
Adoption of Codex Alimentarius guidelines for Ready-To-Use Therapeutic Foods (RUTF)

1. What is CODEX?

Codex Alimentarius provides international food standards, guidelines and codes of practice that contribute to the safety and quality of food. These standards help to protect consumer health and ensure fair practices in the international food trade. The CODEX Alimentarius Commission (CAC) is a joint body of FAO and WHO, that develops international food standards and guidelines.

2. How do national governments use Codex standards and guidelines?

Countries use Codex standards to ensure safe, quality food for their citizens. When national governments introduce food legislation and regulations that are consistent with the Codex standards and guidelines, they reduce the risk of being brought before a World Trade Organization (WTO) disputes panel. In many countries, food legislation is consistent with Codex. However, a government can choose to adopt a higher or lower level of protection provided there is a justification based on scientific, health or other legitimate grounds.

3. How does CODEX relate to RUTF?

At the 45th session of Codex Alimentarius Commission on 21 November 2022, the Codex Guideline for Ready to Use Therapeutic Food (RUTF) was adopted. Previously, there was no internationally accepted standard for RUTF. The Codex guideline defines RUTF as a food for special medical purposes (FSMP) and sets out the rules for food safety and requirements for nutritional composition. The new guideline also enables the development of new versions of this life-saving product that are best suited for the local context. Governments can now use the RUTF Guideline to regulate manufacturers as they scale up RUTF production to tackle the malnutrition crisis currently affecting millions of children.

The Codex Guideline for RUTF includes guidance on:

- **Definition of RUTF**
 - **Intended population**
 - **Nutritional composition**
(including protein and essential fats)
 - **Ingredients for use in RUTF**
 - **Good manufacturing practice and Food hygiene**
 - **Methods and sampling for testing RUTF**
 - **Food additives, Contaminants**
 - **Packaging and Labelling.**
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4. How can I use the RUTF codex guideline in my programming work?

The RUTF Codex guideline complements existing WHO guidelines for the treatment of severe wasting.

The development of the guideline is a critical step in enabling governments to regulate the quality and safety of RUTF during its production and distribution. Having an official reference for a health intervention is often a prerequisite for inclusion into a national essential medicines list (EML) and subsequent domestic funding, thus having the RUTF Codex Guideline is a pivotal step in enabling better access to treatment of severe acute malnutrition.

5. Are there any changes to the RUTF product due to the new guideline?

The RUTF codex guideline is developed based on UNICEF's existing RUTF specification, as well as recommendations taken from WHO guidelines that outline the nutritional needs of children with malnutrition. The guideline introduced a quality score for protein sources and adjusted some nutrient levels.

"The guideline states that a Protein Digestibility Corrected Amino Acid Score (PDCAAS) value of 0.9 or more can be achieved by including a minimum of 50% of protein from dairy sources, in addition to proteins from seeds, cereals and legumes". The guideline also permits the addition of amino acids, to reach the desired level of PDCAAS. The n-3 fatty acid requirement is increased, and level of n-6 fatty acids is reduced, to better support the child's cognitive development. The maximum levels of vitamin A, vitamin D, potassium, magnesium and calcium were slightly increased to allow for raw material and processing variability during manufacture.

As a result of these changes to the nutritional composition, suppliers have re-formulated their products. CODEX compliant RUTF in biscuit form has also been developed and supplied. RUTF biscuit can be an alternative to RUTF paste in different program settings.

Table 1: Nutritional composition per 100g of Codex compliant RUTF

| Nutrients | Unit | Values |
|-------------------|------|------------|
| Proteins | g | 13-17 |
| Lipids | g | 26-37 |
| n-6 fatty acids | g | 1.7-4.3 |
| n-3 fatty acids | g | 0.58-1.530 |
| Trans fatty acids | g | <1.1 |
| Free sugar | g | <28 |
| PDCAAS | | >0.9-1.0 |
| Vitamins | | |
| Vitamin A | mg | 0.8-1.6 |
| Vitamin B1 | mg | >0.5 |
| Vitamin B2 | mg | >1.6 |
| Vitamin B3 | mg | >5 |
| Vitamin B5 | mg | >3 |
| Vitamin B6 | mg | >0.6 |
| Vitamin B7 | mcg | >60 |
| Vitamin B9 | mcg | >200 |
| Vitamin B12 | mcg | >1.6 |
| Vitamin C | mg | >50 |
| Vitamin D | mcg | >15-22 |
| Vitamin E | mg | >20 |
| Vitamin K | mcg | 15-30 |
| Minerals | | |
| Potassium | mg | 1100-1600 |
| Calcium | mg | 300-785 |
| Phosphorus | mg | 300-785 |
| Magnesium | mg | 80-235 |
| Iron | mg | 10,0-14,0 |
| Zinc | mg | 11,0-14,0 |
| Copper | mg | 1.4-1.8 |
| Selenium | mcg | 20-40 |
| Iodine | mcg | 70-140 |
| Sodium | mg | <290 |

6. Will new Codex requirements impact local sourcing of raw materials?

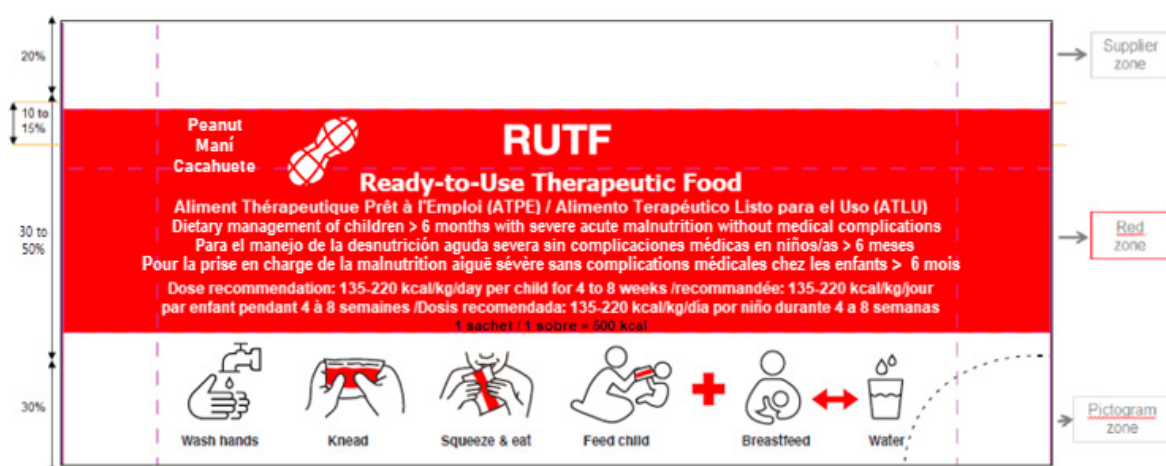
CXG 95-2022 also indicates a ratio of n-3: n-6 fatty acids that requires changes such as the use of high oleic peanuts and increased use of canola oil and/or other oils which are rich in n-3 fatty acids. As locally grown peanuts in Africa and Asia have high levels of n-6 fatty acids, high oleic varieties of peanuts may be required to comply with the new requirement for fatty acids. Hence, UNICEF has offered a longer implementation timeframe for suppliers who face challenges in sourcing local peanuts to meet the guideline. This will enable the local farms to transition to the varieties that are best for the new guidelines and minimize disruption to the local peanut supply chain.

7. Are there any cost implications from the new Codex requirements?

The stipulation of the PDCAAS score of over 0.9 may lead to a slight price increase, as protein sources in RUTF are the major cost drivers. Including alternative ingredients to reduce the cost of RUTF is being explored by UNICEF and other actors.

8. Will the Codex compliant RUTF look or taste different?

The labeling of the sachet and carton has been redesigned to meet the Codex labeling requirements for Foods for Special Medical Purposes. Codex compliant RUTF will have a new label design. Labels are available in combinations of the following languages: English, French, Arabic, and Spanish. The RUTF label also includes the nutritional table, mandatory statements, and dose requirements for SAM treatment. All leaflet information has now been included on the sachet, so leaflets will no longer be supplied with the product. New icons have also been added e.g., washing hands and a glass of water. Codex compliant RUTF will not taste any different from the previous version of RUTF.



9. Now we have a Codex Guideline for RUTF, does it mean that we can program alternative formula?

The ingredients for formulating RUTF listed in the Codex Guideline are milk and other dairy products, legumes and seeds, fats and oils, cereals, roots, tubers and their derived products, vitamins, minerals, carbohydrates, and food additives. The guideline also requires that formulae are scientifically evidenced before being programmed. There is work underway within UNICEF and other partner organizations to trial new variants of RUTF with different ingredients that comply with the Codex Guideline for RUTF. The work on new formulae aims to increase the coverage of malnutrition treatment among children, reducing market barriers and increasing acceptability.

10. Who was involved in the development of the Codex Guidelines for RUTF?

Codex Guidelines for RUTF were developed at the request of UNICEF in collaboration with the Governments of South Africa, Senegal and Uganda. UNICEF worked with MSF and USAID as interagency partners to provide technical inputs. This interagency group consulted extensively with RUTF suppliers. In developing the guideline the Codex Committee also drew on the expertise of scientists, academics, civil society, emergency health experts and practitioners, in addition to partners such as WHO, FAO, WFP.

11. Where can I find the RUTF guideline and other Codex references?

The [RUTF Codex guideline](#) is published online on Codex Alimentarius Commission website along with other Codex standards and texts. The link can be accessed here [Guidelines | CODEXALIMENTARIUS FAO-WHO](#). For other product related enquiries, please reach out to: sd.nutritionsupplies@unicef.org