

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Item 5 **CX/NFSDU 21/42/6**

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

Forty-second Session

Virtual

19, 22 - 25 November and 1 December 2021

DRAFT GUIDELINE FOR READY-TO-USE THERAPEUTIC FOODS

Comments at in reply to CL 2021/31/OCS-NFSDU

Comments of Benin, Brazil, Canada, Cuba, Colombia, Ecuador, Egypt, European Union, Iran, Kenya, Malaysia, New Zealand, Panama, Paraguay, Peru, Republic of Korea, Saudi Arabia, Thailand, UAE, USA, EU Specialty Food Ingredients, GOED, ISDI, IRUFA, MSF, UNICEF

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2021/31/OCS-NFSDU issued in June 2021. 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.

ANNEX I

GENERAL COMMENTS	MEMBER/OBSERVER
<p>Firstly, Cuba supports the document on the Proposed Draft Guideline for Ready-To-Use Therapeutic Foods, as a response to circular letter CI 2021/31/OCS-NFSDU.</p> <p>After reviewing the document, we have the following considerations:</p> <p>Section 5.1.4: Cereals and [tubers] We believe should be expanded to “tubers, roots and by-products”</p> <p>Section 5.2.1 Carbohydrates We agree with the limitation on the use of sugar</p> <p>We agree with the rest of the headings, and with moving the Guideline for Ready-to-use Therapeutic Foods to step 5 for adoption during the next session of the CAC.</p>	Cuba
<p>The European Union (EU) would like to thank South Africa, Senegal and Uganda for their work on the draft Guidelines for Ready-to-use Therapeutic Foods.</p> <p>As explained in previous occasions, the EU supports the completion of the work on these guidelines on Ready-to-use Therapeutic Foods (RUTF) without any delay. The EU therefore can agree with the text of the draft Guidelines.</p> <p>As previously noted the main concern of the EU was to make sure that no doubts exist in the guidelines on the status of RUTF as food for special medical purposes, covered by CODEX Standard 180-1991, and that the language used in the guidelines follows the one used in the Standard on food for special medical purposes. The EU considers that the proposed text of the draft Guidelines for Ready-to-use Therapeutic Foods adequately addresses the EU concerns.</p>	European Union
<p>Kenya supports the progression of the standard without further comments</p>	Kenya
<p>Malaysia appreciates the opportunity given to provide comments on the draft Guidelines for Ready-to use Therapeutic Foods (RUTF). Malaysia has no objection on the proposed draft.</p>	Malaysia
<p>Specific comment (Preamble) - substantive</p> <p>New Zealand is of the view that RUTF is not a breastmilk substitute and to refer to it as such is dangerous and misleading given the very different nutritional composition and use for this product. New Zealand therefore does not support the inclusion of the WHO International code of marketing of breast-milk substitutes (1981) within footnote 1 of the preamble. New Zealand is also opposed to referencing ‘subsequent relevant WHA resolutions’ as these documents have not yet been seen nor reviewed for their relevance to this product category/guideline.</p>	New Zealand
<p>Panama is in agreement with the proposed draft, and recommends its advancement to step 8. We consider the proposed guidelines to be of the utmost importance.</p>	Panama

<p>Peru thanks the Secretariat of the Codex Alimentarius Commission for sending Circular Letter CL 2021/31/OCS-NFSDU Request for comments at Step 6 on the Draft Guideline for Ready-to-use Therapeutic Foods</p> <p>(i) Specific comments</p> <p>Peru has analysed the work and has the following comments:</p> <ol style="list-style-type: none"> 1. Throughout the document the appropriate term is undernutrition, not malnutrition; both concepts are different. 2. With respect to the level of linoleic acid, we agree that this should not be less than 333 mg per 100 kcal 3. We consider the appropriate levels to be a maximum of 1 111 mg/100 kcal for omega-6 fatty acids; a minimum of 33 mg/100 kcal for omega-3 fatty acids; and a minimum of 15 mg/100 kcal and a maximum of 45 mg/100 kcal for magnesium. 	Peru
<p>Republic of Korea has reviewed (1) preamble and (2)the levels for the essential fatty acids.</p> <p>As for Preamble, Korea supports current statements with no further comment.</p> <p>Then, here is our thoughts on n-6:n-3 ratio of RUTF, on nutritional composition table. Because an optimal intake ratio of n-6 to n-3 has yet to be determined, Republic Of Korea supports the position that n=6:n-6=10:1 is acceptable between the given choice [33] or [110], of the minimum range of n-3 fatty acids. The short and long-term benefits to SAM children of the exposure to LC-EFA from the consumption of RUTF are not recognized because there are not much studies regarding the intervention.</p> <p>On the other hand, if we choose to have [110] as an minimum range of n-3 FA, it will lead n-6:n-3 ratio to 3:1 which may not be easily achievable.</p>	Republic of Korea
<p>Saudi Arabia supports the proposed draft guidelines of the requested comments</p>	Saudi Arabia
<ol style="list-style-type: none"> 1. In principle, we agree with the proposed draft guideline. 2. In addition, we would like to request for the clarifications on the inconsistent uses of terminology as follows: <ol style="list-style-type: none"> (1) The term “uncomplicated SAM” as in Preamble and the phase “severe acute malnutrition without medical complications with appetite” as in section 4.1 <ul style="list-style-type: none"> - Whether the term “uncomplicated SAM” and the phase “without medical complications with appetite” provide the same meaning? - If so, we suggest using only a single term/phase that is used by WHO throughout the draft guideline. (2) The term “the persons” as in the introductory part of section 5 and a phase “patients/children with SAM” as in section 5.1.5 <ul style="list-style-type: none"> - Whether a term “the persons” and a phase “patients/children with SAM” provide the same meaning? - If so, we would prefer using a consistent single term or phase, i.e., “children with SAM” to avoid confusion. 	Thailand

The United States notes that this guideline inconsistently uses the word “shall” in some provisions, and the word “should” is more typically used for Codex guidelines rather than the word “shall”.	USA
GOED recommends including the following text from the expert review report entitled “Expert advice on minimum and maximum limits for essential fatty acid levels in Ready to Use Therapeutic Food (RUTF)” - “Consideration of provision of preformed DHA 20-100mg/100g.”	GOED

SPECIFIC COMMENTS	
1. PREAMBLE	
<p>In the CCNFSDU41 Report, it is noted that the Committee agreed to simplify the text of the preamble to include aspects on basic composition of the product, target age group, and that RUTF was one of the options of dietary management of children with uncomplicated SAM. Canada notes that this information is included in the Preamble.</p> <p>Canada questions the need for the reference to the International code of marketing of breast-milk substitutes and relevant WHA Resolutions on infant and young child feeding in the footnote. Canada notes that RUTF are not intended to substitute breast-milk, a statement on the label shall be added to indicate that RUTF should be used in conjunction with breastfeeding (Section 12.4) and they are not available at retail; therefore referencing this document is not necessary.</p> <p>Canada supports retaining the other references in square brackets to ensure that the guidelines are used in accordance with these documents.</p>	Canada
<p>Making reference to section 4.1 RUTF, it is clearly mentioned that adequate protein and other essential nutrients are the compositions of Ready-to-Use Therapeutic Foods. In view of this, we therefore propose to insert the word “protein” in the first sentence of preamble to read as follows:</p> <p>“Children affected by severe acute malnutrition (SAM) need safe, palatable foods with a high energy content and adequate amounts of protein, vitamins, minerals and other nutrients”</p>	Thailand
<p>The EU can support the proposed text of the preamble in square brackets. The EU considers that the proposed text is clear and concise and that it sufficiently describes the role of RUTF.</p>	European Union
1st paragraph	
<p>Children suffering from severe acute malnutrition (SAM) need food that does not present any risks, is palatable and has a high energy content, plus sufficient quantities of vitamins, minerals and other nutrients. Children suffering from SAM need effective, timely treatment and ready-to-use therapeutic food (RUTF) is one of the dietary treatment options for severe acute malnutrition in children aged between 6 and 59 months who have no medical complications. These guidelines should be applied by the WHO, UNICEF and UNICEF, the WFP¹, the FAO and other organisations in accordance with the technical recommendations based on the relevant tests and the texts/documents linked to the Codex.</p>	Benin
<p>Children affected by severe acute malnutrition (SAM) need adequate treatment and care, including safe, palatable foods with a high energy content and adequate amounts of vitamins, minerals and other nutrients. Children with SAM need</p>	Brazil

<p>efficacious and timely intervention and RUTF is one of the options for the dietary management of children with uncomplicated SAM from 6-59 months <u>months without medical complications, in specific situations of food insecurity when local food production is insufficient, water supply is inadequate or inaccessible or under emergency situations and should not undermine national nutrition recommendations and the use of culturally appropriate foods. It is critical that the use of RUTF does not undermine support for continued breastfeeding or to re-establish lactation.</u> These guidelines should be used in accordance with technical recommendations of that are based on the relevant evidence and related Codex texts/documents by WHO, UNICEF and WFP¹.</p> <p>Brazil reiterates comments sent to CL 2019-114/OCS-NFSDU as copied bellow:</p> <p>“Brazil would like to suggest some amendments in the preamble, aiming to clarify that children with SAM from 6 to 59 months without medical complications need adequate treatment and care with the use of safe locally foods with adequate energy content and amounts of vitamins, minerals and other nutrients. Thus, RUTF may be used as an option when local food production is insufficient, water supply is inadequate or inaccessible or under emergency situations and should not undermine national nutrition recommendations and the use of culturally appropriate foods. We are also of the opinion that the importance of breastfeeding should be addressed in the preamble.</p> <p>We also suggest standardizing throughout the Guideline the text referring to the target population for which the product is intended, that is, children from 6 to 59 months with severe acute malnutrition without medical complications.</p>	
<p>Children suffering from severe acute malnutrition need safe, palatable foods with a high energy content and appropriate quantities of vitamins, minerals and other nutrients. These children require effective, timely intervention, and RUTFs are one of the dietary treatment options for children aged between 6 and 59 months with severe acute malnutrition <u>[with undernutrition]</u> that does [sic] not present complications. This Guideline should be applied in accordance with technical recommendations of based on the relevant evidence and the texts of the Codex and similar documents from the WHO, UNICEF and WFP.¹</p> <p>It is suggested to change the word “malnutrition” (<i>malnutrición</i>) for “undernutrition” (<i>desnutrición</i>), because the term malnutrition in Spanish covers both a deficit and an excess in the ingestion of nutrients. In Colombia, malnutrition covers undernutrition and/or vitamin and mineral deficiencies, and overweight. ENSIN 2015</p>	Colombia
<p>Children suffering from severe acute malnutrition need safe, palatable foods with a high energy content and appropriate quantities of vitamins, minerals and other nutrients. These children require effective, timely intervention, and RUTFs are one of the dietary treatment options for children aged between 6 and 59 months with severe acute malnutrition that does not present complications. This Guideline should be applied in accordance with technical recommendations of based on the relevant evidence and the texts of the Codex and similar documents from the WHO, UNICEF and WFP.¹</p> <p>Children suffering from severe acute malnutrition need nutritious, safe, palatable foods with a high energy content and appropriate quantities of micronutrients, vitamins and minerals. These children require effective, timely intervention, and Ready-to-use Therapeutic Foods (RUTFs) are one of the dietary treatment intervention options for children aged between 6 and 59 months with severe acute malnutrition, who do not present complications. This guideline should be applied in accordance with technical recommendations based on the relevant evidence and the texts of the Codex Alimentarius and similar documents from the WHO, UNICEF and WFP.¹</p>	Ecuador

<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 intervention and RUTF is one of the options for the dietary management of children with uncomplicated SAM from 6-59 months. These guidelines should be used in accordance with technical recommendations of that are based on the relevant evidence and related Codex texts/documents by WHO, UNICEF and WFP¹.</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 intervention and RUTF, of which efficiency shall be demonstrated by scientific evidence, is one of the options for the dietary management of children with uncomplicated SAM from 6-59 months. These 2 guidelines should be used in accordance with technical recommendations of that are based on the relevant evidence and related Codex texts/documents by WHO, UNICEF and WFP¹.</p> <p>1) A Joint Statement by the World Health Organization, the World Food Programme, the United Nations System Standing Committee on Nutrition and the United Nations Children’s Fund. 2007. Community-Based Management of Severe Acute Malnutrition; A Joint Statement by the World Health Organization and the United Nations Children’s Fund. 2009. Child growth standards and the identification of severe acute malnutrition in infants and children, Geneva: World Health Organization; World Health Organisation. 2013. Guideline: Updates on the management of severe acute malnutrition in infants and children, Geneva: World Health Organization; World Health Organisation. 2003. Global Strategy for Infant and Young Child Feeding, Geneva: World Health Organization; World Health Organisation. [1981. International code of marketing of breast-milk substitutes, Geneva: World Health Organization and subsequent relevant WHA Resolutions on infant and young child feeding]; Code of Ethics for International Trade in Food including Concessional and Food Aid Transactions (CXC 20-1979); Food and Agriculture Organisation and World Health Organisation. 2016 2021. 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.].</p>	<p>United Arab Emirates (UAE)</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 intervention and RUTF <u>RUTF, of which efficiency shall be demonstrated by scientific evidence,</u> is one of the options for the dietary management of children with uncomplicated SAM from 6-59 months. These guidelines should be used in accordance with technical recommendations of that are based on the relevant evidence and related Codex texts/documents by WHO, UNICEF and WFP¹.</p>	<p>International Special Dietary Food Industries (ISDI)</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 intervention and RUTF <u>RUTF, whose efficiency shall be demonstrated by scientific evidences,</u> is one of the options for the dietary management of children with uncomplicated SAM from 6-59 months. These guidelines should be used in accordance with technical recommendations of that are based on the relevant evidence and related Codex texts/documents by WHO, UNICEF and WFP¹.</p> <p>We believe it is important to mention in the preamble the need for scientific evidence of effectiveness for any RUTF.</p>	<p>International Ready to Use Foods Association (IRUFA)</p>

Footnote 1	
<p>To be clear and user-friendly, we suggest that the reference documents taken from different sources, e.g., Codex; WHO, WFP, UNSCN and UNICEF; and FAO/WHO should be cited in the separated footnotes, instead of placing them all under footnote 1.</p> <p>Furthermore, we suggest that some of references need to be updated with the current version, i.e., (i) “A Joint Statement by WHO, WFP, UNSCN and UNICEF 2007 “Community-Based Management of Severe Acute Malnutrition” and (ii) Code of Ethics for International Trade in Food including Concessional and Food Aid Transactions (CXC 20-1979).</p>	Thailand
<p>¹ 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; 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 Organization (2013): Guideline: updates on the management of severe acute undernutrition [sic] in infants and children, Geneva: World Health Organization; World Health Organization (2003): Global strategy for infant and young child feeding, Geneva: World Health Organization; World Health Organization (1981): <u>Organization</u>. <u>International Code of Marketing of Breast-milk Substitutes, Geneva: World Health Organization, and subsequent relevant WHA resolutions on infant and young child feeding];</u> <u>Code of Ethics for International Trade in Food including Concessional and Food Aid Transactions (CXC 20-1979);</u> Food and Agriculture Organization and World Health Organization (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 Organization.]</p> <p>Bearing in mind the nature and aims and the type of food covered by this draft guideline, we believe that the following reference (1981): International Code of Marketing of Breast-milk Substitutes, Geneva: World Health Organization, and subsequent relevant WHA resolutions on infant and small child feeding, need not be included in the footnote.</p>	Paraguay
<p>UAE recommends removing the reference to guidelines included as part of Footnote 1: 1981. International code of marketing of breast-milk substitutes, Geneva: World Health Organization and subsequent relevant WHA Resolutions on infant and young child feeding. Being irrelevant for the Guidelines for Ready to Use Foods and considers this sentence should be deleted.</p> <p>Same recommendation towards Footnote 1: World Health Organisation. 2003. Global Strategy for Infant and Young Child Feeding, Geneva: World Health Organization. This reference is not relevant to the purpose of the RUTF.</p> <p>UAE proposes to update the date of publication of the 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. A new version of this report was published in 2021 and this should be reflected.</p>	UAE
<p>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. Guideline: <i>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</i></p>	USA

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.]

The United States supports the current simplified version of the preamble developed during CCNFDSU41. It provides sufficient context while minimizing potential misunderstanding and misinterpretations. The United States supports including the technical reference documents from WHO, UNICEF and WFP as they provide additional technical information which supports the guideline, and these references provide information important to developing local RUTF standards. Regarding the references still in brackets, the United States supports including science based technical references but does not support those that are more policy in nature as the RUTF Guidelines is a technical based document. The U.S. proposes removing the following two references, a) 1981. International code of marketing of breast-milk substitutes, Geneva: World Health Organization and subsequent relevant WHA Resolutions on infant and young child feeding]; and b) Code of Ethics for International Trade in Food including Concessional and Food Aid Transactions (CXC 20-1979). The United States notes that RUTF is not a Breast Milk Replacement and the labeling guidelines have been developed state: a) The product should be used in conjunction with breastfeeding; and b) Exclusive breastfeeding is recommended for the first 6 months of life, and continued breastfeeding is recommended for up to two years or beyond.

Finally, the United States would like to note the guidance from CCEXEC75 (2018) on references (REP18/EXEC2-Rev1), in particular the conclusion that concepts and technical information can be incorporated into the text rather than referencing external sources, and that any references should be developed through a transparent process, relevant to the scope of the standard, and have a scientific basis.

These specific technical references have been developed through a transparent process and due to their technical nature, they are helpful in providing more detailed information necessary to implement this guideline.

<p>ISDI proposes to update the date of publication of the 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. A new version of this report was published in 2021 and this should be reflected.</p> <p>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. Guideline: <i>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 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. 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.]</p> <p>ISDI notes that RUTF is not a breastmilk substitute, therefore, ISDI questions the reference to guidelines included as part of Footnote 1: 1981. International code of marketing of breast-milk substitutes, Geneva: World Health Organization and subsequent relevant WHA Resolutions on infant and young child feeding. This information is not specific to the Guidelines for Ready to Use Foods and considers this sentence should be deleted. ISDI also questions the following reference: World Health Organisation. 2003. Global Strategy for Infant and Young Child Feeding, Geneva: World Health Organization. This reference does not provide specific guidance relevant to the purpose of the RUTF.</p>	<p>ISDI</p>
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<p>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. Guideline: <i>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. International code of marketing of breast-milk substitutes, 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. 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.]</p> <p>RUTF is not a breastmilk substitute, therefore, we question the reference to guidelines included as part of Footnote 1: 1981. International code of marketing of breast-milk substitutes, Geneva: World Health Organization and subsequent relevant WHA Resolutions on infant and young child feeding. We note this information is not specific to the Guidelines for Ready to Use Foods and consider this sentence should be deleted.</p> <p>1) A Joint Statement by the World Health Organization, the World Food Programme, the United Nations System Standing Committee on Nutrition and the United Nations Children’s Fund. 2007. <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. Guideline: <i>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 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. 20162021. 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.]</p> <p>We propose to update the date of publication of the 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. A new version of this report was published in 2021 and this should be reflected</p>	<p>IRUFA</p>
<p>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. Guideline: <i>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</i></p>	<p>MSF</p>

<p><i>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. 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.]</p> <p>Please note the new update for the last document: FAO / WHO, Microbial safety of lipid-based ready –to-use foods for management of moderate acute malnutrition and severe acute malnutrition – second report was issued on 23/02/2021.</p>	
Suggest to also include "WHO guideline on the dairy protein content in ready-to-use therapeutic foods for treatment of uncomplicated severe acute malnutrition" WHO 2021	UNICEF
3. SCOPE	
We would like to seek for clarification for the availability of references for "Ready-to-Use Supplementary Foods (RUSF)". If they are available, please additionally include them in the footnotes.	Thailand
5. SUITABLE RAW MATERIALS AND INGREDIENTS	
5.1.2 Legumes and Seeds	
<p>We would like to suggest using the term "shall" instead of "should", noting Faba bean can cause the serious danger of favism in susceptible persons. The proposed revision can read as follows:</p> <p>"Field beans or Faba beans (<i>Vicia faba</i> L) shall not be used in the formulation of RUTF because of the danger of favism."</p>	Thailand
5.1.3 Fats and Oils	
<p>Fats and oils used in the manufacturing of RUTF must comply with the relevant Codex Alimentarius texts. Fats and oils are incorporated as technologically feasible for the purpose of achieving the energy density and providing essential fatty acids. Care must be taken to avoid oxidized fat which will adversely affect nutrition, flavour and shelf life.</p> <p>A relevant Code of Practice is the Code of Practice for the Reduction of 3-Monochloropropane-1,2-Diol Esters (3-MCPDEs) AND Glycidyl esters (GEs) in refined oils and food products made with refined oils CXC 79-2019</p>	UNICEF
5.1.5 Vitamins and Minerals	
We suggest to add additional footnote for citing the reference of formula for approximating the non-metabolizable buffer base.	Thailand
5.2.1 Carbohydrates	
Brazil is aware of the issues raised by UNICEF with regard the challenges to limit the addition of free sugars to less than 20% of the energy in the product. On the other hand, it was mentioned that further efforts were being made by the suppliers of RUTF to explore the possibilities of lowering the contents of free sugars. Taking this into account and the importance of	Brazil

<p>reducing the quantity of free sugars used in RUTF at the minimum level possible in line with the WHO Guidelines for Sugars intake for adults and children (2015), we propose the following amendment:</p> <p>Carbohydrates are used to achieve energy requirements in balance with proteins and lipids. Plant starch, lactose, maltodextrin and sucrose are the preferred carbohydrates in RUTF. Free sugars should be limited and should not exceed 20%-10% of total energy. Only precooked and/or gelatinized starches may be added. Glucose and fructose should not be used. Carbohydrates must adhere to the relevant Codex Alimentarius texts.</p>	
6. NUTRITIONAL COMPOSITION AND QUALITY FACTORS	
6.2 Proteins	
<p>High-quality proteins will could be provided by using RUTF with a formulation containing at least 50 percent protein from dairy products dairy products or eggs.</p>	Benin
6.3 Lipids	
<p>We noticed the inconsistent values of fatty acids between as in 6.3 and as in Table: Nutritional Composition of RUTF.</p> <p>To avoid confusion, we prefer all reference values to be presented only in Table: Nutritional composition of RUTF shown in ANNEX. So, the texts in the square brackets should be deleted.</p> <p>Meanwhile, n-6 fatty acids value stated in this section (min: should not be less than 333 mg per 100 kcal and max: should not be less than 1110 mg per 100 kcal) should replace those values in the Table.</p>	Thailand
<p>The United States recommends that the RUTF guideline reflect current technical and clinical knowledge reflecting RUTF products developed to best meet the nutritional needs of SAM Children using a range of oil sources. These formulations provide the needed essential fatty acids and have been proven to be shelf-stable and safe in delivering a range of 333-1110mg per 100 kcal as n-6 and a minimum of 33 mg/100kcal as n-3. The essential fatty acid ranges reflected by the text in brackets reflects current manufacturing capability of global RUTF suppliers and allows for compliance with WHO recommendation of 45%-60% of total energy in the form of lipids. RUTF suppliers have optimized current formula to achieve n6/n3 ratio values ≤ 4, which also provide the needed energy from fat and the absolute amounts of essential fatty acids. The U.S. recommends retaining the text in square brackets which provides a range of essential fatty acids sufficient to allow for providing both the absolute needs for essential fatty acids while providing flexibility for producing products with a range of n6/n3 ratios as both the clinical evidence regarding the requirements for long chain n/3 fatty acids emerge and technical capabilities are developed. The U.S. has the position that once requirements/benefits for/of long chain n/3 fatty acids are known for SAM Children based on well-designed intervention studies, direct addition of DHA/EPA is the best approach for producing RUTF products rather than depending on conversion from short chain n/3 fatty acids.</p>	USA
2nd paragraph [...]	
<p>Brazil agrees with the following sentence in square brackets:</p> <p>“The level of linoleic acid should not be less than 333mg mg per 100 kcal and shall not be more than 1110 mg per 100 kcal. The level of alpha-linolenic acid should not be less than 33 mg/100kcal.”</p>	Brazil

<p>Canada notes the diverging views presented in the informal discussion on the proposed changes to the essential fatty acid requirements for RUTF.</p> <p>Canada acknowledges that the proposed changes in LA (and ALA) are likely to be beneficial for DHA status based on current knowledge of fatty acid metabolism. However, the expert report does not contain clear evidence confirming that the exact LA and ALA levels proposed will indeed lead to improved DHA status vs. the standard RUTF. There are still many knowledge gaps for defining the optimal formulation.</p> <p>However, Canada supports UNICEF's proposed formulation changes as:</p> <ul style="list-style-type: none"> - the current RUTF formulation is most likely undesirable for DHA status and neurodevelopment and - the proposed changes may bring an improvement in DHA status while being unlikely to cause any harm vs. the current RUTF formulation. - obtaining scientific evidence to determine the exact optimal levels of LA and ALA may take several more years. <p>In summary, Canada supports the proposed levels of n-6 fatty acids (minimum: 330 and maximum: 780 mg/ 100 kcal) and n-3 fatty acids (minimum 110 mg/ 100 kcal).</p>	Canada
<p>The The level of linoleic acid should not be less than 333 346-mg per 100 kcal or greater than 1 110 mg per 100 kcal. The level of alpha-linolenic acid should not be less than 33 mg/100 kcal±.</p> <p>We concur with the proposal of 333 mg per 100 kcal.</p>	Paraguay
<p>The WHO recommendation from 2004 indicates an RNI of 60 mg/day for 1-3 years and 76 mg/day for 4-6 years (respectively a relative ration of 0,05 mg Mg/kcal/day and 0,04 mg Mg/kcal/day). Therefore, UAE would suggest setting the minimum at 15 mg/100 kcal and the maximum at 45 mg/100 kcal</p> <p>UAE supports the proposal based on the evidence presented in the discussion paper. UAE also notes that the level of linoleic acid and alpha-linolenic is detailed in the Annex, therefore, we consider there is no need to repeat the text in this section. UAE proposes the following amendments:</p> <p>3 Lipids should provide 45% to 60% of the total energy.</p> <p>[The level of linoleic acid should not be less than 333mg 316 mg per 100 kcal and shall not be more than 1110 mg per 100 kcal. The level of and alpha-linolenic acid are mentioned in the Annex: Nutritional composition of RUTF. should not be less than 33 mg/100kcal.</p>	UAE
<p>[The level of linoleic acid should not be less than 333mg 346 mg per 100 kcal and shall not be more than 1110 mg per 100 kcal. The level of alpha-linolenic acid should not be less than 33 mg/100kcal.]</p> <p>The outcome of the informal discussion paper for EFAs in RUTF shall be taken into consideration in establishing the level of EFAs.</p> <p>The dosage and ratio of EFAS shall be defined in order to achieve a good conversion rate to DHA and improve LCPUFA metabolism in children recovering from SAM.</p> <p>The option of use of DHA from fish oil (and positive impact on neurocognitive development) or algae oil could also be considered.</p>	MSF

<p>MSF would like to raise awareness on the necessity to do an analysis on the availability of the ingredients necessary to achieve the future recommendations for “local” manufacturers as we would like to ensure that all manufacturers have access to these ingredients. The new proposed values shall not be a barrier for locally based manufacturers as they play an important role in the supply of RUTF, and time shall be given for the implementation of new requirements.</p>	
<p>[The level of linoleic acid should not be less than 333mg and 316 mg per 100 kcal and shall not be more than 1110 mg per 100 kcal. The level of alpha-linolenic acid should not be less than 33 mg/100kcal.] are mentioned in the Annex: <u>Nutritional composition of RUTF.</u></p> <p>ISDI notes that the eWG on RUTF in 2020 and 2021 deliberated and was presented with evidence to modify these values. ISDI would like to reiterate its comments. From a scientific point of view, ISDI supports the proposal based on the evidence presented in the discussion paper. However, ISDI believes that the evidence presented should be complemented by an evaluation of the availability (development of local agricultural sectors) and quality of the raw materials that would allow reaching these recommendations. This work has not yet been done and the current specifications from the joint statement (1) may be noted in a footnote to explain the transition step.</p> <p>Also, it should be noted that while fish oil is unlikely to be used, it may be included as there is no prohibition. If the Committee decides to change the nutritional profile towards higher levels of PUFA, ISDI wishes to point out that fish oil can contain up to 6000 mg/kg of tocopherol.</p> <p>ISDI also notes that the level of linoleic acid and alpha-linolenic is detailed in the Annex, therefore, we consider there is no need to repeat the text in this section.</p> <p>(1) A Joint Statement by the World Health Organization, the World Food Programme, the United Nations System Standing Committee on Nutrition and the United Nations Children’s Fund. 2007. Until the evaluation on the availability (development of local agricultural sectors) and quality of the raw materials that would allow reaching these recommendations has been done, a maximum of 1111 mg/100 kcal for n-6 fatty acids and a minimum of 33 mg/100 kcal n-3 fatty acids are permitted based on the 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.</p>	<p>ISDI</p>
<p>UNICEF proposes that the text regarding linoleic (n-6) and linolenic fatty acids (n-3) as follows: The level of linoleic acid should not be less than 280mg per 100 kcal and shall not be more than 800 mg per 100 kcal. The level of alpha-linolenic acid should not be less than 110 mg/100kcal and not more than 280mg/100kcal.</p> <p>UNICEF commissioned a report on this topic, available as a document in the informal discussion group. https://forum.codex-alimentarius.net/viewforum.php?f=305&sid=bf04bafd7ff90cc8c4bd0950b8f2c302</p> <p>WHO are currently conducting a review on the EFA content of RUTF with reference to the importance of EFAs such as DHA in the SAM population. Supplemental DHA has been demonstrated to effectively increase blood DHA levels in SAM children, see Jones et al. BMC Medicine (2015) 13:93 FAO recommends DHA level for 6-24 months of 10-12mg/kg/d and for 2-4 year olds, 100-200mg/d. Fats and fatty acids in human nutrition Report of an expert consultation. FAO, Rome, 2010http://www.fao.org/3/i1953e/i1953e.pdf</p>	<p>UNICEF</p>

<p>[The level of linoleic acid should not be less than 333mg 316 mg per 100 kcal and shall not be more than 1110 mg per 100 kcal. The level of alpha-linolenic acid should not be less than 33 mg/100kcal.] are given in annex]</p> <p>The level of linoleic acid and alpha-linolenic is detailed in the annex, so there is no need to give details in this section</p>	<p>IRUFA</p>
<p>11 PACKAGING</p>	
<p>The packaging materials must be made only of harmless substances which are suitable for the use they they are intended forintended for. Where the Codex Alimentarius Commission has put in place a standard for one of the substances used as a packaging material, this standard must be applied.</p>	<p>Benin</p>
<p>12. LABELLING</p>	
<p>The United States continues to support current language on labeling</p>	<p>USA</p>

<p>ANNEX</p>	
<p>The EU is not in a position to comment in detail on specific compositional requirements of RUTF, as there is no specific advice from the European Food Safety Authority on them.</p> <p>The EU remains convinced that the composition of RUTF should primarily be based on relevant WHO documents (and their future modifications) and on the advice of UNICEF, WHO and the World Food Program as well as NGOs with extensive experience in the field.</p>	<p>European Union</p>
<p> </p>	

<p>n-6 Fatty acids</p>	
<p>[1111] or [780]</p>	<p>Brazil</p>
<p>[1111] or [780]780</p>	<p>Canada</p>
<p><u>Omega-6 fatty acids Minimum: 330 Maximum: (1 111) Omega-3 fatty acids Minimum: (33) or () Maximum: 280</u></p> <p>Bearing in mind resolution 2350 of 2020, the ready-to-use therapeutic formula is taken as a reference; for every 100 g it contributes 520 – 550 kcal, and it also establishes percentages of essential fatty acids</p> <p>Omega-6: 3% – 10% of total energy</p> <p>Therefore, the following conversions were made</p> <p>550 kcal ----- 6 110 mg Omega-6 100 kcal x</p>	<p>Colombia</p>

<p>= 1 110.9 mg Omega-6</p> <p>Omega-3: 0.3% – 2.5% of total energy</p> <p>=1.56 kcal / 9 g/kg = 0.173 g = 173 mg Omega-3</p> <p>520 kcal ----- 173 mg Omega-3 100 kcal x</p> <p>= 33.3 mg Omega-3</p> <p>Given the above, the following decision was reached:</p> <p>Omega-6: maximum range of 1 111 mg/100 kcal, and Omega-3: minimum range of 33 mg/100 kcal</p>	
<p>Most studies have shown that the appropriate ratio of ω - 6: ω - 3 fatty acids for the treatment of children with severe acute malnutrition (SAM) is approximately 10: 1, therefore, Iran supports the following values: n6 maximum 1111 mg/100 kcal and n3 minimum 33 mg/100 kcal</p> <p>[1111] or [780]</p> <p>1111</p>	<p>Iran</p>
<p>We agreed to a reduction in the maximum value for Omega 6, and also an increase in the minimum level of Omega 3. We also consider it appropriate to double the magnesium values.</p>	<p>Paraguay</p>
<p>The hypothetical minimum n-3 Fatty acids level and maximum n-6 Fatty acids level could theoretically lead to n-6:n-3 ratio of 1.2:1. This is extremely low and deviates substantially from guidelines by authorities for early life nutrition:</p> <p>LA-to-a-LA ratios recommended by authoritative bodies: In the absence of data on functional or clinical outcomes, the nutritional recommendations for LA-to-a-LA ratios in formula for term infants have been established between 5:1 and 15:1. The influence of LA:a-LA ratio in infant formula on ARA and DHA status has been reviewed; an LA:a-LA ratio exceeding 15:1 and below 4:1 was not recommended as it would result in ARA status markedly lower from that of breast-fed infants (1). Most authorities such as Codex (2,3), recommend an LA:a-LA ratio ranging from 5:1 to 15:1 for older infants and young children. This ratio is based on the LA:a-LA ratio in breastmilk, which is on average about 12:1 (4). ESPGHAN recommends an LA:a-LA ratio of 5:1 to 15:1 for enteral nutrition for preterm infants (5) based on breast milk levels and 8:1 for lipid parenteral nutrition for preterm infants (6) based on the LA and a-LA minimum amounts to prevent lipid deficiencies. The minimum essential lipid requirement for LA is 4 E% and for a-LA is 0.5 E% (ratio 8:1) (7).</p> <p>When calculating the theoretical ratio n-6:n-3 using the values in square brackets for the minimum n-3 Fatty acids and the maximum n-6 Fatty acids and the already agreed values, the results show that many options lead to a ratio which is not recommended by the authoritative bodies (see table below):</p>	<p>EU Specialty Food Ingredients</p>

<table style="width: 100%; border-collapse: collapse;"> <tr> <td></td> <td style="text-align: center;">LA min 330</td> <td style="text-align: center;">LA max 1111</td> <td style="text-align: center;">LA max 780</td> </tr> <tr> <td>ALA min 33</td> <td style="text-align: center;">10:1</td> <td style="text-align: center;">33,7:1</td> <td style="text-align: center;">23,6:1</td> </tr> <tr> <td>ALA min 110</td> <td style="text-align: center;">3:1</td> <td style="text-align: center;">10,1:1</td> <td style="text-align: center;">7,1:1</td> </tr> <tr> <td>ALA max 280</td> <td style="text-align: center;">1,2:1</td> <td style="text-align: center;">4:1</td> <td style="text-align: center;">2,8:1</td> </tr> </table> <p>In addition, the level proposed for the minimum of n-6 Fatty acids (330 mg/kcal) is already below the recommendation for an healthy population (4% E n-6 Fatty acids would mean 444 mg n-6 Fatty acids /100 kcal for RUTFs at the minimum energy level and 470 mg/100 kcal for RUTFs at the maximum energy level).</p> <p>Taking this in account, we believe it's key for the health of children suffering SAM to include a ratio in the guidelines in order to avoid recipes with unhealthy n-6:n-3 ratio. We also believe that it could be wise to decrease the n-6 Fatty acids maximum level to 780 µg/100 kcal and increase the minimum n-3 Fatty acids level to 55 mg/100 kcal which seems more in line with the recent recommendations. Even if RUTFs are given for a short duration, it's key to give to these children the maximum chance as soon as they receive the RUTFs.</p> <ol style="list-style-type: none"> 1. Clark J Pediatr 1992 2. JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX ALIMENTARIUS COMMISSION Forty-third Session FAO Headquarters, Rome, Italy 6 - 11 July 2020, REPORT OF THE FORTY- FIRST SESSION OF THE CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES DÜSSELDORF, Germany, 24 – 29 November 2019 3. Codex GUIDELINES ON FORMULATED COMPLEMENTARY FOODS FOR OLDER INFANTS AND YOUNG CHILDREN CAC/GL 8-1991 4. Gibson Essential Fatty Acids and Eicosanoids. Edited by A. Sinclair and R. Gibson American Oil Chemists Society, Champaign IL, 1993 5. Agostini et al. JPGN 2010 6. ESPGHAN/ESPEN/ESPR/CSPEN guidelines on pediatric parenteral nutrition: Lipids. Clin Nutr 2018 7. EFSA https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2010.1461 		LA min 330	LA max 1111	LA max 780	ALA min 33	10:1	33,7:1	23,6:1	ALA min 110	3:1	10,1:1	7,1:1	ALA max 280	1,2:1	4:1	2,8:1	
	LA min 330	LA max 1111	LA max 780														
ALA min 33	10:1	33,7:1	23,6:1														
ALA min 110	3:1	10,1:1	7,1:1														
ALA max 280	1,2:1	4:1	2,8:1														
<p>[1111] or [780]or</p> <p>From a scientific point of view, we support the proposal based on the evidence presented in the discussion paper and the Expert Review. However, we believe that the evidence presented should be complemented by an evaluation of the availability (development of local agricultural sectors) and quality of the raw materials that would allow reaching these recommendations. This work has not been done yet then the current specifications from the 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) could be kept. A footnote should be added below this section in the table to explain the transition step: "an evaluation of the availability (development of local agricultural sectors) and quality of the raw materials that would allow reaching these recommendations should be implemented. Until this evaluation is done, a tolerance is agreed for maximum n-6 fatty acid (1111 mg/100 kcal) and for minimum n-3 fatty acid (33 mg/100 kcal) based on the 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.</p>	<p>IRUFA</p>																

<p>UNICEF proposes that the n-6 and n-3 min and max values are amended to support endogenous essential fatty acid production (namely DHA). proposed amendments are as follows: 1.Omega 6 fatty acids / LA 3-10% of total energy minimum 280 mg/100kcal maximum 800 mg/100kcal 2.Omega 3 fatty acids / ALA 0.3-2.5% of total energy minimum 110 mg/100kcal maximum 280mg/100kcal</p> <p>WHO are currently conducting a review on the EFA content of RUTF and are reviewing the importance of EFAs such as DHA in the SAM population. Supplemental DHA has been demonstrated to effectively increase blood DHA levels in SAM children, see paper by Jones et al. BMC Medicine (2015) 13:93 FAO recommends DHA level for 6-24 months of 10-12mg/kg/d and for 2-4 year olds, 100-200mg/d. Fats and fatty acids in human nutrition Report of an expert consultation. FAO, Rome, 2010http://www.fao.org/3/i1953e/i1953e.pdf</p>	<p>UNICEF</p>
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<p>n-3 Fatty acids</p>	
<p>[33] or [110]</p>	<p>Brazil</p>
<p>[33] or [110]110</p>	<p>Canada</p>
<p>[33] or [110] 33</p>	<p>Iran</p>
<p>The minimum and maximum values of Nutritional Composition of RUTF should comply with the reference values of “A Joint Statement by the WHO, the World Food Programme, the United Nations System Standing Committee on Nutrition and the United Nations Children’s Fund. 2007. Therefore, we suggest the following reference values”:</p> <p>Minimum value should be 33 mg/100kcal. Maximum value should be 280 mg/100kcal.</p>	<p>Thailand</p>
<p>As mentioned in our comment above, we believe it’s key for the health of children suffering SAM to include a ratio in the guidelines in order to avoid recipes with unhealthy n-6:n-3 ratio. We also believe that it could be wise to decrease the n-6 Fatty acids maximum level to 780 µg/100 kcal and increase the minimum n-3 Fatty acids level to 55 mg/100 kcal which seems more in line with the recent recommendations. Even if RUTFs are given for a short duration, it’s key to give to these children the maximum chance as soon as they receive the RUTFs.</p>	<p>EU Specialty Food Ingredients</p>
<p>As noted in the February 2021 expert review report entitled “Expert advice on minimum and maximum limits for essential fatty acid levels in Ready to Use Therapeutic Food (RUTF)” prepared by Andrea T Hsieh, PhD, “Improving DHA status may be achieved in one of two ways – reducing high levels of dietary LA or consumption of preformed DHA.” GOED acknowledges that sources of DHA and EPA may increase the cost of RUTFs, but given the limited scientific evidence available to determine the optimal levels of linoleic and alpha-linolenic acids in RUTFs, it makes sense to include an option for provision of preformed DHA (and by default EPA if source is fish oil). For this reason, GOED recommends the inclusion of the following text from the expert review report:</p> <ul style="list-style-type: none"> • Consideration of provision of preformed DHA 20-100mg/100g • Consideration of provision of preformed EPA, shall not exceed DHA 	<p>GOED</p>

<p>GOED is aware of a manuscript that was submitted for publication within the last month that supports the benefits of adding DHA to RUTF. Assuming the manuscript is accepted in advance of CCNFSDU42, GOED will share the results.</p>	
<p>[33] or [140]</p> <p>From a scientific point of view, we support the proposal based on the evidence presented in the discussion paper and the Expert Review. However, we believe that the evidence presented should be complemented by an evaluation of the availability (development of local agricultural sectors) and quality of the raw materials that would allow reaching these recommendations. This work has not been done yet then the current specifications from the 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) could be kept. A footnote should be added below this section in the table to explain the transition step: "an evaluation of the availability (development of local agricultural sectors) and quality of the raw materials that would allow reaching these recommendations should be implemented. Until this evaluation is done, a tolerance is agreed for maximum n-6 fatty acid (1111 mg/100 kcal) and for minimum n-3 fatty acid (33 mg/100 kcal) based on the 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.</p>	<p>IRUFA</p>

<p>Magnesium</p>	
<p>[15] or [30]</p> <p>[45] or [90]</p>	<p>Brazil</p>
<p>Canada supports the recommendations from UNICEF in the informal discussion to retain the lower values for magnesium in alignment with the 2007 Joint Report, as the current dietary recommendations do not support the proposed higher magnesium values to obtain a Ca:Mg ratio of 2:1.</p> <p>[15] or [30]15</p> <p>[45] or [90]45</p>	<p>Canada</p>
<p><u>Magnesium: Minimum: (15) or () Maximum: (45) or ()</u></p> <p>Under Colombian regulation, this is supported by Resolution 2350 of 2020, which provides the composition of ready-to-use therapeutic formula for every 100 g, contributing 520 – 550 kcal and 80 – 140 mg of magnesium.</p> <p>Magnesium</p> <p>RUTF 520 kcal ----- 80 mg magnesium</p> <p>100 kcal x</p> <p>= 15.4 mg magnesium</p> <p>RUTF 550 kcal ----- 140 mg magnesium</p> <p>100 kcal x</p>	<p>Colombia</p>

<p>= 25.45 mg magnesium</p> <p>Accordingly, the following was decided:</p> <p>Minimum range: 15 mg/100 kcal Maximum range: 45 mg/100 kcal</p>	
<p>[15] or [30]15 [45] or [90]45</p>	Egypt
<p>Due to the competition of calcium and magnesium in absorption, the ratio of calcium to magnesium plays an important role in improving the absorption of these minerals. Blood calcium and magnesium levels in children with severe malnutrition are lower than normal, so the proper ratio between these two minerals should be considered in READY TO USE THERAPEUTIC FOODS (RUTF). In guidelines on formulated complementary foods for older infants and young children CAC/GL 8-1991, this ratio is set at 8.3/1.</p> <p>Thus, Iran supports Therefore, Iran supports a minimum value of 15 mg / 100 kcal and a maximum of 45 mg / 100 kcal</p> <p>[15] or [30] 15 [45] or [90] 45</p>	Iran
<p>The minimum and maximum values of Nutritional Composition of RUTF should comply with the reference values of “A Joint Statement by the WHO, the World Food Programme, the United Nations System Standing Committee on Nutrition and the United Nations Children’s Fund. 2007. Therefore, we suggest the following reference values”:</p> <p>Minimum = 15 mg/100kcal Maximum = 45 mg/100kcal</p>	Thailand
<p>The United States notes that magnesium plays a key secondary metabolic role in ionic transport processes promoting better cellular uptake of both calcium and phosphorus. The levels of both calcium and phosphorus have been increased in the draft RUTF guideline to support catch up growth and bone development. A corresponding increase in magnesium to the levels proposed in the text in square brackets will allow for a favorable calcium/phosphorous/magnesium ratio, leading to better absorption levels of both calcium and phosphorous. The United States supports the proposed increased of magnesium to a minimum of 30mg/100 kcal (from 15 mg/100 kcal) and a maximum of 45mg/100 kcal (from 45mg/100 kcal).</p>	USA

<p>In CCNFSDU 40 (2018) There was widespread agreement amongst the pWG Members to retain the current values on the minerals as stipulated in the 2007 Joint Statement with the exception of the maximum values on potassium, calcium and magnesium to allow for variability in raw materials. This change increased the maximum values for magnesium by about 68%.</p> <p>Values that were agreed in CCNFSDU 2018 :</p> <p>Minimum 80mg/100g (15mg/100kcal)</p> <p>Maximum 235mg/100g (45mg/100kcal)</p> <p>Reference CRD 28, CCNFSDU 2018</p> <p>In an important paper by Hother etal (2016) serum magnesium was measured before and after treatment with F100,(RUTF is based on this formulation) with magnesium values of 15-26mg/100kcal. At admission, the mean serum magnesium levels of 13% of children were below the age specific normal values and 49% children had values above the age specific normal values. At discharge 83% of children had magnesium levels above the normal range.</p> <p>Based on this data shared above, it appears the levels agreed in CCNFSDU 2018 discussions of the RUTF guideline will be adequate to restore Magnesium levels in the majority of children with SAM receiving RUTF. UNICEF therefore supports:</p> <p>Magnesium:</p> <p>Minimum 80mg/100g (15mg/100kcal)</p> <p>Maximum 235mg/100g (45mg/100kcal)</p> <p>There was widespread agreement amongst the pWG Members to retain the current values on the minerals as stipulated in the 2007 Joint Statement with the exception of the maximum values on potassium, calcium and magnesium to allow for variability in raw materials. This change increased the maximum values for magnesium by about 68%. Values that were agreed in CCNFSDU 2018 : Minimum 80mg/100g (15mg/100kcal) Maximum 235mg/100g (45mg/100kcal) Reference CRD 28, CCNFSDU 2018 In an important paper by Hother etal (2016) serum magnesium was measured before and after treatment with F100,(RUTF is based on this formulation) with magnesium values of 15-26mg/100kcal. At admission, the mean serum magnesium levels of 13% of children were below the age specific normal values and 49% children had values above the age specific normal values. At discharge 83% of children had magnesium levels above the normal range. Based on this data shared above, it appears the levels agreed in CCNFSDU 2018 discussions of the RUTF guideline will be adequate to restore Magnesium levels in the majority of children with SAM receiving RUTF. UNICEF therefore supports: Magnesium: Minimum 80mg/100g (15mg/100kcal) Maximum 235mg/100g (45mg/100kcal)</p>	<p>UNICEF</p>
<p>[15] or [30]15</p> <p>The WHO recommendation from 2004 indicates an RNI of 60 mg/day for 1-3 years and 76 mg/day for 4-6 years (respectively a relative ration of 0,05 mg Mg/kcal/day and 0,04 mg Mg/kcal/day). Therefore, ISDI understands the concerns raised that the minimum values suggested may be too low. However, there is no scientific evidence on the specific</p>	<p>ISDI</p>

<p>requirements for managing SAM. Therefore, ISDI would suggest setting the minimum at 15 mg/100 kcal and the maximum at 45 mg/100 kcal.</p> <p>[45] or [90]<u>45</u></p> <p>The WHO recommendation from 2004 indicates an RNI of 60 mg/day for 1-3 years and 76 mg/day for 4-6 years (respectively a relative ration of 0,05 mg Mg/kcal/day and 0,04 mg Mg/kcal/day). Therefore, ISDI understands the concerns raised that the minimum values suggested may be too low. However, there is no scientific evidence on the specific requirements for managing SAM. Therefore, ISDI would suggest setting the minimum at 15 mg/100 kcal and the maximum at 45 mg/100 kcal.</p>	
<p>[15] or [30]</p> <p>To our knowledge, there is no scientific evidence supporting a need for change of Magnesium content in RUTF dedicated to SAM children.</p> <p>[45] or [90]</p> <p>To our knowledge, there is no scientific evidence supporting a need for change of Magnesium content in RUTF dedicated to SAM children.</p>	<p>IRUFA</p>