CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 2 **CX/NFSDU 14/36/2 Add.1**

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

Thirty-sixth Session

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DISCUSSION PAPER ON A STANDARD FOR READY-TO-USE FOODS (RUF)

(Prepared by UNICEF)

Background

1. At the 37th Session of the Codex Alimentarius Commission (CAC) held in Geneva, Switzerland July 14th – 18th 2014, the United Nations International Children's Emergency Fund (UNICEF), as an observer, presented a conference room document (CRD) under agenda item 16, Other Business, which proposed the development of a Codex standard for Ready to Use Foods (RUF) for the management of acutely malnourished children. RUF are energy-dense, mineral and vitamin-enriched foods that deliver macro and micronutrients and are ideally suited to the treatment of acute malnutrition.

2. Several Delegations from various countries supported the need for a Codex standard to guarantee the safety and quality of these products that are widely consumed, produced or traded in their countries.

3. The 37th session of the CAC agreed that UNICEF prepare a comprehensive discussion paper for presentation and discussion at the next session of Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) to clarify scope and recommendations objectives of the proposed work.

Scope

4. The purpose of the work is to establish standards for RUF used in the treatment of acute malnutrition, through the provision of safe foods, designed to address special nutritional needs of consumers, including, but not limited to children from 6 months to 59 months of age who suffer from acute malnutrition, or wasting.

5. The scope of the proposed standard discussion paper includes nutritional composition, hygienic practice for production, contaminant limits and microbiological criteria. RUF categories are low moisture products, having water activity (a_w) in the range of 0.2-0.5, and are in the form of paste such as lipid-based matrices or solid bars.

Introduction

6. The prevalence of acute malnutrition or wasting has been estimated to be approximately 8% globally as of 2012 in children younger than 5 years. This large number of children comprises of around 17 million severely wasted children and around 34 million children who are moderately wasted.[1]

7. Severe acute malnutrition (SAM), is when children suffer severe wasting and which is defined as weight for height which is less than three standard deviations below the median of the WHO growth standard. SAM is diagnosed by measuring the middle upper arm circumference (MUAC). If the circumference is less than 115mm and/or if the child has bilateral oedema (swelling of both feet from fluid retention), the child is diagnosed with SAM. It occurs when infants and children do not have adequate energy, protein and micronutrients in their diet, and if often seen in combination with other health problems such as recurrent infections.[2,5]

8. Moderate acute malnutrition (MAM) is defined as low weight for height and is diagnosed when the weight for height of a child is between two and three standard deviations below the median of the

[1] World Health Organization/World Food Programme/United Nations System Standing Committee on Nutrition/The United Nations Children's Fund,. Community-Based Management of Severe Acute Malnutrition. A Joint Statement by WHO,WFP UNSCN and UNICE; WHO/UNICEF/SCN/UNICEF, 2007.

[2] J Picot; D Hartwell; P Harris;, D Mendes;, AJ Clegg and A Takeda. *The effectiveness of interventions to treat severe acute malnutrition in young children: a systematic review.* Health Technology Assessment 2012; Vol. 16: No. 19

WHOgrowth standard and/or the circumference of the mid upper arm is less than 125mm, but above or equal to 115mm.[3]

9. The United Nations International Children's Emergency Fund (UNICEF) and the United Nations World Food Program (WFP), in addition to many other aid agencies procure specialized nutritional products in the form of Ready-to-use Food (RUF) to treat these children. In 2013 UNICEF and WFP purchased a combined quantity of more than 50,000 Metric Ton (MT) of RUF worth $195 million USD, which reached approximately 2.5 million children with SAM is estimated to be about $2.5 million, and for MAM about $4.5 million with MAM.

RUF production

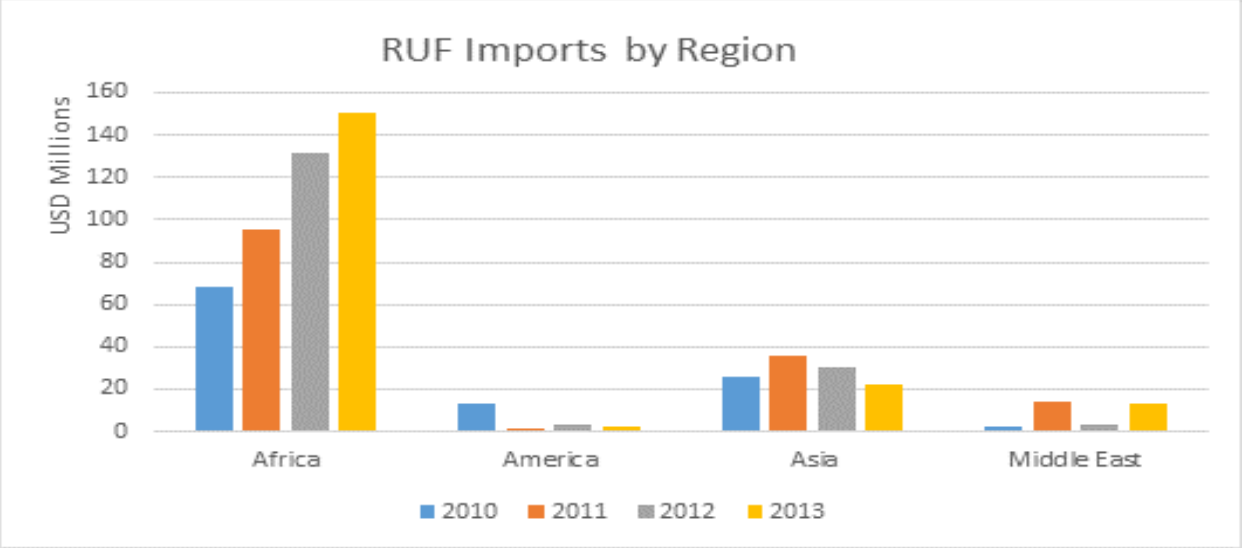
10. At present RUF is manufactured in 19 countries:

- In Africa (Burkina Faso, Ethiopia, Kenya, Madagascar, Malawi, Niger, Sierra Leone, South Africa, North Sudan, Tanzania and Uganda),
- The Americas (USA, Dominican Republic and Haiti),
- Asia (Bangladesh, India, Pakistan) and
- Europe (France and Norway)

11. The major production capacity is located in Europe (56%), followed by America (21%) and Africa (14%), France being the biggest source of these products.

RUF Distribution and Trade

12. RUF are traded in about 60 countries, crossing many borders. As of 2013, the largest market is in Africa (82%), followed by Asia (12%), the Middle East (4%), and Central and South America (1%) (see Graph 1).

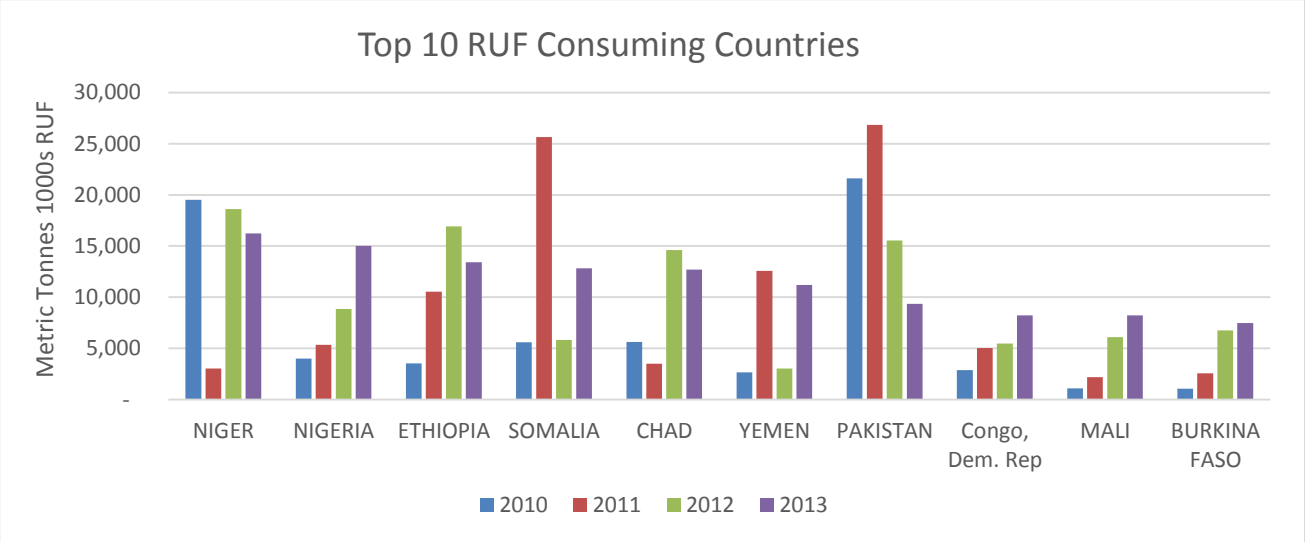


Graph 1: Imported Ready to Use Food by region. (Source UNICEF and WFP procurement data)

Consumption

13. The top 10 largest RUF consuming countries in the period 2010-13 were Niger, Nigeria, Ethiopia, Somalia, Chad, Yemen, Pakistan, Democratic Republic of Congo, Mali and Burkina Faso. Much of this procurement was emergencies related (see Graph 2).

[3] WHO. *Technical note: supplementary foods for the management of moderate acute malnutrition in infants and children 6–59 months of age*. Geneva, World Health Organization, 2012



Graph 2: Consumption of Ready to Use Foods for acute malnutrition, top 10 consuming countries (source WFP and UNICEF procurement data)

Distribution

14. Currently these products are distributed, mostly to developing nations, and are traded extensively across borders (see figure 1). Most recipient countries have incorporated the use of RUF into their national guidelines for outpatient, or community management of malnutrition. Several countries including Ethiopia, Tanzania, Sudan, Burkina Faso, Benin, Cote d'Ivoire, Guinea-Bissau, Mali, Niger, Senegal, Togo, Kenya, Cameroon, Malawi, Guatemala, Haiti, Niger, Nigeria, Bolivia, and Mexico either have these products registered, or are in the process of having them registered with national authorities.

Figure 1: Distribution of RUF Globally

Need for RUFs standards for safety and quality

15. Given the wide acceptance of RUFs in national health care systems for the treatment of malnutrition, governments have raised questions about appropriate standards for imported and domestically produced

RUF, to facilitate its appropriate regulation on their national market, as well as to justify funding the purchases of these products from national budgets.

RUF Ingredients

16. RUF is made of powdered or ground ingredients embedded in a lipid rich paste, or protein-based matrix, resulting in an energy and nutrition-dense food. It is typically a lipid rich paste, made from ground peanuts, milk products, sugar, and a premix containing oil, vitamins and minerals. RUF can also include legumes such as soy or chick peas, and cereal flours such as rice, millet, oats or wheat.

17. RUF can also be in the form of a bar, as an alternative to the paste format, and is made from compressed ingredients such as cereal flour, vegetable oil, sugars and a premix containing vitamins and minerals. As the name implies, RUF does not need preparation prior to consumption, making it practical for use where cooking fuel and facilities are limited.

18. RUF has a very low water activity (<0.5), thus reducing the risk for significant bacterial growth and allowing for a shelf life of around 24 months.[8]

19. RUF manufacturing process involves receiving raw materials, mixing in appropriate proportions, intermediate treatment (heating, grinding) and filling the sachet. For an example of a manufacturing process flow, see Figure 2. Some manufacturers have added thermo-processing as an additional pathogen control step for bacteria such as *Salmonella spp.* and *Cronobacter spp*. For an example of a manufacturing process flow including thermo processing, see Figure 3.

RUF Products applicable for the Codex standard

20. There are two major product categories under the proposed standard: 1) products used for the treatment of Severe Acute Malnutrition (SAM) without complications, which are called ready to use Therapeutic Food (RUTF) and 2) ready to use supplementary foods (RUSF) used for the treatment of Moderately Acute Malnutrition (MAM). Both products are used at the community level and recipients are managed as outpatients. RUTF is used as the only source of food for the beneficiaries, besides breast milk. RUSF is used as food supplementation, and is given to the child in addition to family food to boost the nutritional content of the diet. Both RUF products are fortified with micronutrients, fats, and quality proteins to ensure the recipient's high nutritional needs are met to enable tissue re-growth (e.g. muscles, and fat tissues) and correct nutritional deficiencies, in particular micronutrient deficiencies.

(i) Ready-to-Use Therapeutic Food (RUTF) is energy and nutrition-dense, containing 520-550 kcal/100g. RUTF Treatment recommendations for SAM are to provide 100-135kcal/kg/day of a RUTF[4], for a period of 6-10 weeks, until the child has gained adequate weight. An average severely malnourished child can consume around two sachets per day (1000kcal), and can achieve sufficient nutrient intake for complete recovery. While RUTF must be consumed along with clean drinking water, no other foods besides breast milk are necessary for the rehabilitation of the severely malnourished child.

(ii) Ready-to-Use Supplementary Food (RUSF) is a type of RUF that is specifically designed for the treatment of MAM in children 6-59 months of age. For the treatment of MAM, 92-100 g RUSF, with an energy density of 513-550 kcal/100g, as a daily ration is recommended. It is eaten by the child in addition to breast milk and other family foods for about 3 months.

(iii) Ready-to-Use Bar / Biscuit is a biscuit or bar type of RUF used as an alternative for the paste variety of RUF. It is based on flours rather than peanuts but still meets the same nutrient profile as outlined in the WHO Joint statement. The product is typically made from cereal flour such as wheat and oats, milk proteins, vegetable oils, sugar and added vitamins and minerals.

Purpose of RUFs

21. Children suffering from acute malnutrition need safe, palatable foods with a high energy content and adequate amounts of added vitamins and minerals. The therapeutic foods need to be soft or crushable so that they can be consumed easily by children from the age of six months without adding water. The micro-nutrient levels in RUFs are high to allow for correction of deficiencies. Therefore, tolerable upper limits of intake (ULs) for micronutrients for normal children cannot be applied to the acutely malnourished child, as their need for micronutrients are considerably higher.

22. The treatment aims of the provision of RUFs to acutely malnourished children are to[5]:

[4] WHO. Guideline: updates on the management of severe acute malnutrition in infants and children. World Health Organization, 2013; p44

[5] Manary, MJ. *Technical Background Paper Local production and provision of ready-to-use therapeutic food for the treatment of severe childhood malnutrition*. Professor of Paediatrics, Washington University School of Medicine, St. Louis, MO, USA. 2005.

- Allow catch up growth in weight and height
- Prevent death from acute malnutrition
- Strengthen resistance to infection
- Allow for convalescence from prior illness (such as diarrheal disease) which has contributed to the acutely malnourished state of the child
- Help to restore normal mental, physical and metabolic status

RUF Composition

23. In the absence of international standards, RUF specifications are based on two documents from The World Health Organisation (WHO): (1) the *Joint statement on Community-Based Management of Severe Acute Malnutrition*[6] *2007,* as therapeutic foods for the treatment of SAM, hereafter referred to as 'the joint statement' *and* (2) *Technical Note on Supplementary foods for the management of moderate acute malnutrition in infants and children 6–59 months of age*[7], which provides a range for the nutritional the composition of supplementary foods for the treatment of MAM, hereafter referred to as the 'Technical note.'

24. The specifications recommended in these two documents are used for procurement purposes with the intention of assuring consistent product composition of RUF. However, the specifications do not provide an *official* standard for countries to follow. Development of a codex standard for RUTF and RUSF will provide a reference for manufacturers, purchasers and government regulatory authorities to follow and provide the needed framework for the supply of consistently safe and nutritionally appropriate emergency food aid products across national borders.

Nutritional composition of RUTF for the treatment of SAM[8]

Macronutrients	**per 100g**
Energy	520–550 Kcal/100 g
Proteins	10%–12% total energy
Lipids	45%-60% total energy
n-6 fatty acids	3%–10% of total energy
n-3 fatty acids	0.3%–2.5% of total energy
Moisture content	2.5% maximum

Minerals		**Vitamins**	
Sodium	290 mg maximum	Vitamin A	0.8–1.1 mg
Potassium	1,110–1,400 mg	Vitamin D	15–20 µg
Calcium	300–600 mg	Vitamin E	20 mg mínimum
Phosphorus*	300–600 mg	Vitamin K	15–30 µg
Magnesium	80–140 mg	Vitamin B1	0.5 mg minimum
Iron	10–14 mg	Vitamin B2	1.6 mg minimum
Zinc	11–14 mg	Vitamin C	50 mg minimum
Copper	1.4–1.8 mg	Vitamin B6	0.6 mg minimum
Selenium	20–40 µg	Vitamin B12	1.6 µg minimum
Iodine	70–140 µg	Folic acid	200 µg minimum
		Niacin	5 mg minimum
		Pantothenic acid	3 mg minimum
		Biotin	60 µg minimum

[6] World Health Organization/World Food Programme/United Nations System Standing Committee on Nutrition/The United Nations Children's Fund,. Community-Based Management of Severe Acute Malnutrition. A Joint Statement by WHO, WFP UNSCN and UNICE; WHO/UNICEF/SCN/UNICEF, 2007.

[7] World Health Organisation. Technical note Supplementary foods for the management of moderate acute malnutrition in infants and children 6–59 months of age WHO, 2012.

[8] World Health Organization/World Food Programme/United Nations System Standing Committee on Nutrition/The United Nations Children's Fund,. Community-Based Management of Severe Acute Malnutrition. A Joint Statement by WHO,WFP UNSCN and UNICE; WHO/UNICEF/SCN/UNICEF, 2007.

Proposed nutrient composition of supplementary foods for use in the management of MAM children [9]

Nutrient per 1000 kcal	**Minimum**	**Maximum**			
Protein	20 g	43 g			
Fat	25 g	65 g			
Fatty acids					
ω-6 fatty acid % energy	>4.5	<10			
ω-3 fatty acid % energy	>0.5	<3			
Trans-fatty acids % total fat		3			
Minerals	min	max	**Vitamins, water soluble**	min	
Sodium (Na)	—	500 mg	Thiamin (B1)	> 1 mg	
Potassium (K)	1500 mg	2200 mg	Riboflavin (B2)	> 4 mg	
Magnesium (Mg)	280 mg	420 mg	Pyridoxine (B6)	> 2 mg	
Phosphorus (P)	850 mg	1400 mg	Cobalamine (B12)	> 5 µg	
Zinc (Zn)	20 mg	35 mg	Folate (dietary folate equivalent)	> 400µg	
Calcium (Ca)	1000 mg	1400 mg	Niacin	> 25 mg	
	min	m		min	max
Copper (Cu)	1 mg	3.5 mg	Ascorbate (vitamin C)	> 150 mg	
Iron (Fe)	18 mg	30 mg	Pantothenic acid	> 5 mg	
Iodine (I)	150 µg	350 µg	Biotin	> 20 µg	
Selenium (Se)	35 µg	90 µg	**Vitamins, fat soluble**		
Manganese (Mn)	1 mg	2mg	Retinol (vitamin A)	2000 µg	3000 µg
			Cholecalciferol (vitamin D)	20 µg	60 µg
			Vitamin E (dl-α tocopherol acetate)	>30 mg	
			Phytomenadione (vitamin K)	>50 µg	

25. It is proposed that the Codex standard will apply to the

a. nutritional composition, including appropriate minimum and maximum ranges

b. acceptable contaminant level, particularly aflatoxins,

c. microbiological safety and a related sampling plan.

26. There is an increasing trend to diversify the composition by incorporating by incorporating locally used and sourced ingredients in the recipient countries. UNICEF, WFP and donating partners such as USAID want to support the development of products that utilize locally available ingredients, and bring the manufacture of the products closer to the end user. However, there is no international reference to standardize the essential nutrient composition and the appropriate hygiene regulations to ensure the foods used for treatment of SAM and MAM are based on scientific evidence and are safely produced. Countries will benefit from having an international standard for guidance in the regulation of both current and new products predicted to emerge in the market.

27. At the 37th session of CAC, WHO responded to the UNICEF proposal for a standard for RUF by reporting that the WHO is currently conducting systematic reviews on the effectiveness of the formulations based on the nutrient composition of RUTF, provided in the *Joint Statement 2007* as well as the proposed nutrient composition of RUSF provided in the *2012 Technical note.*

28. These systematic reviews are being carried out as part of WHO's effort to develop an updated guideline on effective and safe use of RUF products, and also reviewing the longer-term effects of the consumption of such products on the health of children. The review is expected to be finalised in 2015. These reviews will provide further guidance on nutritional composition of the RUF products, with specific reference to the dose

[9] World Health Organisation. Technical note Supplementary foods for the management of moderate acute malnutrition in infants and children 6–59 months of age WHO, 2012.

of the product, protein quality and type of oil used. The proposed work of the CCNFSDU could be based on the current product specifications used by agencies and the WHO's on-going evidence review could serve to inform the CCNFSDU's work on the standard once it has been completed.

Population at greatest risk of malnutrition and need RUF for survival

29. Children with Moderate Acute Malnutrition (MAM) and Severe Acute Malnutrition (SAM) are at elevated risk of dying from diarrheal disease, pneumonia, malaria, measles, and other diseases. In children under 5 years of age, under-nutrition is directly or indirectly responsible for at least one third of the 7 million deaths per year.[10,11] A cyclical relationship exists between under-nutrition, immune dysfunction, increased susceptibility to infection, and the metabolic response to infection that further alters nutritional status.[12,13] Under-nutrition increases the risk of infection and death, with acute diarrhoea and acute respiratory infections responsible for most deaths in children less than 5 years of age. Under-nutrition increases the frequency and duration of diarrhoea.[14,15,16] The food borne and water borne bacterial pathogens that cause most cases of severe acute diarrhoea include *Vibrio cholerae*, *Shigella species*, *Salmonella*, and *Escherichia coli* of various pathogenic types. Enterobactereaceae (EB) family members *Klebsiella*, *E. coli*, and *Salmonella* are important causes of pneumonia in SAM, in addition to *Staphylococcus aureus*, *Streptococcus pneumoniae*, and Haemophilus influenza.[11]

30. UNICEF, Médecins Sans Frontières (MSF), WFP, United States Agency for International Development (USAID) or other major purchasers do not have specific records of infections in children who receive RUTF and RUSF that has resulted in morbidity, however, interruptions in supply of these products have been due to findings of *Salmonella* and high EB counts during recent routine testing of batches since 2012, and less recently, *Cronobacter spp.* The risk of *Cronobacter spp.* infection in children under five who are given RUFs as treatment was discussed in a meeting of experts convened by FAO and WHO in 2012, however the intended consumers of RUSF and RUTF are outside the population defined to be at greatest risk for serious disease due to *Cronobacterspp.* Salmonellosis was identified as a relevant risk for the target group who use RUF, and the consultation of FAO and WHO's expert panel lead to interim recommendations that are elaborated further below.

31. Consideration needs to be given to the nutrient levels within RUF for acute malnutrition, as the maximum therapeutic dose is often close or over the adequate intakes of some nutrients. Due to lack of data, there are no tolerable upper intake or recommended dietary allowance levels established for children with acute malnutrition. For example the Potassium level in RUF is set at 1100 mg. min to 1400 mg. max, meaning a 2 kg child suffering from severe acute malnutrition might have a daily intake of 763 mg potassium (based on a diet of 150 kcal per day per child). Which is higher than the adequate intake of 700 mg per day for a healthy infant aged 7-12 months, established by National Academy. [17]

Food Hygiene Aspects

History of the RUTF and RUSF Microbiological Criteria

32. In 2008, WHO suggested that UNICEF include the requirement for the control of *Cronobacter spp.* in finished product, as per the Codex Code of Hygienic practice for Powdered Infant Formulae for Infants and young children (CAC/RCP 66-2008). UNICEF introduced this requirement gradually; initially requiring suppliers to confirm absence of *Cronobacter spp*. in milk powder used for manufacturing RUF followed by introduction of the requirement of *Cronobacter spp*. absence in finished products. In 2011 a United States based supplier alerted UNICEF to the discovery of *Cronobacter* spp. in their finished product, and that

[10] United Nations Children's Emergency Fund. Child mortality estimates. Available at www.childmortality.org. Accessed 20th December 2012.

[11] Black, R. E.; Allen, L.H.; Bhutta, Z.A.; Caulfield, L.E.; de Onis M.; Ezzati, M.; Mathers, C.; Rivera, J. "Maternal and child under-nutrition: global and regional exposures and health consequences." *The Lancet.*2008, vol 371 (9608): -260. 243

[12] Rodríguez, L., Cervantes, E., and Ortiz, R. Malnutrition and gastrointestinal and respiratory infections in children: A public health problem. *International Journal of Environmental Research and Public Health*, 2012, vol 8: 1174-1205.

[13] Schlaudecker, E.P.; Steinhoff, M.C.; and Moore, S.R.. Interactions of diarrhoea, pneumonia, and malnutrition in childhood: recent evidence from developing countries. *Current opinion on infectious diseases*; 2011; vol 24 (5):496-502.

[14] Khatuni, F.; Faruque, A.S.G.; Koeck, J.L.; Olliaro. P.; Millet, P.; Paris, N.; Malek, M.A.; Salam, M.A.; and Luby S. Changing species distribution and antimicrobial susceptibility pattern of *Shigella* over a 29-year period (1980–2008). *Epidemiology Infection*, 2011; 139:446-52.

[15] Guerrant, R.L.; Schorling, J.B.; McAuliffe, J.F.; and de Souza, M.A. Diarrhea as a cause and effect of malnutrition: diarrhoea prevents catch-up growth and malnutrition increases diarrhoea frequency and duration. *American Journal of Tropical Medicine and hygiene*; 1992; 47:28–35

[16] Schmidt, W.P.; Cairncross, S.; Barreto, M.L.; Clasen, T.; and Genser, B. Recent diarrheal illness and risk of lower respiratory infections in children under the age of 5 years. *International Journal of Epidemiology* 2009; vol 38:766–772.

[17] The National Academies. Dietary Reference Intakes for Water, Potassium, Chloride and Sulfate. Available at: www.nap.edu Accessed 14 October, 2014

product was rejected. Subsequently, WFP detected *Cronobacter spp*. in RUF manufactured by the largest supplier of RUF based products in May 2012. UNICEF then instituted systematic testing of all batches of RUTF and discovered that the bacterium was present in the RUTF of all UNICEF-approved suppliers in 2012. This issue created a supply crisis with several months of stock-outs.

33. UNICEF, in collaboration with WFP and MSF approached Food and Agricultural Organization (FAO) and WHO with a request to review the microbiological safety requirements for RUF in June 2012. FAO and WHO held an expert meeting in December 2012 that concluded that *Salmonella* is the single greatest bacterial health risk for the intended consumers of RUF, and that statistically valid sampling of product for *Salmonella* detection in conjunction with quantitative EB analyses as an indicator of process control would better assure the safety of these products than would currently applied specifications [see below, (24)]. As the products are intended for individuals aged 6 months and over, the consumers of RUF are outside the population considered to be at greatest (young infants) for serious disease due to *Cronobacter* spp*.* The expert group considered that control for this bacteria could be encompassed by the recommended EB testing with an appropriate sampling protocol. The expert group subsequently recommended 'interim specifications' together with an appropriate sampling plan, with the aim to collect more finished product data. During the period between the end of June 2013 to end March 2014, 1,057 batches of RUF manufactured by 19 suppliers were tested in an independent laboratory as per the sampling plan advised by FAO and WHO. This data collection resulted in identification of 10 samples (1%) from 5 manufacturers contaminated by *Salmonella* (Table 1). Out of 17 manufacturers, 63 batches identified as containing samples with marginally high (10≤-100cfu/g) Enterobacteracae and 29 samples of high levels of Enterobacteracae (>100cfu) (Table 2). Some of the root causes of these contaminations were identified as contaminated raw materials (e.g: peanuts, soy flour) and inappropriate manufacturing processes (e.g. insufficient cleaning of equipment, breaks in manufacturing process, inadequate pest control etc.).

Table 1*:* Data collection from June 2013-March 2014, *Salmonella spp* testing. (Each sample is 92-100 grams RUF)

Product	**No of samples tested**	**Batches tested**	**Salmonella positive**
RUSF	4000	160	0
RUTF	20,065	981	10
Total	**27,26*5***	**1041**	**10**

Table 2: Data collection from June 2013-March 2014, *Enterobacteracea* testing. (Each sample is 92-100grams RUF)

Product	No of samples tested	Batches tested	Enterobacteracea 10 - ≤100cfu/g	Enterobacteracea 10 - ≤100cfu/g
RUSF	1600	160	8	1
RUTF	10,470	981	55	28
Total	**11,410**	**1141**	**63**	**29**

34. At the 37th session of the CAC the Representative of FAO informed the Commission of ongoing FAO and WHO work to address the microbiological safety of RUTF and RUSF and of the need to also consider chemical contaminants. She noted that the outcome of this work would support the better definition of the safety issues that need to be considered in relation to these products.

35. FAO/WHO will hold another expert meeting in early December 2014 to review collected data from the agencies after the implementation of the revised testing and sampling protocols and to further discuss microbiological safety requirements for RUF. It is anticipated to have new recommendations available from this expert committee by June-July 2015.

36. Listed below is the maximum microbial levels as detailed in the Joint statement (ii) and secondly the revised microbial criteria suggested by the FAO/WHO expert panel (ii).

i. Previously specified microbial criteria as per 2007 'Joint Statement':

Total aerobic count 10,000 colony forming unit (cfu)/g maximum

Coliform test negative in 1 g

Clostridium perfringens negative in 1 g

Yeast maximum 10 cfu in 1 g

Moulds maximum 50 cfu in 1 g

Pathogenic *Staphylococci* negative in 1 g

Salmonella negative in 125 g

Listeria negative in 25 g

Standards referred to in the 'Joint statement':

The product should comply with the *Recommended International Code of Hygienic Practice for Foods for Infants and Children of the Codex Alimentarius Standard CAC/RCP 21-1979 (*this was subsequently updated *to* the "Codex Code of Hygienic practice for Powdered Infant Formulae for Infants and young children (CAC/RCP 66-2008))

All added mineral salts and vitamins should be on the *Advisory List of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children of the Codex Alimentarius Standard CAC/GL 10-1979*

Microorganisms	**n**	**c**	**m**	**M**	**Class plan**
Enterobacteriaceae*	10	2	10/10g	100/10g	3
Salmonella**	**25**	**0**	**0/25g**	**Not applicable**	**2**

ii. **Table 3**. Interim microbial criteria from Expert Panel meeting 2012:

Where n = number of sample units to be take; c = the maximum allowable number of defective sample units in a 2-class plan or marginally acceptable sample units in a 3-class plan; m = a microbiological limit which, in a 2-class plan, separates good quality from defective quality or, in a 3-class plan, separates good quality from marginally acceptable quality; M = a microbiological limit which, in a 3-class plan, separates marginally acceptable quality from defective quality and p = class plan

* method ISO 21528 1/2

** method ISO 6579 (25 separate samples (that may be taken in two composites no greater than 375 grams))

Thus for class 3 plan, 2 sample units out of 10 are allowed to have Enterobacteriaceae in the range of 10-100 cfu/g. In class 2 plan zero sample units should test positive for Salmonella out of 25 sample units tested. The sample size tested in 25g.

Contaminants

37. Contaminants within RUF are an important consideration in the development of the RUF Codex standard, and contaminant risks need to be defined. Many RUF products contain peanuts, which can be contaminated with mycotoxins. In 2011, the WHO defined a maximum acceptable level of aflatoxin for RUF at 10 parts per billion (ppb), as updated by the WHO in 2011. Previously, the acceptable limit for aflatoxin was 5 ppb, as per the 2007 joint statement. UNICEF and USAID still require compliance to this 5 ppb limit, as levels higher than 5 pbb in peanuts used on the production of RUF paste is felt to indicate that aflatoxin in the peanuts is not in control. It is proposed that the level of aflatoxin specified for the RUF standard may take into consideration the ongoing work on safe levels of aflatoxins, with consideration to the aflatoxin limits in the 'Joint statement' and also the relevance of including aflatoxin B1 for this product as further criteria within the standard is also proposed.

38. There is a need to consider and appropriately address the range of potential chemical contaminants relevant to these products which may be introduced through the raw materials or during the process itself. As an example of the latter, suppliers in the United States have carried out some studies with regard to contaminants which could potentially result from the RUF production process, particularly when using thermo-processing to add a kill step, such as acrylamide. Acrylamide has been linked with foods that have been heated higher than 120 °C (248 °F). Even though thermo-processed RUF does not normally reach

such temperatures, exposure of product at temperatures over 90 °C for longer than 40 minutes is possible and thus testing for acrylamide was performed. No acrylamide at detectable levels was found.

39. It is proposed that the current permissible limits for heavy metals, and melamine are reviewed by the CCCF for the inclusion in the RUF standard. Proposed Heavy metal limits, calculated from the protocols and tolerable weekly intake (PTWI) mg/kg body as defined in the *CODEX STAN 193-1995: Codex General Standard for Contaminants and Toxins in Food and Feed.* Calculations are done for a 5kg child.

Proposed Heavy Metal limits:

RUF (100g sachet, 1 sachets per day):

Cadmium: 0.050

Arsenic: 0.107

Lead: 0.179

Mercury: 0.036

Tin: 100.0

Proposed Melamine limits[17]

1mg/kg

[17] *COMMISSION REGULATION (EU) No 594/2012 of 5 July 2012 amending Regulation (EC) 1881/2006 as regards the maximum levels of the contaminants ochratoxin A, non dioxin-like PCBs and melamine in foodstuffs*

Annex

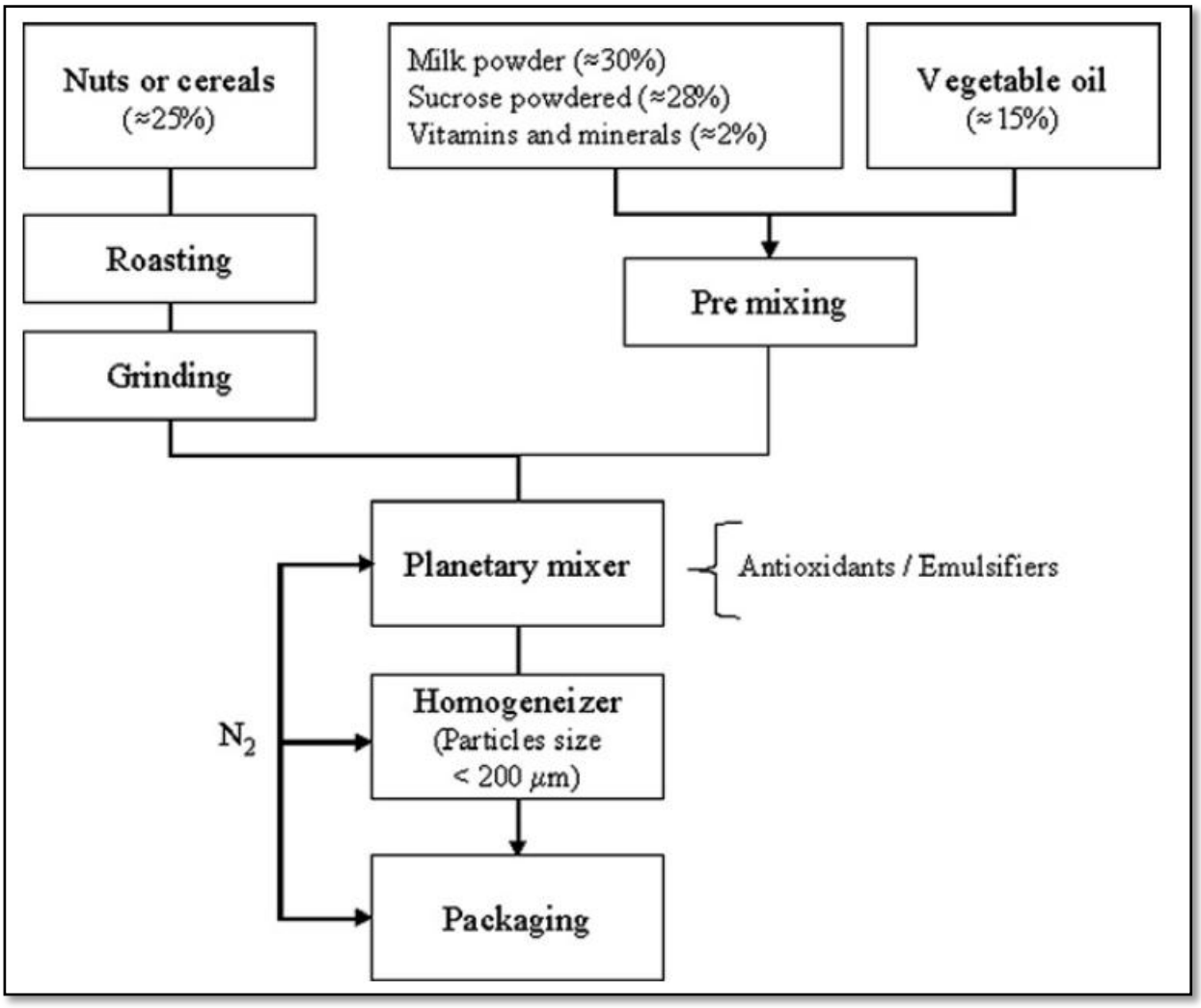


Figure 2[18]: Example Manufacturing Flow diagram of RUF

[18] Santini A, Novellino E, Armini V, and Ritieni A. State of the art of Ready-to-Use Therapeutic Food: a tool for nutraceuticals addition to foodstuff. *Food Chemistry*. 2013; Oct 15; vol 140(4):843-9

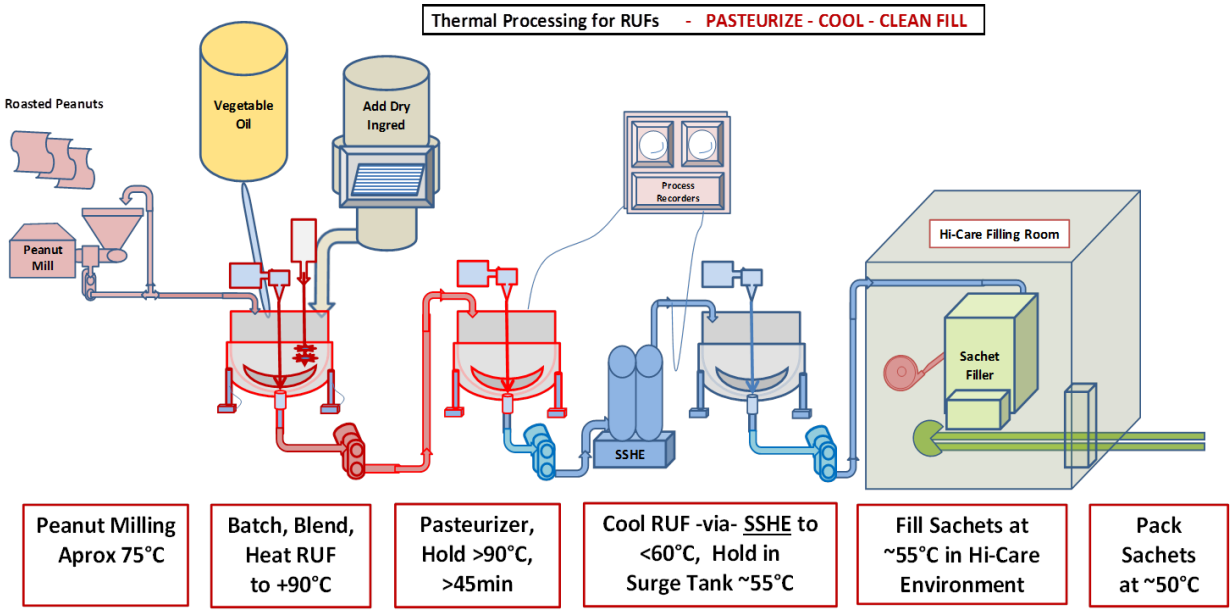


Figure 3: Thermo-processing system for the manufacture of RUFs including a kill-step to reduce at its minimum pathogen survival

Recommendation

40. It is recommended that CCNFSDU consider the development of a Standard for Ready-to-use Foods (RUF). A project document is presented in Appendix I.

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Glossary

Codex Alimentarius Commission	CAC
Conference room document	CRD
Ready to Use Foods	RUF
The United Nations International Children's Emergency Fund	UNICEF
Codex Committee on Nutrition and Foods for Special Dietary Uses	CCNFSDU
Severe acute malnutrition	SAM
Middle upper arm circumference	MUAC
Moderate acute malnutrition	MAM
United Nations World Food Program	WFP
World Health Organisation	WHO
Médecins Sans Frontières (Doctors without Borders)	MSF
United States Agency for International Development	USAID
Enterobactereaceae	EB
Ready-to-Use Food	**RUF**
Readyto-Use Therapeutic Food	**RUTF**
Ready-to-Use Supplementary Food	**RUSF**
Food and Agricultural Organization	FAO
Severe acute malnutrition	SAM
Middle upper arm circumference	MUAC
Moderate acute malnutrition	MAM
Colony forming unit	CFU
Parts per billion	ppb
Protocols and tolerable weekly intake	PTWI
Low moisture foods	LMF

APPENDIX I

PROJECT DOCUMENT

Purpose and Scope of the Standard:

1. The purpose and scope of the work is to develop a standard for RUF with regards to the provision of a science-based nutritional composition, and appropriate criteria and limits for relevant microbiological hazards and contaminants (e.g. Heavy metals, mycotoxins) respectively in order to provide protection to vulnerable consumers of RUF. A standard for RUF will promote fair trade, and benefit developing nations engaged in trade of these products, by providing a framework for harmonised specifications and regulation.

2. **Relevance and Timeliness**:

   Currently RUF products are produced in 19 and consumed in approximately 60 countries, mostly developing nations, and are traded extensively across borders. Most countries where RUF are consumed have incorporated the use of RUF into their national guidelines for outpatient, or community management of malnutrition. In 2013, 7 million children received RUF and as the ability to reach malnourished children increases, there will be a greater demand for RUF products. A codex standard for RUF will provide a reference for industry, consumers and government regulatory authorities to follow and provide the needed framework for the supply of consistently safe and nutritionally appropriate emergency food aid products across national borders.

3. **The main aspects to be covered;**

   (1) Development of a standard including adopting the nutritional composition as specified in existing WHO documents for RUTF as well as RUSF and their future modification,

   (2) Hygienic practice for production, handling, processing, storage and distribution,

   (3) Recommendation for microbiological assessment criteria and

   (4) Contaminant criteria, including appropriate heavy metal, and mycotoxin limits

4. **An assessment against the *Criteria for the establishment of work priorities;***

General criteria

The Codex Alimentarius Commission has a mandate of protecting consumer's health and ensuring fair practices in the food trade.

i. A standard for RUF needs to be developed in order to meet the General criterion: Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade.

ii. The microbiological and contaminants criteria for RUFs will enable harmonized specifications and regulation of these food products at a national level for the protection of the consumers, especially vulnerable children.

iii. The nutritional composition within the standard will protect the consumer's health by providing a scientifically-based composition to facilitate recovery from malnutrition

Criteria applicable to general subjects

a. In terms of work priorities those areas related to the safety of these products need to be addressed at the outset given the lack of global science based specifications for microbial and chemical contaminants. With reference to the criteria for work priorities between various sections of work, the scope in developing a standard for RUFs includes areas of work where the CCFH, CCNFSDU and CCCF will need to be engaged. The priority is the work that will be undertaken by the CCFH, as this work can be included in the scope of the Code of Hygienic practice for Low moisture foods (LMF) which is currently ongoing and serves to address the most pressing issue of protecting large numbers of consumers from a food safety perspective.

   Developing a food safety Codex standard was recommended by the FAO/WHO expert meeting in 2012.[2] The development of the standard by the CCNFSDU would involve the assessment of the work already conducted by FAO and WHO in relation to their consultation with the international partner organisations. Areas in regards to the scientific basis for standards are already being developed to address the micro safety by FAO, such as a meeting of experts in December 2014 and also a revision of the existing evidence for the nutritional composition of RUF in the treatment of SAM and MAM by WHO.

b. The subject of the proposal to standardisation is considered in the criteria for establishing new work priorities.

i. There was support at CAC 37th Session to have a standard for RUTF and RUSF and therefore the subject is amenable to standardisation

ii. Global guidance on the nature of these products exists currently and so the proposal to standardisation is attainable.

c. Referring to the general criteria for work priorities consideration of the global magnitude of the problem or issue needs to be applied.

i. RUFs are traded in 60 different countries, through several borders and have wide distribution, so food quality issues have considerable impact globally.

Relevance to the Codex strategic objectives;

The proposed work will contribute to advancing the following Codex Strategic Goals in the Codex Strategic Plan 2014-2019:

i. **Strategic Goal 1**: Establish international food safety standards that address current and emerging food issues

ii. The provision of a standard for RUFs will address a gap in food safety of a processed food that is traded globally..

iii. **Goal 2**: Ensure the application of risk analysis principles in the development of Codex Standards

The development of the Standard will be consistent with the use of scientific advice and risk analysis principles in the articulation of the safety specifications and nutritional composition. Scientific advice from the FAO/WHO expert bodies, particularly JEMRA, JECFA and JEMNU and scientific input from all countries will be solicited.

Information on the relation between the proposal and other existing Codex documents;

The proposed work could draw on the example of the following:

- Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods (CAC/GL 21-97)
- Code of Hygienic practice for Powdered Infant Formulae for Infants and young children (CAC/RCP 66-2008)
- Standard for Infant formula and Formulas for Special medical purposes intended for infants CODEX STAN 72 – 1981
- Advisory lists of mineral salts and vitamin compounds for use in Foods for Infants and Children (CAC/GL 10-1979)
- General Principles for establishing Minimum and maximum values for the essential composition of Infant formula (Annex II, Codex standard 72-1981)
- CAC/RCP1:1969-- General Principles of Food Hygiene
- AC/RCP-22:1979-- Code of Hygienic Practice for Groundnuts (Peanuts)

As the products composition can be made of ingredients such as peanuts, milk powders, sugar, oil, legumes, cereal mix and vitamin and mineral premix. The relevant standards for these commodity raw materials should be taken into consideration. Ongoing work on the Code of Hygienic Practice for low moisture foods will be highly relevant.

Identification of any requirement for and availability of expert scientific advice;

Scientific advice might be needed to support the establishment of microbiological criteria and contaminant limits for these products. In the case of the microbiological hazards, UNICEF and WFP have already solicited scientific advice from FAO and WHO and further expert meeting to be convened in this area in December 2014 means that there should be adequate scientific basis to address microbiological food safety issues. In the case of contaminants in RUF, scientific advice from JECFA particularly in the area of mycotoxins and heavy metals and any other potential contaminants identified in the course of this work might be necessary. In relation to nutritional aspects, the WHO is conducting a review of the evidence on the efficacy of RUF, with the outcome of updated guidelines for the treatment of SAM and MAM. This expert scientific advice will be utilized as a reference for the nutritional composition within the standard. Any further scientific advice on nutritional aspects identified in the course of the work will be directed to JEMNU. Interaction may be needed with the relevant Codex committees.

Identification of any need for technical input to the standard from external bodies so that this can be planned for;

No need for technical input from external bodies

Proposed timeline

A five-year timeline is proposed for the completion of this work. A proposed draft would be ready for initial discussion by the CCNFSDU in 2015, with a proposed date for adoption at Step 5 in 2018 and adoption at Step 8 in 2019.