# Assessment of the implications of including ready-to-use therapeutic foods for the treatment of severe acute malnutrition in national essential medicines lists and WHO Model List of Essential Medicines

**UNICEF Nutrition Programme Group– WHO Nutrition and Food safety department**

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# Contents



# Acknowledgements

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## Executive summary

An estimated 45.4 million children under 5 years suffer from acute malnutrition at any given time, including 13.6 million with severe acute malnutrition (SAM), the most life-threatening form of child malnutrition. Uncomplicated forms of severe acute malnutrition in children aged 6 to 59 months can be effectively managed at community level through outpatient treatment using Ready-to-Use Therapeutic Food (RUTF) along with standardized medical treatment protocols. This approach, present in 74 countries, has vastly expanded access to treatment for children with SAM, but further scale up is still needed. Most governments in countries with high prevalence of acute malnutrition do not routinely procure RUTF, and many countries rely on short-term humanitarian funding even though three in four children affected by SAM live in a development context.

In 2021, it was estimated that 25 countries had included RUTF in their national Essential Medicines List ('nEML'). The inclusion of medicines and nutritional therapeutic products in the nEMLs can help governments to prioritize which medicines can be funded and procured, leverage domestic funding, and enable the integration of these products into national supply chains. Many countries are guided by the WHO model list of essential medicines ('WHO Model EML'), however the current edition of the WHO Model EML does not include RUTF. After a first application for the inclusion of RUTF in the WHO Model EML submitted to the WHO Expert Committee on the Selection and Use of Essential Medicines in 2017, and a following technical consultation organized by WHO nutrition and food safety department in 2018, the Committee noted the need to better understand the consequences of including RUTF in the WHO Model EML, including the risks of increased costs of RUTF, barriers to local production and more restricted access. The Committee also requested to hear about the process and consequences from officials in countries that have and have not included RUTF in the nEML and that future application may be eligible provided it includes: 1) a clear indication on the potential consequences and implications at country level of including RUTF on the nEML and WHO Model EML, 2) a comprehensive risk-mitigation plan, and 3) Standard and guidelines for RUTF under the Codex Alimentarius.

This report summarized the findings of a study conducted between 2020 and 2022 by UNICEF with the support from WHO, which aimed at addressing the issues highlighted by the last WHO Expert Committee meeting for the inclusion of RUTF in the WHO Model list. The study set out questions on the current status of the inclusion of RUTF in national EMLs in countries with programmes for the treatment of severe acute malnutrition, the process, challenges and lessons learnt from countries that included RUTF in their nEML, the benefits and risks of this inclusion (in nEML and WHO EML) and the possible mitigation measures. Stakeholders from MoH, UN agencies, NGOs and academics at country and regional levels responded to the survey. Chapter 3 of this report details the method used to collect this information, and results are presented in Chapter 4.

Respondents gave several justifications for their country's decision to add RUTF in the national EML, including the public health burden of SAM, the proven efficacy, effectiveness and safety of RUTF to treat SAM, and the absence of a suitable alternative product to treat severe acute malnutrition. Some country stakeholders also referred to the benefits of including RUTF in the national EML, such as the facilitation of national production of RUTF, mobilization of domestic financial resources to procure RUTF, and improved supply and distribution of RUTF. Stakeholders in countries that have not included RUTF in the national EML reported similar potential justifications and triggers. Multiple stakeholders were involved in the decision-making process to include RUTF in the national EML, i.e., The directorate or department of pharmacy, pharmaceuticals or drugs and medical supplies, the regulatory agency and central purchasing organization for medicines, medical supplies and/or food, the department/division of nutrition in the MoH and UNICEF, WHO, NGOs and key stakeholders present at national level (academic institutions, researchers, etc.). Strong MoH leadership and coordination of the process to include RUTF in the nEML were identified as facilitating factors, along with long in-country history of

programmes to treat SAM and national actors being very familiar with RUTF and its benefits. No significant barriers or challenges were reported, except one respondent reported that the process was delayed because it was not possible to arrange a standalone review of the nEML for RUTF, and the inclusion happened at the next periodic review of the nEML. They were also some concerns about having RUTF classified as a medicine versus Food for Special Medical Purposes (FSMP) due to standards and regulations. Additional risks identified by respondents were: the different impacts the inclusion of RUTF in the nEML may have depending on countries' policy and legal frameworks, the risk of decreased external donors' funding due to RUTF in the nEML and that the inclusion of RUTF in nEML could place unnecessary financial burdens on low-income countries. On the consequences of including RUTF in the WHO model EML, many stakeholders agreed that it would encourage countries to add RUTF to their nEMLs or that this inclusion is needed to justify the inclusion of RUTF in nEML. Other consequences were on higher RUTF specifications and increased demand for and production of RUTF particularly at national production.

The finalization of the Codex guidance on RUTFs categorized as Foods for Special Medical Purposes (FSMP) is another key milestone which was achieved in 2022. The Codex establishes standards and guidelines for RUTF to facilitate harmonization of RUTF requirements, and has the capacity to greatly influence safe manufacturing, procurement and availability of RUTF globally. This topic will be developed under chapter 5 of this report.

Finally, Chapter 6 presents the different risks identified by country, regional and global (UNICEF supply division) stakeholders and proposes relevant mitigation measures. Risks identified were the increase in the cost of RUTF (both positive and negative consequences), national production and innovation stifled, deprioritization of other child survival interventions, reduction in support for RUTF by international actors and reduced access to RUTF.

## Abbreviations

| | |
|---|---|
| ACF | Action Contre la Faim |
| CMAM | Community-based Management of Acute Malnutrition |
| EML | Essential Medicines List |
| FSMP | Food for Special Medical Purposes |
| GAM | Global Acute Malnutrition |
| GAP | Global Action Plan |
| IP | Intellectual Property |
| LNS-MQ | Lipid Nutrient Supplement – Medium Quantity |
| MoH | Ministry of Health |
| nEML | National Essential Medicines List |
| NGO | Non-Government Organization |
| RUSF | Ready-to-Use Supplementary food |
| RUTF | Ready-to-Use Therapeutic Food |
| SAM | Severe Acute Malnutrition |
| UN | United Nations |
| UNICEF | United Nations Children's Fund |
| WHO | World Health Organization |

# 1. Background

An estimated 45.4 million children under 5 years suffer from acute malnutrition at any given time, including 13.6 million with severe acute malnutrition, the most life-threatening form of child malnutrition.[1] Uncomplicated forms of severe acute malnutrition (i.e. without medical complications needing inpatient admission) in children aged 6-59 months can be managed effectively in the community through outpatient treatment with ready-to-use therapeutic foods (RUTF) and standardized medical treatment protocols.[2] [3] [4] This approach of linked inpatient and outpatient management of severe acute malnutrition (also known as community-based management of acute malnutrition - CMAM) with RUTF and associated medical treatment has the potential to vastly expand access to treatment with programmes now present in 74 countries.[5] Yet only one in three children under 5 with severe acute malnutrition received treatment in 2020.[6]

One important challenge (amongst many related to health services and health seeking behaviour) to improving the scale and reach of services to treat severe acute malnutrition at community level, is the resources available to procure RUTF. Most governments do not routinely procure RUTF, and many countries rely on short-term humanitarian funding even though three in four children with Severe Acute Malnutrition (SAM) live in a development context. [7] Despite the high prevalence of SAM in many low- and middle-income countries, data compiled in 2018 showed that only 16 countries had included RUTF in the national Essential Medicines List (EML).[8] This is an important gap because governments use national EMLs to determine which medicines and nutritional therapeutic products to fund and procure.[9] Inclusion of medicines and nutritional therapeutic products in the national EMLs can help to achieve more equitable and sustainable access to essential health and nutrition interventions by leveraging development and domestic funding, enabling the integration of these products into national supply chains and facilitating the provision of tax incentives to support local production.[10] [11]

The World Health Organization's Model List of Essential Medicines (hereafter 'WHO Model EML") guides governments on which priority medicines and nutrition products to include in their national EMLs and has been adapted in more than 100 countries.[12] The World Health Organization (WHO) recognizes that inclusion of RUTF in EMLs may improve its availability[13], however, the current edition of the WHO Model EML does not include RUTF.[14]

In 2017, the WHO Expert Committee on the Selection and Use of Essential Medicines considered an application from Action Contre la Faim (ACF) for the inclusion of RUTF in the WHO Model EML. The Committee acknowledged the effectiveness of RUTF for the outpatient management of severe acute malnutrition and the need to improve access to RUTF at country level and in health facilities. However, the Committee did not recommend the addition of RUTF to the WHO Model EML because of concerns that its inclusion may have implications for compliance with requirements for pharmaceutical products and thereby possibly impact on the feasibility of local procurement, cost of, and access to RUTF. [15] To address these concerns, the WHO Expert Committee requested the WHO Department of Nutrition and Food Safety to prepare a report for the 2019 Expert Committee meeting addressing the following:

- Country requirements for the inclusion of RUTF in the national EML (as a medicine/pharmaceutical or food) and the ability of national and international producers to comply with those requirements
- Various cost and access implications of listing RUTF as a medicine/pharmaceutical versus as a food
- Implications of including RUTF in the EML on appropriate use of RUTF (i.e., only for uncomplicated cases of severe acute malnutrition and not for other children or other uses)
- Progress by the Codex Committee on Nutrition and Food for Special Dietary Uses on the development of RUTF guidelines
- Outcome of ongoing systematic reviews of the effectiveness and safety of RUTF.

In 2018, WHO commissioned a series of three papers to address these information gaps. The papers examined where RUTF fits within the category of nutrition-related health products, and the advantages and disadvantages of listing RUTFs in the EML based on a literature review, country case studies, stakeholder perspectives and key informant interviews. These papers were discussed at a WHO technical consultation in 2018 on "*Nutrition-related health products and the World Health Organization Model List of Essential Medicines –practical considerations and feasibility"*. [16] The 2019 WHO Expert Committee again acknowledged the effectiveness of RUTF to treat severe acute malnutrition but felt that the report did not fully address the concerns raised in 2017. In particular, the Committee noted the uncertainty concerning the consequences of including RUTF as a medicine in the WHO Model EML, including the possibility of increased costs of RUTF, barriers to local production and more restricted access. It also noted that the papers in the report did not sufficiently represent the voices of officials in a range of country contexts, including countries that have and have not included RUTF in the national EML. In addition, the Committee recognized the work underway to establish standards and guidelines for RUTF under the Codex Alimentarius to facilitate harmonization for the requirements of RUTF at an international level. The 2019 WHO Expert Committee did not recommend the inclusion for RUTF in the WHO Model EML, but noted that it would be eligible for future consideration provided there is the following:

- A clear indication of the potential consequences and implications at country level of including RUTF on the Model List
- A comprehensive risk-mitigation plan for these potential consequences
- Standards and guidelines for RUTF under the Codex Alimentarius.

# 2. Introduction

Since the last submission in 2019, a series of political and regulatory events have taken place which directly or indirectly influence the discussion on the inclusion of RUTF in the WHO Model EML.

Currently, UNICEF is the largest procurer of RUTF, procuring an estimated 75-80% of RUTF globally. [17] The current suppliers or manufacturers are predominantly based in countries where acute malnutrition exists (18 out of 21 suppliers) and as such procurement can be considered mostly 'national' or 'local' for this product. In order to qualify as a UNICEF supplier, a series of stringent UNICEF quality standards have determined the eligibility of these manufacturers. Over the past ten years UNICEF has succeeded in diversifying its supplier base from just a handful of manufacturers to a variety of manufacturers predominantly based in countries affected by acute malnutrition. National producers therefore dominate the RUTF supplier base and are able to produce RUTF to high quality standards. Local production, whereby RUTF is developed at the point of service delivery using locally available ingredients is not common practice and is not promoted given the risk of salmonella associated to the key ingredient, peanuts. In addition, the micronutrient powders necessary for RUTF are generally not available at this local level. As such, UNICEF has made steps to diversify the production of high quality RUTF in countries where acute malnutrition exists, termed 'national production' rather than 'local production'.

In 2019, UNICEF held an expert meeting on RUTFs with a focus on newer generation of RUTFs. The meeting enabled UNICEF and partners to develop a road map for scientific evaluation and assessment of implementation of newer generation of RUTF formulations. The conclusions of this expert meeting have helped to inform manufacturers of formulation requirements and provide guidance to manufacturers, governments, and programmers regarding the considerations when developing new RUTF formulae and the kind of scientific evidence needed for alternative RUTF recipes.

The finalization of the CODEX guidance on RUTFs categorized as Foods for Special Medical Purposes (FSMP) is another key milestone which was confirmed in 2022. Prior to the Codex guidelines, there has been an absence of international standards for the manufacturing of RUTF. The UNICEF quality standards have thus far determined the eligibility of manufacturers to provide RUTF, however these new international standards provided by Codex have the capacity to greatly influence manufacturing, procurement and availability globally. This topic will be explored further later in this report.

In addition, the United Nations Global Action Plan (GAP) on Child Wasting was published in 2020. The GAP provides a global framework for action to accelerate progress in preventing and managing acute malnutrition in children for achieving the Sustainable Development Goals. This plan is the first ever global initiative and since its publication, 23 countries have developed national roadmaps to accelerate action on acute malnutrition. Concerning RUTF, the GAP on Child Wasting, reaffirmed the need to consider the inclusion of RUTF into the WHO Model EML, recognizing the importance of national mitigation measures to avert any associated risks.[18]

Most importantly however is the impact of the COVID-19 pandemic on rates of child acute malnutrition, combined with additional contextual factors such as the current food security crises in the Horn of Africa and the Sahel and the impacts of the ongoing war in Ukraine on the global market. As the COVID-19 pandemic spread in 2020, an analysis published in The Lancet pointed to an estimated additional 6.7 million children suffering from SAM as a result of lockdown measures, economic downturns and decreased availability of essential services.[19] Whilst treatment services for acute malnutrition remained functional throughout the pandemic, admission rates saw a decline in some countries. A more recent analysis published in 2022 re-emphasized the effects of the pandemic on rates of acute malnutrition in children, suggesting that an additional 9.4 million children under 5 are at risk of developing acute malnutrition. [20] Overall, it is fair to say that the pandemic has significantly increased the needs for treatment services

resulting in increased demand for the availability of RUTF. With much attention now focused on post-pandemic recovery and ongoing global food and nutrition crisis in the Horn of Africa and the Sahel, the demand on a stretched RUTF supply chain, which is currently experiencing gaps of over 50% in some countries in these two regions, means that every effort must be made to ensure increased availability of this life-saving product at national level.

## Study objectives

To address the evidence gaps highlighted by the WHO EML expert committee, UNICEF Nutrition Programme Group, in collaboration with the WHO Department of Nutrition and Food Safety, designed and implemented a study between 2020 and 2022 to examine the experiences and perceptions of country-level stakeholders on the implications of including RUTF in the national EMLs and the WHO Model EML, and measures to mitigate the risks. In addition, the study examined the perspectives of regional-level stakeholders on the inclusion of RUTF into the national EMLs and WHO model EML. The findings of this study, presented in this report, will be used to inform an application to the next WHO Expert Committee planned in April 2023 on the Selection and Use of Essential Medicine for the inclusion of RUTF in the WHO Model EML. The study also reviewed the latest updates on the CODEX guidance process for RUTFs and provide a risk mitigation plan.

The specific objectives of the study were as follows:

- To examine the experiences and perspectives of country and regional stakeholders on the process, benefits and risks of including RUTF in national EMLs
- To solicit the perspectives of country and regional stakeholders on the benefits and risks of including RUTF in the WHO Model EML
- To solicit the perspectives of country, regional and key stakeholders on measures to mitigate the risks of including RUTF in national EMLs and WHO Model EML.

# 3. Methods

## Research questions and design

The study set out to answer the following research questions:

1. What is the current status of inclusion of RUTF in national EMLs in countries implementing the community-based management of severe acute malnutrition with RUTF?
2. In countries that included RUTF in the national EML, what process did countries follow, what were the challenges encountered, and what were the lessons learned?
3. What are benefits and risks of including RUTF in the national EML and WHO model EML?
4. What measures are needed to mitigate the risks of including RUTF in the national EML and WHO model EML?

The study used a mixed methods approach comprising three components to answer the research questions:

- **Survey A** on the status of inclusion of RUTF in national EMLs in countries implementing the community-based management of severe acute malnutrition with RUTF
- **Survey B** on the experiences and perspectives of country-level stakeholders on including RUTF in national EMLs and the WHO Model EML
- **Key information interviews** with country-level and regional-level stakeholders on the experiences and/or perspectives of including RUTF in the national EMLs and WHO Model EML.

The methods used for each of these components are described below.

## Survey A on the status of inclusion of RUTF in national EMLs

*Purpose:* The purpose of this survey was to understand the current status of RUTF inclusion in the national EMLs of countries implementing the community-based management of SAM with RUTF.

*Selected countries:* All 74 countries implementing the community-based management of SAM with RUTF were selected for the survey. These countries were identified by UNICEF regional offices.

*Respondents:* The UNICEF staff members responsible for programmes to prevent and treat SAM in each country responded to the questionnaire.

*Survey instrument:* A structured survey instrument with pre-coded and open-ended questions was developed using Microsoft Excel and included questions on:

- Whether RUTF is included in the country's national EML
- In countries that have included RUTF in the national EML: the year that RUTF was included in the national EML; how RUTF is classified in the country's regulatory framework; and which agency regulates RUTF.
- In countries that have not included RUTF in the national EML: if the country ever began a process to decide whether to include RUTF in the national EML, and if yes, if the process is still ongoing or the country took a decision not to include RUTF.

UNICEF staff members conducted a desk review of the national EML to retrieve the necessary information. Where necessary, they also consulted with government officials and other partners to respond to specific questions. A full list of the questions is provided in Annex 1.

*Administration of the survey:* The survey instrument was self-administered by staff members in the UNICEF country offices of the selected countries in September to November 2021.

*Validation of findings:* For countries that reported RUTF is in the nEML, the latest copy of the nEML in each country was reviewed to verify that RUTF was included.

*Data analysis:* The survey data were analysed using Microsoft Excel to produce descriptive summary statistics and a visual representation of the data.

### Survey B on the experiences and perspectives of including RUTF in national EMLs and the WHO Model EML

*Purpose:* The purpose of this survey was to understand the experiences and perspectives of country-level stakeholders on the inclusion of RUTF into national EMLs and the WHO Model EML.

*Selected countries:* Countries with a national prevalence of acute malnutrition of at least 5 per cent, or countries with vulnerable sub-populations among whom prevalence of acute malnutrition is higher than 5 per cent, were selected for the survey.

*Respondents:* UNICEF and WHO country office staff identified potential country-level respondents from the following stakeholder categories:

- Officials in the Ministry of Health responsible for programmes for the treatment of acute malnutrition and/or the regulation or procurement of RUTF
- National RUTF manufacturers or producers, if RUTF is produced in the country
- Non-government organizations (NGOs) actively involved in programming for the treatment of acute malnutrition.

The survey was sent to a total of 91 potential respondents in 45 countries, covering all countries except four (Burkina Faso, Ethiopia, Suriname and Tajikistan).

*Survey instrument:* A web-enabled questionnaire was developed using the Survey Monkey™ platform in both English and French language versions. The questionnaire was pre-tested in two countries with a Global Acute Malnutrition (GAM) prevalence of at least 5 per cent and revised and finalized based on the feedback received. It included closed and open-ended questions covering the following topics:

- Existence of a national EML and the inclusion of RUTF within the national EML.
- Actual or perceived triggers, rationale and challenges of including RUTF in the national EML
- Actual or perceived consequences of including RUTF in the national EML (government control and regulation, national production, procurement, cost, distribution, availability, quality and use)
- Measures to mitigate the risks of including RUTF in the national EMLs
- Perceived consequences of including RUTF in the WHO model EML

A full list of the questions is provided in Annex 1.

*Administration of the survey:* Respondents were contacted by email and provided with a hyperlink to the online survey. Respondents self-administered the survey between October 2020 and January 2021.

*Data analysis:* The coded responses to the survey questions were analysed using Microsoft Excel to produce descriptive summary statistics. The open-ended qualitative responses were translated and coded and emerging themes identified and analyzed.

## Key informant interviews on the experiences and perspectives of including RUTF in the national EMLs and WHO Model EML

*Purpose:* The purpose of the key informant interviews was to understand the (i) experiences of stakeholders in countries that have included RUTF in the national EMLs on the process, challenges and consequences of including RUTF in the national EMLs, (ii) the perspectives of stakeholders in countries that have not included RUTF in the national EMLs on the challenges and potential consequences of including RUTF in the national EMLs; and (iii) the perspectives of regional stakeholders that provide technical support to countries on the treatment of acute malnutrition on the consequences of including RUTF in the national EMLs and WHO Model EML.

*Key informants:* Two groups of key informants were selected:

- **Group I** were selected from countries that have included RUTF in the national EML The respondents were identified by UNICEF country offices and were all managers in the MoH department or division of nutrition who were involved in the process of including RUTF in the national EML. Six key informants were requested to participate.
- **Group II** were nutrition experts working at regional level for United Nations (UN) agencies, NGOs, regional organizations or regional nutrition networks in Africa and Asia, and researchers on acute malnutrition and/or RUTF. Twenty-one key informants were requested to participate.

*Qualitative instrument:* Three semi-structured interview guides with open-ended questions were developed for the two target groups. The topics discussed by group are provided in Annex 1 and included:

- **Group I**: The process of including RUTF in the national EML, the challenges experienced, how these challenges were resolved, and the lessons learned.
- **Group II:** The benefits and risk of including RUTF in national EMLs and in the WHO Model EML.

*Administration of the interviews:* The interviews were conducted remotely using teleconferencing in English or French by an Anglophone or Francophone researcher between October 2020 and January 2021. The duration of each interview was approximately 25 minutes. All except one interview was audio recorded, with the permission from the key informants. For the interview that was not recorded, the key informant was sent a summary of the discussion immediately following the interview to confirm that his or her insights had been accurately captured.

*Data analysis:* The qualitative responses from the key informant interviews were transcribed, translated (from French to English) and coded and emerging themes identified and analyzed. The findings were triangulated with those from Survey B.

## Ethical considerations

The study protocol for Survey B and the key informant interviews received ethical clearance from the WHO ethics review committee. All survey respondents and key informants were informed of the objectives of the study and intended use of the data and information and provided written consent prior to participation.

# 4. Results

## 4.1 Status of inclusion of RUTF in national EMLs

### Sample

This section analyses the quantitative data from Survey A to assess the current status of RUTF inclusion in national EMLs. Of the 74 countries that have programmes to treat SAM with RUTF, 69 countries completed the survey and provided the copies of the national EML, were relevant (93% response rate, 69 countries out of 74).

### Status of inclusion of RUTF in national EML

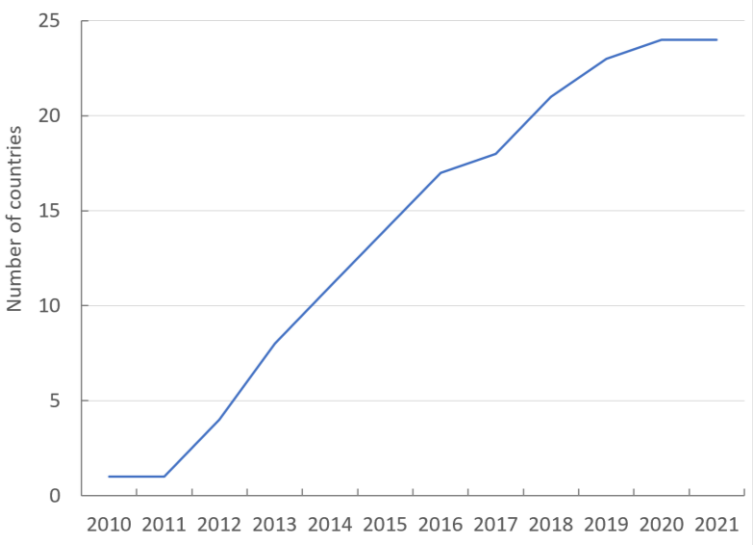
As of November 2021, 25 countries (36%, out of 69 countries) with programmes to treat uncomplicated SAM with RUTF had included RUTF in their country's national EML (*Table 1*). The percentage of countries with RUTF in the national EML was considerably higher in the Africa Region (63% of the 25 countries) than elsewhere: only 18% countries in the Region of the Americas and one in ten of the countries in West Pacific had included RUTF in the national EML, and none in the Eastern Mediterranean Region, Europe Region or Southeast Asia Region. The data by country are provided in Annex 2.

***Table 1: Number and percentage of countries that have included RUTF in the national EML by WHO region***

| | Number of countries with a CMAM programme | Countries with RUTF in national EML | |
|---|---|---|---|
| | | Number | Percentage (%) |
| Africa Region | 35 | 22 | 74 |
| Region of the Americas | 11 | 2 | 18 |
| Eastern Mediterranean Region | 7 | 0 | 0 |
| Europe Region | 2 | 0 | 0 |
| South-East Asia Region | 4 | 0 | 0 |
| West Pacific Region | 10 | 1 | 10 |
| All regions | 69 | 25 | 36 |

Figure 1 shows that the cumulative number of countries with RUTF in the national EML increased steadily between 2010 and 2019 but has since slowed down.

***Figure 1: Cumulative number of countries with RUTF in the national EML by year (24 countries)***



The countries that have not included RUTF in the national EML were asked to report whether they had ever begun a process to include RUTF in the national EML and if so, the outcome of this process (*Table 2*). Only two countries reported that a decision had been taken to not include RUTF in the national EML, citing its absence on the model EML meant that it was not considered an essential product at national level. 18 countries reported that they were in the process of deciding whether to include RUTF in the national EML and 19 countries had not started a process.

**Classification of RUTF and regulatory agency**

Most of the 25 countries with RUTF in the national EML have classified RUTF as a medicine (11 countries) or food for special medical purposes (7 countries) (*Table 3*) and have assigned a medicines regulatory authority (18 countries) or a combined food and drug regulatory authority (2 countries) to regulate RUTF (*Table 4*).

## 4.2 Stakeholder experiences and perceptions of the inclusion of RUTF in the national EML

### 4.2.1 Sample

This section analyses data from Survey B and the key informant interviews to examine the experiences and perceptions of stakeholders on inclusion of RUTF in the national EML. The survey was shared with 57 eligible countries. A total of 64 respondents (89% response rate) in 40 countries responded to the Survey B. Of these respondents, 23 (36%) were unable to answer the question on whether RUTF was in the country's national EML and 11 (17%) respondents answered this question incorrectly (*Table 2*). As this knowledge is a prerequisite for sharing valid experiences or perceptions of including RUTF in the national EML, data from these 34 participants were excluded. One country had two MoH respondents, and so the respondent with the greater number of missing values was excluded to avoid country bias. With these exclusions, the analysis included data from 29 respondents, including 18 MoH officials, 9 NGO officials and 2 RUTF producers. These 29 respondents were from 24 countries in five regions (Table 6). 9 countries (38% of 24 countries) had included RUTF in the national EML, and there were 12 respondents (41% of total respondents) from these countries. Eight countries had at least one national RUTF manufacturer, and there were 10 respondents (34% of total respondents) from these countries.

***Table 2: Number of survey respondents who responded and were included in the analysis***

| Number respondents | MoH officials | NGO officials | RUTF producers | Other respondents* | Total |
|---|---|---|---|---|---|
| Responded to the questionnaire | 34 | 23 | 5 | 2 | 64 |
| Excluded due to lack of knowledge on whether RUTF is in the country's nEML | 11 | 11 | 1 | 0 | 23 |
| Excluded due to incorrect knowledge on whether RUTF is in the country's nEML | 4 | 3 | 2 | 2 | 11 |
| Excluded due to multiple respondents for the same country and stakeholder group | 1 | 0 | 0 | 0 | 1 |
| Included in the analysis | 18 | 9 | 2 | 0 | 29 |

*One pediatrician and one medical doctor

***Table 3: Number of survey respondents included in the analysis by WHO region***

| Respondents | MoH officials | NGO officials | RUTF producers | Total |
|---|---|---|---|---|
| African Region | 8 | 3 | 1 | 12 |
| Region of the Americas | 1 | 0 | 1 | 2 |
| Eastern Mediterranean Region | 2 | 3 | 0 | 5 |
| South-East Asia Region | 3 | 2 | 0 | 5 |
| Western Pacific Region | 4 | 1 | 0 | 5 |
| Total | 19 | 9 | 2 | 29 |

**Key informant interviews**

The number of key informant interviews by group were as follows:

- **Group I:** Six countries with RUTF in the national EML were identified as having informed national Ministry of Health staff to take part in the key informant interviews (Sierra Leone, Nigeria, South Sudan, Madagascar, Niger and Cote d'Ivoire). All six agreed to participate in key informant interviews to examine the experiences of the process followed, the challenges experienced, and the lessons learned.
- **Group II**: Of the 21 key informants identified from country-level and regional-level partners, 14 agreed to participate, including nutrition specialists working at regional level in Africa or Asia for UN agencies (n=3), NGOs (n=4), regional organizations (n=2); researchers who were based at country-level in Africa or involved in country-level research on acute malnutrition and/or RUTF in Africa (n=4); and a public health professional working at country-level in South Asia (n=1).

### 4.2.2 Justification and triggers for including RUTF in the national EML

Country stakeholders described the justifications for including RUTF in the national EML based on their actual experience (for stakeholders in countries that have included RUTF in the national EML) or perceptions (for stakeholders in countries that have not included RUTF in the national EML).

Stakeholders gave several justifications for their country's decision to add RUTF in the national EML, including the public health burden of SAM, the proven efficacy, effectiveness and safety of RUTF to treat SAM, and the absence of a suitable alternative product to treat SAM (*Table 4*). Some country stakeholders also referred to the benefits of including RUTF in the national EML, such as the facilitation of the national production of RUTF, the mobilization of domestic financial resources to procure RUTF, and the improved supply and distribution of RUTF; these benefits are described in more detail in Section 3.2.4.

The triggers that initiated country action to add RUTF in the national EML in these countries included: (1) advocacy by concerned groups, particularly the MoH nutrition department/division and UNICEF; (2) direct requests by the MoH nutrition department/division or recommendation from a technical working group on CMAM to include RUTF in the national EML; and (3) the periodic review and update of the national EML, which provided the opportunity to include RUTF.

Stakeholders in countries that have not included RUTF in the national EML reported similar potential justifications and triggers. In addition, several expressed the need for RUTF to be included in the WHO Model EML to either trigger or justify the addition of RUTF to the national EML:

"The absence of RUTF in the WHO Model List directly resulted in national procurement not considering RUTF as essential, thus excluding it totally [in my country]. Including RUTF in WHO Model EML, together with support from national authority, will trigger the inclusion of RUTF in the national EML" MoH officer

"WHO should include RUTF in the Model list so we can also include it in our essential drug list" – MoH officer

***Table 4: Justifications for including RUTF in the national EML***

| Justification | Experiences of stakeholders in countries with RUTF in the national EML | Perceptions of stakeholders in countries without RUTF in national EML |
|---|---|---|
| Public health burden of SAM | "To respond to a public health problem" – MoH nutrition director<br>"GAM prevalence remains high in country level and there has been commitment to reduce the prevalence" – NGO health specialist | "The importance of acute malnutrition in relation to child mortality and other adverse consequences" – MoH nutrition director<br>"Burden of SAM and its impact on national economy" – NGO nutrition advisor |
| Efficacy, effectiveness and safety of RUTF to treat SAM | "[RUTF has] been added to the list of essential medicines because of its clinical effectiveness and relatively low risk of side effects." – MoH Director<br>"We needed to show and justify that [RUTF] was important in treatment and care… that it was the only product we had that was available and allowed us to properly care for children suffering from acute malnutrition" – MoH nutrition director<br>"The justified request of the Food and Nutrition Unit on the basis of therapeutic evidence" – MoH nutrition director | "As RUTF is used in the treatment of acute malnutrition which contributes to infant mortality, it is rational that it is included in the essential list for routine treatment of acute malnutrition"- MoH officer<br>"Importance of the product for health and well-being … high need/ demand in the country" – MoH nutrition director<br>"RUTF has proven results in treatment of severe acute malnutrition" – NGO manager |

### 4.2.3 Process of including RUTF in the national EML

The six MOH officials explained the process they followed to successfully include RUTF in their national EMLs. In all six countries, the inclusion of RUTF was considered as part of a periodic review and update of the national EML for all medicines and products and was not a standalone process for RUTF only. The timeline for the addition of RUTF in the national EML was therefore determined by the schedule for these reviews; some countries organize reviews every one or two years, whilst there was no set frequency in others.

Multiple stakeholders were involved in the decision-making process to include RUTF in the national EML, each with a specific role. The directorate or department of pharmacy, pharmaceuticals or drugs and medical supplies usually led and coordinated the review of the national EMLs and involved the regulatory agency and central purchasing organization for medicines, medical supplies and/or food. The department/division of nutrition in the MoH was responsible for triggering the request to include RUTF in the national EML, compiling information and evidence to support the submission, and presenting the case to the relevant board or committee responsible for reviewing the national EML. UNICEF, WHO and NGOs advocated with MoH officials on the benefits of including RUTF in the national EML and provided technical assistance to support the process. Academic institutions and researchers generated country-specific data, information and evidence to justify the inclusion of RUTF in the national EML.

***Table 5: Stakeholders involved in the decision-making process to include RUTF in the national EML***

| | |
|---|---|
| Ministry of Health | • Directorate or department of pharmacy/pharmaceuticals/ drugs and medical supplies<br>• Regulatory agency for medicines, medical supplies and/or food<br>• Central purchasing organization<br>• Nutrition department or division |
| UN agencies | • UNICEF<br>• WHO |
| Other national partners | • NGOs supporting community-based programmes to treat SAM<br>• Academia and researchers |

The information and evidence needed to justify the addition of RUTF in the EML varied between countries, but commonly included:

- Information on the prevalence and burden of acute malnutrition in the country and its impact on child survival, growth and development.
- Benefits of scaling up access to services to treat SAM with RUTF at community level.
- Evidence on the efficacy, effectiveness and safety of RUTF to treat SAM, including data from clinical trials conducted within the country or in other countries; and absence of alternative products that are equally efficacious and effective in treating SAM at community level.
- National protocol, guidelines and/or a technical data sheet that explains the specifications of RUTF, the storage requirements and how RUTF is used to treat SAM.
- The history and performance of the programme to treat SAM with RUTF in the country.

The key informants identified several factors than facilitated the process to include RUTF in the national EML. They included strong MoH leadership and coordination of the process and the support of key partners; relatively long in-country history of the programme to treat SAM with RUTF; the familiarity of the MoH officials involved in the review of the national EML with RUTF, and the national production of RUTF in the country:

> "In my opinion, the main thing that helped gain approval [for inclusion of RUTF in the national EML] is that RUTF had already been used for many years as part of care provision in the country, and that there is a company that already produces it nationally. It is already being used on a large scale. All the actors involved in the review [of the national EML] were very familiar with the RUTF because it has been in use for over 15 years. The specifications, etc. are already clearly described on the care protocol." – MoH nutrition director

> "What worked to our advantage was being able to demonstrate that malnutrition was a major public health issue in [our country] … and the leadership of those who led the process." – MoH nutrition director

> "The leadership of the ministry was one group of people that were very helpful in achieving [inclusion of RUTF in the EML]. It was important to have key stakeholders to support the process, including our partners, UNICEF and WHO" – MoH nutrition director

One key informant also mentioned that the existence of CMAM taskforce in their country was helpful because the experts in this group provided a recommendation to the MoH to include RUTF in the national EML and gave technical assistance to the team preparing the documents to justify the inclusion of RUTF in the national EML.

None of the key informants or online respondents reported experiencing any significant constraints or barriers to the process of including RUTF in the national EML. Most described it as, "not difficult", and one even said, "[officials responsible for the review of the national EML] considered it something normal. As far they were concerned, it may as well be already on the

list". However, the respondents described some challenging aspects, including the justification and availability of country-specific evidence on the efficacy or effectiveness of RUTF:

> "I believe the justification process was one of the challenges we had to face.... Because we got the impression there was a limited number of medicines, so our argument had to be convincing to get [RUTF] added to the list "– MoH nutrition director

> "Initially the committee [responsible for reviewing the national EML] required results from a clinical trial from the country but later on agreed to consider the trial from a neighboring country in addition to evidence on in-country usage" – MoH nutrition director

In addition, one MoH respondent remarked that the process was delayed because it was not possible to arrange a standalone review of the national EML for RUTF, and it was put on hold until the next periodic review was scheduled.

Survey respondents in countries that have not included RUTF in their national EML shared their perceptions on challenges to including RUTF in the national EML. The most common challenge was the availability of funding to procure RUTF. However, only middle-income countries in South-East Asia Region and the Western Pacific Region mentioned this challenge, presumably because they were less dependent on donor funding for RUTF:

> "Funding for this item is a challenge. It is a quite expensive product compared to other drugs. Currently only UNICEF is procuring emergency supplies" –MoH nutrition officer

> "The government budget for the health expenditure might be a challenge" – NGO nutrition advisor

> "Cost [of RUTF] and absence of national manufacturer in the country is a challenge" – MoH health officer

Several respondents mentioned that the MoH may oppose the classification of RUTF as a medicine, and this may prevent RUTF from being included in the essential EML. In addition, a stakeholder based in a South Asian country referred to potential opposition by groups opposed to the use of RUTF to treat SAM:

> "Resistance by the groups opposing product-based intervention that may keep a country dependent on imported food/medicine for longer term (not sustainable)" – NGO health and nutrition advisor

### 4.2.4 Consequences of including RUTF in the national EML

Information on the consequences of including RUTF in the national EML is drawn from Survey B for country-level stakeholders and the key informant interviews for country-level and region-level stakeholders. The findings are presented separately for country-level and regional-level stakeholders.

#### Country-level stakeholders

Table 6 shows the consequences of including RUTF in the national EML reported by country-level respondents to the Survey B. The actual experiences of respondents in countries with RUTF in the national EML are compared with the perceptions of respondents in countries that have not included RUTF in the national EML. Only respondents who had correct knowledge on whether RUTF had been added to their national EML are included in the analysis (n=29). A 'triangulated response' is recorded if at least three respondents in a sub-group reported the same consequence. Due to the relatively small number of included respondents, data from NGO respondents are combined with RUTF producers. The number of responses is provided in Annex 3. Additional information on the consequences of included RUTF in the national EML are drawn from the key informant interviews (groups I and II).

**Government regulation and control of RUTF:** Government regulation relates to the standards and rules set by government for the manufacture and import of RUTF, while government control refers to the supply and distribution of RUTF by government. Both government regulation and control are usually favoured, as they help ensure that a quality RUTF product is imported or nationally produced, that barriers to import of the product or its ingredients are removed, and that the supply and distribution of RUTF is integrated into existing government systems.

Country-level respondents, including MoH officials, reported that they experienced more government regulation, more stringent quality requirements for RUTF used in the country, and more government control of RUTF as a result of including RUTF in the national EML (Table 6). Similarly, stakeholders in countries without RUTF in the national EML perceived that RUTF would be more regulated, quality requirements would become more stringent, and there would be greater control over its supply and distribution if RUTF is included in their national EMLs.

**Financing of RUTF**: Stakeholders in countries with RUTF in the national EML agreed that inclusion resulted in the mobilization of government financial resources for the procurement of RUTF (Table 6).

> "When something is put in EML it can be resourced domestically. Federal, state and local government authority levels have budget lines for nutrition-specific interventions in health sector that include procurement of RUTF for treatment of SAM."– MoH nutrition director

Stakeholders in countries without RUTF in the national EML shared similar perceptions of the impact of including RUTF in the national EML on the allocation of government financial resources:

> "Because RUTF is not on our national EML, we will not purchase it" – MoH pharmacist

> "If RUTF is included in the EML, it can be easily procured using government funds at the national and sub-national levels" – MoH health officer

> "Sustainability of fund for RUTF procurement" – MoH nutrition director

> "[Address] bottlenecks and cost for import" – MoH nutrition director

A small number of respondents (1 MoH official, 1 NGO health specialist and 1 RUTF producer, all from different countries) reported that the inclusion of RUTF in the national EML had resulted in an increase in the cost of RUTF, but no explanation was given. On the other hand, stakeholders in countries that have not included RUTF in the national EML perceive it is unlikely that inclusion will increase the cost of RUTF. One stakeholder explained that the inclusion of RUTF would increase demand for RUTF, favour economies of scale and possibly trigger tax reforms, which will drive costs down:

> "Including RUTF on EML will in a way compel the health service to procure and supply them to treatment centres, because it would be regarded as an "essential lifesaving medicine". When this happens, the increased demand may alter the market forces towards increased production and supply of RUTF, thereby influencing the pricing due to economy of scale and supplier competition, if any."– NGO director

**National production:** Country-level stakeholders experienced no negative consequences of the decision to include RUTF in the national EML on the local production of RUTF (Table 6). To the contrary, they reported that the quantity and quality of nationally produced RUTF increased. One MoH official explained how inclusion of RUTF in the national EML directly resulted in one factory starting national production of RUTF.

Stakeholders in countries without RUTF in the national EML also perceived that it would be unlikely that national production of RUTF would be halted if RUTF is included in the national EML, and instead expected that the quantity of nationally produced RUTF would increase. Three respondents explained that the inclusion of RUTF in the national EML would encourage more

companies to produce RUTF and facilitate national production by removing barriers to the import of raw materials and reducing taxes:

> "In the future if RUTF listed in EML there will have more private companies involved [in national RUTF production] which is good for both users and government" – NGO programme officer

> "RUTF's enlistment in the national EML would facilitate national production in all aspects from facilitation of the import of raw materials to reduction in taxes" – MoH nutrition manager

**Procurement of RUTF:** Stakeholders in countries with RUTF in the national EML agreed that inclusion did or would result in greater government and donor involvement in RUTF procurement (Table 6). A MoH official in a country that currently does not have RUTF in the national EML reported the same, that the inclusion of RUTF in the national EML will support requests for support from donors and government for the supply of RUTF.

Key informants in countries that have RUTF in the national EML explained that inclusion increased the government accountability to procure and led to the integration of RUTF procurement into government procurement systems:

> "Before, it was hard for us to integrate RUTF into national procurement. We had a parallel supply, and we had problems with product availability. When we were able to finally add it to the EML, it felt like we could start procuring it officially. The central purchasing organisation was able to integrate RUTF into the cycle, from the procurement stage up to delivery to health facilities and ensure continuous product availability." – MoH nutrition director

**Supply and distribution of RUTF:** Stakeholders in countries that have included RUTF in the national EML reported that the inclusion resulted in 'easier' distribution of RUTF within the country, greater availability of RUTF at treatment centres, and that the quality of RUTF in the market was not negatively affected – all positive impacts (Table 6).

Stakeholders in countries that have not included RUTF in their national EMLs also reported the same potential benefits for the supply, availability and quality of RUTF. These findings concurred with the following justifications given by these stakeholders for including RUTF in the national EMLs:

> "To have a constant and regular supply of RUTF" – MoH pharmacist

> "Improve distribution of RUTF in our community-based centres" – MoH nutrition director

One key informant, who was opposed to the use of RUTF to treat severe acute malnutrition, expressed concerns that the impact of including RUTF in the national EML on improving access was a risk rather than a benefit. Meanwhile, MoH officials in other countries reported that they have not experienced barriers to RUTF procurement, despite the absence of RUTF in the national EML. For example:

> "So far, RUTF is not on the essential drugs list, and we have no problems with its use and supply" – MoH nutrition programme coordinator

Stakeholders in countries that have not added RUTF in the national EML gave a triangulated response for a 'likely' reduction in the quality of RUTF in the market and for RUTF becoming more available outside treatment centres (e.g., in shops, pharmacies and markets), which are both unfavorable impacts. However, these findings were not reported by stakeholders in countries that have included RUTF in the national EML.

**Use:** The survey findings on impact of including RUTF in the national EML on the misuse of RUTF were inconclusive (Table 6). At least three respondents gave "unlikely" and "likely" responses, in both countries with and without RUTF in the national EML.

***Table 6: Consequences of including RUTF in the national EML (nEML) experienced by stakeholders in countries with RUTF in the nEML and perceived by stakeholders in countries without RUTF in the nEML†***

| | | All Stakeholders | | MoH officials | | NGOs and RUTF producers | |
|---|---|---|---|---|---|---|---|
| | | Countries with RUTF in nEML (n=12) | Countries without RUTF in nEML (n=17) | Countries with RUTF in nEML (n=7) | Countries without RUTF in nEML (n=11) | Countries with RUTF in nEML (n=5) | Countries without RUTF in nEML (n=6) |
| GOVERNMENT REGULATION AND CONTROL OF RUTF | | | | | | | |
| Regulation of RUTF | More regulated | X | X | X | X | | X |
| | Less regulated | | | | | | |
| Quality requirements for RUTF used in country | More stringent | X | X | X | X | | |
| | Less stringent | | | | | | |
| Government control of RUTF supply and distribution | More control | X | X | X | X | | X |
| | Less control | | | | | | |
| FINANCING OF RUTF | | | | | | | |
| Increased cost of RUTF | Unlikely | | X | | X | | X |
| | Likely | X | | | | | |
| NATIONAL PRODUCTION OF RUTF | | | | | | | |
| Halting of national production of RUTF | Unlikely | X | X | | X | | |
| | Likely | | | | | | |
| Quantity of national production | More production | X | X | | | | |
| | Less production | | | | | | |
| Quality of national production | Higher quality | X | X | | X | | X |
| | Lower quality | | | | | | |
| PROCUREMENT OF RUTF | | | | | | | |
| Government involvement in RUTF procurement | More involvement | X | X | X | X | | X |
| | Less involvement | | | | | | |
| Donor involvement in/support for RUTF supply | More involvement | X | X | X | X | X | X |
| | Less involvement | | | | | | |
| SUPPLY AND DISTRIBUTION OF RUTF | | | | | | | |
| Distribution of RUTF within the country | Easier | X | X | X | X | | X |
| | More difficult | | | | | | |
| Availability of RUTF at treatment centres | More available | X | X | X | X | | X |
| | Less available | | | | | | |
| Availability of RUTF outside treatment centres | Less available | | | | | | |
| | More available | | X | | X | | |
| | Unlikely | X | X | | X | | |

| | | | | | |
|---|---|---|---|---|---|
| Reduced quality of RUTF available in the market | Likely | | X | | |
| **USE OF RUTF** | | | | | |
| Increased misuse of RUTF | Unlikely | X | X | X | |
| | Likely | X | X | X | |

*† Excludes survey respondents who did not have correct knowledge of the inclusion of RUTF in the nEML; X indicates a 'triangulated response' in which at least three respondents reported the same response.*

## Regional-level stakeholders

Table 7 summarizes the opinions of regional-level stakeholders on the consequences of including RUTF in the national EML.

Most stakeholders reported positive consequences, including increased national ownership and commitment to the treatment of SAM with RUTF, mobilization of government financial resources, integration of RUTF into national procurement, supply and monitoring systems, standardization of the product, stimulation of national production, improved supply and distribution, increased prioritization of services to treat SAM by the health workforce. These benefits are similar to those reported by country-level stakeholders. In addition, these benefits have also been recorded in previous studies documenting the views of global experts on related issues.[21] [22]

However, the presence or absence of RUTF in the national EML affects countries in different ways, according to the policy and legal framework of countries. To illustrate this point, a regional UN nutrition advisor compared the context in the Philippines and Vietnam. Neither country has included RUTF in the national EMLs, but this has only had negative consequences on children's access to treatment services in Vietnam. In the Philippines, the government has allocated financial resources for RUTF procurement and included the treatment of SAM with RUTF in the health benefit package of the national health insurance scheme. In Vietnam, the legal framework for the national health insurance scheme only permits products to be included in the health benefit package if they are in the national EML.

There are other differences between countries that may affect the impact of adding RUTF to the national EML. For example, two regional stakeholders commented that countries which receive donor support for RUTF may have less to gain from inclusion of RUTF in the national EML than countries which procure RUTF with government funds – including middle-income countries:

> "The product is supplied by UNICEF in a parallel system with few or no other players. Getting the RUTF into the country is only the first step the product has to be distributed and this requires planes and other logistical resources which the government does not have. Therefore, even if the product is listed, if the programme remains managed in parallel by UNICEF and others, the impact will remain limited"- NGO regional nutrition expert

> "The absence of RUTF in the EML is a constraint for some countries, particularly for middle income countries. It is less of a constraint for countries like in my region where most of the product comes from donors" – UN regional nutrition expert

On the other hand, middle-income countries may have greater concerns that they will be held accountable for resourcing the supply and distribution of RUTF if it is listed as essential.

Two regional-level key informants opposed to the use of RUTF, except in emergency contexts, perceived that the inclusion of RUTF in the national EMLs could place unnecessary financial burdens on low-income countries, waste resources in middle-income countries, divert financial and human resources from prevention to treatment, disincentivise the identification and use of alternative or local solutions to treat SAM, raise the quality standards for RUTF and enrich international businesses that are able to meet these standards, and lead to the indiscriminate

prescription or administration of RUTF to children. All other regional-level stakeholders (19 out of 21) did not share these concerns. However, two regional stakeholders suggested that UN agencies and NGOs may consider countries responsible for RUTF procurement and programming if they include RUTF in the national EMLs, and lower or withdraw their support as a result.

***Table 7: Perceptions of regional-level stakeholders on the benefits and risks of including RUTF in the national EML***

| | **Benefits** | **Risks** |
|---|---|---|
| National ownership and commitment | Build national ownership of and commitment to the treatment of severe acute malnutrition. | |
| RUTF financing | Increase government accountability to allocate financial resources for the procurement of RUTF, thereby reducing donor dependency and increasing the sustainability of treatment services. | Divert resources from the prevention of undernutrition (and other essential health services) to the treatment of severe acute malnutrition.<br>Increase financial burdens on low-income countries, and waste resources in middle-income countries<br>Lower donor support for RUTF and/or programming. |
| RUTF production | Ensure the product is standardized and of desired quality.<br>Stimulate the national production of RUTF to meet the country's demand for RUTF. | Raise the quality standards of RUTF, which favour international businesses and become an obstacle to national production.<br>Lead to dependency of countries on imported RUTF. |
| RUTF procurement | Ensure RUTF is integrated into government systems and facilities for procurement, storage and supply, which helps to ensure timely supply and prevent stock-outs.<br>Facilitate the import of RUTF or its ingredients by simplifying the necessary approvals and/or providing tax incentives. | |
| RUTF supply and distribution | Increase the supply of RUTF to hospitals and health facilities, in both development and emergency contexts. | |
| Service delivery and use of RUTF | Increase the prioritization of services to treat severe acute malnutrition by the health workforce.<br>Ensure RUTF is integrate into national monitoring systems to improve programme performance.<br>Prevent misuse by establishing protocols for its prescription or administration and monitoring its distribution and use. | RUTF is indiscriminately prescribed or administered to children.<br>Deprioritisation of services to prevent acute malnutrition. |

| | | |
|---|---|---|
| Monitoring of RUTF and service delivery | Ensure RUTF is integrated into government systems for monitoring supplies and service delivery, including end-use. | |
| Innovation | | Stifle the development and use of alternative products and/or innovative approaches to treat severe acute malnutrition, including indigenous approaches, that are potentially more cost-effective and sustainable. |

## 4.3 Stakeholder perceptions of the inclusion of RUTF in the WHO model EML

### 4.3.1 Sample

This section analyses data from the key informant interviews to examine the perceptions of country- and regional-level stakeholders on the consequences of including RUTF in the WHO Model EML. The number of key informant interviews by group were as follows:

- **Group II**: Of the 21 key informants identified from country-level and regional-level partners, 14 agreed to participate, including nutrition specialists working at regional level in Africa or Asia for UN agencies (n=3), NGOs (n=4), regional organizations (n=2); researchers who were based at country-level in Africa or involved in country-level research on acute malnutrition and/or RUTF in Africa (n=4); and a public health professional working at country-level in South Asia.

### 4.3.2 Consequences of including RUTF in the WHO Model EML

**Inclusion of RUTF in the national EML:** Most regional-level stakeholders agreed that the inclusion of RUTF in the WHO Model EML would encourage countries to add RUTF to their national EMLs. That said, this report finds that 25 countries have included RUTF in their national EMLs despite its absence in the WHO Model EML because governments are able to adapt WHO's list to their country context. However, inclusion in the WHO Model EML may provide the necessary impetus to countries that have been struggling to take a decision on whether or not to include. Indeed, MoH officials in some countries that have not added RUTF to their national EMLs reported that the presence of RUTF in the WHO Model EML is needed to justify inclusion of RUTF (see Section 3.2.2). Regional stakeholders also shared this opinion.

**RUTF specifications:** Most regional-level stakeholders anticipate that the inclusion of RUTF in the WHO Model EML will be accompanied with product specifications and higher quality standards. Many stakeholders consider this to be a necessary step to ensure the quality of care in all country contexts.

> "Whether RUTF is nationally produced or internationally produced, the quality has to be with the standard. [inclusion of RUTF in national EML] pushes the national suppliers to align with the global standard and make their product safe for the beneficiary, so I think it is positive" – Regional nutrition expert

However two regional stakeholders and one country-level partner, who were all opposed to the use of RUTF except in specific context, raised concerns that (1) the specifications would be set unnecessarily high and become an obstacle to national production, instead favouring international businesses; and (2) it would discourage the development and use of national alternatives to RUTF. They also felt that the inclusion of RUTF in the WHO Model list would send a strong signal to countries to support the use of RUTF to treat SAM.

**Production of RUTF**: Most regional stakeholders anticipated that inclusion of RUTF in the WHO Model EML would increase demand for and production of RUTF.

> "When this product is made essential, the number of producers will increase. This will ease the price and make it more available to countries" – Academic

However, there was divided opinion as to which producers it would benefit. Some regional stakeholders perceived that inclusion of RUTF in the WHO Model EML would open opportunities for national producers in countries affected by SAM. For example:

> "By including it in the WHO Model EML, I think policymakers in implementing countries could encourage or allow production at the county level so that RUTF will be affordable and accessible widely" – Regional nutrition expert

Other stakeholders cautioned that if inclusion in the WHO Model EML results in stringent RUTF specifications and conditions of manufacture, some national producers may be unable to compete with international suppliers, both in terms of quality and cost. This risk was considered greater if RUTF is classified as a medicine, rather than as a food for special medical purposes.

The consequences of including RUTF in the national EMLs and WHO Model EML are summarized in Figure 2 for benefits and Figure 3 for risks. These figures show the relationships and pathways between consequences. Some consequences, such as higher quality standards for RUTF, were considered both positive and negative by different stakeholders.

***Figure 2: Benefits of including RUTF in national EMLs and WHO Model EML***

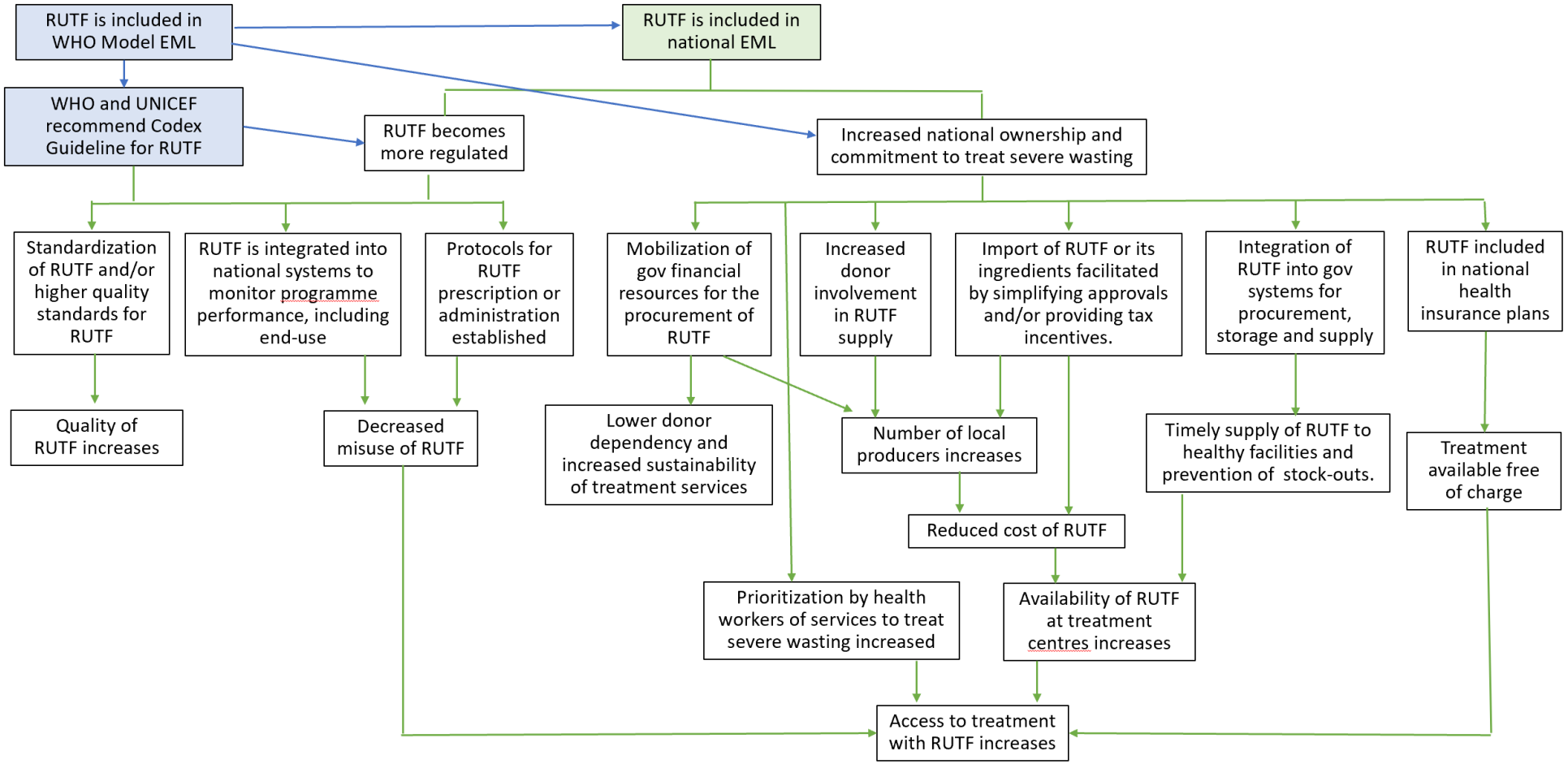
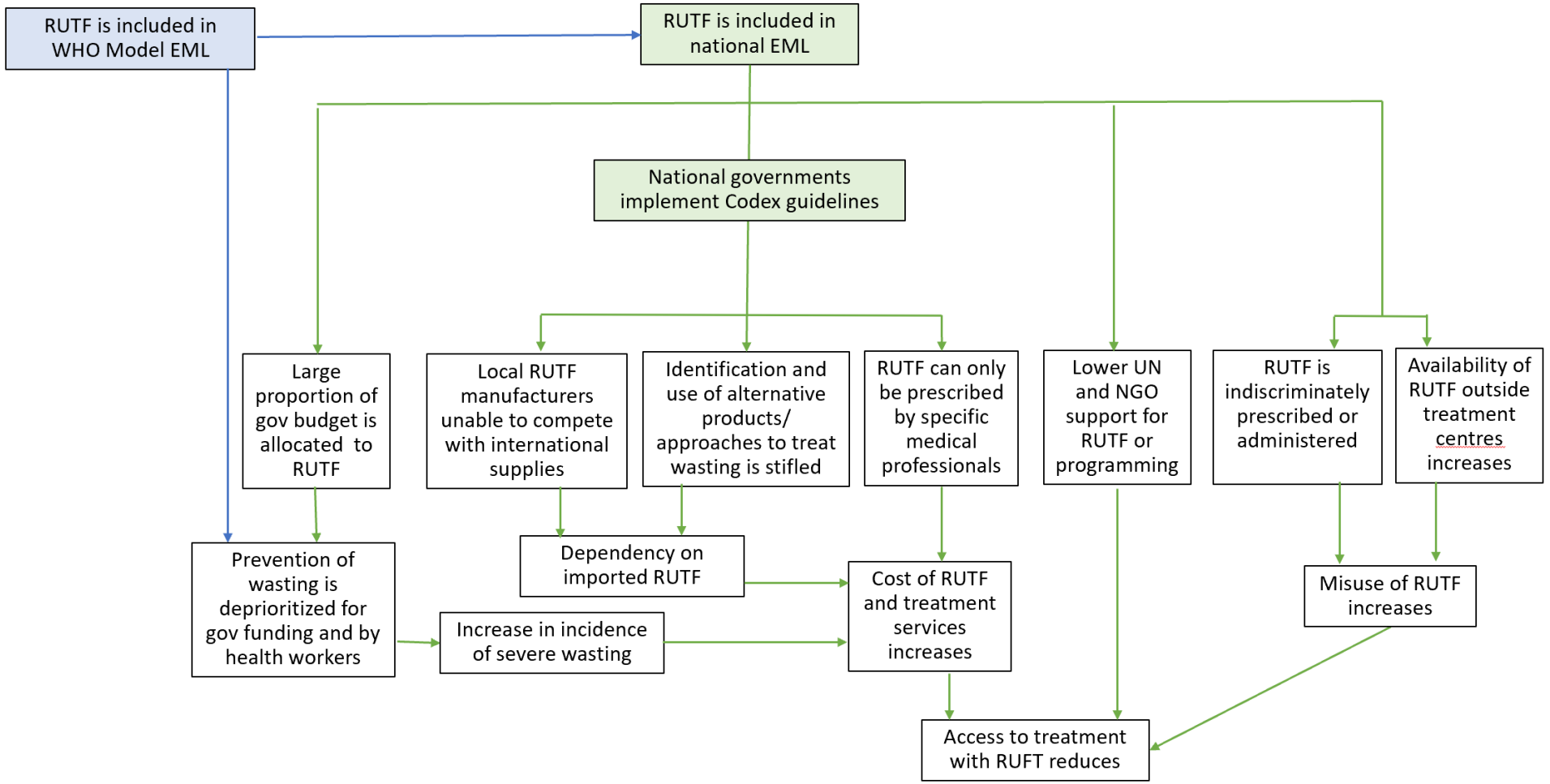


***Figure 3: Risks of including RUTF in national EMLs and WHO Model EML***



# 5. Codex Guidelines for Ready-to-Use Therapeutic Food

## Existing regulations for the composition and manufacturing of RUTFs

RUTF are high energy, fortified, ready-to-eat foods suitable for the dietary management of children with severe acute malnutrition[xxiii]. To date, the only official document outlining the composition of RUTF is the 2007 Joint Statement on the management of severe acute malnutrition[xxiv] which has served to orient the composition of this product. In the absence of official regulation, UNICEF and partners have acted as a regulatory body, imposing high standards on composition and production to ensure quality of RUTF.[xxv]

In 2006, UNICEF and MSF came together to ensure the quality of RUTF by setting up the Interagency Quality Assurance Group. As part of this group's action, a set of specifications for suppliers were established to ensure safe manufacturing, including but not limited to; the presence of a food safety policy, a complete quality management system based on a Hazard Analysis and Critical Control Points (HACCP) approach and an analytical plan on raw materials and RUTF finished products.[xxvi] These specifications have helped to ensure that all suppliers of RUTF manufacture the product safely. In addition to these technical specifications, a series of quality assurance measures have also been put in place, which include: GMP inspections of manufacturing sites, Pre-Delivery Inspections (PDI), Product testing by independent laboratories prior to dispatch and verification of Certificates of Analysis prior to shipment release [xxvii]. Additional tendering requirements apply to all manufacturers of RUTF wishing to supply UNICEF which focus on low moisture environments, zoning systems and foreign particle detection, amongst other things.[xxviii]

These minimum standards and tendering requirements for production, alongside the composition recommendations from the Joint Statement, have oriented the RUTF market over the last 15 years, ensuring that UNICEF, the largest procurers of this product, safely procure this life saving product. However, in the shift towards integrating child SAM treatment services into national health systems, support must be given for Ministries of Health to become more prominent in the procurement of RUTF. As such, the need for international standards which could be used as a reference for national governments was identified. *[xxix]*

## Developing a CODEX guideline for Ready to use Therapeutic Foods (RUTF)

The Codex Alimentarius is now the single international reference point for standards and guidelines regarding food. Whilst these standards and guidelines are not obligatory for governments to adopt, in many countries, most food legislation is consistent with Codex.[xxx] The Codex standards and guidelines provide a framework which can be applied to producers in country to ensure a level of quality and safety for the consumer.

In 2015 the UNICEF proposal was accepted for the Codex Committee for Nutrition and Foods for Special Dietary Uses (CCFSDU) to develop a commodity guideline for RUTF.[xxxi] During the 42nd meeting of the CCFSDU held in November 2021, under the leadership of the Government of South Africa, the final guideline for RUTF was agreed upon.[xxxii] This guideline includes comprehensive information on: (i) Nutritional Composition, (ii) Raw Materials and Ingredients, (iii) Good Manufacturing Practices, (iv) Microbiological and Chemical Contaminant Criteria, (v) Methods of Analysis and Sampling and (vi) Provisions for Packaging and Labelling. Its final adoption will take place in November 2022.

## Implications of the new CODEX guidance for RUTF

The publication of these guidelines provides a series of opportunities for the availability and sustainability of SAM treatment services. The presence of an internationally approved regulatory framework is a key enabling factor in the integration of SAM treatment services at national level.[xxxiii] Over the last decade, UNICEF has been focusing efforts to integrate RUTF into national supply chains and secure domestic funding for this life-saving product. These independent guidelines will be able to orient governments in the quality procurement process and will also be an essential tool to assist in building regulatory capacity within national governments to establish their own regulatory framework for RUTF.

This guideline also clarifies the regulatory status of RUTF as a Food for Special Medical Purposes (FSMP).[xxxiv] One of the key concerns in listing RUTF on the EML was that this listing might lead to the application of pharmaceutical standards to the manufacturing process if categorized as a medicine. [xxxv] The CODEX guidelines have effectively determined that RUTF sit within the regulatory frameworks of food production, with a focus on the fact that it is for specific purposes. The approach of classifying RUTF as an FSMP will assist member states in clarifying that the products are specially processed or formulated,[xxxvi] highlighting that this product is only for use in the treatment of SAM.

In addition, this guidance provides a clear framework for producers with an associated set of quality standards. The market may now become more open for new suppliers given this international guidance. The availability of these guidelines could be helpful for suppliers, and it could also open a pathway for innovation and local acceptability with generic compositional specification with guidance on quality.[xxxvii]

Finally, and importantly, these guidelines can facilitate trade disputes and importation requirements. The guidelines are intended for use as an instrument designed to avoid or reduce difficulties which may be created by diverging legal, administrative, and technical approaches to RUTF and by varying definitions and nutrient compositions of RUTF. [xxxviii]

# 6. Mitigating the risks of including RUTF in EMLs

Any change or update in status of a medication brings with it a certain amount of risks regarding the subsequent implications on availability and utilisation of the product. This risk mitigation section documents risks identified with the addition of RUTF to the WHO and national EML, classifies these risks in terms of likelihood and consequences and proposes mitigation measures to reduce these risks.

## Methodology

A mixed methods approach for this risk mitigation plan has been used, combining the following sources:

- Literature review of WHO technical consultation: Nutrition-related health products and the World Health Organization Model List of Essential Medicines – practical considerations and feasibility. Geneva, Switzerland, 20–21 September 2018
- Questionnaire with country and regional stakeholders
- Consultation with UNICEF supply teams.

Based on the identified risks, a grading of likelihood and consequences of these risks was undertaken to weigh the potential impact of these risks (Table 8). Likelihood was categorised into the following 5 criteria: almost certain, likely, possible, unlikely, or rare. Consequences was categorised into the following 5 criteria: negligible, minor, moderate, major, or crucial. Scores of 1-5 were given to each response, with 1 being the lowest likelihood or consequence and 5 being the highest. These scores were combined to give and overall weighting to each risk presented in table 8.

## Results

**Increase in cost of RUTF:** New regulations may result in cost increases for ingredients, manufacturing, or logistics. Any increases in the cost of RUTF are considered to have crucial consequences. The concern of adding RUTF to the EML is that pharmaceutical standards regarding production and storage may become applicable to this product rather than food standards. This risk is considered a possibility, the consequences of which would be crucial. The newly approved Codex guideline on composition and manufacturing of RUTF provides a unique opportunity to support the classification of RUTF as a 'Food for Special Medical Purposes' (FSMP) and thus apply the correct manufacturing standards for RUTF. This categorisation, which is clarified in the guidance, means that RUTF is not considered a pharmaceutical product and therefore should not be subject to pharmaceutical production standards. However, it is important to note that higher standards for raw materials and manufacture can indeed increase the cost of RUTF, when compared to a substandard RUTF. This can be seen as a positive outcome because governments and regulations also increase, leading to safer manufacture and safer product. Short-term investments could be seen as long-term benefits in this case.

**National production stifled:** National RUTF manufacturers may be unable to abide with new standards associated to RUTF being on the EML. Since 2007, the RUTF market has grown with a boom in producers located in countries where SAM is prevalent, meaning that this market now supplies over 50% of RUTF globally. Efforts must be made to keep promoting and enhancing national production to ensure the sustainability of this intervention.

**Prevention interventions and/or other child survival interventions are deprioritized:** In focusing on the treatment of SAM, there is a risk that prevention interventions or other child

survival interventions would subsequently be deprioritised. Budgets at national level in countries where SAM exists are often limited and under-resourced. Ensuring that positioning RUTF on global and national EMLs does not take priority over prevention or other health interventions is essential and promote a holistic approach for the effective management of SAM, including access to essential health interventions.

**Reduction in support for RUTF procurement and financing by international actors:** In moving towards national purchasing of RUTF, a perceived risk is that international NGOs, UN agencies and donors may withdraw or reduce funding and support. Whilst the long-term goal is for SAM treatment services to become integrated financially into national health system, this process must be gradual and carefully planned to avoid stock-outs. Whilst the risk is perceived as unlikely the consequence is considered major, necessitating clear mitigation actions.

**Reduced access to RUTF:** risks of included RUTF in EML may be associated with question on which cadre of healthcare workers are able to prescribe and administer RUTF, for example this may reduce access to treatment if a country decides that only doctors/pediatricians are able to. This risk is unlikely considering that a routine component of SAM treatment already includes the administration of antibiotics at community level and antibiotics are also subjects to regulations regarding which health workers are able to prescribe and administer and as such, there should be no change to these existing protocols.

**Innovation stifled:** Innovations in the composition of RUTF are key to continue the products evolution and acceptability in certain contexts. Whilst the principal ingredient is usually peanuts, recent trials have tested the use of alternatives such as oats or chickpeas, sometimes more acceptable to a child depending on the regions. UNICEF and other organisations are currently engaged in furthering the research around alternative formulations. The recently finalised Codex guideline also presents an opportunity to mitigate this risk of stifling innovation by providing detailed information on the composition of RUTF. This composition information allows for the use of local ingredients (seeds, cereals, legumes) in the formulation of RUTF. As such, efforts will be made to vulgarise these guidelines, particularly with national authorities and producers with a focus on sensitising on the range of potential ingredients.

The table below sets out the risks identified in weighted order. Seven risks were identified, of which 3 are considered possible and 4 unlikely. The consequences of these risks vary from crucial (2) to major (4) to moderate (1). The table also proposes mitigation measures per risk identified.

***Table 8: Scoring of risks of the inclusion of RUTF into the WHO EML and mitigation measures***

| Risk | Likelihood | Impact | Mitigation measures |
|---|---|---|---|
| Increase in cost of RUTF | Possible | Crucial | 1. Disseminate and provide support for the use of the Codex guidelines to countries: the adoption of the guideline provides guidance to country on how to classify RUTF and will prevent RUTF being the subject to additional manufacturing and/or storage requirements. As part of this roll-out process, it will be important to clarify the implications of the classification as FSMP and to fit within existing national legal frameworks<br>2. Provide public access to UNICEF tender prices of RUTF to facilitate competition for locally and international based suppliers and enable national governments to assess the market price relative to the local prices paid for national procurement.<br>3. Close monitoring of raw material prices and alert on price spikes: governments can access food market data by FAO to track commodities prices and use this information to guide their price expectation for RUTF<br>4. Fundraise for RUTF with donors and governments to increase resources available, either through developing new funding mechanisms or identifying new donors |
| National production stifled | Possible | Major | 1. Develop implementation guidance and share recommendations for the RUTF Codex Guideline to countries to support the production of RUTF, based on previous experiences<br>2. Provide technical assistance and incentives to domestic producers for quality products competitively, in line with existing strategies to promote national production of RUTF<br>3. Support national regulatory frameworks to monitor and approve new products<br>4. Identify barriers related to national production (e.g., availability of raw ingredients) to ensure local producers are Codex compliant<br>5. Get rid of the Intellectual Property (IP) to lower barriers for national suppliers<br>6. Advocate with government for the promotion of domestic production of RUTF<br>7. UNICEF, WHO and key stakeholders to support local facilities for testing of RUTF to reduce the dependence on imported RUTF |
| Prevention interventions and/or other child survival interventions are deprioritised | Possible | Major | 1. Advocate with countries to prioritize the prevention of malnutrition in all contexts<br>2. Counsel caregivers of children who receive RUTF on infant and young child feeding to prevent relapse as well as other core counselling topics from IMCI<br>3. Collaborate with all relevant agencies to implement the GAP roadmaps for action for the prevention and treatment of acute malnutrition<br>4. Fundraise for RUTF using new and innovative financing mechanism, including domestic financing of RUTF |
| Reduction in support for RUTF procurement and | Unlikely | Crucial | 1. Engagement with international NGOs, UN agencies and donors to ensure sustained funding and carefully planned transition plans |

| | | | |
|---|---|---|---|
| financing by international actors | | | 2. Advocate for donors to develop staggered withdrawal strategies in countries where national contribution may be able to cover the RUTF needs, while maintain their presence in countries with lower domestic financing support<br>3. Strengthen national supply chain systems to integrate SAM management in Health systems with support to countries and governments |
| Access to treatment with RUTF reduces | Unlikely | Major | 1. Seek authorisation at national level for administration by adequately trained and supervised community health workers, decentralising the treatment of SAM to the community level<br>2. Work with government in ensuring that the cadre of Health workers able to provide and administer RUTF does not negatively impact access to treatment |
| Innovation on RUTF formulae stifled | Unlikely | Major | 1. Support the development of new Codex compliant formula at country level<br>2. Conduct research trials to diversify available RUTF recipes, adapted to regions |

# 7. Discussion

The findings from this report presents the status, process, challenges, and lessons learnt from countries that included RUTF in their nEML, the consequences of this inclusion in national EML and potential consequences of inclusion in WHO model EML, and risk mitigation measures.

In 2021, 25 countries included RUTF in their nEML. In countries where RUTF is included, contributing factors leading to this inclusion were the public health burden of SAM, the proven efficacy, effectiveness and safety of RUTF to treat SAM and the absence of a suitable alternative product to treat SAM. The benefits identified were the facilitation of national production of RUTF, increased mobilization of domestic financial resources to procure RUTF and improved supply and distribution of RUTF. The process for that inclusion was through the involvement of multiple stakeholders involved in decision-making under the leadership of the department or division of Nutrition in the MoH. Stakeholders included directorates or departments of pharmacy, pharmaceuticals or drugs and medical supplies, regulatory agencies and central purchasing organizations for medicines, medical supplies and/or food, UNICEF, WHO and NGOs and key stakeholders present at national level (academic institutions, researchers, etc.). Facilitating factors to this process were strong leadership and coordination from the MoH, long-history of national SAM programming, familiarity from key stakeholders with RUTF and absence of specific barriers or challenges reported. The classification of RUTF was a concern if it was categorized as a medicine for regulation purpose, while some countries categories it as FSMP, in line with the Codex guideline that went out in 2022. Positive consequences of the inclusion of RUTF in the nEML that were reported by respondents were increased government regulation and higher quality requirements and standards for RUTF used in country, more government control over RUTF procurement, supply and distribution, increased domestic financial resources towards RUTF and growing interest for national production. Risks identified regarding this inclusion were the different policy and legal frameworks in country leading to increased or decreased access to RUTF, decreased external financing support for countries dependent on external donors and additional financial burdens on low-income countries. On the consequences of including RUTF in the WHO Model EML, many stakeholders agreed that it would encourage countries to add RUTF to their nEMLs or that this inclusion is needed to justify the inclusion of RUTF in nEML.

These additional findings, along with the documentation and research already shared with WHO Expert Committee on the Selection and Use of Essential Medicines during previous applications, and the recent release of the Codex guideline on RUTF are all positive factors advocating towards the inclusion of RUTF in WHO model EML to support its inclusion in nEMLs, ultimately leading to increased access to treatment for children affected by SAM.

In this context of global crisis and the increased number of children under five years affected by SAM and living in food and nutrition insecure contexts, all efforts are important to scale up access to treatment for these children and government leadership in countries in humanitarian and development contexts with high prevalence of acute malnutrition. Increasing access to treatment through domestic funding, integrated supply chain, national production and safe programming is key to ensure children’s healthy growth and child survival.

# Annex 1: Survey and key informant questions

## Survey A on the status of inclusion of RUTF in the national EMLs

**Section A: All countries using RUTF**

1. Is RUTF in the national EML?
    - Yes
    - No
    - Don't know
    - Not applicable (country does not have a national EML)
    - Not applicable (RUTF not used in country)

**Section B: Countries that have included RUTF in the national EML**

2. When was RUTF included in the national EML? Give month and year
3. How is RUTF classified in your country's regulatory framework?
    - Food
    - Medicine
    - Food for special medial purposes
    - Food supplement
    - Don't know
    - Other (please specify)
4. Which agency regulates RUTF?
    - Medicines regulatory authority
    - Food regulatory authority
    - Combined food & drug regulatory authority
    - Standards agency
    - Don't know
    - Other (please specify)

**Section C: Countries that have not included RUTF in the national EML**

5. Did the country ever begin a process to decide whether to include RUTF in the national EML?
    - No
    - Yes, and process is still underway
    - Yes, and country decided not to include
    - Don't know
    - Other (please specify)

## Survey B on experiences and perspectives of including RUTF in the national EMLs and the WHO model EML

**Section A: Policy (officials of the Ministry of Health only)**

1. Are you aware about the WHO Model List of Essential Medicines? [Yes/No]
2. Have you seen the WHO Model List used by your country in the last five years? [Yes/No]. Please explain your answer [Open-ended].
3. Does the listing of a medicine/product on the WHO Model List influence your national policies in any way? [Yes/No]. Please explain your answer [Open-ended].
4. Do you think the absence of RUTF on the current WHO Model List has any bearing on its procurement for or use in your country? [Yes/No]. Please explain your answer [Open-ended]
5. What is required by your country for a product to be considered a medicine? [Open-ended]
6. Does your country have an essential medicine list (nEML)? [Yes/No]
7. Does your EML include products in the following categories? [Multiple response]

- Medicines
- Health supplies
- Nutritional products
- Foods for special medical purposes
- Other health commodities (medical supplies, condoms)
- Any special category not listed above? Please specify

8. What roles does your national EML play in the health sector in your country? [Open-ended]

**Section B: RUTF specific (All respondents)**

1. In what capacity are you responding to the survey? [Single response]
   - Ministry of Health official
   - RUTF manufacturer or producer
   - NGO involved in RUTF programming
   - Other (please specify)
2. Is RUTF regulated in your country? [Yes/No/Don't know]
3. How is RUTF classified in your country's regulatory framework? [Single response]
   - Food
   - Medicine
   - Food for special medical purposes
   - Both food and medicine
   - Other health commodity
   - Don't know
   - Other (please specify)
4. What aspects of RUTF are regulated? [Multiple response]
   - Manufacture
   - Sale
   - Importation
   - Use
   - Distribution
   - Other (please specify)
5. Which agency regulates RUTF? [Single response]
   - National medicines regulatory authority
   - Combined food and medicines regulatory authority
   - Food regulatory authority
   - Standards agency
   - Other (please specify)
6. Is your country actively implementing Community-Based Management of Acute Malnutrition (CMAM) programming using RUTFs? [Yes/No/Don't know]
7. Do you have any local manufacturers/producers of RUTFs in your country? [Yes/No/Don't know]
8. If yes to Question 7:
   - List all the manufactures of RUTF in your country that you know.
   - Are local producers currently supplying any of the RUTF used in the public sector in your country? [Yes/No/Don't know]
9. Is Ready-to-use-therapeutic food RUTF included on your national EML? Yes/No/Don't know]
10. If yes to Question 9:
    - What triggered the listing of RUTF on your national EML? [Open-ended]
    - What rationale/justification was required for RUTF inclusion? [Open-ended]
    - What challenges if any were faced in getting RUTF listed? [Open-ended]
11. If no to Question 9:
    - What would trigger the listing of RUTF on your national EML? [Open-ended]
    - What rationale/justification would be required for RUTF inclusion? [Open-ended]
    - What challenges if any would you expect to face in getting RUTF listed? [Open-ended]

**Section C: Actual implications of RUTF listing in countries with RUTF in the national EML**

1. How has the availability of RUTF at treatment centers been impacted by the listing of RUTF on the EML of your country? [More available/Less available/Don't know]

2. How has Government control of the supply and distribution of RUTF been impacted by the listing of RUTF on the EML of your country? [Less control/More control/Don't know]

3. How has procurement of RUTF by Government been impacted by the listing of RUTF on the EML of your country? [More involvement/Less involvement/Don't know]

4. How has the quality of local production been impacted by the listing of RUTF on the EML of your country? [Higher quality/Lower quality/Don't know/Currently our country has no local production]

5. How has the use of RUTF other than for the treatment of severe acute malnutrition been impacted by the listing of RUTF on the EML of your country? [More misuse/Less misuse/Don't know]

6. Has the listing of RUTF on your national EML impacted on the following? [Multiple response]
   - Accessibility of RUTF for those who need it
   - Availability of RUTF at national level in the public sector supply chain
   - Classification of RUTF
   - Cost of RUTF
   - Import control of RUTF or raw materials for its production
   - Taxes on RUTF or raw materials for its production
   - Involvement of local producers in the manufacture of RUTF
7. How has the availability of RUTF outside treatment centres (shops, pharmacies, markets, others) been impacted by listing of RUTF on the EML of your country? [More available/Less available/Don't know]
8. How has the distribution of RUTF within the country been impacted by listing of RUTF on the EML of your country? [Easier to distribute/More difficult to distribute/Don't know]
9. How has donor involvement in/support for RUTF supply been impacted by listing of RUTF on the EML of your country? [More involved/Less involved/Don't know]
10. How has the quality requirements for the RUTF used in the country been impacted by listing of RUTF on the EML of your country? [More stringent/Less stringent/Don't know].
11. How has the quantity of local production been impacted by listing of RUTF on the EML of your country? [More production/Less production/Don't know/Currently our country has no local production]
12. How has the regulation of RUTF been impacted by listing of RUTF on the EML of your country? [More regulated/Less regulated/Don't know]
13. In what category within your national EML is RUTF listed? [Single response]
    - Medicines
    - Foods for special medical purposes
    - Nutritional products
    - Miscellaneous
    - Other (please specify)
14. Has the category in which RUTF is listed make a difference to your answers about the impact of listing? [Yes/No]. Please explain the answer.

15. Indicate the likelihood of the following unintended consequences happening in your country arising from the listing of RUTF on your nEML [Highly likely/Likely/Unlikely/Not applicable]
    - Reduced availability of RUTF at treatment centres
    - Increased cost of RUTF
    - Increased govrnmetn control of RUTF

- Increased misuse of RUTF
- Reduced quality of the RUTF available on the market
- Halting of local production of RUTF

16. What measures could be taken to mitigate any negative consequences from listing RUTF in your national EML? [Open-ended]

**Section D: Perceived implications of RUTF listing in countries without RUTF in the national EML**

1. How would availability of RUTF at treatment centers be impacted by the listing of RUTF on the EML of your country? [More available/Less available/Don't know]

2. How would Government control of the supply and distribution of RUTF be impacted by the listing of RUTF on the EML of your country? [Less control/More control/Don't know]

3. How would procurement of RUTF by Government be impacted by the listing of RUTF on the EML of your country? [More involvement/Less involvement/Don't know]

4. How would the quality of local production be impacted by the listing of RUTF on the EML of your country? [Higher quality/Lower quality/Don't know/Currently our country has no local production]

5. How would the use of RUTF other than for the treatment of Severe Acute Malnutrition (SAM) be impacted by the listing of RUTF on the EML of your country? [More misuse/Less misuse/Don't know]

6. Would the listing of RUTF on your national EML impact on the following? [Multiple response]
   - Accessibility of RUTF for those who need it
   - Availability of RUTF at national level in the public sector supply chain
   - Classification of RUTF
   - Cost of RUTF
   - Import control of RUTF or raw materials for its production
   - Taxes on RUTF or raw materials for its production
   - Involvement of local producers in the manufacture of RUTF
7. How would availability of RUTF outside treatment centres (shops, pharmacies, markets, others) be impacted by listing of RUTF on the EML of your country? [More available/Less available/Don't know]
8. How would the distribution of RUTF within the country be impacted by listing of RUTF on the EML of your country? [Easier to distribute/More difficult to distribute/Don't know]
9. How would the donor involvement in/support for RUTF supply be impacted by listing of RUTF on the EML of your country? [More involved/Less involved/Don't know]
10. How would the quality requirements for the RUTF to be used in the country be impacted by listing of RUTF on the EML of your country? [More stringent/Less stringent/Don't know].
11. How would the quantity of local production be impacted by listing of RUTF on the EML of your country? [More production/Less production/Don't know/Currently our country has no local production]
12. How would the regulation of RUTF be impacted by listing of RUTF on the EML of your country? [More regulated/Less regulated/Don't know]
13. In what category within your national EML is RUTF likely to be listed? [Single response]
    - Medicines
    - Foods for special medical purposes
    - Nutritional products

- Miscellaneous
- Other (please specify)

14. Would the category in which RUTF is listed make a difference to your answers about the impact of listing? [Yes/No]. Please explain the answer.

15. Indicate the likelihood of the following unintended consequences happening in your country arising from the listing of RUTF on your nEML [Highly likely/Likely/Unlikely/Not applicable]
    - Reduced availability of RUTF at treatment centres
    - Increased cost of RUTF
    - Increased government control of RUTF
    - Increased misuse of RUTF
    - Reduced quality of the RUTF available on the market
    - Halting of local production of RUTF
16. What measures could be taken to mitigate any negative consequences from listing RUTF in your national EML? [Open-ended]

## Key information interviews on the experiences and perspectives of including RTUF in the national EMLs and the WHO Model EML

### Group I: MoH officials in countries that have included RUTF in the EML

- Describe the process of including RUTF in your EML in as much detail as you can.
  *Prompts*
  - *Which key stakeholders were involved?*
  - *Who was the lead agency?*
  - *How long did the process take start to end?*
  - *Was it included as part of a broader review? Was the review scheduled?*
  - *Who proposed the inclusion of RUTF?*
  - *Was there need to present any scientific evidence to support its inclusion*
  - *Was there a need to define standards for RUTF?*
- What bottlenecks did you face along the way? how were they resolved?
- What lessons did you learn from the process?
- What should other countries do to fast-track the listing of RUTF in their national EMLs?

### Group II: Country- and regional-level partners

***RUTF in national EMLs***

- Does the absence of RUTF on a national EML impact on access to the product? Please explain?
- Where RUTF has been included in national EMLs, what has been the impact as far as you are aware?
- What additional impact would you anticipate as more countries include RUTF on their national EML?
- For any negative consequences mentioned, how would you rate them in terms of likelihood and impact? How could these **negative** consequences be mitigated?

***RUTF in the WHO Model EML***

- Does the absence of RUTF on the WHO EML impact on access to the product? At country level? At regional level? At flobal level? Please explain.
- What benefits do you think would accrue from the WHO EML listing of RUTF?

- What negative consequences could arise out of the WHO EML listing? How could they be mitigated?

## Annex 2: Status of inclusion of RUTF in the national EMLs by country

| Country | WHO region | UNICEF region | RUTF is included in national EML | Year of inclusion in national EML |
|---|---|---|---|---|
| Afghanistan | EMR | ROSA | No | |
| Angola | AFR | ESARO | No | |
| Argentina | AMR | LACRO | No | |
| Benin | AFR | WCARO | Yes | 2018 |
| Burkina Faso | AFR | WCARO | Yes | 2014 |
| Burundi | AFR | ESARO | Yes | 2012 |
| Cambodia | WPR | EAPRO | Yes | 2015 |
| Cameroon | AFR | WCARO | No | |
| Chad | AFR | WCARO | Yes | 2014 |
| Colombia | AMR | LACRO | No | |
| Comores | AMR | ESARO | Yes | 2014 |
| Congo | AFR | WCARO | Yes | 2013 |
| Cote d'Ivoire | AFR | WCARO | Yes | |
| Democratic Republic of Congo | AFR | WCARO | Yes | 2010 |
| Djibouti | EMR | MENA | No | |
| Dominican Republic | AMR | LACRO | No | |
| El Salvador | AMR | LACRO | No | |
| Equatorial Guinea | AFR | WCARO | Yes | 2019 |
| Eritrea | AFR | ESARO | No | |
| Ethiopia | AFR | ESARO | No | |
| Fiji | WPR | EAPRO | No | |
| Gambia | AFR | WCARO | No | |
| Ghana | AFR | WCARO | No | |

| | | | | |
|---|---|---|---|---|
| Guatemala | AMR | LACRO | Yes | 2013 |
| Guinea | AFR | WCARO | No | |
| Guinea-Bissau | AFR | WCARO | Yes | 2020 |
| Haiti | AMR | LACRO | Yes | 2012 |
| Honduras | AMR | LACRO | No | |
| Indonesia | SEAR | EAPRO | No | |
| Kenya | AFR | ESARO | Yes | 2016 |
| Kiribati | WPR | EAPRO | No | |
| Kyrgyzstan | EUR | ECARO | No | |
| Lao PDR | WPR | EAPRO | No | |
| Lesotho | AFR | ESARO | | |
| Liberia | AFR | WCARO | Yes | 2017 |
| Madagascar | AFR | ESARO | Yes | 2013 |
| Malawi | AFR | ESARO | Yes | 2015 |
| Mali | AFR | WCARO | Yes | 2019 |
| Mauritania | AFR | WCARO | Yes | 2012 |
| Mexico | AMR | LACRO | No | |
| Mongolia | WPR | EAPRO | No | |
| Mozambique | AFR | ESARO | No | |
| Myanmar | SEAR | EAPRO | No | |
| Namibia | AFR | ESARO | Yes | 2015 |
| Nepal | SEAR | ROSA | No | |
| Nicaragua | AMR | LACRO | No | |
| Niger | AFR | WCARO | Yes | 2016 |
| Nigeria | AFR | WCARO | Yes | 2018 |
| Pakistan | EMR | ROSA | No | |
| Papua New Guinea | WPR | EAPRO | No | |
| Perú | AMR | LACRO | No | |

| | | | | |
|---|---|---|---|---|
| Philippines | WPR | EAPRO | No | |
| Rwanda | AFR | ESARO | No | |
| Senegal | AFR | WCARO | Yes | 2018 |
| Sierra Leone | AFR | WCARO | Yes | 2013 |
| Solomon Islands | WPR | EAPRO | No | |
| Somalia | EMR | ESARO | No | |
| South Sudan | AFR | ESARO | No | |
| Sri Lanka | SEAR | ROSA | No | |
| Sudan | EMR | MENA | No | |
| Syrian Arab Republic | EMR | MENA | No | |
| Tajikistan | EUR | ECARO | No | |
| Timor-Leste | SEAR | EAPRO | | |
| Togo | AFR | WCARO | No | |
| Uganda | AFR | ESARO | Yes | 2016 |
| United Republic of Tanzania | AFR | ESARO | No | |
| Vanuatu | WPR | EAPRO | No | |
| Venezuela | AMR | LACRO | No | |
| Viet Nam | WPR | EAPRO | No | |
| Yemen | EMR | MENA | No | |
| Zambia | AFR | ESARO | No | |
| Zimbabwe | AFR | ESARO | | |

## Annex 3: Consequences of including RUTF in the national EML

Table A1 below provides the actual sample sizes for Table 6.

***Table A1: Consequences of including RUTF in the national EML (nEML) experienced by stakeholders in countries with RUTF in the nEML and perceived by stakeholders in countries without RUTF in the nEML†***

| | | All stakeholders | | MoH officials | | NGOs and RUTF producers | |
|---|---|---|---|---|---|---|---|
| | | Experience of countries with RUTF in nEML (n=12) | Perception of countries without RUTF in nEML (n=17) | Experience of countries with RUTF in nEML (n=7) | Perception of countries without RUTF in nEML (n=11) | Experience of countries with RUTF in nEML (n=5) | Perception of countries without RUTF in nEML (n=6) |
| **GOVERNMENT REGULATION AND CONTROL** | | | | | | | |
| Regulation of RUTF | More regulated | 7 | 14 | 5 | 10 | 2 | 4 |
| | Less regulated | 1 | 1 | 0 | 1 | 1 | 0 |
| Quality requirements for RUTF used in country | More stringent | 6 | 11 | 5 | 9 | 1 | 2 |
| | Less stringent | 0 | 0 | 0 | 0 | 0 | 0 |
| Government control of RUTF supply and distribution | More control | 6 | 10 | 5 | 7 | 1 | 3 |
| | Less control | 0 | 0 | 0 | 0 | 0 | 0 |
| **LOCAL PRODUCTION** | | | | | | | |
| Halting of local production of RUTF | Unlikely | 3 | 6 | 1 | 5 | 2 | 1 |
| | Likely | 1 | 0 | 0 | 0 | 1 | 0 |
| Quantity of local production | More production | 4 | 3 | 2 | 2 | 2 | 1 |
| | Less production | 1 | 0 | 0 | 0 | 1 | 0 |
| Quality of local production | Higher quality | 4 | 13 | 2 | 9 | 2 | 4 |
| | Lower quality | 0 | 0 | 0 | 0 | 0 | 0 |
| **PROCUREMENT AND COST** | | | | | | | |
| Government involvement in RUTF procurement | More involvement | 5 | 13 | 5 | 9 | 0 | 4 |
| | Less involvement | 1 | 0 | 0 | 0 | 1 | 0 |
| Donor involvement in/support for RUTF supply | More involvement | 7 | 10 | 4 | 7 | 3 | 3 |
| | Less involvement | 0 | 0 | 0 | 0 | 0 | 0 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Increased cost of RUTF | Unlikely | 2 | 9 | 2 | 6 | 0 | 3 |
| | Likely | 3 | 2 | 1 | 2 | 2 | 0 |
| **DISTRIBUTION** | | | | | | | |
| Distribution of RUTF within the country | Easier | 3 | 11 | 3 | 8 | 0 | 3 |
| | More difficult | 2 | 0 | 2 | 0 | 0 | 0 |
| Availability of RUTF at treatment centres | More available | 7 | 10 | 6 | 7 | 1 | 3 |
| | Less available | 0 | 0 | 0 | 0 | 0 | 0 |
| Availability of RUTF outside treatment centres | Less available | 2 | 2 | 0 | 2 | 2 | 0 |
| | More available | 2 | 5 | 2 | 3 | 0 | 2 |
| Reduced quality of RUTF available in the market | Unlikely | 4 | 8 | 2 | 8 | 2 | 0 |
| | Likely | 1 | 3 | 0 | 1 | 1 | 2 |
| **USE** | | | | | | | |
| Increased misuse of RUTF | Unlikely | 3 | 10 | 2 | 8 | 1 | 2 |
| | Likely | 3 | 5 | 1 | 3 | 2 | 2 |

† Excludes survey respondents who did not have correct knowledge of the inclusion of RUTF in the nEML

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