CODEX ALIMENTARIUS COMMISSION

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World Health Organization

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Agenda Item 5 **NFSDU/40 CRD 10**

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

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PROPOSED DRAFT GUIDELINE FOR READY-TO-USE THERAPEUTIC FOODS

Comments of the European Union

EUROPEAN UNION

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 18/40/6.

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 1 (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.

Recommendation 2 (Vitamins and Minerals)

The EU can support the proposed text for vitamins and minerals in the guidelines.

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 3 (Available carbohydrates)

The EU in general supports the proposed text with the following comments:

With regard to the Chairs` proposal to prohibit the addition of fructose to RUTF, the EU understands that the energy production from substrates such as galactose and fructose is slower than normal in children with severe acute malnutrition and would therefore support that fructose (or galactose) not be added as sources of energy to foods for malnourished children. However, the EU is not aware of any negative effects of small amounts of fructose added for palatability reasons, especially since RUTF is intended to be consumed only for a short period of time (several weeks). Furthermore, the EU assumes that high fructose corn syrup would not be used in RUTF because it is a liquid and would therefore increase the water content of such products.

With regard to the proposed text in the footnote, the EU is pleased that the comments it provided in the eWG were taken into account in the document. The EU welcomes the inclusion of the text "**Any carbohydrate added for sweetness should be used sparingly**" in the footnote which is in line with the Guidelines on Formulated Complementary Foods for Infants and Young Children. In addition, the EU would like to kindly note that if "gluten-free" is deleted from the text the words **"by nature"** should also be removed.

Recommendation 4 (Food additives)

The EU considers that it is premature to agree on the proposed list of food additives and their technological justification (Table 1) and that further discussion is needed on the matter.

Recommendation 5 (The Use of other Matrices in RUTF Formulation)

The EU supports the proposed recommendation, as it ensures legal clarity and, at the same time, addresses the concerns of the eWG Members related to "new formulations".

Recommendation 6 (Energy and Energy values)

See comment on recommendation 2.

Recommendation 7 (Minimum and maximum values for carbohydrates)

See comment on recommendation 2.

Recommendation 8 (Minimum and maximum values for protein)

See comment on recommendation 2.

Recommendation 9 (Protein quality)

The EU considers that quality of protein is important in this context and strongly supports 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.

The EU would like to request clarification on the timeframe over which FAO will undertake and complete the work on the PDCAAS and when and how this can then be reflected in the Guidelines for Ready-to-use Therapeutic Foods.

Recommendation 10 (Lipids/Fats)

See comment on recommendation 2.

Recommendation 11 (Essential Fatty Acids values)

See comment on recommendation 2.

Recommendation 12 (Vitamin A)

While the EU supports the minimum and maximum values proposed by the Chairs for vitamin A it would like to note that there might be no need for an additional provision in µg/100 kcal.

With regard to the wording of the footnote, the EU would like to note that it could be aligned with the similar footnote found in the Codex Standard for infant formula and formulas for special medical purposes intended for infants by adding the prefix "**all**" to trans retinol as follows:

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

Recommendation 13 (Vitamin D)

While the EU supports the minimum and maximum values proposed by the Chairs for vitamin D, it considers that there is no need, in conformity with vitamin A, to establish a GUL for vitamin D. The EU would also like to note that (by calculating with a minimum energy density of 5.2 kcal/g) the min. vitamin D content of 15 µg/100 g is equal to 2.9 µg/100 kcal therefore the currently proposed min. value of 2.7 µg/100 kcal would have to be slightly increased (to 2.9 µg/100 kcal).

As regards the footnote proposed by the Chairs, the EU suggests a minor redrafting to the wording so that the footnote would read as follows: "**1 µg vitamin D = 40 IU**".

This wording would acknowledge the fact that both vitamin D2 and vitamin D3 may be used in RUTF formulation.

Recommendation 14 (Vitamin E)

See comment on recommendation 2.

Recommendation 15 (Recommendations for vitamin K, B1, B2, C, B6, B12 folic acid, niacin, pantothenic acid and biotin)

See comment on recommendation 2.

Recommendation 16 (Recommendations for sodium, potassium, calcium, phosphorus, magnesium, iron, zinc, copper, selenium and iodine)

The EU supports the proposed recommendation.

As to the proposals for higher maximum values for calcium, phosphorus, and magnesium the EU agrees that higher levels of those nutrients might be warranted in products with alternative formulations, by way of example when milk powder is (partly) replaced by other ingredients.

Recommendation 17

The EU supports the proposed recommendation.

Recommendation 18 (Technologies for and Effect for Processing)

No comment.

Recommendation 19 (Good manufacturing and Good hygiene practices)

No comment.

Recommendation 20 (Methods of Analysis and Sampling)

No comment.

Recommendation 21 (Packaging)

The EU can agree with the proposed recommendation.

Recommendation 22 (Labelling)

As noted in previous occasions, the EU considers that the labelling section should, where possible, cross-refer to relevant existing CODEX texts. In this context, the EU welcomes the removal of sub-section on "declaration of nutritive value" since it is already outlined in the Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991). The EU also agrees with 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.