of breast-milk substitutes</i>, Geneva: World Health Organization and subsequent relevant WHA Resolutions on infant and young child feeding; <i>Code of Ethics for International Trade in Food including Concessional and Food Aid Transactions</i> (CXC 20-1979); Food and Agriculture Organisation and World Health Organisation. 2016. <i>FAO/WHO Microbial safety of lipid-based ready-to-use foods for management of moderate acute malnutrition and severe acute malnutrition</i>, Rome: Food and Agriculture Organisation.</del></p>	<p><b>International Special Dietary Food Industries</b></p> <p>ISDI would like to highlight that RUTFs are not prescribed according to weight and therefore this statement should be removed from the text of the preamble.</p> <p>As regards to Footnote 1, ISDI notes that the "Joint Statement on Community-Based Management of Severe Acute Malnutrition by the World Health Organization, the World Food Programme, the United Nations System Standing Committee on Nutrition and the United Nations Children's Fund, 2007" was updated in 2011.</p> <p>In addition, as RUTF is not breastmilk substitutes, ISDI questions the reference to guidelines included as part of Footnote 1.</p>
<p><del>Children affected by severe acute malnutrition (SAM) need safe, palatable foods with a high energy content and adequate amounts of vitamins, minerals and other nutrients. Children with SAM need efficacious and timely treatment and RUTF is part of the care. RUTF are primarily intended for children with uncomplicated SAM from 6-59 months. Although RUTF may be given to other age groups with various forms of malnutrition at the implementation</del></p>	<p><b>International Association of Consumer Food Organizations</b></p>

<p><del>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. RUTFs may be used as a treatment food for older infants and young children with severe acute malnutrition (SAM), when other nutrient rich foods cannot be used. However, it is critical that its use does not undermine support for continued breastfeeding or relactation, since this is the most important requirement for the rehabilitation of children suffering from malnutrition. RUTFs can be used as a treatment food while breastfeeding is re-established and sustained and family foods are gradually introduced. The portion size of RUTFs should be adapted to ensure optimal breastmilk intake. RUTFs can also be used for the feeding of malnourished older infants and young children in emergency situations.</del></p> <p><del>These guidelines provide guidance for the production and labelling of RUTFRUTF products. The guidelines are intended to <del>facilitate ensure that</del> the <del>harmonization of requirements ingredients, nutritional composition, safety and labeling is appropriate</del> for RUTF <del>at the international level intended recipients</del> and <del>may to</del> provide assistance to governments wishing to establish national regulations. <del>The guidelines are also intended for use as an instrument designed to avoid or remove difficulties which may be created by diverging legal, administrative and technical approaches to RUTF and by varying definitions and nutrient compositions of RUTF.</del> These guidelines should be used in accordance with technical recommendations <del>of that are based on</del> the relevant evidence and <del>related Codex texts/documents by WHO free from commercial influence, UNICEF taking into account relevant Codex texts related to food safety and WFP hygiene<sup>4</sup>.</del> Governments and other users should ensure adequate provisions are made <del>for with</del> competent technical experts <del>for to ensure that</del> the <del>use of these products is</del> appropriate <del>in the local context and does not undermine national nutrition recommendations and the</del> use of <del>biodiverse, culturally appropriate foods.</del> If RUTF are considered appropriate, they should be used solely for treatment purposes and not for general use or the prevention of SAM. Appropriate steps must be taken to ensure that there is no "spillover" to the wider population and the black market.</del></p> <p><del>On no account should RUTF products be placed on the open market for general sale or promoted in any way. The production and availability of these guidelines products must comply with the relevant provisions of the WHO International Code of Marketing of Breastmilk Substitutes, the subsequent relevant WHA resolutions, including WHA 69.9, its accompanying WHO Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children and the Codex Guidelines on Nutrition and Health Claims. Paragraph 1.4 of which states that no nutrition and health claims should be made for foods for infants and young children. Convenience and other promotional claims should also not be made for these products, on labels or information materials.</del></p>	
<p>Children affected by severe acute malnutrition (SAM) need [adequate treatment and care] OR [safe, palatable foods with a high energy content and adequate amounts of vitamins, minerals and other nutrients. Children with SAM need timely treatment and RUTF is a critical part of the care]. RUTF are primarily intended for children with uncomplicated SAM from 6-59 months. Although RUTF may be given to other age groups with various forms of malnutrition at the implementation level, the primary focus for these guidelines is children with SAM from 6-59 months. Since RUTF are prescribed according to weight, National Authorities may decide to include the provision of RUTF in their national protocols for use by other age groups.</p> <p>RUTFs may be used as a treatment food for older infants and young children with SAM, when other nutrient rich foods cannot be used. However, it is critical that its use does not undermine support for continued breastfeeding or to re-establish lactation, since this is the most important requirement for the rehabilitation of children suffering from malnutrition. RUTFs can be used as a treatment food while breastfeeding is sustained and family foods are gradually introduced. The portion size of RUTFs should be adapted to ensure optimal breastmilk intake. RUTFs can also be used for the feeding of malnourished older infants and young children in emergency situations.</p> <p>These guidelines provide requirements for the production and labelling of RUTF products. The guidelines are</p>	<p><b>International Association of Consumer Food Organizations</b></p>

intended to ensure that the that the facilitate the harmonization of ingredients, nutritional composition, safety, use and labelling is appropriate for the intended recipients, requirements for RUTF at the international level and and to provide assistance to governments wishing to establish national regulations. The guidelines are also intended for use as an instrument designed to avoid or remove difficulties which may be created by diverging legal, administrative and technical approaches to RUTF and by varying definitions and nutrient compositions of RUTF. These guidelines should be used in accordance with technical recommendations that are based and updated on relevant and convincing evidence free from commercial influence, taking into account relevant Codex texts related to food safety and hygiene<sup>1</sup>. Governments and other users should ensure adequate provisions are made for with competent technical experts to ensure that the use of these products is appropriate in the local context, does not undermine national nutrition recommendations and the use of bio-diverse, culturally appropriate foods. If RUTFs are considered appropriate, they should be used solely for treatment purposes and not for general use or the prevention of SAM. Steps must be taken to ensure that there is no spillover into the wider population and the black market.

On no account should RUTF products be placed on the open market. The production and availability of these products must comply with the relevant provisions of the WHO International Code of Marketing of Breastmilk Substitutes, the subsequent relevant WHA resolutions including the WHA 69.9, its accompanying WHO Guidance on Ending the Inappropriate Marketing of Foods for Infants and Young Children and the Codex Guidelines on Nutrition and Health Claims, Paragraph 1,4 of which states that no nutrition and health claims should be made for foods for infants and young children. Nor should convenience claims be made for these products on labels or information materials.

1)Joint Statement on Community-Based Management of Severe Acute Malnutrition by the World Health Organization, the World Food Programme, the United Nations System Standing Committee on Nutrition and the United Nations Children's Fund, 2007; WHO. Child growth standards and the identification of severe acute malnutrition in infants and children, 2006; A Joint Statement by the World Health Organization and the United Nations Children's Fund; Geneva: World Health Organization; 2009; WHO. Guideline: Updates on the management of severe acute malnutrition in infants and children. Geneva: World Health Organization; 2013; WHO. Global Strategy for Infant and Young Child Feeding. Geneva: World Health Organization; 2003; WHO. International code of marketing of breast-milk substitutes. Geneva: World Health Organization; 1981 and subsequent relevant WHA Resolutions on infant and young child feeding; Code of Ethics for International Trade in Food including Concessional and Food Aid Transactions (CAC/RCP 20-1979; 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; 2016.

[vii. Recommendations for safe use as a therapeutic food only](#)

[viii. Recommendations to restrict marketing to avoid spill-over and needless use.](#)

#### **PURPOSE OF THE GUIDELINES**

To provide guidance on technical and nutritional aspects of the production of Ready to Use Therapeutic Foods for children from the age of 6 to 59 months with severe acute malnutrition, including

- i. Nutritional Composition
- ii. Raw Materials and Ingredients
- iii. Good Manufacturing Practices
- iv. Microbiological and Chemical Contaminant Criteria
- v. Methods of Analysis and Sampling
- vi. Provisions for Packaging and Labelling
- vii. Recommendations for safe use as a therapeutic food only
- viii. Recommendations to restrict marketing to avoid spill-over and needless use.

**IBFAN**

<b>SCOPE</b>	
<p>The provisions of these guidelines apply to Ready to Use Therapeutic Foods for children from age 6 to 59 months with severe acute malnutrition. Ready-to-Use Supplementary Foods (RUSF), micronutrient supplements<sup>2</sup>, processed cereal based foods<sup>3</sup>, formulated complementary foods for older infants and young children<sup>4</sup>, canned baby foods<sup>5</sup> are not specifically covered by these guidelines. To prevent spill over and inappropriate use, the marketing restrictions recommended in this guideline should apply to all products that target malnourished children. RUTFs are to be used for therapeutic use only and not available on the general market.</p> <p>2)Guidelines for Vitamin and Mineral Food Supplements (CXG 55-2005)                      3Standard for Processed Cereal-Based Foods for Infants and Young Children (CXS 74-1981)                      4Guidelines on Formulated Complementary Foods for Older Infants and Young Children (CXG 8-1991)                      5Standard for Canned Baby Foods (CXS 73-1981)</p>	<b>IBFAN</b>
<p>The provisions of these guidelines apply to Ready to Use Therapeutic Foods for children from age 6 to 59 months with severe acute malnutrition. Ready-to-Use Supplementary Foods (RUSF), micronutrient supplements<sup>2</sup>, processed cereal based foods<sup>3</sup>, formulated complementary foods for older infants and young children<sup>4</sup>, canned baby foods<sup>5</sup> are not covered by these guidelines. <a href="#">However, in order to prevent spill-over and inappropriate use, the marketing restrictions recommended in this guideline should apply to all products that target malnourished children. RUTFs are to be used for therapeutic use only and not available on the general market.</a></p>	<b>International Association of Consumer Food Organizations</b>
<p>The provisions of these guidelines apply to Ready to Use Therapeutic Foods for children from age 6 to 59 months with severe acute malnutrition. Ready-to-Use Supplementary Foods (RUSF), micronutrient supplements<sup>2</sup>, processed cereal based foods<sup>3</sup>, formulated complementary foods for older infants and young children<sup>4</sup>, canned baby foods<sup>5</sup> are not covered by these guidelines.</p>	<b>UNICEF</b> should this be a colon? (editorial)
<p>HKI supports the text as proposed.</p>	<b>HKI</b>
<b>4. DESCRIPTION</b>	
<p><b>4.1 Ready-to-Use Therapeutic Foods (RUTF)</b> are foods for special medical purposes and are high-energy and contain adequate protein and other essential nutrients for the dietary management of children from 6 to 59 months with severe acute malnutrition without medical complications with appetite. These foods should be soft or crushable and should be easy for children to eat without any prior preparation.</p>	
<p>We agree with the provisions of the guidelines, but we suggest adding the management of children from 6 to 59 months with severe acute and moderate acute malnutrition without medical complications.</p>	<b>Ecuador</b>
<p>HKI supports the text as proposed.</p>	<b>HKI</b>
<p><b>4.1 Ready-to-Use Therapeutic Foods (RUTF)</b> are foods ..... 6 to 59 months with severe acute malnutrition without medical complications with appetite. These foods should be <del>soft or crushable and should be</del> easy for children to eat without any prior preparation.</p>	<b>MSF</b> The term "soft or crushable" shall be removed, to allow the formulation of new RUTF such as liquid ready to use, etc... Furthermore, existing lipid based RUTF paste is not soft or crushable...
<p><b>4.1 Ready-to-Use Therapeutic Foods (RUTF)</b> are foods ..... 6 to 59 months with severe acute malnutrition without medical complications with appetite. <a href="#">RUTF are made of ingredients embedded in a lipid-rich matrix e.g. paste or biscuit, resulting in an energy and nutrient-dense food.</a> These foods should be soft or crushable and should be easy for children to eat without any prior preparation.</p>	<b>UNICEF</b>
<p>4.1 Ready-to-Use Therapeutic Foods (RUTF) are foods for special medical purposes and are high-energy and contain adequate protein and other essential nutrients for the dietary management of children from 6 to 59 months with severe acute malnutrition without medical complications with appetite. These foods should be soft or crushable and should be easy for children to eat without any prior preparation.</p>	<b>IBFAN</b>
<b>4.2 Severe Acute Malnutrition</b> is defined by weight for height (or length) less than -3 Z-score of the median WHO growth standards, or by mid upper arm circumference	

(MUAC)<11.5 cm, or by the presence of bilateral oedema.	
<p><b>4.2 Severe Acute Malnutrition</b> is defined by weight for height (or length) less than –3 Z-score of the median WHO growth standards, <del>or and</del> by mid upper arm circumference (MUAC)&lt;11.5 cm, <del>or and</del> by the presence of bilateral oedema–.</p> <p><b>4.3 Moderate acute malnutrition: weight-height ratio (or stature) less than two z-scores below the median of WHO growth patterns.</b></p>	<p><b>Colombia</b></p> <p>Additionally, it is proposed to include the definition of moderate acute malnutrition because in Colombia as in other countries FTLC is used for the treatment of moderate acute malnutrition (&lt;-2 SD) and severe acute malnutrition (&lt;-3 SD).</p>
<p>We agree with the definition of severe acute malnutrition, but we also suggest including the definition of moderate acute malnutrition with the following text: “Moderate acute malnutrition occurs when the Z score of the W/H indicator is between -2 and -3DE. It may be accompanied by some degree of emaciation or thinness due to recent weight loss.”</p>	<p><b>Ecuador</b></p>
<p><b>4.2 Severe Acute Malnutrition</b> is defined by weight for height (or length) less than –3 Z-score of the median WHO growth standards, or by mid upper arm circumference (MUAC)&lt;11.5 cm, or by the presence of bilateral oedema.</p>	<p><b>Jamaica</b></p>
<p>4.2 Severe Acute Malnutrition is defined by weight for height (or length) less than –3 Z-score of the median WHO growth standards, or by mid upper arm circumference (MUAC)&lt;11.5 cm, or by the presence of bilateral oedema.</p>	<p><b>IBFAN</b></p>
<p><b>4.2 Severe Acute Malnutrition</b> is defined by weight for height (or length) less than –3 Z-score of the median WHO growth standards, or by mid upper arm circumference (MUAC)&lt;11.5 cm, or by the presence of bilateral oedema.</p>	<p><b>UNICEF</b></p> <p>suggest to include a reference to the WHO guideline. WHO. Guideline: Updates on the management of severe acute malnutrition in infants and children. Geneva: World Health Organization; 2013.</p>
<p><b>5. SUITABLE RAW MATERIALS AND INGREDIENTS</b></p> <p>RUTF are made of ingredients embedded in a lipid-rich matrix e.g. paste 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 <i>Standard for the Labelling of and Claims for Foods for Special Medical Purposes</i> (CXS 180-1991).</p>	
<p>ISDI would like to raise a comment which is out of the scope of the recommendation put forward by the eWG Chair. The comment concerns para 5 “SUITABLE RAW MATERIALS AND INGREDIENTS” in the Proposed Draft Guidelines. The introduction of the paragraph refers to section 3 of the Standard for Labelling of and Claims for Foods for Special Medical Purposes (CXS 180-1991), however, ISDI believes it should be clearly mentioned in the Guidelines that alternative ingredients to peanut in RUTF should be submitted to efficacy studies.</p>	<p><b>International Special Dietary Food Industries</b></p> <p>Rationale:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Use of alternative ingredients to peanut in RUTF may have significant impact on quality, safety and efficacy of the product. Appropriate studies should therefore be conducted at all necessary levels, not only to avoid contaminants but also to guarantee that such products, which may eventually be given to treat children affected by SAM, are as safe, acceptable and efficacious as the now well-established peanut formula.</li> <li><input type="checkbox"/> Depending on the composition of the untreated plant raw material used, adequate processing steps may have to be selected in order to guarantee its microbiological quality, nutritional quality and the absence of off-flavours.</li> <li><input type="checkbox"/> All plant raw material processing steps (e.g. roasting, drum drying, extrusion etc.) may contribute to reaching the microbiological specifications. However, the challenge to maintain the high microbiological quality on the long run may be more related to compliance with Good Manufacturing Practices (packaging steps, storage etc.).</li> <li><input type="checkbox"/> All plant raw material processing steps may not have the</li> </ul>

	<p>same impact on the nutritional quality of these raw materials. For example, roasting will usually help solving the off-tastes and the potential microbiology issues, but will only have a limited impact on the starch gelatinization in cereals, which is a key issue. This should be addressed beforehand, when selecting the plant raw materials and the corresponding processing steps.</p> <ul style="list-style-type: none"> <li>□ Based on manufactures' experience, it's strongly recommended that each raw material envisaged for use in RUTF should be evaluated for their content in:             <ul style="list-style-type: none"> <li>o gelatinized starch (considered as easily digestible), for cereals and pulses</li> <li>o anti-nutritional factors such as phytates (which can limit iron and zinc absorption) and anti-trypsin factors.</li> </ul> </li> </ul> <p>More broadly, it should be noted that changing a significant part of the raw materials in RUTF may influence the digestibility and bioavailability of the nutrients, which may impact the efficacy of the finished product. This is all the more critical as these products are to be given to sick, SAM-affected children, whose digestive system is not functioning properly. Therefore, ISDI strongly recommends that any new RUTF formula incorporating alternative ingredients is thoroughly validated through acceptability, efficacy and (if appropriate) effectiveness studies, conducted by independent third parties. As a consequence, ISDI recommends the addition of the following sentence at the end of the introduction of the para 5. This section includes cereals, pulses and seeds as possible ingredients to prepare RUTF. These ingredients are not used in most current formulations of RUTF. Any RUTF should be shown to be efficacious in clinical trials before being introduced in programmes.</p>
<p>Any decisions regarding the suitability and appropriate composition of RUTF must be based on relevant and convincing evidence of efficacy, which is free from commercial influence. RUTF are made of ingredients embedded in a lipid-rich matrix e.g. paste 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 (CXS 180-1991). Ingredients produced from genetically modified organisms shall not be used in the production of RUTFs. Ingredients must be produced and processed to ensure that they are safe and suitable for consumption by this vulnerable population.</p>	<p><b>IBFAN</b></p>
<p>RUTF are made of ingredients embedded in a lipid-rich matrix e.g. paste 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 <i>Standard for the Labelling of and Claims for Foods for Special Medical Purposes</i> (CXS 180-1991).</p>	<p><b>International Association of Consumer Food Organizations</b></p>

<a href="#">Ingredients used must be grown under conditions that ensure the product is fit for human consumption.</a>	
<del>RUTF are made of ingredients embedded in a lipid-rich matrix e.g. paste or biscuit, resulting in an energy and nutrient dense food.</del> 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 <i>Standard for the Labelling of and Claims for Foods for Special Medical Purposes</i> (CXS 180-1991).	<b>UNICEF</b>
<b>5.1.1 Milk and other Dairy Products</b> Milk and other dairy products used in the manufacturing of RUTF must comply with the <i>Standard for Milk Powders and Cream Powder</i> (CXS 207-1999) and the <i>Standard for Whey Powders</i> (CXS 289-1995), and other Codex milk and milk product 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 <i>Code of Hygienic Practice for Milk and Milk Products</i> (CXC 57-2004) and the <i>Code of Hygienic Practices for Low-Moisture Foods</i> (CXC 75-2015).	
Milk <del>and or</del> other dairy products used in the .....	<b>MSF</b> and shall be removed by OR
Milk and other dairy <del>products</del> <a href="#">products, including other animal milk sources</a> , used in the manufacturing of RUTF must comply with ..... and the <i>Code of Hygienic Practices for Low-Moisture Foods</i> (CXC <del>75-2015</del> ) <a href="#">75-2015</a> ) and <a href="#">the Code of Hygienic Code of Practice for Powdered Infant Formula (CAC/RCP 66 – 2008)</a> .	<b>International Association of Consumer Food Organizations</b>
Milk and other dairy products, <a href="#">including other animal milk sources</a> , used in the manufacturing of RUTF must comply with the <i>Standard for Milk Powders and Cream Powder</i> (CXS 207-1999) <a href="#">and the Standard for Whey Powders (CXS 289-1995)</a> , and other Codex milk and milk product 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 <i>Code of Hygienic Practice for Milk and Milk Products</i> (CXC 57-2004) and the <i>Code of Hygienic Practices for Low-Moisture Foods</i> (CXC 75-2015), <a href="#">and the Code of Hygienic Code of Practice for Powdered Infant Formula (CAC/RCP 66 – 2008)</a> .	<b>IBFAN</b>
<b>5.1.2 Legumes and Seeds</b> Legumes and seeds such as soybeans, lentils, chickpeas, cowpeas, beans, peanut, sesame and other types of legumes and seeds must comply with the relevant Codex Alimentarius texts when used in the manufacturing of RUTF. Legumes and pulses must be appropriately processed to reduce, as much as possible, the anti-nutritional factors normally present, such as phytate, lectins (haemagglutinins), trypsin and chymotrypsin inhibitors.	
We suggest adding locally produced seeds and beans, such as chocho beans, broad beans, sambo seeds and squash seeds, among others.	<b>Ecuador</b>
Legumes and pulses must be appropriately processed to reduce, as much as possible, the anti-nutritional factors normally present, such as phytate, lectins ( <del>haemagglutinins</del> ) <a href="#">(haemagglutinins)</a> , trypsin and chymotrypsin inhibitors. Legumes and pulses must be appropriately processed to reduce, as much as possible, the anti-nutritional factors normally present, such as phytate, lectins (haemagglutinins), trypsin <del>and</del> chymotrypsin <del>inhibitors</del> <a href="#">inhibitors and phytoestrogens</a> <a href="#">Lectins can be reduced by moist heat treatment. Trypsin inhibitor activity may be reduced to acceptable levels by heating to high temperatures or by prolonged boiling. Phytate can be reduced enzymatically or by soaking or fermentation. Phytoestrogens can be reduced by fermentation. Field beans or Faba beans (Vicia faba L) should not be used in the formulation of RUTF because of the danger of favism. Heat treatment does not completely inactivate the toxic components (vicine and co-vicine)</a> Legumes and <del>pulses</del> <del>seeds</del> must be appropriately processed to reduce, as much as possible, the anti-nutritional factors normally present, such as phytate, lectins (haemagglutinins), trypsin and chymotrypsin inhibitors.	<b>UNICEF</b>  similar text is used in the GUIDELINES ON FORMULATED COMPLEMENTARY FOODS FOR OLDER INFANTS AND YOUNG CHILDREN CAC/GL 8-1991 (2017).

<p>Legumes and seeds such as soybeans, lentils, chickpeas, cowpeas, beans, peanut, sesame and other types of legumes and seeds must comply with the relevant Codex Alimentarius texts when used in the manufacturing of RUTF.</p> <p>Legumes and seeds pulses must be appropriately processed to reduce, as much as possible, the anti-nutritional factors normally present, such as phytate, lectins (haemagglutinins), trypsin and chymotrypsin inhibitors.</p>	<p><b>IBFAN</b></p> <p>The high phytoestrogen content of soybeans makes these unsuitable for the rehabilitation of children with SAM).</p>
<p><b>5.1.2 Legumes and Seeds</b> <b>5.1.4 Cereals</b></p>	
<p>5.1.3 We suggest adding the type of fats and oils that may be used. The use of trans fats should be restricted. 5.1.4 We suggest adding grains with high nutritional value, such as quinoa.</p>	<p><b>Ecuador</b></p>
<p><b>5.1.5 Vitamins and Minerals (Recommendation 2)</b></p>	
<p>Argentina agrees with this recommendation about vitamins and minerals</p>	<p><b>Argentina</b></p>
<p>Regarding the minerals salts and vitamins specified in the “WHO Management of severe malnutrition: A manual for physicians and other senior health workers (1999)”, Brazil notes that these compounds (potassium chloride, tripotassium citrate, magnesium chloride, zinc acetate, copper sulfate, sodium selenite, potassium iodide) are already listed in CAC/GL 10-1979. Moreover, we do not find specific vitamins compounds in the WHO document. Thus, Brazil considers that the reference of CAC/GL 10-1979 is enough</p>	<p><b>Brazil .</b></p> <p>We request clarification about the need of including the last sentence in square brackets since the CAC/GL 10-1979 sets criteria for the inclusion and deletion of nutrient compounds from the advisory lists which already consider stability and biological availability (item 2.1) .</p>
<p>Colombia supports the proposed text and suggests mentioning the most efficient chemical form for each of the vitamins and minerals that are part of the RUTF.</p>	<p><b>Colombia</b></p>
<p>With respect to vitamins and minerals, it is important to emphasise that children with acute malnutrition have high nutritional needs due to metabolic imbalances and the need to maintain rapid rates of growth during the recovery phase. In addition, high levels of certain minerals (magnesium, potassium and phosphorus), low levels of sodium and an adequate level of vitamin A and zinc are required for optimal recovery. In addition, essential fatty acids and high-quality proteins enriched with micro-nutrients are also necessary to ensure that the high nutritional needs of recipients are met, allow the regeneration of tissue and permit the correction of micro-nutrient deficiencies which are common in these populations.</p>	<p><b>Ecuador</b></p>
<p>Agree</p>	<p><b>India</b></p>
<p>All added vitamins and minerals must be in accordance with the <i>Advisory Lists of Nutrient Compounds for use in Foods for Special Dietary Uses Intended for Infants and Young Children (CXG 10-1979)</i>. Examples of vitamin and mineral forms for RUTF formulation can be found in the <i>WHO Management of severe malnutrition: A manual for physicians and other senior health workers (1999)</i>. [The amount of vitamins and minerals added to achieve the target level must be adjusted based on the chemical form and scientific evidence showing adequate stability and bioavailability in the finished <del>product</del><b>product without compromising the nutritional value</b>]</p>	<p><b>Jamaica</b></p>
<p>HKI supports that the 2007 Joint Statement (A Joint Statement by the World Health Organization, the World Food Programme, the United Nations System Standing Committee on Nutrition and the United Nations Children’s Fund. 2007. Community-based Management of Severe Acute Malnutrition) also be added as an example of vitamins and minerals for RUTF formulation.</p>	<p><b>HKI</b></p>
<p>ICAAS suggests to add the following phrase to the sentence in brackets: “interaction and impaired absorption with other nutrients and non-nutrients”, so that the sentence currently in brackets is formulated as follows: [The amount of vitamins and minerals added to achieve the target level must be adjusted based on the chemical form, interaction and impaired absorption with other nutrients and non-nutrients and scientific evidence showing adequate stability and bioavailability in the finished product].</p>	<p><b>International Council on Amino Acid Science</b></p>

<p>ISDI supports the recommendation.</p> <p><del>[Vitamin and mineral Mineral</del> forms used must be soluble and easily absorbed by patients with SAM. Children with SAM have low or absent gastric acid ..... (sodium + potassium + calcium + magnesium) - (phosphorus + chloride.)</p> <p>All added vitamins <del>and minerals</del> must be in accordance with the <i>Advisory Lists of Nutrient Compounds for use in Foods for Special Dietary Uses Intended for Infants and Young Children</i> (CXG 10-1979..... and bioavailability in the finished product.]</p>	<p><b>International Special Dietary Food Industries</b></p> <p><b>UNICEF</b></p> <p>the mineral forms listed in the Advisory Lists of Nutrient Compounds for use in Foods for Special Dietary Uses Intended for Infants and Young Children (CXG 10-1979 approve certain minerals that are not suitable for SAM children to consume.</p>
<p><b>5.2 Other Ingredients</b></p>	
<p><b>5.2 Other <del>Ingredients</del> Ingredients</b></p> <p><u>Oil Seed Flours and Oil Seed Protein Products. Flours, protein concentrates and protein isolates of oil seeds are acceptable if manufactured to appropriate specifications which assure sufficient reduction of anti-nutritional factors and undesirable toxic substances such as trypsin and chymotrypsin inhibitors and gossypol. The decision to add oil seeds flour to RUTF should consider local conditions and requirements. Defatted oil seed flours and protein isolates, if produced and appropriately processed for human consumption, can be good sources of protein (50-95%). Such oil seeds may include:</u></p> <ul style="list-style-type: none"> <li>- <u>Soya beans: dehulled flour, (full fat and defatted) protein concentrate, protein isolate</u></li> <li>- <u>Groundnuts: paste, protein isolate</u></li> <li>- <u>Sesame seed: whole ground and defatted flour</u></li> <li>- <u>Cottonseed: defatted flour</u></li> <li>- <u>Sunflower seed: defatted flour, full fat</u></li> <li>- <u>Low erucic acid rapeseed: full fat flour.</u></li> </ul> <p><u>Animal source foods (other than milk and milk products) such as meat, fish, poultry, eggs, are nutrient dense and are good sources of high quality proteins and micronutrients. Incorporation of these foods or their derived protein concentrates in RUTFs should consider technological feasibility and compliance to the relevant Codex Alimentarius texts.</u></p>	<p><b>UNICEF</b></p>
<p><b>5.2.1 Available Carbohydrates<sup>6</sup> (Recommendation 3)</b></p>	
<p>Argentina agrees with this recommendation about available carbohydrates</p>	<p><b>Argentina</b></p>
<p>Brazil requests clarification about the sentence “Available carbohydrates must adhere to the relevant Codex Alimentarius texts”. In our opinion the proposed text is non-specific and it does not set an objective criterion. We also are of the opinion that the guideline should include a recommendation about the importance of reducing the amount of quantity of free sugars used in RUTF at the minimum level possible in light of the WHO Guidelines for Sugars intake for adults and children (2015). So, we propose the inclusion of the sentence “The addition of mono- and disaccharides should be added at the minimum level possible in order to not exceed 10% product”.</p>	<p><b>Brazil</b></p>
<p><sup>6</sup>Sucrose, <b>glucose</b>, plant starch, maltodextrin, should be the preferred carbohydrates in RUTF. Fructose, <b>glucose</b> and corn syrup as ingredients should be avoided in RUTF, because of potential adverse effects in SAM children. Only precooked and/or gelatinized starches <del>[gluten free]</del> by nature may be added. Any carbohydrate added for sweetness should be used sparingly.</p>	<p><b>Colombia</b></p> <p>We reiterate the position sent by Colombia in the second round of review and Colombia considers glucose should not be excluded of preferred carbohydrates in RUTF.</p>
<p>Ecuador believes it is necessary to eliminate the text “The palatability of the ATLC may be increased by adding available carbohydrates”, as this information does not provide a technical contribution to the document and may indicate that, by itself, the product is not suitable for consumption. In fact, the text “carbohydrates with a sweetening effect should be added infrequently” should appear at the beginning of the paragraph and not as an explanatory note.</p>	<p><b>Ecuador</b></p>

<p>The palatability of the RUTF can be increased by the addition of available carbohydrates. Available carbohydrates must adhere to the relevant Codex Alimentarius <del>texts</del><u>texts and should be limited to the WHO Guideline: Sugars intake for adults and children, Geneva, WHO (2015).</u></p> <p><sup>6)</sup>Sucrose, plant starch, maltodextrin, should be the preferred carbohydrates in RUTF. Fructose, glucose and corn syrup as ingredients should be avoided in RUTF, because of potential adverse effects in SAM children. Only precooked and/or gelatinized starches <del>[gluten-free]</del> by nature may be added. <del>Any carbohydrate.</del><u>The free sugars added for sweetness should be used sparingly limited to 10% to 5% of total energy.</u></p>	<p><b>India</b></p>
<p><sup>6)</sup>Sucrose, plant starch, maltodextrin, should be the preferred carbohydrates in RUTF. Fructose, glucose and corn syrup as ingredients should be avoided in RUTF, because of potential adverse effects in SAM children. Only precooked and/or gelatinized starches <del>[gluten-free]</del> by nature may be added. Any carbohydrate added for sweetness should be used <del>sparingly</del><u>sparingly</u>.</p>	<p><b>Jamaica</b> sparingly seems like a vague term. More specific guidance is needed especially as there is a move towards reducing consumption of free sugars. Reference should be made to the technical guidance (from scientific evidence) available at this time.</p>
<p>We support the recommendation. We suggest deleting “gluten-free by nature” in the sentence “Only precooked and/or gelatinised starches gluten-free by nature may be added” in the footnote. Considering that cereals are considered suitable ingredients for the production of RUTF (according to section 5.1.4), demanding gluten-free starches should in our opinion not be necessary here.</p>	<p><b>Norway</b></p>
<p><sup>6)</sup>Sucrose, plant starch, maltodextrin, should be the preferred carbohydrates in RUTF. Fructose, glucose and corn syrup as ingredients should be avoided in RUTF, because of potential adverse effects in SAM children. Only precooked and/or gelatinized starches <del>[gluten-free]</del> by nature may be added. <del>Any carbohydrate added for sweetness</del><u>carbohydrates should not be used sparingly to add sweetness to product.</u></p>	<p><b>Sri Lanka</b></p>
<p>The palatability of the RUTF can be increased by the addition of <del>available carbohydrates</del><u>sucrose</u> . Available carbohydrates must adhere to the relevant Codex Alimentarius texts.</p> <p><sup>6)</sup>Sucrose, plant starch, maltodextrin, should be the preferred carbohydrates in RUTF. Fructose, glucose and corn syrup as ingredients should be avoided in RUTF, because of potential adverse effects in SAM children. Only precooked and/or gelatinized starches <del>[gluten-free]</del> by nature may be added. Any <del>carbohydrate</del><u>sucrose</u> - added for sweetness should be used sparingly.</p>	<p><b>International Special Dietary Food Industries</b> ISDI partially supports the recommendation but would like to explain the various purposes of carbohydrates. <u>Available carbohydrates are added in the formulation to complement other ingredients needed to reach the protein and lipid specifications.</u></p>
<p>The palatability of the RUTF can be increased by the addition of available carbohydrates. Available carbohydrates must adhere to the relevant Codex Alimentarius <del>texts</del><u>texts and be in line with the WHO Guideline: Sugars intake for adults and children, Geneva, WHO (2015).</u></p> <p><sup>6)</sup><del>Sucrose, plant starch, maltodextrin, Lactose</del> should be the preferred <del>carbohydrates</del><u>carbohydrate</u> in RUTF. Fructose, <del>glucose</del><u>glucose, high fructose corn syrup</u> and corn syrup as ingredients should <del>not be avoided</del><u>not be avoided</u> in RUTF, because of potential adverse effects in SAM children. Only precooked and/or gelatinized starches <del>[gluten-free]</del> by nature may be added. Any carbohydrate added for sweetness should be used sparingly.</p>	<p><b>International Association of Consumer Food Organizations</b></p>
<p>The palatability of the RUTF <del>should not be done</del> by the addition of available carbohydrates. <del>The addition of permissible sugars</del> Available carbohydrates must adhere to <u>the WHO recommended levels of no more than 5 to 10% of total energy (WHO Guideline: Sugars intake for adults and children, Geneva, WHO, 2015).</u> relevant Codex Alimentarius texts.</p> <p>Honey should not be used in RUTF due to the risk of infant botulism from Clostridium botulinum.</p> <p><sup>6)</sup>Sucrose, plant starch, maltodextrin, should be the preferred carbohydrates in RUTF. Fructose, glucose and corn syrup as ingredients should not be used in RUTF, because of potential adverse effects in SAM children. Only recommended free sugars precooked and/or gelatinized starches [gluten-free] by nature may shall be added.</p>	<p><b>IBFAN</b></p>
<p><sup>6)</sup>Sucrose, plant starch, maltodextrin, should be the preferred carbohydrates in RUTF. Fructose, glucose and corn syrup as ingredients should be avoided in RUTF, because of potential adverse effects in SAM children. Only</p>	<p><b>EU Specialty Food Ingredients</b> EU Specialty food ingredients believes that the first sentence</p>

<p>precooked and/or gelatinized starches [<del>gluten-free</del>] by nature may be added. Any carbohydrate added for sweetness should be used sparingly.</p>	<p>of the footnote is sufficient. Should the full footnote remain, we are of the opinion that the requirement for “gluten free” is indeed not needed. In addition, while we could understand the wish to limit fructose, we don't understand the limitation of glucose or corn syrup. What could be limited is the use of “high fructose corn/glucose syrup”. We are not aware of potential adverse effect of glucose or corn syrup in SAM children.</p>
<p><del>The palatability of the RUTF</del> Carbohydrates are used to provide energy and can be increased by the addition used to increase palatability of available carbohydrates the RUTF. Available Lactose, plant starch, maltodextrin and sucrose are the preferred carbohydrates in RUTF. Only precooked and/or gelatinized starches may be added. Carbohydrates must adhere to the relevant Codex Alimentarius texts. <u>Glucose and corn syrup ingredients and fructose ingredients should be avoided in RUTF, because of potential adverse effects in SAM children. Honey must not be used in RUTF due to the risk of infant botulism from Clostridium botulinum. Free sugars added for sweetness should be used sparingly.</u></p>	<p><b>UNICEF</b></p>
<p><b>5.2.2 Food Additives and Flavours (Recommendation 4)</b></p>	
<p>Argentina agrees with Recommendation 4. However, it should be noted that propylene glycol (INS 1520) has no maximum use level for categories 13.1, 13.2 and 13.3, so it may not be appropriate for use in RUTF.</p>	<p><b>Argentina</b></p>
<p>Colombia supports the proposed text.</p>	<p><b>Colombia</b></p>
	<p><b>India</b></p> <ul style="list-style-type: none"> <li>• Comments on individual additives are as per Annexure-1.</li> <li>• However, foods for older infants and young children should not include food additives and flavours. 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.</li> <li>• Examples of detrimental effects of some of the additives currently being used are as follows:             <ul style="list-style-type: none"> <li>- 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.</li> <li>- Carmine: Cochineal carmine, or simply carmine (E120), is a red colouring that is obtained from the dried bodies of the female insect <i>Dactylopius coccus</i> 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.</li> <li>- Polysorbates: Polysorbate 80 can cause severe nonimmunologic anaphylactoid reactions and therefore its' use</li> </ul> </li> </ul>

as an additive requires due diligence.

References:

i. (Pongsavee M. Effect of sodium benzoate preservative on micronucleus induction, chromosome break, and Ala40Thr superoxide dismutase gene mutation in lymphocytes. Biomed Res Int. 2015;2015:103512

<https://www.ncbi.nlm.nih.gov/pubmed/25785261>

ii. <https://www.ncbi.nlm.nih.gov/pubmed/11285683>

iii.

<https://www.fda.gov/food/ingredientspackaginglabeling/foodadditivesingredients/ucm488219.htm>

iv. <https://www.ncbi.nlm.nih.gov/pubmed/16400901> )

Annexure-I

Recommendation 4- Food Additives

Ascorbyl palmitate- Before adding the same has to be examined by CCFA

Tochopherol- INS need to be specified

Lecithin - INS need to be specified

Tocopherols rich extract - Before adding the same has to be examined by CCFA

Mixed tocopherol concentrate- Already covered above, need to be deleted

Carbon dioxin - it should be Carbon dioxide

Sodium Tri-phosphates - INS need to be specified as 145(i) and 145(ii)

Silicium dioxide - it should be Silicon dioxide

NATA - 5 - Since Codex GSFA do not recognize the premix/composed additives, Hence, it need to be reviewed again.

Grindsted PS - 209 (Composed of Mono-diglyceride & Triglyceride - Since Codex GSFA do not recognize the premix/composed additives, Further Mono and Di and triglyceride and tocopherols are already allowed above. Hence, it need to be reviewed again.

Fortium APT 10 (composed of mono & di-glycerides, propylene glycol, mixed tocopherols, and ascorbylpalmitate) - Since Codex GSFA do not recognize the premix/composed additives, Further Mono and Di and triglyceride and tocopherols are already allowed above. Hence, it need to be reviewed again.

N-ATA 1 -Since Codex GSFA do not recognize the premix/composed additives, Hence, it need to be reviewed again.

<p>The use of food additives must be restricted in foods for children with SAM. Children suffering from SAM are immunocompromised and the chemical body burden of additives can exacerbate their fragile condition.</p> <p>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.</p> <p>IBFAN notes that many food additives used are for technical and/or appearance or consistency purposes Hence this imposes known and unknown risks for older infants and young children who are fed these products. This may pose an even greater risk for those children suffering from SAM.</p> <p>IBFAN proposes that thickeners such as Guar Gum, Xanthan Gum and Gum Arabic are not necessary and should not be used, nor should mono and di glycerides be on the list.</p> <p>Adverse effects have been reported in children due to additives, such as benzoates, carmine and polysorbates and these should be avoided.</p> <p>IBFAN wishes to note and concurs with the JECFA principle:          “Baby foods should be prepared without food additives whenever possible. Where the use of food additives becomes necessary in baby foods, great caution should be exercised regarding both the choice of additive and its level of use.” (Annex 3of TRS488):</p>	<p><b>IBFAN</b></p>
	<p><b>International Special Dietary Food Industries</b></p> <p>ISDI welcomes the progress made in developing a list of food additives that provide a necessary technical function in RUTF products, based on current use by producers of these products. In the further work on the additives section proposed here, we have included all of the additives in the eWG Table that have an INS number. For those without an identified INS number, we propose to allow for additional input by producers in order to ensure that essential substances are not inadvertently omitted.</p> <p>ISDI proposes to consider the food additives shown in the Table (sent via email to Codex Secretariat on 31 October 2018), grouped according to functional class, according to CAC/GL 36-1989 (Class Names and the International Numbering System for Food Additives). In addition, the Table provides information on the INS number, the ADI assigned by JECFA, technological justification, proposed use level and Maximum Use Level, and whether the additive was previously endorsed by the CCFA.</p> <p>For the latter, as a proxy, we provided information on whether the proposed additives are currently authorized in the Infant Formula Standard and Formulas for Special Medical Purposes Intended for Infants (Section A or B) (Codex Stan 72-1981) or the Follow-up Formula Standard (Codex Stan 156-1987). We consider that this is appropriate given the similar age range for the Guidelines under consideration and the description as “food for special medical purpose” of RUTF. The approach is</p>

	<p>consistent with information provided in the Codex Procedural Manual (26th Ed) (page 51) pertaining to Elaboration of Codex Standards, Food Additives section, as follows:                  “When forwarding a food additive section of a commodity standard for endorsement by the Committee on Food Additives, the Secretariat should prepare a report to the Committee that includes the International System (INS) number, the Acceptable Daily Intake (ADI) assigned by the Joint FAO/WHO Expert Committee on Food Additives, technological justification, proposed level, and whether the additive was previously endorsed by the Codex Committee on Food Additives.”</p> <p>With this background, ISDI proposes the following for further consideration of the Food Additives section of the Proposed Draft Guidelines for Ready-to-Use Therapeutic Foods. Only the food additives listed in this Section or in the Advisory List of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children (CAC/GL 10-1979) may be present in the foods described in this Guidelines, as a result of carry-over from a raw material or other ingredient (including food additive) used to produce the food.</p>
	<p><b>International Association of Consumer Food Organizations</b>                  The use of food additives must be restricted in foods for children with SAM. Children suffering from SAM are highly sensitive and immunocompromised.                  IACFO wishes to note and concurs with the JECFA principle: “Baby foods should be prepared without food additives whenever possible. Where the use of food additives becomes necessary in baby foods, great caution should be exercised regarding both the choice of additive and its level of use.” (Annex 3of TRS488):                  IACFO is of the opinion that colourings and flavourings should never be permitted as they are unnecessary and often substitute for nutritious ingredients, and may pose adverse effects. Similarly, IACFO proposes that thickeners such as Guar Gum, Xanthan Gum, Tragacanth Gum and Gum Arabic are not necessary and should never be used. Tragacanth gum has caused occasional severe allergic reactions. Emulsifiers such as polysorbates and carboxymethylcellulose can trigger changes in the gut and should never be used in these products.</p>
<p><b>5.3 The Use of other Matrices in RUTF formulation (Recommendation 5)</b></p>	
<p>Argentina agrees with this paragraph.</p>	<p><b>Argentina</b></p>

<p>Brazil supports recommendation 5.</p> <p>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 <i>Standard for Labelling of and Claims for Foods for Special Medical Purposes</i> (CXS 180-1991). <u>although several scientific studies have reported that use of formulation with other ingredients are less effective in terms of recovery rates in comparison to standard, peanut and milk (25%) based formulation.</u></p>	<p><b>Brazil</b></p> <p><b>India</b></p> <p>1. 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.</p> <p>2. 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 &lt; 0.001). Children receiving 25% milk RUTF also had higher rates of weight and height gain compared with children receiving 10% milk RUTF.</p>
<p>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 <i>Standard for Labelling of and Claims for Foods for Special Medical Purposes</i> (CXS 180-1991). <u>However nothing should be added to RUTF unless there is relevant and convincing evidence – free from commercial influence - of its efficacy and safety. Promotional claims should not be allowed for the labelling, presentation or information regarding these products. Descriptors should be restricted to scientific and factual information.</u></p> <p>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 <i>Standard for Labelling of and Claims for Foods for Special Medical Purposes</i> (CXS 180-1991)–, <u>particularly regarding their use that 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.</u></p>	<p><b>International Special Dietary Food Industries</b></p> <p>ISDI supports this recommendation and would like to add the following text for more clarity.</p>
<p><b>Recommendation 7: Agree not to set the minimum and maximum /GUL values for carbohydrates</b></p> <p><b>6. NUTRITIONAL COMPOSITION AND QUALITY FACTORS</b></p>	
<p>Argentina agrees with recommendation 7</p>	<p><b>Argentina</b></p>
<p>Colombia recommends including the percentage (%) of carbohydrates that the RUTF must provide.</p>	<p><b>Colombia</b></p>
<p><b>Recommendation 6</b></p> <p><b>6.1 Energy</b></p>	
	<p><b>India</b></p> <p>The amount of carbohydrates must adhere to the WHO Guideline: Sugars intake for adults and children, Geneva, WHO (2015)'. The free sugars added for sweetness should be limited to 10% to 5% of total energy.</p> <p>Sugars such as fructose and corn syrups should be prohibited because of their possible adverse effects which may be exacerbated by the condition of SAM.</p> <p>References (Malik VS, Hu FB. Fructose and Cardiometabolic Health: What</p>

	<p>the Evidence From Sugar-Sweetened Beverages Tells Us. J Am Coll Cardiol. 2015 Oct 6;66(14):1615-24</p> <p>Hu FB, Malik VS. Sugar-sweetened beverages and risk of obesity and type 2 diabetes: epidemiologic evidence. Physiol Behav. 2010 Apr 26;100(1):47-54. )</p> <ul style="list-style-type: none"> <li>• There is no scientific basis for suggesting an energy density of 5.2 - 5.5 kcal per gram. This is empirical and hence needs more discussion before finalising a value. Energy content of the product is dependent on the amount of protein, carbohydrates and lipids present. Therefore, an effort should be made to use appropriate balance of ingredients rather than increasing energy density which will be mainly achieved by adjusting the amount of fats and sugars in the product, which may have health implications and the product will also not conform to the WHO recommendations.</li> <li>• Also, the additional energy required will depend on the amount of breastmilk the older infant and young child is receiving.</li> </ul>
The energy density of the formulated RUTF should be between 5.2 –to 5.5 kcal per gram. The energy density of 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 Section 8.	<b>Jamaica</b>
ISDI supports this recommendation.	<b>International Special Dietary Food Industries</b>
<b>Recommendations 8 and 9</b>	
<b>6.2 Proteins</b>	
Recommendation 9: We support maintaining the text in squared brackets until there is guidance from the FAO Expert Working Group on protein quality assessment in follow-up formula for young children and Ready to Use Therapeutic Foods. In this matter, we consider that other sources of high quality protein could also be considered.	<b>Brazil</b>
Colombia supports the proposed text.	<b>Colombia</b>
Japan supports keeping the proposed text “at least 50 % of protein is provided by milk products” in square brackets until there is further guidance from FAO on determining protein quality using PDCAAS. (It is better to discuss it once the guidance is available from FAO.)	<b>Japan</b>
Malawi does not support this requirement. Protein should provide 10% - 12% of the total energy. <del>["at least 50% of protein is provided by milk products"]</del> .	<p><b>Malawi</b></p> <p>The Codex draft guidelines Clause 6.2 indicates that at least 50 % of the protein to be provided by milk products. However, we have some RUTFs which are mainly produced from cereals and legumes without adding any milk product, so this restriction is not economical as milk is expensive compared to cereals and legumes. Scientifically, the protein levels in RUTFs can also be achieved by other sources other than milk products. Hence the proposal to remove this strict requirement in order to allow other sources of proteins other than milk products to be used in the production of RUTFs.</p>
HKI supports the protein range (10-12%) content of the total energy yet does not support the statement: ["at least 50% of protein is provided by milk products"]	<p><b>HKI</b></p> <p>While likely beneficial, the minimum dairy protein requirement</p>

	<p>is not based on scientific evidence. Thus, setting such a high level of protein from milk products may be unnecessarily restrictive to local production and innovation (i.e. the development of alternative 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. Thus, it may be necessary to specify that RUTF formulations with less than 50% protein from milk product have adequate effectiveness data.</p> <p>Bahwere et al have 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).</p>
<p>Protein should provide 10% - 12% of the total energy. <del>at</del> <u>at</u> least 50% of protein is provided by milk <del>products</del> <u>products</u>.</p>	<p><b>IDF</b></p> <p>IDF strongly supports removing square brackets around the statement “at least 50% of protein is provided by milk products” and retaining this language in the Codex Guideline on Ready-to-Use Therapeutic Foods (RUTF).</p> <p>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.</p> <p>There are numerous studies showing that dairy ingredients are effective in RUTF used in the treatment and recovery of severe acute malnutrition. There is no scientific evidence showing the need to remove milk from RUTF, and the literature continues to support making dairy protein available for this vulnerable population. 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, non-milk protein source is available which meets the amino acid, micronutrient, and</p>

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.<sup>7</sup> 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.<sup>8</sup> 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.

- o Bahwere et al., (2014) compared the effects of RUTF containing whey protein (WPC34) vs a RUTF containing dried skimmed milk (DSM).<sup>10</sup> 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.<sup>11</sup> 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.<sup>12</sup> 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.

Striking the verbiage “at least 50% of protein is provided by milk products” from this guideline or substantiating a recommendation to remove “all milk-sourced products from all

RUTF formulations" require a large and robust 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:

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- Ryan KN, Adams KP, Vosti SA, Ordiz MI, Cimo ED, Manary

	<p>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.</p> <ul style="list-style-type: none"> <li>• Weber JM, Ryan KN, Tandon R, et al. Acceptability of locally produced ready-to-use therapeutic foods in Ethiopia, Ghana, Pakistan and India. Maternal &amp; child nutrition. Jan 18 2016.</li> <li>• UNICEF, WHO, World Bank Group. 2017. Joint malnutrition estimates. <a href="https://data.unicef.org/wp-content/uploads/2017/06/JME-2017_brochure_June-25.pdf">https://data.unicef.org/wp-content/uploads/2017/06/JME-2017_brochure_June-25.pdf</a>.</li> </ul>
<p>Protein should provide 10% - 12% of the total energy. <del>["at, and at</del> least 50% of protein <del>is</del> provided by milk <del>products"]products.</del>  <b>remove brackets</b></p>	<p><b>International Association of Consumer Food Organizations</b></p>
<p>Protein should provide 10% - 12% of the total energy. at least 50% of protein is provided by milk products". <b>REMOVE BRACKETS</b></p>	<p><b>IBFAN</b>  Rationale:  Several scientific studies have reported that the formulation with ingredients other than milk are less effective in achieving desired recovery rates when compared to the standard, peanut and milk (25%) based formulation."  (An equivalence non-blinded cluster randomized controlled trial from Zambia determined that recovery rates of a milk-free soy-maize-sorghum-based RUTF (SMS-RUTF) compared to 25% milk content in standard peanut-based RUTF (P-RUTF) were lower.  A randomized, double blind, clinical, quasi-effectiveness trial from Malawi concluded that treating children with SAM with 10% milk (plus Soy) RUTF is less effective when compared to 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 weeks, and 84% compared with 81% after 8 weeks. Children receiving 25% milk RUTF also had higher rates of weight and height gain compared with children receiving 10% milk RUTF.)</p>
<p>ISDI does not support the proposed Protein minimum limit of 12.8 g protein/100 g and value of 2.3 g/100kcal.</p>	<p><b>International Special Dietary Food Industries</b>  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  - 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.</p>

	<p>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 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:  Unit: g/100g; Minimum:13g; Maximum:16.5g; GUL-  Unit:g/kcal; Minimum:2.4; Maximum:3.2</p>
<p>Protein should provide 10% - 12% of the total energy. ["at least 50% of protein is provided by milk products"]products"]When no mixture of vegetable and/or animal proteins makes it possible to obtain an adequate protein quality, semi essential and essential amino acids may be added. The added amino acids should be solely in the L-form, and included only in amounts necessary to improve the protein quality of the RUTF  <u>The Protein Digestibility Corrected Amino Acid Score (PDCAAS) should 100, &gt;90</u></p>	<p><b>UNICEF</b>  Permitting the addition of amino acids that are low in formulated foods can facilitate the use of locally available ingredients. There is a precedent for including this clause in (1) GUIDELINES ON FORMULATED COMPLEMENTARY FOODS FOR OLDER INFANTS AND YOUNG CHILDREN CAC/GL 8-1991; (2) STANDARD FOR PROCESSED CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN CODEX STAN 74-1981 (3) STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS CODEX STAN 72-1981(Amended 2016)</p>
<p><b>Recommendations 10 and 11</b>  <b>6.3 Lipids</b></p>	
<p>Does not agree.</p>	<p><b>India</b>  A product deriving high energy from fats is not scientifically sound and is abnormal composition for a diet. WHO recommends that total fat should not exceed 30% of total energy intake. Accordingly, the guidelines should 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.”</p>
<p>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 not a recommended level for the diet of young children. Accordingly, this guideline should not aim to permit the use of fats as a technological fix but rather keep negative health implications of high fat intake a priority. However, if the WHO recommendation of keeping fat levels below 30% of total energy is not observed, the label should include text stating, “ This is a high fat product”.</p>	<p><b>IBFAN</b></p>
<p>ISDI partially supports this recommendation and suggests to widen the range in the last sentence as follows:  The level of linoleic acid should not be less than 333 mg per 100 kcal. The level of alpha-linolenic acid should not be less than 33mg/100kcal. The level of linoleic acid should ensure a ratio between linoleic acid and alpha-linolenic acid of between 1:1 and 15:1.</p>	<p><b>International Special Dietary Food Industries</b>  Rationale:  Available evidence suggests that the content of linoleic acid (LA) in current RUTF formulation is too high. This results in</p>

	<p>poor conversion of alpha linolenic acid (ALA) into DHA. The content of LA in the lower part of the permitted range is preferable.</p> <p>Having a low LA/ALA ratio does not guarantee a good conversion of ALA to DHA as ALA competes with intermediate metabolites in the final stage of DHA synthesis. The best DHA status at the end of treatment was achieved with an RUTF with a low LA content and a LA/ALA ratio of 1:1..</p> <p>Reference:          Brenna JT, Akomo P, Bahwere P, Berkley JA, Calder PC, Jones KD, Liu L, Manary M, Trehan I, Briend A. Balancing omega-6 and omega-3 fatty acids in ready-to-use therapeutic foods (RUTF). BMC Med. 2015 May 15;13:117.          Hsieh JC, Liu L, Zeilani M, Ickes S, Trehan I, Maleta K, Craig C, Thakwalakwa C, Singh L, Brenna JT, Manary MJ. High-Oleic Ready-to-Use Therapeutic Food Maintains Docosahexaenoic Acid Status in Severe Malnutrition. J Pediatr Gastroenterol Nutr. 2015 Jul;61(1):138-43.  <i>Category : SUBSTANTIVE</i></p>
<p>The level of linoleic acid should not be less than <del>333</del><u>316</u> mg per 100 kcal and shall not be more than <u>1115 mg per 100 kcal</u>. The level of alpha-linolenic acid should not be less than <del>33</del><u>mg/100kcal</u> and shall not be more than <u>280 mg/100kcal RUTF</u>. The level of linoleic acid should ensure a ratio between linoleic acid and alpha-linolenic acid of between 5:1 and 15:1.</p>	<p><b>MSF</b></p> <p>The specifications according to the WHO Community-based management of severe acute malnutrition are as following:          linoleic acid (n-6): 3 to 10% of total energy = 1.7 - 6.1 g/100 RUTF = 316-1115 mg/100 kcal RUTF          alpha-linolenic acid (n-3): 0.3%–2.5% of total energy = 0.172 - 1.5 g/100 RUTF = 32 - 279 mg/100kcal RUTF  <a href="http://www.who.int/maternal_child_adolescent/documents/a91065/en/">http://www.who.int/maternal_child_adolescent/documents/a91065/en/</a></p>
<p>The level of linoleic acid should not be less than <del>333</del><u>330</u> mg per 100 kcal. The level of alpha-linolenic acid should not be less than 33 mg/100kcal. The level of linoleic acid should ensure a ratio between linoleic acid and alpha-linolenic acid of between <del>5</del><u>1</u>:1 and 15:1.</p>	<p><b>UNICEF</b></p> <p>Research in SAM children has shown that if linoleic acid is too high, then conversion of alpha linolenic acid to DHA is inhibited, due to competition for enzymes pathways during metabolism. According to the literature at hand, the ratio of 1:1 of ALA: LA seems to produce the most optimal DHA levels in these children. Low levels of DHA may adversely impact on neural development in SAM children. the maximum limit of ALA would need to either be increase to 330 or preferably removed so there is no maximum limit for ALA, following the CODEX STAN 72-1981 for infant formula, as there is no evidence of toxic or adverse events for ALA.</p>
<p>ISDI would like to raise a general comment in regard to the calculation of the nutrients in g/100 kcal.</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> The minimum “g/100 kcal” should be calculated with: minimum “g/100g” / 5.5</li> <li><input type="checkbox"/> The maximum “g/100 kcal” should be calculated with: maximum “g/100g” / 5.2</li> </ul>	<p><b>International Special Dietary Food Industries</b></p>

<b>Recommendation 17 – additional nutrients</b>	
That CCNFSDU consider that the current formulation of RUTF, as well as the proposed nutrients as stipulated in the 2007 Joint Statement be the basis for RUTF formulation, unless there is scientific evidence on any additional nutrients that has been demonstrated to be safe and beneficial in meeting the nutritional requirements of SAM children	
Brazil supports recommendation 17.	<b>Brazil</b>
<b>7. CONTAMINANTS</b>	
Jamaica supports text in square brackets.	<b>Jamaica</b>
[It is recommended that the products covered by the provisions of these guidelines <a href="#">at a minimum</a> comply with the <i>General Standard for Contaminants and Toxins in Food and Feed</i> (CXS 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].	<b>International Association of Consumer Food Organizations</b>
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 of less than 5ppb µg/kg. (NOTE: Aflatoxin is a well-documented carcinogen and should be limited as much as possible for this vulnerable population.)	<b>IBFAN</b>
<b>[Other Contaminants]</b>	
The product should not contain contaminants or other undesirable substances (e.g. biologically active substances, metal fragments) <del>in amounts</del> 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]. <del>[A maximum of 10 ppb (µg/kg) for aflatoxin is allowed in the RUTF products.]</del>	<b>Jamaica</b>
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]. <del>[A maximum of 10 ppb (µg/kg) for aflatoxin is allowed in the RUTF products.]</del>	<b>IBFAN</b>
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 <del>Commission].</del> <del>[Commission] A maximum of 10ppb(ug/kg) for aflatoxin is allowed for the RUTF product.</del> <del>A maximum of 10 ppb (µg/kg) for aflatoxin is allowed in the RUTF products.]</del>	<b>UNICEF</b> UNICEF notes that it is convention to refer to primary codex texts for microbial and contaminant specification criteria. While respecting this convention, allows for efficient updating of codex texts, we find that partners and suppliers appreciate the ease of having specific criteria listed in the one reference document, and find that inclusion of specific limits within documents used as reference for global trade, advantageous when technical issues arise with import and export transactions.
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]. <del>[A maximum of 10 ppb (µg/kg) for aflatoxin is allowed in the RUTF products.]</del>	
<b>8. PROCESSING TECHNOLOGIES (Recommendation 18)</b>	
Argentina agrees with this item	<b>Argentina</b>
Colombia supports the proposed text.	<b>Colombia</b>
Agreed subject to adoption by individual country.	<b>India</b>
[In addition to the practices described below, Good Hygiene Practices ( <i>General principles of food hygiene</i> (CXC 1-1969)) should be implemented to avoid cross contamination during the packing and storage of raw materials.]	<b>Jamaica</b> Jamaica supports retention of text within square brackets.
ISDI partially supports this recommendation and proposes the following amendment in the introduction. Processing technologies described below are given as examples of treatment mainly on raw materials. Any technologies used for raw materials and for RUTF have to be validated according to Guidelines for the	<b>International Special Dietary Food Industries</b>

<p>Validation of Food Safety Control Measures (CXG 69-2008), to prove that:</p> <ul style="list-style-type: none"> <li>- they do not alter the nutritional value,</li> <li>- they allow reduction of anti-nutritional factors,</li> <li>- they allow to guaranty the microbial quality of the food.</li> </ul> <p>In addition to the practices described below, Good Hygiene Practices (General principles of food hygiene CXC 1-1969) should be implemented to avoid cross contamination during the packing and storage of raw materials.</p>	
<b>8.1 Preliminary Treatment of Raw Materials</b>	
<p><del>Cleaning or washing: to eliminate dirt, damaged grains, foreign grains and noxious seeds, insects and insect excreta and any adhering material.</del></p>	<p><b>MSF</b></p> <p>This section about preliminary treatment of raw materials shall be removed, or completely re-organised. The preliminary treatments are already covered in the section 5.1.2. RUTF must be manufactured in compliance with the Code of Hygienic Practices for Low-Moisture Foods (CXC 75-2015), and most of the processes described in this section can not be done according to this Code of Hygienic Practices for Low-Moisture Foods (CXC 75-2015). If the section were kept, it is important to reorganise and remove all processes involving introduction of water. Cleaning or washing shall not be mentioned in a standard for low moisture food, such as RUTF.</p>
<b>8.2 Milling</b>	
<b>8.2.1 Milling</b>	<b>MSF</b>
<p>Formulations containing milled cereals, legumes, pulses and/or oilseeds that have not been otherwise processed require adequate boiling to gelatinize the starch portions and/or eliminate anti-nutritional factors present in cereals, legumes and pulses. Boiling improves the digestibility and absorption of nutrients.</p>	<p>This is part of preliminary treatment for raw materials, and shall be presented as the cleaning, dehulling or degermination steps.</p>
<p><del>The bulkiness of foods from food formulations containing dry ingredients obtained by milling of the raw materials can be reduced by adding, during the formulation, adequate amounts of enzymes such as alpha-amylase which, during the slow heating to boiling, predigest partially the starch and reduce the amount of water needed for the preparation of the food.</del></p>	<p>This is not allowed for low moisture food process. Bulkiness does not apply here. This all paragraph does not apply to ready to use food (RUF).</p>
<b>8.3 Toasting</b>	
	<p><b>Colombia</b></p> <p>Colombia requests clarification of the term "appropriate Enzymes".</p>
<b>8.3.1 Toasting</b>	<b>MSF</b>
<ul style="list-style-type: none"> <li>• Toasting (dry heating) enhances the flavour and the taste of the food through dextrinization of starch. It also improves digestibility <del>and contributes to reducing the bulkiness of the formulated food. Moreover, it reduces microorganisms and enzyme activity and destroys insects, thus improving keeping qualities.</del></li> </ul>	<p>This is part of preliminary treatment for raw materials, and shall be presented as the cleaning, dehulling or degermination steps</p> <p>This is part of preliminary treatment for raw materials, and shall be presented as the cleaning, dehulling or degermination steps</p>
<b>8.4 Sprouting, Malting and Fermentation</b>	
<ul style="list-style-type: none"> <li>• <del>Cereals and pulses can be induced to germinate by soaking or humidifying. It is necessary, however, to ensure that growth of mycotoxin-producing microorganisms does not occur. The action of natural amylases</del></li> </ul>	<p><b>MSF</b></p> <p>This does not apply to RUTF. This can not be done in</p>

<p><del>contained in the grains results in the pre-digestion of the starchy portion of the grain (dextrinization) thus reducing the bulk of the food when prepared for feeding and, ultimately, increasing the nutrient density of the food. Sprouting, malting and fermentation can induce hydrolysis of phytates and decrease its inhibitory effect on mineral absorption, and may improve B-vitamin content.</del></p> <ul style="list-style-type: none"> <li><del>During the germination process, the seed coat of the grain splits and can be removed by washing. The malted raw material is milled or ground after drying.</del></li> </ul>	<p>compliance with codex standard for low moisture food process Does not apply to RUTF. no washing in low moisture food process</p>
<b>8.5 Other Processing Technologies</b>	
Colombia supports the proposed text.	<b>Colombia</b>
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. [ <i>Guidelines for the Validation of Food Safety Control Measures</i> (CXG 69-2008) and <i>Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)</i> (CXG 63-2007) should be adhered to.]	<b>Jamaica</b> Jamaica agrees to retaining text in square brackets.
Whenever feasible, RUTF <u>and /</u> or their raw materials should be treated with a validated microbial reduction treatment in order to inactivate pathogens such as <i>Salmonella</i> , noting that some pathogens have increased heat resistance characteristics at reduced water activities in food matrices.	<b>MSF</b> RUTF shall preferably be heat treated at a late step during process.
<b>9. MANUFACTURING PRACTICES AND GOOD HYGIENE PRACTICES (Recommendation 19)</b>	
Argentina agrees with this text	<b>Argentina</b>
Brazil supports recommendation 19.	<b>Brazil</b>
Agreed subject to adoption by individual country.	<b>India</b>
ISDI supports this recommendation.	<b>International Special Dietary Food Industries</b>
The product should comply with any microbiological criteria established in accordance with the <i>Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods</i> (CXG <del>21-1997</del> ) <u>21-1997</u> <u>And annex of CODE OF HYGIENIC PRACTICE FOR LOW-MOISTURE FOODS CXC 75-2015 Adopted in 2015. Revised in 2016. Amended in 2018.</u>	<b>MSF</b> And annex of CODE OF HYGIENIC PRACTICE FOR LOW-MOISTURE FOODS CXC 75-2015 Adopted in 2015. Revised in 2016. Amended in 2018.
The product should comply with any microbiological criteria established in accordance with <u>Annex 1 Code of Hygienic Practice for Low-Moisture Foods (CXC 75-2016)</u> , the <i>Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods</i> (CXG 21-1997).	<b>UNICEF</b>
<b>10. METHODS OF ANALYSIS AND SAMPLING (Recommendation 20)</b>	
Agreed subject to adoption by individual country.	<b>India</b>
ISDI supports this recommendation.	<b>International Special Dietary Food Industries</b>
<b>11. PACKAGING (Recommendation 21)</b>	
Agreed subject to adoption by individual country.	<b>India</b>
ISDI supports this recommendation.	<b>International Special Dietary Food Industries</b>
<b>12. LABELLING (Recommendation 22)</b>	
Argentina agrees with this item.	<b>Argentina</b>
Colombia supports the proposed text.	<b>Colombia</b>
Ecuador believes it is important to retain the text “exclusive breastfeeding for the first six months of life and continued breastfeeding up to at least 24 months”. The instructions for use should clearly indicate how to store the product properly.	<b>Ecuador</b>
It is recommended that the labelling of RUTF for children from 6 to 59 months be in accordance with the Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CXS 180-991), Codex General Standard for the Labelling of Pre-packaged Foods (CODEX STAN 1-1985), the General Standard for the Labelling of and Claims for Pre-packaged Foods for Special Dietary Uses (CXS 146-1985), Guidelines for Use of Nutrition and Health Claims	<b>IBFAN</b>

(CAC/GL 23-1997) and Guidelines on Nutrition Labelling (CXG 2- 1985).	
<p>ISDI supports the recommendation with the following amendments.</p> <p>1. ISDI recommends that the following statement should be reworded since RUTF can be consumed at home without medical supervision. This statement as currently worded is inapplicable. Delete " "USE UNDER MEDICAL SUPERVISION" shall appear on the label in bold letters in an area separated from the written, printed, or graphic information".</p> <p>ISDI suggests: To be prescribed by a trained health and nutrition professional only</p> <p>2. ISDI recommends that the following statement should be deleted since there is no evidence to support it. A prominent warning statement consisting of an explanatory statement in bold letters indicating that RUTF are for special medical purposes. Delete "and may pose a health hazard when consumed by individuals who do not have the disease(s), disorder(s) or medical condition(s) for which the food is intended".</p> <p>3. ISDI recommends removing the word rectal in the following sentence: The product is not to be used for parenteral, rectal or Nasogastric Tube (NG tube) administration. A 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 rectal administration.</p>	<b>International Special Dietary Food Industries</b>
<p>It is recommended that the labelling of RUTF for children from 6 to 59 months be in accordance with the <i>Standard for the Labelling of and Claims for Foods for Special Medical Purposes</i> (CXS 180-991), <del><i>Codex General Standard for the Labelling of Pre-packaged Foods</i> (CODEX STAN 1-1985)</del>, the <i>General Standard for the Labelling of and Claims for Pre-packaged Foods for Special Dietary Uses</i> (CXS 146-1985), <a href="#">Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997)</a> <del><i>Guidelines for Use of Nutrition and Health Claims</i> (CAC/GL 23-1997)</del> and <i>Guidelines on Nutrition Labelling</i> (CXG 2- 1985).</p>	<b>International Association of Consumer Food Organizations</b>
<b>The Name of the Food (Recommendation 22)</b>	
	<p><b>Argentina</b> Argentina considers that this phrase is unnecessary given that RUTF are high-energy, fortified, ready-to-eat food for special medical purposes that should be soft or crushable and that should be easy for children to eat without any prior preparation.</p>
	<p><b>Brazil</b> Brazil would like to request clarification about Recommendation 22, specially about the decision to delete the reference to Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997). These requirements include a prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation. In this regard, we consider that the reference should be maintained. However, if the Committee agrees to delete the sentence, we consider that it is necessary to include a new specific item in the labelling requirements which clearly states that nutrition and health claims shall not be permitted for RUTF. In our opinion, this approach is important to reaffirm the statement presented in the CXG 23-1997 clarifying in the</p>

	<p>guideline that the Committee considered that the use of nutrition and health claims are not appropriate for RUTF. We also consider that it is not necessary to include a specific item for the List of Ingredients since it is already covered by CODEX STAN 146-1985:</p> <p>4.2 List of ingredients The declaration of the list of ingredients shall be in accordance with Section 4.2 of the General Standard.</p> <p>Brazil supports maintaining the sentence: Exclusive breastfeeding is recommended for the first 6 months of life, and continued breastfeeding is recommended for at least 24 months.</p>
<b>Additional Mandatory Labelling Requirements</b>	
<ul style="list-style-type: none"> <li>The product is not to be used for parenteral, <del>rectal</del> or Nasogastric Tube (NG tube) administration.</li> <li>[Exclusive breastfeeding is recommended for the first 6 months of life, and <del>continued complementary</del> breastfeeding is recommended for at least 24 months.]</li> </ul>	<p><b>Colombia</b> Colombia proposes adjustment in the drafting.</p>
<p>[Exclusive breastfeeding is recommended for the first 6 months of life, and continued breastfeeding is recommended for at least 24 months.]<u>Should be retained.</u></p> <ul style="list-style-type: none"> <li><u>National authorities may take a decision regarding the use of RUTF for management of severe acute malnutrition based on the extant legislations/policies.</u></li> <li><u>A statement indicating that RUTF are high-fat and high-sugar products.</u></li> <li><u>The products should carry no health, nutrition or other promotional claims nor any idealizing text or pictures or representation that might suggest use for infants under the age of 6 months (including references to milestones and stages).</u></li> <li><u>The product must not convey an endorsement or anything that may be construed as an endorsement by a professional or other body, unless relevant national, regional or international regulatory authorities have specifically approved this.</u></li> </ul>	<p><b>India</b> Declaration of nutritive value is essential on the package of RUTF products</p>
<ul style="list-style-type: none"> <li>A prominent warning statement consisting of an explanatory statement in bold letters indicating that RUTF are for special medical purposes and may pose a health hazard when consumed by individuals who do not have the <del>disease(s), disorder(s) or</del> medical condition(s) for which the food is intended.</li> <li>[Exclusive breastfeeding is recommended for the first 6 months of life, and continued breastfeeding is recommended for at least 24 months.]</li> </ul>	<p><b>Jamaica</b> Since the product is intended for children 6 to 59 months, Jamaica supports inclusion of a statement reminding that exclusive breastfeeding for 6 months is recommended, followed by continued breastfeeding from 6 months for up to/at least 24 months.</p>
<ul style="list-style-type: none"> <li>Exclusive breastfeeding is recommended for the first 6 months of life, and continued breastfeeding is recommended for at least 24 months. <b>REMOVE BRACKETS</b></li> <li>The labeling of these products should carry no nutrition or health or other promotional claims nor have any idealising text or pictures or representation that might suggest the use for infants under the age of 6 months (including references to milestones and stages)</li> <li>The product must not convey an endorsement or anything that may be construed as an endorsement by a professional or other body, unless relevant national, regional or international regulatory authorities have specifically approved this.</li> </ul>	<p><b>IBFAN</b></p>

<ul style="list-style-type: none"> <li>• <del>"USE UNDER MEDICAL SUPERVISION" shall appear on the label in bold letters in an area separated from the written, printed, or graphic information. _</del></li> <li>• A prominent warning statement consisting of an explanatory statement in bold letters indicating that RUTF are for special medical purposes and <del>may pose a health hazard when consumed by individuals who do not have the disease(s), disorder(s) or medical condition(s) for which the food is intended. _</del></li> <li>• The product is not to be used for parenteral, <del>rectal _</del> or Nasogastric Tube (NG tube) administration.</li> </ul>	<p><b>International Special Dietary Food Industries</b></p>
<p><del>[Exclusive Exclusive breastfeeding is recommended for the first 6 months of life, and continued breastfeeding is recommended for at least 24 months.]</del></p>	<p><b>International Association of Consumer Food Organizations</b> Remove brackets</p>
<p>Feeding instructions shall be given; preferably accompanied by graphical presentations. <u>Feeding instructions must indicate the daily quantities to be used at the appropriate ages and as a complement to breastfeeding. Quantities recommended must not undermine continued breastfeeding.</u></p>	<p><b>International Association of Consumer Food Organizations</b></p>
<p><b>Instructions for use</b></p>	
<p>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.</p> <p>Feeding instructions shall be given; preferably accompanied by graphical presentations. <u>Feeding instructions must indicate the daily quantities to be used at the appropriate ages and as a complement to breastfeeding. Quantities recommended must not undermine continued breastfeeding.</u></p> <p>The time in which the product should be consumed after opening should be clearly indicated.</p> <p>The risk of inadequate consumption, dilution or portioning should be clearly declared at the label product.</p>	<p><b>IBFAN</b></p>
<p><b>ANNEX</b> <b>Table: Nutritional Composition for RUTF</b></p>	
	<p><b>IBFAN</b></p> <p>Caution should be taken to prevent excess consumption of industrially produced, non-food based micronutrients. Children suffering from SAM have decreased ability to absorb excess micronutrients as a result of gut damage and the use of industrial micronutrients can exacerbate gut damage. Studies have documented a negative impact on the gut microbiome such as the increased growth of pathogens such as <i>Escherichia coli</i>.</p>
<p>ICAAS wishes to make a technical note related to the levels of iron and zinc, which are significantly influenced by the levels of phytic acid in final foods (References).</p> <p>Specifically, ICAAS recommends to make a note in the Annex stating that it is necessary to enhance the iron and zinc levels to compensate for a high levels of phytic acid in some RUTF products (the addition of iron/zinc should achieve the phytic acid/iron molar ratio lower than 15 and phytic acid/zinc molar ratio lower than 2.5).</p> <p>References:</p> <ul style="list-style-type: none"> <li>• Gibson RS, Bailey KB, Gibbs M, Ferguson EL. A review of phytate, iron, zinc, and calcium concentrations in plant-based complementary foods used in low-income countries and implications for bioavailability. Food Nutr Bull 2010;31(2 Suppl):S134–46.</li> <li>• Hurrell RF. Influence of vegetable protein sources on trace element and mineral bioavailability. J Nutr 2003;133:2973S–7S.</li> <li>• Abizari AR, Moretti D, Schuth S, Zimmermann MB, Armar-Klemesu M, Brouwer ID. Phytic acid-to-iron molar</li> </ul>	<p><b>ICAAS</b></p>

ratio rather than	
<ul style="list-style-type: none"> <li>polyphenol concentration determines iron bioavailability in whole cowpea meal among young women. J Nutr 2012;142:1950–5.</li> <li>Afify Ael-M, El-Beltagi HS, El-Salam SM, Omran AA. Bioavailability of iron, zinc, phytate and phytase activity during soaking and germination of white sorghum varieties. PLoS One 2011;6:e25512.</li> </ul>	
	<b>International Special Dietary Food Industries</b> ISDI would like to raise a general comment in regard to the calculation of the nutrients in g/100 kcal. <ul style="list-style-type: none"> <li>The minimum “g/100 kcal” should be calculated with: minimum “g/100g” / 5.5</li> <li>The maximum “g/100 kcal” should be calculated with: maximum “g/100g” / 5.2</li> </ul>
<b>Energy</b>	
<b>Energy</b> <u>as per FAO convention, kJ values should be included. kJ/100g 2175.7kJ (min) and 2301.2 kJ (max)</u>	<b>UNICEF</b>
	<b>International Special Dietary Food Industries</b> ISDI supports this recommendation.
<b>Protein</b>	
<b>Protein</b> <u>g/100kcal min should be 2.43</u> <u>g/100kJ (min) 588.8 kJ and (max) 747.3 kJ</u>	<b>UNICEF</b> kJ to be included
Finally, ICAAS suggests: (A) changing the expression “protein” to “available protein” and, (B) keeping the provision on protein quality in square brackets and until the expert guidance from FAO is received. We note that the provision “50% of protein source from milk products” directly contradicts the sub-chapter 5.1.1 on the importance of locally sourced materials. Indeed, allowing for alternative sources of protein in RUTF, such as cereals or plant protein, based on scientific evidence of efficacy, and based on PDCAAS (or DIAAS) methodology, would allow use of local dairy protein sources which provide formulation flexibility to lower RUTF costs and reduce environmental footprint, as well as to lessen the risks of allergy reactions. Finally, when appropriate to improve protein quality, amino acids should be allowed to be added to cereal and plant sources of protein. Naturally present amino acids have been extensively used to improve protein quality in foods and they are considered as safe substances when added to foods for that purpose.	<b>ICAAS</b>
	<b>International Special Dietary Food Industries</b> ISDI suggests the following: Unit:g/100g; Minimum:13g; Maximum:16.5g; GUL: -; Unit:g/kcal; Minimum:2.4; Maximum: 3.2; GUL: -;
<b>Lipids</b>	
<b>Lipids</b> <u>correction : g/100g (min) 25.8 (max) 36.3g</u> <u>g/100kcal correction (max) 7</u> <u>g/100kJ (min) 1.2 and (max)1.7</u>	<b>UNICEF</b>
<b>Lipids</b>	<b>MSF</b> lipids g/100kcal: min shall be 4.7
<b>n-6 Fatty acids</b>	

<p><b>n-6 Fatty acids</b>  <u>correction</u>  <u>g/100g (min) 1.7 and (max) 6.1</u>  <u>mg/100kcal (min) 330.3 (max) 1165</u>  <u>mg/100kJ (min) 79.02 (max) 278.6</u></p>	<p><b>UNICEF</b></p>
	<p><b>MSF</b>  MSF (n-6 fatty acid.  as per WHO joint statement:  <a href="http://apps.who.int/iris/bitstream/handle/10665/44295/9789280641479_eng.pdf;jsessionid=F512C754C8AD74D7CC6A0634874768BA?sequence=1">http://apps.who.int/iris/bitstream/handle/10665/44295/9789280641479_eng.pdf;jsessionid=F512C754C8AD74D7CC6A0634874768BA?sequence=1</a>  specifications for n-6 fatty acids : 3-10 % total energy (unit mistake). which is 1.7-6.05 g/100g or 316-1114 mg/100 kcal</p>
<p><b>-n-6 Fatty acids</b></p>	<p><b>International Special Dietary Food Industries</b>  ISDI supports this recommendation but would like to bring to the attention of the eWG Chair that there is a difference between the recommendation and the Annex in the Proposed Draft Guidelines.  In the Annex there is a typo for the line n-6 fatty acids and n-3 fatty acid, regarding the unit and the values in mg/100 kcal. Corrections are shown below:  n-6 Fatty acids  Unit: g/100g (to be deleted) kcal/100 kcal; Minimum: 3; Maximum:10; GUL: -;  Unit: mg/100kcal; Minimum: 333; Maximum: 1111; GUL: - ;  Unit: mg/100g; Minimum: 1731.6; Maximum: 6111; GUL: -;</p>
<p><b>n-3 Fatty acids</b></p>	
<p><b>n-3 Fatty acids</b>  <u>correction</u>  <u>g/100g (min) 0.17 (max) 1.5</u>  <u>mg/100kcal (min) 33 and (max) 330 or no max</u>  <u>mg/100kJ (min) 7.9 (max) 78 or no max</u></p>	<p><b>UNICEF</b></p>
	<p><b>MSF</b>  MSF  n-3 fatty acid.  as per WHO joint statement:  <a href="http://apps.who.int/iris/bitstream/handle/10665/44295/9789280641479_eng.pdf;jsessionid=F512C754C8AD74D7CC6A0634874768BA?sequence=1">http://apps.who.int/iris/bitstream/handle/10665/44295/9789280641479_eng.pdf;jsessionid=F512C754C8AD74D7CC6A0634874768BA?sequence=1</a>  specifications for n-3 fatty acids : .3-2.5 % total energy (unit mistake). which is 0.172-1.514 g/100g or 32-279 mg/100 kcal</p>
	<p><b>International Special Dietary Food Industries</b>  Unit: g/100g (to be deleted) kcal/100 kcal; Minimum: 0.3; Maximum: 2.5; GUL: -</p>

	Unit: mg/100kcal; Minimum: 33; Maximum: 278; Unit: mg/100g; Minimum: 172; Maximum: 1529;
<b>Vitamin A (recommendation 12)</b>	
Colombia agrees with the maximum values proposed for Vitamin A.	<b>Colombia</b>
<b>Vitamin A</b> <u>UNICEF supports the higher maximum limits of Vitamin A WHO GUIDELINE: UPDATES ON THE MANAGEMENT OF SEVERE ACUTE MALNUTRITION IN INFANTS AND CHILDREN states : “Children with severe acute malnutrition should be provided with about 5000 IU (1500mcg) vitamin A daily, either as an integral part of therapeutic foods or as part of a multi-micronutrient formulation” As this nutrient degrades during transport and storage, the maximum limit of 1.2mg would allow manufacturers to include appropriate overages to maintain vitamin A during the 24 month shelf life.</u>	<b>UNICEF</b>
ISDI supports this recommendation.	<b>International Special Dietary Food Industries</b>
<b>Vitamin D (recommendation 13)</b>	
<b>Vitamin D</b> <u>UNICEF supports the higher maximum limits of Vitamin D allow manufacturers to include appropriate overages to maintain vitamin D during the 24 month shelf life.</u>	<b>UNICEF</b>
	<b>International Special Dietary Food Industries</b> ISDI agrees with the proposed minimum of 15 mcg/100g if the maximum accepted limit is [22]. ISDI agrees with the note 3 1 µg cholecalciferol = 40 IU vitamin D with respect to the following clarification required here: ISDI would like to highlight that 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”. ISDI support the above cited approach.
	<b>Colombia</b> Colombia agrees with the maximum values proposed for Vitamin D.
<b>Vitamin E (recommendation 14)</b>	
<b>Vitamin E</b> <u>correction</u> <u>mg alpha TE/100kcal 3.84 (min)</u>	<b>UNICEF</b>
	<b>MSF</b> vit E: max shall be 3.68 mg/100 kcal
	<b>EU Specialty Food Ingredients</b> The last name in parentheses in the footnote should read “di-α-tocopherol” and not “di-α-tocopherol”.

	<b>International Special Dietary Food Industries</b> ISDI supports this recommendation and proposes to keep to add $\alpha$ -TE in the first line, and to keep a point number with one decimal in the second line. Unit: 4mg $\alpha$ -TE / 100 g; Minimum: 20; Maximum: -; GUL: -; Unit: 4mg $\alpha$ -TE /100 kcal; Minimum: 3.6; Maximum: -; GUL: -;
<b>Vitamin K (recommendation 15)</b>	
	<b>International Special Dietary Food Industries</b> ISDI supports this recommendation
<b>Vitamin B1, Vitamin B2 Vitamin C, Vitamin B6, Vitamin B12, and Folic Acid (recommendation 15)</b>	
	<b>International Special Dietary Food Industries</b> ISDI supports the recommendations
<b>Niacin</b>	
<u>correction (rounding)</u> <u>mg/100kcal (min) 1</u>	<b>UNICEF</b>
	<b>International Special Dietary Food Industries</b> ISDI supports this recommendation
<b>Pantothenic Acid, Biotin (recommendation 15)</b>	
	<b>International Special Dietary Food Industries</b> ISDI supports the recommendations
<b>Recomenation 16</b>	
<b>Sodium</b>	<b>International Special Dietary Food Industries</b> ISDI believes that no Sodium should be added in the RUTF formulation. There will be some sodium naturally present in the raw materials used. In addition, ISDI would like to recommend the following upper limits to take into account the variability of raw materials and manufacturing processes.
<b>Potassium</b>	<b>International Special Dietary Food Industries</b> 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.
<b>Calcium</b>	<b>Colombia</b> Colombia agrees with the maximum values proposed for Calcium.
<b>Phosphorus</b>	
	<b>Colombia</b> Colombia agrees with the maximum values proposed for phosphorus.
<u>Correction :</u> <u>mg/kcal (min) 57.6</u>	<b>UNICEF</b>
<b>Magnesium</b>	
	<b>Colombia</b>

	Colombia agrees with the maximum values proposed for magnesium.
<u>Correction</u> <u>mg/100kcal (max) 25.4 or 42.7</u> <u>UNICEF prefers 42.7</u>	<b>UNICEF</b>
<b>Zinc</b>	
<u>Correction</u> <u>mg/100kcal (max) 2.5</u>	<b>UNICEF</b>
<b>Copper</b>	<b>International Special Dietary Food Industries</b> 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.
<b>Selenium</b> <u>correction (rounding)</u> <u>µg /100 kcal (min) 3.84 and (max) 7.3</u>	<b>UNICEF</b>
<b>Iodine</b>	
<u>Correction</u> <u>µg /100 kcal (min) 13.5</u>	<b>UNICEF</b>
	<b>International Special Dietary Food Industries</b> 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.
<b>Moisture Content</b>	
<del>Moisture Content</del> <b><u>Water Activity (aW) Maximum 0.60</u></b>	<b>Norway</b> We would at this stage also like to comment on the current indication of moisture content of 2.5% in the table of nutritional composition for RUTF, in the annex of the draft guideline. We suggest using “water activity (aW)” of maximum 0.60, instead of a “moisture content” of maximum 2.5%. Rationale: Water activity is a more precise measure than “moisture content”, indicating the concentration of water available for biological reactions. Pathogenic micro-organisms are not capable of growing in low-moisture foods with a water activity of maximum 0.60, according to the FAO/WHO report from 2016 on microbial safety of lipid-based ready-to-use foods. The moisture content in products which have the same water activity, can vary significantly depending on the ingredients used. However, bacterial growth is correlated with water activity. A maximum moisture content of 2.5 % in the guideline would limit possible ingredients used for producing RUTF, even though they have a low water activity (below 0.6). Peanuts have a very low moisture of 2 % due to a very high oil content.

	<p>However, in other ingredients such as wheat and barley, it is not possible to reduce the moisture to a maximum moisture of 2.5 % due to a higher natural water content. Nevertheless, the water activity can be reduced to below 0.6 also in these ingredients, which means that pathogenic micro-organisms would not be capable of growing.</p>
<p><u>Addition:</u> <u>aW (min) 0.2 and (max) 0.6</u></p>	<p><b>UNICEF</b> UNICEF currently specified a water activity max of &lt;0.6 but notes that the definition of a low moisture food as described in the CODE OF HYGIENIC PRACTICE FOR LOW-MOISTURE FOODS CXC 75-2016 is &lt;0.85. UNICEF suggests the water activity be 0.2-0.4</p>