IBFAN COMMENT

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

GENERAL COMMENTS

IBFAN considers that the Guidelines are not ready for adoption at Step 6.

- **IBFAN has always maintained that there is no need for a Codex Guideline for RUTF – and that the risks of having one outweigh the benefits. If a Guideline is necessary then it should be produced by appropriate bodies such as WHO and UNICEF, whose remit is solely the pursuit of public health.**
- **While Codex has an important role in ensuring that all foods and commodities are as safe and nutrition as possible, it is not the appropriate forum for discussions about vulnerable malnourished children. Decisions at Codex invariably encourage increased global trade and are taken on the basis on politically and commercially influenced consensus, not on sound credible evidence. The Guidelines risks subverting "the UN Strategy to build capacity within countries to produce RUTF where needed, while ensuring appropriate use".**
- **The Guidelines fail to include safeguards to prevent the marketing of RUTF products and in so doing leave the door open for commercial exploitation that increases the risk of unnecessary and inappropriate use.**
- **The Guidelines may trigger diversion of public funds away from support for sustainable solutions such as breastfeeding and locally sourced, culturally appropriate, bio-diverse family foods.**
- **The Codex Standard covering Formulas for Special Medical Purposes (CODEX STAN 72 –1981) is not a sufficient safeguard, because FSMPs are designed to be sold on the open market. Categorisation as an FSMP has lead to an increase in inappropriate marketing of these products.**
- **The Codex process is not adequately safeguarded from conflicts of interest, therefore undue influence from manufacturers and distributors of the products under discussion is likely to subvert the public health purpose.**
- **The Guidelines are likely to be used by manufacturers and distributors to put pressure on governments to accept imports of products that may not be needed or wanted.**

IBFAN SPECIFIC COMMENTS AND ADDITIONS IN RED:

[1. PREAMBLE

Children affected by severe acute malnutrition (SAM) need safe, palatable foods with a high energy**, high nutrient** content ~~and adequate amounts of vitamins, minerals and other nutrients~~. Children with SAM need efficacious and timely **treatment** and RUTF is one of the options for the dietary **treatment** of children with uncomplicated SAM. **However, it is critical that it's 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 may also be used for the feeding of malnourished older infants and young children in emergency situations.**

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,** and recommendations by WHO, UNICEF and WFP[1]**. Governments and other users should ensure adequate provisions are made 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 mainstream 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) A Joint Statement 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. *Community-Based Management of Severe Acute Malnutrition*; A Joint Statement by the World Health Organization and the United Nations Children's Fund. 2009. *Child growth standards and the identification of severe acute malnutrition in infants and children*, Geneva: World Health Organization; World Health Organisation. 2013. Guideline: *Updates on the management of severe acute malnutrition in infants and children,* Geneva: World Health Organization; World Health Organisation. 2003. *Global Strategy for Infant and Young Child Feeding*, Geneva: World Health Organization; World Health Organisation. [1981. *International code of marketing of breast-milk substitutes,* Geneva: World Health Organization 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* (CXC 20-1979); Food and Agriculture Organisation and World Health Organisation. 2016. FAO/WHO Microbial safety of lipid-based ready-to-use foods for management of moderate acute malnutrition and severe acute malnutrition, Rome: Food and Agriculture Organisation.]

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. Appropriate use of these products for the treatment SAM
vii. Provisions for Packaging and Labelling

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 without medical complications. 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 covered by these guidelines.

[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 **in conjunction with supports to sustain breastfeeding for the recommended two years or beyond.** 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

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. Any 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) including the specification that their use should have been demonstrated, by scientific evidence, to be safe and beneficial in meeting the nutritional requirements of the persons for whom they are intended.

5.1 Basic Raw Materials and Ingredients

5.1.1 Milk and other Dairy Products

Milk and other dairy products 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).

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.

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

Field beans or Faba beans (Viciafaba L) should not be used in the formulation of RUTF because of the danger of favism.

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, Roots and Tubers and their derived Products

All milled cereals, roots and tubers and their derived products 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-metabolizable buffer base. The non-metabolizable buffer 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 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, interaction, and impaired absorption with other nutrients and non-nutrients and scientific evidence showing adequate stability and bioavailability in the finished product.

5.2 Other Ingredients

5.2.1 Carbohydrates

Carbohydrates are used to achieve energy requirements in balance with proteins and lipids. Plant starch, lactose, maltodextrin and sucrose **are** the preferred carbohydrates in RUTF. Free sugars should be limited and should not exceed ~~20%~~ **10%** of total energy. Only precooked and/or gelatinized starches may be added. Glucose and fructose should not be used. Carbohydrates must adhere to the relevant Codex Alimentarius texts.

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

5.2.2 Food Additives

The only food additives permitted for this vulnerable population, should be those necessary for the safety of the product. Food Additives lasted in Table A of the guideline. If it is necessary for food safety requirements they must not exceed the specified maximum use levels.

NOTE: IBFAN is not convinced that the additives listed in Table meet this requirement and adds the following provisions:

Flavourings, artificial or natural are not permitted.

Genetically modified ingredients and those produced by bioengineering are not permitted.

Only the food additives listed in this Section or in the *Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children* (CXG 10-1979) may be present in the foods described in section 4.1 of this Guideline. Other than by direct addition, an additive may be present in RUTF as a result of carry-over from a raw material or other ingredient (including food additive) used to produce the food, subject to the following conditions:

a) The additive is acceptable for use in the raw materials or other ingredients (including food additives) according to the *General Standard for Food Additives* (CXS 192-1995)
b) The amount of the additive in the raw materials or other ingredients (including food additives) does not exceed the maximum use level specified in the General Standard for Food Additives (CXS 192-1995); and
c) The food into which the additive is carried over does not contain the additive in greater quantity than would be introduced by the use of the raw materials or ingredients under proper technological conditions or good manufacturing practice, consistent with the provisions on carry-over in the Preamble of the General Standard for Food Additives (CXS 192-1995).

Table A: Food Additives in RUTF Formulation

Functional Class	Food Additive	International Numbering System (INS)	Maximum Use Level
Emulsifier	Mono & diglycerides of fatty acids	471	4000 mg/kg
	Citric and fatty acid esters of glycerol	472c	9000 mg/kg
	Lecithin	322(i)	5000 mg/kg

Antioxidants	Ascorbyl palmitate	304	10 mg/kg
	Tocopherol concentrate, mixed	307b	10 mg/kg
	Ascorbic acid, L	300	GMP
Acidity regulator	Citric acid	330	GMP
Packaging gas	Nitrogen	941	GMP
	Carbon dioxide	290	GMP
Carrier	Silicon dioxide, amorphous	551	10 mg/kg

6. NUTRITIONAL COMPOSITION AND QUALITY FACTORS

The nutritional composition of RUTF shall comply with the requirements set out in the table in the Annex. Furthermore, the following requirements shall be complied with.

6.1 Energy

The energy density of the formulated RUTF should be between 5.2 - 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 shall provide 10% to 12% of the total energy.

Protein quality should be determined using Protein Digestibility Corrected Amino Acid Score (PDCAAS), calculated according to the reference amino acid requirement and scoring patterns related to catch up growth of 10g/kg/day in the target population for RUTF which is children with SAM aged 6 to 59 months.

For all RUTF formulations, the PDCAAS shall not be less than 90. The PDAAS shall be calculated using appropriate digestibility values and the reference amino acid pattern as stipulated in the *Report of the FAO Expert Working Group Protein quality assessment in follow-up formula for young children and ready to use therapeutic foods* (2018).

High quality protein will be achieved with RUTF formulations containing a minimum of 50% protein from milk products.

In formulations with lower PDAAS scores, the quality and/or quantity of protein should be adjusted to achieve the desired value. The addition of limiting amino acids, solely in the L-form, shall be permitted only in amounts necessary to improve the protein quality of the RUTF.

6.3 Lipids

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

[The level of linoleic acid should not be less than 333mg ~~316~~ mg per 100 kcal and shall not be more than 1110 mg per 100 kcal. The level of alpha-linolenic acid should not be less than 33 mg/100kcal.]

6.4 Vitamins **and Minerals**

RUTF should contain the vitamins and minerals presented in the annex: Nutritional Composition of RUTF.. RUTF should comply with the minimum and maximum or guidance upper levels in the annex.

6.5 Water activity

RUTF is a low moisture food with a water activity of 0.6 or below.

7. CONTAMINANTS

It is recommended that the products covered by the provisions of these guidelines and the ingredients used in such products 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 (CXM 2-2015) and Codex Maximum Residue Limits for Pesticides.

Further guidance is given by codex Codes of practice and should be adhered to.

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. **Aflatoxin levels should be kept to below 10ppb,**

8. PROCESSING TECHNOLOGIES

Processing technologies used for RUTF and their ingredients shall be validated to prove that they do not alter the nutritional value of RUTF and that they allow the reduction of anti-nutritive factors. Milling or grinding, roasting, toasting are examples of processing technologies that can be used on ingredients.

Any technologies used should take into consideration the target group and any impact on the integrity of the nutrient content of the products. In addition to the practices described above, Good Hygiene Practices should be implemented for manufacturing of RUTF, according to the *General Principles of Food Hygiene* (CXC 1-1969) and *Code of Hygienic Practices for Low Moisture Foods* (CXC 75-2015) to avoid cross contamination during the storage of raw materials and the manufacturing process.

RUTF and/or their raw materials should be treated with a validated microbial reduction treatment in order to inactivate pathogens such as *Salmonella*, noting that some pathogens have increased heat resistance characteristics at reduced water activities in food matrices. Commonly used microbial reduction treatments that could be applied to RUTF and/or their raw materials include both thermal and non-thermal control measures.

For additional information on validation of control measures, refer to the *Guidelines for the Validation of Food Safety Control Measures* (CXG 69-2008). Additionally, refer to the *Principles and Guidelines for the Conduct of Microbiological Risk Management* (MRM) (CXG 63-2007).

9. GOOD 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), and other relevant Codex texts.

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).

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

IBFAN proposes the following labelling provisions to ensure safe use of RUTF for the treatment of SAM:

It is recommended that the labelling of RUTF for children from 6 to 59 months with SAM be in accordance with the *Standard for the Labelling of and Claims for Foods for Special Medical Purposes* (CXS 180-1991), ~~and~~ the *General Standard for the Labelling and Claims for Pre-packaged foods for Special Dietary Uses* (CSX 146-1985), ~~an~~d *Guidelines on Nutrition Labelling* (CSG 2-1985) a**nd the Guidelines for Use of Nutrition and Health Claims (CXG 23-1997) that include a prohibition on the use of nutrition and health claims for foods for infants and young children.**

There should also be a prominent WARNING that these products must only be used for the treatment of SAM and strictly under medical supervision and a STATEMENT that potable drinking water must be available for children receiving RUTF treatment

12.1 The Name of the Food

The name of the food to be declares on the label shall indicate that the food is a Ready-To-Use Therapeutic Food for Children from 6 to 59 months with SAM. 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.

12.2 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 Food*s (CSX 1-1985)

12.3 Additional Mandatory Labelling Requirements

Provisions of the section 4.4 and 4.5 of the *Standard for the labelling of and Claims for Foods for Special Medical Purposes* (CSX 180-1991) shall apply. **There should be no nutrition or health claims for these products. Great care must be taken that 4.5.3 *"A statement of the rationale for the use of the product and a description of the properties or characteristics that make it useful",* is not presented as a nutrition or health claim.**

12.4 The following additional statements shall appear on the label of RUT:

The product is not to be used for Nasogastric Tube (NG tube) administration.

The product shall be used in conjunction with breastfeeding.

Exclusive breastfeeding is recommended for the first six months of life, and continued breastfeeding is recommended for up to two years or beyond.

IBFAN proposes the following additional statement to appear on the label:

The product is to be used for exclusively for the treatment of SAM.

- **12.5 Instructions for use**
- The label should indicate clearly from which age the product is recommended for use. This age shall not be less than six months for any product.
- Feeding instructions shall be given; preferably accompanied by geographical presentations.
- The time within which the product should be consumed after opening should be clearly indicated.

IBFAN proposes the following additional instruction for safe and appropriate use:

- **Storage and packaging instructions to minimize spoilage and contamination.**
- **Serving sizes must be indicated for the ages of older infants and young children in 3-month incremental stages to ensure that breastmilk intakes are not compromised.**

ANNEX

Table: Nutritional Composition of RUTF

Energy			
Unit	**Minimum**	**Maximum**	**GUL**
g/100g	5.2	5.5	-
g/100 kcal/100g	520	550	-
Protein			
Unit	**Minimum**	**Maximum**	**GUL**
g/100g			
g/100kcal	2.5	3.0	-
Lipids			
Unit	**Minimum**	**Maximum**	**GUL**
g/100kcal	5	7	-
n-6 Fatty acids			
Unit	**Minimum**	**Maximum**	**GUL**
mg/100kcal	330	[1111] or [780]	-
n-3 Fatty acids			
Unit	**Minimum**	**Maximum**	**GUL**
mg/100kcal	[33] or [110]	280	-
Vitamin A			
Unit	**Minimum**	**Maximum**	**GUL**
[2]µg RE/100kcal	145	308	-

[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] µg100 kcal	2.7	4.2	-

[3] 1 µg calciferol = 40 IU vitamin D.

Two forms of Vitamin D allowed in RUTF formulation are cholecalciferol (D3) and ergocalciferol (D2).

Vitamin E

Unit	Minimum	Maximum	GUL
[4] mg α-TE /100 kcal	3.6	-	-

[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 (dl- α-tocopherol)

Vitamin K

Unit	Minimum	Maximum	GUL
µg/100 kcal	2.7	6	-

Vitamin B1

Unit	Minimum	Maximum	GUL
mg/100 kcal	0.09	-	-

Vitamin B2

Unit	Minimum	Maximum	GUL
mg/100 kcal	0.29	-	-

Vitamin C

Unit	Minimum	Maximum	GUL
mg/100 kcal	9	-	-

Vitamin B6

Unit	Minimum	Maximum	GUL
mg/100 kcal	0.11	-	-

Vitamin B12

Unit	Minimum	Maximum	GUL
µg/100 kcal	0.29	-	-

Folic Acid

Unit	Minimum	Maximum	GUL
[5] µg/100 kcal	36	-	-

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

Niacin

Unit	Minimum	Maximum	GUL
mg/100 kcal	0.91	-	-

Pantothenic Acid

Unit	Minimum	Maximum	GUL
mg/100 kcal	0.55	-	-

Biotin

Unit	Minimum	Maximum	GUL
µg/100 kcal	11	-	-

Minerals

Sodium

Unit	Minimum	Maximum	GUL
mg/100 kcal	-	56	-

Potassium

Unit	Minimum	Maximum	GUL
mg/100 kcal	200	308	-

Calcium

Unit	Minimum	Maximum	GUL
mg/100 kcal	55	151	-

Phosphorus

Unit	Minimum	Maximum	GUL
mg/100 kcal	55	151	-

Magnesium

Unit	Minimum	Maximum	GUL
mg/100 kcal	[15] or [30]	[45] or [90]	-

Iron

Unit	Minimum	Maximum	GUL
mg/100 kcal	1.8	2.7	-

Zinc

Unit	Minimum	Maximum	GUL
mg/100 kcal	2	2.7	-

Copper

Unit	Minimum	Maximum	GUL
mg/100 kcal	0.25	0.35	-

Selenium

Unit	Minimum	Maximum	GUL
µg /100 kcal	3.6	8	-

Iodine

Unit	Minimum	Maximum	GUL
µg /100 kcal	13	27	-