22 October 2019

Proposed draft Guidelines for Ready-to-use Therapeutic Foods[1]

ISDI reply to Circular Letter (CL 2019/79-NFSDU) at STEP 4

Recommendation 1
That CCNFSDU agree to the proposed list of food additives and their functional class in **Table I** (in this document) for use in RUTF and that the table be utilised as the basis for further discussions on additives in RUTF.

ISDI Comment

ISDI believes that Table I lists all the additives currently used and required to manufacture RUTF, as reflected by global ISDI membership.

ISDI would like to provide an editorial comment regarding citric acid. ISDI notes that the functional use for INS 330 is as an acidity regulator (not an antioxidant) in all the reference Codex Standards. Therefore, ISDI suggests that a separate line for acidity regulators is included in the table and citric acid is listed under this line. We have made the change in the table below – shown in green.

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[1] For the background information, please refer to CX/NFSDU 19/41/6.

+32 (0)2 761 16 80
secretariat@isdi.org
Legal seat: 3200 Windy Hill Road, Marietta GA 30339, Atlanta, USA
Operating office: Avenue de Tervueren 188a, Postbox 4,
1150 Brussels, Belgium
www.isdi.org

Table I: Food Additives currently used by the industry in the manufacturing of RUTF, and their comparison to food additives permitted for use in existing Codex texts aimed at infants and young children

Item	Food Additive	International Numbering System (INS)	ADI	Functional Class	Technological Justification	Maximum Use Level**	Currently Permitted in CXS 72-1981 or CXS 156-1987 or CXG 10-1979	Currently Permitted in Food Category in the General Standard for Food Additives (GSFA, CXS 192-1995)
Emulsifiers								
1	Mono & diglycerides of fatty acids	471	17th JECFA (1973) ADI not specified	Emulsifier	Forms or maintains a uniform emulsion of two or more phases in a food (definition GL 36-1989)	4000 mg/kg of RUTF	CXS 72-1981 CXS 156-1987	13.1.1; 13.1.2; 13.1.3; 13.2
2	Citric and fatty acid esters of glycerol	472c	Not of concern at proposed use level 79th JECFA (2014)	Emulsifier	Forms or maintains a uniform emulsion of two or more phases in a food	9000 mg/kg of RUTF	CXS 72-1981	13.1; 13.2
3	Lecithin	322(i)	17th JECFA (1973) ADI not specified	Emulsifier	Forms or maintains a uniform emulsion of two or more phases in a food.	Up to 5000 mg/kg of RUTF	CXS 72-1981 CXS 156-1987 CXS 73-1981 CXS 74-1981	13.1.1; 13.1.2; 13.1.3; 13.2
Antioxidants								
4	Ascorbyl palmitate	304	17th JECFA (1973) ADI 0 - 1.25 mg/kw bw	Antioxidant	Prolongs the shelf-life of foods by protecting against deterioration caused by oxidation.	max 10 mg/kg of RUTF	CXS 72-1981 CXS 156-1987 CXS 73-1981 CXS 54-1981	13.1.1; 13.1.2; 13.1.3; 13.2
5	Tocopherol concentrate, mixed*	307b	17th JECFA (1973): ADI 0-2 mg/kg for alphatocopher and mixed tocopherols concentrate	Antioxidant	Prolongs the shelf-life of foods by protecting against deterioration caused by oxidation.	10 mg/kg of RUTF	CXS 72-1981 CXS 156-1987 CXS 73-1981 CXS 74-1981	13.1.1; 13.1.2; 13.1.3; 13.2; 13.3
6	Ascorbic acid	300		Antioxidant	Prolongs the shelf-life of foods by protecting against deterioration caused by oxidation.	GMP	CXS 156-1987 CXS 74-1981	13.1.2; 13.2
Acidity regulators								
7	Citric acid	330	17th JECFA (1973) ADI not specified	Acidity regulator	Prolongs the shelf-life of foods by protecting against deterioration caused by oxidation.	GMP	CXS 72-1981 CXS 156-1987 CXS 73-1981 CXS 74-1981	13.1.1; 13.1.2; 13.1.3; 13.2

Item	Food Additive	International Numbering System (INS)	ADI	Functional Class	Technological Justification	Maximum Use Level**	Currently Permitted in CXS 72-1981 or CXS 156-1987 or CXG 10-1979	Currently Permitted in Food Category in the General Standard for Food Additives (GSFA, CXS 192-1995)
Packaging gas								
8	Nitrogen	941	24th JECFA (1980): n ADI necessary	Packaging Gas	Products are nitrogen flushed before sealing so that oxygen is displaced. This inhibits oxidation and thereby spoilage throughout the product's mentioned shelf life.	GMP	CXS 72-1981 CXS 156-1987 CXS 73-1981	13.1.1; 13.1.3; 13.2
9	Carbon dioxide	290	29th JECFA (1985): ADI not specified	Packaging Gas	Products are flushed with car- bon dioxin before sealing so that oxygen is displaced. This inhibits oxidation and thereby spoilage throughout the product's mentioned shelf life.	GMP	CXS 72-1981 CXS 156-1987 CXS 73-1981	13.1.1; 13.1.3; 13.2
Carrier								
10	Sillicon dioxide, amorphous	551	80th JECFA (2015): ADI not specified	Carrier	Used to dissolve, dilute, disperse or otherwise physically modify a food additive or nutrient without altering its function (and without exerting any technological effect itself) in order to facilitate its handling, application or use of the food additive or nutrient. (Definition CXG 36-1989)	10 mg/kg of RUTF	CXG 10-1979	13.2 (may also be used as is also authorized for foods for infants and young children by CXG 10-1979)

***Only 307b is allowed for 13.1.1 and 13.1.3 while for 13.1.2, 307 a, b, c are permitted**
****Maximum use levels for RUTF are less than or equal to the maximum use levels for the currently permitted food categories**

Recommendation 2
Seeking advice from CCFA It is recommended that CCNFSDU agree to ask CCFA to confirm if RUTF Guidelines belong to FC 13.3; and if FC 13.3 is the right FC, then CCFA should consider aligning the proposed food additives listed in Table I of this document with F.C 13.3 of the GSFA.

ISDI Comment

ISDI agrees with the proposal that CCNFSDU should seek advice from CCFA on the question of the best way to approach the GSFA Food Category for the case of the RUTF Guidelines.

ISDI acknowledges certain challenges with identifying the appropriate GSFA Food Category (FC) for the RUTF Guideline. We note from paragraph 1.2 of the preamble of the GSFA , that the GSFA "sets forth the conditions under which food additives may be used in all foods, whether or not they have previously been standardized by Codex", thus, whether a Standard or a Guideline, additive provisions for RUTF guideline can be addressed. On one hand, the description for food category 13.3 is highly aligned with the intended use of RUTF. The vast majority of additive provisions that are currently permitted in Food Category 13.3 are not required to manufacture RUTF, and in some cases, may not be considered appropriate for use in foods for older infants (for example, colours and sweeteners). At the same time, as identified in Question 1 of this Response, and provided in Table 1, the additive provisions in FC 13.1.1, 13.1.2, 13.1.3 include additives required for RUTF manufacture, and these FCs are associated with similar age range as the target consumers for RUTF (children 6 to 59 months).

To address the challenge described, ISDI proposes a more flexible approach which is to make reference in the RUTF Guideline document to the permitted use of the food additive provisions in Codex Standards CXS 72-1981, CXS 156-1987, and CXG 10-1979. This approach was recently used in the CXG 8-1991 (amended 2017) Guidelines on Formulated Complementary Foods for Older Infants and Young Children. The text in the Guideline for RUTF would then read:

Food additives and flavourings listed in the Standard for Infant Formula and Formulas for Special Medical Purposes (72-1981) and the Standard for Follow Up Formula (156-1987) may be used in Ready To Use Therapeutic Foods to the maximum limits given in those Standards.

Alternatively, if the committee considers it preferable to manage additives only through the GSFA, we suggest identifying a new GSFA Food Category under parent category 13.0. In this case, all the allowed additives could be populated in this new Food Category.

Recommendation 3
That CCNFSDU agree to the following texts on "Carry-Over of Additives and Carriers" in RUTF Guidelines: **<u>Proposed Texts</u>** Only the food additives referenced in this Section or in the *Advisory List of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Children* (CXG 10-1979) may be present in the foods described in section 2.1 of this Standard, 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).*

+32 (0)2 761 16 80
secretariat@isdi.org
Legal seat: 3200 Windy Hill Road, Marietta GA 30339, Atlanta, USA
Operating office: Avenue de Tervueren 188a, Postbox 4,
1150 Brussels, Belgium
www.isdi.org

ISDI Comment

ISDI agrees with recommendation 3.

ISDI would like to note that the text in the recommendation should refer to 'Guidelines' and not 'Standard'. The Committee has previously agreed to develop 'Guidelines for Ready to Use Therapeutic Foods' and not a Standard.

Recommendation 4

4.1:

That CCNFSDU agree to the proposed protein values of the Guidelines for RUTF.

Unit	Minimum	Maximum	GUL
g/100g	13	16.5	-
g/100kcal	2.4	3.2	-

ISDI Comment

ISDI agrees with recommendation 4.1.

Recommendation 4

4.2:

That CCNFSDU agree to the proposed texts on protein quality assessment in RUTF Guidelines.

Proposed texts

Protein should provide 10% to 12% of the total energy. Protein quality should be determined using PDCAAS, calculated according to the reference amino acid requirement and scoring patterns related to catch up growth of 10 g/kg/day in the target population of children 6 to 59 months for RUTF. The PDCAAS shall not be less than 90, when determined using PDCAAS methodology, appropriate fecal Digestibility values and the reference amino acid pattern 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*. High quality protein will be achieved with RUTF formulations containing a minimum of 50% of protein from milk products.

In formulations with lower scores, the quality and/or quantity of protein should be adjusted to achieve the desired value. The quality of protein can be achieved by adding the limiting amino acids. Any added amino acids should be solely in the L-form, and included only in amounts necessary to improve the protein quality of the RUTF.

Detail on how to calculate the PDCAAS is listed 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*[2].

ISDI Comment

ISDI generally supports the recommendation, but would like to propose the following to ensure that the intention is well understood.

"Protein should 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 10 g/kg/day in the target population ~~of~~**, which is**

[2] Report of the Expert Working Group on Protein Quality Assessment in Follow-up Formula for Young Children and Ready to Use Therapeutic Foods. FAO, Rome, 2018.pp38

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children 6 to 59 months for RUTF.
~~The PDCAAS shall not be less than 90%, when determined using PDCAAS methodology, appropriate digestibility values and the reference amino acid pattern in the Report of the FAO Expert Working Group (2018): Protein quality assessment in follow-up formula for young children and ready to use therapeutic foods.~~
The PDCAAS calculated using appropriate digestibility values and the reference amino acid pattern as based on FAO Expert Working Group (2018): Protein quality assessment in follow-up formula for young children and ready to use therapeutic foods, shall be not less than 90 %.
High quality protein will be achieved with RUTF formulations containing a minimum of 50% of protein from milk products. In formulations with lower scores, the quality and/or quantity of protein should be adjusted to achieve the desired value. The **required** quality of protein ~~can~~ **may** be achieved by adding ~~the limiting~~ **essential** amino acids. Any added amino acids should be solely in the L-form and included only in amounts necessary to improve the protein quality of the RUTF. Detail on how to calculate the PDCAAS is listed 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*[3]."

ISDI notes that RUTF formulations shall comply with Section 3 of the Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CXS 180-1991) and therefore efficacy of formulations containing a smaller proportion of milk should be demonstrated through rigorous randomized controlled trials providing evidence of its ability to support catch-up growth as evaluated in major outcomes of SAM treatment such as weight gain and recovery rates.

Recommendation 5
That CCNFSDU agree to the proposed texts on Processing Technologies in RUTF Guidelines. **Proposed Texts** *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)*.

ISDI Comment

ISDI agrees with recommendation 5.

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[3] Report of the Expert Working Group on Protein Quality Assessment in Follow-up Formula for Young Children and Ready to Use Therapeutic Foods. FAO, Rome, 2018.pp38

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