CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 8 **CX/NFSDU 15/37/8**

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

Thirty-seventh Session

Bad Soden am Taunus, Germany

23 – 27 November 2015

DISCUSSION PAPER ON A STANDARD FOR READY-TO-USE FOODS

(Prepared by United Nations International Children's Emergency Fund (UNICEF) with assistance from Senegal)

BACKGROUND

1. At the 36th session of the CCNFSU in 2014 a discussion paper, which proposed the development of a standard for Ready to Use Foods (RUF) for acute malnutrition, was presented by UNICEF. Ready to Use Therapeutic Foods (RUTF) are intended for the treatment of severe acute malnutrition (SAM), and Ready to Use Supplementary Foods (RUSF) are intended for the treatment of moderate acute malnutrition (MAM). These foods are energy-dense mineral and vitamin-enriched products.
2. Several Delegations at the 36th session of the CCNFSDU from various countries supported the need for a Codex standard to guarantee the safety and quality of these products that are widely produced, traded and consumed by individuals with SAM, the largest proportion of whom are children and infants 6-59 months.
3. Some delegations also requested further clarification on the inclusion of a food that is 'therapeutic' within the scope of food regulations, as the use of the word 'therapeutic' implies foods designed to cover the special nutrient requirements of individuals with a specific condition.
4. WHO informed the plenary that there a review of the safety and efficacy of lipid-based RUTF and similar products was underway and that the evidence review could inform the codex work once it was completed.
5. Observer groups raised the concern that a global guideline would lead to commercial interests negatively influencing governments' nutrition policies, and such a guideline should be draft to include appropriate labelling and marketing of products aligned with World Health Assembly resolutions.
6. Other delegations opposed the proposal for a standard, and put forward that a guideline would allow for the incorporation of local, indigenous foods to be included in RUTF products, which would be both more culturally acceptable and sustainable.
7. The Chair of the 36th session noted that it was premature to decide on the development of a Codex standard or guideline for RUF and requested UNICEF to prepare a revised draft discussion paper and project document, with the support of the Government of Senegal, to be presented at the next session in of the CCNFSDU November 2015.This revised discussion paper and appendixes provide a re-drafted proposal for a Codex guideline that only includes RUTF within its scope. It does not include RUF for use in MAM or other forms of undernutrition

SCOPE

8. The purpose of the work is to establish a guideline for RUTF used in the management of SAM through the provision of safe and efficacious foods, designed to address special nutritional needs of individuals with SAM, the largest proportion of whom are children and infants 6-59 months.
9. The scope of the proposed guideline discussion paper includes guidance for the selection of ingredients and nutritional composition, using existing WHO guidelines for the management of SAM, manufacturing standard for production, microbiological criteria, packaging, labelling and chemical contaminant criteria of RUTF, in the form of pastes, such as lipid-based matrices, or solid bars.
10. In specific settings where there is provision of adequate resources, the treatment of SAM is based on a therapeutic diet using locally available nutrient-dense foods prepared by the carer at home, without the use of commercially produced products such as RUTF.[1] UNICEF acknowledges that some regions adopt this approach to managing SAM as they believe it be more sustainable and better suited to the countrys'

healthcare system. The scope of this discussion paper only refers to RUTF that are produced in food manufacturing facilities and traded internationally.

INTRODUCTION

11. Globally, in 2013, 51 million children under five were wasted and 17 million were severely wasted. In 2013 approximately two thirds of all wasted children lived in Asia and almost one third in Africa, with similar proportions for severely wasted children.[2] Children with severe wasting or SAM have a risk of death eleven times higher that of children without SAM.[18]

12. SAM is diagnosed when children suffer severe wasting as defined by a weight for height more than three standard deviations below the median of the WHO growth standard or by measuring the middle upper arm circumference (MUAC) and if the circumference is less than 115mm and/or if the child has bilateral oedema (swelling of both feet from fluid retention). The condition occurs when infants and children do not have adequate energy, protein and micronutrients in their diet, and is often seen in combination with other health problems such as recurrent infections and chronic illness.[3,14]

13. The underlying causes of SAM are poverty, lack of access to nutritious food, disease, and poor hygiene and sanitation.[4,5]

14. The United Nations International Children's Fund (UNICEF), United States Agency for International Development (USAID), Doctors without Borders, Action Against Hunger, and the International Red Cross in addition to many other aid agencies procure RUTF to manage cases of SAM. Many governments also procure RUTF for use in community programs and hospitals. In 2014 UNICEF procured more than 30,440 Metric Ton (MT) of RUTF worth $ 112 million USD, which reached approximately 2.6 million children with SAM. RUTF is provided to aid organisations and governments who have programs established to manage cases of SAM.

15. RUTF is given to recipients free of charge, as a targeted therapy for SAM and is not intended as an item for sale on the free market. Carers are educated about the importance of the specialised therapeutic food only going to the child diagnosed with SAM, as a special treatment to help them recover which usually takes 4-8 weeks.

SEVERE ACUTE MALNUTRITION AND THE USE OF RUTF

16. In children under 5 years of age, acute malnutrition is directly or indirectly responsible for at least 4.7% of all deaths of children under the age of 5 years.[9,10] When children are undernourished, their immune systems respond less effectively to microbes, increasing the incidence and severity of infections. They have an increased risk of infection and death, acute diarrhoea and acute respiratory infections being responsible for most deaths in children less than 5 years of age. Children suffering from SAM may experience long term developmental delay if not treated appropriately.

17. Evidence accumulated over a ten year period, in numerous countries suggests that large numbers of children with medically uncomplicated SAM can be treated in their communities without the need for inpatient hospital treatment. The community-based approach involves timely detection of SAM in the community and provision of treatment for those without medical complications with ready-to-use therapeutic foods (RUTF) at home and regular medical monitoring at a health facility. Over a period of just 4 years the number of children having access to treatment has almost tripled, many citing this model as a breakthrough in public health.[11]

18. RUTF can be used safely at home without refrigeration, even in areas where hygiene conditions are not optimal. As a result, more opportunities now exist for severely malnourished children to be discharged early from hospital for continuing care in the community. Evidence shows that RUTF home/outpatient therapy is successful, and that the production of RUTF is possible and safe in most countries worldwide. For this reason, WHO developed international guidelines published in *The Joint Statement on Community-Based Management of Severe Acute Malnutrition 2007*[12], (hereafter referred to as the Joint Statement.') which incorporate basic information for local production, including aspects of nutrition composition and food safety measures, however more detailed guidance is needed for countries to sustain and regulate their own supply of this product.

19. The nutritional composition recommended in the Joint statement was developed from research in hospital settings by paediatricians specialising in managing cases of SAM. Several formulations were trialled until an ideal nutritional composition was reached. In comparison to adequately nourished infants and children, the researchers found the nutrient needs of those children with SAM are high to account for metabolic imbalances and to support the rapid rates of catch-up growth during recovery. In particular, SAM cases require high levels of specific minerals (magnesium, potassium, phosphorus) low sodium, and adequate of vitamin A and zinc for optimal recovery.[13, 25] RUTF provide essential fatty acids, quality proteins and are fortified with micronutrients, to ensure the recipient's high nutritional needs are met to

enable tissue re-growth (e.g. muscles, and fat tissues) and to also correct the micronutrient deficiencies that are common in these populations.

20. Children suffering from SAM need safe, palatable foods with a high nutrient density to address multiple macro- and micronutrient deficiencies. The therapeutic foods need to be soft or crushable so that they can be consumed easily by children from the age of 6 months.

21. The proposed guideline for RUTF products used for the treatment of SAM without medical complications is nutrient-dense, containing 520-550 kcal/100g. Treatment recommendations for children with SAM from the WHO are to provide 100-135kcal/kg/ day of a RUTF as the sole food for recipients[14], until the child has gained adequate weight, usually for a period of 4-8 weeks. An average child with SAM can consume around two sachets per day (1000kcal), and can achieve sufficient nutrient intake for complete recovery. While RUTF is given with instructions to be consumed along with clean drinking water, and/or breast milk, no other foods are necessary for the rehabilitation of the child with SAM.

22. RUTF are designed specifically to be eaten directly from the packaging without the addition of water. Mixing with water would increase the chance of microbial contamination if followed by a storage period that lead to the proliferation of intrinsic contaminants to a level that would cause infection. RUTF have a low water activity (aW 0.2-0.6), which prevents microbial growth in the product, and when produced in accordance with good hygienic practices and handled appropriately, are microbiologically safe foods to be consumed at home by this susceptible population. RUTF being a low moisture food is an important feature, as the product is often used in locations where poor water sanitation is a major health risk for children with SAM. In addition, since RUTF do not need cooking, refrigeration or preparation so families are not burdened with the cost of fuel and time for cooking several meals per day.[15]

23. RUTF have a shelf life of around 24 months.[16] This means that RUTF can be stored for months at a time for emergency preparedness in circumstances of conflict, famine and extreme weather or emergencies without spoiling.

OUTPATIENT COMMUNITY MANAGEMENT OF SAM (CMAM)

24. Most importing and recipient countries of RUTF have incorporated the product into their national guidelines for community outpatient clinics. The use of RUTF for uncomplicated cases of SAM (the majority of SAM cases) is endorsed by the World Health Organization[12, 13] and has been adopted for use by more than 61 countries since 2005.

25. In countries where the outpatient clinics have incorporated the management of severe acute malnutrition, they are part of a larger community-based, multi-sectorial health service typically offering routine primary medical care. Specifically-trained professionals at community-based health centres provide care to children and their mothers with SAM who do not have medical complications. Guidance is provided on how to consume RUTF, how to hygienically keep the food in between use, and to continue to breastfeeding and provide to drinking water as needed.[11]

26. Children with severe acute malnutrition who have medical complications or severe oedema are managed as in-patients, usually in hospitals, until their health situation is stabilized.[14]

UNICEF'S LONG TERM STRATEGY

27. Together with WHO, UNICEF and WFP are the lead UN agencies providing support on CMAM to national governments**.** As the largest purchaser of RUTF, it is UNICEF's strategy to ensure CMAM becomes part of the primary health care services offered by governments. Therefore, helping to building capacity of manufacturers to produce RUTF in countries with high SAM burden is one of UNICEF's major strategies to help increase access to treatment.

28. As part of achieving this strategy, a Codex guideline for RUTF to be used as a regulatory tool for national governments to regulate the market and the production facilities in their countries is needed.

RUTF PRODUCTION

29. At present RUTF are manufactured in 18 countries:

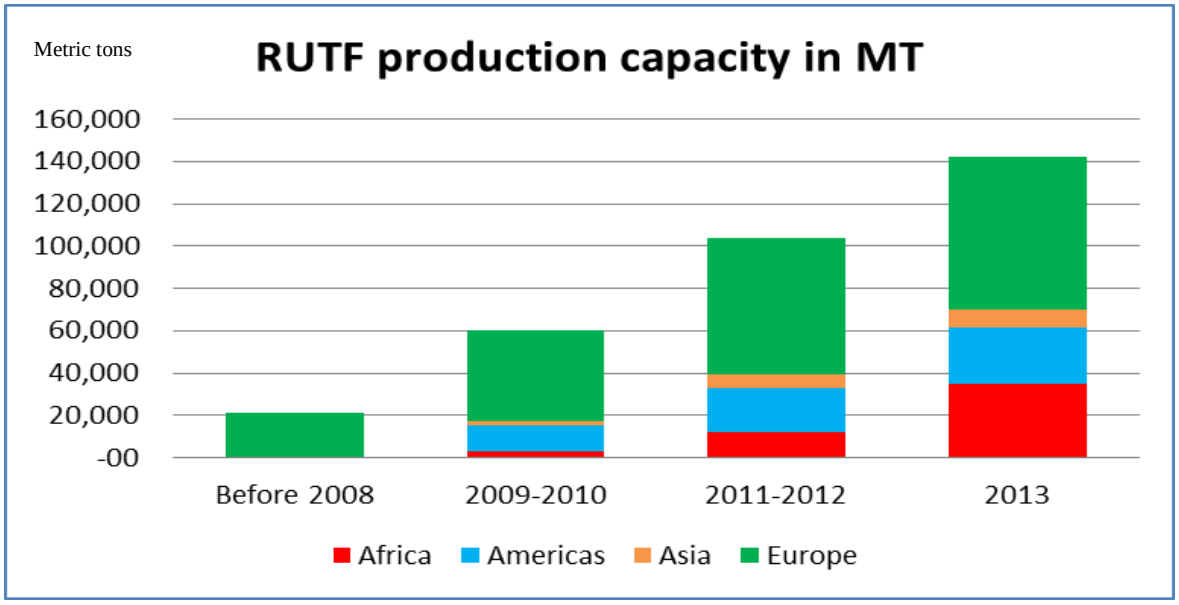
    i. In Africa (Burkina Faso, Ethiopia, Kenya, Madagascar, Malawi, Niger, Sierra Leone, South Africa, Sudan and Uganda),

    ii. The Americas (USA and Haiti),

    iii. Asia (India, Pakistan and Vietnam) and

    iv. Europe (France and Norway)

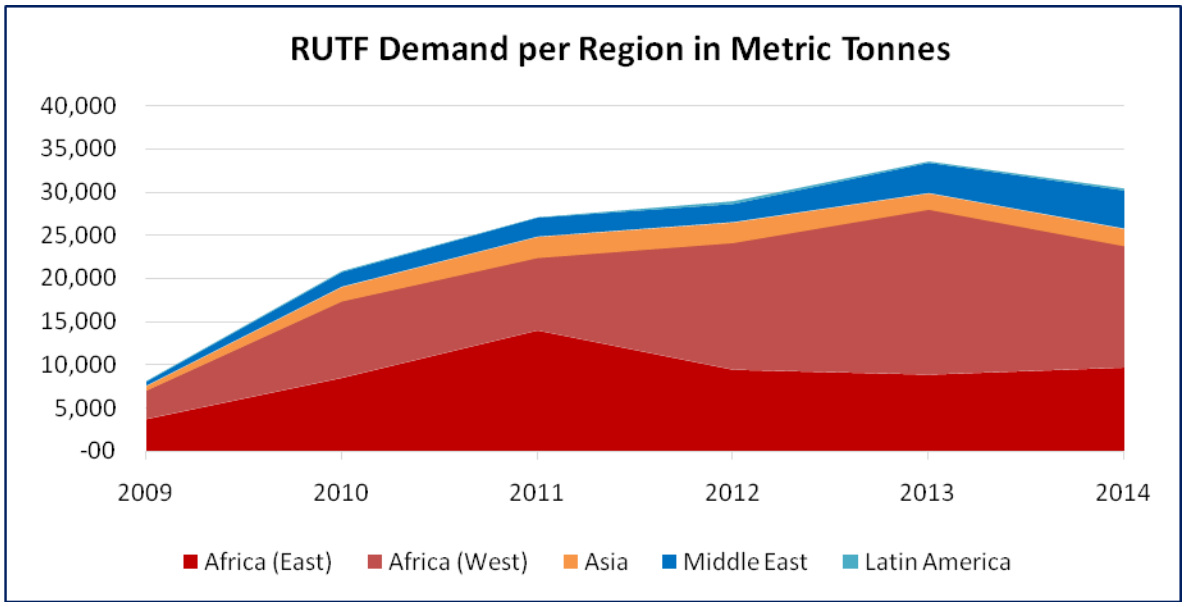
30. The major production capacity is located in Europe (56%), followed by America (21%) and Africa (14%), France being the biggest source of these products.



Graph 1: RUTF capacity growth by region before 2008 to 2013

RUTF DISTRIBUTION AND TRADE

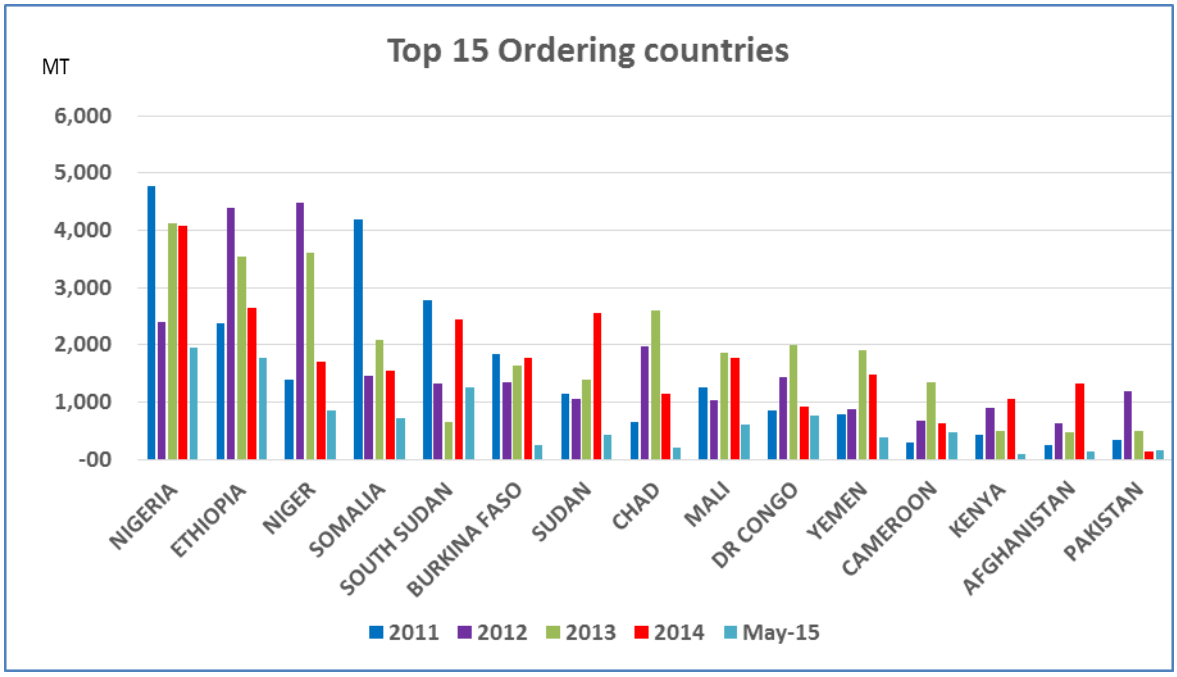
31. RUTF are distributed in about 60 countries, crossing many borders. As of 2014, the largest demand is in Africa (82%), followed by Asia (12%), the Middle East (4%), and Central and South America (1%) as represented in graph 2.



Graph 2: Demand for Ready to Use Therapeutic Food by region. (Source UNICEF procurement data)

PROCUREMENT OF RUTF

32. The top 15 RUTF procuring countries for UNICEF in the period 2011-to May 2015 are shown in Graph 3. A large proportion of this procurement was for humanitarian aid during emergencies.



Graph 3: Procurement of Ready to Use Therapeutic Foods for treatment of SAM, top 15 consuming countries. (Source UNICEF procurement data)

DISTRIBUTION AND USE OF RUTF

33. Currently RUTF are distributed mostly to developing nations (see Figure 1).

Figure 1: Distribution of RUTF Globally. Size of circle corresponds to funding spent on RUTF in 2013.

REGULATION OF RUTF TRADE

34. Some countries included RUTF on their essential drug or essential supply/commodity lists. The importance of including RUTF as an essential supply/commodity is to allow easier integration into national supply system (easier clearance of supplies at ports, government storage at central medical stores, and government-led distribution and logistics). Most importantly, inclusion of RUTF onto a

national supplies list will ensure there is dedicated national health budget for community programs that use RUTF, and therefore more sustainable treatment of children suffering from SAM.

35. A codex guideline will assist countries with incorporating RUTF into their essential supply list, as it will help provide a better normative definition of RUTF, including a criteria for efficacy and safety, important requirements if a product is to be procured by national governments.

NEED FOR RUTFS GUIDELINE

36. Given the wide acceptance of RUTFs in national health care systems for the management of SAM, governments have raised questions about appropriate normative classification and standards to apply to RUTF for imported and domestically produced RUTF, to facilitate its appropriate regulation on their national market, as well as to justify funding the purchases of these products from national budgets.

37. There is currently a lack of harmonised regulatory classification of RUTF, with some countries registering RUTF as a food and some countries registering it as a drug or medicine. Harmonised standards for this international and regionally traded commodity will facilitate trade and ensure that an effective and safe product reaches the children who need it without unnecessary delays. This is especially relevant during emergencies where timely delivery of RUTF through country borders can directly impact on population survival.

RUTF PRODUCTS APPLICABLE FOR THE CODEX GUIDELINE

38. There are two kinds of RUTF, paste and biscuit or bar. Both kinds of RUTF are applicable for the proposed Codex guideline.

39. RUTF in the form of paste are specially formulated to satisfy the particular dietary requirements due to the physiological condition of SAM.

40. RUTF Bars / Biscuits are Therapeutic Food in a form of Bar / Biscuit biscuits or bar-types of RUTF used as an alternative to the paste variety of RUTF.

41. As both RUTF paste and biscuit are the sole food given for those with SAM, and are provided under the guidance of trained professionals, these products can be classified in the Codex category of Foods for Special Medical Purposes, as defined in the *Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes. Codex Stan 180-1991.*

INGREDIENTS AND COMPOSITION

42. Systematic reviews are being carried out as part of WHOs' effort to develop an updated guideline on effective and safe use of lipid-based nutrient supplements including RUTF pastes. The WHO has confirmed that the review will not lead to changes in the recommendation of composition for the product, but rather, aims to provide an update on the evidence for RUTF pastes and also investigate the longer-term effects of the consumption of such products on the health of children. The literature reviews are currently ongoing. The WHO have advised that the composition reviewed in the most recent guideline update from the *WHO, Guideline: Updates on the management of severe acute malnutrition in infants and children. Geneva: World Health Organization; 2013*, can be used for the proposed guidelines. Therefore the proposed work of the CCNFSDU can still be based on the current product composition as outlined in the Joint Statement 2007 (Appendix 1), and the WHO's ongoing evidence review could serve to inform the CCNFSDU's work on the proposed Codex guideline.

RUTF INGREDIENTS

43. RUTF are made of powdered or ground ingredients embedded in a lipid-rich paste, or protein-based matrix, resulting in energy and nutrition-dense food. They are typically, made from ground peanuts, milk products, sugar, and a premix containing oil, vitamins and minerals. RUTF can also be made with legumes such as soy or chick peas, and cereal flours such as rice, millet, oats, wheat or barley and other locally produced plant-derived flours. As the name implies, RUTF need no preparation prior to consumption, making them practical for use where cooking fuel and facilities are unavailable, both in emergency settings and also in households.

RUTF INGREDIENT DIVERSIFICATION

44. UNICEF, and donor agencies such as DFID and 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. For example in Vietnam a RUTF with rice and lentils is used, in Pakistan chick peas have replaced peanuts as a source of protein while in Africa peanuts are included as a source of oil and protein in RUTF.

45. There is increasing interest to replace the typically used peanut ingredient with other ingredients that can be found locally, that better reflect the cultural dietary customs of a particular country, leading to a more

acceptable solution for the treatment of SAM by communities. Countries can use local recipes incorporating locally and regionally available ingredients, helping to overcome logistics and supply issues. However, diversification of recipes needs overarching international guidance in order to ensure that the products meet the quality and safety standards and nutrient composition that lead to an effective recovery for children. For example certain ingredients such as cereals and legumes contains anti-nutritive factors that may impair the absorption of micro and macronutrients that are critical for recovery. In addition, the guideline could include a dietary protein quality scoring method (such as PDCAAS or DIAAS) to ensure the appropriate protein quality is included in RUTFs.

46. The nutrient composition recommended in the 'Joint statement' can be used as a basis to develop an official standard for countries to follow. National governments will benefit from having an international guideline to assist regulation of both current and new products predicted to emerge in the market.

CHEMICAL CONTAMINANTS

47. At the 37th session of the CAC the Representative of FAO informed the Commission of on-going work by FAO and WHO to address the microbiological safety and 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.

48. Chemical contaminants within RUTF are an important consideration in the development of the RUTF Codex guideline, and chemical contaminant risks need to be defined. Many RUTF products contain peanuts, and other ingredients that may be a source of chemical contaminants therefore, the proposed guideline including, but not limited to work on mycotoxins, heavy metals and pesticides would address these risks.

RUTF MANUFACTURING PROCESS & FACILITY STANDARD

49. The RUTF 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 Appendix 3. Some manufacturers have added thermo-processing as an additional pathogen control step for bacteria such as *Salmonella spp*. For illustration of an example of a manufacturing process flow including thermal-processing, see Figure 3, Appendix 3.

50. It is proposed that the manufacturing standards for the facilities producing RUTF maintain quality standards suitable for producing Food for Special Medical Purposes. Such facilities should be inspected and licenced by national authorities. The Code of Hygienic Practice for Low Moisture Foods CAC/RCP 75-2015 could be referred to within the RUTF guideline.

MICROBIAL SAFETY AND ASSOCIATED SAMPLING PLAN

51. At the 38th session of the CAC the Code of Hygienic Practice for Low Moisture Foods was adopted as a final Codex Code of Practice. As RUTF are low moisture foods, the progress of this work is highly relevant for the development of a guideline for RUTF. The ongoing work on annexes included in this Code will include consideration of information from an expert committee tasked with conducting a risk assessment on RUTF and its consumers.

52. FAO and WHO have convened two expert meetings to conduct a risk assessment of RUTF for microbial contamination over the last 2 years. Several recommendations for the safe manufacturing of RUTF and also a revised microbiological criteria and sampling plan have been put forward. More detailed information is found in Appendix 2

LABELLING AND PACKAGING

53. It is proposed that the RUTF guideline will follow the *Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes*, *Codex Stan 180-1991 and* include the Codex STAN 1-1985: General Standard for the Labelling of Pre-packaged Foods. The labelling guidance including but not limited to the following additional labelling requirements: statements:

    i. RUTF is intended as the sole source of nutrition for children aged 6 months and over with Severe Acute malnutrition

    ii. For the dietary management of Severe Acute Malnutrition

    iii. USE UNDER MEDICAL SUPERVISION.

    iv. Serving size 100-135kcal/kg/day .Eat directly from the sachet. Do not add to other foods.

    v. RUTF may pose a health risk when consumed by persons who do not have severe acute malnutrition.

    vi. The statement "Not for resale"

vii. Breastfeeding message:“Exclusive breastfeeding is recommended for the first 6 months of life and continued breastfeeding, with adequate complementary feeding, is recommended from 6 months up to 2 years or beyond and accompanying pictogram image

viii. Stipulated ‘supplier zone’ area on the packaging for branding, limited to 20% of the printed area

RECOMMENDATION

54. RUTF is currently traded extensively across international borders and is used as a special medical purpose food for children with SAM without international regulation. Development of a Codex guideline for RUTF will provide both a reference for manufacturers, purchasers and government regulatory authorities and a needed framework for the supply of consistently nutritionally appropriate and safe RUTF across national borders. It is recommended that CCNFSDU consider the development of a Guideline for Ready-to-use Therapeutic Foods (RUTF).

55. A project document is presented in Appendix 7.

Appendix 1

Composition of RUTF as listed in the "Joint Statement'[2] & example of therapeutic feeding dose for a child with SAM of 6 months

Macronutrients	**per 100g (approximately 1 sachet) Example of SAM child weight of approximately 5.5 kg consuming 1 sachet per day for 4-8 weeks (age estimate 6-7 months)**	**Recommended Daily Allowance (RDA) or Individual Nutrient Level (7-12-months)**	**Percentage Recommended Daily Allowance (RDA) (7-12 months)**
Energy	520–550 Kcal/100 g	653kcal[25]	80-84%
Proteins	10%–12% total energy (50% of protein sources from Milk products)	14 grams[22]	71-86%
Lipids	45%-60% total energy	40-60% E[20]	105-100%
n-6 fatty acids	3%–10% of total energy	3-4.5% E[20]	100-222%
n-3 fatty acids	0.3%–2.5% of total energy	0.4-0.6% E[20]	75-416%
Moisture content	2.5% maximum	n/a	
Vitamin A RE	0.8–1.1 mg/100 g	400µg[21]	200-275%
Vitamin D	15–20 µg/100 g	5 µg[21]	300-400%
Vitamin E	20 mg/100 g minimum	2.7mg[21]	740%
Vitamin K	15–30 µg/100 g	10 µg[21]	150-300%
Vitamin B1	0.5 mg/100 g minimum	0.3 mg[21]	166%
Vitamin B2	1.6 mg/100 g minimum	0.4 mg[21]	400%
Vitamin C	50 mg/100 g minimum	30 mg[21]	167%
Vitamin B6	0.6 mg/100 g minimum	0.3 mg[21]	200%
Vitamin B12	1.6 µg/100 g minimum	0.7 µg[21]	228%
Folic acid	200 µg/100 g minimum	80 µg[21]	250%
Niacin	5 mg/100 g minimum	4 mg[21]	125%
Pantothenic acid	3 mg/100 g minimum	1.8 mg[21]	166%
Biotin	60 µg/100 g minimum	6 µg[21]	1000%
Minerals			
Sodium	290 mg maximum	370mg[23]	<78%
Potassium‡	1,110–1,400 mg	700mg[23]	157-200%
Calcium	300–600 mg	400 mg[21]	75-150%
Phosphorus‡	300–600 mg (*excluding phytate)	460 mg[24]	65-130%
Magnesium	80–140 mg	54 mg[21]	133-233%
Iron	10–14 mg	7.7 mg*[21]	130-182%
Zinc	11–14 mg	4.1mg**[21]	268%-340%
Copper‡	1.4–1.8 mg	0.34 mg[24]	411-529%
Selenium	20–40 µg	10 µg[21]	200-400%
Iodine	70–140 µg	90 µg[21]	78-155%

*Iron values given at 10% dietary bioavailability

**Zinc Values given for medium dietary zinc bioavailability

‡Dietary Reference Intakes 1997/2001 (Source for copper, potassium, sodium, and Phosphorus).

Table 1. Composition of RUTF, taken from 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 UNICEF; WHO/UNICEF/SCN/UNICEF, 2007.

Appendix 2

Development of the RUTF Microbiological Criteria

1. UNICEF, in collaboration with WFP and MSF, approached the Food and Agricultural Organization (FAO) and WHO with a request to review the microbiological safety requirements for RUTF in June 2012 and again in December 2014. FAO and WHO held the first expert meeting in December 2012 that concluded that Salmonella is the single greatest bacterial health risk for the intended consumers of RUTF, and that statistically valid sampling of products for Salmonella detection, in conjunction with quantitative Enterobacteriaceae (EB) analyses as an indicator of process control would better assure the safety of these products than would the currently applied specifications.

2. In the first expert consultation held in 2012, the risk of *Cronobacter spp* was deliberated, and the appropriateness of applying the microbial criteria for *Cronobacter spp* in Annex 1 of the Code of Hygienic Practice for Powdered Formulae for Infants and Young Children(CAC/RCP 66-2008). As the products are intended for individuals aged 6 months and over, the consumers of RUTF are outside the population considered to be at greatest risk (young infants) for serious disease due to *Cronobacter* spp. The committee agreed that by applying an appropriate sampling protocol focusing on Salmonella in conjunction with using EB as an indicator organism of process control, that the risks of *Cronobacter spp* could be adequately managed.

3. The expert group subsequently recommended 'interim specifications' together with an appropriate sampling plan, with the aim to collect more finished product data, which was then considered in a second meeting convened by FAO and WHO in December 2014. In the expert meeting convened in December 2014, the risk of receiving contaminated product from the 21 suppliers currently supplying UNICEF RUTF was considered.

4. The committee also conducted a risk assessment of the microbes listed in the 2007 Joint statement and reviewed a panel of pathogens that cause illnesses of diverse severity in childhood infections and assessed their likelihood of being transmitted by low moisture foods. Out of the seven microbes originally listed in the 2007 Joint statement, the greatest hazard deemed to be likely to be found in RUF including RUTF was *Salmonella spp*.

5. Testing data collected from over 4000 tests between 2013 and 2014 indicated that the *Salmonella* contamination of each product serving ranged from 0.2% to 20% from current producers of RUF. The level of Enterobacteriaceae was also tested during this time period. Out of 10,000 samples, approximately 1.3% were manufactured under marginally unhygienic conditions and approximately 0.3% were manufactured under unhygienic conditions. 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.)

6. The committee concluded that the risk of foodborne illness posed by lipid-based RUF produced under the current conditions and standards is likely to be very low in comparison to the risk of infections from other sources.

7. The recommendation was made to continue maintaining focus on *Salmonella* as the highest priority infectious hazard and its control as the primary food safety programme goal. The committee found that the target population for lipid-based RUF is likely to be exposed to serious pathogens, including *Salmonella*, from multiple sources (including other foods, water, animals and the surrounding environment) and that the risk of consuming contaminated RUTF was minimal.

8. Based on the above considerations, new criteria for Salmonella are being proposed, taking into consideration a range of factors, such as source and quality of ingredients, and process control.

Appendix 3

Flow Diagram of Typical RUTF Manufacture

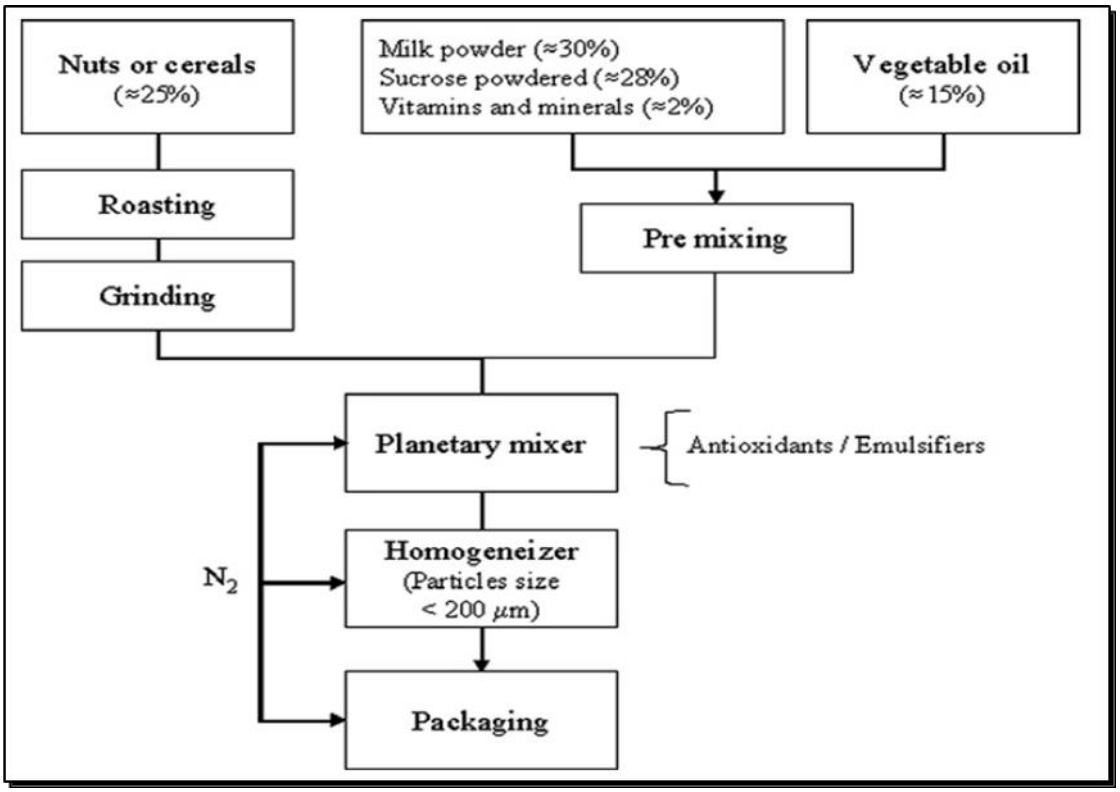


Figure 2: Example Manufacturing Flow Diagram of RUF[18]

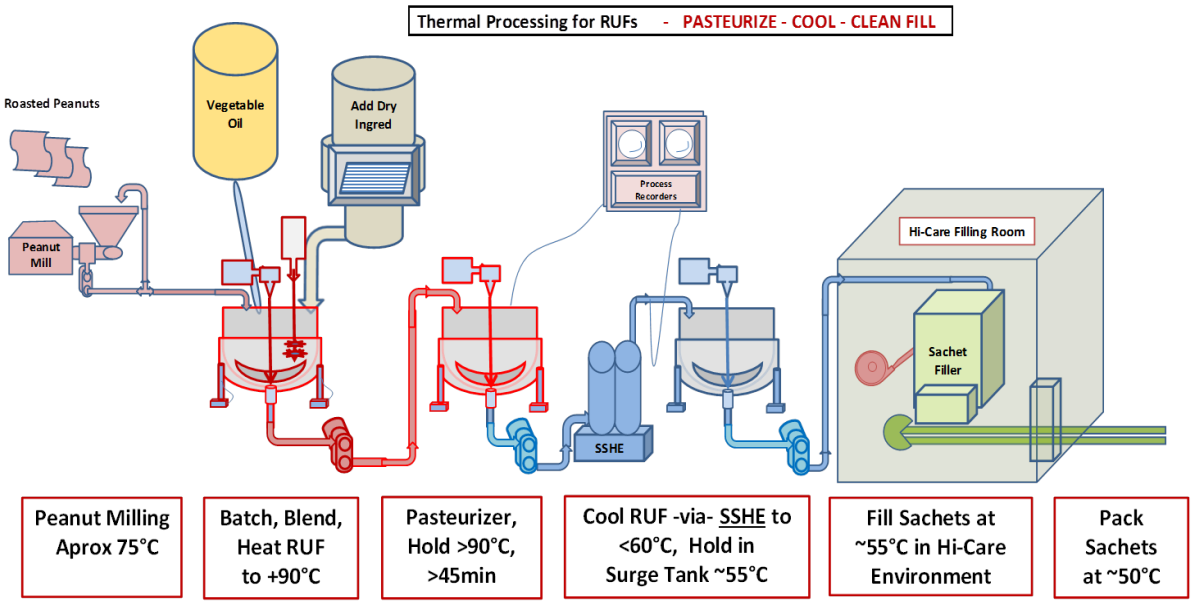


Figure 3: Thermo-processing system for the manufacture of RUFs including a kill-step to reduce at its minimum pathogen survival. Equally effective temperatures and heating times may also be used.

Appendix 4

Applicable Codex Standards

i. Guidelines for formulated Complementary Foods for older infants and young children. CAC/GL 8-1991

ii. Code of Hygienic practice for Powdered Infant Formulae for Infants and young children (CAC/RCP 66-2008)

iii. Code of Hygienic Practice for Low Moisture Foods CAC/RCP 75-2015

iv. Advisory lists of nutrient compounds for use in foods for special dietary uses intended for infants and young children (CAC/GL 10-1979)

v. General Principles for establishing Minimum and maximum values for the essential composition of Infant formula (Annex II, Codex standard 72-1981)

vi. CAC/RCP1:1969-- General Principles of Food Hygiene

vii. CAC/RCP-22:1979-- Code of Hygienic Practice for Groundnuts (Peanuts)

viii. Codex standard 146-1985 (amended 2009) as a Food for Special Medical Purposes

ix. CODEX STAN 228-2001: General Methods of Analysis for Contaminants

x. CODEX STAN 193-1995: Codex General Standard for Contaminants and Toxins in Food and Feed

xi. CODEX STAN 229-1993, REV.1-2003: Analysis of Pesticide Residues: Recommended Methods

xii. Codex STAN 146-1985: General Standard for the Labelling of and Claims for Pre-packaged Foods for Special Dietary Uses

xiii. Codex STAN 1-1985: General Standard for the Labelling of Pre-packaged Foods

Appendix 5

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Appendix 6

Glossary of terms

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

Appendix 7

PROJECT DOCUMENT

1. Purpose and Scope of the Guideline

The scope of the work is to clearly define RUTF in terms of its composition and safety aspects related to suitable ingredients, incorporation of the nutritional composition as outlined in the WHO Guideline, 2007[1], appropriate criteria and limits for relevant microbiological hazards and chemical contaminants (e.g. heavy metals, mycotoxins and pesticides) and labelling requirements respectively in order to provide protection to vulnerable consumers of RUTF.

2. Relevance and Timeliness

Currently RUTF products are produced in 19 and consumed in approximately 60 countries, mostly developing nations, and are traded extensively across borders. Most countries where RUTF are consumed have incorporated the use of RUTF into their national guidelines for outpatient, or community management of SAM. As the ability to reach malnourished children increases, there will be a greater demand for RUTF products produced in more appropriate sites, closer to the recipients. A codex guideline for RUTF 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

i. Minimum requirements for appropriate ingredients to be included in RUTF taking into consideration the effects of anti-nutritive factors that can affect macro and micro nutrient absorption. Consideration of inclusion of a protein quality score such as PDCAAS or DIAAS within the nutritional composition requirements.

ii. Provisions for composition based on the adoption of the nutritional composition as specified in existing WHO documents for RUTF and their future modification.

iii. Provisions for hygienic practice for production, handling, processing, storage and distribution and associated microbiological criteria for RUTF with reference to the General Principles of Food Hygiene and other relevant codex texts.

iv. Provisions for chemical contaminants/criteria with reference to the *General Standard for Contaminants and Toxins in Food and Feed*.

v. Provisions for labelling and marking of RUTF in accordance with the *General Standard for the Labelling of Pre-packaged Foods* and the *Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes*, *Codex Stan 180-1991.*

vi. Reference Methods of Analysis and Sampling.

All work will be coordinated with the applicable general subject Codex Committee to ensure the appropriate application of Codex expertise and resources.

4. General criteria

The Codex Alimentarius Commission has a mandate of protecting consumer's health and ensuring fair practices in food trade. The proposed new standard will meet this criterion by promoting consumer protection from the point of view of health, food safety and ensuring fair practices in the food trade and in particular:

i. The nutritional composition will protect the consumer's health by providing a scientifically-based composition to facilitate recovery from malnutrition. The definition of the nutritional and food safety aspects for RUTF will enable harmonized specifications and regulation of these food products at a national level for the protection of the consumers, especially vulnerable children;

ii. Appropriate labelling of RUTF in accordance with the *Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes. Codex Stan 180-1991* will protect consumer health by clearly communicating the appropriate use, purpose and target group for RUTF thereby protecting intended and unintended consumers.

[1] http://www.who.int/maternal_child_adolescent/documents/a91065/en/

5. Criteria applicable to general subjects

(a) Diversification of national legislations and potential impediments to international trade

National legislations for RUTF are not harmonised and this impedes trade of this commodity due to the lack of a clear international normative definition of this food.

(b) Scope of work and priorities between safety of RUTF, microbial and chemical contaminants

The scope of work in developing a guideline for RUTF includes areas of work where the CCNFSDU, CCFH, CCCF and CCFL will need to be engaged. 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.

(c) Work already conducted by FAO and WHO in this field

The development of the guideline 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.

In relation to nutritional aspects, the scientific basis for standards have already been developed for the existing nutritional composition of RUTF by WHO in 2013, this can be assessed by CCNFSDU for inclusion into the RUTF guideline. The WHO published an updated guideline for the treatment of SAM in 2013 that can be used as a basis for the nutritional composition within the guideline.

In reference to the microbiological hazards, UNICEF and WFP have already solicited scientific advice from FAO and WHO and an additional expert meeting was convened in this area in December 2014, so an adequate scientific basis to address microbiological food safety issues has been established.

An assessment of the work that has been undertaken to address microbiological safety both by the CCFH, and also the meeting of experts in December 2014 is also important as this will serve to address the most pressing issue of protecting large numbers of consumers from a food safety perspective.

(d) Amenability of the subject to standardization

Taking into account the existing global guidance from WHO on these products standardisation in this area is attainable through defining: energy levels; protein content; lipids contents; moisture content; micronutrients; allowed minerals; raw material requirements etc.

(e) Global magnitude of the problem

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

ii. Globally, in 2013, 51 million children under five were wasted and 17 million were severely wasted. In 2013 approximately two thirds of all wasted children lived in Asia and almost one third in Africa, with similar proportions for severely wasted children.[2] Children with severe wasting or SAM have a risk of death eleven times higher that of children without SAM.[18]

iii. RUTF is provided to aid organisations and governments who have programs established to manage cases of SAM. The United Nations International Children's Fund (UNICEF), United States Agency for International Development (USAID), Doctors without Borders, Action against Hunger, and the International Red Cross in addition to many other aid agencies procure RUTF to manage cases of SAM. Many governments procure RUTF for use in community programs and hospitals.

iv. For example, in 2014 UNICEF procured more than 30,440 Metric Ton (MT) of RUTF worth $112 million USD, which reached approximately 2.6 million children with SAM. The product was mostly distributed to the regions of West and Central Africa (14 MTs) including Nigeria, Niger, Burkino Faso, Mali, Chad, Democratic Republic of Congo and Cameroon; followed by the region of East Africa (9 MTs) including Ethiopia, South Sudan, Sudan, Somalia and Kenya; the region of the Middle east (4 MTs) including Afghanistan and Yemen and Asia (2 MTs) including Pakistan.

(f) 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 guidelines that address current and emerging food issues

   The provision of a guideline for RUTF will address a gap in food safety of a processed food that is traded globally.

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

6. Information on the relation between the proposal and other existing Codex documents

The proposed work will make reference to relevant standards and related texts in particular of the following:

- Guidelines on Formulated Complementary Foods for Older Infants and Young Children, CAC/GL 8-1991
- Standard for Infant formula and Formulas for Special medical purposes intended for infants CODEX STAN 72 – 1981
- Advisory lists of nutrient compounds for use in foods for special dietary uses intended for infants and young 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)
- Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods (CAC/GL 21-97)
- Code of Hygienic Practice for Low Moisture Foods CAC/RCP 75-2015 Code of Hygienic practice for Powdered Infant Formulae for Infants and young children (CAC/RCP 66-2008) Ongoing work on the Code of Hygienic Practice for low moisture foods annexes will be relevant.
- CAC/RCP1:1969 - General Principles of Food Hygiene
- AC/RCP-22:1979 - Code of Hygienic Practice for Groundnuts (Peanuts)
- General Standard for the Labelling of and Claims for Pre-packaged Foods for Special Dietary Uses. Codex Standard 146-1985 (amended 2009)
- As the products composition can be made of ingredients such as peanuts, milk powders, sugar, oil, legumes, cereal and vitamin and mineral premix, the relevant standards for these commodity raw materials should be taken into consideration.

7. Identification of any requirement for and availability of expert scientific advice

The development of the Guideline will be consistent with the use of scientific advice and risk analysis principles in the articulation of the nutritional ingredient composition and safety aspects. Scientific advice from the FAO/WHO expert bodies, particularly JECFA in addition to scientific input from all countries will be solicited.

8. Identification of any requirement for technical input to the standard from external bodies so that this can be planned for

No need for technical input from external bodies

9. Proposed timeline

Subject to approval by the Commission in 2016, the development of the Guideline will be submitted for consideration by CCNFSDU in 2016 and expected to take four session of CCNFSDU or less depending upon the relevant inputs and agreement from members. Final adoption by the Commission is foreseen for 2020.