PROPOSED DRAFT GUIDELINES FOR READY TO USE THERAPEUTIC FOODS (RUTF)
(REP20/NFSDU, Appendix VI)
Jointly prepared by South Africa, Uganda, Codex secretariat, WHO and FAO

Introduction
The preamble of the proposed draft guidelines for ready to use therapeutic foods (RUTF) was placed in square brackets following CCNFSDU41 for further discussion by the committee. CL 2021/31/OCS-NFSDU received extensive comments on the preamble as per CX/NFSDU 21/42/6. As a result, this CRD is being presented to provide a revised proposal for consideration by CCNFSDU42.

Background
At CCNFSDU38, when the Committee considered the scope of the Guidelines and the appropriate use of RUTF, it was noted that a preamble or an introduction to the guideline could be an option when working on the development of the text relating to appropriate use. At this session, Codex Secretariat also noted that an introduction or preamble could set the scene for the guideline and that in developing such a text, reference to how the guideline should be used, could be considered. The Committee consequently agreed that an introduction or preamble would be developed for consideration by the Committee.1

The EWG on RUTF subsequently developed a preamble for the Guidelines and it was agreed that the preamble would be considered once technical part of the guidelines had been considered.2

At CCNFSDU41 the discussions on the preamble considered that the section would in general take into account: the appropriate use of RUTF; integration of RUTF into sustainable local family-food-based solutions and how the guidelines on RUTF would be used. The Committee agreed to simplify the text of the preamble to include aspects on basic composition of the product; target age group; and that RUTF is a recommended option of dietary management of children with uncomplicated SAM from 6-59 months. These guidelines should be used in accordance with technical recommendations that are based on the relevant evidence and related Codex texts/documents by WHO, UNICEF and WFP3.

Current Preamble Text in Square Brackets:
[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 intervention and RUTF is one of the options for the dietary management of children with uncomplicated SAM from 6-59 months. These guidelines should be used in accordance with technical recommendations that are based on the relevant evidence and related Codex texts/documents by WHO, UNICEF and WFP].


1 REP 17/NFSDU, paras 158 - 163
2 REP 18/NFSDU, para. 107
3 REP 21/NFSDU, paras 118 - 121
Proposal for a revised Preamble Text:

Children affected by severe acute malnutrition (SAM) need efficacious and timely interventions including safe, palatable foods with a high energy content and adequate amounts of vitamins, minerals and other nutrients.

In accordance with the Joint Statement by the World Health Organization (WHO), the World Food Programme (WFP), the United Nations System Standing Committee on Nutrition (UNSCN) and the United Nations Children's Fund (UNICEF) (2007) and taking note of other relevant documents by WHO and FAO, Ready-to-use therapeutic food (RUTF) is a WHO recommended option for the dietary management of children aged 6-59 months with SAM without medical complications.

Rationale:

In the revision of the text proposal, the following aspects were taken into account:

Simplification of the text:

Based on the CCNFSDU 41 discussions, there was committee agreement that the preamble should be kept as simple as possible. At the same time, it needed to remain understandable and cover all important aspects as follows:

1. Basic composition of the product
2. Target age group
3. RUTF is a recommended option of dietary management of children aged 6 – 59 months with SAM without medical complications

In addition, the advice of CCEXE75 on references to WHO/WHA documents in the draft CCNFSDU text on follow-up formulae and the advice of CCEXE78 on references to standards of other standard setting organizations was also taken into account. The latter advice states that while there may on occasion be merit in including reference to standards of another standard setting organization, it should keep references to a minimum since they become an integral part of a Codex text and require life-long monitoring. Furthermore, explicitly mentioning a large number of other documents carries the risk of omitting some other relevant documents. Taking these CCEXEC advice into consideration, it is proposed to omit the footnote and make reference in the actual text to the Joint Statement of WHO, WFP, UNSCN and UNICEF which essentially sets the frame for this proposed draft guideline for ready to use therapeutic foods (RUTF).

Integration of RUTF into local- family food-based solutions

Previous committee discussions took into account the use of local products and local food consumption patterns. There were some strong recommendations by some CCNFSDU Members and observers that RUTF should be integrated into local family food-based solutions. Therefore, the recommended text recognizes that RUTF is a recommended option of dietary management of children aged 6 – 59 months with SAM without medical complications. Thus, allowing for the use of RUTF in conjunction with other local family foods.

Promotion of breastfeeding:

It must be noted that there are several passages which support the promotion of breastfeeding that have already been agreed upon, namely:

12.4 The following additional statements shall appear on the label of RUTF:

• The product is not to be used for Nasogastric Tube (NG tube) administration.
• The product should be used in conjunction with breastfeeding.
• Exclusive breastfeeding is recommended for the first 6 months of life, and continued breastfeeding is recommended for up to two years or beyond

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4 In 2020, the United Nations System Standing Committee on Nutrition (UNSCN) and the UN Network for SUN (UNN) merged together to form a new entity, called UN Nutrition
5 REP 18/EXEC2-Rev 1, para. 14
6 REP 20/EXEC1, para. 64
It may be important to take note that, in the general part of the draft guideline, the Standard for the labelling of and claims for foods for Special Medical Purposes is quoted. According to section 3 (General principles) of this standard all FSMPs are prohibited from advertising. Ready to use therapeutic foods (RUTFs) are indeed considered to be FSMPs and therefore are prohibited from advertising.

Conclusion:

Based on the above discussion and rationale, it is recommended to consider the following proposal for a revised preamble text for discussion at CCNFSDU42:

1. **Preamble (Proposed Draft Guidelines for Ready to Use Therapeutic foods)**

   Children affected by severe acute malnutrition (SAM) need efficacious and timely intervention including safe, palatable foods with a high energy content and adequate amounts of vitamins, minerals and other nutrients.

   In accordance with the Joint Statement by the World Health Organization (WHO), the World Food Programme (WFP), the United Nations System Standing Committee on Nutrition (UNSCN) and the United Nations Children's Fund (UNICEF) (2007) and taking note of other relevant documents by WHO and FAO, Ready-to-use therapeutic food (RUTF) is a WHO recommended option for the dietary management of children aged 6 – 59 months with SAM without medical complications.