22.11.2016

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Thirty-eighth Session

Hamburg, Germany, 5-9 December 2016

AGENDA ITEM 8

Proposed Draft Guideline for Ready-to-use Therapeutic Foods at Step 4

CX/NFSDU 16/38/9

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 16/38/9.

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 (Purpose and structure of the guidelines)

The EU can support the recommendation.

The EU is satisfied that the introductory text refers to the entire range of children 6-59 months, thus ensuring consistency with other sections of the guidelines.

Recommendation 2 (Scope)

The EU can support the recommendation. The EU would like to receive clarification as to the background to determining the upper age limit as described in the scope as 59 months.

The EU is satisfied that the text clearly lists the categories of products excluded from the scope of the guidelines.

The EU notes that there is a minor typo in the text which should be corrected:

The provisions of these guidelines apply to Ready to Use Therapeutic Foods for children from 6 to 59 months with severe acute malnutrition. Ready-to-Use Supplementary Foods (RUSF), micronutrient supplements, processed cereal based foods, formulated complementary foods for older ~~children~~ **infants** and young children, canned baby foods are not covered by these guidelines. These guidelines should be used in accordance with the 2007 Joint Statement of the UN Agencies, 2013 WHO document on Updates on the Management of Severe Acute Malnutrition in infants and children or any other relevant upgrade of the latest version.

Recommendation 3 (Description)

The EU can support the recommendation.

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.

As noted in the comments submitted to the eWG, the EU would like to seek clarification on whether there is a specific reason to mention that these foods should be "*soft or crushable and should be easy for **young children** to eat without any prior preparation*". Shouldn't the requirement that the foods are soft or crushable and easy to eat be valid also for infants aged 6-12 months or children aged 36-59 months? If this is the case, then it would be probably easier to refer, more generally, to "children".

The EU notes that there is a typo in the definition of severe acute malnutrition and would like to propose minor redrafting for better reading:

Severe Acute Malnutrition is defined ~~as~~ **by** weight for height (or length) less than –3 Z-score of the median WHO growth standards, ~~or~~ **by** mid upper arm circumference (MUAC) <115 ~~cm~~ **mm**, or **by** the presence of bilateral oedema.

The EU would like to ask the WHO representative whether the definition of Severe Acute Malnutrition should not also refer to "visible severe wasting", in line with the Joint Statement by WHO, WFP, UNSCN and UNICEF "*Community-Based Management of Severe Acute Malnutrition*".

Recommendation 4 (Food additives)

The EU notes that, being food for special medical purposes, RUTF would be covered by section 13.3 (Food for Special Medical Purposes) of the CODEX General Standard on Food Additives.

The EU appreciates and welcomes the intention to carry out further discussions and decide on the best approach to handle the use of food additives in RUTF.

Recommendation 5 (Other matrices)

The EU supports the approach proposed by the Chairs, which cross-refers to Section 3 of the CODEX Standard 180-1991 on food for special medical purposes.

Recommendation 6 (Raw materials and ingredients)

The EU notes that there is a minor typo in the text:

[New formulations] or [Composition] of RUTF with other ingredients may be used if they **are** formulated in accordance with Section 3 of the Standard for Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991).

Recommendation 7 (Nutritional composition and quality factors)

The EU is not in a position to comment 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.

As noted in the eWG contribution, the project document agreed at CCNFSDU37 underlines that the nutritional composition of RUTF should be based on relevant WHO documents and their future modification. The EU is therefore of the view that WHO should provide its opinion on all cases where the proposed composition diverges from the recommendations in WHO's documents.

Recommendation 8 (Minimum and maximum vitamins and minerals levels)

See comment on recommendation 7.

Recommendation 9 (Essential fatty acids)

See comment on recommendation 7.

Recommendation 10 (Additional nutrients)

See comment on recommendation 7.

In addition, the EU notes that the inclusion of other nutrients in RUTF would be covered by the general requirement in section 4.3 of the guidelines, which cross-refers to section 3 of the Codex Standard on food for special medical purposes 180-1991.

Recommendation 11 (Protein quality)

See comment on recommendation 7.

Recommendation 12 (Milk protein)

See comment on recommendation 7.

Recommendation 12 (Contaminants, residues of veterinary drugs and pesticide residues)

The EU considers that a recommendation on contaminants should be limited to the contaminants listed in the General Standard for Contaminants and Toxins in Food and Feed. Rather than listing specific contaminants, the recommendation should cover all contaminants listed in this standard. Provisions related to residues of veterinary drugs and of pesticides in food should be kept separately from the recommendation on contaminants.

To this purpose, the recommendation should be:

"***It is recommended that:***

- For contaminants in RUTF reference is made to the provisions of the General Standard for Contaminants and Toxins in Food and Feed (CODEX STAN 193-1995)."

- For residues of veterinary drugs in RUTF reference is made to the Maximum Residue Limits (MRLs) and Risk Management Recommendations (RMRs) for Residues of Veterinary Drugs in Foods provided for in CAC/MRL 2-2015 and to the Codex Veterinary Drug residues in Food Online Database ()http://www.fao.org/fao-who-codexalimentarius/standards/vetdrugs/veterinary-drugs/en/)

- For pesticide residues in RUTF, reference is made to Maximum Residue Levels (MRLs) provided for in the Codex Pesticides Residues in Food Online Database (http://www.fao.org/fao-who-codexalimentarius/standards/pestres/en/)"

Recommendation 13 (Processing)

The EU can support this recommendation.

Recommendation 14 (Hygiene)

The EU can support this recommendation.

Recommendation 15 (Microbiological safety for RUTF)

The EU can support this recommendation.

Recommendation 16 (Methods of analysis and sampling)

The EU can support this recommendation.

Recommendation 17 (Packaging)

No comment.

Recommendation 18 (Single-use sachets)

No comment.

Recommendation 19 (Labelling)

The EU agrees with the Chairs that this section should, where possible, cross-refer to relevant existing CODEX texts, in particular the Standard on food for special medical purposes. In addition to the Standards listed in document CX/NFSDU 16/38/9, the EU wonders whether reference should also be made to the CODEX guidelines on nutrition labelling (CAC/GL 2-1985).

Specific labelling provisions should be included in the guidelines only where these are different from the existing requirements in other relevant CODEX texts, and are necessary to take into account the specificities of RUTF.

As regards the inclusion of possible statements on breastfeeding, the EU agrees with the Chairs that, while the 2007 Joint Statement by the WHO, WFP, UNSCN and UNICEF "*Community-Based Management of Severe Acute Malnutrition*" recognises the essential contribution of exclusive breastfeeding for the first six months of a child's life to prevent severe acute malnutrition, it also notes that treatment is needed for those children who already are suffering from severe acute malnutrition.