CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 5a **NFSDU/41 CRD 23**

Original language only

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

Forty-first Session

Dusseldorf, Germany
24 – 29 November 2019

PROPOSED DRAFT GUIDELINE FOR READY-TO-USE THERAPEUTIC FOODS

Comments by ISDI

General comments

ISDI submitted comments in reply to CL 2019/79-NFSDU requesting feedback on several sections of the draft Guidelines including proteins, additives and processing technologies. However, ISDI was not able to submit comments on the other section of the draft Guidelines, especially those that were not considered at CCNFSDU40. CCNFSDU41 will discuss these sections under agenda item 5a) and ISDI would like to formally submit its comments in this CRD.

Specific comments

Wording at STEP 4

1. PREAMBLE

Children affected by severe acute malnutrition (SAM) need safe, palatable foods with a high energy content and adequate amounts of vitamins, minerals and other nutrients. Children with SAM need efficacious and timely treatment and RUTF ~~is~~ may be part of the care. RUTF are primarily intended for children with uncomplicated SAM from 6-59 months. Although RUTF may be given to other age groups with various forms of malnutrition at the implementation level, the primary focus for these guidelines is children with SAM from 6-59 months. [Since RUTF are prescribed according to weight, National Authorities may decide to include the provision of RUTF in their national protocols for use by other age groups].

These guidelines provide guidance for the production and labelling of RUTF. The guidelines are intended to facilitate the harmonization of requirements for RUTF at the international level and may provide assistance to governments wishing to establish national regulations. The guidelines are also intended for use as an instrument designed to avoid or remove difficulties which may be created by diverging legal, administrative and technical approaches to RUTF and by varying definitions and nutrient compositions of RUTF. These guidelines should be used in accordance with technical recommendations of that are based on the relevant evidence and related Codex texts/documents by WHO, UNICEF and WFP1. Governments and other users should ensure adequate provisions are made for competent technical experts for the appropriate use of these guidelines.

1) A Joint Statement by the World Health Organization, the World Food Programme, the United Nations System Standing Committee on Nutrition and the United Nations Children's Fund. 2007. *Community-Based Management of Severe Acute Malnutrition*; A Joint Statement by the World Health Organization and the United Nations Children's Fund. 2009. *Child growth standards and the identification of severe acute malnutrition in infants and children*, Geneva: World Health Organization; World Health Organisation. 2013. Guideline: *Updates on the management of severe acute malnutrition in infants and children,* Geneva: World Health Organization; World Health Organisation. 2003. *Global Strategy for Infant and Young Child Feeding*, Geneva: World Health Organization; World Health Organisation. [1981. *International code of marketing of breast-milk substitutes,* Geneva: World Health Organization and subsequent relevant WHA Resolutions on infant and young child feeding]; *Code of Ethics for International Trade in Food including Concessional and Food Aid Transactions* (CXC 20-1979); Food and Agriculture Organisation and World Health Organisation. 2016. FAO/WHO Microbial safety of lipid-based ready-to-use foods for management of moderate acute malnutrition and severe acute malnutrition, Rome: Food and Agriculture Organisation.

ISDI comment

ISDI would like to highlight that RUTFs are not always prescribed according to weight and therefore this statement should be amended in the text of the preamble.

With regards to Footnote 1, ISDI notes that the "Joint Statement on Community-Based Management of Severe Acute Malnutrition by the World Health Organization, the World Food Programme, the United Nations System Standing Committee on Nutrition and the United Nations Children's Fund, 2007" was updated in 2011.

In addition, as RUTF is not breastmilk substitutes, ISDI questions the reference to guidelines included as part of Footnote 1.

Wording at STEP 4

5. SUITABLE RAW MATERIALS AND INGREDIENTS

RUTF are made of ingredients embedded in a lipid-rich matrix e.g. paste or biscuit, resulting in an energy and nutrient-dense food. The following raw materials, many of which can be sourced locally, are suitable ingredients for the production of RUTF under the specified conditions given below. Any formulation of RUTF shall comply with Section 3 of the *Standard for the Labelling of and Claims for Foods for Special Medical Purposes* (CXS 180-1991) including the specification that their use should have been demonstrated, by scientific evidence, to be safe and beneficial in meeting the nutritional requirements of the persons for whom they are in-tended.

ISDI comment

ISDI would like to raise a comment with regards to para 5 "SUITABLE RAW MATERIALS AND INGREDIENTS" in the Proposed Draft Guidelines. The introduction of the paragraph refers to section 3 of the Standard for Labelling of and Claims for Foods for Special Medical Purposes (CXS 180-1991), however, ISDI believes it should be clearly mentioned in the Guidelines that alternative ingredients to peanut and milk in RUTF should be subjected to efficacy studies.

Rationale:

- Use of alternative ingredients to peanut and milk in RUTF may have significant impact on quality, safety and efficacy of the product. Appropriate studies should therefore be conducted at all necessary levels, not only to avoid contaminants but also to guarantee that such products, which may eventually be given to treat children affected by SAM, are as safe, acceptable and efficacious as the now well-established peanut formula.
- Depending on the composition of the untreated plant raw material used, adequate processing steps may have to be selected in order to guarantee its microbiological quality, nutritional quality and the absence of off-flavours.
- All plant raw material processing steps (e.g. roasting, drum drying, extrusion etc.) may contribute to reaching the microbiological specifications. However, the challenge to maintain the high microbiological quality on the long run may be more related to compliance with Good Manufacturing Practices (packaging steps, storage etc.).
- All plant raw material processing steps may not have the same impact on the nutritional quality of these raw materials. For example, roasting will usually help solving the off-tastes and the potential microbiology issues, but will only have a limited impact on the starch gelatinization in cereals, which is a key issue. This should be addressed beforehand, when selecting the plant raw materials and the corresponding processing steps.
- More broadly, it should be noted that changing a significant part of the raw materials in RUTF may influence the digestibility and bioavailability of the nutrients, which may impact the efficacy of the finished product. Therefore, ISDI strongly recommends that any new RUTF formula which incorporates alternative ingredients should thoroughly validated through randomised control trials demonstrating their acceptability and efficacy in individuals for whom they are intended.

As a consequence, ISDI recommends that the paragraphs reads as follows:

RUTF are made of ingredients embedded in a lipid-rich matrix e.g. paste or biscuit, resulting in an energy and nutrient-dense food. The following raw materials, many of which can be sourced locally, are suitable ingredients for the production of RUTF under the specified conditions given below. Any formulation of RUTF shall comply with Section 3 of the *Standard for the Labelling of and Claims for Foods for Special Medical Purposes* (CXS 180-1991) ~~including the specification that their use should have been demonstrated, by scientific evidence, to be safe and beneficial in meeting the nutritional requirements of the persons for~~

~~whom they are in-tended.~~***) and efficacy of RUTF formula shall be demonstrated through rigorous randomized controlled trials providing evidence of its ability to support catch-up growth as evaluated in major outcomes of SAM treatment such as weight gain and recovery rates.***

Wording at STEP 4

Additional Mandatory Labelling Requirements

The following statements shall appear on the label of RUTF:

- "USE UNDER MEDICAL SUPERVISION" shall appear on the label in bold letters in an area separated from the written, printed, or graphic information.
- "For the dietary management of severe acute malnutrition" shall appear on the label.
- A prominent warning statement consisting of an explanatory statement in bold letters indicating that RUTF are for special medical purposes and may pose a health hazard when consumed by individuals who do not have the disease(s), disorder(s) or medical condition(s) for which the food is intended.
- The product is not to be used for parenteral, rectal or Nasogastric Tube (NG tube) administration.
- A statement indicating whether the product is or is not intended as the sole source of nutrition.
- A statement indicating that RUTF are not breastmilk substitutes and shall not be presented as such.
- [Exclusive breastfeeding is recommended for the first 6 months of life, and continued breastfeeding is recommended for at least 24 months.]

ISDI comment

For the section on additional mandatory labelling requirements, ISDI recalls that section 4.4. of the Standard for the Labelling of and Claims for Foods for Special Medical Purpose (CODEX STAN 180-1991) already establishes mandatory additional requirement for FSMP.

ISDI considers that the additional mandatory labelling requirements section in the RUTF Guidelines should only address specific additional labelling requirements relevant for RUTF beyond the requirements already established in CODEX STAN 180-1991.

ISDI recommends to clearly cross reference the Standard for the Labelling of and Claims for Foods for Special Medical Purpose (CODEX STAN 180-1991) and its labelling provisions.

Redundant statements

In order to avoid duplication and redundancy, ISDI recommends the deletion of the following statement from this section:

- ~~"USE UNDER MEDICAL SUPERVISION" shall appear on the label in bold letters in an area separated from the written, printed, or graphic information.~~
- ~~A statement indicating whether the product is or is not intended as the sole source of nutrition.~~
- ~~A prominent warning statement consisting of an explanatory statement in bold letters indicating that RUTF are for special medical purposes and may pose a health hazard when consumed by individuals who do not have the disease(s), disorder(s) or medical condition(s) for which the food is intended.~~

These statements are required by section 4.4 of the Standard for the Labelling of and Claims for Foods for Special Medical Purpose (CODEX STAN 180-1991). These statements should not be added to the additional mandatory labelling requirements section of the RUTF guidelines.

Necessary additional mandatory statements

In addition to the labelling requirements established by the Standard for the labelling of and claims for Foods for Special Medical Purpose (CODEX STAN 180-1991), the following statements shall appear on the label of RUTF:

- For the dietary management of severe acute malnutrition.
- The product is not to be used for parenteral, ~~**rectal**~~ or Nasogastric Tube (NG tube) administration.
- A statement indicating that RUTF are not breastmilk substitutes and shall not be presented as such.

- [Exclusive breastfeeding is recommended for the first 6 months of life, and continued breastfeeding is recommended for at least 24 months.]

However, ISDI recommends removing the word rectal in the following sentence. No other type of food mentions such purposes for the product use, as well as there is no evidence on the potential use of RUTF for rectal administration.

CLEAN VERSION

Additional Mandatory Labelling Requirements

In addition to the labelling requirements established by the Standard for the labelling of and claims for Foods for Special Medical Purpose (CODEX STAN 180-1991), the following statements shall appear on the label of RUTF:

- "For the dietary management of severe acute malnutrition"
- “The product is not to be used for parenteral or Nasogastric Tube (NG tube) administration.”
- A statement indicating that RUTF are not breastmilk substitutes and shall not be presented as such.
- [Exclusive breastfeeding is recommended for the first 6 months of life, and continued breastfeeding is recommended for at least 24 months.]