Local production of ready-to-use therapeutic food for the treatment of severe acute malnutrition

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Ready-to-use therapeutic food (RUTF) is a nutrient-dense paste that is an effective treatment for children with severe acute malnutrition using community-based therapeutic care (CTC). This paper describes the background to the development of local production of RUTF in famine-affected countries, its composition and standards, method of production, packaging, and quality assurance.

Keywords: malnutrition, ready-to-use therapeutic foods, RUTF, community-based therapeutic care, CTC, production, quality assurance

Therapeutic foods are designed for the treatment of children (and adults) with severe acute malnutrition (SAM). Different types of therapeutic foods have been developed but the most widely used are F75 and F100 fortified milk powders. However, these require a supply of potable water and/or fuel to prepare them, and their use requires hospitalization in centralized feeding centres in the affected areas. Ready-to-use therapeutic foods (RUTFs) are designed to treat severe acute malnutrition and can be consumed directly from the pack without further preparation or cooking. They are energy-dense, micronutrient-enriched pastes that have a nutritional profile similar to F-100 milk.

Peanut-based RUTF was formulated in 1996 by André Briend (Briend, 1997; Briend et al., 1999), a French paediatric nutritionist then working at the French Institut de Recherche pour le Développement (IRD). It is a thick paste made from peanut butter, sugar, vegetable oil, milk powder, and a vitamin/mineral premix. This complete food provides the energy, proteins, and other nutrients that are needed by malnourished children to recover and resume their growth. Its low water activity enables suitably packaged RUTF to be stored for up to two years at ambient temperatures. It was subsequently commercialized as 'Plumpy'Nut'® by the French company, Nutriset. Although

RUTF is a complete food that allows malnourished children to recover and resume their growth

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relief agencies began using RUTF at emergency feeding centres, it was the development of community-based therapeutic care (CTC) that led to its widespread use.

RUTF and CTC

Therapeutic feeding centres have a number of limitations

Therapeutic feeding centres have been the usual method of treating severely malnourished children in emergencies, but they have a number of limitations: they are difficult to establish, expensive to operate, and they often have very limited coverage; they do not build on the capacity of the community and they can undermine traditional coping strategies. Mothers are required to stay with their malnourished children for three weeks or longer in the feeding centre, which has significant opportunity costs and disrupts family life. Moreover, the congregation of people in and around feeding centres can lead to the spread of infection, an important cause of increased morbidity and mortality in an already weakened population.

CMAM provides therapeutic care in the home by easy access to RUTF

Valid International developed the CTC concept to improve the coverage and impact of humanitarian feeding programmes to treat acute malnutrition in emergencies (Collins, 2001; Collins et al., 2006). Its central innovation is to provide therapeutic care in the home by providing easy access to RUTF (Isanaka et al, 2009, Ashworth, 2005). CTC, later renamed community-based management of acute malnutrition (CMAM) upon adoption by the UN, uses decentralized networks of outpatient treatment sites to provide a take-home ration of RUTF (Valid International, 2008; CMAM, 2011). The aim is to provide rapid, effective, low-cost assistance that is least disruptive to affected communities and builds a foundation to link relief and development interventions for long-term solutions to food insecurity and threats to public health. CTC aims to build local capacity to better manage care of acutely malnourished children, and address repeated cycles of relief and recovery.

Unlike therapeutic milks, RUTF is safe to use in the home without medical supervision

Unlike therapeutic milks, RUTF is safe to store and use in the home and it can be administered without medical supervision. Mothers take sufficient packets of RUTF from a local distribution centre to last a few weeks. This enables parents, especially mothers, to remain in the home and care for other children and continue to earn a living. Because it is highly palatable, most children can eat it without assistance, allowing them to control their own intake and decreasing the potential for the food to be shared throughout the family.

There is now universal agreement that CTC is the preferred intervention approach for the treatment of malnutrition. In 2007, the World Health Organization (WHO) reported: '…large numbers of children with severe acute malnutrition can be treated in their communities without being admitted to a health facility or a therapeutic feeding centre' (WHO, 2007). CTC is being adopted in national strategies in many of the countries most affected by malnutrition and the WHO has incorporated the principles of CTC into its revised guidelines for the treatment of severe acute malnutrition.

RUTF production

Nutriset (www.nutriset.fr) produces RUTF at its site in Normandy, France, distributing it according to demand to areas where nutritional emergencies occur. By 2011 the company had a production capacity of 61,500 MT (million tonnes) and had shipped nearly 36,000 MT of its products to 80 destinations in Africa, Latin America, and Asia, with a turnover of €101 m in 2011 (Nutriset, 2010–12a). The Nutriset/IRD patent (US 6346284, 2002) has been defended to prevent non-licensees in industrialized countries from producing similar products. In 2009, Médecins Sans Frontières called for the establishment of a more flexible licensing policy (von Schoen-Angerer, 2009) and in 2010, two American non-profit organizations challenged the patent protections (Schofield, 2010). The issues surrounding licensing of RUTF were reviewed by Kraemer (2010). Nutriset introduced a 'Usage Agreement' that enables NGOs in many African countries to make the patented paste (Nutriset/IRD, 2010a) and made clear that its patent refers only to Plumpy'Nut®: 'Nutriset and IRD do not … have any patent rights for "RUTFs" as a whole, only for their own innovation. Furthermore, several companies currently offer products … meeting the specifications of RUTFs, without falling within the scope of Nutriset/IRD patents' (Nutriset/IRD, 2010b).

To increase access to high-quality, affordable RUTF, in 2003 Valid International (www.validinternational.org) began to investigate the possibility of local RUTF production and, in 2005, set up Valid Nutrition (VN) (www.validnutrition.org) as a social enterprise with a humanitarian ethos. This was incorporated as a not-for-profit company and registered as a charity in Ireland, to promote and manage the production of RUTF in developing countries. In the same year, Nutriset began a programme named PlumpyField® (www.plumpyfield.com), which licenses producers in developing countries to manufacture and market Plumpy'Nut® locally. In 2011, the PlumpyField® network had 15 members with 12 franchisees in developing countries producing over 11,000 MT of RUTF (Nutriset, 2010–12b).

In 2007, VN signed a licence agreement with Nutriset to enable VN to independently manufacture in developing countries peanut-based RUTF covered by the Nutriset patent. It has established production in a number of countries, either using VN-owned facilities (in Malawi) or in collaboration with local food manufacturers (in Kenya, Ethiopia, and Zambia). Training is provided locally by VN and where possible equipment is locally sourced. Profits from sales are used to expand local production. Other companies that are currently producing RUTF include Compact AS, producing 'eeZee Paste NUT™' at factories in India and Norway (Anon, 2012), Tabatchnick Fine Foods has a nut-based RUTF named 'Nutty Butta' and Challenge Dairy is marketing a milk-based RUTF 'Challenge Dairy RUTF' (Anon, 2010). UNICEF is a major purchaser of RUTF and Komrska (2012) describes the organization's procurement strategy and suppliers.

The potential annual worldwide demand for RUTF is estimated at 250,000 MT

The current potential annual worldwide demand for RUTF to treat severe acute malnutrition is estimated at 250,000 MT, with a value of approximately US$1 bn (25 million cases of SAM, each requiring 10 kg of product at ≈$4), but lack of international donor funds and the limited capacity of many countries to implement CTC at scale, means that currently only a small proportion of this demand is being met. By 2011, 61 countries were implementing CTC/CMAM programmes with almost 2 million cases of SAM being treated (UNICEF, 2012).

Requirements for local RUTF production facilities

It is possible for individual groups to make RUTF for their own use, to be stored for a relatively short period (e.g. 4–6 months). This requires a production room equipped with basic utensils, weighing scales, and an electric mixer, and two storerooms for ingredients and RUTF. The product may be filled by hand into plastic pots and sealed with screw-on lids. The production facilities described below are intended to produce RUTF for long-term (up to two years) storage, distribution, and sales. However, the requirements for quality assurance, hygiene, and sanitation described below apply to all scales of operation.

An RUTF production unit should be constructed to have all the sanitary features that are required for other types of food production. The building should be separated internally into different areas for production and storage, including: ingredient reception, quarantine, and storage; packaging storage; a production room; and RUTF quarantine area and storeroom. Other rooms should be set aside for staff changing room(s) and toilets, and storage for cleaning materials. There should be separate facilities for washing equipment that should not be used for any other purpose. Potable chlorinated water is used for washing equipment and hand-washing and no water is allowed into the sanitary area as it would present a significant hazard to RUTF quality (see Table 2). The ingredient storeroom, production area, and RUTF storeroom are designated as a 'sanitary area' that has specific staff routines and sanitation procedures to minimize the risk of contamination of RUTF. The sanitary area should also be sealed against pests: opening windows and air vents are screened with fine insect mesh; doorways are fitted with close-fitting insect mesh screens and self-closing devices. Insect electrocutors are used to kill airborne insects and traps are located throughout the factory to monitor any activity of rodents and crawling insects.

Equipment

The minimum equipment is a mixer, scales, a filler, and a sealer

The minimum equipment required to produce RUTF is a set of stainless steel or food grade plastic utensils and containers, electronic weighing scales, a mixer, a filler, and a heat sealer. At smaller scales of operation, planetary mixers (Figure 1) can be suitable but horizontal helical mixers (Figure 2) are more efficient and effective at larger scales. Batches of mixed RUTF are pumped to fillers typically using a progressing cavity pump. There are several designs of paste fillers that are suitable for use with RUTF: a vertical form-fill-seal filler is typically used but horizontal form-fill-seal and multi-lane sachet machines are also employed effectively. The layout of equipment should maintain a logical flow of materials around the production room to prevent the risk of contamination of RUTF by incoming ingredients.

Figure 1. Planetary mixer

Figure 2. Horizontal helical mixer

Packing options

Packaging for RUTF has a number of functions:

Field workers calculate the number of packs required for treatment of each malnourished child

- It contains a known quantity of food that enables field workers to calculate the number of packs that are required for treatment of each malnourished child. The calculation is based on the energy content of RUTF and the energy required to be consumed by children according to their body weight. Each 92 g (net weight) sachet contains 500 kCal and each child should receive 200 kCal/kg of body weight/day; hence charts calculating the weekly ration for children at any particular weight are easy to develop and use.
- The pack protects RUTF against contamination by microorganisms, insects, soils, and other contaminants during its expected shelf life. In particular, it is essential to prevent RUTF from picking up moisture from the air or accidental wetting, as this would increase its water activity and potentially allow the growth of pathogenic bacteria.
- The packaging prevents RUTF from coming into contact with atmospheric oxygen, shields it from light, and helps prevent the product temperature from rising excessively, each of which reduces the development of rancidity in the product.

The most suitable types of packaging are laminated or coextruded sachets made from polyester or polypropylene with an aluminium layer in the laminate or a metallized surface on the coextruded film. These materials provide an effective barrier to oxygen, moisture, light, microorganisms, and other contaminants. Sachet film is supplied as pre-printed rolls for use in form-fill-seal machines. The sachets are coded with a batch or lot number and a use-by date. The sachets may be packed into 3–5 ply corrugated cardboard boxes to give protection against damage during storage and distribution. Cartons are printed with the company logo and storage instructions, as well as the batch number and use-by date.

RUTF production

The low water activity prevents growth of spoilage or pathogenic microorganisms during storage

RUTF is a thick paste (≈ 69,000 centipoise / 69 PA s) of solids suspended in oil. It has a pale brown/cream colour, with a sweet taste and the odour and flavour of peanuts and milk. The important characteristic of RUTF is its low moisture content (<2.5 per cent), which produces a low water activity (aw ≈ 0.40–0.45) that prevents the growth of spoilage or pathogenic microorganisms during storage. The shelf life is normally 12 months, after which the development of rancidity may make the product unacceptable, particularly in areas that have high ambient temperatures. If RUTF is packed using

The shelf life is normally 12 months at ambient temperature

a nitrogen atmosphere the shelf life may be increased to two years at ambient temperatures.

RUTF production requires a quality assured supply of vegetable oil, peanut butter, dried milk powder, sugar, and mineral/vitamin premix. In most developing countries, there are local suppliers of oil, sugar, and peanut butter, but dried milk and mineral/vitamin premix may require importation. The crystals in granulated sugar produce a 'gritty' texture in RUTF and sugar may therefore be ground locally using a hammer mill to produce icing sugar, which has smaller crystals that are not detectable on the tongue. If peanut butter is not locally available, peanuts may be ground to a paste in a peanut butter plate mill.

A typical basic formulation for RUTF is shown in Table 1 and its production (Figure 3) has the following steps:

1. Ingredients for the day's production are taken from stock and moved to a weighing area using covered mobile stainless steel or food-grade plastic ingredient bins. At larger scales of operation, oil may be pumped from a storage tank using a metering pump.
2. Ingredients for each batch are weighed into plastic/stainless steel containers and weighed ingredients are transferred to the mixer(s).
3. Ingredients are mixed in a sequence and timing that produces a homogeneous product.
4. The mixed product is pumped to the filling machines.
5. Filled sachets are sealed and marked with a batch code and durability date either as a seal embossed code, ink-jet code or other coding method such as hot foil.
6. Sachets are packed into cartons lined with polyethylene and sealed with tape. Cartons are moved to the RUTF quarantine store until satisfactory analytical results permit distribution.

Table 1. Typical RUTF formulation

Ingredient	*(%)*
Peanut butter	25.0
Vegetable oil	20.0
Dried skimmed milk powder	25.0
Icing sugar	28.0
Mineral/vitamin premix	2.0
Total	100

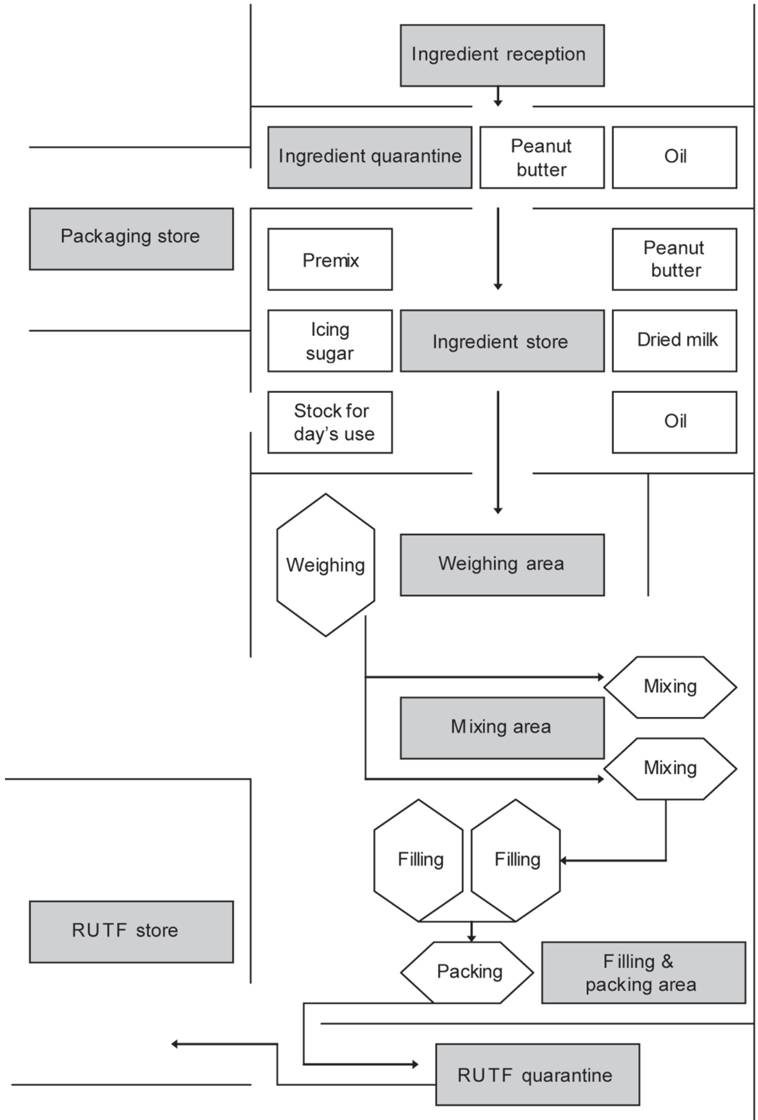

Figure 3. RUTF production flow diagram

Potential hazards are substandard ingredients, incorrect processing or inadequate packaging

Quality assurance

Hazard analysis and critical control points (HACCP)

The potential hazards in RUTF production are associated with sub-standard ingredients, incorrect processing conditions or inadequate packaging.

The required characteristics of RUTF are: 1) that it has the correct nutritional composition to enable severely malnourished children to recover; and 2) that it does not present a microbiological or other hazard to children that would injure them or slow their recovery. The correct nutritional composition of RUTF is determined by the composition of ingredients and the amounts that are mixed together. Analysis of the fat content of peanut butter, which is likely to have the most variable composition, and control over weighing and mixing are therefore important. Oil and peanut butter that contain free fatty acids may also reduce the shelf life of RUTF and produce a rancid taste. Peroxide value analyses of these ingredients are therefore routine components of the QA plan.

Microbiological or other hazards

Of the ingredients, peanut butter presents a potential hazard

Of the ingredients, peanut butter presents a potential health hazard through contamination by pathogenic bacteria from poor hygiene practices or by aflatoxins as a result of mould growth on stored peanuts. The moisture content of peanut butter is also variable and its analysis, together with control over the process, ensures that the moisture content of RUTF remains low. All ingredients may be randomly contaminated with foreign bodies and this is checked as part of process control, as is the seal integrity of packs.

The critical control points (CCPs) in the HACCP plan therefore include chemical and microbiological analyses of peanut butter for aflatoxins, moisture, pathogens, and rancidity; and chemical analysis

Table 2. Typical control measures and critical limits for CCPs in RUTF ingredients

Control measure for hazard	*Target critical limits*	*Corrective action(s) if critical limits not met*
Chemical analysis of oil	Moisture <0.1%	Oil returned to supplier
	Peroxide value <10 mEq O_2/kg	
	Fat 40–55%	Peanut butter blended with other stock to raise/lower fat content or returned to supplier
Chemical analysis of peanut butter	Moisture <2.5% Peroxide value <10 mEq O_2/kg Total aflatoxins <10 µg/kg	Peanut butter returned to supplier
Microbiological analysis of peanut butter	*Salmonella* sp. absent/125 g Coliforms absent/1 g Total viable count <10,000 cfu	Peanut butter returned to supplier

Table 3. Standards for RUTF

Content	*Acceptable level*
Microorganisms	
Clostridium perfringens (cfu/g)	Absent in 1 g
Coliforms (MPN/g)	Absent in 1 g
E. coli (cfu/g)	Absent in 1 g
Listeria sp.	Absent in 25 g
Mesophillic aerobes (cfu/g)	<1,000
Moulds (cfu/g)	<50
Salmonella sp.	Absent in 25 g
Pathogenic staphylococci (cfu/g)	Absent in 1 g
Total viable count (cfu/g)	<10,000
Yeasts (cfu/g)	<10
Cronobacter sakazakii (cfu/10g)	Absent in 10 g
Biochemical component	
Aflatoxin (μg/kg)	<5
Ash (%)	3–4
Fat (%)	26–36
Lipids	45–60% of total energy
Moisture (%)	<2.5
Protein (%)	13–16
Proteins	10–12% of total energy
Total energy value per 100 g (kCal)	520–550
Water activity	<0.6
Vitamins and minerals/100 g	
Biotin	>60 μg
Calcium	300–600 mg
Copper	1.4–1.8 mg
Folic acid	>200 μg
Iodine	70–140 μg
Iron	10–14 mg
Magnesium	80–140 mg
n-3 fatty acids	0.3% to 2.5% of total energy
n-6 fatty acids	3% to 10% of total energy
Niacin	>5.0 mg
Pantothenic acid	>3.0 mg
Phosphorus (excluding phytate)	300–600 mg
Potassium	1,100–1,400 mg
Selenium	20–40 μg
Sodium	<290 mg
Vitamin A (RE)	800–1,100 μg
Vitamin B1	>0.5 mg
Vitamin B12	>1.6 μg
Vitamin B2	>1.6 mg
Vitamin B6	>0.6 mg
Vitamin C	>50 mg
Vitamin D	15–20 μg
Vitamin E	>20 mg
Vitamin K	15–30 μg
Zinc	11–14 mg

Source: UNICEF, 2012

of oil for rancidity. Typical control measures and critical limits are shown in Table 2. Verification of the effectiveness of control systems is primarily through periodic analyses of samples of RUTF.

The control measures are based on ISO 22000:2005 Food Safety Management Systems, CODEX recommended international code of practice – general principles of food hygiene (CAC/RCP 1-1969, Rev. 4-2003), code of hygienic practice for foods for infants and children (CAC/RCP 21-1979), and individual CODEX standards for ingredients (STAN 207-1999 for milk powder, CAC/GL 10-1979 (amended 1991) for mineral salts and vitamins for use in foods for infants and children, STAN 210-2005 for vegetable oils, STAN 200-1995 for peanuts, STAN 212-1999 for sugar) (CODEX, 2012). When correctly produced, RUTF has the composition described in Table 3 (see also Caron, 2012).

Prerequisite programmes (PRPs) and operational prerequisite programmes (OPRPs)

Components of quality assurance that are not part of HACCP are included in prerequisite programmes

Components of the quality assurance programme that are not part of the HACCP scheme are included in PRP/OPRPs. PRPs cover personal hygiene, first-in, first-out (FIFO) stock control, storeroom temperatures, factory and equipment cleaning and maintenance, and pest control. OPRPs cover inspection of ingredients on delivery and before weighing, and monitoring the following aspects of production: ingredient weighing and the accuracy of weighing scales; mixing; contamination of empty packs before filling; fill weights; seal integrity; and examination of RUTF for sensory properties and foreign bodies. Control measures, corrective actions, records, and persons responsible are identified for each component of the PRP/OPRP and written in an operations manual for the processing unit.

Production staff routinely check the quality of ingredients to be used each day by examining their appearance, colour, and odour. Any contaminated or abnormal ingredients are identified and corrective actions taken. The amount of each ingredient in a mix and the mixing time are recorded and checked to ensure that there are no omissions and that the correct weights have been added. Production staff check to ensure that food contact packaging is not contaminated by foreign bodies before filling. Any contaminated or abnormal packaging is identified and removed. Containers are taken at scheduled intervals during filling for fill-weight checking. Under- or over-filling by a specified amount, typically +/-2 per cent from the declared weight, is corrected by adjusting the filler. Production staff check sachets to confirm that seals are correctly formed, and ensure that cardboard distribution cartons are not contaminated by foreign bodies before filling. Cartons are also weight checked on a scheduled basis.

Staff training includes awareness of their roles and responsibilities to protect RUTF from contamination, the importance of personal hygiene, pest control, maintenance of premises and equipment, cleaning and sanitation procedures, and safe storage and handling of cleaning chemicals. Clean-as-you-go procedures are used to deal with any accidental spillages of ingredients or product. A cleaning record details the frequency with which routine cleaning procedures are to be carried out, the method of cleaning, and cleaning agents to be used.

Future developments

The current (2012) price for RUTF is around $3,500–4,500 per MT, depending on the local ingredient and production costs. To reduce the price and facilitate the production of RUTF from locally available crops, VN has investigated the possibilities of using other cereal/legume mixtures in place of peanut butter and milk. A sesame/chickpea/maize product that contains no milk or peanuts has been shown to be efficacious in the treatment of SAM in HIV-positive adults (Bahwere et al., 2009, 2011). Other work includes the development of CTC/CMAM interventions for use in non-emergency contexts, addressing the nutritional needs of people living with HIV/AIDS, expanding local ready-to-use food (RUF) production and developing approaches for addressing chronic malnutrition.

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