IBFAN Policy Brief

October 2017

IBFAN briefing on Proposed draft guideline for Ready To Use Therapeutic Food (RUTF) to be discussed in the 39th session of Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU)

INTRODUCTION

This briefing paper explores the process of development of Codex guidelines for RUTF for children 6-59 months (IBFAN's concerns relate to children 6-36months). The briefing questions whether ready to use therapeutic foods (RUTFs) are the most appropriate food for the treatment and community management of Severe Acute Malnutrition (SAM) or Moderate Acute Malnutrition (MAM).

IBFAN is of the opinion that current evidence does not support the widespread use of RUTF products instead of real food for the community management of SAM or MAM and sees many risks in creating a Codex instrument for products intended for therapeutic use.

Risks of a Codex instrument on RUTF

1. The aim of Codex is to facilitate global trade. As such, any Codex instrument risks subverting *"the UN Strategy to build capacity within countries to produce RUTF"*[i] where needed, while ensuring appropriate use.
2. 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 still has not been clarified.
3. It can trigger diversion of public funds away from support for sustainable solutions such as breastfeeding and locally sourced, culturally appropriate, bio-diverse family foods. (See figure 1 and 2). The Codex Standard covering Formulas for Special Medical Purposes (CODEX STAN 72 – 1981) has led to an increase in inappropriate marketing of these products.
4. It can be used by manufacturers and distributors to put pressure on governments to accept imports of products that may not be needed or wanted.
5. Such instruments are voluntary.If the safety aspects are to be effective, they must be implemented in national law. There are already Codex texts dealing with food safety that national authorities can use to improve the safety of products, (eg.*Codex Code of Practice for Low-Moisture Foods*(CAC/RCP 75-2015).
6. Such instruments are developed through a process which 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.

Steps to mitigate risks

If there is to be a Codex instrument relating to RUTF it must contain safeguards to mitigate the above risks. It must include a comprehensive preamble highlighting the following points:

- 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 essential component of this package. Other critical components include: the prevention of early child bearing; the strengthening of health systems; literacy and the improvement of water supply, sanitation and hygiene.
- 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 resource implications, sustainability, social and economic risks, how outcomes were measured and risk of bias.
- RUTF should not be made available or sold on the open market or promoted in any way.

- National authorities must be free to stop the import of food products that they consider to be inappropriate or unnecessary.
- RUTFs should not be placed on the WHO's Essential Drugs List, as has been demanded by some agencies.

PROCESS SO FAR IN CCNFSDU

During the 36th Session of Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) in November 2014 in Bali, Indonesia, UNICEF presented a discussion paper for developing a Codex standard for Ready to Use Foods (RUFs). There was discussionon the appropriateness of ingredients and the lack of evidence for the efficacy and safety of these products compared to home-prepared foods in combination with the treatment of infections and nutrition education. The committee noted that *"...it was premature to decide on the development of a Codex standard or guideline for RUTF."* It was decided to postpone further discussion until the next session when reviews from WHO would be available.

During the 37th Session of CCNFSDU in Bad Soden, Germany in November 2015,UNICEF presented a revised discussion paper to establish a guideline (and not a standard) for a single product known as "Ready to Use Therapeutic Food" (RUTF) to be used for community management of severe acute malnutrition (SAM). There was concern in the Committee that the evidence for use of RUTF in the treatment of SAM was still not conclusive and that the Committee should wait for more evidence including the review by WHO on the effectiveness of RUTF. Nevertheless, the Committee agreed to establish an eWG, led by South Africa and co-Chaired by Senegal and Uganda. Subject to the approval of new work by CAC39, the Committee would develop the proposed guideline for consideration at the next session.

During the 38th Session of CCNFSDU in 2016 in Hamburg, Germany, the Committee agreed to continue the eWG, to develop the proposed guideline for circulation for comments at Step 3 and consideration at the next session. The eWG developed the draft document that will be considered by the Committee during the 39th session in Berlin in December 2017.

WHY IBFAN QUESTIONS THE USE OF RUTF IN THE MANAGEMENT OF SAM IN THE COMMUNITY?

Questions have been raised about the definition and concept of Community Management of Acute Malnutrition (CMAM)***: "****In other words, there is little of the'community' in CMAM."*[ii]The justification for the use of RUTF in CMAM seems to relate more to convenience and a resistance to change, than how best to prevent and manage children with SAM. Indeed current evidence does not support the use of RUTF in CMAM. Our view is substantiated by the arguments given below on the evidence and related issues.

1. **Systematic reviews of available trials as well as a recent Randomised Control Trial (RCT) from India do not support the view that use of RUTF provides better results in terms of treatment, sustained recovery and prevention of mortality from SAM in programme settings:**

   To facilitate sound decision making on this important topic, the background to the process being pursued in the CCNFSDU, needs to include more robust evidence of the validity of using RUTF in the 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 evidence.

   a. A Cochrane review (Schoonees A et al 2013)[iii] of *Ready-to-use therapeutic food for home-based treatment of severe acute malnutrition in children from six months to five years of age* concluded that there is inadequate data to recommend the use of RUTF over a flour porridge-based treatment regime and that either RUTF or flour porridge can be used to treat children at home depending on availability, affordability and practicality.
   b. A review of evidence-based interventions for the improvement of maternal and child nutrition published in the Lancet series (2013)[iv]included interventions to treat SAM in community settings comparing RUT with standard care. The review found no significant difference in mortalitybetween these modalities.
   c. The Lancet review article (2013) stated that *"Substantial programmatic evidence supports*

the use of RUTF for community-based treatment … .” To substantiate this statement, the authors referred to a paper written by Dr. Steve Collins, the founder of Valid International [v] and Valid Nutrition[vi] (a profit-making social business) in which he shared his experience of Community-based Therapeutic Care (CTC) in humanitarian crisis situations such as famine and crop-failures in three African countries, Ethiopia, Sudan (Darfur) and Malawi. While referring to recommendations given by the Lancet Series on maternal and child nutrition 2013, Dr. Ted Greiner, in a review document, in IBFAN's Breastfeeding Brief[vii], states: *“Admitting the lack of hard research evidence, the Lancet article cites “substantial programmatic evidence” as a basis for its recommendations. This, it turns out, is a single article by Steve Collins who happens to run an organization that makes money selling RUTF.”*

d. A review (Lenters et al 2013)[viii], which looked into the treatment of SAM and MAM in low- and middle-income settings concluded, *“Gaps in our ability to estimate effectiveness of overall treatment approaches for SAM and MAM persist. In addition to further impact studies conducted in a wider range of settings, more high quality program evaluations need to be conducted and the results disseminated.”*

e. A multi-centric randomised trial from India (2016)[ix] compared the efficacy of RUTF (centrally produced and locally prepared) with augmented energy-dense home-prepared foods (comparison group) for home-based management of uncomplicated SAM. The study addresses the gaps cited by the Cochrane review and the review by Lenters et al 2013 about the lack of adequate data and a need for further impact studies. The study revealed that the prevalence of SAM in over 100,000children between 6 months and 5 years of age, who were screened for SAM was 1.1%. The study compared the use of centrally produced RUTF (RUTF - C) and locally prepared RUTF (RUTF – L) with augmented home prepared food (A-HPF). Results showed mortality was low in all three groups and that: i) Recovery was better with the use of RUTF-L in comparison with the A-HPF; ii) There was no significant difference in recovery between RUTF – C (the *globally preferred mode of procuring RUTF*) and A-HPF iii) Recovery was not sustained 16 weeks after stopping the treatment (dropping from 56.9% to 17.3% for RUTF-L and from 47.5% to 12.1% for RUTF-C). **Even though recovery was marginally better with the use of RUTF-L compared to A-HPF, this did not stand the test of sustainability when the research team did a follow up 16 weeks after the treatment stopped.**

   Referring to this study, the Ministry of Health & Family Welfare in India has stated that while RUTF or home augmented food for children with SAM is *“temporarily helpful in nutritional rehabilitation under proper supervision and support. However, RUTF may not benefit a common household in developing appropriate food habits for children's against home augmented food.”*[x]

f. In a study conducted by Médecins Sans Frontières (MSF)[xi] in 2015 in the state of Bihar, India uncomplicated SAM cases were treated as outpatients in the community by using a WHO-standard, ready-to-use, therapeutic lipid-based paste produced in India while complicated cases were treated as inpatients by using F75/F100 WHO-standard milk until they could complete treatment in the community. The study has reported a high default rate of 38% and higher relapse and non-recovery from SAM in food insecure environment in community. This again raises serious questions about the sustainability of the approach using RUTF in reducing SAM prevalence.

2. Misinterpretation of research studies in the World Bank's 'Investment framework for nutrition' (2017)[xii]:

The chapter on scaling up the treatment of severe wasting in this recent World Bank report states, *“WHO recommends outpatient treatment of children with uncomplicated severe acute malnutrition (85–90 percent of cases) using ready-to-use therapeutic food and a seven-day preventive course of antibiotics (WHO 2013). This treatment has been shown to reduce mortality and lead to recovery in about 80 percent of cases (Hossain et al. 2009; Khanum, Ashworth, and Huttly 1994, 1998; Lenters et al. 2013)”.* Close examination of the statement reveals that there seems to have been a misinterpretation of the cited studies:

neither their design nor their results substantiate the second part of the statement or the assertion that outpatient treatment of children with SAM had a beneficial effect on recovery and mortality. Points 'a' to 'd' below explain it.

a. Hossain et al. (2009)[xiii]: It was a hospital-based study (not a community treatment of SAM) with a small sample size (30 in each arm). The study compared the WHO protocol using F-75, F-100 and the Institute of Child and Mother Health (ICMH) protocol using food prepared from locally available ingredients such as cow's milk, micronutrients etc. Both protocols were equally effective.

b. Lenters LM et al (2013):It was a systematic review and meta-analysis, which concluded that *"Gaps in our ability to estimate effectiveness of overall treatment approaches for SAM and MAM persist. In addition to further impact studies conducted in a wider range of settings, more high quality program evaluations need to be conducted and the results disseminated."*

c. Khanum, Ashworth, and Huttly (1994)[xiv]: It was a trial to compare inpatient, day-care, and at-home treatment of severely malnourished children. It concluded that at-home treatmenthad economic and practical advantages over other methods,while mortality was low (<5%) in all three groups.

d. Khanum S, Ashworth A, Huttly SR (1998)[xv]:This was aprospective follow-up study of children treated for SAM and discharged from hospital with fortnightly monitoring. It was not a study to determine recovery and mortality with the use of RUTF.

3. Efforts to achieve World Health Assembly targets seem to focus on treatment rather than prevention

The **assertions** of global institution such as the World Bank, have a powerful impact generally, and can result in the skewing of nutrition funding in favor of treatments rather than prevention.

An analysis of current nutrition funding by the World Bank Group, Results for Development Institute and 1,000 Days[xvi]reveals that a major portion of funding by many donors is already being spent on treating wasting (see here). Also, a large proportion of nutrition funding in many countries is spent on treating rather than preventing severe wasting. It is important to note that the WHA nutrition target for wasting is to reduce and maintain childhood wasting to less than 5%.[xvii] The treatment of wasting, mainly SAM, will not achieve the WHA target for wasting. **It is important to note that other WHA targets such as exclusive breastfeeding, stunting and anemia are receiving less funding than the treatment of wasting.**

Figure 1 and 2 shows donor funding and use of funds by countries in wasting.

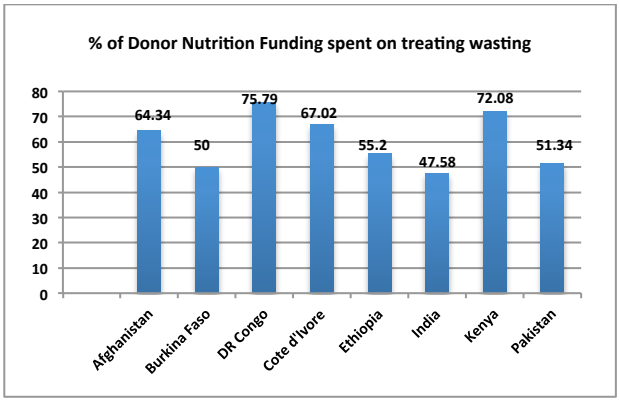

Figure 1: Proportion of donor nutrition funding spent on treating wasting in some countries of Asia and Africa
(Source: http://www.investinnutrition.org/countries)

Figure 1 shows the proportions of donor nutrition funding spent on treating wasting alone in some African and Asian countries. It varies from 47% to 75%. (Adapted from http://www.investinnutrition.org/countries)

Figure 2 shows that a major proportion of nutrition funding by donors/ countries/agencies/ is being spent on treating wasting globally. It ranges from 15% -60%.

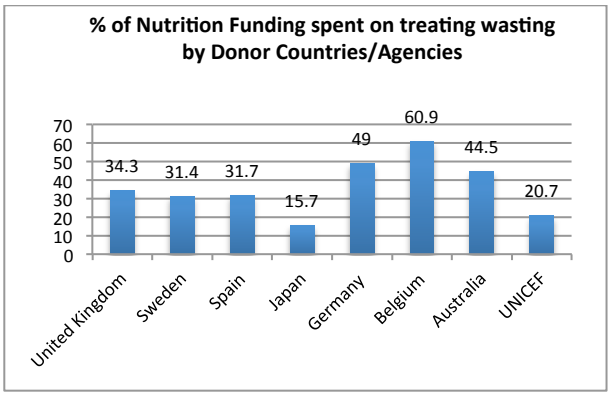

Figure 2: Proportion of nutrition funding by donor countries/agencies spent on treating wasting globally
(Source: Adapted fromhttp://donors4nutrition.r4d.org)

4. Potential impact of RUTF on long-term health

A recent review article by Bazzano AN et al (2017)[xviii] has highlighted the potential long-term health risks of RUTF use. Increased consumption of RUTF may result in permanent alteration of the epigenome and associated metabolic functions. Exposure of the young child to a single sweet and fatty food such as RUTF, may shape and be detrimental to a young child's taste preferences and eating habits. Here, it is important to note what WHO Report of the Commission on Ending Childhood Obesity[xix] has stated: *"Undernutrition in early childhood places children at an especially high risk of developing obesity when food and physical activity patterns change."*

Other related issues

5. Conflicts of interest in the use of RUTF

IBFAN is concerned about undue commercial influence on the process for guidelines development, programme implementation and regulatory and approval processes for the trade, import and use of RUTFs as identified in several write-ups.[xviii,xx] Valid Nutrition, an Ireland based company produces RUTF in Malawi and India. According to Bazzano AN et al (2017) Valid Nutrition's sister company Valid International is a consulting group which provides technical support on implementation, monitoring and evaluation of health and nutrition programs, including CMAM.[xviii] Conflicts of interest in conducting research, results of which are used as evidence for the efficacy and the use of RUTF is another problematic issue that requires attention. For example, several key references used in the joint and referenced in the Lancet series were either funded by or carried out by those who have a financial interest in the outcome.[xxi,xxii]

6. High-energy food items such as RUTF are likely to displace breastmilk:

The proposed consumption of 2 packs of over 500 kcal each of RUTF for a total of approximately 1000 calories risks the reduction of breastmilk consumption that is so critical for nutritional recovery and immunological protection. Between the ages of 6 to 9 months an infant breastfed on demand needs only 100 to 200 extra calories per day while from 9 to 11 months 300 kcal and from 12 to 23 months approximately 500 calories daily respectively are required. Over-consumption of RUTF could seriously compromise the intake of breastmilk during the time of rehabilitation.

7. Mortality assigned to SAM needs re-examination:

UNICEF, WHO, WFP and UNSCN joint statement on community-based management of severe acute malnutrition[xxiii], which is the main basis for drafting the Codex guidelines on RUTF, attributes a high mortality rate of 10-21% due to SAM. Schofield and Ashworth (1996)[xxiv] estimated a high mortality rate of 30% for SAM. It is important to note that these projections of mortality risks of severely wasted children have been drawn from studies conducted/reported two-three decades back and need re-examination.

The 2017 World Bank Investment Framework for Nutrition report mentioned earlier, states that the mortality risk estimation of severe wasting uses the *Lives Saved Tool* (LiST)[1] modelling. This is inappropriate because it refers to specific underlying diseases such as pneumonia and diarrhoea. The prevalence of underlying diseases, and access to health facilities to treat them, will affect the mortality attributed to SAM.

Furthermore, the report proposes a calculation of baseline mortality risk [in LiST] by calculating the number of deaths from a change in wasting prevalence at country level (see pages 130-134 of the Framework for more details). An analysis using this method in 24 countries with high SAM prevalence showed that the pooled risk of mortality due to SAM is 1.43% with a range from 0.1% in Sri Lanka to 6.2% in Chad. The mortality is higher in countries with higher mortality risks due to underlying diseases such as pneumonia and diarrhoea etc.

A recent study from India published in 2017[xxv] also reported a much lower mortality rate. This study evaluated the recovery and survival of severely wasted children in an area without a formal treatment programme of community management of acute malnutrition (CMAM). Of the 409 children diagnosed with SAM, 55% were between 6 to 24 months. During the first month of the follow-up, only5 children (case-fatality 1.2%) and overall 11 children died during 1 to 7.4 months follow up (case-fatality 2.7%).

[1]The Lives Saved Tool (LiST), developed by the Institute for International Programs at Johns Hopkins Bloomberg School of Public Health and funded by the Bill & Melinda Gates Foundation, is a model that estimates the impact of scaling up health and nutrition interventions on maternal, newborn, and child health, and stillbirths. See details at: http://livessavedtool.org//how-list-works

CONCLUSIONS:

IBFAN considers all child malnutrition and fatalities to be a matter of serious concern and an abuse of child rights. To effectively prevent and address malnutrition, health, development and trade policies must be based on sound and independent evidence. Policies must prioritise child health and survival, with the availability of diverse foods at home as a key prevention measure.

Policies encouraging dependency on RUTF instead of food as the first option in the community management of SAM need to be re-examined. Unless evidence for the *sustained* efficacy of RUTF in community settings is provided, it seems inappropriate for the UN, governments and donors to allocate funds to facilitate the growth of the RUTF market, as is currently happening. Such funding, alongside the commercial imperative, risks distorting nutrition planning in favour of dependency on imports and the consumption of highly processed foods - with all their known related risks. Support for breastfeeding and for bio-diverse, sustainable and culturally acceptable foods and agriculture must be at the heart of all health and development policies.

Poor diet is now the biggest underlying cause of ill health and disease globally. IBFAN calls on national governments to give full consideration to the issues raised in this briefing during the 39th session of CCNFSDU in December 2017.

[i] ftp://ftp.fao.org/codex/meetings/CCNFSDU/CCNFSDU37/nf37_8e.pdf

[ii] Prasad V. Foregrounding 'Community' in Community Management of Severe Acute Malnutrition: An Indian Perspective. World Nutrition 2017;8(1): 79-86

[iii] Schoonees A, Lombard M, Musekiwa A et al. Ready-to-use therapeutic food for home- based treatment of severe acute malnutrition in children from six months to five years of age. Cochrane Database of Systematic Reviews 2013,Issue 6. Art. No.: CD009000. DOI: 10.1002/14651858.CD009000.pub2

[iv] Bhutta ZA, Das JK, Rizvi A, Gaffey MF, Walker N, Horton S et al. Evidence-based interventions for improvement of maternal and child nutrition: what can be done and at what cost? Lancet. 2013 Aug 3; 382(9890): 452-77.

[v] http://www.validinternational.org/

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[viii] Lenters LM, Wazny K, Webb P, Ahmed T, Bhutta ZA. Treatment of severe and moderate acute malnutrition in low- and middle-income settings: a systematic review, meta-analysis and Delphi process. BMC Public Health. 2013;13 Suppl 3:S23

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[xv] Khanum S, Ashworth A, Huttly SR. Growth, morbidity, and mortality of children in Dhaka after treatment for severe malnutrition: a prospective study. Am J ClinNutr. 1998 May;67(5):940-5.

[xvi] The World Bank Group, Results for Development Institute, and 1,000 Days. Investing in Nutrition. Available at:http://www.investinnutrition.org/dashboards/global

[xvii] WHO. WHA global nutrition targets 2025: Wasting policy brief. Available at: http://www.who.int/nutrition/topics/globaltargets_wasting_policybrief.pdf

[xviii] Bazzano AN, Potts KS, Bazzano LA, Mason JB.The Life Course Implications of Ready to Use Therapeutic Food for Children in Low-Income Countries.Tchounwou P, ed. International Journal of Environmental Research and Public Health. 2017;14(4):403. doi:10.3390/ijerph14040403

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