CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Thirty-ninth Session

Berlin, Germany, 4-8 December 2017

European Union comments on

AGENDA ITEM 7

Proposed Draft Guideline for Ready-to-use Therapeutic Foods at Step 3

CX/NFSDU 17/39/7

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 17/39/7.

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 so far.

Specific comments on the recommendations

Recommendation 1 (Preamble)

The EU is pleased that the reference to RUTF in the preamble is now consistent with the product definition, in particular as regards the reference to the status of RUTF as food for special medical purposes.

At the same time, however the EU proposes the first paragraph of the draft preamble to be deleted because the Code of Ethics for International Trade in Food including Concessional and Food Aid Transactions should be implemented and followed in any case and in connection with all work of Codex Alimentarius, not only with regard to RUTF. If still deemed necessary by the Committee, a reference to the Code of Ethics could be included in the last paragraph of the preamble, beginning with *"These guidelines should be used in accordance with… "*

In addition, the EU is of the opinion that the Preamble may not be the right place to elaborate on possible strategies to prevent SAM and would therefore suggest removing the first three sentences of the third paragraph. However, the EU proposes to insert the following text to emphasize the role and function of RUTF within nutritional interventions to combat

malnutrition: "*RUTF is not regarded as a substitute for best nutritional practices or normal household food, but as one option for the dietary management that should only be used within the community-based management of uncomplicated severe acute malnutrition in children, in accordance with international standards for such care and in conjunction with essential primary health care."*

Altogether, the following changes are proposed:

> ~~*The major objectives of the work of the Codex Alimentarius Commission are to protect the health of the consumer and ensure fair practices in the trade in food through the elaboration and harmonization of definitions and requirements for food. In order to realize this objective CAC developed a Code of Ethics for International Trade in Food including Concessional and Food Aid Transactions (CAC/RCP 20-1979) embodying the principles of sound consumer protection. The objective of this code is to establish standards of ethical conduct for all those engaged in international trade in food or for those responsible for regulating food and thereby protecting the health of the consumers and promoting fair trade practices. It is within this context that all those engaging in the international trade in food with specific reference to Ready-To-Use Therapeutic Foods (RUTF) commit themselves to the provisions of the code.*~~
>
> ~~*Investing in prevention of SAM through sustainable measures and interventions is crucial. Such interventions could include the improvement of access to high quality food and safe water through improving water and sanitation systems, improved access to health care, and the effective promotion of exclusive breastfeeding for the first six months of a child´s life combined with continued breastfeeding up to 24 months and beyond. Thus, preventive programmes have an immense job to do in the context of poverty, and in the meantime children who already are suffering from SAM need to receive appropriate treatment.*~~ ***RUTF is not regarded as a substitute for best nutritional practices or normal household food, but as one option for the dietary management that should only be used within the community-based management of uncomplicated SAM in children, in accordance with international standards for such care and in conjunction with essential primary health care.***

Recommendation 2 (Description)

The EU is satisfied that the text clearly refers to the fact that the products are food for special medical purposes and speaks of "dietary management" of severe acute malnutrition (instead of "treatment") to ensure consistency with the language used in Codex Standard 180-1991 on foods for special medical purposes. At the same time, however, the EU proposes a minor redrafting to the description of RUTF as follows:

Ready to Use Therapeutic Foods (RUTF) are high energy, fortified, ready to eat foods for special medical purposes for the dietary management of children from 6 to 59 months with severe acute malnutrition without medical complications and **with appetite**. These foods should be soft or crushable and should be easy for children to eat without any prior preparation.

The proposed modification would be in line with the criteria of the Joint Statement on community-based management of severe acute malnutrition (2007) and the update on the

management of severe acute malnutrition in infants and children made by WHO in 2013. The idea of children having appetite is mentioned along both documents.

Recommendation 3 (Raw Materials and Ingredients)

The EU can agree with the proposed text. 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 these products are not on the EU market and 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.

The EU is pleased that the reference to Section 3 of the Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991] is fully consistent with the language used in STAN 180-1991. This ensures a higher level of consumer protection, as it requires that not only the ingredients, taken one by one, but also the overall formulation of RUTF complies with Section 3 of STAN 180-1991.

Recommendation 4 (Milk and dairy products)

The EU can agree with the proposed text. 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 these products are not on the EU market and 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 5 (Legumes and Pulses)

See comments on recommendation 4.

Recommendation 6 (Fats and Oils)

See comments on recommendation 4.

Recommendation 7 (Cereals)

See comments on recommendation 4.

Recommendation 8 (Vitamins and Minerals)

See comment on recommendation 4.

Recommendation 9 (Available carbohydrates)

With regard to recommendation 9.1 the EU would like to ask for clarification as to why the wording "energy density" at the beginning of the paragraph was removed. From the draft text as proposed now, it could be understood that available carbohydrates are only added for improving the palatability, while available carbohydrates can also serve as a source of energy.

With regard to the Chairs` proposal to prohibit the addition of fructose and high fructose corn syrup 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 inclusion of a footnote on the acceptable available carbohydrates, the EU would like to add maltodextrin to the list of as follows:

[Sucrose, vegetable starch, **maltodextrin**, glucose, glucose syrup should be the preferred carbohydrates in RUTF. Fructose and corn syrup as ingredients should be avoided in RUTF, because of potential adverse effects in SAM children. Only precooked and/or gelatinised starches gluten -free by nature may be added]

With regard to the question on whether or not an acceptable limit of available carbohydrates should be included in the guidelines, the EU is of the opinion that currently no limit of available carbohydrates should be included in the guidelines, taking into consideration that there are many questions arising, e.g. with respect to the acceptability and efficacy of feeding RUTF with less sugar and the technological possibilities of replacing sugar. With respect to sugars that are added only for improving the palatability of RUTF, the EU suggest to include the sentence *"Any carbohydrate added for sweetness should be used sparingly."* in the text which would be in line with the Guidelines on Formulated Complementary Foods for Older Infants and Young Children.

Recommendation 10 (Food additives)

The EU can support the recommendation.

The EU considers the proposed stepwise approach as pragmatic and appropriate.

As regards the text in section '5.2.2 Food Additives and Flavours' the EU has the following observations:
The title of the section should be amended to '5.2.2 Food Additives'. The Codex definition of a food additive includes "flavourings" as well (see the definition in the Procedural Manual, 25th edition, page 23). Moreover, the term "flavour" is not appropriate since it refers to the characteristics/ properties of a substance, whilst a substance imparting the flavour is called "flavouring" (see the Guidelines for the Use of Flavourings, CAC/GL 66-2008).

In addition, the EU recommends amending the text in the brackets to "[This section will contain a list of food additives or make a reference to the General Standard for Food Additives (CODEX STAN 192-1995)]".
The EU understands that the final goal would be to include the reference to the GSFA. However, both options (i.e. (i) to list the individual additives and (ii) reference to the GSFA) are in line with the Codex procedures. The Committee should keep flexibility in case the individual additives would need to be listed as an intermediate solution before the provisions are introduced in an appropriate food category of the GSFA.

Recommendation 11 (The Use of other Matrices in RUTF Formulation)

The EU can support the recommendation.

The EU is pleased with new wording proposed by the Chairs, as it ensures legal clarity and, at the same time, addresses the concerns of the eWG Members related to "new formulations".

Recommendation 12 (Energy and Energy values)

See comment on recommendation 4.

Recommendation 13 (Minimum and maximum values for protein)

The EU can support the recommendation.

Recommendation 14 (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.

Recommendation 15 (Lipids/Fats)

The EU would like to ask for clarification as to how the Chairs of the eWG have calculated the minimum level for linoleic acid of 576.9 mg/100 kcal and for alpha linolenic acid of 57.69 mg/100 kcal. The EU considers that the values proposed here are not compatible with other specifications of the document. If the minimum for n-6 fatty acids is 3% of the total energy (as explained in the 2007 Joint Statement), it corresponds to 3 kcal /100 kcal coming from n-6 fatty acid. This is equivalent to **333 mg/100 kcal**, considering that 1g of lipids corresponds to 9 kcal.
The same problem applies to alpha linolenic acid (ALA), therefore the minimum level of ALA should be **33.33 mg/100kcal** instead of 57.69mg/100kcal.

In light of this, the text should read as follows:

"[Incorporation of fats and/or oils in RUTF serves to increase the energy density and the amount of essential

fatty acids. At least 45% to 60% of energy derived from fat is desirable. The level of linoleic acid should not be less than ~~576.9~~ **333 mg** per 100 kcal when used in the production of RUTF and should ensure a ratio between linoleic acid and alpha-linolenic acid of between 5:1 and 15:1.]

Fats/Lipids should provide 45%-60% of the total energy.

Unit	Minimum	Maximum	GUL
g/100g	26	37	-
g/100kcal	5	6.7	-“

Recommendation 16 (Essential Fatty Acids values)

The EU would like to ask for clarification as to how the Chairs of the eWG have calculated the minimum level for linoleic acid of 576.9 mg/100 kcal and for alpha linolenic acid of 57.69 mg/100 kcal. The EU considers that the values proposed here are not compatible with other specifications of document. If the minimum for n-6 fatty acids is 3% of the total energy (as explained in the 2007 Joint Statement), it corresponds to 3 kcal /100 kcal coming from n-6 fatty acid. This is equivalent to 333 mg/100 kcal, considering that 1g of lipids corresponds to 9 kcal.
The same problem applies to alpha linolenic acid (ALA), therefore the minimum level of ALA should be 33.33 mg/100kcal instead of 57.69mg/100kcal.

In light of this, the recommendation should read as follows:

Essential Fatty acids values
Linoleic Acid = 3-10% of total energy
[The level of linoleic acid should not be less than ~~576.9~~ **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 ~~57.69~~ **33 mg** per 100 kcal]”

Recommendation 17 (Vitamin A)

The EU supports the minimum and maximum values proposed by the Chairs for vitamin A, however, the EU proposes the term "trans" to be replaced either by **all-trans-retinol** or **retinol** in line with recent scientific opinion of EFSA on Dietary Reference Values for vitamin A

Recommendation 18 (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.

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 that fact that both vitamin D2 and vitamin D3 may be used in RUTF formulation.

Recommendation 19 (Vitamin E)

See comment on recommendation 4.

Recommendation 20 (Recommendations for vitamin K, B1, B2, C, B6, B12 folic acid, niacin, pantothenic acid and biotin)

See comment on recommendation 4.

Recommendation 21 (Recommendations for sodium, potassium, calcium, phosphorus, magnesium, iron, zinc, copper, selenium and iodine)

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. However, noting that in recent scientific advice on the composition of infant and follow-on formulae (EFSA 2014) and on Dietary Reference Values for phosphorus (EFSA 2015) certain molar ratios of calcium-to-phosphorus have been considered, the basis for the proposed maximum value for phosphorus of 785 mg/100g is unclear.

In addition, the EU would like to add a statement indicating that the addition of sodium is not permitted. It could be added in paragraph 5.1.5.

Recommendation 23 (Contaminants)

The EU agrees with the recommendation.

Recommendation 24 (Technologies for and Effect for Processing)

The EU can agree with the proposed recommendation.

Recommendation 25 (Good manufacturing and Good hygiene practices)

No comment.

Recommendation 26 (Methods of Analysis and Sampling)

No comment.

Recommendation 27 (Packaging)

The EU can agree with the proposed recommendation.

Recommendation 28 (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 "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. In addition, these products are used under medical supervision and are not placed on the market to be bought directly by the final consumer.

As regards the proposed text on the instructions for use, the EU proposes the following redrafting to the wording taking into account possible innovation and product development in the future:

The text ~~**"The product should be consumed within 24 hours after opening]**~~ should be replaced by the following wording: **"The time within which the product should be consumed after opening should be clearly indicated".**