Proposed Draft Guideline for Ready-to-use Therapeutic Foods
(at step 3) CX/NFSDU 16/38/9

Comment: IBFAN (International Baby Food Action Network)

General comments:

IBFAN is concerned that the proposed guidelines place too much emphasis on a product-based approach to the treatment of malnutrition. We request that the committee considers:

- how to ensure that more sustainable and appropriate strategies to manage and prevent malnutrition are not undermined;
- how to ensure the efficacy and safety of RUTFs
- the appropriateness of Codex a forum for the in depth discussion needed on this topic
- the risk of bias in the evidence base, promotion and use of RUTF.

1 Food Security

The first step in the sustainable management of malnutrition is to ensure the establishment of appropriate emergency preparedness protocols as are now used for breastmilk substitutes in emergencies.[1]

Strategies to improve access to food must aim to reduce dependence on quick fixes and improve food security in the long term. It follows that land and sea grabbing, deforestation and mono cropping that all too often undermine peoples' rights to food must be controlled and discouraged.[2]

Reports from IBFAN's global network demonstrate that the focus on production and distribution of products can divert attention away from and discourage optimal Infant and Young Child Feeding (IYCF) and the use of family foods that are invariably more sustainable, bio diverse, minimally processed and nutritious.

2 Lack of evidence of efficacy of RUTF

Since the 2014 CCNFSDU IBFAN and developing countries, including those targeted with programs based on RUTF, have been calling for evidence of the efficacy and safety of these products and whether the can provide the diversified diet children need. WHO's systematic review on the effectiveness and safety of RUTF formulations is yet to be reported. In 2014 CCNFSDU noted that *"…..it was premature to decide on the development of a Codex standard or guideline for RUTF. The Chairperson therefore suggested that the decision be postponed until the next session of the Committee when the review from WHO would be available and there would be a better basis for a decision."* The Guidelines should not be finalized before the WHO systematic reviews are reported.

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[1] *Potentials, Experiences and Outcomes of a Comprehensive Community Based Programme to Address Malnutrition in Tribal India* Vandana Prasad* and Dipa SinhaPotentials, Experiences and Outcomes of a Comprehensive International Journal of Child Health and Nutrition, 2015, Vol. 4, No. 3 11

[2] **Landgrabbing** https://wd Dipa SinhaPotentials, Experiences and Outcomes of a Comprehensive International Journal of Child Health and Nutrition, 2015, Vol. 4, No. 3 11ww.youtube.com/watch?v=ieioj-036hA
May 11, 2015 The *world's farmland is at risk. Demand for land has soared as investors look for places to grow food for export, grow crops for biofuels or simply buy up land for profit. The film gives an inside look into the world of investors in the international agro-business and shows the consequences for families kicked off the land. Land Grabbing shows how "colonialism 2.0" works.* Script: Christian Brüser, Kurt Langbein http://www.langbein-partner.com/

European Union and the Global Landgrab: TNI/FIAN/IGO/FDCL paper.
https://www.tni.org/files/download/european_union_and_the_global_land_grab-a5.pdf

Cochrane systematic reviews determined that evidence is limited regarding the benefits of RUTF and flour porridge as home treatment for severely malnourished children.[3]

3 The risks of using Codex to establish safeguards for therapeutic foods

Codex standards or guidelines are a compromise between the marketing needs of the food and drinks industries and the protection of public health and safety. A Codex instrument (a standard or Guideline) that is weak on health protection can leave a government open to challenges (through WTO or other means) if it brings in more stringent legislation to control the nutrition content, quality, safety, marketing and trade of products. Any Guideline should provide national governments with specific text that will help governments overcome such challenges.

The RUTF Guideline must reflect the intent of WHA 55.25 that urged Member States "*as a matter of urgency:(4) to ensure that the introduction of micronutrient interventions and the marketing of nutritional supplements do not replace, or undermine support for the sustainable practice of, exclusive breastfeeding and optimal complementary feeding…'* It must consider a wide range of issues such as:

- the extent of the burden of SAM as well as the related mortality;
- the need for national and regional planning that responds to local needs;
- seasonal changes and circumstances;
- the importance of nutrition education (free from commercial influence) especially on complementary feeding and the support for exclusive and sustained breastfeeding;
- the use of bio-diverse, nutritious, minimally processed family foods;
- the impact of infections (malaria, diarrheal disease and parasites) – a major cause of malnutrition especially after 6 months of age;
- the cost of imported RUTF compared to family based food approaches and the appropriateness of diverting substantial development funds to their provision.

These broad social and ethical issues cannot be decided in fora where global commercial forces dominate, as they do in Codex. Any Codex Guidelines must prevent RUTFs being used by the food industry to promote the notion that micronutrients are 'typically lacking' and 'hard to get' and that processed fortified foods invariably confer special health benefits. Such marketing obscures the fact that processing and storage can deplete nutrients.

5 Categorizing RUTFs and RUFs as Foods for Special Medical Purposes (FSMP)

The categorizing of therapeutic products as 'Special Medical Purposes' will not provide protection from inappropriate use. The labelling and marketing requirements of the Codex Standard for FSMPs are ambiguous and inadequate.[4] Advertising to the general public is not the only concern. Promotional claims, NGO and agency fundraising appeals, press releases, donations can all be problematic. [5] [6]

6 Conflict of Interest

IBFAN is concerned that manufacturers of RUTF seem to have a disproportionate influence on the CCNFSDU discussion on RUTF and its efficacy. Historically the studies that were used to proclaim the "efficacy" of RUTF compared RUTF with *no interventions* [7] or interventions with *a corn or wheat soy*

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[3] *Ready-to-use therapeutic food as home-based treatment for severely malnourished children between six months and five years old, Cochrane Database, June 2013 Anel Schoonees[1], Martani Lombard[2], Alfred Musekiwa[1, 3], Etienne Nel[4], Jimmy Volmink[1, 5, *]*

[4] Codex Standard For The Labelling of and Claims For Foods For Special Medical Purposes Codex Stan 180-1991

[5] www.plumpyfield.com,

[6] http://www.edesiaglobal.org/about-us/our-founders-story/

[7] Collins & Sadler Ethiopia 2002[1]; Isanaka et al, Niger, 2006[2], 2009[3]; V. Gaboulaud et al. Niger 2006[4]; Ferguson et al. Malawi 2008[5]; Eklund & Girma Ethiopia 2008[6];

blend [8] or *F100*.[9] Studies showing the efficacy of family foods were not taken into consideration at all. [10]

(ii) Specific comments:

2.1 PURPOSE

Please add:
vii. **Instructions for use**

Rationale:

Since the guidelines are for the treatment of severe malnourished children it is critical that the purpose should include examination of the evidence that the use of RUTFs are suitable therapeutic foods for the treatment of older infants and young children suffering from malnutrition.

The purpose should include an examination of the quality of the evidence used as a basis for development of these guidelines – risk of bias (independence), safety, risk analysis of benefit versus harm, and a statement on the quality of evidence as well as an evidence based recommendation regarding the efficacy and safety of RUTFs – this should include the social and economic implications, and the monitoring of health outcomes and any unintended side effects if implemented.

2.2 SCOPE
Please add:
These guidelines should be used in accordance with the **International Code of Marketing of Breastmilk Substitutes and all relevant WHA resolutions for the protection of exclusive breastfeeding for the first six months of life and sustained breastfeeding to two years or beyond and optimal complementary feeding** and…

The Guideline should be restricted to RUTF only – NOT to RUSF or other products marketed and used for the prevention of malnutrition.

Rationale:
IBFAN strongly opposes the notion that products other than RUTF should be included. The decision to go forward with the Guidelines was based on UNICEF's clear message that the scope would not be expanded and that RUTF products would not be placed on the market. Codex must take special care to ensure that it does not inadvertently boost the international trade for the many unnecessary risky products such as Plumpy Mum that are supposedly designed to boost maternal nutrition.

It is essential that the International Code and WHA resolutions on infant and young child feeding underpin the use, labelling and marketing of these products. Resources must be found to ensure the training necessary to ensure that knowledge regarding breastfeeding skin-to-skin is available as the first priority wherever possible for all malnourished infants and young children, Breastfeeding assists in the healing of the damaged gut, it helps maintain the microbiome, provides critical immunological constituents that are not available in packaged commercial foods.

2.3 DESCRIPTION
Ready to Use Therapeutic Foods (RUTF) are high-energy, fortified **with industrial nutrients**, ready-to-eat foods and **may be used as part of** ~~for special medical purposes that are suitable~~ **for** the dietary ~~management~~ **treatment** of children from 6 to ~~59~~ **24** months with severe acute malnutrition **as outlined in the 2007 Joint Statement by WHO, WFP, UNSCN and UNICEF. The composition of the product and its ingredients should not exacerbate the incidence of obesity, cardiac disease, cancers or diabetes. These foods should be manufactured from ingredients that are safe, hygienic and have a high bioavailability to prevent malabsorbtion and increased diarrheal disease resulting from gut damage as a consequence of malnutrition. Older infants and young children receiving treatment require additional fluids.**
The use of RUTFs must not displace breastfeeding. Training and support for breastfeeding should be provided to maintain sustained breastfeeding wherever possible. All staff should be trained in keeping the mother and baby dyad together; relactation counselling and skin-to-skin care.

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[8] Manary et al Malawi 2004[7]; Michael A. Ciliberto et al. Malawi 2005[8]; Patel, Sandige et al, Malawi 2005)[9];
[9] Diop et al. Senegal, 2003[10]);*Nutriset's Plumpy Nut against analogues made in other countries* Diop et al. Senegal 2004[11]; Sandige et al. Malawi 2004[12]
[10] *"…Andre Briend, the French nutritionist who developed Plumpy'nut in collaboration with Nutriset, went on to work for the World Health Organization, and co-authored a nutrition policy paper on new developments in the treatment of severe malnutrition in the community published in 2006 by the UN's Standing Committee on Nutrition. The WHO, World Food Programme, and UNICEF issued a statement endorsing ready to use therapeutic foods (RUTFs) in 2007….."* Arie S. Hungry for profit. British Medical Journal 9 October 2010, 341, c5221.

These foods should be soft or ~~crushable (~~?) and should be easy for young children to eat without any prior preparation.

Rationale:
The use of these products should be limited to therapeutic, medically indicated uses only and then only as part of the full range of treatments and care that are required for the rehabilitation of malnourished children. These products should not be used for "preventive" purposes. The use of the word treatment – rather than management - should be used to avoid confusion. The protection and support of breastfeeding as a fundamental component of the treatment is essential.

Recommendation 4

The Chairs propose that CCNFSDU consider conducting further discussions and decide on the best approach to handle the use of food additives **and flavours** in RUTF.

Rationale
The use of food additives is an additional body-burden for severely malnourished children and should not be used. Artificial flavours not only contribute to the chemical body-burden but may also affect the child's taste palate, introducing commercially flavoured foods risks undermining children's acceptance of normal family foods.

Recommendation 5
"***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;*** **the safety and composition of these products must be based on evidence that meets WHO's definition of scientific substantiation: "Relevant convincing / generally accepted scientific evidence or the comparable level of evidence under the GRADE classification'** ~~***to be safe and beneficial***~~ ***in*** ~~***meeting***~~ ***supplementing the nutritional requirements of the persons for whom they are intended.***"

RAW MATERIALS ANS INGREDIENTS

4.2.2 Digestible Carbohydrates

There is no recommendation to limit the extent of added sugars. This should be part of the discussion. The use of various forms of added sugars - can contribute to obesity and create preferences for sweet foods. Added sugars are nutritionally empty sources of energy.

Recommendation 10

IBFAN is opposed to the addition of optional ingredients and consider that they should be kept to an absolute minimum. Optional or novel ingredients compound the risks safety and pose challenges to Government regulatory authorities. Codex should use a precautionary approach and pre-authorise any optional ingredient. Suitability and safety must be demonstrated through a systematic review to determine safety and efficacy

In addition to the safety risks, optional ingredients open the door to promotional claims that are rarely scientifically substantiated.

a) all ingredients are pre-authorised following rigorous independent scrutiny, (with particular care over new technologies, such as nanotechnologies;
b) systematic reviews of all available evidence is carried out *independently* of the manufacturers and distributers of the products in question;
c) evidence is reviewed on a regular basis to ensure infants are not exposed to levels of nutrients that may impact negatively on growth, development and health;
d) there is regular post market surveillance to monitor side effects and the frequency of such reviews;

2.10 PACKAGING
2.10.1

Portion sizes must consider the impact on breastfeeding. Infants at the age of six to eight months require only about 200 calories in addition to breastmilk. There is only a gradual increase in caloric requirement from additional foods during the second half of the first year. Breastmilk provides the bulk of the energy, nutrients and immunology, hence the support for breastfeeding is essential during this critical period of growth and development.

2.11 LABELLING

IBFAN strongly supports the addition of additional statements as previously recommended by the eWG. The labelling provisions in existing Codex texts are far from adequate:

For example with the following statements are needed:

a. This product should be provided free by the public health authorities on prescription only for therapeutic /treatment purposes.
b. This product is not for resale and must not be placed on the market.
c. This product must not replace or undermine sustained breastfeeding or the use of locally available nutritious, bio-diverse family foods
d. This product is a high fat, ~~high sugar product~~ and the long-term effects of using this category of products in children are not known. The product **should only be used for [state specific treatment period]**
e. This product must not be not labelled, promoted or idealized by health or nutrition claims or other means such as press releases, fundraising appeals etc.
f. This product is for the **treatment** of severe acute malnutrition **only and should not be used as a routine complementary food.**
g. This product must be used under the strict supervision of an **independent medical practitioner.**
h. This product must not be used for preventative purposes
i. The provision and distribution of this product must comply with all provisions of the International Code or WHA Resolutions and WHO recommendations, including WHA69.9