CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 5b **CX/NFSDU 19/41/6 Add.1**

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

Forty-first Session

Dusseldorf, Germany
24 - 29 November 2019

PROPOSED DRAFT GUIDELINE FOR READY-TO-USE THERAPEUTIC FOODS

SECTION 5.2.2 (FOOD ADDITIVES) AND SECTION 6.2 (PROTEIN)

Replies to CL 2019/79-NFSDU

Comments of Argentina, Brazil, Burkina Faso, Colombia, Egypt, Iraq, Kenya, Peru, Philippines, USA, CCTA, European Vegetable Protein Association, EU Speciality Food Ingredients, International Council on Amino Acid Science, International Special Dietary Food Industries, HKI, IDF/FIL, MSF, UNICEF

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to **CL 2019/79-NFSDU** issued October 2019. 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: COMMENTS ON THE PROPOSED DRAFT GUIDELINES FOR READY-TO-USE THERAPEUTIC FOODS

COMMENTS	Name of Country or Observer
GENERAL COMMENTS	
Canada thanks South Africa, Senegal and Uganda for chairing the eWG and preparing the proposed draft guidelines for the use Ready-to-Use Therapeutic Foods (RUTF) in the management of severe acute malnutrition (SAM), for consideration by the Committee. Canada supports the five recommendations and has provided comments for some of the recommendations	**Canada**
The recommendation is approved.	**Colombia**
MSF agrees that the need to efficacy study is already catered for in the introduction of the section 5: Any formulation of RUTF shall comply with Section 3 of the Standard for the Labelling of and Claims for Foods for Special MedicalPurposes(CXS 180-1991) including the specification that their use should have been demonstrated, by scientific evidence, to be safe and beneficial in meeting the nutritional requirements of the persons for whomthey are in-tended. However MSF would like to amend this section with a list of minimum requirements/criteria to be included in the scientific evidence, MSF would like to propose the following: Any formulation of RUTF shall comply with Section 3 of the Standard for the Labelling of and Claims for Foods for Special MedicalPurposes(CXS 180-1991) including the specification that their use should have been demonstrated, by scientific evidence, to be safe and beneficial in meeting the nutritional requirements of the persons for whom they are intended (e.g. children from 6 to 59 months with severe acute malnutrition without medical complication). Children 6 to 12 months shall be included. New formulation of RUTF should demonstrate a minimum weight gain of 5g/kg/day. Moreover the new RUTF should be compared by at least non-inferiority trials with the standard formula and a difference in weight gain bigger than 1g/kg/day should not be considered as non-inferior Other recovery indicators such as body composition, cognitive development, anaemia, morbidity… should ideally be included.	**MSF**
Kenya agreed with the eWG that table 1 should be used as basis of discussion. Our specific comments are as follows: <u>1. Food Category for RUTF</u> In regard to the Food Category, Kenya agrees that RUTF should be in FC 13.3. However, given the primary targets of the product - including infants & young children, there is need for the food additives to be assessed on a case by case basis thus Kenya proposes that CCNFSDU should request CCFA to create a new FC 13.3.1 specifically for RUTF and have the same category included in to the annex of Table III as is the case with FC 13.1 & 13.2. Once the proposed table is concluded, the same additives may be included in the GSFA <u>Table 1</u>: Kenya recommends the eWG for the comprehensive compiling of this table. However, Kenya notes that some food additives without ADI such as INS 471 (Mono & diglycerides of fatty acids) have been assigned numerical value yet according to GSFA it should be used at GMP level. In addition, the listed food additives should accurately state their	**Kenya**

function in the products for example citric acid (INS 330) is listed under antioxidants and the function listed as acidity regulator while the description is that of antioxidants. Kenya supports the eWG proposal that once the food category is agreed on, and the table fully discussed and agreed within CCNFSDU, the same may be forwarded to CCFA for endorsement for the specific category of RUTF. 3.Carry over food additives We support the adoption of proposed text which is similar to that in CXS 72 and which clearly makes reference to the preamble of GSFA 4. Protein We support the proposed level of proteins for RUTF	
Peru thanks the Federal Government of Germany, as host country of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU), for the report on the Proposed Draft Guidelines for Ready-To-Use Therapeutic Foods: Sections 5.2.2 (food additives) and 6.2 (proteins). In accordance with the revision of the document, Peru is considering approving/rejecting the following recommendations according to the enclosed table.	**Peru**
The Philippines supports the proposed Draft Revised Guidelines for Ready to Eat Foods (RUTF). This has been consistent with the outcome of the electronic working group and consensus of the previous Committee Session as justified by generally accepted scientific evidence. These are also in line with the previous Philippine Positions.	**Philippines**
The International Council on Amino Acid Science (ICAAS) supports the compromise texts of the section 5.2.2 (food additives) and section 6.2 (proteins) of the proposed draft Guidelines for RUTF.	**International Council on Amino Acid Science**
We are agree with proposal draft and we have no comments.	**Iraq**
TECHNICAL COMMENTS	
Recommendation 1: That CCNFSDU agree to the proposed list of food additives and their functional class in **Table I** (in this document) for use in RUTF and that the table be utilised as the basis for further discussions on additives in RUTF.	
We support Recommendation 1. Only food additives and flavours appropriate for 6-59 month old infants and young children and their prescribed limits in reference to the General Standard for Food Additives (Codex Stan 192-1995) shall be permitted.The Philippines could support food additives used currently permitted in Infant Formula Standard (STAN 72-1981) or Codex Standard for Follow-Up Formula (STAN 156-1987) or GL 10-1979. Thus, we prefer Option 2: Referencing the Food Categories within GSFA (CXS 192-1995)	**Philippines**
As long as there are no major studies and reviews on the subject, it is necessary to maintain the recommended additives and doses.	**Peru**

Brazil agrees with recommendation 1. We do not have specific comments on the proposed list of food additives. Nevertheless, we call the attention about the importance of considering the ongoing work in the CCNFSDU on the framework for the technological justification of food additives used in RUTF.	**Brazil**
BURKINA FASO agrees with the proposed list in table 1	**Burkina Faso**
Canada supports Recommendation #1. Canada notes that the Maximum Use Level column in Table I provides the maximum use level permitted in existing Codex texts aimed at infants and young children, and are not specific to RUTF. We would thus expect that information is available to support the safety and efficacy of these additives, specifically in RUTFs to justify their use at the proposed maximum levels.	**Canada**
We support Recommendation 1 as the preferred approach and can also support referencing other commodity standards as appropriate.	**USA**
Egypt agrees to the recommendation 1, but when CCNFSDU take a decision about the food category for RUTF this table may be need a further consideration.	**Egypt**
EU Specialty Food Ingredients supports the recommendation.	**EU Specialty Food Ingredients**
MSF is in agreement.	**MSF**
UNICEF agrees with this proposal, as the table 1 provided is limited to the additives that are currently used in RUTF manufacturing – antioxidants, emulsifiers, acidity regulators and packaging gases – thus is aligned with the current specification.	**UNICEF**
ISDI believes that Table I lists all the additives currently used and required to manufacture RUTF, as reflected by global ISDI membership.	**International Special Dietary Food Industries**
TABLE I Food Additives currently used by the industry in the manufacturing of RUTF, and their comparison to food additives permitted for use in existing Codex texts aimed at infants and young children	
ISDI would like to provide an editorial comment regarding citric acid. ISDI notes that the functional use for INS 330 is as an acidity regulator (not an antioxidant) in all the reference Codex Standards. Therefore, ISDI suggests that a separate line for acidity regulators is included in the table and citric acid is listed under this line.	**International Special Dietary Food Industries**
Change "Sillicon" to "Silicon"	**CCTA**
Recommendation 2: It is recommended that CCNFSDU agree to ask CCFA to confirm if RUTF Guidelines belong to FC 13.3; and if FC 13.3 is the right FC, then CCFA should consider aligning the proposed food additives listed in **Table I** of this document with F.C 13.3 of the GSFA.	
The Philippines is of the opinion that consulting the Codex Committee on Food Additives to confirm classification of RUTF and consider alignment of the proposed food additives in Table with Food Category 13:3 would be the most appropriate approach to manage food additives for this type of product. This is consistent witht the view of majority of EWG members. In addition, the additive provisions in Food Categories (FC) 13.1.1., 13.1.2 and 13.1.3 include all additives that have technological need in the manufacture of RUTF.	**Philippines**
There must be consistency between the standards.	**Peru**

Brazil agrees with recommendation 2. We are of the opinion that CCNFSDU should seek advice from CCFA on the best way to approach the GSFA Food Categories for RUTF Guidelines, considering the proposed food additives listed in Table I of this document as the basis for aligning with F.C 13.3 of the GSFA. It is also important to consider the targeted age group for RUTF of 6-59 months.	**Brazil**
Burkina Faso agrees with the recommandation	**Burkina Faso**
Canada supports Recommendation #2. Canada notes that the recommendation does not propose a course of action should CCNFSDU receive a negative response from CCFA/ Perhaps the Committee could consider the additional request as part of the recommendations to include the proposed text: “If not, then CCFA should offer advise on the most appropriate FC listing.”	**Canada**
As this document is a guideline rather than a formal standard we do not feel it is necessary to define a FC for RUTF and therefore there is no need to consult with CCFA. We prefer the approach of agreeing the technological justification for additive classes as per Table I. Consultation with CCFA will not add enough value and will create unnecessary delay in completing this work.	**USA**
Egypt agrees that RUTf fall under Food Category 13.3 with associated amendments that would be required in this Food Category to identify conditions of use specific to RUTF. Rational: - RUTF could fall under the food category 13.3 but it would require the amendment of the said category since RUTF are different from other products. - FC 13.3 is a general category for dietetic foods for special medical purposes and it does not reflect the targeted age group for RUTF (i.e. 6-59 months). - Some permitted additives in this FC may not be suitable for SAM children and the technological needs for these additives have not been evaluated for RUTF. Egypt supports creating a sub-category 13.3.1 for RUTF in this FC (13.3) to identify conditions of use specific to RUTF with a prescriptive closed list of additives. Egypt agrees with seeking advice from CCFA for any amendments needed.	**Egypt**
EU Specialty Food Ingredients supports the recommendation.	**EU Specialty Food Ingredients**
Since category 13.1.3 is oriented more towards enteral foods, this type of products is proposed to have a different category to existing ones.	**Colombia**
MSF agrees with the recommendation. This Food category as this is in accordance with the description of RUTF already agreed by the CCNFSDU in 2018.	**MSF**
While we recognize that this will delay the initial timeline of the guideline development, as the committee did not gain consensus on the correct category of additives within the Codex framework, seeking advice from the CCFA is supported as a way to gain resolution of this issue.	**UNICEF**

ISDI agrees with the proposal that CCNFSDU should seek advice from CCFA on the question of the best way to approach the GSFA Food Category for the case of the RUTF Guidelines. ISDI acknowledges certain challenges with identifying the appropriate GSFA Food Category (FC) for the RUTF Guideline. We note from paragraph 1.2 of the preamble of the GSFA, that the GSFA "sets forth the conditions under which food additives may be used in all foods, whether or not they have previously been standardized by Codex", thus, whether a Standard or a Guideline, additive provisions for RUTF guideline can be addressed. On one hand, the description for food category 13.3 is highly aligned with the intended use of RUTF. The vast majority of additive provisions that are currently permitted in Food Category 13.3 are not required to manufacture RUTF, and in some cases, may not be considered appropriate for use in foods for older infants (for example, colours and sweeteners). At the same time, as identified in Question 1 of this Response, and provided in Table 1, the additive provisions in FC 13.1.1, 13.1.2, 13.1.3 include additives required for RUTF manufacture, and these FCs are associated with similar age range as the target consumers for RUTF (children 6 to 59 months). To address the challenge described, ISDI proposes a more flexible approach which is to make reference in the RUTF Guideline document to the permitted use of the food additive provisions in Codex Standards CXS 72-1981, CXS 156-1987, and CXG 10-1979. This approach was recently used in the CXG 8-1991 (amended 2017) Guidelines on Formulated Complementary Foods for Older Infants and Young Children. The text in the Guideline for RUTF would then read: Food additives and flavourings listed in the Standard for Infant Formula and Formulas for Special Medical Purposes (72-1981) and the Standard for Follow Up Formula (156-1987) may be used in Ready To Use Therapeutic Foods to the maximum limits given in those Standards. Alternatively, if the Committee considers it preferable to manage additives only through the GSFA, we suggest identifying a new GSFA Food Category under parent category 13.0. In this case, all the allowed additives could be populated in this new Food Category	**International Special Dietary Food Industries**
IDF supports the eWG way forward with regards to the FA section	**IDF/FIL**
<u>Recommendation 3:</u> That CCNFSDU agree to the following texts on "Carry-Over of Additives and Carriers" in RUTF Guidelines Only the food additives referenced in this Section or in the *Advisory List of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Children* (CXG 10-1979) may be present in the foods described in section 2.1 of this Standard, as a result of carry-over from a raw material or other ingredient (including food additive) used to produce the food, subject to the following conditions: a) The additive is acceptable for use in the raw materials or other ingredients (including food additives) according to the General Standard for Food Additives (CXS 192-1995) b) The amount of the additive in the raw materials or other ingredients (including food additives) does not exceed the maximum use level specified in the General Standard for Food Additives (CXS 192-1995); and The food into which the additive is carried over does not contain the additive in greater quantity than would be introduced by the use of the raw materials or ingredients under proper technological conditions or good manufacturing practice, consistent with the provisions on carry-over in the Preamble of the General Standard for Food Additives (CXS 192-1995	
We are in agreement with Recommendation 3 as this is consistent with the provisions of the General Standard for Food Additives.	**Philippines**

Canada supports Recommendation #3.	**Canada**
Egypt agrees with the proposed text.	**Egypt**
The recommendation is approved.	**Colombia**
Brazil agrees with recommendation 3. However, we note that the CAC/GL 10-1979 allows the use of some food additives as nutrient carriers which are not listed in table I of this document . Therefore, it is necessary to promote alignment between provisions. We also suggest considering the same approach proposed by the Chairs of the eWG on the Review of the Standard for Follow-up formula (CXS 156-1987), i.e., to insert a reference to Section 4 of the Preamble of the GSFA (CXS 192-1995). Referencing the GSFA would follow the principle to reference existing Codex texts rather than repeat requirements in commodity standards.	**Brazil**
Burkina Faso agrees with the proposed text	**Burkina Faso**
We support recommendation 3 as a practical approach to carry over additive and feel this approach provides sufficient flexibility while being responsible.	**USA**
For the sake of consistency with the GSFA, the proposed text for carry over should apply to the age range up to 36 weeks of age. The rules should be applied in consistency with the GSFA. The text could state: For the age range up to 36 months of age, the carry-over rules as set for food category 13.1 and 13.2 in section 4.3 of the GSFA equally apply. For all others, the carry-over rules in section 4.1 and 4.2 of the GSFA shall apply. Our key point is the consistency with the GSFA and avoidance of unnecessary overlaps and potential areas of uncertainty in interpretation.	**EU Specialty Food Ingredients**
ISDI agrees with recommendation 3. ISDI would like to note that the text in the recommendation should refer to 'Guidelines' and not 'Standard'. The Committee has previously agreed to develop 'Guidelines for Ready to Use Therapeutic Foods' and not a Standard. "Only the food additives referenced in this Section or in the *Advisory List of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Children* (CXG 10-1979) may be present in the foods described in section 2.1 of this ~~Standard~~Guideline, as a result of carry-over from a raw material or other ingredient (including food additive) used to produce the food, subject to the following conditions:	**International Special Dietary Food Industries**
UNICEF agrees with this text The amount of the additive in the raw materials or other ingredients (including food additives) does not exceed the maximum use level specified in the *General Standard for Food Additives* (CXS 192-1995); and	**UNICEF**
Recommendation 4.1	
The Philippines concurs with Recommendation 4 in line with the majority of the EWG members.These guidelines on quantity and quality of proteinare critical considerations in the production of RUTF	**Philippines**

We support recommendations 4.1 and the Text in 4.2. These texts provide the needed flexibility for selecting high quality proteins and note that high quality proteins can be achieved with RUTF formulations containing a minimum of 50% protein from milk.	**USA**
Egypt agrees with the proposed texts in clauses (4.1 and 4.2).	**Egypt**
Canada supports Recommendation #4.1.	**Canada**
We agree with the proposed texts on protein quality assessment in RUTF.	**Colombia**
Brazil has no comments on recommendation 4.1.	**Brazil**
ISDI agrees with recommendation 4.1.	**International Special Dietary Food Industries**
Burkina Faso agrees with the proposed values as indicated	**Burkina Faso**
UNICEF agrees with this proposal with **GUL**	**UNICEF**
Recommendation 4.2: Paragraph 1 Protein should provide 10% to 12% of the total energy. Protein quality should be determined using PDCAAS, calculated according to the reference amino acid requirement and scoring patterns related to catch up growth of 10 g/kg/day in the target population of children 6 to 59 months for RUTF. The PDCAAS shall not be less than 90, when determined using PDCAAS methodology, appropriate fecal Digestibility values and the reference amino acid pattern in the *Report of the FAO Expert Working Group: Protein quality assessment in follow-up formula for young children and ready to use therapeutic foods.* High quality protein will be achieved with RUTF formulations containing a minimum of 50% of protein from milk products.	
That CCNFSDU agree to the proposed texts on protein quality assessment in RUTF Guidelines.	**Philippines**
Canada supports Recommendation #4.2.	**Canada**
We refrain from commenting because there are no inputs available to determine the proposed methodology for assessing the protein quality of the products in question. The recommendation is that the Codex Committee on Methods of Analysis and Sampling (CCMAS) should be responsible, in accordance with its powers, for determining the methodology proposed in the document.	**Colombia**
Brazil is of the opinion that sources of high quality protein other than milk products as well as other methods for providing higher protein quality scores should be discussed and considered by the Committee. Thus, we understand that the following proposed texts require further discussion: “High quality protein will be achieved with RUTF formulations containing a minimum of 50% of protein from milk products. In formulations with lower scores, the quality and/or quantity of protein should be adjusted to achieve the desired value. The quality of protein can be achieved by adding the limiting amino acids. Any added amino acids should be solely in the L-form and included only in amounts necessary to improve the protein quality of the RUTF”.	**Brazil**
Burkina Faso agrees with the proposed text	**Burkina Faso**

The European Vegetable Protein Association (EUVEPRO) generally supports this recommendation, in particular the use of the PDCAAS method to determine the quality of protein used in RUTF as recommended by the FAO Expert Working Group. It is acknowledged that the current body of evidence on RUTF is based on formulations with dairy proteins, yet high quality protein sources can also be derived from plant-based proteins and evidence of their efficacy in treating children with SAM is growing (1) Moreover, EUVEPRO would like to highlight that RUTF formulations with other local and culturally acceptable protein sources may be appropriate (provided that scientific evidence supports the effectiveness of these RUTF formulations in treating SAM children), and can allow more flexibility for national and/or regional authorities in terms of product formulation and innovation. The potential to use such formulations should therefore not be precluded. (1) Hossain, M. I., Huq, S., Islam, M. M., & Ahmed, T. (2019). Acceptability and efficacy of ready-to-use therapeutic food using soy protein isolate in under-5 children suffering from severe acute malnutrition in Bangladesh: a double-blind randomized non-inferiority trial. European journal of nutrition, 1-13.	**European Vegetable Protein Association**
HKI supports the protein range (10-12%) content of the total energy yet does not support the statement: ["High quality protein will be achieved with RUTF formulations containing a minimum of 50% of protein from milk products"]. While likely beneficial, the minimum dairy protein requirement 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. 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)	**HKI**
The sentence "In formulations with lower scores, the quality and/or quantity of protein should be adjusted to achieve the desired value. " is confusing, as it suggests that formulation with lower score can be accepted. MSF suggests to remove this sentence, and the following one, to have the following text: High quality protein will be achieved with RUTF formulations containing a minimum of [50%] of protein from milk products	**MSF**
The following values shall apply for the proteins: 13-17 g/100g and 2.5 – 3.0 g /100kcal as these represent the values for a minimum of exactly 10% of total energy and a maximum of exactly 12% of total energy	**MSF**
MSF would like to mention 2 studies that aim to demonstrate that RUTF containing lower amounts of dairy ingredients or other non-dairy protein sources are as efficacious as the standard milk and peanut paste–based formulation. However, MSF has noticed that the choice of the indicators and the results are questionable:	**MSF**

- for the weight gain for Bahwere et al, 2017. Soya, maize, and sorghum–based ready-to-use therapeutic food with amino acid is as efficacious as the standard milk and peanut paste–based formulation for the treatment of severe acute malnutrition in children: a non-inferiority individually randomized controlled efficacy clinical trial in Malawi. The American journal of clinical nutrition AJCN 106(4):1100-1112 : this study aims to show that a Soya, maize, and sorghum–based RUTF with amino acid was found as efficacious as the standard milk and peanut paste–based formulation. Although several recovery indicators demonstrated non-inferiority, the new proposed RUTF was associated with a significantly lower weight gain (figure 4). All the confidence intervals of the difference which are below 0 are significantly inferior, also all the confidence intervals of weight gain encroach the inferiority zone. The weight gain remains one of the most important recovery indicators in the successful treatment of Severe Acute Malnutrition. - Another study (Hossain MI, Huq S, Islam MM, Ahmed T. Acceptability and efficacy of ready-to-use therapeutic food using soy protein isolate in under-5 children suffering from severe acute malnutrition in Bangladesh: a double-blind randomized non-inferiority trial. Eur J Nutr. 2019 Apr 29) aimed to show that a soy based RUTF as efficacious as the standard milk and peanut paste–based formulation. Although the difference in the weight gain is not significant, it was found lower by 1.3 g/kg/day. This difference would be excluded with the minimum criteria for efficacy study proposed by MSF -see comment (46) by MSF-.	
MSF agrees that the need to efficacy study is already catered for in the introduction of the section 5: Any formulation of RUTF shall comply with Section 3 of the Standard for the Labelling of and Claims for Foods for Special MedicalPurposes(CXS 180-1991) including the specification that their use should have been demonstrated, by scientific evidence, to be safe and beneficial in meeting the nutritional requirements of the persons for whom they are in-tended. However MSF would like to amend this section with a list of minimum requirements/criteria to be included in the scientific evidence, MSF would like to propose the following: "Any formulation of RUTF shall comply with Section 3 of the Standard for the Labelling of and Claims for Foods for Special MedicalPurposes(CXS 180-1991) including the specification that their use should have been demonstrated, by scientific evidence, to be safe and beneficial in meeting the nutritional requirements of the persons for whom they are intended (e.g. children from 6 to 59 months with severe acute malnutrition without medical complication). Children 6 to 12 months shall be included. New formulation of RUTF should demonstrate a minimum weight gain of 5g/kg/day. Moreover the new RUTF should be compared by at least non-inferiority trials with the standard formula and a difference in weight gain bigger than 1g/kg/day should not be considered as non-inferior. Other recovery indicators such as body composition, cognitive development, anaemia, morbidity… should ideally be included."	**MSF**
UNICEF notes that the word 'will' has substituted the word 'can' with reference to the use of 50% dairy proteins and achieving high quality protein. While UNICEF has no objection to use of the word 'will', UNICEF supported the previously selected word 'can' in reference to achieving protein quality using 50% protein from milk products, as it reflects that dairy is the preferred source of protein, while allowing for future modifications of the product and local adaption of the guideline for the safe manufacture of local products. UNICEF supports the guideline that allows for new science to emerge using different ingredients that have scientifically demonstrated efficacy.	**UNICEF**

ISDI generally supports the recommendation, but would like to propose the following to ensure that the intention is well understood. Protein should provide 10% to 12% of the total energy. Protein quality should be determined using ~~PDCAAS~~Protein Digestibility Corrected Amino Acid Score (PDCAAS), calculated according to the reference amino acid requirement and scoring patterns related to catch up growth of 10 g/kg/day in the target population ~~of~~ which is children 6 to 59 months for RUTF. The PDCAAS ~~shall not be less than 90, when determined~~ calculated using ~~PDCAAS methodology,~~ appropriate ~~fecal Digestibility~~ digestibility values and the reference amino acid pattern as based on FAO Expert Working Group (2018): Protein quality assessment in ~~the~~ follow-up formula for young children and ready to use therapeutic foods, shall be not less than 90 %. ~~*Report of the FAO Expert Working Group: Protein quality assessment in follow-up formula for young children and ready to use therapeutic foods.*~~ High quality protein will be achieved with RUTF formulations containing a minimum of 50% of protein from milk products.	**International Special Dietary Food Industries**
ISDI notes that RUTF formulations shall comply with Section 3 of the Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CXS 180-1991) and therefore efficacy of formulations containing a smaller proportion of milk should be demonstrated through rigorous randomized controlled trials providing evidence of its ability to support catch-up growth as evaluated in major outcomes of SAM treatment such as weight gain and recovery rates.	**International Special Dietary Food Industries**
IDF strongly supports the retaining of the reference of 50% of proteins from milk products to achieve high protein quality.This approach is aligned with the current scientific evidence and supported by the majority of eWG members, as summarised in the second Consultation paper. IDF consider the broader text regarding assessment of protein quality could be streamlined and similar wording used to that included in the draft Follow Up Formula Std. This includes; • Reference to DIAAS methodology, as per. the FAO 2013 Report* recommendations. This would allow for future use of the most up-to-date measures of protein quality. Therefore in line with the revised Follow-up Formula Standard the following text could be inserted in the paragraph. We have also marked this as a tracked change within the proposed footnote "DIAAS could also be considered should it be recognized by FAO in the future" • *FAO (2013) Dietary protein quality evaluation in human nutrition: Report of an FAO Expert Consultation, FAO Food and Nutrition Paper 92. Rome: FAO) • An Annex that outlines how PDCAAS should be calculated, as was the intention for the FUF protein quality footnote text, could also be considered for inclusion as a Technical amend • The revised text could therefore read; Protein should provide 10% to 12% of the total energy. Protein ~~quality should be determined using PDCAAS, calculated according to~~ Digestibility Corrected Amino Acid Score (PDCAAS) is the ~~reference amino acid requirement and scoring patterns related~~ preferred method to ~~catch up growth of 10 g/kg/day~~ determine protein quality. Digestible Indispensable Amino Acid Score (DIAAS) could also be considered should it be recognized by FAO in the ~~target population of children 6 to 59 months for RUTF~~future. The PDCAAS shall not be less than ~~90~~90%, when ~~determined~~ calculated using PDCAAS methodology, appropriate fecal Digestibility values and the reference amino acid pattern related to catch up growth of 10g/kg/day in the target population of children 6 to 59 months in the *Report of the FAO Expert Working Group: Protein*	**IDF/FIL** The **revised text could therefore read;** Protein should provide 10% to 12% of the total energy. Protein Digestibility Corrected Amino Acid Score (PDCAAS) is the preferred method to determine

quality assessment in follow-up formula for young children and ready to use therapeutic foods. High quality protein will be achieved with RUTF formulations containing a minimum of 50% of protein from milk products. • High quality protein will be achieved with RUTF formulations containing a minimum of 50% of protein from milk products. In formulations with lower scores, the quality and/or quantity of protein should be adjusted to achieve the desired value. The addition of limiting amino acids, solely in the L-form, shall be permitted only in amounts necessary to improve the protein quality of the RUTF.	protein quality. Digestible Indispensable Amino Acid Score (DIAAS) could also be considered should it be recognized by FAO in the future. The PDCAAS shall not be less than 90%, when calculated using PDCAAS methodology, appropriate fecal Digestibility values and the reference amino acid pattern related to catch up growth of 10 g/kg/day in the target population of children 6 to 59 months in the *Report of the FAO Expert Working Group: Protein quality assessment in follow-up formula for young children and ready to use therapeutic foods*.
Recommendation 4.2 paragraph 2 In formulations with lower scores, the quality and/or quantity of protein should be adjusted to achieve the desired value. The quality of protein can be achieved by adding the limiting amino acids. Any added amino acids should be solely in the L-form, and included only in amounts necessary to improve the protein quality of the RUTF.	
In formulations with lower scores, the quality and/or quantity of protein should be adjusted to achieve the desired value. The required quality of protein ~~can~~ may be achieved by adding ~~the limiting~~ essential amino acids. Any added amino acids should be solely in the L-form, and included only in amounts necessary to improve the protein quality of the RUTF.	**International Special Dietary Food Industries**
In formulations with lower scores, the quality and/or quantity of protein should be adjusted to achieve the desired value~~. The quality of protein can be achieved by adding~~ .the addition of limiting amino ~~acids. Any added amino acids should be~~ acids solely in the L-form, ~~and included~~ shall be permitted only in amounts necessary to improve the protein quality of the RUTF.	**IDF/FIL**
Recommendation 5: Processing Technologies Processing technologies used for RUTF and their ingredients shall be validated to prove that they do not alter the nutritional value of RUTF and that they allow the reduction of anti-nutritive factors. Milling or grinding, roasting, toasting are examples of processing technologies that can be used on ingredients. Any technologies used should take into consideration the target group and any impact on the integrity of the nutrient content of the products. In addition to the practices described above, Good Hygiene Practices should be implemented for manufacturing of RUTF, according to the General Principles of Food Hygiene	

(CXC 1-1969) and Code of Hygienic Practices for Low Moisture Foods (CXC 75-2015) to avoid cross contamination during the storage of raw materials and the manufacturing process. RUTF and/or their raw materials should be treated with a validated microbial reduction treatment in order to inactivate pathogens such as Salmonella, noting that some pathogens have increased heat resistance characteristics at reduced water activities in food matrices. Commonly used microbial reduction treatments that could be applied to RUTF and/or their raw materials include both thermal and non-thermal control measures. For additional information on validation of control measures, refer to the Guidelines for the Validation of Food Safety Control Measures (CXG 69-2008). Additionally, refer to the Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM) (CXG 63-2007).	
We are in agreement with Recommendation 5 as the need to maintain nutritional integrity and food safety of RUTF is paramount since the product is intended for the most vulnerable group of older infants and children	**Philippines**
Canada supports Recommendation #5.	**Canada**
We support the text in recommendation 5. However, we note that some processing technologies may alter the nutritional quality of an ingredient such as those used to lower antinutritional factors. So long as the change in nutritional quality is corrected for by adding back those nutrients lost, the ingredient may still be suitable for use in RUTF.	**USA**
Egypt agrees with the proposed text.	**Egypt**
We agree with the proposal.	**Colombia**
Brazil has no specific comment on the recommendation 5. We note that the issue raised by one Member of the eWG regarding the evidence that a range of water activity between 0.2-0.45 would ensure best results in terms of fat and fat-soluble vitamin stability may be considered by the Committee.	**Brazil**
ISDI agrees with recommendation 5.	**International Special Dietary Food Industries**
BURKINA FASO agrees with the proposed text	**Burkina Faso**
Add final "	**CCTA**
Processing technologies used for RUTF and their ingredients shall be validated to prove that they do not alter the nutritional value of RUTF and that they allow the reduction of anti-nutritive factors. Milling or grinding, roasting, toasting and extrusion are examples of processing technologies that can be used on ingredients.	**UNICEF**