CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 5 **NFSDU/42 CRD 16**

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

Forty-second Session

Virtual
19 - 25 November and 1 December 2021

PROPOSED DRAFT GUIDELINE FOR READY-TO-USE THERAPEUTIC FOODS (AT STEP 7)

UNICEF SUPPLIER FEEDBACK: ESSENTIAL FATTY ACIDS IN RUTF

Prepared by UNICEF

Survey 1: Feedback on the proposed lipid composition change in current RUTF recipe

1st Supplier Survey: Lipid composition change questions

1. *Is it possible to achieve this change in EFA levels in your product?*
2. *Would you be able to provide an estimated percent cost difference, if applicable?*
3. *Initial feedback shared with UNICEF revealed the change in the EFA requirements could mean increasing canola oil and decreasing palm oil in the formulation, and potentially increasing the antioxidants and emulsifiers. Some suppliers have also suggested they would need to use high oleic peanuts which may be more difficult to source locally. Can you comment on your company's situation?*
4. *Has there been any formulation work done since last year in adjusting your product formulation to attempt to achieve these new levels?*
5. *Some suppliers have reported that its easier for them to achieve these new levels in the alternative versions of RUTF that replace peanuts with other legumes. Do you have any feedback on this?*

A survey of UNICEF's RUTF suppliers base was conducted to request feedback on the feasibility and implications of altering their RUTF formulations to accommodate the new proposed limits of n-3 and n-6 fatty acids. (Table 1)

Proposed RUTF composition with improved lipid composition to support LCPUFA/DHA status

Nutrient	% total energy	kcal/100g	g/100g	g/100kcal
Energy		520 - 550		
Lipids	45 - 60%	234 - 330	26 - 36.67	5.0 - 6.67
n-6 fatty acid/LA	2.5 – 7.2%	13.0 – 39.6	1.44 – 4.40	0.28 – 0.80
n-3 fatty acid/ALA	1.0 – 2.5%	5.2 – 13.75	0.58 – 1.53	0.11 - 0.28

A ratio between linoleic acid (LA) and alpha-linolenic acid (ALA) of between 1:1 and 5:1.

Consideration of provision of preformed DHA 20-100mg/100g, shall not exceed n-6 FA
Consideration of provision of preformed EPA, shall not exceed DHA

Table 1: Hsei A. Expert advice on minimum and maximum limits for essential fatty acid levels in Ready to Use Therapeutic Food (RUTF), February 2021

The survey questionnaire was provided by UNICEF during the period of January – February 2021 (listed in side panel). Table 2 below summarizes the supplier survey responses.

Out of twenty suppliers contacted, seventeen reported that the proposed levels of n-3 and n-6 fatty acids would be feasible and can be achieved in their existing product, the remaining 3 suppliers who responded to this question could not provide feedback on the feasibility at this stage.

Out of the twenty suppliers, fifteen had already initiated work on a reformulation to allow for the new proposed EFA levels.

When asked if the change would result in an increased cost, 20% of suppliers reported no change in costs, seven out of twenty suppliers reported that a price change could not be determined, and another five out of twenty suppliers estimated that there might be an increase in cost from 0.5% ($0.001US/sachet) up to 20% ($0.05US/sachet). A further three suppliers estimated a 1% ($0.003US/ sachet) cost increase with one additional supplier suggesting an estimated 5% ($0.01US/sachet) increase.

To achieve the changes in the fatty acid composition, most suppliers suggested a combination of strategies to achieve the proposed new EFA levels. Seven out of twenty stated they would reduce the palm oil, increase the addition of canola oil, (rich in omega-3 with lower levels of omega 6) and use high oleic peanuts if available. Seven out of out of twenty suppliers stated they would use oils that are high in omega-3 such as flaxseed or perilla oils and replace some of the palm oil. Two suppliers assessed that they already met the proposed levels of EFAs and would not need to change their formulation and a further two suppliers suggested that replacing peanuts with another ingredient such as chickpea or soy and using a high omega-3 oil would be their approach. Five out of the twenty suppliers consulted commented that they could not source high oleic peanuts, and this meant they had to employ other strategies to reduce the omega-6 content.

The outcomes of this survey revealed that the current supplier base of RUTF can achieve the proposed n-3 and n-6 fatty acid levels. Cost estimates of changing the current formulation of oils to achieve the proposed n-3 and n-6 are reported in table 3. The impact of this change to the cost of the formula is an estimate and precise cost implications cannot be fully determined at this stage. The impact on cost is likely to be minimized with scaling and manufacturers employing strategies to bring cost efficiencies in time.

Are the proposed EFA levels feasible?	**Formulation preparation started**	**Potential Cost differential**	**Approach to implement the proposed EFA change**
85% reported the proposed changes are possible	79% of suppliers-initiated reformulation work	35% unable to answer	35% reported they would increase canola oil, reduce palm oil, use high oleic peanuts
15% could not respond	21% are yet to initiate any work on reformulation	25% estimated a 5-20% potential cost increase	10% would replace some or all the peanuts with another legume such as chickpea or soy in addition to high omega-3 oil
		15% estimated up to 1% cost increase	35% reported they would use high n-3 oils such as flax or perilla oils and reduce palm oil
		5% estimated 5-6% cost increase	10% reported that they already meet the proposed EFA levels
		20% estimated no cost increase	25% commented that they could not source high oleic peanuts

Table 2. UNICEF supplier survey feedback responses to the proposed lipid composition change in current RUTF recipe.

Percent reported cost change estimate	$US cost change/sachet
0.5%	$0.001
1%	$0.05
5%	$0.003
20%	$0.01
Mean: 6.6%	Mean: $0.02
Median: 3%	Median: $0.007

Table 3: Cost summary of amending n-3 and n-6 of RUTF composition as reported by RUTF supplier base.

2. Survey Two: Feedback from Suppliers of preformed DHA

UNICEF posted a Request for Information (RFI) from the 20th- 30th of September and requested suppliers of marine oil powders to provide indicative pricing of additional marine based sources of DHA to RUTF. A total of three responses from large global suppliers of powdered omega three fish oil products responded. (Table 4)

The suppliers were requested to provide pricing data according to the below addition rates:

a) DHA equivalent dose to provide 72mg/100g* RUTF or about 0.24%w/wDHA. Based on Stevensen, 2021[i]

b) DHA equivalent dose to provide 104mg/100g RUTF equivalent to 20mg DHA/100kcal or 0.5-1% of total fatty acids (as per the European Commission Delegated Regulation (EU) 2016/127 of 25 September 2015. (EPA content shall not exceed DHA content)

	Product	Product input in mg†	a. Cost $US at 72mg/100g RUTF	b. Cost $US at 104mg/100g RUTF
Supplier 1	DHA Powder grade 1	0.55g for 72mg DHA /100g 0.79g for 104mg DHA/100g	$0.02	$0.03
	High DHA Powder Soluble	0.63g for 72mg DHA (as TG) /100g 0.91g for 104mg DHA (as TG)/100g	$0.02	$ 0.03
Supplier 2	Encapsulated DHA powder (fish oil)	442mg for 72mg DHA/100g	$0.01	$0.02
	Encapsulated DHA Powder (fish oil)	630mg for 104mg DHA/100g	$0.01	$0.02
Supplier 3	Dry powder n-3 grade1	1075mg for 72mg DHA/100g 1552mg for 104mg DHA/100g	$0.02 USD	$0.03 USD
	Dry powder n-3 grade 2	686mg for 72mg DHA /100g 990mg for 104mg/DHA/100g	$0.02 USD	$0.02 USD
	Tuna Oil‡ (Oil Form)	294mg for 72mgDHA/100g 424mg for 104mgDHA/100mg	$0.005 USD $0.007 USD	$0.007 USD $0.009 USD
DHA (vegetarian)	0.41g for 72mg DHA (as TG) per 100g	90 $/kg (indicative price)	$ 0.04	$ 0.05

	0.59g for 104mg DHA (as TG) per 100g			
DHA powder (infant grade)	0.63g for 72mg DHA (as TG) per 100g 0.91g for 104mg DHA (as TG) per 100g	120 $/kg (indicative price)	$ 0.08	$ 0.11

† Measured as triglycerides. ‡Tuna oil sources are provided for comparison only. Tuna oil prices were not included in the cost summary as the liquid form of omega 3 is not recommended for the RUTF paste format.

Table 4: Product input and cost of 72mg/100mg and 104mg/100mg in RUTF

Percent cost change adding 72mg DHA	**$US cost change/sachet adding 72mg DHA**	**Percent cost change adding 104mg DHA**	**$US cost change/sachet adding 104mg DHA**
Mean: 0.04%	Mean: $0.02	Mean: 0.06%	Mean: $0.03
Median: 0.05%	Median: $0.02	Median: 0.06%	Median: $0.03

Table 5: Mean and median cost estimates in percentage and USD value based on 72mg and 104mg / 100g in RUTF.

Feasibility of adding preformed sources of DHA to RUTF

2nd Supplier Survey: Manufacturing Feasibility questions

a) *Would the current DHA rich product be able to be incorporated into the RUTF matrix and retain its functional properties as a source of preformed DHA?*

b) *Would the added DHA retain its functional properties for the required shelf life of 24 months?*

c) *Are there any future or forthcoming issues or initiatives that may be important to consider from the industry perspective that would help to further inform the WHO review?*

UNICEF's RFI also included questions to the suppliers to understand the feasibility and expected challenges of including preformed DHA in the RUTF formulation. The suppliers responded highlighting that technical challenges may arise during incorporation of a DHA or omega 3 rich powder in the RUTF matrix due to the high level of unsaturated fatty acids and their rapid oxidation. In contrast to omega 3 blends, which can have a fishy odor which increases over time, using omega 3 fatty acids as DHA has been found to be more stable.

Producing a stable product with low fish odor will depend on product manufacturing processes and product properties. Important factors that will influence DHA stability are the dose of DHA or omega 3 used and its exposure to oxygen (air), light, trace minerals, temperature and time and impact. However, initial testing shows it is feasible to add DHA to a RUTF paste and new methods for encapsulation are under development and shows promising results. Typical shelf life for commercially available encapsulated DHA is 24 months. The products must be tested into the specific application to verify the shelf life.

Sensory testing has been conducted on a similar product, a 20gram lipid based nutritional supplement (LNS) with 75mg/20g of added omega 3. It demonstrated sensory acceptance up to 24 months.[ii] (Siziba L, 2020)

Good processing and lipid handling are required to ensure that the oxidation is avoided.

Formulation and production recommendations:

- Barrier packaging (protect against light and oxygen)
- Nitrogen flush of packaging and production under a nitrogen blanket is recommended to protect the DHA from oxidation.
- Time and temperature combinations (e.g. shelf life)
- Monitor the matrix: e.g. low oxidative quality of the other ingredients (fats)
- Use of less reactive forms of iron and copper

- Use of antioxidants such as dl-alpha-tocopherols, tocopherols and ascorbyl palmitate compounds.
- The current food additives listed for use in RUTFs are limited and the permitted tocopherols levels to adequately prevent DHA from oxidation if added to RUTF.
- The inclusion of preformed omega 3 or DHA as part of RUTF will require appropriate labelling of fish milk as declared allergens

Future Developments

The market for marine oils has grown rapidly over the last 20 years, and the development of Algae based DHA is predicted to become more cost efficient, so we can expect the prices for encapsulated algae DHA to go down. At present the price of marine sourced DHA is around 80-100% more than fish sources. For fish based DHA the price level is probably going to stay at the same level as today or slightly decrease.

Conclusion

Amending the current RUTF essential fatty acid profile by reducing the omega 6 level and increasing the omega 3 level may add an additional cost of around $0.02US. Adding preformed DHA to RUTF may results in a cost increase of $0.02 - $0.03US, depending on the dose. Both strategies of formulation change are of a similar cost. Using the approach with the best scientific data with manufacturing feasibility is recommended.

[i] Stephenson K, Callaghan-Gillespie M, Maleta K, Nkhoma M, George M, Park HG, Lee R, Humpheries-Cuff I, Lacombe RS, Wegner DR, Canfield RL. Low linoleic acid foods with added DHA given to Malawian children with severe acute malnutrition improves cognition: a randomized, triple blinded, controlled clinical trial. MedRxiv. 2021 Jan 1.

[ii] Siziba LP, Baumgartner J, Rothman M, Matsungo TM, Faber M, Smuts CM. Efficacy of novel small-quantity lipid-based nutrient supplements in improving long-chain polyunsaturated fatty acid status of South African infants: a randomized controlled trial. European journal of clinical nutrition. 2020 Jan;74(1):193-202.