CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 4a and 5 **NFSDU/40 CRD 23**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

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Comments of India

ITEM 4A

General Comments:

1. India is of the view that Follow-up Formula is not necessary and is unsuitable when used as a breastmilk replacement from six months of age onwards. The same is also observed by WHO (WHO 2013: Information concerning the use and marketing of follow-up formula).

2. Alignment of the Codex standards with World Health Assembly Resolution 69.9 (2016) and the accompanying guidance: It is essential that there is policy alignment between Codex instruments and the norms, standards, resolutions and recommendations adopted by the World Health Assembly, especially those relating to infant and young child feeding. This is essential for the protection of optimal infant and young child health and to support WHO infant and young child feeding recommendations. The decisions made at the WHA by Member States need to be imbedded into Codex standards and national legislation. Any Codex standard covering products targeted to children less than 36 months must at the very least conform to WHA Resolution 69.9 (2016) and accompanying guidance (2016).

3. Also, Follow-up Formula should not replace the culturally acceptable complementary foods. We do not support developing two separate standards for older infants and young children.

4. Further, these formulations should meet the relevant National Regulations in terms of Essential Composition and a footnote to this effect should be inserted under each category of essential composition.

Specific Comments

SECTION A: FOLLOW-UP FORMULA FOR OLDER INFANTS

3 ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 **Essential composition**

3.1.1 Follow-up formula for older infants is a product based on milk of cows or other animals or a mixture thereof and/or other ingredients which have been proven to be safe and suitable for the feeding of older infants.The nutritional safety and adequacy of follow-up formula for older infants shall be scientifically demonstrated to support growth and development of older infants.

3.1.2 When prepared ready for consumption in accordance with the instructions of the manufacturer, the products shall contain per 100 ml not less than 60 kcal (250 kJ) and not more than 70 kcal (295 kJ) of energy

3.1.3 Follow-up Formula prepared ready for consumption shall contain per 100 kcal (100 kJ) the following nutrients with the following minimum and maximum or guidance upper levels (GUL) [1]as appropriate.

a) Protein[2), 3), 4)]

Unit	Minimum	Maximum	GUL
g/100 kcal	1.8[5), 6)]	3.0	-

g/100 kJ	0.43[5), 6)]	0.72	-

[2)] For the purpose of this standard the calculation of the protein content of the final product ready for consumption should be based on N x 6.25, unless a scientific justification is provided for the use of a different conversion factor for a particular product**.** The protein levels set in this standard are based on a nitrogen conversion factor of 6.25. For information the value of 6.38 is used as a specific factor appropriate for conversion of nitrogen to protein in other Codex standards for milk products.

[3)] For an equal energy value the formula must contain an available quantity of each essential and semiessential amino acid at least equal to that contained in the reference protein (breast-milk as defined in Annex I of the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-1981)); nevertheless for calculation purposes the concentrations of tyrosine and phenylalanine may be added together and the concentrations of methionine and cysteine may be added together.

[4)] Isolated amino acids may be added to follow-up formula only to improve its nutritional value for infants. Essential and semi-essential amino acids may be added to improve protein quality, only in amounts necessary for that purpose. Only L-forms of amino acids shall be used.

[5)] The minimum value applies to cows' and goats' milk protein. For follow-up formula based on non-cows'or non-goats'milk protein other minimum values may need to be applied. For follow-up formula based on soy protein isolate, a minimum value of 2.25 g/100 kcal (0.54 g/100 kJ) applies.

[6)] A lower minimum protein level between 1.6 and 1.8 g/100 kcal (0.38 and 0.43 g/100 kJ) in follow-up formula based on non-hydrolysed milk protein can be accepted. Suchfollow-up formula and follow-up formula based on hydrolysed protein should be evaluated for their safety and suitability and assessed by a competent national and/or regional authority based on clinical evidence.

b) Lipids

Total Fat [7), 8)]

Unit	Minimum	Maximum	GUL
g/100 kcal	~~4.4~~ **3.8**	~~6.0~~ 5.3	-
g/100 kJ	~~1.1~~ 0.72	~~1.4~~ 1.3	-

[7)] Partially hydrogenated oils and fats shall not be used in follow-up formula for older infants.

[8)] Lauric acid and myristic acids are constituents of fats, but combined shall not exceed 20% of total fatty acids. The content of trans fatty acids shall not exceed 3% of total fatty acids. Trans fatty acids are endogenous components of milk fat. The acceptance of up to 3% of trans fatty acids is intended to allow for the use of milk fat in infant formulae. The erucic acid content shall not exceed 1% of total fatty acids. The total content of phospholipids should not exceed 300 mg/100 kcal (72 mg/100 kJ).

Rationale: Values are higher than the National draft Regulations.

Linoleic acid

Unit	Minimum	Maximum	GUL
mg/100 kcal	300	-	1400
mg/100 kJ	72	-	335

α-Linolenic acid

Unit	Minimum	Maximum	GUL
mg/100 kcal	50	N.S.*	-
mg/100 kJ	12	N.S.	-

*N.S. = not specified

Ratio linoleic acid/ α-Linolenic acid

Min	Max
5:1	15:1

c) Carbohydrates

Available carbohydrates [9)]

Unit	Minimum	Maximum	GUL
g/100 kcal	9.0	14.0	-
g/100 kJ	2.2	3.3	-

[9)] Lactose and glucose polymers should be the preferred carbohydrates in formula based on cow's milk protein and hydrolysed protein. Only precooked and/or gelatinised starches gluten-free by nature may be added. Sucrose and/or fructose should not be added, unless needed as a carbohydrate source, and provided the sum of these does not exceed 20% of available carbohydrate.

d) Vitamins

Vitamin A

Unit	Minimum	Maximum	GUL
µg RE[10)]/100 kcal	75	~~180~~ 85	-
µg RE[10)]/100 kJ	18	~~43~~ 20	-

[10)] expressed as retinol equivalents (RE)

1 µg RE = 3.33 IU Vitamin A = 1 µg trans retinol. Retinol contents shall be provided by preformed retinol, while any contents of carotenoids should not be included in the calculation and declaration of vitamin A activity.

Rationale: Values are significantly higher than the National draft Regulations.

Vitamin D

Unit	Minimum	Maximum	GUL
µg[11)] /100 kcal	1.0	~~3.0~~ 2.10	-
µg[11)] /100 kJ	0.24	~~0.72~~ 0.50	-

[11)] Calciferol. 1 µg calciferol = 40 IU vitamin D.

Rationale: Values are higher than the National draft Regulations.

Vitamin E

Unit	Minimum	Maximum	GUL
mg α-TE[12)] /100 kcal	0.5 [13)]	1.30	5
mg α-TE[12)] /100 kJ	0.12 [13)]	0.31	1.2

[12)] 1 mg α-TE (alpha-tocopherol equivalents) = 1 mg d-α-tocopherol

[13)] Vitamin E shall be at least 0.5 mg α-TE per g PUFA, using the following factors of equivalence to adapt the minimal vitamin E content to the number of fatty acid double bonds in the formula: 0.5 mg αTE /g linoleic acid (18:2 n-6); 0.75 α-TE/g α-linolenic acid (18:3 n-3); 1.0 mg α-TE/g arachidonic acid (20:4 n-6); 1.25 mg α-TE/g eicosapentanoic acid (20:5 n-3); 1.5 mg α-TE/g docosahexaenoic acid (22:6 n-3).

Rationale: A maximum value for Vitamin E should be mentioned at 1.30 mg/100 Kcal since the GUL of 5 mg/100 Kcal is very high as per the National draft Regulations.

Vitamin K

Unit	Minimum	Maximum	GUL

µg /100 kcal	~~4~~ 1.6	3.2	27
µg /100 kJ	~~1.0~~ 0.38	0.76	6.5

Rationale: The Minimum value is significantly higher than the National Regulations. Also, the maximum limit needs to be mentioned at 3.2 microgram/100 Kcal since the GUL of 27 is very high as per the National Regulations.

Thiamin

Unit	Minimum	Maximum	GUL
µg /100 kcal	~~60~~ 42.50	63.80	300
µg /100 kJ	~~14~~ 10	15	72

Rationale: The Minimum value is significantly higher than the National draft Regulations. Also, the maximum limit needs to be mentioned at 63.80 microgram/100 Kcal since the GUL of 300 is very high as per the National Regulations.

Riboflavin

Unit	Minimum	Maximum	GUL
µg /100 kcal	80	425	500
µg /100 kJ	19	102	119

Rationale: Maximum limit needs to be mentioned at 425 microgram/100 Kcal since the GUL of 500 is high as per the National draft Regulations.

Niacin [14)]

Unit	Minimum	Maximum	GUL
µg /100 kcal	~~300~~ 808	1170	1500
µg /100 kJ	~~72~~ 193	280	360

[14)] Niacin refers to preformed niacin

Rationale: As per the National draft Regulations, the product should contain Niacin not less than 808 microgram/100 kcal. Further, maximum limit needs to be mentioned at 1170 microgram/100 Kcal since the GUL of 1500 is high.

Vitamin B_6

Unit	Minimum	Maximum	GUL
µg /100 kcal	~~35~~ 21.30	85.10	175
µg /100 kJ	~~8.4~~ 5.1	20.3	41.8

Rationale: The Minimum value is significantly higher than the National draft Regulations. Also, the maximum limit needs to be mentioned at 85.10 microgram/100 Kcal since the GUL of 175 is very high as per the National Regulations.

Vitamin B_{12}

Unit	Minimum	Maximum	GUL
µg /100 kcal	~~0.1~~ 0.05	0.10	1.5
µg /100 kJ	~~0.024~~ 0.012	0.24	0.36

Rationale: The Minimum value is significantly higher than the National draft Regulations. Also, the maximum limit needs to be mentioned at 0.10 microgram/100 Kcal since the GUL of 1.5 is very high as per the National Regulations.

Pantothenic acid

Unit	Minimum	Maximum	GUL
µg /100 kcal	400	-	2000
µg /100 kJ	96	-	478

Folic acid

Unit	Minimum	Maximum	GUL
µg /100 kcal	~~10~~ 1.92	6.36	50
µg /100 kJ	~~2.4~~ 0.46	1.52	12

Rationale: The Minimum value is significantly higher than the National draft Regulations. Also, the maximum limit needs to be mentioned at 6.36 microgram/100 Kcal since the GUL of 50 is very high as per the National Regulations.

Vitamin C [15)]

Unit	Minimum	Maximum	GUL
mg /100 kcal	~~10~~ 5.30	8.50	70 [16)]
mg /100 kJ	~~2.4~~ 1.27	2.03	17 [16)]

15) expressed as L-ascorbic acid

16) This GUL has been set to account for possible high losses over shelf-life in liquid formulas; for powdered products lower upper levels should be aimed for.

Rationale: The Minimum value is significantly higher than the National draft Regulations. Also, the maximum limit needs to be mentioned at 8.50 mg/100 Kcal since the GUL of 70 is very high as per the National Regulations.

Biotin

Unit	Minimum	Maximum	GUL
µg /100 kcal	1.5	-	10
µg /100 kJ	0.4	-	2.4

e) Minerals and Trace Elements

Iron [17)]

Unit	Minimum	Maximum	GUL
mg /100 kcal	~~1.0~~ 0.6	~~2.0~~ 1.0	-
mg /100 kJ	~~0.24~~ 0.14	~~0.48~~ 0.24	-

17) For Follow-up formula based on soy protein isolate a minimum value of 1.5 mg/100 kcal (0.36/100 kJ) and maximum of 2.5 mg/100 kcal (0.6 mg/100 kJ) applies.

Rationale: Values are significantly higher than the National draft Regulations.

Calcium

Unit	Minimum	Maximum	GUL
mg /100 kcal	50	148	180
mg /100 kJ	12	35	43

Rationale: Maximum limit needs to be mentioned at 148 mg/100 Kcal since the GUL of 180 is high as per the National draft Regulations.

Phosphorus

Unit	Minimum	Maximum	GUL
mg /100 kcal	25	-	100 [18)]
mg /100 kJ	6	-	24 [18)]

[18)] This GUL should accommodate higher needs withFollow-up formula based on soy protein isolate.

Ratio calcium/phosphorus

Min	Max
1:1	2:1

Magnesium

Unit	Minimum	Maximum	GUL
mg /100 kcal	5	8.5	15
mg /100 kJ	1.2	2.03	3.6

Rationale: Maximum limit needs to be mentioned at 8.5 mg/100 Kcal since the GUL of 15 is high as per the National draft Regulations.

Sodium

Unit	Minimum	Maximum	GUL
mg /100 kcal	20	60	-
mg /100 kJ	5	14	-

Chloride

Unit	Minimum	Maximum	GUL
mg /100 kcal	50	160	-
mg /100 kJ	12	38	-

Potassium

Unit	Minimum	Maximum	GUL
mg /100 kcal	60	180	-
mg /100 kJ	14	43	-

Manganese

Unit	Minimum	Maximum	GUL
µg /100 kcal	1.0	-	100
µg /100 kJ	0.24	-	24

Iodine

Unit	Minimum	Maximum	GUL
µg /100 kcal	~~10~~ 19.15	25.50	60
µg /100 kJ	~~2.4~~ 4.6	6.1	14.3

Rationale: The Minimum value is lower than the National draft Regulations. Also, the maximum limit needs to be mentioned at 25.50 microgram/100 Kcal since the GUL of 60 is very high as per the National Regulations.

Selenium

Unit	Minimum	Maximum	GUL
µg /100 kcal	~~2~~ 1.0	3.60	9
µg /100 kJ	~~0.48~~ 0.24	0.86	2.2

Rationale: Values are significantly higher than the National draft Regulations.

Copper [19)]

Unit	Minimum	Maximum	GUL
µg /100 kcal	35	100	120
µg /100 kJ	8.4	23.9	29

[19)] Adjustment may be needed in these levels for Follow-up formula made in regions with a high content of copper in the water supply.

Rationale: The maximum limit needs to be mentioned at 100 microgram/100 Kcal since the GUL of 120 is higher than the National draft Regulations.

Zinc [20)]

Unit	Minimum	Maximum	GUL
mg /100 kcal	0.5	-	1.5
mg /100 kJ	0.12	-	0.36

[20)] For Follow-up formula based on soy protein isolate a minimum value of 0.75 mg/100 kcal (0.18 mg/100 kJ).

3.2 Optional Ingredients

3.2.1 In addition to the compositional requirements listed under 3.1.3 Section A, other ingredients or substances may be added to follow-up formula for older infants **in compliance to the National Regulations**, where the safety and suitability of the optional ingredient for particular nutritional purposes, at the level of use, is evaluated and demonstrated **as safe and nutritional useful by relevant convincing scientific evidence or the comparable level of evidence under the GRADE classification** ~~by generally accepted scientific evidence~~.

3.2.2 When any of these ingredients or substances is added the formula shall contain sufficient amounts to achieve the intended effect, taking into account levels in human milk.

3.2.3 The following substances may be added in conformity with national legislation, in which case their content per 100 kcal (100kJ) in the Follow-up Formula ready for consumption shall not exceed the levels listed below. This is not intended to be an exhaustive list, but provides a guide for competent national and/or regional authorities as to appropriate levels when these substances are added.

Taurine

Unit	Minimum	Maximum	GUL
mg /100 kcal	-	12	-
mg /100 kJ	-	3	-

Comments: The

Total nucleotides

Levels may need to be determined by national authorities.

Docosahexaenoic acid [21)]

Unit	Minimum	Maximum	GUL
mg /100 kcal	-	-	30
mg /100 kJ	-	-	7.2

[21)] If docosahexaenoic acid (22:6 n-3) is added to follow-up formula, a minimum level of 20 mg/100 kcal (4.8 mg/100 kJ)should be reached, and arachidonic acid (20:4 n-6) contents should reach at least the same concentration as DHA. The content of eicosapentaenoic acid (20:5 n-3), which can occur in sources of LC-PUFA, should not exceed the content of docosahexaenoic acid. Competent national and/or regional authorities may deviate from the above conditions, as appropriate for the nutritional needs.

Choline

Unit	Minimum	Maximum	GUL
mg /100 kcal	-	-	50
mg /100 kJ	-	-	12

Myo-inositol

Unit	Minimum	Maximum	GUL
mg /100 kcal	-	-	40
mg /100 kJ	-	-	9.6

L-carnitine

Levels may need to be determined by national authorities.

L (+) lactic producing cultures

Only L (+) lactic producing cultures may be used for the purpose of producing acidified follow-up formula for older infants. The acidified final formula product should not contain significant amounts of viable L (+) lactic acid-producing cultures, and residual amounts should not represent any health risk.

The safety and suitability of the addition of specific strains of L(+) lactic acid producing cultures for particular beneficial physiological effects, at the level of use, must be demonstrated by clinical evaluation and generally accepted scientific evidence. When added for this purpose, the final product ready for consumption shall contain sufficient amounts of viable cultures to achieve the intended effect.

Rationale**:** There is no robust scientific evidence to support benefits of prebiotics uses in infants and children. However, if they are used, it should be ensured that only lactic acid producing bacteria listed/approved for use by the relevant National authorities should be used.

SECTION B: [FOLLOW-UP FORMULA] FOR YOUNG CHILDREN

3 ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Essential composition

3.1.1 **[Follow-up Formula] for young children** is a product based on milk of cows or other animals or a mixture thereof and/or other ingredients which have been proven to be safe and suitable for the feeding of young children.The nutritional safety and adequacy of [**Follow-up Formula**] for young children shall be ~~scientifically~~ demonstrated **through relevant convincing scientific evidence or the comparable level of evidence under the GRADE classification** to support growth and development of young children.

3.1.2 When prepared ready for consumption in accordance with the instructions of the manufacturer, the products shall contain per 100 ml not less than 60 kcal (250 kJ) and not more than 70 kcal (295 kJ) of energy. National and/or regional authorities can deviate from the minimum energy content in line with national/regional dietary guidelines taking into account the nutritional needs of the local population.

3.1.3 (**Follow-up Formula**) for young children prepared ready for consumption shall contain per 100 kcal (100 kJ) the following nutrients with the following minimum and maximum or guidance upper levels (GUL)*, as appropriate. The general principles for establishing these levels are identified in Annex I of this standard.

a) Protein[1), 2)]

Unit	Minimum	Maximum	GUL
g/100 kcal	1.8	-	-
g/100 kJ	0.43	-	-

1) For the purpose of this standard the calculation of the protein content of the final product ready for consumption should be based on N x 6.25, unless a scientific justification is provided for the use of a different conversion factor for a particular product**.** The protein levels set in this standard are based on a nitrogen conversion factor of 6.25. For information the value of 6.38 is used as a specific factor appropriate for conversion of nitrogen to protein in other Codex standards for milk products.

2) When determined by PER methodology,the quality of protein shall not be less than 85% of that of casein.

The protein quality shall be determined provisionally using the PER or PDCAAS and other methods that come available in the future.

b) Lipids [3)]

Total fat

Unit	Minimum	Maximum	GUL
g /100 kcal	~~3.5~~ 3.0	6.0	-
g /100 kJ	~~0.84~~ 0.72	1.43	-

Comments: The minimum value for total fat is more than the National draft Regulation. Also, a maximum level needs to be added at 6.0 g/100 Kcal as per the National Regulation.

α-linolenic acid

Unit	Minimum	Maximum	GUL
mg /100 kcal	50	-	-
mg /100 kJ	12	-	-

Linoleic acid

Unit	Minimum	Maximum	GUL
mg /100 kcal	300	-	-
mg /100 kJ	72	-	-

3) Partially hydrogenated oils and fats shall not be used in [name of product] for young children.

* Guidance upper levels are for nutrients without sufficient information for a science-based risk assessment. These levels are values derived on the basis of meeting nutritional requirements of young children and an established history of apparent safe use. They may be adjusted based on relevant scientific or technological progress. The purpose of the GULs is to provide guidance to manufacturers and they should not be interpreted as goal values. Nutrient contents in [name of product] for young children should usually not exceed the GULs unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of [name of product] for young children or due to technological reasons. When a product type or form has ordinarily contained lower levels than the GULs, manufacturers should not increase levels of nutrients to approach the GULs.

c) Carbohydrates

Available carbohydrates [4)]

Unit	Minimum	Maximum[5)]	GUL
g /100 kcal	-	12.5	-
g /100 kJ	-	3.0	-

[4)] [Lactose should be the preferred carbohydrates in [name of product] based on milk protein. For products not based on milk protein, carbohydrate sources (like starch) that have no contribution to the sweet taste should be preferred.

Mono- and disaccharides, other than lactose, either added as ingredients, or constituents of ingredients and/or increased above the amount contributed by the ingredients by some other means, should not exceed 2.5 g/100kcal (0.60 g/100kJ) of available carbohydrate. National and/or regional authorities may limit this level to 1.25 g/100 kcal (0.30 g/100 kJ). Sucrose and/or fructose or other carbohydrates contributing to the sweet taste of [name of product] should not be added, unless needed as a carbohydrate source. Other non-carbohydrate ingredients should not be added with the purpose of imparting or enhancing a sweet taste.]

[5)] For [Name of the product] for young children with a protein level below 3.0 g/100 kcal a maximum level of available carbohydrates up to 14 g/100 kcal (3.3 g/100 kJ) may be permitted by competent national and/or regional authorities.

d) Vitamins and Minerals

Iron[6)]

Unit	Minimum	Maximum	GUL
mg /100 kcal	~~1.0~~ 0.6	~~3.0~~ 1.0	-
mg /100 kJ	~~0.24~~ 0.14	~~0.72~~ 0.24	-

[6)] For [name of product] based on soy protein isolate a minimum value of 1.5 mg/100 kcal (0.36 mg/100 kJ) applies.

Comments: Values are significantly higher than the National draft Regulations.

Vitamin C[7)]

Unit	Minimum	Maximum	GUL
mg /100 kcal	~~10~~ 5.30	8.50	70
mg /100 kJ	~~2.4~~ 1.27	2.03	17

[7)] expressed as L-ascorbic acid

Comments: The Minimum value is significantly higher than the National draft Regulations. Also, the maximum limit needs to be mentioned at 8.50 mg/100 Kcal since the GUL of 70 is very high as per the National Regulations.

Calcium

Unit	Minimum	Maximum	GUL
mg /100 kcal	~~90~~ 86	170	280
mg /100 kJ	~~22~~ 21	41	67

Comments: The Minimum value is higher than the National draft Regulations. Also, the maximum limit needs to be mentioned at 170 mg/100 Kcal since the GUL of 280 is very high as per the National Regulations.

Riboflavin

Unit	Minimum	Maximum	GUL
µg /100 kcal	80	425	650

µg /100 kJ	19	102	155

Comments: Maximum limit needs to be mentioned at 425 microgram/100 Kcal since the GUL of 500 is high as per the National Regulations.

Vitamin B_{12}

Unit	Minimum	Maximum	GUL
µg /100 kcal	~~0.1~~ 0.05	0.10	2.0
µg /100 kJ	~~0.024~~ 0.012	0.24	0.48

Comments: The Minimum value is significantly higher than the National draft Regulations. Also, the maximum limit needs to be mentioned at 0.10 microgram/100 Kcal since the GUL of 1.5 is very high as per the National Regulations.

Zinc

Unit	Minimum	Maximum	GUL
mg /100 kcal	0.5	-	1.5
mg /100 kJ	0.12	-	0.36

Vitamin A

Unit	Minimum	Maximum	GUL
µg RE[8)] /100 kcal	60	~~180~~ 85	-
µg RE[8)] /100 kJ	14	~~43~~ 20	-

[8)] expressed as retinol equivalents (RE)

1 µg RE = 3.33 IU Vitamin A = 1 µg all-trans retinol. Retinol contents shall be provided by preformed retinol, while any contents of carotenoids should not be included in the calculation and declaration of vitamin A activity.

Comments: Values are significantly higher than the National draft Regulations.

[Vitamin D_3[9)]]

Unit	Minimum	Maximum	GUL
µg[10)] /100 kcal	~~[1.5]~~ [1.0]	~~[4.5]~~ [2.10]	-
µg[10)] /100 kJ	~~[0.36]~~ [0.24]	~~[1.08]~~ [0.50]	-

[[9)] Competent national and/or regional authorities may deviate from the conditions as appropriate for the nutritional needs of their population.]

[10)] Calciferol. 1 µg calciferol = 40 IU vitamin D.

Comments: Values are significantly higher than the National draft Regulations.

Sodium chloride should not be added to [name of the product] for young children.

3.1.4 National and/or regional authorities may add mandatory requirements for essential nutrients listed under 3.1.3, Section B. Any additional mandatory nutrients should be chosen from the essential composition of follow-up formula for older infants under 3.1.3 Section A. If additional mandatory nutrients are added, the nutrient levels must be based on the nutrient composition of follow-up formula for older infants (3.1.3 Section A) which is informed by the composition of breast milk, and take into account the inherent levels of nutrients in cows' milk.

All nutrient levels may be amended if the nutritional needs of the local population and scientific justification warrants such deviation.

3.2 Optional Ingredients

3.2.1 In addition to the essential compositional requirements listed under 3.1.3 Section B, other ingredients, substances or nutrients may be added to [name of the product] for young children **in compliance to the National Regulations,** where the safety and suitability of the optional ingredient for particular nutritional purposes, at the level of use, is evaluated by national and/or regional authorities and demonstrated **as safe and nutritional useful by relevant convincing scientific evidence or the comparable level of evidence under the GRADE classification** ~~by generally accepted scientific evidence~~. Optional ingredients listed in 3.2.3 Section A are also permitted.

3.2.2 When any of these ingredients, substances or nutrients is added the formula shall contain sufficient amounts to achieve the intended effect.

3.2.3 Additional nutrients may also be added to [name of the product] for young children provided these nutrients are chosen from the essential composition of follow-up formula for older infants and levels are as per the minimum, maximum, GULs stipulated for follow-up formula for older infants (3.1.3 Section A) and take into account the inherent levels of nutrients in cows' milk; or amended by national and/or regional authorities if the nutritional needs of the local population and scientific justification warrants such deviation.

ITEM 5

General comments:

1. India does not support the use of RUTF as enough evidence is not available for the use of commercially manufactured RUTF for management of SAM *vis-a-vis* other interventions like home augmented foods. Further, in a recent trial conducted in India comparing the efficacy of RUTF (centrally produced and locally produced) with augmented energy-dense home-prepared foods (comparison group) for home based management of uncomplicated severe acute malnutrition (SAM); results showed that (i) homemade foods were as effective *vis-a-vis* as centrally produced RUTF; (ii) 16 weeks after stopping RUTF, recovery rates dropped from 56.9% to 17.3% for locally produced RUTF and from 47.5% to 12.1% for centrally produced RUTF and not for use of these products in India.
2. India strongly supports the need for using local foods to manage the condition in accordance with the national policy. Therefore, the comments of India are limited only to the guideline formulation process for standardization of the product.
3. Further, if the use of RUTF in national/sub-national programme for the management of SAM is approved by the national authorities, these formulations should meet the relevant country specific recommendations for Essential composition as specified by the National Authorities and a footnote to this effect should be inserted under the recommendation for each Nutrient (macronutrients as well as micronutrients).

Specific Comments:

Section	India's View point
Recommendation 1: That CCNFSDU agree to the following text for the Preamble of the Guidelines for RUTF: Children affected by severe acute malnutrition (SAM) need safe, palatable foods with a high energy content and adequate amounts of vitamins, minerals and other nutrients. Children with SAM need efficacious and timely treatment and RUTF is part of the care. RUTF are primarily intended for children with uncomplicated SAM from 6-59 months. Although RUTF may be 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. These guidelines provide guidance for the production and labelling of RUTF. The guidelines are intended to facilitate the harmonization of requirements for RUTF at the international level and may provide assistance to governments wishing to establish national regulations. The guidelines are also intended for use as an instrument designed to avoid or remove 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 should be used in accordance with technical recommendations of the relevant evidence and related Codex texts/documents by WHO, UNICEF and WFP[1]. Governments and other users should ensure adequate provisions are made for competent technical experts for the appropriate use of these guidelines. [1)] 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. 2007. Community-Based Management of Severe Acute Malnutrition; A Joint Statement by the World Health Organization and the United Nations Children's Fund. 2009. Child growth standards and the identification of severe acute malnutrition in infants and children, Geneva: World Health Organization; World Health Organisation. 2013. Guideline: Updates on the management of severe acute malnutrition in infants and children, Geneva: World Health Organization; World Health Organisation. 2003. Global Strategy for Infant and Young Child Feeding, Geneva: World Health Organization; World Health	**Older infants and** Children affected by severe acute malnutrition (SAM) need safe, palatable foods with a high energy content and adequate amounts of vitamins, minerals and other nutrients*. Children with SAM need ~~efficacious and~~ timely treatment and RUTF is ~~part of the care. RUTF are primarily~~ **one of the dietary options** intended for children with uncomplicated SAM from 6-59 months. ~~Although RUTF may be 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.~~ **Other options include augmented home prepared foods. It is important to sustain breastfeeding and homemade, culturally acceptable complementary foods. It is absolutely necessary that RUTFs are used only under Medical Supervision for children in the age group of 6 – 59 months.** These guidelines provide guidance for the production and labelling of RUTF. The guidelines are intended to facilitate the harmonization **and standardization** of requirements for **production of** RUTF at the international level and may provide assistance to governments wishing to establish national regulations **as per their policy regulations**. The guidelines are also intended for use as an instrument designed to avoid or remove difficulties which may be created by diverging legal, administrative and technical approaches to RUTF and by varying definitions and nutrient compositions of RUTF **products**. These guidelines should be used in accordance with technical recommendations of the relevant evidence**,** ~~and~~ related Codex texts/documents by WHO, UNICEF and WFP[1] **and relevant National regulations of the implementing Nation**. Governments and other users should ensure adequate provisions are made for competent technical experts for the appropriate use of these guidelines **so that these products are used only to treat SAM under strict medical supervision and to avoid general use of them**. **<u>These guidelines are not intended for providing any programmatic recommendations for the use of RUTF in national/sub-national programme for the management of SAM and national authorities may take appropriate decisions to use alternatives like augmented home</u>**

Organisation. 1981. International code of marketing of breast-milk substitutes, Geneva: World Health Organization and subsequent relevant WHA Resolutions on infant and young child feeding; Code of Ethics for International Trade in Food including Concessional and Food Aid Transactions (CXC 20-1979); Food and Agriculture Organisation and World Health Organisation. 2016. FAO/WHO Microbial safety of lipid-based ready-to-use foods for management of moderate acute malnutrition and severe acute malnutrition, Rome: Food and Agriculture Organisation.	**prepared foods.** [1)] 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. 2007. Community-Based Management of Severe Acute Malnutrition; A Joint Statement by the World Health Organization and the United Nations Children's Fund. 2009. Child growth standards and the identification of severe acute malnutrition in infants and children, Geneva: World Health Organization; World Health Organisation. 2013. Guideline: Updates on the management of severe acute malnutrition in infants and children, Geneva: World Health Organization; World Health Organisation. 2003. Global Strategy for Infant and Young Child Feeding, Geneva: World Health Organization; World Health Organisation. 1981. International code of marketing of breast-milk substitutes, Geneva: World Health Organization and subsequent relevant WHA Resolutions on infant and young child feeding **and the WHO Guidance on ending inappropriate marketing of foods for infant and young children**; Code of Ethics for International Trade in Food including Concessional and Food Aid Transactions (CXC 20-1979); Food and Agriculture Organisation and World Health Organisation. 2016. FAO/WHO Microbial safety of lipid-based ready-to-use foods for management of moderate acute malnutrition and severe acute malnutrition, Rome: Food and Agriculture Organisation. **Specific Comments:** **1.** The statement “Since RUTF is prescribed according to weight, National Authorities may decide to include the provision of RUTF in their national protocols for use by other age groups” may be deleted as enough scientific evidence is not available to recommend their use in age groups beyond the age of 5 years. Moreover, the use of RUTF by other age-groups is not under the scope of these guidelines. **2.** Reference for the relevant WHA resolutions needs to be given in the footnote. **3.** *Other Nutrients needs to be specified. 4. Additional suggested changes have been highlighted at appropriate place in the text of the preamble.

Recommendation 2: Vitamins and Minerals That CCNFSDU agree to the following texts for the Vitamins and Minerals section [Vitamin and mineral forms used must be soluble and easily absorbed by patients with SAM. Children with SAM have low or absent gastric acid which means that they should not be given inorganic salts of minerals that are insoluble or requiring an acid gastric environment for absorption, in order to avoid metabolic acidosis. It is important that RUTF should have a mineral composition that leads to a moderate excess of non metabolisable base. The non-metabolizable base can be approximated by the formula: estimated absorbed millimoles (sodium + potassium + calcium + magnesium) - (phosphorus + chloride.] All added vitamins and minerals must be in accordance with the Advisory Lists of Nutrient Compounds for use in Foods for Special Dietary Uses Intended for Infants and Young Children (CXG 10-1979). Examples of vitamin and mineral forms for RUTF formulation can be found in the WHO Management of severe malnutrition: A manual for physicians and other senior health workers (1999). [The amount of vitamins and minerals added to achieve the target level must be adjusted based on the chemical form and scientific evidence showing adequate stability and bioavailability in the finished product.]	**Agree**
Recommendation 3: Available Carbohydrates: That CCNFSDU agree to the following texts for the Available Carbohydrates section **Available Carbohydrates[2]** The palatability of the RUTF can be increased by the addition of available carbohydrates. Available carbohydrates must adhere to the relevant Codex Alimentarius texts. Honey should not be used in RUTF due to the risk of infant botulism from Clostridium botulinum. 2)Sucrose, plant starch, maltodextrin, should be the preferred carbohydrates in RUTF. Fructose, glucose and corn syrup as ingredients should be avoided in RUTF, because of potential adverse effects in SAM children. Only precooked and/or gelatinized starches [gluten-free] by nature may be added. Any carbohydrate added for sweetness should be used sparingly.	The palatability of the RUTF can be increased by the addition of available carbohydrates. Available carbohydrates must adhere to the relevant Codex Alimentarius texts **and should be limited to the WHO Guideline: Sugars intake for adults and children, Geneva, WHO (2015).'** Honey should not be used in RUTF due to the risk of infant botulism from Clostridium botulinum. 2) Sucrose, plant starch, maltodextrin should be the preferred carbohydrates in RUTF. Fructose, glucose and corn syrup as ingredients should be avoided in RUTF, because of potential adverse effects in SAM children. Only precooked and/or gelatinized starches [gluten-free] by nature may be added. ~~Any carbohydrate added for sweetness should be used sparingly~~. **The free sugars added for sweetness should be limited to 10% to 5%of total energy.**
Recommendation 4: Food Additives	• Comments on individual additives are as per Annexure-1.

It is recommended that: 4.1 CCNFSDU take note and agree with the proposed list of food additives (Table 1) and their technological justification that are currently used in RUTF. 4.2 CCNFSDU agree that the electronic working group recommend a proposed list of food additives to the Committee for consideration on their technological justification.	• However, foods for older infants and young children should not include food additives and flavours. These are primarily for aesthetic and cosmetic purposes and expose the vulnerable gut of a child suffering from SAM to unnecessary chemicals, many of which have detrimental effects and can prolong rehabilitation. Exposing infants to unnecessary chemicals at such an early age adds to the lifelong chemical burden. • Examples of detrimental effects of some of the additives currently being used are as follows: - **Benzoates:** In a report from Thailand, Sodium benzoate has been reported to be mutagenic and cytotoxic which may have serious health implications. Use of this additive, therefore may be dangerous for the health of children. - **Carmine:** Cochineal carmine, or simply carmine (E120), is a red colouring that is obtained from the dried bodies of the female insect Dactylopius coccus Costa (the cochineal insect). A number of cases of an IgE-mediated hypersensitivity due to carmine following ingestion have been reported which requires due diligence before allowing this additive in RUTF. US FDA requires carmine to be identified by name on the food label due to the risk of potential allergic reaction. - **Polysorbates:** Polysorbate 80 can cause severe nonimmunologic anaphylactoid reactions and therefore its' use as an additive requires due diligence. **References:** i. (Pongsavee M. Effect of sodium benzoate preservative on micronucleus induction,chromosome break, and Ala40Thr superoxide dismutase gene mutation in lymphocytes. Biomed Res Int. 2015;2015:103512 https://www.ncbi.nlm.nih.gov/pubmed/25785261 ii. https://www.ncbi.nlm.nih.gov/pubmed/11285683 iii. https://www.fda.gov/food/ingredientspackaginglabeling/foodadditivesingredients/ucm488219.htm

	iv. https://www.ncbi.nlm.nih.gov/pubmed/16400901)
Recommendation 5: The Use of other Matrices in RUTF Formulation That CCNFSDU agree to the proposed text which reference Section 3 of the CXS 180-1991 on the use of other matrices in RUTF formulations as follows: 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 (CXS 180-1991).	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 (CXS 180-1991), **although several scientific studies have reported that use of formulation with other ingredients are less effective in terms of recovery rates in comparison to standard, peanut and milk (25%) based formulation.** **Rationale:** **1. An equivalence non-blinded cluster randomized controlled trial from Zambia has found that the effectiveness of a milk-free soy-maize-sorghum-based RUTF (SMS-RUTF) with 25% milk content in standard peanut-based RUTF (P-RUTF) in treatment of children with SAM is not equal, recovery rates being lower in children who received SMS-RUTF.** **2. A randomized, double blind, clinical, quasi-effectiveness trial from Malawi has concluded that treating children with SAM with 10% milk (plus Soy) RUTF is less effective compared with treatment with the standard 25% milk RUTF. Recovery among children receiving 25% milk RUTF was greater than children receiving 10% milk RUTF, 64% compared with 57% after 4 wk, and 84% compared with 81% after 8 wk (*P* < 0.001). Children receiving 25% milk RUTF also had higher rates of weight and height gain compared with children receiving 10% milk RUTF.**
Recommendation 6: Energy That CCNFSDU agree to the proposed text on energy and the energy values as follows: **Draft Text** The energy density of the formulated RUTF should be between 5.2 to 5.5 kcal per gram. The energy density of RUTF can be achieved during manufacturing by the addition of energy containing ingredients (i.e. fats and oils and/or digestible carbohydrates) and/or processing the basic raw materials and ingredients as indicated in Section 8.	• **There is no scientific basis for suggesting an energy density of 5.2 - 5.5 kcal per gram. This is empirical and hence needs more discussion before finalising a value. Energy content of the product is dependent on the amount of protein, carbohydrates and lipids present. Therefore, an effort should be made to use appropriate balance of ingredients rather than increasing energy density which will be mainly achieved by adjusting the amount of fats and sugars in the product, which may have health implications and the product will also not conform to the WHO recommendations.**

Energy Values Unit Minimum Maximum GUL Kcal/100g 520 550 -	• **Also, the additional energy required will depend on the amount of breastmilk the older infant and young child is receiving.**
Recommendation 7: That CCNFSDU agree not to set the minimum and maximum/GUL values for carbohydrates.	**The amount of carbohydrates must adhere to the WHO Guideline: Sugars intake for adults and children, Geneva, WHO (2015)'. The free sugars added for sweetness should be limited to 10% to 5%of total energy.** **Sugars such as fructose and corn syrups should be prohibited because of their possible adverse effects which may be exacerbated by the condition of SAM.** (Malik VS, Hu FB. Fructose and Cardiometabolic Health: What the Evidence From Sugar-Sweetened Beverages Tells Us. J Am Coll Cardiol. 2015 Oct 6;66(14):1615-24 Hu FB, Malik VS. Sugar-sweetened beverages and risk of obesity and type 2 diabetes: epidemiologic evidence. Physiol Behav. 2010 Apr 26;100(1):47-54.)
Recommendation 8: Protein That CCNFSDU agree to the proposed protein values in RUTF. Protein should provide 10%-12% of the total energy. Unit Minimum Maximum GUL g/100g 12.8 16.2 - g/100kcal 2.3 3.1 -	**Agree**
Recommendation 9: That CCNFSDU agree to keeping the statement "at least 50% of protein is provided by milk products" in square brackets until there is further guidance from FAO on determining protein quality using PDCAAS. ["at least 50% of protein is provided by milk products"]	**Agree**
Recommendation 10: Lipids That CCNFSDU agree to the proposed text on fats/lipids and the proposed	**Comments: Does not agree.** **Rationale:** A product deriving high energy from fats is not scientifically sound and is abnormal composition for a diet. WHO recommends that

minimum and maximum fats/lipids values as follows: Lipids should provide 45% to 60% of the total energy. The level of linoleic acid should not be less than 333 mg per 100 kcal. The level of alpha-linolenic acid should not be less than 33mg/100kcal. The level of linoleic acid should ensure a ratio between linoleic acid and alpha-linolenic acid of between 5:1 and 15:1.] Unit Minimum Maximum GUL g/100g 26 37 - g/100kcal 5 6.7 -	total fat should not exceed 30% of total energy intake. Accordingly, the guidelines should keep negative health implications of high fat intake in view. However, if WHO advice of keeping fat level below 30% is not observed, the label should include text saying that "This is a high fat product."
Recommendation 11: Essential Fatty acids values That CCNFSDU agrees to retaining the linoleic acid and alpha-linolenic acid values as stipulated in the 2007 Joint Statement in the current RUTF nutritional composition as follows: Linoleic Acid = 3-10% of total energy The level of linoleic acid should not be less than 333 mg per 100 kcal Alpha- linolenic acid = 0.3-2.5% of total energy The level of alpha-linolenic acid should not be less than 33 mg per 100 kcal	**Agree**
Recommendation 12: Vitamin A That CCNFSDU agree to the minimum, maximum and associated footnote for vitamin A as follows: Unit Minimum Maximum GUL mg RE/100g 0.8 [1.1] or [1.2] - mg/ RE/100kcal 0.15 [0.2] or [0.22] - [2]µg RE/100kcal 150 [200] OR [220] - [2]1µg RE = 3.33 IU Vitamin A = 1 µg trans retinol. Retinol contents shall be provided by preformed retinol, while any contents of carotenoids should not be included in the calculation and declaration of vitamin A activity.	**Comment**: Does not Agree. **Rationale**: The proposed levels of Vitamin A are very high. The RDA for Indian Children from 6 months to 6 years is 350 to 400 mcg (ICMR, 2010). Vitamin A values should not exceed these levels as high values can cause serious adverse effects.

Recommendation 13: Vitamin D That CCNFSDU agree to the minimum, maximum/GUL and associated footnote for vitamin D as follows: Unit Minimum Maximum GUL [3] µg/100 g 15 [20] OR [22] [30] [3] µg100 kcal 2.7 [3.6] OR [4] - [3] 1 µg cholecalciferol = 40 IU vitamin D	**Comment**: Does not Agree. **Rationale**: The proposed maximum levels of Vitamin D are very high. The RDA for Indians is 10 mcg (ICMR, 2010) and 15 mcg according to the National institutes of Health, US department of health and human services for children from birth to 13 years. Maximum Vitamin D values should not exceed these levels as high values can cause serious adverse effects.
Recommendation 14: Vitamin E That CCNFSDU agree to the minimum and associated footnote for vitamin E as follows: Unit Minimum Maximum GUL 4 mg/100 g 20 - - 4 mg (α-TE /100 kcal) 4 - - [4] 1 mg α-tocopherol = 1 mg RRR-α-tocopherol (d-α-tocopherol) [4] 1 mg α-tocopherol =2.00 mg all-rac-α-tocopherol (dl- α-tocopherol)	**Comment**: Does not Agree. **Rationale**: The proposed minimum levels of Vitamin E is high. Recommended Dietary Allowances (RDAs) for Vitamin E for children from birth to 13 years is 4 - 7 mg according to the National institutes of Health, US department of health and human services. Vitamin E values should not exceed these levels as high levels can cause serious adverse effects.
Recommendation 15: That CCNFSDU agree to the following recommendations for vitamin K, vitamin B1, vitamin B2, vitamin C, vitamin B6, vitamin B12, folic acid, niacin, pantothenic acid and biotin for RUTF as follows: **Vitamin K** Unit Minimum Maximum GUL µg/100 g 15 30 - µg/100 kcal 2.9 5.5 - **Vitamin B1** Unit Minimum Maximum GUL mg/100 g 0.5 - -	**Vitamin-K** **Comment**: Does not Agree. **Rationale**: The proposed minimum and maximum values for Vitamin K are high for infants. Recommended Adequate Intakes for Vitamin K for infants is 2 – 2.5 mcg according to the National institutes of Health, US department of health and human services. **Vitamin-B1** **Comment:** Agree **Vitamin-B2** **Comment**: Does not Agree. **Rationale**: The proposed minimum values for Vitamin B2 are very high for children. Recommended Dietary Allowances for Vitamin B2 for children (6

mg/100 kcal 0.1 - - **Vitamin B2** Unit Minimum Maximum GUL mg/100 g 1.6 - - mg/100 kcal 0.3 - - **Vitamin C** Unit Minimum Maximum GUL mg/100 g 50 - - mg/100 kcal 9.6 - - **Vitamin B6** Unit Minimum Maximum GUL mg/100 g 0.6 - - mg/100 kcal 0.12 - - **Vitamin B12** Unit Minimum Maximum GUL µg/100 g 1.6 - - µg/100 kcal 0.3 - - **Folic Acid** Unit Minimum Maximum GUL [5] µg/100 g 200 - - [5] µg/100 kcal 38.5 - - [5] 1 µg of folic acid = 1.7 µg of Dietary Folate Equivalents (DFE) **Niacin** Unit Minimum Maximum GUL	m - 3 years) is 0.4 – 0.6 mg (RDA 2010). **Vitamin-C** **Comment**: Does not Agree. **Rationale**: The proposed values for Vitamin C are high for children. Recommended Dietary Allowances (RDAs) for Vitamin C for children 0-8 years according to the National institutes of Health, US department of health and human services and Recommended Dietary Allowances for Indian, ICMR, 2010, are 25-40 mg.[1] Vitamin C values should not exceed these levels. **Vitamin-B6** **Comment:** Agree **Vitamin-B12** **Comment**: Does not Agree. **Rationale**: The proposed minimum value for Vitamin B12 is high for children between 0-8 years. Recommended Dietary Allowances (RDAs) for Vitamin B12 for children 0 - 8 years according to the National institutes of Health, US department of health and human services are 0.4 – 1.2 mcg. The RDA for Indian Children is 0.2 - 1.0 mcg. Vitamin B12 values should not exceed these levels. **Folic Acid** **Comment**: Does not Agree. **Rationale**: The proposed minimum value for Folic Acid is high for children between 0-3 years. Recommended Dietary Allowances (RDAs) for Folic Acid for children 0 - 3 years according to the National institutes of Health, US department of health and human services are 65 – 150 mcg DFE. The RDA for Indian Children is 25-100 mcg. Folic Acid values should not

[1] https://ods.od.nih.gov/factsheets/Riboflavin-HealthProfessional/

mg/100 g 5 - - mg/100 kcal 0.96 - - **Pantothenic Acid** Unit Minimum Maximum GUL mg/100 g 3 - - mg/100 kcal 0.6 - - **Biotin** Unit Minimum Maximum GUL µg/100 g 60 - - µg/100 kcal 11.5 - -	exceed these levels. **Niacin** **Comment:** Agree **Pantothenic Acid** **Comment:** Agree **Biotin** **Comment**: Does not Agree. **Rationale**: The proposed minimum value for Biotin is high. Recommended Dietary Allowances (RDAs) for children 7 months - 8 years according to the National institutes of Health, US department of health and human services are 6 – 12 mcg/d.[2]
Recommendation 16: Minerals That CCNFSDU agree to the following recommendations for sodium, potassium, calcium, phosphorus, magnesium, iron, zinc, copper, selenium and iodine for RUTF as follows: **Sodium** Unit Minimum Maximum GUL mg/100 g - 290 - mg/100 kcal - 53 - **Potassium** Unit Minimum Maximum GUL mg/100 g 1100 1400 - mg/100 kcal 212 255 - **Calcium** Unit Minimum Maximum GUL	**Sodium** Sodium level should be much less than 290 mg/100g. For sodium (sodium chloride), the adverse effect concerned does not have a defined threshold, but is a continual graded response such that risk increases with increasing intake. Therefore, it is important to keep it to minimum. **Potassium:** Agree **Calcium :** Maximum value should be 600 mg/100g **Phosphorus :** Maximum value should be 600 mg/100g **Magnesium :** The proposed values are higher than the RDA. The Recommended Dietary Allowance of Magnesium for Indian children (6 m - 6 yrs) is 45 - 70 mg/day (ICMR, 2010). **Iron:** Agree **Zinc:** The proposed values are higher than the RDA. The Recommended Dietary Allowance of Zinc for Indian children (1-6 yrs) is 5-7 mg/day (ICMR, 2010) **Copper :** Agree

[2] https://medlineplus.gov/ency/article/002410.htm

mg/100 g	300	[600] or [785]	-
mg/100 kcal	58	[109] or [143]	-
Phosphorus			
Unit	Minimum	Maximum	GUL
mg/100 g	300	[600] or [785]	-
mg/100 kcal	58	[109] or [143]	-
Magnesium			
Unit	Minimum	Maximum	GUL
mg/100 g	80	[140] or [235]	-
mg/100 kcal	15.4	[26] or [43]	-
Iron			
Unit	Minimum	Maximum	GUL
mg/100 g	10	14	-
mg/100 kcal	1.9	2.6	-
Zinc			
Unit	Minimum	Maximum	GUL
mg/100 g	11	14	-
mg/100 kcal	2.0	2.6	-
Copper			
Unit	Minimum	Maximum	GUL
mg/100 g	1.4	1.8	-
mg/100 kcal	0.27	0.33	-
Selenium			
Unit	Minimum	Maximum	GUL
mcg/100 g	20	40	-

Selenium : Agree

Iodine : Agree

mcg/100 kcal 4.0 7.0 - **Iodine** Unit Minimum Maximum GUL mcg/100 g 70 140 - mcg/100 kcal 13.46 25.5 -	
Recommendation 17: Additional Nutrients That CCNFSDU consider that the current formulation of RUTF, as well as the proposed nutrients as stipulated in the 2007 Joint Statement be the basis for RUTF formulation, unless there is scientific evidence on any additional nutrients that has been demonstrated to be safe and beneficial in meeting the nutritional requirements of SAM children.	Agreed subject to adoption by individual country.
Recommendation 18: Processing Technologies That CCNFSDU agree to the proposed text of "Processing Technologies" section of the Guidelines as follows: In addition to the practices described below, Good Hygiene Practices (General principles of food hygiene CXC 1-1969) should be implemented to avoid cross contamination during the packing and storage of raw materials. **1. Preliminary Treatment of Raw Materials:** Cereals, legumes, pulses and oilseeds should first be treated to obtain wholesome and clean raw materials of good quality. Such treatments include, but are not limited to: • **Cleaning or washing:** to eliminate dirt, damaged grains, foreign grains and noxious seeds, insects and insect excreta and any adhering material. • **Dehulling:** When necessary, pulses, legumes, oilseeds and certain cereals such as oats, barley, sorghum, millet and teff may be dehulled as completely as is feasible to reduce the fibre content to acceptable levels and to decrease, and/or if possible, to eliminate phytates, tannins and other phenolic materials, trypsin and chymotrypsin inhibitors which can lower the protein digestibility and amino acid bioavailability and mineral absorption. • **Degermination**: where necessary and appropriate, degermination of wheat, corn, soy and other crops should be considered in order to reduce the phytate content.	Agreed subject to adoption by individual country.

2. Milling • Milling or grinding of suitable raw materials should be carried out in such a way as to minimize the loss of nutritional value and to avoid undesirable changes in the technological properties of the ingredients. • Dry raw materials may be milled together, if technologically feasible, or mixed after milling or grinding. • Formulations containing milled cereals, legumes, pulses and/or oilseeds that have not been otherwise processed require adequate boiling to gelatinize the starch portions and/or eliminate anti-nutritional factors present in cereals, legumes and pulses. Boiling improves the digestibility and absorption of nutrients. • The bulkiness of foods from food formulations containing dry ingredients obtained by milling of the raw materials can be reduced by adding, during the formulation, adequate amounts of enzymes such as alpha-amylase which, during the slow heating to boiling, predigest partially the starch and reduce the amount of water needed for the preparation of the food. **3. Toasting** • Toasting (dry heating) enhances the flavour and the taste of the food through dextrinization of starch. It also improves digestibility and contributes to reducing the bulkiness of the formulated food. Moreover, it reduces microorganisms and enzyme activity and destroys insects, thus improving keeping qualities. • Protein damage due to the Maillard reaction may occur in the presence of reducing carbohydrates. The toasting process should therefore be carefully controlled. • Pulses as well as oilseeds such as soya beans, groundnuts and sesame seeds can be toasted as whole grains directly or after soaking. • Toasted raw materials can be milled or ground for use as ingredients. • [The use of appropriate enzymes may be considered to decrease anti-nutrients in ingredients.] **4. Sprouting, Malting and Fermentation** • Cereals and pulses can be induced to germinate by soaking or humidifying. It	

is necessary, however, to ensure that growth of mycotoxin producing microorganisms does not occur. The action of natural amylases contained in the grains results in the pre-digestion of the starchy portion of the grain (dextrinization) thus reducing the bulk of the food when prepared for feeding and, ultimately, increasing the nutrient density of the food. Sprouting, malting and fermentation can induce hydrolysis of phytates and decrease its inhibitory effect on mineral absorption, and may improve B vitamin content. • During the germination process, the seed coat of the grain splits and can be removed by washing. The malted raw material is milled or ground after drying. **5. Other Processing Technologies** Whenever feasible, RUTF 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 or their raw materials include both thermal (e.g. roasting, steam treatment followed by a drying step) and non-thermal (e.g. antimicrobial fumigation) control measures. Guidelines for the Validation of Food Safety Control Measures (CXG 69-2008) and Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM) (CXG 63-2007) should be adhered to.	
Recommendation 19: Good manufacturing practices and good hygiene practices: That CCNFSDU agree to the proposed draft text for "good manufacturing practices and good hygiene practices" section as follows: It is recommended that the products covered by the provisions of this guidelines be prepared and handled in accordance with the appropriate sections of the General Principles of Food Hygiene (CXC 1-1969), and Code of Hygienic Practice for Low-Moisture Foods (CXC 75-2015). The product should comply with any microbiological criteria established in accordance with the Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods (CXG 21-1997). The ingredients and final product should be prepared, packed and held under sanitary conditions and should comply with relevant Codex texts.	Agreed subject to adoption by individual country.

Recommendation 20: Methods of analysis and sampling That CCNFSDU agrees to the proposed text for "the methods of analysis and sampling" section of the guidelines as follows: It is recommended that methods of analysis and sampling of RUTF be in accordance with the Recommended Methods of Analysis and Sampling (CXS 234-1999), General Standard for Contaminants and Toxins in Food and Feed (CXS 193-1995), The Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods (CXG 21-1997), Code of Hygienic Practice for Low Moisture Foods (CXC 75-2015), and other relevant Codex Alimentarius texts. When needed, specific methods of analysis should be developed in accordance with appropriate Guidelines on Measurement Uncertainty (CXG 54-2004), Protocol for the Design, Conduct and Interpretation of Method Performance Studies (CXG 64-1995), and Harmonized IUPAC.	Agreed subject to adoption by individual country.
Recommendation 21: Packaging That CCNFSDU agrees to the proposed text for "packaging" section of the guidelines as follows: It is recommended that RUTF be packaged in such a way to safeguard the hygienic and other qualities including nutritional properties of the food for the duration of its defined shelf-life. The packaging materials shall be made only of substances which are safe and suitable for their intended uses. Where the Codex Alimentarius Commission has established a standard for any such substance used as packaging materials, that standard shall apply.	Agreed subject to adoption by individual country.
Recommendation 22: Labelling That CCNFSDU agree with the proposed draft text for the "labelling" section of the guidelines as follows: It is recommended that the labelling of RUTF for children from 6 to 59 months be in accordance with the Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CXS 180-1991), ~~Codex General Standard for the Labelling of Pre-packaged Foods (CODEX STAN 1-1985)~~, the General Standard for the Labelling of and Claims for Pre-packaged Foods for Special Dietary Uses (CXS 146-1985), ~~Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997)~~ and Guidelines on Nutrition Labelling (CXG 2- 1985).	It is recommended that the labelling of RUTF for children from 6 to 59 months be in accordance with the Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CXS 180-1991), ~~Codex General Standard for the Labelling of Pre-packaged Foods (CODEX STAN 1-1985)~~, the General Standard for the Labelling of and Claims for Pre-packaged Foods for Special Dietary Uses (CXS 146-1985), ~~Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997)~~ and Guidelines on Nutrition Labelling (CXG 2- 1985) **and the International Code of Marketing of Breastmilk Substitutes and subsequent relevant WHA resolutions on labeling and claims, including the WHO Guidance on ending inappropriate marketing of foods for infants and**

The Name of the Food The name of the food to be declared on the label shall indicate that the food is a Ready to Use Therapeutic Food for Children from 6 to 59 months. The appropriate designation indicating the true nature of the food should be in accordance with national legislation. The age from which the product is recommended for use shall appear in close proximity to the name of the food. **List of Ingredients** The list of ingredients shall be declared in accordance with Section 4.2 of the Codex General Standard for the Labelling of Prepackaged Foods (CXS 1 -1985). **Additional Mandatory Labelling Requirements:** The following statements shall appear on the label of RUTF: • "USE UNDER MEDICAL SUPERVISION" shall appear on the label in bold letters in an area separated from the written, printed, or graphic information. • "For the dietary management of severe acute malnutrition" shall appear on the label. • A prominent warning statement consisting of an explanatory statement in bold letters indicating that RUTF are for special medical purposes and may pose a health hazard when consumed by individuals who do not have the disease(s), disorder(s) or medical condition(s) for which the food is intended. • The product is not to be used for parenteral, rectal or Nasogastric Tube (NG tube) administration. • A statement indicating whether the product is or is not intended as the sole source of nutrition. • A statement indicating that RUTF are not breastmilk substitutes and shall not be presented as such. • [Exclusive breastfeeding is recommended for the first 6 months of life, and continued breastfeeding is recommended for at least 24 months.] • Instructions for use • The label should indicate clearly from which age the product is recommended for use. This age shall not be less than six months for any product. • Feeding instructions shall be given; preferably accompanied by graphical	**young children.** **Declaration of nutritive value is essential on the package of RUTF products** **Additional Mandatory Labelling Requirements:** The following statements shall appear on the label of RUTF: • "USE UNDER MEDICAL SUPERVISION" shall appear on the label in bold letters in an area separated from the written, printed, or graphic information. • "For the dietary management of severe acute malnutrition" shall appear on the label. • A prominent warning statement consisting of an explanatory statement in bold letters indicating that RUTF are for special medical purposes and may pose a health hazard when consumed by individuals who do not have the disease(s), disorder(s) or medical condition(s) for which the food is intended. • The product is not to be used for parenteral, rectal or Nasogastric Tube (NG tube) administration. • A statement indicating whether the product is or is not intended as the sole source of nutrition. • A statement indicating that RUTF are not breastmilk substitutes and shall not be presented as such. • [Exclusive breastfeeding is recommended for the first 6 months of life, and continued breastfeeding is recommended for at least 24 months.] – **Should be retained.** • **National authorities may take a decision regarding the use of RUTF for management of severe acute malnutrition based on the extant legislations/policies.** • **A statement indicating that RUTF are high-fat and high-sugar products.** • **The products should carry no health, nutrition or other promotional claims nor any idealizing text or pictures or representation that might suggest use for infants under the age**

presentations. • The time in which the product should be consumed after opening should be clearly indicated.	**of 6 months (including references to milestones and stages).** • **The product must not convey an endorsement or anything that may be construed as an endorsement by a professional or other body, unless relevant national, regional or international regulatory authorities have specifically approved this.**

Annexure-1

Recommendation 4: Food Additives

S. No	Additive allowed for RUTF in draft	INS No.	FSSR category 13.3 (FSMP)	Codex category 13.3 (FSMP)	Remarks
1.	**Mono & diglycerides**	471	Yes	Yes	Agreed
2.	**Ascorbyl palmitate**	304	No	No	Before adding the same has to be examined by Food additive committee.
3.	**Tochopherol**	307	No	Yes	Agreed but INS need to be specified as (307a, 307b and 307c)
4.	**Citric acid**	330	Yes	Yes	Agreed
5.	**Lecithin**	322	Yes but only 322 (i)	Both 322 (i) and (ii)	Agreed but INS need to be specified as (322 (i), and 322 (ii))
6.	**Tocopherols rich extract**	306	No	No	Before adding the same has to be examined by Food additive committee.
7.	**Ascorbic acid**	300	Yes	Yes	Agreed
8.	**Citric and fatty acid esters of glycerol**	472c	Yes	Yes	Agreed
9.	**Mixed tocopherol concentrate**	307b	No	Yes	Already covered under S. No 3. Hence may be deleted.
10.	**Nitrogen**	941	Yes	Yes	Agreed
11.	**Carbon dioxin**	290	Yes	Yes	Agreed. However, name need to revised as Carbon dioxide (editorial)
12.	**Sodium Tri-phosphates**	451	Yes (451 (i) and 451 (ii))	Yes (451 (i) and 451 (ii))	Agreed but INS need to be specified as (451 (i), and 451 (ii))
13.	**Silicium dioxide**	551	Yes	Yes	Agreed. However, name need to revised as Silicon dioxide, amorphous (editorial)
14.	**NATA - 5**	-	No	No	Not agreed since

15.	**Grindsted PS - 209 (Composed of Mono-diglyceride & Triglyceride**	-	No	No	codex GSFA do not recognize the premix/formulated additives for commercial purpose.
16.	**Fortium APT 10 (composed of mono & di-glycerides, propylene glycol, mixed tocopherols, and ascorbyl palmitate)**	-	No	No	
17.	**N-ATA 1**	-	No	No	