



## 37<sup>th</sup> CCNFSDU

### IBFAN Comment on the UNICEF Discussion Paper on a Standard for Ready-to-Use-Foods CX/NFSDU 15/37/8)

#### Agenda item 8

IBFAN is pleased to have the opportunity to respond to the UNICEF discussion paper on a standard for Ready-to-Use-Foods (RUTFs).

IBFAN understands that UNICEF is proposing to develop a Codex instrument in order to improve the quality, safety and timely delivery of products used for the treatment of Severe Acute Malnutrition (SAM), a concern that IBFAN shares. (However for the purpose of trade and the use of a Codex global trading instrument presents, the effect of a guideline or standard is similar<sup>1</sup>)

IBFAN's comments draw on IBFAN's 20-year experience of participating in the Codex standard setting process and hence we question whether a Codex commodity standard or guideline is an appropriate and proportionate way to address RUTFs. As therapeutic products they have highly specific and limited function for a decreasing number of children.

It should also be noted that at the 36<sup>th</sup> CCNFSDU meeting the majority of Member States from the developing world rejected the idea of a Standard. They cited concern about the ingredients and the lack of evidence for the efficacy and safety of RUTF, compared to home-prepared foods in combination with the treatment of infections and nutrition education.

We wish to make **general** comments on the Codex process and on the use of RUTFs, as well as **specific** comments on UNICEF's discussion paper.

#### Prevention and sustainable management of malnutrition

The first steps in the prevention and sustainable management of malnutrition must be to address the root causes of malnutrition by alleviating poverty and reduce the global economic disparity in access to food and health care.<sup>2</sup> Nutrition interventions need to be part of a structured community-based program where appropriate food security measures are integrated into all policies<sup>3</sup>. Policies must ensure that products supplied for emergencies are time bound and accompanied by strategies that reduce dependence on quick fixes.

Codex cannot be the appropriate forum to discuss such highly sensitive, political and humanitarian issues when 40% of the delegates are from food and related industries that are currently marketing

<sup>1</sup> FAO Review of the Status and Objectives of Codex Texts Summary of highlights of report CX/GP 98/9 July 98. J. GUIDELINES 29. "There are two basic groups of Codex texts known as 'Guidelines'. Those in the first group expand upon, interpret or provide information of the application of other Codex standards or texts; those in the second group are in the form of standards and could be used as such." <http://www.fao.org/docrep/meeting/005/W9809E/w9809e09.htm#bm9>

<sup>2</sup> Schaetzel T, Nyaku A, IYCN Project. The case for preventing malnutrition through improved infant feeding and management of childhood illness. USAID IYCF Project. Presented at the 10<sup>th</sup> Commonwealth Association of Paediatric Gastroenterology and Nutrition (CAPGAN) Congress on Diarrhoea & Malnutrition in Blantyre, Malawi, August 2009

<sup>3</sup> Potentials, Experiences and Outcomes of a Comprehensive Community Based Programme to Address Malnutrition in Tribal India Vandana Prasad\* and Dipa Sinha Potentials, Experiences and Outcomes of a Comprehensive International Journal of Child Health and Nutrition, 2015, Vol. 4, No. 3 11

<sup>3</sup> Improve the food security of farming families affected by volatile food prices. Short film on Cambodia supported by the Food and Agriculture Organisation (FAO) and the EU. <http://info.babymilkaction.org/update/update45page26>

foods and products for infants and young children contrary to the recommendations of WHO, the International Code of Marketing of Breastmilk Substitutes and WHA resolutions, and promoting policies such as land, water and sea grabbing, deforestation, biofuels and mono-cropping. All these activities are contrary to the right to adequate food and nutrition and undermine sustainable access to food.

## 1 General risks of using Codex to address malnutrition:

Although the purpose of Codex is to ensure fair trade – it is more often used to facilitate global trade and break down barriers to trade. The Discussion Paper needs to address the harmful unintended consequences of such expansion of the RUTF market.

- A Codex instrument is voluntary so will not necessarily bring about the improved safety standards UNICEF hopes to achieve.
- Due to the structure and working methods of Codex and its lack of Conflict of Interest safeguards, Codex instruments are invariably a compromise between the marketing needs and the protection of public health and safety. It will be very difficult to embed effective safeguards into a Codex instrument for RUTF.
- Codex instruments are the benchmarks used by the World Trade Organisation in trade disputes, so even when safeguards are embedded, they can be used to force governments to accept imported products that may not be needed or wanted. They are also used to weaken national food policy and marketing regulations.

## 2 General comments on the use of RUTFs to treat Severe Acute Malnutrition (SAM)

1. **Cost:** The advantage of RUTFs in the treatment of Severe Acute Malnutrition (SAM) in children is their convenience and the fact that they can be used for at-home treatment so reducing the cost on in-patient health facilities.<sup>4</sup> However the manufacturing, importation and distribution costs of RUTFs make them prohibitively expensive as a treatment food. Even for local production, in some parts of Africa, costs remain high since ingredients such as the micronutrients, powdered milk and oil are imported. 77% of the products are manufactured in Europe and the US. As reported in the discussion paper, in 2013 UNICEF and WFP purchased 50,000 metric tone at a cost of \$(USD) 195 million without solid evidence of effectiveness. Funding for the treatment of malnutrition is primarily dependent on external donors, humanitarian and emergency aid. Such funding is often short term and not sustained. In some countries for example Swaziland, RUTF was introduced through UNICEF for the first 5 years. After the 5 years, the purchasing role was passed on to Government.
2. There needs to be strong justification for such costs, especially since they are likely to divert funds away from support for breastfeeding and the sustainable management of home-prepared bio-diverse foods.
3. The evidence of the effectiveness of RUTF as a treatment for SAM when compared to other treatments remains weak.<sup>5 6 7</sup>

<sup>4</sup> 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. Community-based management of severe acute malnutrition. Geneva, WHO/WFP/UN/UNICEF, 2007

<sup>5</sup> Karakochuk C, van den Briel T, Stephens D et al. Treatment of moderate acute malnutrition with ready-to-use supplementary food results in higher overall recovery rates compared with a corn-soya blend in children in southern Ethiopia: an operations research trial. *Am J Clin Nutr.* 2012;98 (4): 911-6

<sup>6</sup> 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

<sup>7</sup> Lazzarini M<sup>1</sup>, Rubert L, Pani P. Specially formulated foods for treating children with moderate acute malnutrition in low- and middle-income countries. *Cochrane Database Syst Rev.* 2013 Jun 21;6:CD009584. doi: 10.1002/14651858.CD009584.pub2

4. In terms of strengthening resistance to infection and restoring nutritional deficiencies there is little or no evidence that RUTFs are more effective than home-based family food treatments.
5. The treatment with RUTFs requires the child to consume extra water. If clean, potable water is not available (which is the case in most settings with malnourished children) then the risk of infections is increased and the proposed treatment aims cannot be achieved. Research on access to safe water and the risk of natremic dehydration with the use of RUTFs appears to be lacking.
6. The concentrated energy content of RUTFs risks the reduction of breastmilk consumption, critical for nutritional recovery and for its immunological capacity as breastfed children regulate their intake. Paragraph 21 in the UNICEF discussion paper cites the consumption of 2 packs of over 500 kcal for a total of approximately 1000 calories. Between the ages of 6 to 9 months a breastfed infant needs only 100 to 200 extra calories per day from 9 to 11 months 300 kcal and from 12 to 23 months approximately 500 calories daily. Over-consumption of RUTF would seriously compromise the intake of immunologically and nutritionally important breastmilk during the time of rehabilitation.
7. The use of RUTFs is problematic in relation to sustained nutritional rehabilitation. Children fed a single treatment food will not develop a taste for normal, local, bio-diverse, nutritious family foods essential for their recovery and their long-term rehabilitation.<sup>8</sup> Studies have not been done to determine the effects of the introduction of RUTFs on local complementary feeding practices.
8. Before scaling up the use of RUTFs, there is an urgent need for sound, independently funded evidence of their effectiveness and their safety, compared to nutrition education combined with the use of appropriate home-prepared foods. The use of RUTFs cannot be justified unless it is integrated into sustainable, local, family based solutions.<sup>9</sup> This also raises concerns about the ethical nature of the testing of products on malnourished infants and young children in poverty settings.
9. The systematic reviews being undertaken by WHO (mentioned in Para 42) on the economic implications and cost-effectiveness of interventions using lipid-based nutrient supplements (LNS), their safety and effectiveness for health, nutrition and development outcomes compared to other foods are not yet available.
10. Programs for the treatment of SAM and all forms of malnutrition must be human rights based; and first and foremost must address the right to adequate and appropriate nutritious food.<sup>10</sup> This should include the right to breastfeeding supports such as implementation of the International Code and WHA resolutions, maternity protection and the Baby-Friendly birthing/breastfeeding initiative.
11. Before scaling up the use of RUTF there must be effective safeguards in place that strictly control marketing and messaging that suggests that fortified foods are essential for optimal infant and young child feeding. Such messaging undermines confidence in the use of normal sustainable family based foods.<sup>11</sup> Safeguards are essential to prevent the inappropriate spill-over of these products to the complementary feeding of infants and young children. Advertisements suggesting RUTFs and RUFs are superior have already been noted in Africa, India and elsewhere. The widespread use and distribution by health authorities of these products as “superior” to local foods has a negative impact on the use and perception of local family foods.

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<sup>8</sup> Ali E, Zachariah R, Shams Z et al. Peanut-based ready-to-use therapeutic food: how acceptable and tolerated is it among malnourished pregnant and lactating women in Bangladesh? *Matern Child Nutr* 2013 doi: 10.1111/mcn.12050

<sup>9</sup> FAO. Report, International Scientific Symposium, Biodiversity and Sustainable Diets, United Against Hunger, Rome, 3-5 November 2010 <http://www.fao.org/ag/humannutrition/29186-021e012ff2db1b0eb6f6228e1d98c806a.pdf>

<sup>10</sup> Report submitted by the Special Rapporteur on the right to food, Olivier De Schutter. Human Rights Council Nineteenth session, Agenda item 3, Promotion and protection of all human rights, civil and cultural rights, political, economic, social, including the right to development. 26 December 2011, United Nations General Assembly, A/HRC/19/59

<sup>11</sup> Greiner T. Draft Guidelines for the Marketing of Ready to Use Supplemental Foods for Children. Field Exchange (Emergency Nutrition Network) 41:47-51, 2011 <http://www.enonline.net/pool/files/ife/fex41-draft-guidance-on-marketing-rusf-for-children-&-responses-fex41.pdf>

12. Conflicts of interest, inherent in the “scaling-up” of the use of RUTFs are a serious problem. For example: partnerships with manufacturers of RUTFs at both the international program levels with UN agencies and at national levels allow undue commercial influence over the regulatory and approval processes for the importation and use of RUTFs; the funding of research to develop evidence for the efficacy and the use of RUTFs; NGO implementation programs at community levels. The close integration between manufacturers and programs to address malnutrition create situations where governments and health facilities have become facilitators for the marketing of these products. The business of malnutrition is alive and well.
13. The argumentation for scaling up these products is entrenched with conflicts of interest. Donor countries, based in the industrialised north, support and develop the research, programming, manufacture and advocacy for the use of products. Developing countries, where the bulk of malnutrition exists, have hardly any say.

### 3 Specific comments on the discussion paper

#### Scope (Paras 8-10)

IBFAN is of the opinion that Codex is not the appropriate forum for the development of a guideline for therapeutic foods. This is best left to national governments with the guidance of UN agencies such as WHO, FAO and UNICEF.

In Para 10 UNICEF acknowledges that some regions consider that the treatment of SAM with “*locally available nutrient-dense foods prepared by the carer at home, without the use of commercially produced products such as RUTF*” may be “*more sustainable and better suited to the countrys’ healthcare system.*” UNICEF also envisages that “*RUTF is given to recipients free of charge, as a targeted therapy for SAM and is **not intended as an item for sale on the free market.***”

However, the discussion paper fails to acknowledge that increased global trade of these products will encourage the expansion of the range of products for the ‘prevention’ of malnutrition and will increase the risk of ‘spill-over’ and inappropriate use.

#### Introduction: Prevalence of SAM (Paras 11-15)

IBFAN is concerned that the numbers of cases of SAM may be inflated. It is well known that 45% of under-5 deaths in the developing world occur during the first month of life with 75.73% during the first year. It is also well known that in developing countries the disease burden from SAM has been decreasing while the incidence of childhood obesity has been rising.<sup>12,13</sup>

**India:** The population of children 0-5 years in India is 12,058,1000.<sup>14</sup> The total number of under-5 deaths in India is 1,201,000, of which 696,000 die during the first month of life. 505,000 children die between 1 month and 5 years.<sup>15</sup> Recent data from India shows a prevalence of 4.6% (RSOC 2013-14)<sup>16</sup> for SAM - 5,908,469 - down from 6.4% reported in 2005-6 (NFHS 3) and WHO suggests a case fatality

<sup>12</sup> Extrapolated from UN Inter-agency Group for Child Mortality Estimation report on levels and trends in Child Mortality 2015 (WHO, UNICEF, World Bank Group, United Nations) See Annex 1 for more details

<sup>13</sup> *Global obesity rise puts UN goals on diet-related diseases 'beyond reach' Westernised diets blamed as figures predict failure to meet 2025 target of no increase in obesity or diabetes beyond 2010 levels. " ... Child obesity figures are also rising in many developing countries, particularly in the Middle East, Latin America, China and parts of south-east Asia..."* <http://www.theguardian.com/society/2015/oct/09/obesitys-global-spread-un-goals-diet-related-diseases-fail>

<sup>14</sup> UNICEF. SOWC, 2014 (Demographic Indicators). <http://www.unicef.org/sowc2014/numbers/>

<sup>15</sup> Numbers extrapolated from **Levels of Child Mortality - 2015**, UN Inter-agency Group for Child Mortality Estimation report. Available at: [http://www.childmortality.org/files\\_v20/download/IGME%20Report%202015\\_9\\_3%20LR%20Web.pdf](http://www.childmortality.org/files_v20/download/IGME%20Report%202015_9_3%20LR%20Web.pdf)

<sup>16</sup> Ministry of Women and Child Development, Government of India and UNICEF. Rapid Survey on Children (2013-14). Available at: [http://wcd.nic.in/issnip/National\\_Fact%20sheet\\_RSOC%20\\_02-07-2015.pdf](http://wcd.nic.in/issnip/National_Fact%20sheet_RSOC%20_02-07-2015.pdf)

rate for SAM of 30- 50%.<sup>17</sup> A 50% case fatality rate would result in 2,954,234 deaths due to SAM, a 30% case fatality rate would result in 1,772,540 deaths. The fact that India's total child deaths are 1,201,000 suggests that the high child mortality figures associated with SAM need to be re-examined.

The high % of neonatal mortality in both India and Bangladesh (both countries on the global RUTF radar) cannot be the result of SAM. Clearly the establishment of early and exclusive breastfeeding during the neonatal period is critical to reduce these deaths. The **Rapid Survey of Children 2014** by the Government of India and UNICEF shows that SAM rates have gone down from 6.4% to 4.6%, with reductions of more than 50% in 8 states. Since India does not use RUTFs these changes must be due to the increased rates of early and exclusive breastfeeding alongside better health care, water, sanitation etc.

**Nepal.** The reported prevalence of SAM in 2011 was 2.6%.<sup>18</sup> After the earthquake the actual prevalence was found to be 0.29%. (1,119 of the 374,441 children aged 6–59 months screened.)<sup>19</sup>

#### **SAM and the Use of RUTFs (Paras 16-23)**

Treatment aims are theoretical and not evidence based. IBFAN notes that the research cited should be independent (not funded by manufacturers or distributors of RUTFs) and should make the appropriate comparisons to home-based family foods combined with nutrition education.

The training of care workers on the safe use of RUTFs combined with breastfeeding support knowledge and nutrition education on the use of home based complementary feeding must be integrated into any programming where RUTFs are used.

*“Breastfeeding was associated with lower odds of wasting and underweight while diarrheal disease was associated with higher odds of wasting and underweight. Low dietary diversity scores, inappropriate age of complementary feeding initiation and bottle feeding were identified to be significant predictors of stunting. Those factors should be considered for any intervention aimed to reduce under nutrition among infants and young children in Filitu town, Somali region, Ethiopia.”*<sup>20</sup>

#### **Outpatient Community Management of SAM (CMAM) (Paras 24-26)**

This section is focused only on RUTF and does not stress the need for guidance and support from WHO, FAO and UNICEF on how to ensure that RUTF does not undermine the appropriate support for breastfeeding and sustainable complementary feeding. It is at community level that inappropriate messaging can be so harmful.

#### **UNICEF's Long-term Strategy (Paras 27-28)**

UNICEF's Long-Term Strategy is to build capacity within countries to produce RUTF but the Discussion Paper seems to focus on *“RUTF that are produced in food manufacturing facilities and traded internationally.”* IBFAN believes that a more comprehensive approach should be taken to the prevention and treatment of SAM rather than single product based approaches. As said before, the unintended consequences of increasing production and trade in these products – whether nationally or globally - needs to be addressed.

#### **RUTF Production (Paras 29-32)**

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<sup>17</sup> [http://www.who.int/nutrition/topics/severe\\_malnutrition/en/](http://www.who.int/nutrition/topics/severe_malnutrition/en/)

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[http://www.unicef.org/evaluation/files/Nepal\\_Evaluation\\_of\\_Community\\_Management\\_of\\_Acute\\_Malnutrition\\_CMAM\\_-\\_Nepal\\_Country\\_Case\\_Study.pdf](http://www.unicef.org/evaluation/files/Nepal_Evaluation_of_Community_Management_of_Acute_Malnutrition_CMAM_-_Nepal_Country_Case_Study.pdf)

<sup>19</sup> *Delivering essential nutrition services for children after the Nepal earthquake*

<http://www.thelancet.com/journals/langlo/article/PIIS2214-109X%2815%2900184-9/fulltext#>

<sup>20</sup> Fekadu Y et al. Factors associated with nutritional status of infants and young children in Somali Region, Ethiopia: a cross-sectional study. [BMC Public Health](https://doi.org/10.1186/s12889-015-2190-7). 2015 Sep 2;15:846. doi: 10.1186/s12889-015-2190-7.

Increased global trade will lead to bigger markets for these products. IBFAN has received reports that countries are expected to scale up a national RUTF plan in terms of procurement and distribution. *“When communities, for example, try producing an equivalent of RUTF using community resources to manage their malnourished children, they are discouraged given that the government directive is to use only ‘imported RUTF given the high safety standards’ used in its production. Supplies are however erratic.”*

#### **Regulation of RUTF Trade (Paras 34, 35)**

These paragraphs assume that RUTF is an essential commodity for all countries without any strong national or local justification. As mentioned in Para 10 and raised by Member States at the 36<sup>th</sup> CCNFSU meeting, many countries are adopting what they consider to be more sustainable approaches (support for breastfeeding, education, sustainable management of home-prepared bio-diverse foods etc) and have chosen not to use RUTF.

A Codex instrument may be used to put pressure on governments to accept RUTF. In some cases governments have come under pressure to weaken marketing regulations and to allow marketing of products for non-therapeutic purposes, such as the ‘prevention of malnutrition.’

#### **Need for RUTFs Guideline (Paras 36, 37)**

Any encouragement of local manufacture of RUTFs must be accompanied by Guidance for national governments on the protection of breastfeeding and optimal infant and young child feeding

#### **RUTF Product Applicable for the Code Guidelines (Paras 38-41)**

If the bars and pastes are strictly to be used as therapeutic tools for the treatment of SAM, IBFAN does not see the need for a Codex guideline.

#### **Ingredients and Composition (Para 42)**

**RUTF Ingredients (Para 43):** There is a lack of independent evidence that ingredients such as cow’s milk powder, sugar and industrially-produced nutrient mixes, are nutritionally complete or better than home-prepared foods made from local ingredients, breastfeeding and nutrition education.

**RUTF Ingredient Diversification (Para 44-46):** Guidance and support by WHO and UNICEF should encourage national nutrition policies and programming to favour culturally appropriate ingredient diversification and the support of optimal breastfeeding and complementary feeding practices.

**Chemical Contaminants (Paras 47-48):** The use of peanuts contaminated with mycotoxins, aflatoxin is near impossible to avoid. Will the use of a single treatment of industrially produced food increase the risk of illnesses related to mycotoxins? Children suffering from SAM are immunocompromised and hence may have increased health risks associated with the chemical body burden inherent in RUTF products when fed a single food.

#### **Microbial Safety and Associated Sampling Plan (Paras 51-52)**

RUTF products are used primarily in Africa, where ambient temperatures are conducive to rapid microbial growth. The risk of infection and illness with the use of these products is high in children with SAM. Although the hygienic standards for these products have not yet been determined at the CCFH, the risk for infections from contaminated products in a immunocompromised population remains for those suffering from SAM who are already at increased risk for secondary infections and illness. The CCFH guidance on the microbial criteria must be included in guidance for national governments.

#### **Labelling and Packaging (Para 53)**

UNICEF proposes that the RUTF guideline will follow the *Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes*. The labelling and promotion safeguards included in the FSMP Standard are ambiguous and inadequate for the protection of vulnerable children.<sup>21</sup> Although direct advertising to the general public is banned, the door is left open for other more subtle forms of promotion such advertising to health professional, health and nutrition claims, fundraising appeals, press releases, donations. National FSMP controls have been shown to be utterly inadequate in curbing unethical marketing and the growth of the global market for specialised formulas and foods – very few of which are needed.

This section should include all the marketing restrictions and the provisions of the International Code of Marketing of Breastmilk Substitutes and subsequent relevant WHA Resolutions. Since this is a therapeutic product the labels should make it clear that the product be available on prescription only from independent and qualified health care workers only. NGOs and Agencies should be discouraged from using RUTF – especially branded RUTF - in fund-raising appeals.

See initiatives such as *PlumpyField Network*<sup>22</sup> and *EDESIA*.<sup>23</sup>

**Recommendation** (Para 54,55)

IBFAN does not support the development of a guideline through the Codex process. IBFAN is of the opinion that WHO, FAO and UNICEF should provide guidance and support to national governments on comprehensive treatment of SAM appropriate to national needs and cultural practices rather than single product approaches.

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<sup>21</sup> Codex Standard For The Labelling of and Claims For Foods For Special Medical Purposes Codex Stan 180-1991

<sup>22</sup> [www.plumpyfield.com](http://www.plumpyfield.com).

<sup>23</sup> <http://www.edesiaglobal.org/about-us/our-founders-story/>