

CODEx ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEx ALIMENTARIUS COMMISSION

Forty-fifth Session

COMMENTS ON DRAFT STANDARDS AND RELATED TEXTS SUBMITTED BY THE 42ND SESSION OF CODEx COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES¹

BACKGROUND

This document compiles the comments on the draft standards submitted at Step 8 or Step 5/8 and the proposed draft standards submitted at Step 5 of the Procedure. The comments are those received through the Codex Online Commenting Systems (OCS), or via email by the time this document was issued. The comments are as shown in Appendix I.

OCS is an online tool that enables Codex Contact Points to submit comments on draft texts in a standardized way, thus providing more transparency and better management of comments on different Codex texts as requested through Circular Letters. Since its launching at CAC39 (2016), the OCS has been used for different Codex Committees.

EXPLANATORY NOTES ON APPENDIX I

The comments received are presented in a table format, with two columns as follows:

First column – Presents the comments with the rationale.

Second column – Presents the provider of the comments (name of country or observer)

¹ This document compiles comments submitted through OCS, or via email by the time this document was issued, in reply to CL 2022/57/OCS-NFSDU

COMMENTS IN REGARD TO THE GUIDELINES FOR READY-TO-USE THERAPEUTIC FOODS (RUTF), AT STEP 8 IN REPLY TO CL 2022/57/OCS-NFSDU

Comments of Australia, Botswana, Brazil, Canada, Colombia, Cuba, Egypt, European Union, Iran, Malaysia, New Zealand, Peru, Philippines, Republic of Korea, Saudi Arabia, Uganda, USA and ENCA, HKI, IBFAN, ICUMSA, UNICEF, WHO

COMMENT	MEMBER/OBSERVER
Australia supports the adoption of this guidance	Australia
We support the adoption of the standard at step 8	Botswana
<p>Brazil appreciates the excellent work made by South Africa, Senegal and Uganda and the efforts made by CCNFSDU to reach a consensus and forward the Guidelines for Ready-to-Use Therapeutic Foods to CAC45 for adoption at Step 8.</p> <p>Brazil has no objection to the text agreed by CCNFSDU at its last session (42a session: 19 – 25 November 2021) and in the spirit of compromise agrees with it. Nevertheless, Brazil would like to highlight some important issues to be considered by the Committee in the future.</p> <p>Preamble</p> <p>Brazil acknowledges the consensus reached by CCNFSDU on the revised and simplified text to clearly take into account concepts such as: the promotion of continuation of breastfeeding, transition to nutritious family food; psycho-social support for recovery; the use of locally based foods; RUTF is not for general retail sale.</p> <p>We understand that the text covers the main issues of concern raised by members. Nevertheless, we would like to emphasize that an appropriately designed programme should support continuation of breastfeeding, training re-lactation and appropriate transition to nutritious family food and psycho-social support for recovery. Furthermore, the use of RUTF should not preclude other more culturally appropriate dietary options including the use of nutrient dense, family-based local foods.</p> <p>Section 5.2.1 - Carbohydrates</p> <p>Brazil would like to recall the discussion that took place at the 39^a session of CCNFSDU (2017) when the Representative of WHO mentioned that there were clear recommendations to reduce the consumption of sugars and understanding that it may be possible to further reduce the content of sugars with future technological advances, clearer relevant language could be included in the guideline to address this issue. At the same session, the Representative of UNICEF explained that sugar was normally added to RUTF to enhance palatability of the product, and for technological reasons to act as a filler and a binder and extend the shelf-life. It was currently only possible to reduce sugar by 5%, but in future, with technological advances, sugar might be further reduced (para. 117 – 118 REP18/NFSDU).</p> <p>Brazil is aware of the issues raised by UNICEF regarding the challenges to limit the addition of free sugars to less than 20% of the energy in the product. On the other hand, reducing the quantity of free sugars used in RUTF at the minimum level possible shall be a goal to be achieved. Considering that further efforts were being made by the suppliers of RUTF to explore the possibilities of lowering the contents of free sugars, Brazil is of the opinion that free sugars should be limited and should not exceed 10% of total energy.</p>	Brazil
Canada has no further comments on the Guidelines for Ready-to-Use Therapeutic Foods (RUTF); we support its adoption at Step 8.	Canada

<p>Colombia esta de acuerdo con la aprobación de documento en el trámite 8.</p> <p>Se presentan las siguientes observaciones:</p> <p>- Preámbulo ... dentro de un programa adecuadamente diseñado para la promoción, protección, apoyo a la lactancia materna, y entrenamiento en relactación y la transición adecuada a alimentos nutritivos preparados en el hogar y el apoyo psicosocial para la recuperación... Los cambios resaltan la importancia a la práctica de la lactancia y evidenciar la necesidad de preservarla o reestablecerla, como mejor opción para el tratamiento de la malnutrición.</p> <p>-12.4 Deberán figurar en la etiqueta de los ATLC las siguientes declaraciones adicionales:</p> <ul style="list-style-type: none"> • El consumo de este producto debe acompañarse de una adecuada alimentación complementaria y agua potable <p>Se propone incluir el texto para la etiqueta del producto.</p>	<p>Colombia</p>
<p>Cuba agradece emitir sus comentarios a la carta circular CL 2022/57/OCS-INFSDN y apoya en principio la aprobación del Proyecto de Directrices para los alimentos terapéuticos listos para el consumo</p>	<p>Cuba</p>
<p>Egypt agrees that the text of the "Draft Guidelines for Ready to Use Therapeutic Foods (RUTF)" is ready for adoption at Step 8"</p>	<p>Egypt</p>
<p>As explained on 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 also notes that the text of the draft guidelines reflects what was agreed during the last Committee meeting. The EU therefore agrees with the text of the draft Guidelines and considers that the text is ready for adoption at Step 8.</p> <p>The EU has some minor editorial comments on the text, which are as follows:</p> <ul style="list-style-type: none"> - The footnotes in the main document as well as in the Annex would need to be renumbered (as there is no footnote 1). - In section 5, first paragraph, a hyphen would need to be added to the word "energy" to clarify that the phrase refers to energy-dense foods: <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."</p> <ul style="list-style-type: none"> - In paragraph 6.4, the abbreviation "GUL" would need to be inserted, for easier reference to the Annex: <p>6.4 Vitamins and Minerals "RUTF should contain the Vitamins and minerals presented in the Annex: Nutritional Composition of RUTF. RUTF should comply with the minimum and maximum or guidance upper levels (GUL) in the Annex."</p> <p>In the Annex, minor editorial changes are suggested to the footnotes on Vitamin A and vitamin D, to properly reflect the terminology and relationships between conversion factors:</p> <p>ANNEX</p> <p>Footnote 1: 1µg RE = 3.33 IU Vitamin A = 1 µg trans retinol. Retinol contents shall be provided by preformed vitamin A (retinol), while any contents of carotenoids should not be included in the calculation and declaration of vitamin A activity.</p>	<p>European Union</p>

Footnote 2: 1 µg = 40 IU vitamin D.	
Iran agrees with adoption draft "GUIDELINES FOR READY TO USE THERAPEUTIC FOODS (RUTF)" at step 8	Iran
Malaysia supports the Draft Guidelines for Ready To Use Therapeutic Foods is ready for adoption at Step 8.	Malaysia
New Zealand supports adoption of the Guidelines for Ready-to-Use Therapeutic Foods (RUTF).	New Zealand
<p>1. Párrafo 1,2,3, 4.1, 4.2, 5.1.5, 6.2, 12 y 12.1. Dice: Malnutrición. Debería decir: Desnutrición. Sustento: A lo largo de todo el documento se sigue manteniendo el término malnutrición, el adecuado es desnutrición ya que ambos conceptos son diferentes. Según la Organización Mundial de la Salud , la malnutrición es un término que "abarca la desnutrición (emaciación, retraso del crecimiento e insuficiencia ponderal), los desequilibrios de vitaminas o minerales, el sobrepeso, la obesidad, y las enfermedades no transmisibles relacionadas con la alimentación". No obstante, en el documento revisado se hace referencia a un estado carencial cuya denominación más apropiada es el término desnutrición. Por lo tanto, consideramos que el término malnutrición debe ser reemplazado por desnutrición.</p> <p>2. Cuadro: composición nutricional de los ATLC Ácidos grasos omega 6. Dice: Máximo: 780 mg/100 kcal. Debería decir: Máximo: 1111 mg/100 kcal. Sustento: Respecto a los niveles para ácidos grasos omega 6 seguimos considerando adecuado un nivel máximo de 1111mg/100 kcal, tal como se consideró en la consulta en trámite 6.</p> <p>3. Cuadro: composición nutricional de los ATLC Ácidos grasos omega 3. Dice: Mínimo: 110 mg/100 kcal. Debería decir: Mínimo: 33 mg/100 kcal. Sustento: Respecto a los niveles para ácidos grasos omega 3 seguimos considerando adecuado un nivel mínimo de 33 mg/100 kcal, tal como se consideró en la consulta en trámite 6.</p>	Peru
<p>Philippine Comments in reply to CL 2022/57/OCS-NFSU</p> <p>The Philippines supports the final draft of the Revised Guidelines for Ready to Use Therapeutic Foods (RUTF) with no additional specific comments for adoption at Step 8. This has been consistent with the outcome of the electronic working group and consensus of the 42nd Codex Committee on Foods for Special Dietary Uses Session as justified by generally accepted scientific evidence. These are also in line with the previous Philippine Positions.</p> <p>The proposed Revised Guidelines for Ready to Use Therapeutic Foods (RUTF) defined this product as food for special medical purposes and it should conform with the general principles of the Codex Standard on Labeling of and Claims for Foods for Special Medical Purposes (Codex STAN 180-1991) to wit "Its use should have been demonstrated, by scientific evidence, to be safe and beneficial in meeting the nutritional requirements of children with uncomplicated severe acute malnutrition (SAM).</p> <p>These guidelines should be used in accordance with the Joint Statement by the World Health Organization (WHO), the World Food Programme (WFP), the United Nations System Standing Committee on Nutrition (UNSCN) and the United Nations Children's Fund (UNICEF) (2007) and taking into account other relevant documents by WHO and FAO. We are in agreement with retention of all supporting WHO and FAO references on infant and young child feeding. The Preamble and additional labeling requirements highlighted the need to promote continuation of breastfeeding and recommend exclusive breast feeding for the first six months and its continuation up to two years old and beyond. These are safeguard measures to ensure that RUTF is used in conjunction with breastfeeding.</p> <p>The Philippines is of the opinion that the proposed draft guidelines is ready for adoption at Step 8 as we believe that it is necessary to have a guidance document for RUTF manufacturers and regulatory authorities to adhere to agreed reference standards on definition, ingredients and nutrient composition, labeling, contaminants, processing, good manufacturing and hygienic practices and methods of sampling and analysis based on the latest scientific evidence. It is high time to have uniform guidelines that ensures good quality and safe ready to use therapeutic foods for severely acute malnourished older infants and children without medical complications. We firmly believe that these guidelines should be complemented by national nutrition policies highlighting the use of local foods and that RUTF should be used in specific situations such as insufficient local food production, food insecurity or under emergency situations.</p>	Philippines

<p>General comment: Thank you very much for this opportunity of reviewing the guideline. The Republic of Korea would like to express gratitude to the CCNFSDU for the outstanding work done as the guideline is ready for adoption at Step 8. The ROK appreciates the amazing team leadership with such dedication.</p>	Republic of Korea
<p>The Kingdom of Saudi Arabia has reviewed the document and supports the progress of the proposed draft standard for Guidelines for Ready-to-Use Therapeutic Foods (RUTF) to the next step.</p>	Saudi Arabia
<p>Uganda supports that the text is ready for adoption at step 8.</p>	Uganda
<p>The United States fully supports adoption of the draft Guidelines for Ready-to-Use Therapeutic Foods (RUTF) at Step 8.</p>	USA
<p>Some important safeguards were added to the text of the Guidelines last year and it is important that these are not lost, in particular the clear ban on the use of health and nutrition claims, clarity that RUTF is not for general retail sale, and the recommendation that RUTF should be used in an “appropriately designed programme that promotes continuation of breastfeeding, appropriate transition to nutritious family food and psycho-social support for recovery.” However, we did not succeed in getting restrictions on sweetness, or references to training on re-lactation despite some support from USA, Brazil and Colombia. If the issue is opened up for discussion ENCA proposes the following improvements:</p> <p>PREAMBLE Children affected by severe acute malnutrition (SAM) need efficacious and timely intervention including safe, palatable foods with a high energy content and adequate amounts of vitamins, minerals and other nutrients within an appropriately designed programme that promotes supports continuation of breastfeeding, training in re-lactation and appropriate transition to nutritious family food and psycho-social support for recovery. In accordance with the Joint Statement by the World Health Organization (WHO), the World Food Programme (WFP), the United Nations System Standing Committee on Nutrition (UNSCN) and the United Nations Children’s Fund (UNICEF) (2007) and taking note of other relevant documents by WHO and FAO, Ready-to-Use Therapeutic Food (RUTF) is a WHO recommended option for the dietary management of children aged 6 to 59 months with SAM without medical complications. However, this does not preclude other more culturally appropriate dietary options including the use of nutrient dense, family-based local foods. RUTF is not for general retail sale.</p> <p>5.2.1 Carbohydrates 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% 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. Honey should not be used in RUTF due to the risk of infant botulism from <i>Clostridium botulinum</i>. The total CHO can be 20% of total energy and since the peanut pastes use sucrose and maltodextrin to make them palatable, this creates a high level of sweetness as well as the use of a non-nutritive CHO as 20% of total energy. ENCA recommends that sucrose and maltodextrin be no more than 10% of the total CHO of the product.</p> <p>12.4 The following additional statements shall appear on the label of RUTF: The product is not to be used for Nasogastric Tube (NG tube) administration. The product should be used in conjunction with breastfeeding. Exclusive breastfeeding is recommended for the first 6 months of life, and continued breastfeeding is recommended for up to two years or beyond.</p> <p>12.5 Instructions for use The label should indicate clearly from which age the product is recommended for use. This age shall not be less than six months for any product. Feeding instructions shall be given; preferably accompanied by graphical presentations. Feeding instructions must include the availability of potable water needed to address thirst conditions when consuming RUTF. The time within which the product should be consumed after opening should be clearly indicated.</p>	ENCA
<p>Helen Keller International considers the text of the Draft Guidelines for Ready to Use Therapeutic Foods (RUTF) ready for adoption at Step 8.</p>	HKI

<p>DRAFT GUIDELINES FOR READY TO USE THERAPEUTIC FOODS (RUTF) (For adoption at Step 8) IBFAN Comment 1. PREAMBLE Children affected by severe acute malnutrition (SAM) need efficacious and timely intervention including safe, palatable foods with a high energy content and adequate amounts of vitamins, minerals and other nutrients within an appropriately designed programme that promotes supports continuation of breastfeeding, training in re-lactation and appropriate transition to nutritious family food and psycho-social support for recovery. In accordance with the Joint Statement by the World Health Organization (WHO), the World Food Programme (WFP), the United Nations System Standing Committee on Nutrition (UNSCN) and the United Nations Children's Fund (UNICEF) (2007) and taking note of other relevant documents by WHO and FAO, Ready-to-Use Therapeutic Food (RUTF) is a WHO recommended option for the dietary management of children aged 6 to 59 months with SAM without medical complications. However, this does not preclude other more culturally appropriate dietary options including the use of nutrient dense, family-based local foods. RUTF is not for general retail sale. 5.2.1 Carbohydrates 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% 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. Honey should not be used in RUTF due to the risk of infant botulism from Clostridium botulinum. The total CHO can be 20% of total energy and since the peanut pastes use sucrose and maltodextrin to make them palatable, this creates a high level of sweetness as well as the use of a non-nutritive CHO as 20% of total energy. IBFAN recommends that sucrose and maltodextrin be no more than 10% of the total CHO of the product. 12.4 The following additional statements shall appear on the label of RUTF: • The product is not to be used for Nasogastric Tube (NG tube) administration. • The product should be used in conjunction with breastfeeding. • Exclusive breastfeeding is recommended for the first 6 months of life, and continued breastfeeding is recommended for up to two years or beyond. 12.5 Instructions for use • The label should indicate clearly from which age the product is recommended for use. This age shall not be less than six months for any product. • Feeding instructions shall be given; preferably accompanied by graphical presentations. • Feeding instructions must include the availability of potable water needed to address thirst conditions when consuming RUTF. • The time within which the product should be consumed after opening should be clearly indicated.</p>	<p>IBFAN</p>
<p>GUL in the English document and NSR in the Spanish document are not described but Limite indicative maxima is used in the French document - better to clarify what GUL/NSR mean. There is a strange page break in the Spanish document, as section 4.2 is on it's own separate page. The table in the Annex would be improved by re-formatting it with borders, in order to distinguish between the different categories.</p>	<p>ICUMSA</p>
<p>UNICEF supports the adoption of the text as it is at step 8.</p>	<p>UNICEF</p>
<p>WHO would like to request for the following 2 corrections:</p> <ol style="list-style-type: none"> 1. On the 1st page, last sentence regarding the definition of Severe Acute Malnutrition (4.2): "bilateral oedema" should be corrected as "bilateral pitting oedema of nutritional origin" in accordance to WHO (2013) Guideline: updates on the management of severe acute malnutrition in infants and children (page 10). 2. On the 5th page, Section 12.4, 3rd bullet, last sentence: "up to two years or beyond" should read "up to two years and beyond" based on the WHO recommendation. <p>Since these are corrections to ensure the alignment with WHO guideline and recommendation, and not technical content changes, we very much hope that these corrections be made on the draft guidelines before they are adopted by CAC45.</p>	<p>WHO</p>