Stakeholder perceptions of adding ready-to-use therapeutic foods and other nutrition-related products to the World Health Organization Model List of Essential Medicines

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Abstract
The WHO [World Health Organization] Model List of Essential Medicines (EML) serves as a guide for national medicines lists aimed at prioritizing effective, safe and cost-effective medicines to meet a population’s health-care needs. Access to nutrition-related products in low- and middle-income countries with high burdens of severe acute undernutrition, anaemia and other nutrition-related conditions is often low, and adding ready-to-use therapeutic foods (RUTFs) and other nutrition-related products to the EML has been proposed as one strategy to improve access. This paper synthesizes input from a diverse set of stakeholders on the potential impacts of adding these products to the EML. Although there were some areas of relative consensus among stakeholders, their perceptions varied substantially regarding the likely impacts on product regulation and cost, and how in-country perceptions of these products might change if they are added to the EML or national essential medicines lists. Stakeholders also differed in their views of whether the addition of RUTFs to the EML would inhibit or support local production of these products, and how the scope for development of alternative formulations would be affected. The variation in stakeholder perceptions, which stems largely from uncertain categorization and regulation at country level if nutrition-related products are added to the EML or national essential medicines lists, illuminates uncertainty about whether and how access to these products would change in different settings. Considering this uncertainty, the need for a risk assessment is suggested, to evaluate the primary concerns raised by stakeholders.

Keywords: essential medicines list; nutritional products; ready-to-use therapeutic foods; RUTFs; trade-offs

Introduction
Essential medicines, as defined by the World Health Organization (WHO), are the collection of medicines that best meet a population’s priority health-care needs (1). To meet those needs, essential medicines must be continuously available with adequate supply, quality and affordability. Disease prevalence and public health relevance, evidence on clinical efficacy and safety, and cost effectiveness are therefore key considerations in the selection of essential medicines. The WHO Model List of Essential Medicines (EML) and the WHO Model List of Essential Medicines for Children (EMLc) were established and are maintained with the intention of guiding the contents of national and institutional essential medicines lists (2). Nearly all low- and middle-income countries maintain a national essential medicines list (or equivalent), guided by the EML but adapted to fit the local
conditions, including prevalent diseases, availability of medicines, health facilities and workforce, affordability, and demographic and environmental factors (3).

WHO guidelines on the management of severe acute undernutrition in children aged 6–59 months recommend that F-75, F-100 and ready-to-use therapeutic foods (RUTFs) be used as part of the inpatient management of this condition (4), and that RUTFs be provided as therapeutic feeding for the community-based management of uncomplicated wasting (4, 5). Other nutrition-related products, including iron-containing micronutrient powders for point-of-use fortification of foods (6), are recommended by WHO to prevent nutritional anaemias in infants aged 6–23 months and children aged 2–12 years in areas where the prevalence of anaemia is 20% or higher. Daily or intermittent iron + folic acid supplements are also recommended as part of routine antenatal care (7). RUTFs and other nutrition-related products, such as the intermittent iron + folic acid dosage for use in pregnancy, are not currently included in the EML, but it has been proposed that adding them to the list may improve the access of target populations to these products.

The EML and EMLc undergo review every 2 years (2). During the review process, the Expert Committee on the Selection and Use of Essential Medicines reviews applications and takes decisions about deleting existing medicines from the list; revising the indications of existing medicines; and adding new products. The addition of RUTFs to the EML was first proposed in March 2017, when the Expert Committee reviewed an application put forward by Action Against Hunger to add RUTFs to the miscellaneous category of the EML and EMLc, for dietary management of uncomplicated severe acute undernutrition (8). The miscellaneous category is a subsection of Section 26 of the current EML, entitled “Solutions correcting water, electrolyte and acid–base disturbances”. Listing RUTFs and, possibly, other nutrition-related products under this subsection has been proposed as a way to discourage the application of pharmaceutical standards to these products (9).

Action Against Hunger’s decision to put forward the application was based on its findings from a literature review, two case-studies and interviews with key informants to explore the arguments for and against adding RUTFs to the EML and national essential medicines lists, and the potential impacts of doing so (9). Action Against Hunger found a substantial public health need for access to RUTFs in low- and middle-income countries. The assessment suggested that the EML could play an important role in accelerating access to RUTFs for the dietary management of uncomplicated severe acute undernutrition and could contribute to improving public health outcomes and reducing morbidity and mortality.

The Expert Committee did not recommend the addition of RUTFs to the EMLc, and considered that listing RUTFs in the EML “may have implications for the availability of alternative products or formulations”. The Expert Committee further stated that “in some countries and for some manufacturers, inclusion of RUTF in the EML may carry implications about the need to comply with requirements for pharmaceutical products and thus potentially have an impact on cost and access” (10). Nevertheless, the Expert Committee recognized that adding RUTFs and other nutrition-related products to the EML may improve access to these products for populations in need. The Expert Committee recommended further analysis of the implications and impacts of including RUTFs in the EMLc, and requested the WHO Department of Nutrition for Health and Development to prepare a report for the next Expert Committee meeting, addressing various aspects, including country requirements if RUTFs were included in national essential medicines lists; costs and access implications; progress of the Codex guidelines on RUTFs by the Codex Committee on Nutrition and Foods for Special Dietary Uses; and the systematic reviews being prepared on the effectiveness and safety of RUTFs (9).

The Department of Nutrition for Health and Development, in collaboration with the Department of Essential Medicines and Health Products, convened a technical consultation in Geneva, Switzerland in September 2018. In preparation for the technical consultation, WHO extended a call for authors for the preparation of review papers on diverse topics related to the criteria and implications of listing nutrition-related products in the EML.

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1 Ferrous salt + folic acid in tablet form equivalent to 60 mg iron and 400 μg folic acid for use as a nutritional supplement during pregnancy already appears in the EML.
This paper presents the potential impacts, as perceived by stakeholders, of adding RUTFs and other nutrition-related products to the EML. Stakeholder perceptions of potential impacts cover regulation; product quality; development of alternative formulations; local production; cost, procurement and budgetary implications; and other country-level considerations. Informed by a synthesis of the perceptions of stakeholders, the paper reflects on whether or not RUTFs and other nutrition-related products should be added to the EML.

Materials and methods

Stakeholders along the whole supply chain for RUTFs, including local and international RUTF producers, United Nations agencies, bilateral aid agencies, nongovernmental organizations, governmental organizations, and other international organizations engaged in addressing undernutrition, were contacted via email in June–July 2018 and asked to participate in a survey to provide their perspectives on the potential trade-offs associated with adding RUTFs and other nutrition-related products to the EML. The survey consisted of a series of qualitative questions (see Appendices A3.2.1 and A3.2.2) on different dimensions of potential impact. Questions about RUTFs were posed separately from questions about other nutrition-related products but each set culminated in a question asking whether the stakeholder would support adding RUTFs or other nutrition-related products to the EML.

The same survey was given to all stakeholders, but they were told that they were free to skip any particular questions that covered issues on which they did not care to comment. All stakeholders were told that their names, positions and organizations might appear in this paper.

Completed surveys were compiled by question and by stakeholder type, to facilitate comparison across and within stakeholder types in perceptions of the potential effects of adding nutrition-related products to the EML. By gradually aggregating the survey responses, perceived positive and negative impacts were identified within each dimension of potential impact.

Results

Stakeholders

A total of 43 stakeholders were contacted, and completed surveys were received from 18 stakeholders (41.9% response rate). Appendix A3.2.3 lists the stakeholders who provided their perspectives. It is relevant to note that the majority of participating stakeholders were engaged in providing RUTFs for children with uncomplicated severe acute undernutrition, via RUTF production or programmatically, or they were involved from a research standpoint. One nongovernmental organization not engaged in the provision of RUTFs also participated.

Stakeholder perceptions: ready-to-use therapeutic foods

Regulation

As the EML is a model list that serves as a guide for the development of national and institutional essential medicines lists, the listing of a product in the EML does not carry with it any legal or regulatory requirements. However, almost all stakeholders anticipated that the regulation of RUTFs will change if they are added to the EML. A number of stakeholders (several RUTF producers, participants from a United Nations agency, stakeholders at a bilateral aid agency, and several participants from nongovernmental organizations) noted that the likely impacts of adding RUTFs to the EML on how the products are regulated will be country specific. In particular, many stakeholders noted that, depending on how individual countries would classify RUTFs if they are added to the EML, it may be more likely that they are treated as medicines, and therefore local regulation of RUTFs could become more stringent and inhibit the availability and accessibility of the products. On this issue, participants from a United Nations agency noted:
It will be important to assess how food, food for specialized medical purposes and medicines are regulated in different countries. It will be especially important to find out how they would classify RUTF when it is placed in the miscellaneous category of the EML, and whether there would be specific restrictions to the manufacturing (e.g. only in a facility that is qualified to produce drugs) and/or distribution (e.g. can only be provided by registered health professionals) and/or consumption (e.g. must be under clinical/controlled conditions).

The importance of clarity on this issue cannot be overstated. If the inclusion on the essential medicines list in a specific country requires RUTF to meet pharmaceutical standards for manufacturing, importation and distribution, this could effectively eliminate the accessibility of RUTF in some contexts. Where this would not be the case, the inclusion on the EML is much more acceptable. A key question is whether inclusion on the EML could make this point of conditionality very clearly.

A participant from a nongovernmental organization stated:

... addition of RUTF on [the] EML, even in the category miscellaneous ... could bring confusion with the pharmaceutical standards which are not applicable for RUTF. This might result in higher standard requirements that cannot be reached by current manufacturers, blockade in import at country level and, as a result, shortage of RUTF availability.

A participant from a governmental organization noted that some manufacturers may not be able to meet more stringent regulatory requirements, and, coupled with more rigorous monitoring, this could have negative impacts on availability.

Input from a participant from another governmental organization highlights the potential for divergence in how different stakeholders may perceive the most appropriate categorization for RUTFs:

It is my opinion that the addition of RUTF to the EML will help improve the emphasis on the importance of RUTF as a medication and not as a food commodity. In many countries, RUTF is seen as just a food commodity and this downplays the importance of the commodity in the treatment of malnutrition. It may also be the foundation of the reason why misuse of RUTF is so notorious.

A participant from an international organization argued:

Regulatory, monitoring and enforcement systems are weak in many low- and middle-income countries, which have the highest prevalence of severe acute malnutrition. The inclusion of RUTF into the EML would put added costs in governing these products to ensure their quality, safety, use and access are adequately managed. Spill over, inappropriate distribution and use ... and the monitoring of these risks can be a considerable problem.

Other stakeholders foresaw that the likely changes in the regulation of RUTFs would positively impact access to the products. A RUTF producer perceives:

[Addition of RUTFs to the EML] will help the international and local producers to meet the need as per the specifications of the regulatory norms. In other words, more regulatory systems will accept RUTF as a legitimate remedy for [severe acute undernutrition] amelioration, and the production and thus the availability of RUTF [will] improve drastically.
A participant from a nongovernmental organization foresaw that the addition of RUTFs to the EML would be catalytic in engaging the global community in addressing RUTF regulation outside procurement and regulation primarily by United Nations agencies. In particular, they felt that it would lead to a process that addresses issues of regulation and procurement in a way that accounts for the needs of national governments and other national stakeholders, which would result in a more “viable/open ecosystem for RUTF production and distribution” and ultimately improve access:

At present, the procurement via [United Nations] agencies means that regulation is solely determined by the [United Nations] agencies involved (mostly UNICEF [United Nations Children’s Fund]). This is conducive neither to government ownership nor to a transparent discussion about regulation from a government-led perspective. The debate about RUTF regulation will not advance if this continues to be managed as a conversation about how to regulate the [United Nations]-managed system. Only when national governments become accountable for sourcing the product will the regulatory framework be assessed outside of the current parameters.

Finally, drawing a parallel with the history of oral rehydration solution, participants from an international organization foresaw that changes in the regulation of RUTFs under the EML would foster an environment in many countries in which there is scope for all types of companies to produce RUTFs (e.g. local, regional, multinational, small and medium-sized enterprises, dairy cooperatives):

We can learn from the success of the [oral rehydration solution] model, where we see different types of producers, which led to [oral rehydration solution] becoming affordable, convenient to procure and use and easily accessible/available even in remote rural areas. Clear regulations on standards and labelling support a level playing field. This requires a strong regulatory monitoring capacity of governments, however.

Product quality

Almost all stakeholders anticipated that adding RUTFs to the EML would either improve or have no impact on product quality. Among those who anticipated improvements in quality, participants from an international organization, a nongovernmental organization, two governmental organizations and a RUTF producer all emphasized that quality might improve as the result of development of a common set of standards and guidelines that are applied to all RUTF producers and are used by all buyers, whether they are governments, nongovernmental organizations, multinational, small and medium-sized enterprises, dairy cooperatives:

Being placed in the EML/EMLc provides basis for governments to include this in the national formulary and also be one of those to be registered at the Food and Drug Regulatory Office. As such, [by] being registered or licensed in a country, through existing regulatory bodies, quality of the product is thereby assured.

Several stakeholders also mentioned the relevance of the Codex standard in ensuring high-quality products. A stakeholder from a nongovernmental organization noted: "Quality will, I think, mainly improve as a result of clear Codex standards and enforcement of product specifications, which is why it is imperative that these process[es] continue in parallel". Another participant from a nongovernmental organization emphasized that RUTF should meet food quality standards under the Codex.

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1 Work is currently under way to establish guidelines for RUTFs under the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) (9). The development of a new Codex guideline involves an eight-step process (11). The 40th session of the CCNFSDU on 26–30 November 2018 reviewed the proposed draft guideline for RUTFs and agreed to hold the text at Step 4 and to consider the remaining recommendations of the physical working group at its next session and to continue developing Sections 5.2.2 and 6.2 for circulation for comments and consideration at the next session in 2019 (12). From there, comments from member countries and other interested parties are again solicited and finalized by the CCNFSDU, and the draft is submitted to the 5/8 Step (conclusion).
Among stakeholders that anticipated there would be no change in product quality, two RUTF producers stated that RUTFs already meet very high quality standards and they are highly regulated by the interagency group of the United Nations Children’s Fund, the World Food Programme, the United States Agency for International Development, Médecins Sans Frontières and national authorities. Stakeholders at a bilateral aid agency noted recent improvements by the interagency group to the process for auditing approved suppliers, adding that, although the addition of RUTFs to the EML may improve some food-safety testing procedures, they did not believe the overall quality of the products procured by members of this interagency group would be impacted.

Development of alternative formulations

Stakeholder perceptions of the effects of adding RUTFs to the EML on the development of alternative formulations varied across and within stakeholder types. Stakeholders participating in the survey noted that this is an important issue, since developing alternative formulations for RUTFs has the potential to reduce costs and improve efficacy and acceptability (e.g. development of RUTFs with organoleptic properties that are preferred by a particular target population) in some settings.

Beginning with perceived negative impacts, participants from a United Nations agency, a bilateral aid agency, several nongovernmental organizations and several RUTF producers perceived that adding RUTFs to the EML could introduce prohibitive barriers to the development of alternative formulations, including a standard that is very specific (e.g. a list of ingredients) or very rigid, or stipulations that a new formulation would require (potentially lengthy) approval for modifications to the standard. A participant from a nongovernmental organization noted:

> If the standard is too specific, then potentially it could hinder innovation. Reducing the cost of RUTF has been a public health priority, which requires innovation related to RUTF formulation, including the use of ingredients that could lower overall product cost. Much research has already been conducted and is ongoing, related to alternative formulations. It will also be important that there is some flexibility or understanding that testing of alternative formulations to treat severe acute malnutrition is possible.

On the other hand, other participants, including a RUTF producer, an international organization and several governmental organizations, expected advances in the development of alternative formulations if RUTFs are added to the EML. These stakeholders contended that the addition of RUTFs to the EML may increase support for RUTFs (from policy-makers, governments, donors and private-sector food manufacturers) and attract more investments in research and development for the development of alternative formulations. However, one participant from a nongovernmental organization felt that the development of alternative formulations should be bound by Codex guidelines:

> The question of alternative formulations should not be left open, but rather, clear references to [the] Codex should be made to ensure that whilst governments are given space to explore alternative sources, there remains a minimum framework of what is considered to be acceptable deviations from the standard formula and global sourcing from patent holders.

Finally, a participant from an international organization felt that investments in the development of alternative formulations for RUTF are, in general, misplaced:

> Product innovation should be based on independent scientific evidence that any change in product formulation is effective for the treatment of [severe acute malnutrition] ... Product “innovations” in RUTF, which [are] costly and usually done to increase markets for these products, should not be a priority over long-term, sustainable and culturally appropriate approaches to reduce the prevalence [of severe acute malnutrition] and [for] the prevention of [severe acute malnutrition] and the underlying causes of malnutrition.
This participant was also concerned that adding RUTFs to the EML would give unwarranted credibility to the single-recipe globally traded products that need to have a long shelf-life:

We also understood that there has been general agreement that the focus should be on locally made, culturally appropriate products, rather than on single-recipe, globally traded products – especially those that have a long shelf-life, and contain high levels of added sugar and other ingredients – that manufacturers claim are needed to improve palatability. It seems highly likely that listing RUTF on the EML will undermine any move to home or local preparation/production and will disproportionately promote single-recipe globally traded products.

Local production

While the vast majority of RUTFs are produced by international companies, local production is expanding and is being promoted as a way to improve sustainability (13, 14). Among stakeholders participating in the survey who had a perception of negative implications for local production, several mentioned that if adding RUTFs to the EML creates the perception that they are medicines, then local production could be restricted to pharmaceutical companies instead of food manufacturers, effectively curtailing local production. It was also mentioned by some participants that it may be harder and more costly for smaller local producers to meet more stringent requirements, particularly in countries with limited laboratory capacity, again discouraging local production. Moreover, some noted that local producers already face significant costs in the form of importation taxes on raw materials and registration, and additional fees for registering a new pharmaceutical product, if applied, could constrain local production, which, as noted by a participant from a nongovernmental organization, “runs contrary to some recent initiatives to encourage local production of RUTF [among other nutrition commodities].”

Other participants, however, indicated that they expected that adding RUTFs to the EML would boost local production. Some noted that adding RUTFs to the EML may lead to a stable market for the products, which would help expand local production. In particular, participants from an international organization noted:

Local producers typically find it difficult to attract investment to produce, expand or for [research and development on] alternative formulas, have high local cost of capital and rely on expensive external labs for quality tests. They are likely to benefit the most once RUTF is considered as an essential medicine.

Others foresaw that adding RUTFs to the EML may lead to increased roles for national governments in determining RUTF suppliers, probably resulting in increased demand for and production of locally produced RUTFs. Moreover, a participant from a nongovernmental organization noted that “inclusion in the EML might accelerate local and regional production, as governments seek to tap into domestic/regional producers in part to reduce transport-associated costs.”

Cost, procurement and budget implications

In general, stakeholders were uncertain about the likely impacts of adding RUTFs to the EML on the cost and procurement of RUTFs and the likely budget implications. Some stakeholders raised concerns that the cost of RUTFs, which accounts for a large portion of the total cost of managing uncomplicated severe acute undernutrition and is often cited as a barrier to increased coverage (15, 16), may rise as a consequence of being added to the EML. In particular, many stakeholders mentioned concerns that stricter regulatory standards and more required clearances for producers and distributors will raise the cost of production and distribution, and, as a result, access to RUTFs will decline. According to a participant from an international organization:
It is therefore essential that inclusion in the EML does not inadvertently lead to an irrational/non-evidence-based raising of standard. Provided RUTF is added in a way that does not inadvertently lead to senseless additional production standards (e.g. as a “miscellaneous” item and distinct from conventional medicines), inclusion in the EML is likely to be positive and lead to greater access to treatment and therefore save lives. If inclusion inadvertently raises production standards, it is likely to be negative, reducing access to treatment and therefore resulting in avoidable child deaths.

Participants from several nongovernmental organizations also noted the potential for increases in RUTF transport and storage costs if the products are added to the EML. One of these nongovernmental organization participants noted that transport and storage costs may rise if local production is curtailed and procurement is limited to international producers, while another cited existing challenges with adequate infrastructure for the transport and storage of RUTFs in some countries, which could be compounded if adding RUTFs to the EML increases the supply of RUTFs in such countries.

On the other hand, other stakeholders predicted that the price of RUTFs will decrease as a result of increased competition and economies of scale. For example, participants from an international organization noted:

Standards for RUTF will support competition and more competition can lead to lower price points, as well as through economy of scale if/when demand/use of RUTF increases.

A RUTF producer similarly noted:

What is likely to happen is that EML addition [will] lead to widespread adoption and production of RUTF. This in turn is likely to lead to massive economies of scale (scale procurement of milk powder, and peanut for instance). This, in turn, is likely to put a downward pressure on prices.

A stakeholder from a nongovernmental organization saw potential improvements in predictability and planning around procurement and transport:

Procurement and transport will likely become more predictable and can be better planned, which currently is a major disadvantage. Funding waves determine procurement. If EML can strengthen the budgeting for RUTF from domestic budgets, then procurement and transport will be smoother and more predictable.

Several governmental organizations also anticipated positive implications for national-level budgeting. A participant from one governmental organization noted:

Adding RUTF to the EML will serve as a way of showing all stakeholders the importance of the product and its availability. As a result, this might also, in turn, influence the decision of stakeholders in committing to support the procurement and transportation of the product to ensure availability like other products on the EML.

A participant from another governmental organization observed:

Regulatory agencies and policy-makers use the EML/EMLc as a basis for resource management planning and also for programme commodity alignment as well. National policies on managing severe acute malnutrition will benefit from [an] official [essential medicines list] that will reflect RUTF in it.
Other country-level considerations

Several additional questions were posed to stakeholders that were specific to national-level effects of the inclusion of RUTFs in the EML. Most stakeholders, including all participants from governmental organizations, were in agreement that individual countries would be more likely to add RUTFs to their national essential medicines lists if they were listed in the EML, although some noted that the process could take time. A participant from a governmental organization noted that in recognition of reductions in morbidity and mortality after RUTFs were introduced for the management of severe acute undernutrition, their country’s department of health had applied for RUTFs to be added to the country’s medical catalogue. Meanwhile, a participant from an international organization raised concerns that if RUTFs were added to the EML, then they would be more likely to be added to national essential medicines lists, owing to “pressure from manufacturers, aid organizations, researchers and those who receive funding from these industries, to add these products to the EML”.

Stakeholders had varying viewpoints on the effect of adding RUTFs to the EML on in-country perceptions of the purpose of the product from the perspective of ministries of health, health-care providers and households. Some foresaw positive impacts. A RUTF producer, for example, noted:

> RUTF addition to [the] EML would give more clarity, visibility and authentic acceptance to the role of RUTF as a therapeutic treatment for [children with uncomplicated severe acute malnutrition] ... It would also facilitate product acceptance and a significant shift in the perspective of [the] ministry of health, health-care providers and consumers.

Similarly, a participant from a nongovernmental organization noted that “it would help frame the condition it is meant to address [acute malnutrition] as a governmental responsibility, not just a civil society/United Nations responsibility.” Finally, participants from a United Nations agency noted that if, as a result of being added to the EML, RUTFs became viewed more as foods with a medical purpose, then sharing and use by unintended consumers may be reduced. On the other hand, participants from this United Nations agency and several other stakeholders cautioned that it could also result in a return to a more medicalized approach to the treatment of severe acute undernutrition, where distribution is limited to pharmaceutical channels, and community-based distribution via unskilled or less skilled health workers is restricted. In particular, a participant from a nongovernmental organization noted:

> The risk is that some countries would specify that RUTF can only be used as a medicine by trained and registered medical staff or only in health structure – this could call into question the model of community-based management of acute malnutrition, which is the raison d’être of RUTF.

Finally, a participant from an international organization felt that there was not sufficient evidence on the efficacy of RUTFs to justify their addition to the EML and cautioned that adding RUTFs to the EML would lead to unwarranted perception of the efficacy of these products and increase pressure on countries to “accept these products, including countries that have spent considerable time deliberating the best way to tackle malnutrition and have decided not to use these products”.

Most stakeholders, including each governmental organization, also perceived that adding RUTFs to the EML may be catalytic in the integration of treatment of severe acute undernutrition, generally, into country-level health systems. However, some stakeholders felt that, while this is a possibility, the potential risks of negative impacts are not worth the potential benefits of greater integration of the treatment of severe acute undernutrition in health systems.

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1 One participant noted that, although adding RUTFs to the EML may accelerate the addition to national essential medicines lists in countries already committed to using RUTFs, it is unlikely to have an effect in countries that are reluctant to adopt and use RUTFs.
Assessment of adding ready-to-use therapeutic foods to the WHO Model List of Essential Medicines

Table A3.2.1 presents stakeholders’ assessments of whether or not they would support adding RUTFs to the EML.

Among RUTF producers, one supported and two did not support the addition of RUTFs to the EML. Participants from a United Nations agency chose not to make an expression of support but suggested that a more detailed risk assessment be undertaken to ensure that manufacturing, distribution and use will not be restricted compared with continued classification of RUTFs as foods with a medical purpose.

Table A3.2.1. Stakeholders’ assessments of adding ready-to-use therapeutic foods to the World Health Organization Model List of Essential Medicines

<table>
<thead>
<tr>
<th>Stakeholder type</th>
<th>Support adding RUTFs to the EML</th>
<th>Do not support adding RUTFs to the EML</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>RUTF producers</td>
<td>1</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>(n = 3)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>United Nations agencies (n = 1)</td>
<td>1</td>
<td></td>
<td>More detailed risk assessment is required, to ensure manufacturing, distribution and use will not be restricted compared with continued classification of RUTFs as foods with a medical purpose (not as medicines), and when standards provide sufficient room for innovation on product formulation and for formulation of buyer specifications that also enable smaller (local) manufacturers to enter the market</td>
</tr>
<tr>
<td>Bilateral aid agencies (n = 2)</td>
<td>2</td>
<td></td>
<td>Support is conditional on RUTFs being added in a category that does not refer to medicines, pharmaceutical items or medicinal food items. Prefer a new category of “therapeutic foods” or “special dietary foods”, but categorization as a “miscellaneous” item is also acceptable. Supply-chain and procurement planning and last-mile delivery must be addressed for EML as a whole; Supportive unless strong evidence is presented by relevant stakeholders to support their hypotheses around the likely net effect on health and nutrition outcomes being negative</td>
</tr>
<tr>
<td>Nongovernmental organizations (n = 5)</td>
<td>4</td>
<td>1</td>
<td>Supportive, but as foods or essential Commodities, and not necessarily as medicines. Appropriate categorization depends on country-specific regulatory environments and the implications of classification in that context on the ability of international and local suppliers to operate production of safe products according to existing international specifications; It will institutionalize RUTFs and allow countries to take full ownership, include RUTFs in budget decisions, and better integrate RUTFs and management of severe acute malnutrition into health systems. On the production and supply side, predictability will improve, leading to better planning and more stable production, quality and price; No value added, and the risk of confusion with pharmaceutical products and standards is too high. Importation would be blocked, resulting in a shortage of RUTFs. Innovation and local manufacturing could also be negatively impacted</td>
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![WHO Technical Consultation: Nutrition-Related Health Products and the World Health Organization Model List of Essential Medicines - Practical Considerations and Feasibility](Image)
<table>
<thead>
<tr>
<th>Stakeholder type</th>
<th>Support adding RUTFs to the EML</th>
<th>Do not support adding RUTFs to the EML</th>
<th>Other</th>
<th>Conditions, caveats and comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>International organizations (n = 3)</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>Fully support but recommend deferring addition of RUTFs to the EML until a Codex guideline is available. Treating severe acute undernutrition with RUTFs must not be viewed as conflicting with investments to improve access to high-quality food. Treating the millions of severely undernourished children, many of whom die every day, is as pressing a need as prevention of further undernutrition through improved access to food; RUTFs are food products that should be subject to regulatory and other guidelines for foods. Even if classified as medicines, they should not be added to the EML as such, since efficacy and safety must be established before medicines are added to the EML. The International Baby Food Action Network has serious reservations about the use of RUTFs in management of severe acute malnutrition (as either foods or medicines) because (i) existing evidence does not unequivocally support use of RUTFs for recovery from and prevention of mortality from severe acute malnutrition in programme settings; and (ii) there is potential for harmful long-term effects on health; Addition to the EML as a miscellaneous item may be positive step</td>
</tr>
<tr>
<td>Governmental organizations (n = 4)</td>
<td>4</td>
<td></td>
<td></td>
<td>Serious resource mobilization must be undertaken by WHO, to support countries to procure RUTFs in a more sustainable manner</td>
</tr>
</tbody>
</table>


* The numbers in each row represent the number of stakeholders whose response fell within each category. Stakeholders that did not respond to this question have been omitted.

Individual stakeholders’ comments are separated by a semicolon.

Participants chose not to make an expression of support.

Among participants from bilateral aid agencies conditionally supported adding RUTFs to the EML. For participants from one agency, support was conditional on RUTFs being added in a category that does not refer to medicines, pharmaceutical items or medicinal food items; they also noted that if RUTFs were added to the EML, then supply-chain and procurement planning and last-mile delivery must be addressed for the EML as a whole. The participant from the other bilateral aid agency supported adding RUTFs to the EML, unless there was strong evidence showing that the likely net effect on health and nutrition outcomes would be negative.

Among participants from nongovernmental organizations, four supported and one did not support inclusion of RUTFs in the EML. Among the nongovernmental organization supporters, one participant supported inclusion of RUTFs, but only as foods or essential commodities, and not necessarily as medicines, adding that the appropriate categorization depended on country-specific regulatory frameworks and the implications of classification in that context on the ability of international and local suppliers to operate the production of a safe product according to existing international specifications. The participants from the non-supporting nongovernmental organization noted that they saw no value added and a high risk of confusion with pharmaceutical products and standards.

Among participants from international organizations, one felt that adding RUTFs to the EML may be a positive step; another supported their inclusion but recommended deferring until the Codex guidelines for RUTFs are available; a third did not support adding RUTFs to the EML.
All participants from governmental organizations supported adding RUTFs to the EML, although a participant from one governmental organization noted that it will require resource mobilization by WHO to support countries to procure RUTFs in a more sustainable manner.

**Stakeholder perceptions: other nutrition-related products**

In general, stakeholders were more engaged with questions about RUTFs compared with questions about other nutrition-related products. Moreover, some perceived impacts of adding RUTFs to the EML, such as the risk that product distribution might be limited to pharmacies, health facilities or trained health workers, or the projection that countries would be more likely to place RUTFs on their national essential medicines lists, were very similar to stakeholders’ perceptions about other nutrition-related products. Differences in expected impacts that were mentioned by stakeholders are discussed next.

Specifically, several stakeholders perceived that for some nutrition-related products that currently suffer from poor or inconsistent quality, the development and enforcement of common standards could result in quality improvements. Participants from an international organization echoed the importance of enforcement, noting:

> Standard-setting benefits everyone, from the producer to the citizen. But standards are only as effective as their monitoring and enforcement system. If audits are not conducted on a regular basis, you can increase the risk for counterfeit products. For food-type products, standards would go beyond formulation and shelf-life to include quality such as hygiene, microbial content, [and] nutritional content.

In terms of impacts on how nutrition-related products would be perceived by ministries of health, health-care providers, households and consumers if they were added to the EML, participants from a nongovernmental organization noted that the addition of F-75, F-100 and iron + folic acid would demonstrate that these are important commodities for treating serious conditions (severe acute undernutrition with complications and iron-deficiency anaemia); but for other products that are used for a variety of purposes, both preventive and curative, adding them to the EML could be interpreted as those products being indicated to treat a single or limited conditions, therefore discouraging their procurement for other conditions. These participants additionally noted:

> From the perspective of the government or ministry of health, there is a likelihood that putting these products on the EML will promote the perception of products as a silver bullet for treating a single condition, and therefore discourage other important, complementary preventive interventions presently provided alongside distribution of these commodities, such as social and behaviour-change communication for improved dietary intake, water, sanitation and hygiene messages.

Finally, these participants warned of potential negative programmatic impacts and reductions in coverage, if adding nutrition-related products that are commonly distributed at the community level by frontline development workers (such as ready-to-use supplementary foods [RUSFs], micronutrient powders, lipid-based nutrient supplements and iron + folic acid) to the EML, limited their distribution to health facilities or by trained health workers.

Participants from an international organization perceived that adding nutrition-related products to the EML “would force health-care providers to be more knowledgeable about nutrition, including appropriate training on the causes and use of the nutrition-related products”. Moreover:

> At the very least it would prompt government review into how these products are delivered through various service mechanisms ... It would also prompt a more careful surveillance of the public health problems (e.g. anaemia) that are to be address[ed] through nutrition-related products at the health centres.
One participant from a governmental organization reported that many of these other nutrition-related products are already in the process of being included in national medical catalogues, which will allow for funding for procurement. A participant from another governmental organization foresaw that the “addition of these products to the EML may serve as a springboard for governments in taking ownership and making their personal commitment in funding the procurement, storage and supply-chain management issues of these products”.

Finally, several stakeholders perceived that nutrition-related products that are typically delivered through the health system might, as a result of being added to the EML, become more integrated into national health systems. Participants from an international organization also noted the potential for further integration and coordination between health systems and national food and drug administration-type regulatory bodies, and predicted that the most critical issues associated with food-type nutritional products (e.g. label requirements, shelf-life, good manufacturing practices) already exist in most countries and can be strengthened further through meeting EML standards.

**Assessment of adding other nutrition-related products to the WHO Model List of Essential Medicines**

Table A3.2.2 presents stakeholders’ assessments of whether or not they would support adding other nutrition-related products to the EML.¹

Neither of the RUTF producers that responded to this question supported adding other nutrition-related products to the EML. Participants from a United Nations agency supported adding products such as F-75, F-100, RUSFs and iron + folic acid, as these products are not available through non-health-sector channels, but they did not support adding products that can also be distributed through markets or schools. These participants also urged that RUTFs and RUSFs be considered jointly:

> ... we should avoid situations where there would be two separate pipelines for products for the treatment of severe versus moderate acute malnutrition, where RUTF would be available from the health clinic and RUSF would have to be sourced differently. Related to this, it would also be important that in case of a simplified/harmonized protocol, where RUTF is used for treatment of both [severe and moderate acute malnutrition], that this is possible, i.e. use of RUTF does not become restricted only to [severe acute undernutrition] when it would be placed on the EML.

¹ Owing to an oversight, it was not made clear to stakeholders that ferrous salt + folic acid in tablet form for use as a nutritional supplement during pregnancy already appears in the EML. Although intermittent iron + folic acid supplements for menstruating women are not currently in the EML, this distinction in target population and regimen was not made explicit to stakeholders. Support for adding iron + folic acid to the EML should thus be interpreted with this in mind.
Table A3.2.2. Stakeholder support for inclusion of other nutrition-related products in the World Health Organization Model List of Essential Medicines

<table>
<thead>
<tr>
<th>Stakeholder type*</th>
<th>Support inclusion of other nutrition-related products in general in the EML</th>
<th>Do not support inclusion of other nutrition-related products in the EML</th>
<th>Support inclusion of only specific other nutrition-related products in the EML</th>
<th>Comments</th>
</tr>
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<tbody>
<tr>
<td>RUTF producers</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(n = 3)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>United Nations agencies (n = 1)</td>
<td>1</td>
<td>Only products that are not (to be made) available through non-health-sector channels (F-75, F-100, RUSFs, iron + folic acid)</td>
<td>Nutrition-related products that can also be distributed through markets or schools, and those that should be part of a normal dietary pattern (e.g. complementary feeding) should not be in the EML. Adding them would give a wrong message about these foods and would probably reduce innovation and limit efforts to scale up availability, access and consumption</td>
<td></td>
</tr>
<tr>
<td>Bilateral aid agencies (n = 2)</td>
<td>1</td>
<td>1</td>
<td>F-75 and F-100</td>
<td></td>
</tr>
<tr>
<td>Nongovernmental organizations (n = 5)</td>
<td>0</td>
<td>2</td>
<td>Micronutrient powders, iron + folic acid; F-75, F-100, iron + folic acid</td>
<td>Use experiences and implications of adding RUTFs to EML before adding other nutrition-related products; Iron + folic acid and micronutrient powders are fully developed and ready for scale at programme level, but this is not case for lipid-based nutrient supplements. Corn-soya blends are food products used for supplementary rations; Supportive of F-75, F-100, and iron + folic acid for specific purposes. Unsure about other nutrition-related products; Strongly disagree with addition of other nutrition-related products unless a specific list is created for nutritional products</td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th>Stakeholder type</th>
<th>Support inclusion of other nutrition-related products in general in the EML</th>
<th>Do not support inclusion of other nutrition-related products in the EML</th>
<th>Support inclusion of only specific other nutrition-related products in the EML</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>International organizations (n = 3)</td>
<td>0</td>
<td>1</td>
<td>1 Iron + folic acid, micronutrient powders, Super Cereal Plus</td>
<td>Adding other nutrition-related products to the EML would be premature, unhelpful and distracting from high-priority need to further establish the efficacy and effectiveness of these products; Support adding iron + folic acid, micronutrient powders and Super Cereal Plus, but the supply chain (from production to procurement) should be clearly understood, and inclusion in the EML should facilitate rather than impair access. Robust supply-chain monitoring systems would be required to ensure adherence to standards, so products received by end-users are safe and efficacious.</td>
</tr>
</tbody>
</table>

Governmental organizations (n = 4) | 1 | 0 | 1 F-75, F-100, RUSFs, micronutrient powders, iron + folic acid | Support addition of these products because they are required and should be readily available for treatment of complicated malnutrition (F-75, F100), stunting (RUTFs) and other nutrition-related conditions such as anaemia. |

Among participants from bilateral aid agencies, one conditionally supported the addition of nutrition-related products, while the other supported only the inclusion of F-75 and F-100, as they considered these to be a complete therapeutic diet with similar considerations to those of RUTFs.

Among participants from nongovernmental organizations, one supported adding micronutrient powders and iron + folic acid, and another was supportive of adding F-75, F-100 and iron + folic acid. A third was not supportive but rather recommended deferring the consideration of other products so that the experiences and implications of adding RUTFs to the EML could be applied. Finally, one participant from a nongovernmental organization strongly opposed adding other nutrition-related products unless a list specific to nutritional products was created. Among participants from international organizations, one supported adding iron + folic acid, micronutrient powders and Super Cereal Plus but cautioned that a clear understanding of the supply chain (from production to procurement) is needed and that the inclusion of these products should facilitate rather than impair access. Another did not support adding other nutrition-related products at this time and felt that their addition would be premature and distracting from the high-priority need to further establish the efficacy and effectiveness of these products.

Finally, among participants from governmental organizations, one supported adding nutrition-related products in general to the EML, while the other supported adding F-75, F-100, RUSFs, micronutrient powders and iron + folic acid, citing that these products should be readily available for the treatment of complicated undernutrition, stunting and other nutrition-related conditions such as anaemia.
Discussion

All stakeholders were told that their names, positions and organizations might appear in this paper. A majority of stakeholders consented to being quoted with attribution. Ultimately, it was decided to anonymize all stakeholders and their perceptions. It is possible, however, that asking stakeholders to provide their input under the assumption that they might be identified and quoted with attribution (if consenting) may have introduced bias in their reported perceptions.

The perceptions of a diverse group of stakeholders on the potential impacts of adding RUTFs and other nutrition-related products to the EML were varied, highlighting the uncertainty around the potential implications for access. For some issues, there was some consensus among stakeholders about the likely impacts. In particular, most stakeholders foresaw changes in how RUTFs are regulated, with many stakeholders noting that changes could be country specific. Most stakeholders also perceived likely improvements in the quality of RUTFs if they are added to the EML, with some noting that quality standards should be set by (or be in parallel with) Codex guidelines. Most stakeholders predicted that if RUTFs and other nutrition-related products are added to the EML, then individual countries will be more likely to add them to their national essential medicines lists. Many stakeholders also perceived that in-country decision-making and funding for RUTFs for the management of severe acute undernutrition, and integration of the treatment of severe acute undernutrition into national health systems, would improve with the addition of RUTFs to the EML.

However, there were many dimensions in which stakeholder perceptions about the likely impacts were in stark contrast to one another. Stakeholder perceptions about the implications of likely changes in the way RUTFs are regulated range from RUTFs (and some other nutrition-related products) being treated as medicines and therefore subject to prohibitively stringent pharmaceutical standards, to expectations that a more formal regulatory framework will lead to greater acceptability and facilitate production by a broader range of producers. Stakeholders also disagreed on the likely impacts on local production and the development of alternative formulations, with some predicting that innovation will be stifled and others foreseeing an environment that fosters local production and developments of alternative formulations. While many stakeholders raised concerns that more stringent regulation of nutrition-related products could result in higher costs, other foresaw greater competition and economies of scale leading to lower costs. Stakeholders also had very different views on how in-country perceptions of RUTFs and other nutrition-related products might change if added to the EML, including cultivating greater acceptance of RUTFs, to concerns over a more “medicalized” approach to treating severe acute undernutrition and other nutrition-related conditions.

In light of the contrasting perceptions about many of the impacts of adding RUTFs and other nutrition-related products to the EML, it is not surprising that stakeholders varied, within and across stakeholder types, in whether or not they supported adding RUTFs and other nutrition-related products to the EML. Considering the differing views of stakeholders and the varying degrees of uncertainty in the effects on many potential areas of impact, we suggest, as proposed by participants from a United Nations agency, that a rigorous risk assessment be undertaken to evaluate the primary concerns raised by stakeholders. In particular, the decision to add RUTFs and other nutrition-related products to the EML should be based upon a firmer understanding of (i) how the products would probably be categorized and regulated in individual countries; (ii) the associated implications for production, cost and distribution; and (iii) the effect on the scope for the development of alternative formulations and local production. In the authors’ view, the decision to add RUTFs and other nutrition-related products to the EML should be contingent upon demonstrating, with reasonable confidence, that the cumulative effect of adding RUTFs and other nutrition-related products to the EML on these factors would result in improved access among the populations most in need, while providing sufficient latitude for local production and for the development and testing of alternative formulations.
References


Appendix A3.2.1
Stakeholder questions on ready-to-use therapeutic foods (RUTFs) and the WHO [World Health Organization] Model List of Essential Medicines (EML)*

1. How do you think the addition of RUTFs to the EML would affect product quality? Do you have specific concerns about potential negative impacts on product quality or expectations about potential positive impacts on product quality? To the extent possible, please provide explanations for your perceptions about the potential effects on product quality.

2. Do you think the addition of RUTFs to the EML would impact the standards of formulation for RUTFs? If yes, in what ways? If no, why not?

3. Do you think the addition of RUTFs to the EML would impact product innovation, including both local production and the development of alternative formulations? If yes, in what ways? If no, why not?

4. How do you think the addition of RUTFs to the EML would affect the regulatory environment for RUTFs? Please include consideration of how the ability of international and local producers of RUTFs may be impacted by regulatory changes and, subsequently, the likely implications for the availability of RUTFs.

5. If you expect that adding RUTFs to the EML might impact the regulatory environment or formulation standards, what would be the likely implications for the cost of production, transport and storage of RUTFs? How might access to RUTFs be impacted by potential changes in these costs?

6. In what ways might the procurement and transport of RUTFs, at both international and country levels, be impacted by adding RUTFs to the EML?

7. If RUTFs are added to the EML, do you think it is likely that individual countries would then add RUTFs to their national essential medicines lists?

8. If RUTFs are added to the EML, how might in-country perceptions of these products be impacted? In particular, how might views regarding the purpose or function or RUTFs, from the perspective of the ministry of health, health-care providers, households and consumers, change as a result of adding RUTFs to the EML? Similarly, how would these perceptions potentially change if countries also added RUTFs to their national essential medicines lists?

9. If RUTFs are added to the EML, how might in-country decision-making around and funding for the treatment of uncomplicated severe acute malnutrition be affected? That is, would you anticipate that adding RUTFs to the EML might spur greater governmental prioritization of ensuring RUTFs are continuously available for treating uncomplicated severe acute malnutrition (including addressing procurement, storage, and supply-chain management issues)? Would decision-making and funding decisions around RUTFs for the treatment of severe acute malnutrition be contingent upon RUTFs being added to the national essential medicines list?

10. Related, do you anticipate that adding RUTFs to the EML might be catalytic in the integration of severe acute malnutrition treatment into country-level health systems?

11. Given all the considerations above, would you support adding RUTFs to the EML? If your support is conditional, please specify the conditions.

* Questions were also available in French.
Appendix A3.2.2
Stakeholder questions on other nutrition-related products and the WHO [World Health Organization] Model List of Essential Medicines (EML)

This set of questions pertains to nutrition-related products other than ready-to-use therapeutic foods (RUTFs), including F-75, F-100, ready-to-use supplementary foods (RUSFs), fortified blended foods (e.g. Super Cereal, Super Cereal Plus), small-quantity lipid-based nutrient supplements, micronutrient powders and iron + folic acid supplements. Your answers can apply generally to these other nutrition-related products, or you can provide input for specific products as you see fit.

1. How do you think the addition of other nutrition-related products to the EML would affect product quality?
2. Do you think the addition of other nutrition-related products to the EML would impact the standards of formulation for these products? If yes, in what ways? If no, why not?
3. Do you think the addition of other nutrition-related products to the EML would impact product innovation, including both local production and the development of alternative formulations? If yes, in what ways? If no, why not?
4. How do you think the addition of other nutrition-related products to the EML would affect the regulatory environment for these products? Please include consideration of how the ability of international and local producers of these products may be impacted by regulatory changes and, subsequently, the likely implications for the availability of these products, if applicable.
5. If you expect that adding other nutrition-related products to the EML might impact the regulatory environment or formulation standards, what would be the likely implications for the cost of production, transport and storage of these products? How might access to these products be impacted by potential changes in these costs?
6. In what ways might the procurement and transport of other nutrition-related products, at both international and country levels, be impacted by adding these products to the EML?
7. If other nutrition-related products are added to the EML, do you think it is likely that individual countries would then add these products to their national essential medicines lists?
8. If other nutrition-related products are added to the EML, how might in-country perceptions of these products be impacted? In particular, how might views regarding the purpose or function of these products, from the perspective of the ministry of health, health-care providers, households and consumers, change as a result of adding them to the EML? Similarly, how would these perceptions potentially change if countries also added these products to their national essential medicines lists?
9. If other nutrition-related products are added to the EML, how might in-country decision-making around and funding of the use of these products for the treatment of severe acute malnutrition and prevention of stunting and other nutrition-related outcomes (e.g. anaemia) be affected? That is, would you anticipate that their addition to the EML might spur greater governmental prioritization of ensuring these products are continuously available (including addressing procurement, storage, and supply-chain management issues)? Would decision-making and funding decisions be contingent upon these products also being added to national essential medicines lists?
10. Related, do you anticipate that adding other nutrition-related products to the EML might be catalytic in their integration into country-level health systems?
11. Given all the considerations above, would you support adding other nutrition-related products to the EML? If your support is conditional or extends only to specific products, please specify the conditions or products.

ª Questions were also available in French.
Appendix A3.2.3
Participating stakeholders

<table>
<thead>
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<th>Stakeholder type</th>
<th>Context</th>
<th>Position of participant(s)</th>
<th>Personal or official organization input</th>
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<tr>
<td>Local RUTF producer</td>
<td>India</td>
<td>Director; Chief Executive Officer</td>
<td>Personal</td>
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<tr>
<td>Local RUTF producer</td>
<td>Sub-Saharan Africa</td>
<td>Executive Director</td>
<td>Official</td>
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<td>International RUTF producer</td>
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<td>Chief Operating Officer</td>
<td>Official</td>
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<tr>
<td>United Nations agency</td>
<td>Italy</td>
<td>Senior Technical Adviser; Nutrition Adviser; Food Technologist; Commodity Specialist</td>
<td>Official</td>
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<td>Bilateral aid agency</td>
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<td>Nutrition Advisor</td>
<td>Personal</td>
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N/A: not applicable; RUTF: ready-to-use therapeutic food.