**IBFAN Comment**

**PROPOSED DRAFT GUIDELINES FOR READY TO USE THERAPEUTIC FOODS (RUTF)**

**(for comments at Step 3)**

**IBFAN wishes to thank South Africa, Senegal and Uganda for their work on this agenda item and their leadership of the Electronic Working Group.**

**General Comments:**

- **IBFAN is of the opinion that current scientific evidence does not support the wide spread use of RUTF products compared to the use of culturally appropriate energy dense family foods for the community management of SAM and MAM and the support of sustained breastfeeding.**

- **National Authorities should ensure that any decisions to provide food products are based on sound independent evidence. Such evidence should meet WHO's definition of scientific substantiation: *'Relevant convincing / generally accepted scientific evidence or the comparable level of evidence under the GRADE classification'*. The evidence should cover the effectiveness of RUTF as a treatment food, resource implications, sustainability, social and economic risks, and how outcomes were measured and risk of bias. (See IBFAN's review of literature in the IBFAN Brief on the Use of RUTF).**

- **Access to nutritious and appropriate foods is just one aspect of a full package of treatments and care that are required for sustained rehabilitation of malnourished children and the prevention of recurrence. The protection and support of breastfeeding and culturally appropriate complementary feeding must be a fundamental and an essential component of a rehabilitation package. Other critical components must include: nutrition education; the treatment of infections; support for maternal care; the strengthening of health systems; the prevention of early child bearing; literacy and the improvement of water supply, sanitation and hygiene.**

- **The widespread use of RUTF products has and continues to trigger diversion of public funds away from support for sustainable solutions such as breastfeeding and locally sourced, culturally appropriate, bio-diverse family foods.**

- **To safeguard against needless and inappropriate use of these products IBFAN is of the opinion that these products should not be on the open market. The marketing and trade of RUTF products introduces a commercial element that increases the risk of unnecessary and inappropriate use.**

- **Products that are intended for infant and young child feeding and are legally available on the open market require stringent marketing restrictions in order to protect breastfeeding, complementary feeding and child health from commercial influence. For this reason the marketing of breastmilk substitutes and related products are all covered by the International Code of Marketing and subsequent relevant WHA Resolutions. Similarly, these safeguards are needed for products intended for this vulnerable population. RUTFs intended for therapeutic use only and although the International Code and WHA resolutions provide some important safeguards, extra safeguards are needed to prevent misuse.**

- **Since Codex Guidelines are voluntary instruments, for the safety aspects to be effective, they must be implemented into national law. Codex texts dealing with food safety are already integrated into the regulatory mechanisms of many countries. National authorities can use these to improve the safety of products (eg. *Codex Code of Practice for Low-Moisture Foods* (CAC/RCP 75-2015).**

- **Importantly, this Codex Guideline is being developed through a process, which is not adequately safeguarded from conflicts of interest. Undue influence from manufacturers and distributors, their associations and the organizations funded by them is likely to subvert the public health purpose. It will lead to increased global trade of a single commodity and its widespread use at the expense of sustainable solutions. Manufacturers and distributors might also put pressure on governments to accept imports of products that may not be needed or wanted.**

- **To facilitate sound decision making on this important topic, the support to the process being pursued in the CCNFSDU, needs to include more robust evidence of the validity of using RUTF in community management of SAM. Lack of such evidence and concern about the marketing and misuse of these products continues.**

- **The scope of RUTF has been limited in the recent management of SAM children of Rohingya refugees in Bangladesh. Mothers and caretakers successfully managed SAM children with their own home-prepared foods, which they use for home foods. These children improved within two months, completely gaining to 0 Z score of WH after feeding. The ingredients were rice powder, soya oil, sugar and egg. The cost is nominal 25-30 cents per day. Ingredients were supplied and mothers were shown how to cook in their camp house. Every family had cooking facilities. The intervention was followed with a two-month observation period without supply of ingredients but alongside continued advice on family**

**feeds. The results showed that improvements continued. This strongly suggests that the promotion of RUTF is not essential nor always efficacious for the treatment of SAM children**

## 1. PREAMBLE

~~Children affected by severe acute malnutrition (SAM) need [adequate treatment and care] OR [safe, palatable foods with a high energy content and adequate amounts of vitamins, minerals and other nutrients. Children with SAM need timely treatment and RUTF is a critical part of the care]. RUTF are primarily intended for children with uncomplicated SAM from 6-59 months. Although RUTF may be given to other age groups with various forms of malnutrition at the implementation level, the primary focus for these guidelines is children with SAM from 6-59 months. Since RUTF are prescribed according to weight, National Authorities may decide to include the provision of RUTF in their national protocols for use by other age groups.~~

**RUTFs may be used as a treatment food for older infants and young children with SAM, when other nutrient rich foods cannot be used. However, it is critical that its use does not undermine support for continued breastfeeding or to re-establish lactation, since this is the most important requirement for the rehabilitation of children suffering from malnutrition. RUTFs can be used as a treatment food while breastfeeding is sustained and family foods are gradually introduced. The portion size of RUFTs should be adapted to ensure optimal breastmilk intake. RUTFs can also be used for the feeding of malnourished older infants and young children in emergency situations**.

These guidelines provide requirements for the production and labelling of RUTF **products. The guidelines are intended to ensure that the ~~that the facilitate the harmonization of~~ ingredients, nutritional composition, safety, use and labelling is appropriate** for the **intended recipients,** ~~requirements for~~ RUTF ~~at the international level and~~ **and to** provide assistance to governments wishing to establish national regulations. ~~The guidelines are also intended for use as an instrument designed to avoid or remove difficulties which may be created by diverging legal, administrative and technical approaches to RUTF and by varying definitions and nutrient compositions of RUTF.~~ These guidelines should be used in accordance with technical recommendations **that are based and updated on relevant and convincing evidence free from commercial influence, taking into account relevant Codex texts related to food safety and hygiene**[1]. Governments and other users should ensure adequate provisions are made ~~for~~ with competent technical experts **to ensure that the use of these products is appropriate in the local context, does not undermine national nutrition recommendations and the use of bio-diverse, culturally appropriate foods. If RUTFs are considered appropriate, they should be used solely for treatment purposes and not for general use or the prevention of SAM. Steps must be taken to ensure that there is no spillover into the wider population and the black market.**

**On no account should RUTF products be placed on the open market. The production and availability of these products must comply with the relevant provisions of the WHO International Code of Marketing of Breastmilk Substitutes, the subsequent relevant WHA resolutions including the WHA 69.9, its accompanying WHO Guidance on Ending the Inappropriate Marketing of Foods for Infants and Young Children and the Codex Guidelines on Nutrition and Health Claims, Paragraph 1,4 of which states that no nutrition and health claims should be made for foods for infants and young children. Nor should convenience claims be made for these products on labels or information materials.**

.

- [1)]Joint Statement on Community-Based Management of Severe Acute Malnutrition by the World Health Organization, the World Food Programme, the United Nations System Standing Committee on Nutrition and the United Nations Children's Fund, 2007; WHO. Child growth standards and the identification of severe acute malnutrition in infants and children, 2006; A Joint Statement by the World Health Organization and the United Nations Children's Fund; Geneva: World Health Organization; 2009; WHO. Guideline: *Updates on the management of severe acute malnutrition in infants and children*.
  Geneva: World Health Organization; 2013; WHO. Global Strategy for Infant and Young Child Feeding. Geneva: World Health Organization; 2003; WHO. *International code of marketing of breast-milk substitutes.* Geneva: World Health Organization; 1981 and subsequent relevant WHA Resolutions on infant and young child feeding; *Code of Ethics for International Trade in Food including Concessional and Food Aid Transactions* (CAC/RCP 20-1979; FAO/WHO microbial risk assessment report (FAO/WHO Microbial safety of lipid-based ready-to-use foods for management of moderate acute malnutrition and severe acute malnutrition; 2016.

## 2. PURPOSE OF THE GUIDELINES

To provide guidance on technical and nutritional aspects of the production of Ready to Use Therapeutic Foods for children from the age of 6 to 59 months with severe acute malnutrition, including

i. Nutritional Composition
ii. Raw Materials and Ingredients
iii. Good Manufacturing Practices
iv. Microbiological and Chemical Contaminant Criteria
v. Methods of Analysis and Sampling
vi. Provisions for Packaging and Labelling
**vii. Recommendations for safe use as a therapeutic food only**
**viii. Recommendations to restrict marketing to avoid spill-over and needless use.**

## 3. SCOPE

The provisions of these guidelines apply to Ready to Use Therapeutic Foods for children from age 6 to 59 months with severe acute malnutrition. Ready-to-Use Supplementary Foods (RUSF), micronutrient supplements[2], processed cereal based foods[3], formulated complementary foods for older infants and young children[4], canned baby foods[5] are not **specifically** covered by these guidelines. **To prevent spill over and inappropriate use, the marketing restrictions recommended in this guideline should apply to all products that target malnourished children. RUTFs are to be used for therapeutic use only and not available on the general market.**

[2)]Guidelines for Vitamin and Mineral Food Supplements (CXG 55-2005)

[3]*Standard for Processed Cereal-Based Foods for Infants and Young Children* (CXS 74-1981)

[4]*Guidelines on Formulated Complementary Foods for Older Infants and Young Children* (CXG 8-1991)

[5]*Standard for Canned Baby Foods* (CXS 73-1981)

## 4. DESCRIPTION

**4.1 Ready-to-Use Therapeutic Foods (RUTF)** are foods for special medical purposes and are high-energy and contain adequate protein and other essential nutrients for the dietary management of children from 6 to 59 months with severe acute malnutrition without medical complications with appetite. These foods should be soft or crushable and should be easy for children to eat without any prior preparation.

**4.2 Severe Acute Malnutrition** is defined by weight for height (or length) less than –3 Z-score of the median WHO growth standards, or by mid upper arm circumference (MUAC)<11.5 cm, or by the presence of bilateral oedema.

## 5. SUITABLE RAW MATERIALS AND INGREDIENTS

**Any decisions regarding the suitability and appropriate composition of RUTF must be based on relevant and convincing evidence of efficacy, which is free from commercial influence.**

RUTF are made of ingredients embedded in a lipid-rich matrix e.g. paste or biscuit, resulting in an energy and nutrient-dense food. The following raw materials, many of which can be sourced locally, are suitable ingredients for the production of RUTF under the specified conditions given below. The formulation of RUTF shall comply with Section 3 of the *Standard for the Labelling of and Claims for Foods for Special Medical Purposes* (CXS 180-1991).

**Ingredients produced from genetically modified organisms shall not be used in the production of RUTFs. Ingredients must be produced and processed to ensure that they are safe and suitable for consumption by this vulnerable population.**

### 5.1 Basic Raw Materials and Ingredients

#### 5.1.1 Milk and other Dairy Products

Milk and other dairy products, **including other animal milk sources,** used in the manufacturing of RUTF must comply with the *Standard for Milk Powders and Cream Powder* (CXS 207-1999) and the *Standard for Whey Powders* (CXS 289-1995), and other Codex milk and milk product standards as well as other guidelines and Codes of Practice recommended by Codex Alimentarius Commission which are relevant to these products. Relevant codes of practice include the *Code of Hygienic Practice for Milk and Milk Products* (CXC 57-2004) ~~and the~~ *Code of Hygienic Practices for Low-Moisture Foods* (CXC 75-2015), **and the Code of Hygienic Code of Practice for Powdered Infant Formula (CAC/RCP 66 – 2008).**

#### 5.1.2 Legumes and Seeds

Legumes and seeds such as ~~**soybeans**~~, lentils, chickpeas, cowpeas, beans, peanut, sesame and other types of legumes and seeds must comply with the relevant Codex Alimentarius texts when used in the manufacturing of RUTF.

**(RATIONALE: The high phytoestrogen content of soybeans makes these unsuitable for the rehabilitation of children with SAM).**

Legumes and **seeds** ~~**pulses**~~ must be appropriately processed to reduce, as much as possible, the anti-nutritional factors normally present, such as phytate, lectins (haemagglutenins), trypsin and chymotrypsin inhibitors.

#### 5.1.3 Fats and Oils

Fats and oils used in the manufacturing of RUTF must comply with the relevant Codex Alimentarius texts. Fats and oils are incorporated as technologically feasible for the purpose of achieving the energy density and providing essential fatty acids. Care must be taken to avoid oxidized fat which will adversely affect nutrition, flavour and shelf life.

Partially Hydrogenated fats and oils should not be used in RUTF.

#### 5.1.4 Cereals

All milled cereals suitable for human consumption may be used provided that they are processed in such a way that the fibre content is reduced, when necessary, and that the effects of anti-nutritional factors such as phytates, tannins or other phenolic materials, lectins, trypsin, and chymotrypsin inhibitors which can lower the protein quality and digestibility, amino acid bioavailability and mineral absorption are removed or reduced, whilst retaining maximum nutrient value.

### 5.1.5 Vitamins and Minerals

**[**Vitamin and mineral forms used must be soluble and easily absorbed by patients with SAM. Children with SAM have low or absent gastric acid which means that they should not be given inorganic salts of minerals that are insoluble or requiring an acid gastric environment for absorption, in order to avoid metabolic acidosis. It is important that RUTF should have a mineral composition that leads to a moderate excess of non metabolisable base. The non-metabolizable base can be approximated by the formula: estimated absorbed millimoles (sodium + potassium + calcium + magnesium) - (phosphorus + chloride.**]**

All added vitamins and minerals must be in accordance with the *Advisory Lists of Nutrient Compounds for use in Foods for Special Dietary Uses Intended for Infants and Young Children* (CXG 10-1979). Examples of vitamin and mineral forms for RUTF formulation can be found in the *WHO Management of severe malnutrition: A manual for physicians and other senior health workers (1999).* **[**The amount of vitamins and minerals added to achieve the target level must be adjusted based on the chemical form and scientific evidence showing adequate stability and bioavailability in the finished product.**]**

### 5.2 Other Ingredients

### 5.2.1 Available Carbohydrates[6]

The palatability of the RUTF **should not be done by** the addition of available carbohydrates. **The addition of permissible sugars** ~~Available carbohydrates~~ must adhere to **the WHO recommended levels of no more than 5 to 10% of total energy (WHO Guideline: Sugars intake for adults and children, Geneva, WHO, 2015).** ~~relevant Codex Alimentarius texts~~.

Honey should not be used in RUTF due to the risk of infant botulism from *Clostridium botulinum*.

[6)]Sucrose, **plant starch**, ~~**maltodextrin**~~, should be the preferred carbohydrates in RUTF. Fructose, glucose and corn syrup as ingredients **should not be used** in RUTF, because of potential adverse effects in SAM children. **Only recommended free sugars** precooked and/or gelatinized starches [gluten-free] by nature ~~may~~ **shall** be added.

### 5.2.2 Food Additives and Flavours

**The use of food additives must be restricted in foods for children with SAM. Children suffering from SAM are immunocompromised and the chemical body burden of additives can exaccerbate their fragile condition.**

**IBFAN is of the opinion that additives and flavours are an added health risk to children with SAM compromised with gut damage and in a food that is fortified with industrial nutrients. Moreover food additives and flavours are used for cosmetic purposes. Therefore IBFAN does not agree that food additives and flavours should be used as ingredients for RUTF.**

**IBFAN notes that many food additives used are for technical and/or appearance or consistency purposes**
**Hence this imposes known and unknown risks for older infants and young children who are fed these products. This may pose an even greater risk for those children suffering from SAM. IBFAN proposes that thickeners such as Guar Gum, Xanthan Gum and Gum Arabic are not necessary and should not be used, nor should mono and di glycerides be on the list.**
**Adverse effects have been reported in children due to additives, such as benzoates, carmine and polysorbates and these should be avoided.**

**IBFAN wishes to note and concurs with the JECFA principle:**
**"Baby foods should be prepared without food additives whenever possible. Where the use of food additives becomes necessary in baby foods, great caution should be exercised regarding both the choice of additive and its level of use." (Annex 3of TRS488):**

[This section will make reference to the *General Standard for Food Additives* (CXS 192-1995)]. [1]

**5.3 The Use of other Matrices in RUTF formulation**

RUTF may be manufactured with formulations different from the one laid down in these guidelines provided that these formulations comply with Section 3 of the *Standard for Labelling of and Claims for Foods for Special Medical Purposes* (CXS 180-1991).

**6. NUTRITIONAL COMPOSITION AND QUALITY FACTORS**

**6.1 Energy**

The energy density of the formulated RUTF should be between 5.2 - to 5.5 kcal per gram. The energy density of RUTF can be achieved during manufacturing by the addition of energy containing ingredients (i.e. fats and oils and/or digestible carbohydrates) and/or processing the basic raw materials and ingredients as indicated in Section 8.

**6.2 Proteins**

Protein should provide 10% - 12% of the total energy. at least 50% of protein is provided by milk products".
**REMOVE BRACKETS**

**Rationale:**

**Several scientific studies have reported that the formulation with ingredients other than milk are less effective in achieving desired recovery rates when compared to the standard, peanut and milk (25%) based formulation."**
**(An equivalence non-blinded cluster randomized controlled trial from Zambia determined that recovery rates of a milk-free soy-maize-sorghum-based RUTF (SMS-RUTF) compared to 25% milk content in standard peanut-based RUTF (P-RUTF) were lower.**
**A randomized, double blind, clinical, quasi-effectiveness trial from Malawi concluded that treating children with SAM with 10% milk (plus Soy) RUTF is less effective when compared to treatment with the standard 25% milk RUTF. Recovery among children receiving 25% milk RUTF was greater than children receiving 10% milk RUTF, 64% compared with 57% after 4 weeks, and 84% compared with 81% after 8 weeks. Children receiving 25% milk RUTF also had higher rates of weight and height gain compared with children receiving 10% milk RUTF.)**

**6.3 Lipids**

Lipids should provide 45% to 60% of the total energy.

The level of linoleic acid should not be less than 333 mg per 100 kcal. The level of alpha-linolenic acid should not be less than 33 mg/100kcal. The level of linoleic acid should ensure a ratio between linoleic acid and alpha-linolenic acid of between 5:1 and 15:1.

**WHO recommends that total fat should not exceed 30% of total energy intake. A product deriving high energy from fats is not scientifically sound and is not a recommended level for the diet of young children. Accordingly, this guideline should not aim to permit the use of fats as a technological fix but rather keep negative health implications of high fat intake a priority. However, if the WHO recommendation of keeping fat levels below 30% of total energy is not observed, the label should include text stating, " This is a high fat product".**

**6.4 Please see Annex "Nutrition Composition for RUTF".**

**7. CONTAMINANTS**

[1] See recommendation 4 in CX/NFSDU 18/40/6

[It is recommended that the products covered by the provisions of these guidelines comply with the *General Standard for Contaminants and Toxins in Food and Feed* (CXS 193-1995), Maximum Residue Limits (MRLs) and Risk Management Recommendations (RMRs) for Residues of Veterinary Drugs in Foods (CAC/MRL 2-2015) and Codex Maximum Residue Limits for Pesticides].

**The maximum level of permissible aflatoxin RUTF should be 5 ppb (µg/kg). In a report by UNICEF (2013-14), of all the samples tested, 99.5% had aflatoxin of less than 5ppb µg/kg.**

**(NOTE: Aflatoxin is a well-documented carcinogen and should be limited as much as possible for this vulnerable population.)**

**[Other Contaminants**

The product should not contain contaminants or other undesirable substances (e.g. biologically active substances, metal fragments) in amounts which may represent a risk to the health of children. The product covered by the provisions of these Guidelines shall comply with those maximum residue limits and maximum levels established by the Codex Alimentarius Commission]. [~~A maximum of 10 ppb (µg/kg) for aflatoxin is allowed in the RUTF products.~~]

**8. PROCESSING TECHNOLOGIES**

[In addition to the practices described below, Good Hygiene Practices (*General principles of food hygiene* (CXC 1-1969)) should be implemented to avoid cross contamination during the packing and storage of raw materials.]

**8.1 Preliminary Treatment of Raw Materials**

Cereals, legumes, pulses and oilseeds should first be treated to obtain wholesome and clean raw materials of good quality. Such treatments include, but are not limited to:

- **Cleaning or washing**: to eliminate dirt, damaged grains, foreign grains and noxious seeds, insects and insect excreta and any adhering material.
- **Dehulling**: when necessary, pulses, legumes, oilseeds and certain cereals such as oats, barley, sorghum, millet and teff may be dehulled as completely as is feasible to reduce the fibre content to acceptable levels and to decrease, or if possible, to eliminate phytates, tannins and other phenolic materials, trypsin and chymotrypsin inhibitors which can lower the protein digestibility and amino acid bioavailability and mineral absorption**.**
- **Degermination:** where necessary and appropriate, degermination of wheat, corn, soy and other crops should be considered in order to reduce the phytate content.

**8.2 Milling**

- Milling or grinding of suitable raw materials should be carried out in such a way as to minimize the loss of nutritional value and to avoid undesirable changes in the technological properties of the ingredients.
- Dry raw materials may be milled together, if technologically feasible, or mixed after milling or grinding.
- Formulations containing milled cereals, legumes, pulses and/or oilseeds that have not been otherwise processed require adequate boiling to gelatinize the starch portions and/or eliminate anti-nutritional factors present in cereals, legumes and pulses. Boiling improves the digestibility and absorption of nutrients.
- The bulkiness of foods from food formulations containing dry ingredients obtained by milling of the raw materials can be reduced by adding, during the formulation, adequate amounts of enzymes such as alpha-amylase which, during the slow heating to boiling, predigest partially the starch and reduce the amount of water needed for the preparation of the food.

**8.3 Toasting**

- Toasting (dry heating) enhances the flavour and the taste of the food through dextrinization of starch. It also improves digestibility and contributes to reducing the bulkiness of the formulated food. Moreover, it reduces microorganisms and enzyme activity and destroys insects, thus improving keeping qualities.

- Protein damage due to the Maillard reaction may occur in the presence of reducing carbohydrates. The toasting process should therefore be carefully controlled.
- Pulses as well as oilseeds such as soya beans, groundnuts and sesame seeds can be toasted as whole grains directly or after soaking.
- Toasted raw materials can be milled or ground for use as ingredients.
- [The use of appropriate enzymes may be considered to decrease anti-nutrients in ingredients.]

**8.4 Sprouting, Malting and Fermentation**

- Cereals and pulses can be induced to germinate by soaking or humidifying. It is necessary, however, to ensure that growth of mycotoxin producing microorganisms does not occur. The action of natural amylases contained in the grains results in the pre-digestion of the starchy portion of the grain (dextrinization) thus reducing the bulk of the food when prepared for feeding and, ultimately, increasing the nutrient density of the food. Sprouting**,** malting and fermentation can induce hydrolysis of phytates and decrease its inhibitory effect on mineral absorption, and may improve B vitamin content.
- During the germination process, the seed coat of the grain splits and can be removed by washing. The malted raw material is milled or ground after drying.

**8.5 Other Processing Technologies**

Whenever feasible, RUTF 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 or their raw materials include both thermal (e.g. roasting, steam treatment followed by a drying step) and non-thermal (e.g. antimicrobial fumigation) control measures. [*Guidelines for the Validation of Food Safety Control Measures* (CXG 69-2008) and *Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)* (CXG 63-2007) should be adhered to.]

**9. MANUFACTURING PRACTICES AND GOOD HYGIENE PRACTICES**

It is recommended that the products covered by the provisions of these guidelines be prepared and handled in accordance with the appropriate sections of the *General Principles of Food Hygiene* (CXC 1-1969), and *Code of Hygienic Practice for Low-Moisture Foods* (CXC 75-2015).

The product should comply with any microbiological criteria established in accordance with the *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21-1997).

The ingredients and final product should be prepared, packed and held under sanitary conditions and should comply with relevant Codex texts

**10. METHODS OF ANALYSIS AND SAMPLING**

It is recommended that methods of analysis and sampling of RUTF be in accordance with the *Recommended Methods of Analysis and Sampling* (CXS 234-1999), *General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995), *The Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21-1997), *Code of Hygienic Practice for Low Moisture Foods* (CXC 75-2015), and other relevant Codex Alimentarius texts. When needed, specific methods of analysis should be developed in accordance with appropriate *Guidelines on Measurement Uncertainty* (CXG 54-2004), *Protocol for the Design, Conduct and Interpretation of Method Performance Studies* (CXG 64-1995), and Harmonized IUPAC.

**11. PACKAGING**

It is recommended that RUTF be packaged in such a way to safeguard the hygienic and other qualities including nutritional properties of the food for the duration of its defined shelf-life.

The packaging materials shall be made only of substances which are safe and suitable for their intended uses. Where the Codex Alimentarius Commission has established a standard for any such substance used as packaging materials, that standard shall apply.

**12. LABELLING**

It is recommended that the labelling of RUTF for children from 6 to 59 months be in accordance with the *Standard for the Labelling of and Claims for Foods for Special Medical Purposes* (CXS 180-991), ~~*Codex General Standard for the Labelling of Pre-packaged Foods* (CODEX STAN 1-1985)~~, the *General Standard for the Labelling of and Claims for Pre-packaged Foods for Special Dietary Uses* (CXS 146-1985), ***Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997)** and *Guidelines on Nutrition Labelling* (CXG 2- 1985).

**The Name of the Food**

The name of the food to be declared on the label shall indicate that the food is a Ready-To-Use Therapeutic Food for Children from 6 to 59 months. The appropriate designation indicating the true nature of the food should be in accordance with national legislation. The age from which the product is recommended for use shall appear in close proximity to the name of the food.

**List of Ingredients**

The list of ingredients shall be declared in accordance with Section 4.2 of the *General Standard for the Labelling of Prepackaged Foods (*CXS 1 -1985).

**Additional Mandatory Labelling Requirements**

**The following statements shall appear on the label of RUTF:**

- "USE UNDER MEDICAL SUPERVISION" shall appear on the label in bold letters in an area separated from the written, printed, or graphic information.
- "For the dietary management of severe acute malnutrition" shall appear on the label.
- A prominent warning statement consisting of an explanatory statement in bold letters indicating that RUTF are for special medical purposes and may pose a health hazard when consumed by individuals who do not have the disease(s), disorder(s) or medical condition(s) for which the food is intended.
- The product is not to be used for parenteral, rectal or Nasogastric Tube (NG tube) administration.
- A statement indicating whether the product is or is not intended as the sole source of nutrition.
- A statement indicating that RUTF are not breastmilk substitutes and shall not be presented as such.
- Exclusive breastfeeding is recommended for the first 6 months of life, and continued breastfeeding is recommended for at least 24 months. **REMOVE BRACKETS**
- **The labeling of these products should carry no nutrition or health or other promotional claims nor have any idealising text or pictures or representation that might suggest the use for infants under the age of 6 months (including references to milestones and stages)**
- **The product must not convey an endorsement or anything that may be construed as an endorsement by a professional or other body, unless relevant national, regional or international regulatory authorities have specifically approved this.**

**Instructions for use**

- The label should indicate clearly from which age the product is recommended for use. This age shall not be less than six months for any product.
- Feeding instructions shall be given; preferably accompanied by graphical presentations. **Feeding instructions must indicate the daily quantities to be used at the appropriate ages and as a complement to breastfeeding. Quantities recommended must not undermine continued breastfeeding.**
- The time in which the product should be consumed after opening should be clearly indicated.
- **The risk of inadequate consumption, dilution or portioning should be clearly declared at the label product.**

**Please note that comments can be made for each of the nutrients. When revising or commenting on a value in the table, please specify which value (e.g. Minimum, Maximum, etc.) the comment is referring to and please include the unit (g/100kcal, etc.) as well.**

**IBFAN Comment:**
**Caution should be taken to prevent excess consumption of industrially produced, non-food based micronutrients. Children suffering from SAM have decreased ability to absorb excess micronutrients as a result of gut damage and the use of industrial micronutrients can exacerbate gut damage. Studies have documented a negative impact on the gut microbiome such as the increased growth of pathogens such as *Escherichia coli.***

**ANNEX**

**Table: Nutritional Composition for RUTF**

| **Energy** | | | |
|---|---|---|---|
| **Unit** | **Minimum** | **Maximum** | **GUL** |
| kcal/100g | 520 | 550 | - |
| **Protein** | | | |
| **Unit** | **Minimum** | **Maximum** | **GUL** |
| g/100g | 12.8 | 16.2 | - |
| g/100kcal | 2.3 | 3.1 | - |
| **Lipids** | | | |
| **Unit** | **Minimum** | **Maximum** | **GUL** |
| g/100g | 26 | 37 | - |
| g/100kcal | 5 | 6.7 | - |
| **n-6 Fatty acids** | | | |
| **Unit** | **Minimum** | **Maximum** | **GUL** |
| g/100g | 3 | 10 | - |
| mg/100kcal | 576.9 | 1818.2 | - |
| **n-3 Fatty acids** | | | |
| **Unit** | **Minimum** | **Maximum** | **GUL** |
| g/100g | 0.3 | 2.5 | - |
| mg/100kcal | 57.69 | 454.5 | - |
| **Vitamin A** | | | |
| **Unit** | **Minimum** | **Maximum** | **GUL** |

| | | | |
|---|---|---|---|
| mg RE/100g | 0.8 | [1.1] OR [1.2] | - |
| mg/ RE/100kcal | 0.15 | [0.2] OR [0.22] | - |
| [2]µg RE/100kcal | 150 | [200] OR [220] | - |

[2] 1µg RE = 3.33 IU Vitamin A = 1 µg trans retinol. Retinol contents shall be provided by preformed retinol, while any contents of carotenoids should not be included in the calculation and declaration of vitamin A activity.

**Vitamin D**

| Unit | Minimum | Maximum | GUL |
|---|---|---|---|
| [3] µg/100 g | 15 | [20] OR [22] | [30] |
| [3] µg100 kcal | 2.7 | [3.6] OR [4] | - |

[3] 1 µg cholecalciferol = 40 IU vitamin D

**Vitamin E**

| Unit | Minimum | Maximum | GUL |
|---|---|---|---|
| [4] mg/100 g | 20 | - | - |
| [4] mg α-TE /100 kcal | 4 | - | - |

[4] 1 mg α-tocopherol = 1 mg RRR-α-tocopherol (d-α-tocopherol)

[4]1 mg RRR-α-tocopherol =2.00 mg *all-rac*-α-tocopherol (di- α-tocopherol)

**Vitamin K**

| Unit | Minimum | Maximum | GUL |
|---|---|---|---|
| µg/100 g | 15 | 30 | - |
| µg/100 kcal | 2.9 | 5.5 | - |

**Vitamin B1**

| Unit | Minimum | Maximum | GUL |
|---|---|---|---|
| mg/100 g | 0.5 | - | - |
| mg/100 kcal | 0.1 | - | - |

**Vitamin B2**

| Unit | Minimum | Maximum | GUL |
|---|---|---|---|
| mg/100 g | 1.6 | - | - |
| mg/100 kcal | 0.3 | - | - |

**Vitamin C**

| Unit | Minimum | Maximum | GUL |
|---|---|---|---|
| mg/100 g | 50 | - | - |
| mg/100 kcal | 9.6 | - | - |

**Vitamin B6**

| Unit | Minimum | Maximum | GUL |
|---|---|---|---|
| mg/100 g | 0.6 | - | - |
| mg/100 kcal | 0.12 | - | - |

**Vitamin B12**

| Unit | Minimum | Maximum | GUL |
|---|---|---|---|
| µg/100 g | 1.6 | - | - |
| µg/100 kcal | 0.3 | - | - |

**Folic Acid**

| Unit | Minimum | Maximum | GUL |
|---|---|---|---|
| [5] µg/100 g | 200 | - | - |
| [5] µg/100 kcal | 38.5 | - | - |

[5] 1 µg of folic acid = 1.7 µg of Dietary Folate Equivalents (DFE)

**Niacin**

| Unit | Minimum | Maximum | GUL |
|---|---|---|---|
| mg/100 g | 5 | - | - |
| mg/100 kcal | 0.96 | - | - |

**Pantothenic Acid**

| Unit | Minimum | Maximum | GUL |
|---|---|---|---|
| mg/100 g | 3 | - | - |
| mg/100 kcal | 0.6 | - | - |

**Biotin**

| Unit | Minimum | Maximum | GUL |
|---|---|---|---|
| µg/100 g | 60 | - | - |
| µg/100 kcal | 11.5 | - | - |

**Sodium**

| Unit | Minimum | Maximum | GUL |
|---|---|---|---|
| mg/100 g | - | 290 | - |
| mg/100 kcal | - | 53 | - |

**Potassium**

| Unit | Minimum | Maximum | GUL |
|---|---|---|---|
| mg/100 g | 1,100 | 1,400 | - |
| mg/100 kcal | 212 | 255 | - |

**Calcium**

| Unit | Minimum | Maximum | GUL |
|---|---|---|---|
| mg/100 g | 300 | [600] or [785] | - |
| mg/100 kcal | 58 | [109] or [143] | - |

**Phosphorus**

| Unit | Minimum | Maximum | GUL |
|---|---|---|---|
| mg/100 g | 300 | [600] or [785] | - |
| mg/100 kcal | 58 | [109] or [143] | - |

**Magnesium**

| Unit | Minimum | Maximum | GUL |
|---|---|---|---|
| mg/100 g | 80 | [140] or [235] | - |
| mg/100 kcal | 15.4 | [26] or [43] | - |

**Iron**

| Unit | Minimum | Maximum | GUL |
|---|---|---|---|
| mg/100 g | 10 | 14 | - |
| mg/100 kcal | 1.9 | 2.6 | - |

**Zinc**

| Unit | Minimum | Maximum | GUL |
|---|---|---|---|
| mg/100 g | 11 | 14 | - |
| mg/100 kcal | 2 | 2.6 | - |

**Copper**

| Unit | Minimum | Maximum | GUL |
|---|---|---|---|
| mg/100 g | 1.4 | 1.8 | - |
| mg/100 kcal | 0.27 | 0.33 | - |

**Selenium**

| Unit | Minimum | Maximum | GUL |
|---|---|---|---|
| µg /100 g | 20 | 40 | - |
| µg /100 kcal | 4 | 7 | - |

**Iodine**

| Unit | Minimum | Maximum | GUL |
|---|---|---|---|
| µg /100 g | 70 | 140 | - |
| µg /100 kcal | 13.46 | 25.5 | - |

**Moisture Content**

| Unit | Minimum | Maximum | GUL |
|---|---|---|---|
| Percentage(%) | - | 2.5 | - |