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European Union Comments

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

41st Session

Düsseldorf, Germany

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AGENDA ITEM 5 a)

Proposed Draft Guidelines for Ready-to-use Therapeutic Foods at Step 4 (CX/NFSDU 19/41/6)

European Union competence
European Union vote

General comments

The European Union (EU) would like to thank South Africa, Senegal and Uganda for their work on document CX/NFSDU 19/41/6.

The EU is pleased that the comments it provided in the eWG were taken into account in the document. As explained in previous occasions, the EU supports the work on these guidelines on ready-to-use therapeutic foods (RUTF). Its main concern was to make sure that no doubts exists in the Guidelines on the status of RUTF as food for special medical purposes, covered by CODEX Standard 180-1991, and that the language used in the guidelines follows the one used in the Standard on Food for Special Medical Purposes. The EU considers that the text proposed by the Chairs adequately addresses the EU concerns.

Specific comments on the recommendations

Recommendation 6 (Carbohydrates)

The EU in general supports the proposed text as it reflects what was discussed and agreed in the pWG and in the Committee meeting in 2018.

In terms of the free sugar content of RUTF the EU reiterates the importance of limiting the addition of free sugars to the products to ensure, amongst other, a safeguard against overly sweet taste products that may negatively influence the taste preferences of young children.

However, as already noted in previous occasions, the EU is not in a position to comment in detail on specific compositional requirements of RUTF, as there is no specific advice from the European Food Safety Authority on them.
The EU remains convinced that the composition of RUTF should primarily be based on relevant WHO documents (and their future modifications) and on the advice of UNICEF, WHO and the World Food Program as well as NGOs with extensive experience in the field.

Recommendation 7 (Lipids/Fats)

The EU agrees with the recommendation in line with what was agreed in pWG 2018.

Recommendation 8 (Essential fatty acids)

The EU agrees with the proposed minimum and maximum n-3 and n-6 fatty acid values as discussed in pWG 2018. However, the EU suggests that the values be presented in the same way as those for lipids, i.e. in mg or g per 100 g and in mg or g per 100 kcal, while values in kcal/100 kcal provided in the table could be removed:

n-6 fatty acids

Unit	Minimum	Maximum	GUL
~~kcal/100 kcal~~	~~3~~	~~10~~	~~-~~
mg/100 g	**1732**	**6111**	**-**
mg/100 kcal	333	1110	-

n-3 fatty acids

Unit	Minimum	Maximum	GUL
~~kcal/100 kcal~~	~~0.3~~	~~2.5~~	~~-~~
mg/100 g	**172**	**1529**	**-**
mg/100 kcal	33	280	-

Recommendation 9 (Vitamins and minerals)

The EU in general agrees with the recommendation in line with what was agreed in pWG 2018. However, the EU has some editorial comments to improve the proposed text:

*RUTF should contain the vitamin**s** and minerals presented in the Annex **"**Nutrition**al** Composition of RUTF**"**. **Products should comply with the** ~~following~~ minimum and maximum or guidance upper values **(GUL)** in the annex.*

Recommendation 10 (Vitamin A)

The EU agrees with the recommendation in line with what was agreed in pWG 2018.

Recommendation 11 (Vitamin D)

The EU in general agrees with the proposed minimum and maximum levels for vitamin D, however it would like to note that (by calculating with a minimum energy density of 520 kcal/100g and a maximum energy density of 550 kcal /100g the minimum/maximum values in µg/100kcal are 2.9 µg/100kcal and 4 µg/100kcal respectively. As regards the proposed GUL, the EU would like to ask for clarification on why such a GUL level is needed taking into account that a maximum limit for Vitamin D is already set.

As regards the associated footnote, the EU wishes to note that the European Food Safety Authority could not identify any difference between the Vitamin D2 and D3 in terms of efficacy. Therefore, the EU suggests that both forms of Vitamin D are allowed for use in RUTF. Against this background, the EU suggests that the footnote is amended as follows:

1 µg ~~chole~~calciferol = 40 IU vitamin D

Recommendation 12 (Vitamin E)

The EU in general agrees with the recommendation in line with what was agreed in pWG 2018. However, the EU would like to ask whether there is any reason for saying "mg/100 g" in the first line and "mg α-TE/100 kcal" in the second line of the entry for Vitamin E.

Recommendation 13 (Recommendations for vitamin K, B1, B2, C, B6, B12 folic acid, niacin, pantothenic acid and biotin)

The EU agrees with the recommendation in line with what was agreed in pWG 2018.
However, the EU suggests that values expressed in µg/100 kcal be systematically reviewed and revised, if needed, in line with the rounding logic proposed by the eWG to avoid rounding errors

Recommendation 14 (Recommendations for sodium, potassium, calcium, phosphorus, magnesium, iron, zinc, copper, selenium and iodine)

The EU agrees with the recommendation in line with what was agreed in pWG 2018.

However, the EU suggests that values expressed in µg/100 kcal be systematically reviewed and revised, if needed, in line with the rounding logic proposed by the eWG to avoid rounding errors.

Recommendation 15 (Contaminants)

The EU agrees with the recommendation to reference the existing codex standards and codes of practice throughout the RUTF guidelines as suggested by UNICEF in its expert report last year.

Recommendation 16 (Good manufacturing and Good hygiene practices)

The EU can agree with the proposed text.

Recommendation 17 (Methods of Analysis and Sampling)

The EU can agree with the proposed text.

Recommendation 18 (Packaging)

The EU can agree with the proposed recommendation.

Recommendation 19 (Labelling)

The EU in general agrees with the proposed text with the following remarks:

The EU welcomes the Chairs` proposal to remove the references to Codex General Standard for the Labelling of Pre-packaged Foods (CODEX STAN 1-1985) and the Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997) to avoid unnecessary duplication.

As regards the additional labelling requirements, the EU would kindly like to reiterate its request for more information on the rationale for the inclusion of the statements on breastfeeding in the guidelines. The EU does not have problems with the content of the statements, but wonders whether their inclusion is really necessary, taking into account that the 2007 Joint Statement by the WHO, WFP, UNSCN and UNICEF on "Community-Based Management of Severe Acute Malnutrition", while recognising the essential contribution of exclusive breastfeeding for the first six months of a child's life to prevent severe acute malnutrition, also notes that treatment is needed for those children who already are suffering from severe acute malnutrition. In addition, the EU would propose the deletion of the words "parenteral" and "rectal" in order to make sure that the labelling of the products, which are usually distributed in very small packs, is clearly legible. It seems that there is no problem of parenteral or rectal use and it is not usually required. Furthermore, these products are used under medical supervision and are not placed on the market to be bought directly by the final consumer.

Recommendation 20 (Preamble)

The EU can support the proposed text.

The EU is pleased that the first paragraph of the Preamble has been deleted and reference to the *Code of Ethics for International Trade in Food including Concessional and Food Aid Transactions* has been inserted to the end of the text to ensure legal clarity. The EU supports the Chairs` proposal to remove the definition of RUTF from the Preamble in order to avoid unnecessary duplication. The EU also welcomes that the text of preamble has been simplified by listing the relevant guidelines only in the footnote. The EU also welcomes that the editorial changes proposed by the EU in the eWG were taken into account.

However, the EU would like to note that WHO / UNICEF / WFP are due to issue an updated joint statement and there is agreement among these agencies to look again, at how acute malnutrition is addressed. In the immediate term, the new joint statement will supersede the 2007 one and in the longer-term updated evidence, ways of working could have relevance to the further developments of the Codex. Therefore, the EU would like to ask for clarification on how and when these developments can be accommodated, addressed in the Guidelines for Ready-to-use Therapeutic Foods.