IACFO comment

PROPOSED DRAFT GUIDELINES FOR READY-TO-USE THERAPEUTIC FOODS CX/NFSDU 17/39/7 at Step 3

IACFO supports IBFAN's comments on this tops and thanks South Africa, Senegal and Uganda for their work on this agenda item

General Comments:

- IACFO and IBFAN are 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 or 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, 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 IACFO and IBFAN are 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. During the 2015 CCNFSDU session, the Chair suggested that conditions relating to marketing could not be addressed by Codex (Para 82, REP16/NFSDU). This issue needs to be clarified and addressed urgently.

- 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. The

Codex Standard covering Formulas for Special Medical Purposes (FSMP)(CODEX STAN 72 – 1981**) is an inadequate safeguard for vulnerable children. Indeed the adoption of the Standard** has led to increased promotion and, growth in the FSMP market, with subsequent inappropriate use. RUTF are 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 was among the reasons UNICEF's proposal was rejected in the 35th CCNFSDU session in Bali. The situation has not changed and there continues to be a serious lack of such evidence.

IACFO and IBFAN do not see the need for creating a Codex instrument for products that are intended for therapeutic use in the management of SAM. Increased marketing will lead to increased use of these products and the replacement of locally sourced, culturally appropriate and bio-diverse foods. If there is to be a Codex instrument relating to RUTF it must have adequate safeguards to mitigate the risks of needless use and misuse.

Recommendation 1

Preamble

The preamble is improved from previous versions, referring to the need for prevention and several important safeguards. However it still fails to address key concerns.

1. Para 1 While it is true that one of the objectives of Codex is to protect health, and that the Code of Ethics contains important safeguards, the preamble fails to mention that another evident aim of Codex is to facilitate global trade. The last Paragraph of the Preamble is an admission of this purpose and states: '***These guidelines can also be used, if applicable, by governments in case of international trade disputes.'***

2. The Preamble rightly mentions the importance of the International Code and Resolutions and the Codex Code of Ethics in International Trade in Food including Concessional and Food Aid. It fails to include a specific statement that the products must not be placed on the market and not promoted in any way. This is essential.
3. Para 2 claims that RUTF are a critical part of the treatment of SAM – this ignores the use of energy dense local family foods and promotes a single product based solution.

Rationale: As mentioned above, products intended for infant and young child feeding and that are legally allowed to be on open sale, require stringent marketing restrictions in order to protect breastfeeding, complementary feeding and child health from commercial influence. Since 1981 the WHO has recommended that the marketing of all such products are covered by the International Code of Marketing of Breastmilk Substitutes and subsequent relevant WHA Resolutions, and not should not be promoted. The Code and Resolutions are also highlighted in the Codex Code of Ethics.

RUTF are a different matter in that they are intended for therapeutic use only. In view of the risks of misuse they should not be on open sale in retail outlets. For this reason the International Code and Resolutions, while important safeguards, do not provide sufficient safeguards. The Codex Standard covering Formulas for Special Medical Purposes (FSMP) (CODEX STAN 72 – 1981) is also inadequate. Although FSMPs are intended for use only in very specific conditions, the existing controls are far from adequate and inappropriate marketing of these products has continued regardless with widespread misuse use of these products.

Rather than make an unqualified claim that RUTF is a 'critical part of treatment' of SAM, the Preamble must acknowledge that current scientific evidence does not demonstrate that RUTF products are better than culturally appropriate energy dense family foods for the community management of SAM and the support of sustained breastfeeding. National Authorities must base any decisions to provide food products on sound independent evidence that meets WHO's definition of scientific substantiation. *'Relevant convincing / generally accepted scientific evidence or the comparable*

Investing in prevention of SAM through sustainable measures and interventions is crucial. In addition to access to nutritious and appropriate foods, a full package of treatment and care is required for sustained rehabilitation of malnourished children and the prevention of recurrence. These include effective promotion **and support** of exclusive breastfeeding for the first six months of a child´s life combined with continued breastfeeding to 24 months and beyond; nutrition education; the treatment of infections; support for maternal care; prevention of early child bearing; the strengthening of health systems; the improvement of water and sanitation systems; and improved access to health care. Thus, preventive programmes have an immense job to do in the context of poverty, and in the meantime children who already are suffering from SAM need to receive appropriate treatment.

The Statement in Para 2 of the Preamble should be altered as follows:
"Children with SAM need timely and appropriate treatment **DELETE***: ~~and RUTF is a critical part of the treatment.~~ RUTF are high energy, fortified, ready-to-eat foods ~~for special medical purposes suitable~~ for that can – if considered appropriate and under strict conditions – be used for the dietary management of children with SAM.* **INSERT***:* Energy dense home-prepared family foods are as effective as RUTF for the treatment of uncomplicated SAM.
RUTF are primarily intended for children with uncomplicated SAM from 6-59 months. Although RUTF are 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."

RATIONALE: The statement as proposed in the Preamble is misleading. The attached briefing includes evidence that energy dense home-prepared family foods can be as effective as RUTF for the treatment of uncomplicated SAM. The use of RUTF is a market driven intervention, which can provide energy with added nutrients, however it is only one option, that is costly, not culturally appropriate, not community based, not bio-diverse, encourages dependency on imported products and is not sustainable.

The second part of Para 4 should be changed as follows:

"These guidelines have been prepared for the purpose of providing an agreed upon approach to the requirements which underpin the production of, and the labelling **DELETE** ~~and claims for~~, **INSERT: OF** RUTF.

The guidelines are intended to-**DELETE**~~: facilitate the harmonization of requirements for RUTF at the international level and may~~ provide assistance to governments wishing to establish national regulations in this area.

DELETE: ~~**The guidelines are also intended for use as an instrument designed to avoid or reduce 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 can also be used, if applicable, by governments in case of international trade disputes. Governments and other users should ensure adequate provisions are made for competent technical experts for the appropriate use of these guidelines.**~~

ADD: Governments **DELETE:** ~~**and other users should**~~ have a duty to ensure that adequate provisions are made for competent technical experts for the appropriate use of these guidelines. National Governments must be free to ban the import of RUTF and safeguard their national nutrition policies.

ADD: These Guidelines are not intended to provide program recommendations for the treatment and management of SAM and national authorities should develop programs that are appropriate to their cultural, economic and social needs that are based on sound independent scientific evidence.
RUTF products should not be promoted in any manner nor sold in the open market.

Recommendation 6
Fats and Oils

ADD: The addition of fats and oils must be in accordance with the recommended limit of less than 30% of total energy as set by the WHO Fact Sheet No. 394. http://www.WHO.int/mediacentre/factsheets/fs394/en/

Recommendation 8
Vitamins and Minerals

It should be noted that the scope proposes that the Guidelines can be applicable for children from 6 to 59 months, while the *Advisory Lists of Nutrient Compounds for use in Foods for Special Dietary Uses Intended for Infants and Young Children* (CAC/GL 10-1979) is intended for older infants and young children 0 to 36 months.

Recommendation 9
Available carbohydrates

The palatability of the RUTF can be increased by the addition of appropriate available carbohydrates. **The addition of added sugars to not exceed the WHO recommendation of 5% of total energy.**

Remove the brackets and add: NOT be used.
[Sucrose, vegetable starch, glucose, glucose syrup] should be the preferred carbohydrates in RUTF. Fructose and high fructose corn syrup as ingredients should **NOT be used** in RUTF, because of potential adverse effects in SAM children. Only precooked and/or gelatinised starches gluten-free by nature may be added].

Recommendation 10
Food Additives and Flavours

IACFO and IBFAN are 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 IACFO and IBFAN do not agree that food additives and flavours should be used as ingredients for RUTF.

Recommendation 11

"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* (CODEX STAN 180-1991)."[1]

COMMENT: If such variety of formulation is envisaged the question must be raised: why is a global Guideline necessary? Why make a claim about the benefits of harmonisation? If it is agreed that a Guideline is necessary – it is essential that it does not subvert the *"UN Strategy to build capacity within countries to produce RUTF"*[1] or undermine national nutrition strategies.

Section 3 of the FSMP Standard does not help. It is ambiguous and does not provide an adequate safeguard for the protection of vulnerable children.[1] For example it refers loosely to unqualified 'scientific evidence' and its only marketing safeguard is a prohibition of advertising to the general public. This leaves the door open for the many other more subtle forms of promotion, such as sponsorship, advertising to health professionals, health and nutrition claims, fundraising appeals, press releases, donations etc. The EU Commission has recognized that its weak FSMP legislation has been exploited by the baby food industry and that claims and marketing of FSMPs for infants and young children have been misleading and have led to growth in the market and widespread inappropriate use. EU legislation that will come into force in 2020 will ban health and nutritional claims for FSMPs.[2]

Can products that are not produced according to these guidelines be labelled as RUTF?

[1] **Section 3 of the *Standard for Labelling of and Claims for Foods for Special Medical Purposes* (CODEX STAN 180-1991)** 3. GENERAL PRINCIPLES The formulation of foods for special medical purposes should be based on sound medical and nutritional principles. 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. The labels, accompanying leaflets and/or other labeling and advertising of all types of foods for special medical purposes should provide sufficient information on the nature and purpose of the food as well as detailed instructions and precautions for their use. The advertising of these products to the general public should be prohibited. The format of the information given should be appropriate for the person for whom it is intended.
[2] COMMISSION DELEGATED REGULATION (EU) 2016/128 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for food for special medical purposes

IACFO and IBFAN do not agree that any formulation can be used for the treatment of SAM. If RUTF is considered necessary – National Governments have a duty to ensure that the formulation is culturally appropriate, safe and adequate.

See attached briefing for the documented evidence showing that formulation with other ingredients resulted in reduced effectiveness in the treatment of SAM.

Recommendation 12
Energy

Add:
The energy density of the formulated RUTF should be at least 5.2 - to 5.5 kcal per gram. The energy density of the RUTF can be achieved during manufacturing by the addition of energy containing ingredients (i.e. fats and oils and/or digestible carbohydrates **in amounts that do not exceed the WHO recommendations for added fats and free sugars**) and/or processing the basic raw materials and ingredients as indicated in the Section on "Technologies for and effects of processing.

IACFO and IBFAN are of the opinion that the energy density of 5.2 – 5.5 kcal/g should have a solid scientific basis.

Recommendation 14

The recommendation of 50% of protein provided by milk products needs to be evidence based. Such a high level of cow's milk proteins may aggravate compromised ability to digest non-breastmilk proteins.

Recommendation 27

IACFO and IBFAN propose that the package size should be researched to determine:

a) **the risk of contamination of opened and stored packages**
b) **the possibility of overfeeding the product and the risk of reducing breastmilk intake.**

Recommendation 28

IACFO and IBFAN recommend the additional labelling provisions:

A clear statement on the label: This product is not to be sold on the open market.

Nutrition, health and convenience claims are not permitted for RUTF products.

There should be no idealised pictures or text

To be used under medical supervision by an independent qualified health care worker.

Rationale: why has the reference to: *Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997) been deleted? This contains the essential safeguard in Para 1.4 *Nutrition and health claims shall not be permitted for foods for infants and young children except where specifically provided for in relevant Codex standards or national legislation*.
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