



The use of nutrition products for the prevention and treatment of undernutrition

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List of Abbreviations

BRACBangladesh Rural Advancement CommitteeCCTsConditional cash transfersCHDChild health dayCMAMCommunity management of acute malnutritionCSBCorn soya blendDALYDisability-adjusted life years	
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ECHO European Commission Humanitarian Office	
EU European Union	
EAOB Eood Aid Quality Beview	
EBE Eortified blended foods	
FTF Feed the Future	
GAIN Global Alliance to Improve Nutrition	
GDP Gross domestic product	
HIV Human immunodeficiency virus	
IERE Improved fortified blended food	
il iNS The International Linid-based Nutrient Supplements Proje	ct
IEPBI International Food Policy Research Institute	01
IBD Institute of Research for Development	
IVCE Infant and young child feeding	
INS Linid-based nutrient supplements	
MAM Moderate acute malnutrition	
MDG Millennium Development Goal	
MNP Micronutrient nowders	
NGO Non-governmental organisation	
NUGAG Nutrition Guidance Expert Advisory Group	
OFDA Office for Foreign Disaster Assistance	
OBS Oral rehydration salts	
PCI Per capita income	
PIW Pregnant and lactating women	
PPP Public private partnerships	
B&D Besearch and development	
RDA Becommended dietary allowance	
RUSE Beady-to-use supplementary foods	
RUTE Ready-to-use-therapeutic foods	
SAM Severe acute malnutrition	
SUN Scaling up nutrition	
UN United Nations	
UNHCR United Nations High Commissioner for Refugees	
UNICEF United Nations Children Fund	
US United States	
USAID United States Agency for International Development	
WB World Bank	
WFP World Food Programme	
WHO World Health Organisation	
WSB Wheat soya blend	

Executive Summary

A range of nutrition products is increasingly being used to tackle undernutrition, and over the last 10 years the number of products available on the market has multiplied. These include ready-to-use therapeutic foods (RUTFs), ready-to-use supplementary foods (RUSFs), fortified blended foods (FBFs) and micronutrient powders (MNPs). The objectives and composition of the products differ and are referred to generically as 'nutrition products' in this report. While some products are designed to completely replace the normal diet for short periods of time (for example RUTFs used to treat severe acute malnutrition (SAM)), the majority are designed to provide a supplement to the normal diet, based on an estimate of the macronutrient and/or micronutrient gap.

The aim of this technical report is to provide greater clarity on what is known and where the evidence and information gaps are, to help develop clear guidance on the use of, and appropriate areas of support for, nutrition products for governments and other international agencies. The content of the report is based on key informant interviews and literature review.

Impact on nutrition and public health

There is good evidence that RUTFs are effective for the treatment of SAM without medical complications.

There is some evidence that ready-to-use foods (RUTFs and RUSFs) result in improved nutritional status for children with Moderate Acute Malnutrition (MAM) compared standard approaches using Fortified Blended Foods (FBF). However, the formulation of products and the quantities provided to recipients vary between studies, making it difficult to develop an evidence-based protocol for treating MAM with these products.

Ready-to-use foods have been found to have a variable impact on prevention of chronic malnutrition and there is insufficient evidence to demonstrate an impact on micronutrient status. There is evidence that MNPs are effective in reducing iron deficiency anaemia though no impact on stunting or wasting has been demonstrated.

There has been some research showing the potential for increasing birth weight through maternal energy and protein supplementation.

Scale-up of nutrition products to prevent acute and chronic malnutrition and micronutrient deficiencies is dependent on an array of issues including efficacy, costeffectiveness, sustainability, safety and longer-term impacts on health and nutrition. Very little research has been undertaken to examine the broader factors surrounding the use of nutrition products. In particular there are concerns about the potentially adverse effects of nutrition products on breastfeeding practices dietary habits, later obesity and chronic disease, but there is little independent information available.

Research on nutrition products is extremely variable and much of it is been linked to product manufacturers, , raising concerns about conflict of interest. Well-designed large-scale studies to examine the relative impact, cost-effectiveness and acceptability of different nutrition products are required.

Production

The first RUTF (brand name *plumpy'nut*TM) was developed in 1996 through the French public private partnership (PPP) of Nutriset and the Institute of Research for Development. Nutriset and its franchisees are the biggest manufacturers of RUTFs and the growing range of ready-to-use lipid-based nutrient products worldwide. Nutriset has developed a network of local producers (known as franchisees) which has enabled local production and commercialisation of products in developing countries using the brand and protected know-how. These now operate in more than 10 countries.

Nutriset holds a patent for *plumpy'nut*[™], the production process and ingredients, which is valid in 41 countries and expires in 2018. It has also patented all of its RUSF products in the plumpy line and others. Two US companies have challenged the Nutriset patent in court, claiming anti-competitive practices. In October 2010, Nutriset relaxed its patent licensing application process for companies with at least 51% shareholders from developing countries (and up to 49% developed country shareholders), opening the door to production of local versions of LNSs, RUTFs and RUSFs, without the strict plant certification and safety criteria met by its current franchisees.

It was also in 1996 that the first MNP was developed (brand name $sprinkles^{TM}$) and a PPP was developed in 2001 between the Sprinkles Global Health Initiative based out of the Sick Kids Hospital in Toronto, Canada, and the HJ Heinz Company.

Local production in developing countries has the potential of stimulating the local economy, contributing to self-sufficiency and reducing environmental waste. It does not guarantee lower prices, however, largely because of the high cost of some ingredients that have to be imported. There are various initiatives

to develop local production sites and experiment with new formulations for RUTFs. More and more FBF's and MNPs are also being produced in developing countries. Nevertheless, huge challenges remain. Set-up investments are high for updating production sites, equipment, capacity development, monitoring and evaluation mechanisms. Quality control for local production sites is essential because of the need for stringent hygiene and other requirements, but is particularly difficult to maintain in hot, humid environments.

Procurement

Ready to use food products are mainly bought by international agencies and are not widely available for retail purchase directly by consumers. UNICEF is mandated to provide RUTF. Between 2008 and 2010, UNICEF placed approximately 750,000 orders for RUTF, costing around USUS\$40 million and delivered to around 50 countries. WFP is mandated to address moderate acute malnutrition in emergencies but procurement of RUSFs is currently low relative to the large quantity of FBFs purchased.

Composition and standards

Nutrient composition is standardised for RUTFs and for the MNPs delivering the iron and folate content developed for *sprinkles*TM. Nutrient composition has not been set for other nutrition products, however. Setting standard specifications for each nutrition product to specify purpose, standard nutrient composition and appropriate safety and quality controls would allow different companies to offer generic products to meet set generic specifications in terms of ingredients and nutrient profile of the finished product that would differ mainly in terms of price.

Delivery systems

Nutrition products are usually supplied as part of a nutrition-specific intervention. They are delivered through a variety of mechanisms: primary health care and community-based nutrition programmes, social marketing, vouchers and cash transfer programmes. The appropriateness and cost of a delivery system depends on the type of intervention and available infrastructure and capacities.

Health system delivery of products can be successful where there is a wellfunctioning system. There is a risk, however, that health workers become overloaded and prioritise product distribution over other preventative tasks. Communitybased nutrition programmes offer an opportunity for delivering products though integration of programmes, such as the community management of acute malnutrition (CMAM), into government services has been slow, due partly to the very high cost of RUTFs. Key requirements for this form of delivery are high literacy rates, women's empowerment, community organisational capacity and appropriate legislation.

Social marketing models involving PPPs have been used to deliver MNPs, which are bought at a subsidised price through existing commercial channels. Vouchers have the potential to be cost-effective and allow recipients greater choice, although there has been limited delivery of nutrition products. Cash transfer programmes frequently include health conditionalities and some include nutrition products. The impact on stunting of transfer programmes has been mixed but nutritional products appear to enhance nutritional results..

Cost and cost-effectiveness of different interventions

The WHO criterion for cost-effectiveness was used: interventions that can save a disability adjusted life year (DALY) for under US\$400 are considered cost-effective. The most cost-effective direct nutrition interventions are breastfeeding promotion, vitamin A supplementation and distribution of MNPs at a cost of less than US\$12 per DALY. The cost effectiveness of these interventions is comparable to priority child health interventions such as immunization, and treatment of pneumonia and diarrhoea. RUTFs for treatment of SAM, are also relatively cost-effective due to the precise targeting of children with SAM. Iron-folate supplements for pregnant women are also cost-effective at a cost per DALY of US \$66-\$115. There is limited data on the cost-effectiveness of RUSFs and FBFs.

Policies, strategies and operational guidance

Nutritional products are being developed fast. Policy-makers are lagging behind; there is no consensus on the use of nutrition products and guidance on their use. There are also strong polarized views about their use within the development community. To move the debate forward, this report recommends the need to develop consensus and guidance based on sound evidence.

The absence of international guidance and an agreed strategic framework is causing confusion in programmes with different agencies following different protocols. While there are UN endorsed statements on the use of RUTFs within CMAM programmes and the provision of MNPs for women and young children in emergencies, there is no guidance on the use MNPs in non-emergency situations, or on the role of nutrition products in the prevention or treatment of MAM.

The majority of stakeholders interviewed as part of this review expressed the view that initiatives to tackle undernutrition should focus on 'progammes' and not on 'products'. The consensus is that there is no 'magic bullet' solution and it is essential

to concentrate on how nutrition products can add value to existing programmes in a cost-effective manner without causing harm. Comprehensive nutrition strategies, which emphasize investment in many sectors, are needed to address chronic long-term undernutrition.

Public and private sector roles in marketing nutrition products

Market trends indicate a strong growth in sales of manufactured food in developing countries where three quarters of the world's consumers live. There is also a growing demand for nutrition products to address undernutrition in children but the potential market is relatively small. It is estimated at around US\$200 million compared to the US\$25 billion dietary supplement market in the US. The market has been supplier driven, with dominance by one company and its worldwide franchise model. Sales are limited to a small number of large volume institutional buyers.

The private sector is best placed to evaluate the potential of the global nutrition products market: what products are possible to produce; the potential returns on research and development (R&D) and risk of investment weighed against the potential profits. It is yet to be seen, whether there is a commercial incentive for manufacturers to develop and manufacture preventative nutrition products at prices low enough to attract low income retail consumers.

The commercial development of food products for the public good is being accomplished through a variety of partnerships. Some PPPs advance the science and evidence base, while others concentrate on product R&D and marketing affordable nutritional products for low income consumers.

Current issues in relation to future market development are linked to government bureaucracy, sustainability and patents. Key issues which will also need to be addressed include consumer demand and acceptability, packaging requirements (particularly distribution of small quantities), distribution mechanisms (through public or private channels) and marketing (whether as food or medicine).

Finally, it is important to plan for the entry of baby food, drink and snack food companies into the nutrient product market. As the marketplace expands beyond treatment of SAM and MAM into prevention of undernutrition, it will be important to make sure the pitfalls of the way in which infant formula has been marketed are avoided. Here, it is recommended that the role of the international bodies and agencies will need to provide leadership and guidelines for corporate responsibility.

The way forward

There are a number of areas in which it is recommended that development partners and international agencies could focus future attention and resources.

1. Investment in research

A more robust evidence base is required for:

- (a) Alternative strategies to address MAM, chronic malnutrition, maternal malnutrition and low birth weight (with or without nutrition products) in different settings and in a sustainable manner.
- (b) Efficacy and effectiveness of different nutrition products on nutrition outcomes (acute malnutrition, chronic malnutrition and micronutrient status) in diverse contexts. Potentially adverse effects of nutrition products (IYCF, later obesity and chronic disease, dietary habits) among different populations. Operational implications (sustainability, acceptability, cost-effectiveness) of nutrition products for different purposes and among different populations.

2. Development of international guidance

- (a) Support for development of internationally accepted operational guidance regulating the use of nutrition products by galvanising key UN agencies
- (b) Set interim guidance programme advisers to allow them to take decisions with regard to the use of nutrition products on a case by case basis.
- (c) Support development of guidance on operational research methods to ensure that future evidence reaches minimum quality standards

3. Support engagement with the food industry

- (a) Support constructive engagement with the food industry. There are three areas which especially require promotion:
 - (i) Development of nutrition products with set nutrient contents and defined objectives
 - (ii) Development of transparent harmonised international procurement and quality assurance standards.
 - (iii) Development of guiding principles and a framework for how to engage responsibly with the private sector.
- (b) Engage with national governments to bring together key people from several sector ministries to help set in place policies that will attract private sector investment.

4. Support local production of nutrition products

(a) Consider funding the setting up of local production sites for RUTF and MNPs for use in emergency-prone regions.

Definitions

Cost-effectiveness: This type of analysis aims to inform policy-makers and decision-makers on the economic attractiveness (or returns on investment) of interventions to reduce disease-related mortality and morbidity. The cost-effectiveness of a given intervention is typically expressed as costs per unit of effectiveness, with costs measured in monetary terms and effectiveness measured in years of life saved or gained.

DALY: The impact of an intervention on the quality of life (morbidity) and length of life (mortality) of a population is measured and expressed as a single number: the disability adjusted life year or DALY which is the sum of years of potential life lost due to premature mortality and the years of productive life lost due to disability and morbidity.

Fortified blended food: In our report, this refers to corn and wheat soya blends widely used by WFP, USAID, and others in feeding programmes. Two improved fortified blended foods (IFBFs) have recently been developed: CSB_+ which has a different micronutrient profile and is suitable for older children, pregnant and lactating women; CSB_{++} which has an improved micronutrient profile (particularly for type II nutrients), better protein quality by addition of 8% milk powder, dehulling of soya (less fibre), higher fat content and tighter microbiological specifications; CSB_{++} is suitable for younger children. Other FBFs programmed in food aid include soya fortified sorghum grits, soya fortified maize meal, soya fortified bulgur wheat and soya fortified wheat flour.

Generic brands: These are consumer products or drugs which are produced and distributed without a brand name or patent protection. They are generally cheaper than branded products produced for the same purposes.

Lipid-based nutrient supplements: This refers generically to a range of nutrient and calorie-dense, fortified, lipid-based supplementary food products, including ready-to-use supplements, both therapeutic and supplementary (RUTF and RUSF). LNS also include brand name ready to use supplements such as nutributter^{TM.}

Moderate acute malnutrition: A measure of moderate 'wasting' reflecting short-term undernutrition. It is a weight-for-height measurement of 80% or less below the median or two standard deviations or more below the mean international reference values, the presence of bilateral pitting oedema, or a mid-upper arm circumference of less than 125 millimetres in children 6-60 months old¹. For pregnant and lactating women it is a Body Mass Index (BMI) of less than 18 kg/m2 or MUAC of less than 190mm.

Nutritional products: There is no agreed generic name for the range of food products including ready-to-use therapeutic foods (RUTFs), ready-to-use supplementary foods (RUSFs), fortified blended foods (FBFs) and micronutrient powders (MNPs) and products. In this report the term 'nutritional products' is adopted to refer to these foods.

Public private partnership: A public-private partnership brings public and private sectors together in partnership for mutual benefit. The term public-private partnership covers a wide range of different partnerships, including the introduction of private sector ownership into businesses that are currently state-owned, the Private Finance Initiative, and selling Government services into wider markets

Severe acute malnutrition: A measure of severe 'wasting' reflecting short-term undernutrition. It is a weight-for-height measurement of 70% or less below the median or three standard deviations or more below the mean international reference values, the presence of bilateral pitting oedema, or a mid-upper arm circumference of less than 115 millimetres in children 6-60 months old1. For pregnant and lactating women, it is a BMI of less than 16 kg/m2 or MUAC less then 170mm.

Stunting: When a child has low stature compared to other children of his age because of inadequate nutrition, care, and environment. It is a proxy measure for long-term malnutrition defined as less than two standard deviations below the median (minus 2 z-scores) or 80 percent or less of the median. When stunting is the result of undernutrition the impact is permanent once the child has reach 2-3 years of age. This decreases the child's productivity and negatively impacts on their health for life.

Undernutrition: When the body contains lower than normal amounts of one or more nutrients, i.e. deficiencies in macronutrients and/or micronutrients. Undernutrition encompasses stunting, wasting and deficiencies of essential vitamins and minerals (collectively referred to as micronutrients)². Undernutrition is also indicated by clinical

¹ WHO/UNICEF (2009) WHO child growth standards and the identification of severe acute malnutrition in infants and children – A Joint Statement by the World Health Organization and the United Nations Children's Fund: Geneva.

² Black, RE; Allen, LD; A Bhutta, ZG; Caulfield, LE; De Onis, M; Ezzati, M; Mathers, C; Rivera, J. (2008) for the Maternal and Child Undernutrition Study Group *Maternal and child undernutrition: global and regional exposures and health consequences.* The Lancet, Vol 371, February 2, 2008.

signs (e.g. bilateral oedema, goitre for iodine deficiency) or biochemical indices (e.g. haemoglobin level for iron deficiency anaemia).

Note: Brand names for nutrition products are denoted by *italics* and $^{\text{TM}}$

Introduction

1.1 Background

A range of nutrition products is increasingly being used to tackle undernutrition. Over the last 10 years there has been a significant increase in the number of products available on the market. These nutrition products include Ready-to-use foods (both therapeutic and supplementary), micronutrient powders (MNP), and products which require additional preparation including Fortified Blended Foods (FBF). The objectives and composition of these differ and are referred to generically as 'nutrition products' in this report. While some products are designed to completely replace the normal diet for short periods of time (for example RUTF used to treat severe acute malnutrition), the majority are designed to provide a supplement to the normal diet, based on an estimate of the macronutrient and/or micronutrient gap.

The use of RUTF for the treatment of severe acute malnutrition (SAM) is largely uncontroversial in emergency settings when reliance on external assistance is common. However, their use in the treatment of SAM and moderate acute malnutrition (MAM) in non-emergency settings has been challenged, most notably in India (see *Annex 4*). There is concern about the promotion of imported, manufactured and expensive products for tackling such a widespread problem. Additional questions arise in relation to the use of nutrition products designed mainly for consumption by young children in development and emergency settings for prevention of undernutrition.

DFID is increasingly being asked to support programmes which include the use of nutrition products. This technical report deals specifically with nutrition products targeted at addressing undernutrition from conception to 24 months of age. It discusses a range of issues relating to their use:

These cover:

- 1. Context: the increased focus and use of nutrition products, types and classification of nutrition products;
- 2. Impact: evidence for impact on nutrition and public health in terms of efficacy and effectiveness, longer-term and potentially adverse impacts;
- 3. Production: manufacture, availability and procurement, issues around imported nutrition products and local production;
- 4. Delivery systems: through the health system, community nutrition programmes and social marketing, voucher and conditional transfer programmes;
- Cost and cost-effectiveness: evidence on costs and cost-effectiveness of different nutrition interventions including nutrition products for addressing micronutrient deficiencies, SAM and MAM in children and undernutrition in pregnant and lactating women (PLW);
- 6. Policies, strategies and operational guidance: agency positions, development of guidelines and systematic reviews of the evidence;
- 7. Public and private sector roles in marketing nutrition products;
- 8. Future priorities

1.2 Objective

The overall objective of this report is to provide greater clarity on what is and is not known about the use of nutrition products. It also describes the information and evidence gaps which need to be filled in order to; a) develop clear guidance on the use of nutrition products and b) areas where further research is required.

1.3 Methods

A team of Consultants compiled this report over a 30 day period. The following methods were used:

- **Interviews** with 23 key informants from a range of international agencies (see acknowledgements). The interviews were semi-structured based on a set of questions contained in *Annex 1*. All those interviewed were sent notes of their interview and invited to amend or add comments to ensure accuracy.³
- Literature searches were performed for relevant documentation on effectiveness and cost-effectiveness of nutrition products, delivery systems, and production of the products using a variety of sources; the peer-review literature (Pubmed and Google scholar), the grey literature published by commercial food companies, USAID, NGOs, UNICEF and WHO on their websites. The search included articles published from 1990 onwards.

1.4 Limitations

The report represents a general overview of nutrition products rather than an in-depth study. It is based on published documentation and the views of a selected group of key informants from international agencies. It was not possible to interview some key informants due to time constraints. There was also very limited country-level input into the report.

The review was also limited in scope, as it only looked at nutrition products targeted at pregnant women and young children, rather than the general population.

³ Unattributed quotations contained in this report come from key informant interviews.

Context

2.1 The scale of undernutrition

Undernutrition affects large numbers of children (see *Box 1*) particularly in sub-Saharan Africa and South Asia. Chronic malnutrition is most prevalent and affects 1 in 3 children under the age of 5. Acute malnutrition affects fewer children (63 million compared to 195 million who are chronically malnourished) but over one third have Severe Acute Malnutrition (SAM) and require immediate medical care⁴. Deficiencies of vitamin A, iron, iodine, zinc and folate are known to be highly prevalent and have important adverse consequences in young children. Progress has been made in reducing the prevalence of iodine and vitamin A deficiencies through improved household use of iodized salt and the provision of high-dose vitamin A supplements to young children and lactating women. There has been limited success in reducing the burden of other micronutrient deficiencies, particularly iron deficiency anaemia.

The inter-generational effects of undernutrition are well described. Children born from mothers who are short (less than 145 cm) have a 40% increased risk of mortality and 70% higher risk of being stunted than children born to taller women⁵.



Box 1: Numbers of children affected by undernutrition

Source: UNICEF: 2009, Tracking Progress on Child and Maternal Nutrition – A survival and development priority, New York.

2.2 Increased focus on nutrition products

The impetus to include nutritional products as an integral approach to addressing undernutrition has come from a number of directions:

 frustration with the lack of progress in combating undernutrition both in development and emergency situations

⁴ UNICEF. (2009) Tracking Progress on Child and Maternal Nutrition. UNICEF New York

⁵ Ozaltin E. *et al.* (2010) Association of maternal stature with offspring mortality, underweight, and stunting in low- to middle-income countries JAMA vol 303(15) pp. 1507-16

- advances in nutrition technologies that has led to an increase in the number of ready to use products available, and
- the expansion of food manufacturers and markets in developing countries and greater opportunities for public-private partnership.

2.3 Failure to combat undernutrition

Each year 3.5 million children under-five years of age die as a consequence of undernutrition⁶ while 54 countries (out of a total of 117 countries with available data) have either made insufficient or no progress in achieving the Millennium Development Goal 1 (MDG 1) target of a 50% reduction of underweight prevalence among children under-five years of age between 1990 and 2015⁷.

Traditional responses to undernutrition have had limited impact in some countries. There are a host of reasons for this including poor governance, the low priority given to nutrition, failure to scale up interventions known to be effective, and the impact of global issues such as climate change and economic recession. In many low-income countries, children's growth starts to falter around 6 months. Nutrient (macro and micronutrient) demands increase but household foods are often unable to meet the requirements for growth. This is usually because there is not sufficient food in the home, the caregiver is unaware of what foods a child needs, and/or diets are not sufficiently diverse due to problems of food access and availability. This, combined with frequent infections, can cause a failure to grow.

After a certain age undernourished children are unable to 'catch-up' and remain permanently stunted. These children do less well at school and have lower incomes as adults. Women who were undernourished as children are more likely to have complications during childbirth and to deliver low birth weight babies who, in turn, often grow up to be stunted. It has been shown that the period from conception to 24 months is when chronic malnutrition can be prevented most effectively and as such has been identified as the 'window of opportunity' for investment in nutrition. One area where there has been particularly limited progress is in improving complementary feeding for children aged 6-24 months. A systematic review concluded that improved growth during this period can be best achieved by combining fortified foods or home-fortification products with educational messages⁸.

In emergency contexts, prevalence of undernutrition (in the form of SAM and MAM) can increase rapidly despite large-scale responses, as witnessed in Niger during 2010 (see *Box 9*). General food rations currently provided in emergency settings (generally comprisin a cereal, pulses, oil, sugar, salt and a FBF) are often not designed to meet the nutritional needs of infants and young children⁹. Productary feeding programmes that are targeted at children (primarily those with MAM) have had very mixed results¹⁰. The lack of progress in addressing undernutrition in food

⁶ Black, R; Allen, LH; Bhutta, Z; Caulfield, L; de Onis, M; Ezzati, M. (2008) Maternal and child undernutrition 1 - *Maternal and child undernutrition: global and regional exposures and health consequences.* Lancet 2008; 371(9608):243-260

⁷ **United Nations Children's Fund**. (2009) *Tracking Progress on Child and Maternal Nutrition: A survival and development priority*. UNICEF, New York, November 2009.

⁸ **Dewey, K; Adu-Afarwuah, S,** (2008) *Systematic review of the efficacy and effectiveness of complementary feeding interventions in developing countries.* Blackwell Publishing Ltd. Maternal and Child Nutrition, 4, pp. 24–85

 ⁹ Chaparro, C; Dewey, K. (2009) Use of Lipid-based Nutrient Supplements (LNS) to Improve the Nutrient Adequacy of General Food Distribution Rations for Vulnerable Sub-groups in Emergency Settings. Prepared for the Inter-Agency Standing Committee Global Nutrition Cluster. July 2009
 ¹⁰ Navarro-Colorado, C; Mason, F; Shoham, J. (2008) Measuring the effectiveness of Supplementary Feeding Programmes in emergencies. HPN Network Paper No. 63, September 2008 ODI.

insecure and emergency contexts has driven the search for appropriate alternative solutions.

2.4 Technological developments

Advances in food technology have led to the formulation of new nutrition products. In the mid 1990s, two new products came into use; $sprinkles^{TM}$ and $plumpy'nut^{TM}$.

Sprinkles[™] was developed principally as a new method of iron delivery which overcame many of the side effects and disadvantages of iron drops. Sachets containing powders to sprinkle onto a young child's meal to deliver iron or a number of micronutrients in one go. The lipid encapsulation of the iron was an improvement that prevented interaction with food, thereby avoiding changes to colour, taste or texture. Shelf life is 2 years.

*Plumpy'nut*TM, inspired by the popular *nutella*TM spread, was designed as an RUTF to enable children with SAM to be treated in the home. Until the invention of *plumpy'nut*TM, all cases of SAM had to be treated as in-patients because the therapeutic milks used (F75 and F100) require careful preparation with water and refrigeration. The RUTF was formulated to deliver the nutrient profile of F100 in a peanut-based paste to reduce the possibility of contamination. It requires no water for preparation, does not need to be refrigerated and has a 2-year shelf life, making it easy to deploy in difficult conditions. MSF, for example, claims that in 2010, it will treat more children with acute malnutrition than the total number of children treated between 1971 and 2005 before RUTFs were developed¹¹.

Since *sprinkles*TM and *plumpy'nut*TM many additional products have been developed. *Plumpy'nut*TM seeded the market for a generation of lipid-based nutrient supplements (LNS) now produced in a number of countries – all various types of Ready to Use Supplementary Foods. These have a variety of nutrient compositions with a range of different uses. The products have been developed to treat or prevent MAM, as a nutrient-dense supplement to complementary foods for breastfeeding infants and young children. The products also have other nutrition-related objectives for different target groups and settings, e.g. in emergencies, as "food by prescription" to accompany medicine for people with HIV/AIDS, and for pregnant and lactating women.

Technological developments have been supported by specialists and stimulated by an increasing interest in finding solutions to the problems of the developing world through innovative and appropriate technology. One of 15-guiding principles of the Gates Foundation, for example, is that science and technology have great potential to improve lives around the world. A major recipient of Gates funds is the Global Alliance to Improve Nutrition (GAIN) which invests heavily in support for food technologies, including fortification and new nutrition products.

2.5 Expansion of new market opportunities and public-private partnerships

The growth of the middle classes in developing countries has provided new market opportunities for multi-national companies. The increase in the number of consumers, albeit with limited resources means that companies have to respond with products at prices that are attractive and affordable to low-income customers. This has implications for the 'snack' and 'baby-food' market as illustrated by the case of Nestlé (see *Box 2*).

¹¹ **Doyon, S.** (2010) (personal communication) 6th August 2010

The relationship between the private and public sector in delivering services to poor people in developing countries raises a number of ethical issues. Public health motives and profit motives may be difficult to reconcile in the area of food and nutrition. There has been a long history of criticism of the food industry with respect to the marketing of baby foods.

Nevertheless, PPPs provide new opportunities for addressing global undernutrition more effectively. The fact that the food industry is successfully expanding its markets among poor consumers has opened the door to the potential of partnerships with private companies to deliver nutrition solutions. For example the United States Agency for International Development (USAID) has expanded its Global Development Alliance (GDA) approach which involves PPPs in a variety of sectors. In its first 10 years, it has fostered successful partnerships between universities, food companies and food trade associations to develop local commercial food sector solutions. The US Government signature food security programme, Feed the Future (FTF), which encompasses the "whole of government" approach, is encouraging new country FTF initiatives to identify and develop PPPs to lay the foundation for sustainable food and nutrition security approaches over the long term. FTF initiatives promote agriculture-led economic development, with a strong focus on gender and improving childhood nutrition from conception to 24 months of age.

Box 2: Nestlé

Nestlé has operations in almost every country in the world with the core aim of enhancing "the quality of consumers' lives every day, everywhere by offering tastier and healthier food and beverage choices and encouraging a healthy lifestyle". The company is expanding operations in East, Central and Southern Africa where it will invest US\$138.32 million over the next three years to enhance its competitiveness in the food industry. "With 400 million people and an emerging middle-class and ever-rising purchasing power, this region has major potential for Nestlé products," Nestlé Chief Executive Officer Paul Bulcke.

Nestlé remains the most boycotted company in the UK because of its marketing of baby milk substitutes in developing countries. Groups committed to protecting breastfeeding strongly condemn the activities of Nestlé claiming that it continues to violate the International Code of Marketing of Breastmilk Substitutes. Despite 14 revisions of the Code since 1981, the long-standing opposition between food companies, such a Nestlé, and activist groups remains.

Sources: <u>www.babymilkaction.org</u> London 22 June 2010 www.<u>AllAfrica.com</u> Nairobi 19 July 2010 www.Nestle.com

Much of the research into nutrition products has been done with private sector support (i.e. financed in large part by the company manufacturing the products being tested). While this raises issues about conflict of interest (discussed in more detail below), it illustrates a willingness on the part of food companies to engage with the development and humanitarian community.

2.6 The role of nutrition products in tackling undernutrition

This chapter provides an overview of the range of interventions that are commonly implemented to address undernutrition and outlines where nutrition products fit within the range of programming options. Responses can be divided into nutrition-specific interventions that are targeted at the immediate causes of undernutrition (inadequate dietary intake and disease), and nutrition-focused development which addresses the underlying and basic causes of undernutrition¹².

There is strong evidence that there are a number of nutrition-specific interventions that are effective in addressing undernutrition during the critical window from conception to two years of age¹³.. Evidence for the effect of nutrition-focused development is less consistent and there has been slower progress in developing an evidence base for these approaches. Interventions include: social protection; food security and agricultural interventions; water, sanitation and hygiene; and women's empowerment.

Nutrition products are generally linked to the delivery of nutrition-specific interventions through the health system. *Box 3* lists the nutrition-specific interventions commonly used to address undernutrition. Only interventions that are targeted at pregnant women and young children are included. Interventions for the general population (such as food fortification) have not been included. Nutrition products that are currently being used or considered for use within a particular intervention are included in the bottom row.

 ¹² DFID (2010) The neglected crisis of undernutrition: DFID's strategy. UKaid:. London
 ¹³ Bhutta, ZA; Ahmed, T; Black, RE; Cousens, S; Dewey, K; Giugliani, E; Haider, BA;
 Kirkwood, B; Morris, SS; Sachdev, HPS; Shekar, M. (2008) for the Maternal and Child
 Undernutrition Study Group What works? Interventions for maternal and child undernutrition and survival. The Lancet, Vol 371, February 2, 2008

Treatment of severe acute malnutrition	Treatment of moderate acute malnutrition	Prevention of malnutrition and/or micronutrient deficiencies	
Target Groups			
Children 0-59 months	Children 6 – 59 months	Children 6-59 months Pregnant Women	
Nutrition-specific Interver	ntions to address undernutrition	on in children and women	
Inpatient, outpatient and community management of severe (and sometimes moderate) malnutrition	Supplementary feeding (targeted or blanket)	 Periodic vitamin A supplements for diarrhoea management Iodized oil capsules where iodized salt is unavailable De-worming drugs Multiple micronutrient powders Iron-Folic acid supplements for pregnant women Protein/energy supplements for pregnant women 	
Nutritional products			
Ready to Use Therapeutic Foods such as p <i>lumpy'nut™</i> Products that require additional preparation: F75 and F100 used in in-patient care	Ready to Use Supplementary Foods such as . <i>plumpy'doz™</i> <i>Products that require</i> <i>additional preparation:</i> Fortified Blended Foods	Micronutrient powders (MNPs) used as a dietary supplement such as (e.g. <i>sprinkles™) or</i> Ready to Use Supplementary Foods including lipid-based nutrient supplements (e.g. <i>nutributter™</i> <i>Products that require</i> <i>additional preparation:</i> Fortified Blended Foods used as dietary supplement in emergencies	

Box 3: The role of nutrition products within direct interventions to address undernutrition in pregnant women & young children

2.7 Types and classification of nutrition products

Overview of nutrition products currently in use or under development

The nutrition products currently available for use in emergency or development contexts to address undernutrition can be categorized as:

- Ready-to-use products (therapeutic RUTF & supplementary- RUSF)
- Micronutrient products
- Nutrition products that require additional preparation

Ready-to-use products

Ready-to-use products are designed to be consumed directly and do not require preparation. They include lipid-based nutrient supplements (e.g. nutributterTM) and ready-to-eat biscuits. Ready-to-use products can be divided into two groups: Ready-to-use therapeutic foods (RUTFs) and and Ready-to-use supplementary foods.

- RUTFs are foods specially developed for the treatment of children over 6 months with SAM and replace the existing diet (except for breastfed children who should continue breastfeeding).
- RUSFs are developed to supplement the usual diet, and used for the prevention and treatment of MAM and micronutrient deficiencies. As RUSFs tend to be sweet they are not generally mixed with the food eaten by the household.

Micronutrient products

Micronutrient products include micronutrient powders (MNPs), such as *sprinkles*TM which are added to meals. They provide micronutrients but no additional calories and are likely to be compatible with meals eaten at home. MNPs are classified separately from ready-to-use products, even though they do not require preparation, because they are mixed with the normal diet.

Micronutrients are also added to oral rehydration salts (e.g. zinc) and to sweets. For example, in 2006, the Micronutrient Initiative launched a joint venture with a local manufacturer in Bihar, India to produce a fortified lozenge, called "nutri-candy." The lozenges come in various flavours and colours and deliver about 50% of the recommended daily allowances (RDA) for Indian children of vitamin A, vitamin C, folic acid and iron.

Nutrition products that require additional preparation

The nutrition products that require home preparation include therapeutic milks and fortified blended foods.

New fortified forms of Corn Soya Blend (CSB+ and CSB++) have recently been developed by the World Food Programme. CSB+ is CSB with an enhanced micronutrient profile and is rapidly replacing standard CSB. CSB++ is CSB+ with dairy protein and other compositional improvements for higher nutritional needs .By end of 2010 WFP intends to use CBS++ for the treatment of MAM.

Classification of nutrition products according to use

The three categories of nutrition products can be classified according to their intended use. *Box 4* illustrates the classification of ready-to-use products and *Box 5* illustrates the classification of micronutrient powders and products that require preparation for the following uses:¹⁴

- Treatment of SAM
- Treatment of MAM
- Prevention of undernutrition (chronic or acute) and/or micronutrient deficiencies
- Other uses (general nutrition support for emergency-affected populations, nutritional support for pregnant and lactating women or for individuals affected by HIV and AIDS)

The boxes illustrate the range of nutrition products available. Examples of branded products have been included that are targeted at children under two years and pregnant and lactating women. There are additional products such as *Ultra RiceTM* and *Ying Yang BaoTM* that are not specifically targeted at these groups and therefore not discussed in detail in this report.

Classification of products according to use is not straightforward. There are a growing number of products, with various uses and some are classified for several uses. For example, RUTFs originally developed for the treatment of SAM are being used for the treatment of MAM. Detailed specifications for these nutrition products can be found in *Annex 2*.



Box 4: Classification of ready-to-use products by objective

¹⁴ The layout of *Annexes 4* and *5* was inspired by the Save the Children product overview produced by Caroline Tanner. Product specification for most of the items featured in the Boxs is given in *annex 2*.

Treatment of severe acute malnutrition	Treatment/prevention of moderate acute malnutrition	Prevention of malnutrition and/or micronutrient deficiencies	General nutritional support including for PLW and those with HIV/AIDS
F-75			
• F-100	•FBF (CSB/WSB/UNIMIX)	FBF/IFBF/IFBF plus	• FBF
• F-75	•IFBF (CSB+/WSB+)	• MNPs (Sprinkles, MixMe)	•IFBF
	 IFBF plus (CSB++) 	• TopNutri	• IFBF plus
		• MixMe plus	• NutrRice
		• QBmix	
Proven to be efficacious and/or effective for this purpose?			
Yes—included as part of WHO guidelines for in-patient care of severe acute malnutrition	Evidence that FBFs can promote recovery from MAM. No published studies to date for IFBFs.	No evidence for impact on FBFs on growth but shown to be effective for reducing micronutrient deficiencies. MNPs shown to be efficacious.	FBFs shown to be effective for reducing micronutrient deficiencies. No studies published for NutriFice.
Current use and location of production			
Widesprood	Widespread – all FBFs available from 2010 onward will be IFBFs Production of IFBF plus has been slow but will be available from mid-2010 onwards	Widespread	Widespread Availability of NutriRice is not clear at present

Box 5: Classification of micronutrient products that require additional preparation by objective

Extent of nutrition product use

It is difficult to identify where nutrition products are currently being distributed, by whom and for what purpose. In general, RUTFs for treatment of SAM are widely distributed in Africa and but less so in Asia. MNPs have been widely distributed in Asia but not in Africa, due to concerns about providing iron supplements in malaria endemic areas. RUSFs have been distributed on a mass scale in some emergency contexts, for example Niger, but only on a small scale in other countries. FBFs are currently distributed by WFP in most of their countries of operation, 90% of which are emergencies, (which encompass protracted, relief and rehabilitation situations)¹⁵

2.8 Conclusions

Over a relatively short time (15 years), since the first nutrition products aiming to address malnutrition were developed, there has been a significant increase in the number of products available. This expanision has largely been unregulated. The lack of information about the nutrient contents and objectives of the products makes comprehensive classification difficult. There is also an absence of available information about the extent of their use. It appears that nutrition products are being used more widely used in an expanding number of countries there is regional variation.

¹⁵ **WFP** (2010) *Fighting Hunger Worldwide*: WFP annual report 2010.

Impact on nutrition and public health

3.1 Evidence of efficacy and effectiveness of nutrition products

Treatment of severe acute malnutrition

The most substantial evidence-base for nutrition products included in this review is for RUTFs (studies have mainly used *plumpy'nutTM*). RUTFs have been proven to be efficacious for the treatment of SAM without medical complications¹⁶. RUTF was endorsed for this use by the WHO, UNICEF, WFP and the UN Standing Committee on Nutrition in 2007¹⁷.

F-75 and F-100 therapeutic milks have proven efficacious for in-patient treatment of SAM (both with and without medical complications) and are a standard treatment as outlined in the WHO protocol for treatment of SAM.

Treatment of moderate acute malnutrition

There are few published studies that have tested the effectiveness of nutrition products that are used for the treatment of MAM. The majority of efficacy studies have compared one product with another.

FBFs compared to RUSFs

A review done by de Pee and Bloem in 2009 noted that agencies that treat MAM are currently using a wide range of nutritional products¹⁸. These include FBFs (plus oil and sugar), BP5 biscuits, and Lipid based nutrient supplements. Several programmes use locally-produced fortified food products. It has been acknowledged that FBF-based treatments might not be most effective for treating MAM because they are relatively low in energy¹⁹ and often shared among the family. There is a lack of empirical evidence on the extent of sharing and how this impacts on treatment.

A number of studies have compared lipid-based ready-to-use foods with FBFs for the treatment of MAM. Maleta *et al.* found that children with MAM recovered as well when given a lipid-based ready-to-use food as those who were given an FBF-based product²⁰. Adherence in both intervention arms was relatively poor however. Matilsky *et al.* compared a standard FBF-based treatment for MAM with a milk/peanut RUSF and a soy/peanut RUSF among MAM children in Malawi²¹. Children given the RUSFs had a higher recovery rate than children given the FBF and gained more weight in the first two weeks. There was no difference in length gain between the groups and

¹⁶ WHO/UNICEF/WFP/SCN (2007): Community based management of

severe acute malnutrition. Joint Statement May 2007.

¹⁷ WHO/UNICEF/WFP/SCN (2007): *Community based management of severe acute malnutrition*. Joint Statement May 2007.

¹⁸ De Pee, S, Bloem, MW. (2009) Current and potential role of specially formulated foods and food supplements for preventing malnutrition among 6 to 23-month-old children and for treating moderate malnutrition among 6 to 59 month-old children. Food and Nutrition Bulletin, 30 (supplement) ¹⁹ WFP/UNICEF/WHO (2010) Joint position with regard to the management of moderate malnutrition,

using improved formulations of fortified blended foods. Letter to Director ECHO, March 2010. ²⁰ Maleta K, Kuittinen J, Duggan MB, Briend A, Manary M, Wales J, Kulmala T, Ashorn P. (2004)

²⁰ Maleta K, Kuittinen J, Duggan MB, Briend A, Manary M, Wales J, Kulmala T, Ashorn P. (2004) Supplementary feeding of underweight, stunted Malawian children with a ready-to-use food. J Pediatr Gastroenterol Nutr. 2004 Feb; 38(2):152-8.

²¹ Matilsky DK, Maleta K, Castleman T, Manary MJ. (2009) Supplementary feeding with fortified spreads results in higher recovery rates than with a corn/soy blend in moderately wasted children. J Nutr. Apr;139(4):773-8

there was no difference in outcomes between the groups receiving the milk or the soy-based RUSF.

FBFs compared to RUTFs

Ciliberto *et al.* compared the recovery of children in Malawi with MAM when given RUTF versus a standard FBF-based treatment²². The authors noted that children given the RUTF gained more weight and had better health outcomes than those on the standard treatment for MAM. Nackers *et al.* compared provision of RUTF (*plumpy'nut*TM) for treatment of MAM with a standard FBF(plus oil and sugar) among children in Niger²³. Children given RUTF gained significantly more weight, spent less time in the programme and more recovered compared with those given the FBF. There was no significant difference in mid-upper arm circumference gain, haemoglobin, height gain or height-for-age z-score between the groups.

Summary

There is some evidence that ready-to-use foods result in better outcomes for children with MAM than the standard FBF-based approaches, though this has not always been found. Further research is warranted and ongoing. The formulation of products and the quantities given varied in the different studies and hence it is difficult to develop an evidence-based protocol for treating MAM with these products. Although the IFBFs with added milk powder have been designed specifically to treat MAM, there have been no studies published to date showing their efficacy.

There are no published effectiveness studies using ready-to-use products to treat MAM. However, the roll out of RUSF (in this case supplementary' $plumpynut^{TM}$) by WFP in Somalia was reportedly successful though there is no formal evaluation available at present²⁴..Further, there have been no studies published that have considered the cost-effectiveness (or relative cost-effectiveness) of the different approaches.

Prevention of undernutrition

FBFs compared to no intervention

Few studies have investigated the efficacy of FBFs for preventing malnutrition. The reviews of feeding programmes that have been done have tended to focus on the challenges of these types of programmes rather than on the potential efficacy of FBF *per se.* A recent review noted that whilst FBFs have been shown to have a positive impact on recovery from MAM and on weight gain there is insufficient evidence for the impact on linear growth²⁵. A study by Ruel *et al.* in Haiti found that provision of

²² Ciliberto MA, Sandige H, Ndekha MJ, Ashorn P, Briend A, Ciliberto HM, Manary MJ.(2005) Comparison of home-based therapy with ready-to-use therapeutic food with standard therapy in the treatment of malnourished Malawian children: a controlled, clinical effectiveness trial. Am J Clin Nutr. 2005 Apr;81(4):864-70.

²³ Nackers,F., Broillet,F., Oumarou,D., Djibo,A., Gaboulaud,V., Guerlin,P., Rusch,B., Grais,R.F., Captier,V. (2010) *Effectiveness of ready-to-use therapeutic food compared to a corn/soy-blend-based*

pre-mix for the treatment of childhood moderate acute malnutrition in Niger. J. Trop. Pediatr ²⁴ WFP.(2010) Use of RUSF at scale in Somalia 2008-2010. Presentation at the WHO Consultation on Moderate Malnutrition. Geneva, February 2010.

²⁵ **Perez-Exposito,AB, Klein,BP**. (2009) *Impact of fortified blended food aid products on nutritional status of infants and young children in developing countries*. Nutrition Reviews, 67, 706-718

WSB plus oil to all children aged six to 24 months did reduce the prevalence of both wasting and stunting²⁶.

RUSFs compared to no intervention

Results from a large-scale blanket distribution of RUSF (*plumpy'doz*TM) to children less than 3 years of age in Niger suggested that this product could prevent incidence of SAM during the hunger gap²⁷. A programme-based study done in Niger by Isanaka *et al.* found that the mean weight-for-height z-score of the intervention group that received ready-to-use food was significantly higher during the hunger gap than a control group who did not receive the product, but that there was no difference in nutritional status of the groups throughout the rest of the year²⁸. Although the mean height-for-age z-score of the intervention group was lower than the controls for the entire year, this was not statistically significant. The study cohort included children older than 2 years and hence it is possible that the lack of difference was due to the fact that interventions to promote linear growth are most effective when implemented among children less than 2 years.

FBF compared to RUSFs

A comprehensive review done by Dewey and Adu-Afarwuah in 2008 highlighted that provision of any fortified food product to young children in low-income countries generally has a positive impact on weight gain and linear growth when compared with not giving a food product at all²⁹. The authors found that provision of a low dose of *nutributter*TM had significant impacts on weight gain and growth (effect size of 0.31 for weight-for-age and 0.26 for length-for-age). However, they also showed that provision of a fortified cereal/legume mix (a product that is similar to IFBF) significantly increased weight and length of young children when compared with providing no additional food product (effect size of 0.57 for weight-for-age and 0.69 for length-for-age). It is inadvisable to conclude that this latter product is more effective than nutributterTM because in both cases the effect sizes are for single studies in different contexts.

Another efficacy study done in Malawi (Phuka *et al.*) compared fortified porridge with a low and higher-dose ready-to-use food (similar to *nutributter*TM)³⁰. Weight and length gains were similar in all groups although the investigators suggest that the higher-dose ready-to-use food may have decreased the prevalence of severe stunting.

An as-yet unpublished study in Darfur compared blanket supplementation using RUSF (*plumpy'doz*TM) with provision of IFBF. The RUSF apparently had a greater impact on weight-for-height z-scores but both interventions prevented an increase in

²⁶ **Ruel,,MT, Menon,P, Habicht,JP** *et al.* (2008) *Age-based preventive targeting of food assistance and behaviour change and communication for reduction of childhood undernutrition in Haiti: a cluster randomised trial.* Lancet, 371: 588-595

 ²⁷ Defourny I, Minetti A, Harczi G, Doyon S, Shepherd S, Tectonidis M, Bradol JH, Golden M.
 (2009) A large-scale distribution of milk-based fortified spreads: evidence for a new approach in regions with high burden of acute malnutrition. PLoS One, 4(5):e5455. Epub 2009 May 6
 ²⁸ Isomaka S, Nambala M, Dirit A, Marchala M, Stata A, Stata A

 ²⁸ Isanaka,S. Nombela,N., Djibo,A., Poupard,M., Van Beckhoven,D., Gaboulaud, V., Guerin, P. J., Grais, R.F. (2009) Effect of preventive supplementation with ready-to-use therapeutic food on the nutritional status, mortality, and morbidity of children aged 6 to 60 months in Niger. JAMA, 301, 277–285
 ²⁹ Dewey KG, Adu-Afarwuah S. (2008) Systematic review of the efficacy and effectiveness of

complementary feeding interventions in developing countries. Matern Child Nutr. Apr;4 Suppl 1:24-85. ³⁰ Phuka, JC, Maleta, K, Thakwalakwa, C. *et al.* (2008) Complementary feeding with fortified spread and

incidence of severe stunting in 6 to 18 month-old rural Malawians. Arch. Pediatr. Adolesc. Med., 162, 619-626.

acute malnutrition. This trial will be published soon but differences in linear growth have not yet been analysed³¹.

FBFs compared to RUTFs

An efficacy study done by Lin *et al.* in Malawi comparing fortified porridge with RUTF found that whilst weight gain was higher in the RUTF group, there was no difference in height gain³².

Summary

The available evidence suggests that whilst lipid-based ready-to-use foods can prevent acute malnutrition, there is variable impact on chronic malnutrition and insufficient evidence for their impact on micronutrient status. Only one study done so far using these products has shown a significant impact on growth and this was an efficacy trial³³. It is interesting to note that a programme intervention using these types of products showed no impact on linear growth³⁴. Again, there are currently no published studies looking at the impact of IFBFs on the prevention of acute or chronic malnutrition. There are few published cost-effectiveness studies and, even though the impact of products on preventing acute malnutrition looks promising, it is still not clear what dosage, duration and formulation is most effective.

RUSFs compared with RUTFs

Another study in Niger compared blanket distribution of RUTF ($plumpy'nut^{TM}$) for 4 months with blanket distribution of RUSF ($plumpy'doz^{TM}$) for 6 months. There does not appear to be a significant difference in wasting or stunting between the two intervention groups although the analyses are not particularly clear³⁵.

Prevention of micronutrient deficiencies

As outlined in the review by Perez-Expositio and Klein of FBFs, several studies have shown that FBFs can prevent scurvy, beriberi, pellagra and clinical signs of deficiencies³⁶.

It seems that only one study which used lipid-based ready-to-use products has looked at the impact on micronutrient status. Adu-Afarwuah *et al.* found that *nutributter*TM significantly increased haemoglobin concentration and reduced anaemia

³³ Adu-Afarwuah S, Lartey A, Brown KH, Zlotkin S, Briend A, Dewey KG. (2008) Home fortification of complementary foods with micronutrient supplements is well accepted and has positive effects on infant iron status in

Ghana. Am J Clin Nutr., ;87(4):929-38. ³⁴ Isanaka,S. Nombela,N., Djibo,A., Poupard,M., Van Beckhoven,D., Gaboulaud, V., Guerin, P. J., Grais, R.F. (2009) Effect of preventive supplementation with ready-to-use therapeutic food on the nutritional status, mortality, and morbidity of children aged 6 to 60 months in Niger. JAMA, 301, 277–285 ³⁵ Isanaka,S. Nombela,N., Djibo,A., Poupard,M., Van Beckhoven, D., Gaboulaud,V., Guerin, P.J., P.J., D. J., D. J., D. J., D. J., J., D. J., D. J., J., D. J.

³¹ **UNICEF** (July 2010) presentation at Global Nutrition Cluster meeting (personal communication),

³² Lin,CA, Manary,MJ, Maleta,K, Briend,A, Ashorn, P. (2008) An energy-dense complementary food is associated with a modest increase in weight gain when compared with a fortified porridge in Malawian children aged 6 to 18 months. J Nutr, 138: 593-598.

Grais, R.F. (2009) Effect of preventive supplementation with ready-to-use therapeutic food on the nutritional status, mortality, and morbidity of children aged 6 to 60 months in Niger. JAMA, 301, 277–285 ³⁶ **Perez-Exposito,AB, Klein,BP.** (2009) Impact of fortified blended food aid products on nutritional status of infants and young children in developing countries. Nutrition Reviews, 67, 706-718

prevalence when compared with no intervention, but that there was no difference between this product and an MNP³⁷.

On the basis of 16 studies of *sprinkles*TM a recent report by UNICEF concluded that MNPs are effective for preventing iron deficiency anaemia³⁸. The studies show that sprinklesTM has been as efficacious in treating and preventing anaemia as iron syrup, but is better accepted and with fewer side effects. Generally, no significant adverse events were reported and there was no evidence of iron overload. A study in a refugee population in Nepal, however, found no reduction in anaemia prevalence despite excellent compliance and knowledge of the dosage and use of MNPs³⁹. Based on existing evidence, provision of micronutrients alone through MNPs has not been demonstrated to reduce stunting and wasting.

Summary

There is evidence that FBFs and MNPs can address micronutrient deficiencies. The former are particularly effective in emergency contexts. Further research is needed, however, to compare the effectiveness (including cost-effectiveness) of the new IFBFs versus ready-to-use products for preventing malnutrition and micronutrient deficiencies in a range of settings (emergency and non-emergency).

Prevention of undernutrition through maternal supplementation40

Maternal energy and protein supplements have been found to increase birth weight, however. A 5-year study of chronically undernourished pregnant women from the Gambia found that maternal supplementation with daily high energy groundnut biscuits (4.3MJ/day) for about 20-weeks before delivery (intervention) or after delivery (control) led to increased weight gain in pregnancy and significantly increased birth weight compared to a control group who received the biscuits after delivery. This was particularly pronounced during the nutritionally debilitating 'hungerseason'⁴¹. Birth length was not affected. A trial in Guatemala⁴², gave women supplement contingency a high energy and protein and multiple micronutrient supplement or a supplement with the same micronutrients but less energy and no protein. There was no significant difference in birth weight but the children of the mothers with high energy, protein and micronutrients grew taller.

Despite the potential for increasing birth weight and reducing later undernutrition through maternal supplementation, very little attention has been given to this area. The Gambia study was published in 1997 and very little work has been carried out since. Given that the 28% of babies who are born with low birth weight in South

³⁷ Adu-Afarwuah S, Lartey A, Brown KH, Zlotkin S, Briend A, Dewey KG. (2008) Home fortification of complementary foods with micronutrient supplements is well accepted and has positive effects on infant iron status in Ghana. Am J Clin Nutr., ;87(4):929-38. ³⁸ UNICEF (2009): Workshop Report on Scaling Up the Use of Multiple Micronutrient Powders to

Improve the Quality of Complementary Foods for Young Children in Asia. Summary - Outcomes, Conclusions and Next Steps, 10 May 2009

UNHCR/DSM/WFP (2009) Micronutrient powder use and outcomes in refugee camps in Nepal (Asia) Issue 1, no 1 ⁴⁰ This section is largely based on a draft Maternal and Reproductive Health Evidence Paper: Maternal

nutrition and maternal mortality review by Natasha Mesko, DFID, July 2010.

Cessay S. et al (1997) Effects on birth weight and perinatal mortality of maternal dietary supplements in rural Gambia: 5 year randomised controlled trial. BMJ vol 315 pp.786-90 ⁴² Webb A. et al (2005) Maternal and childhood nutrition and later blood pressure levels in young

Guatemalan adults International Journal of Epidemiology vol. 34 pp. 898-904

Asia⁴³ are likely to become undernourished children, it is surprising that investment in examining the potential for maternal supplementation has been so limited.

3.2 Evidence for scale-up (sustainability and cost-effectiveness)

Research on nutrition products is extremely variable. There have been some welldesigned randomised control trials with various products but the majority are smallscale efficacy studies which do not provide sufficient evidence for roll-out at scale. Currently, there is limited evidence on the efficacy and effectiveness of nutrition products with the notable exception of RUTFs for the treatment of SAM, and MNPs in non-malaria areas for reduction of iron deficiency anaemia.

Most research on the impact of nutrition products has concentrated on efficacy in terms of treating and preventing acute malnutrition over the short-term. No studies have set out to examine impact over the long-term (greater than 6 months). Lessons are being learnt about scale-up of treatment of SAM using RUTF but there is still a gap in evaluation of treatment scale up.

Furthermore, there have been few studies published that have considered the relative cost-effectiveness of different approaches to treat MAM or to prevent undernutrition (both acute and chronic), taking account of the costs of the products and programming elements. This is discussed in more detail in a later section.

3.3 Evidence on longer term dietary and health impacts

Infant and young child feeding

Published evidence on the impact of nutrition products on infant and young child feeding (IYCF) is lacking. There are a number of concerns raised by interviewees that nutrition products, particularly RUSFs will undermine breastfeeding and complementary feeding:

- Products will displace breastmilk or disrupt breastfeeding due to inappropriate promotion of products.
- Essential IYCF advice will be lost because giving the product itself becomes the priority or there is no time. There is a risk that products are distributed indiscriminately.
- Unlike breast milk or cooked home foods, RUTFs and RUSFs do not contain water. Consequently children will drink water from another (potentially contaminated) source.

Two studies have looked at the effects of nutrition products on breast milk intake. One study randomly assigned Zambian infants at 6 months of age to receive a fortified complementary blended food with an energy density of either 68 kcal/100 g or 106 kcal/100 g. These groups were compared with a control group of infants who were not given the diets. No difference in breast milk intake was found between the control and intervention groups at 9 months of age⁴⁴. A study from Malawi compared breast milk intake of infants aged 6 months receiving complementary food either as

⁴³ **UNICEF** (2002) *Reduction of low birth weight*: A South Asia priority

⁴⁴ Owino VO, Kasonka LM, Sinkala MM, Wells JK, Eaton S, Darch T, Coward A, Tomkins AM and Filteau SM. (2007) Fortified complementary foods with or without á-amylase treatment increase hemoglobin but do not reduce breast milk intake of 9-mo-old Zambian infants. American Journal of Clinical Nutrition, 86, 1094-1103

traditional CSB porridge or a fortified spread⁴⁵. After 1 month, there was no difference between the groups in terms of breast milk intake. An observational study of a small group (n=16) of underweight Malawian infants aged from 6-18 months who were given fortified spread observed no decrease in the number of breastfeeds per day⁴⁶.

There is no documented evidence that nutrition products are being distributed or marketed in a way that is contrary to WHO Resolutions or the international code for the marketing of breast-milk substitutes⁴⁷.

Many projects deliberately combine IYCF activities with distribution of nutrition products. For example, promotion of breastfeeding and appropriate complementary feeding are usually included as part of Community-based management of acute malnutrition (CMAM) programmes using RUTF. Training materials for providing IYCF guidance as part of CMAM have been developed and training is being rolled out⁴⁸.

There is no documented evidence of increased exposure of children to contaminated water. However, this, and other potential adverse impacts of nutrition products on IYCF among children at different ages need to be explored further.

3.1.2 Later obesity and chronic disease

There is a lack of evidence of the impact of nutritional products on obesity or chronic disease. There are studies that demonstrate associations between nutritional interventions early in life to prevent/treat growth retardation (stunting) and greater levels of obesity in adulthood. One well-known study done in Guatemala showed that stunted children who were given an energy/protein drink during early childhood were less likely to become stunted in childhood, but more likely to be obese in adulthood and to have higher birth weight offspring⁴⁹.

Research has shown that greater fat mass during the first 6 months of life is associated with greater lean mass during early adulthood but not fatness⁵⁰. This may be because greater fatness during the growing period leads to an increase in the overall structure of the body (i.e. lean mass) but this trend will decrease as the child gets older.

The potential negative effect of nutrition products on dental health (due to the relatively high sugar content of some products) is also a concern, particularly in light of the link between dental problems and cardiovascular disease.

Dietary habits and acceptability

There is insufficient information provided in the efficacy studies described above about sharing and how much of the nutrient product was actually consumed by target

⁴⁵ Galpin L, Thakwalakwa C, Phuka J, *et al.* (2007) <u>Breast milk intake is not reduced more by the</u> <u>introduction of energy dense complementary food than by typical infant porridge.</u> J Nutr;137:1828-33

 ⁴⁶ Flax, VL, Phuka, J, Cheung, YB, Ashorn, U, Maleta, K, Ashorn P. (2010) Feeding patterns and behaviors during home supplementation of underweight Malawian children with lipid-based nutrient supplements or corn-soy blend. Appetite. Volume 54, Issue 3, June 2010, Pages 504-51
 ⁴⁷ WHO International code of marketing of breast-milk substitutes. (1981) Geneva

⁴⁸ http://www.ennonline.net/resources/722

⁴⁹ **Corvalán, C, Gregory, CO, Ramirez-Zea, M, Martorell, R and Stein, AD.** (2007) *Size at birth, infant, early and later childhood growth and adult body composition: a prospective study in a stunted population* International Journal of Epidemiology 36(3):550-557

⁵⁰ **Grijalva-Eternod, C.** (2010) Institute of Child Health, University College London (personal communication), August 2010

children or about alternative sources of food consumed in addition to the product. These factors are crucial in understanding why impact is sometimes limited.

While there has been some research on the acceptability of MNPs,⁵¹,⁵² there is very limited published research on the acceptability of LNSs by target children, their caregivers and the community at large. Unpublished small-scale acceptability tests (implemented before large-scale distribution) in refugee camps in Algeria and Djibouti showed that *nutributterTM* was well accepted⁵³. Another unpublished study among MAM children in Somalia found that knowledge on purpose, dosage, and key messages was almost universal in target population and that the product was well accepted by children and caregivers⁵⁴. Acceptability studies from Asia have been less promising and it does seem that children in this region do not find peanut-based products particularly palatable⁵⁵.

UNHCR is developing operational guidance for nutrition products (see below for more details) that emphasizes the importance of assessing current feeding practices, perception and knowledge of nutrition products. Household observations will also be carried out. The findings will indicate the acceptability of the nutrition product to refugee communities and will help to identify barriers to use⁵⁶.

There are concerns about additional costs for poor families and changing traditional dietary patterns.By introducing nutrition products into poor communities, an expectation is set up that packaged foods are better for children as they improve growth. Families may start to look for and purchase packaged nutrition products or baby products in favour of traditionally available foods. The cost of buying products puts additional burdens on already poor families and may not be necessary.

Box 6: Concerns about disruption to dietary habit

"Young children in every country, clan, or tribe that I know, are learning to eat, and to like, and appreciate, the diverse foods that their culture enjoys, and often cherish. In fact the foods that a mother consumes during her first six months of breastfeeding are flavoring her breastmilk to taste like the foods of her culture.

Source: Letter from Professor Michael Latham to Dr. Werner Schultink on RUTF's and Breastfeeding

Safety

There is little research on the safety of nutrition products. One area of concern relates to iron supplementation in malaria-endemic areas. MNPs and LNSs contain

⁵¹ Hyder S, Haseen F, IP H, Zlotkin SH. (2005) Acceptability of Sprinkles in rural Bangladesh: A new home fortification approach to deliver micronutrients among young children. Experimental Biology and XXXV International Congress of Physiological Sciences meeting abstracts [accessed at http://select.biosis.org/faseb]. The FASEB Journal, 19, Abstract #967.3.

Christofides, A, Schauer, C, Sharieff, W, Zlotkin, SH. (2005) Acceptability of micronutrient sprinkles: a new food-based approach for delivering iron to First Nations and Inuit children in northern *Canada.* Chronic Dis Can. 2005;26:114–20 ⁵³ **Tondeur, M.** (2010) Institute of Child Health (personal communication) August 2010

⁵⁴ WFP (2010) Using LNS at scale for treatment and prevention of malnutrition: The Somalia

experience. Presentation at Global Nutrition Cluster, Geneva, 23rd February 2010

Walsh, A. (2010) Valid International (personal communication) August 2010

iron which may exacerbate infections, in particular malaria, as the parasite requires iron for growth. UNHCR is conducting an expert consultation on this issue⁵⁷. Food allergies with peanut-based products may also be a cause for concern in some populations.

3.4 Conflict of interest

Much of the research on nutrition products has been linked to the food industry. This is not surprising given that corporate funding for research has expanded substantially in recent years⁵⁸. It does raise concerns, however, about financial conflicts of interest, objectivity and about whether industry has undue influence in research. A recent consensus study recommended that "researchers with a significant conflict of interest should not participate in research with human participants-for example, if a researcher holds the patent on an intervention being tested in a trial"59.

Whilst industry support for research should not be undermined, donors can play an important role in funding independent research and commissioning systematic reviews where there is no commercial link.

3.5 Conclusions

Any fortified food product given to young children in low-income countries is likely to have a positive impact on weight gain and linear growth when compared with not giving a product at all. Most studies, however, have been confined to small-scale efficacy trials that show varying impacts on growth. This approach encourages a "winner's approach" (i.e. one product is better than another) rather than a broader approach that examines both the potential role for different nutrition products in different contexts and types of programming, and the operational implications for the use of products.

A recent meeting convened by WHO on the management of MAM in young children concluded that more evidence is needed to evaluate the effectiveness and costeffectiveness of a range of approaches.⁶⁰ There is an urgent need for well-designed large-scale studies to examine the relative impact, cost effectiveness, acceptability and safety of the different nutrition products that are now available. Research should aim to measure impact on local dietary practices (including breastfeeding, sharing behaviours, additional dietary intake, and the development of complementary feeding practices and taste preferences), micronutrient status and markers of nutrition-related chronic diseases and obesity (given the high fat and sugar content of some nutrition products). Research needs to include observational studies, as well as clinical trials.

The majority of stakeholders interviewed as part of this review expressed the view that the focus should be on 'progammes' and not on 'products'. There is no 'magic bullet' solution and the essential point here is to concentrate on how nutrition products can add value to existing programmes in a cost-effective manner and without causing harm.

⁵⁷ Tondeur, M. (2010) Institute of Child Health (personal communication), August 2010

⁵⁸ Field,M. (2009) Conflict of interest in medical research, education and practice. Institute of Medicine of the National Academies, 2009 ⁵⁹ Field M. (2009) *Conflict of interest in medical research, education and practice*. Institute of Medicine

of the National Academies 2009

⁶⁰ WHO, UNICEF, WFP and UNHCR (2010) Consultation on the

Programmatic Aspects of the Management of Moderate Acute Malnutrition in Children under five years of age. 24-26 February 2010, WHO: Geneva

Too great a focus on nutrition products will take away from investment in preventative programming that addresses the different causes of undernutrition. There have been few studies on effective programmes to prevent acute and chronic malnutrition through combining nutrition-specific interventions and nutrition-focused development interventions to address the immediate, underlying and basic causes of undernutrition. This is particularly true in emergency contexts, where the traditional approach has been heavily food based. The Lancet Series concentrated mainly on nutrition-specific interventions either because other interventions were judged to be outside the scope of the review or because evidence was lacking.⁹³

The fact that prevention is context dependent and requires multiple interventions, makes research in this area difficult. Furthermore, there are a raft of programmatic factors including coverage, targeting, delivery mechanisms, political will and community participation that affect outcome.

Production

4.1 Manufacturers

Ready-to-use foods

The first RUTF (*plumpy'nut*TM) was developed in 1996 through the French *PPP* of Nutriset and the Institute of Research for Development (IRD). Its franchisees are the biggest producers of RUTFs and the growing range of RUSFs e.g. the lipid based nutrient products. Nutriset has developed a network of franchisees for local production in developing countries using the brand and protected know-how. These operations are now in place in more than 10 countries.

The *plumpy'nut*TM patents last until 2018 and cover not only the product itself but also the production process and ingredients. Although both IRD and Nutriset appear as owners, after initial registration, IRD granted Nutriset an exclusive exploitation license for the patents and brand name, subject to certain conditions of appropriate use. The patent is valid in 10 high income countries and 31 low and middle income countries. See Annex 3. Nutriset has patented all its products in the plumpy line and others such as *zinCfant*TM. Two US companies, Breedlove Foods of Texas and Mama Cares Foundation of California, have challenged the Nutriset patent in court, claiming anticompetitive practices to protect their share of an estimated USUS\$ 200 million market61.

Nutriset recently relaxed its patent licensing process (Nutriset Press Release, October 14, 2010), making licensing a simple one-stop online application process for qualifying local companies and/or joint ventures with at least 51% developing-country shareholders. This allows "North-South" joint ventures and partnerships with the developed country company(ies) able to hold up to a 49% share in the venture. Companies will be able to manufacture local variants of LNS, RUTF and RUSF products that use the patented approach and market them under local names and brands. The plants will not be required to undergo the stringent certification process that the franchisee members of the plumpy'field network have to meet. This could lead to a proliferation of local production of LNS products, making the need more urgent for standardisation and harmonisation of ingredients options, finished product nutrient specifications, quality assurance, and procurement processes.

Nutriset dominates the market for RUTF and the growing range of RUSFs supplying 90% of all RUTF and RUSF to UNICEF in 2009 (cited in Rice, 2010). Nutriset has developed a network of local producers (PlumpyField) as a way to protect its patented products while ramping up supply of RUTF and RUSF to meet the growing global demand. *PlumpyField*, was initiated in 2005 to produce *plumpy'nut*TM. The willingness of Nutriset to share its knowledge and allow manufacturing in the field through franchises, licenses and partnership agreements has enabled local production and commercialization of the product line in developing countries using the brand and protected know-how. The franchising system is based on the transfer of Nutriset's know-how (production, management and distribution) to a local, independent producer known as the "franchisee". The first local factory was opened in Malawi and franchisees have since been established in more than 10 countries including Ethiopia, Malawi, Niger, Democratic Republic of Congo, Dominican Republic, Mozambique and USA. By the end of 2010, Nutriset and its franchisees will be producing in 12 locations globally with an annual production capacity of 57,660 tonnes (see Annex 3).

⁶¹ **Rice, A.** (2010) *The Peanut Solution*, Article in the New York Times Magazine, 5 September 2010

Currently, the international suppliers of RUSFs are Nutriset in France, Vitaset in Dominican Republic, Diva Nutritional Products in South Africa, Insta EPZ in Kenya, Challenge Dairy Products Inc. in USA, Tabatchnick Fine Foods in USA, Edesia LLC in USA, and Compact in India (*See Annex 3*). Valid Nutrition, a social enterprise business, produces a similar RUTF (*VN peanut formula*TM) in Malawi, Kenya, and Zambia and is planning to start production in Ethiopia.

Compact AS produces a range of nutrition products ($eeZeePaste Nut^{TM}$, $BP-100^{TM}$, $BP-5^{TM}$, $TopNutri^{TM}$ and $AFYA^{TM}$) which include LNS paste and biscuit formats. The high energy biscuits, $BP-100^{TM}$ and $BP-5^{TM}$, are typically provided during the first few days or weeks in emergencies while $BP-100^{TM}$ is used for malnourished individuals, including infants and young children. $TopNutri^{TM}$ and $AFYA^{TM}$ are specifically for individuals with HIV/AIDS. Compact's main production site is in Norway although it also operates through Compact India, Denmark, Kenya and Dubai.

Micronutrient powders

MNPs (brand name *sprinklesTM*) were first developed by Stanley Zlotkin, a Canadian doctor, also in 1996. A *PPP* was agreed in 2001 between the Sprinkles Global Health Initiative (SGHI) based out of the Sick Kids Hospital in Toronto, Canada, and the H.J. Heinz Company. Stanley Zlotkin has a patent on the intellectual property rights for *sprinklesTM* and has set up a process of technology transfer through H.J. Heinz to promote the local production and scale-up of *sprinklesTM* and MNP distribution as, for example, in Bangladesh. There do not seem to be patent issues in this arena.

At present, DSM and HJ Heinz are the biggest producers of MNPs. These powders are usually based either on iron formulations or multi-micronutrient formulations although other formulations are being developed. Brand names vary from country to country for example, *chispitas*TM in Latin America, *monimix*TM and *pushtika*TM in Bangladesh, and *vitalita*TM in Indonesia.

HJ Heinz has production sites in India and Indonesia and in 2006, UNICEF designated Heinz India as one of its two official partners in the distribution of micronutrient sachets. Heinz Micronutrient has coordinated production with suppliers in India for the majority of the MNPs that have been distributed worldwide. Renata in Bangladesh also produces a micronutrient powder and Compact AS manufactures its own version known as *topNutri*TM. Nutriset produces *QBmix*TM which is a micronutrient powder supplied in a larger pot intended for home fortification of meals for entire families or for use in institutional settings (it has been used by the International Committee of the Red Cross in prisons).

DSM specializes in micronutrient blends and fortification of products and collaborates closely with WFP. It produces its own brand of micronutrient powders ($mixme^{TM}$) as well as a fortified rice ($nutriRice^{TM}$).

There is no information available about the production capacity for FBFs. There continues to be large potential capacity in the USA and many countries are making their own FBFs, though not always to the standards required. There are a number of premix plants around the world that are approved by WFP, including in South Africa, Denmark, Brazil, USA, Malaysia, India and Germany. According to WFP, all FBFs available from 2010 will be IFBFs (CSB+ or WSB+). UNIMIX will also be reformulated to be equivalent to CSB+/WSB+. USAID is reviewing its FBF product formulations and is likely to approve an enhanced set of specifications for CSB, WSB and other FBFs.

4.2 Local production

There has been increasing focus on local production of nutrition products because of the benefits for local economies, job creation, technology transfer and achieving selfsufficiency to address food security and nutrition crises. Environmentalists support local food production because it requires less fossil fuel, both in production and transportation. The disposal of increasing numbers of individual sachets has yet to be addressed, and using bio-degradable packaging drastically reduces shelf life.

Local production costs vary. According to Collins et al. (2006), the RUTF production cost in Nutriset's French factory was around US\$3,500 per ton, while local manufacturing allowed for a price reduction of US\$1,000 per ton, without taking into account the savings of transport costs⁶². Similarly, Sandige *et al.* (2004) report cost savings of around 50% for local production in Niger. Local production does not, however guarentee lower prices; 40% of RUTF purchased by UNICEF is locally produced but is more expensive. UNICEF pays US\$60 to purchase and ship a box of 150 packets from Nutriset in France to Niger while it costs US\$65 to manufacture in country. Production in Niger is expensive, due to the high cost of electricity, high taxes and interest rates. It would be cheaper if the ingredients used could be bought locally, the only available ingredient from Niger is peanut. Others, such as milk powder, sugar oil, and the micronutrient mix, are purchased internationally and local producers holding a license from Nutriset have the obligation to buy specific products, such as micronutrients and packaging, from Nutriset in order to respect the formula⁶³.

Similarly in Ethiopia, the price of *plumpy'nutTM* purchased from HILINA, a local company with a franchise agreement with Nutriset, is as much as double the price of *plumpy'nut*TM produced in France by Nutriset (see Annex 4).

Valid Nutrition is supporting a project in Malawi for local production of a new chickpea-sesame-maize RUTF that uses predominantly local ingredients and significantly less expensive imported milk powder. It is equally effective but at a lower cost than the current peanut-based RUTF. Cheaper RUTF would dramatically reduce the cost of CMAM and may remove a major constraint to expansion of treatment programmes⁶⁴.

WFP procures about 50% of its CSB and other FBFs in the countries or from the regions where it distributes these products. In Ethiopia, for example, WFP purchases FBF in the form of FAMIX from seven factories that have an average capacity of about 10,000 – 12,000 metric tons month, which covers most of Ethiopia's 'normal' needs (see Annex 4). Raw materials are sourced in country with the exception of the micronutrient mix which is purchased overseas. Making CSB+ and WSB+ should not be difficult, as producers in developing countries can obtain premixes from global suppliers through an arrangement with GAIN, at a very competitive price.

⁶² Sandige, H., Ndekha, M.J., Briend, A., Ashorn, P., Manary, M.J. (2004) Home-based treatment of malnourished Malawian children with locally produced or imported ready-to-use food. J Pediatr Gastroenterol Nutr 2004; 39: 141-146

NIGER (2010) Local Plumpy'nut production soars with demand

http://www.irinnews.org/report.aspx?ReportID=90242&utm_source=twitterfeed&utm_medium=twitter The World Bank (2007) Summary of Finalist Proposals Development: Market Place

4.3 Procurement

UNICEF

UN agencies are the major purchasers of RUTF and RUSF worldwide. UNICEF is responsible for the treatment of malnourished children and provides RUTF as part of the treatment while WFP is responsible for supplementary feeding for which it provides FBFs, RUSFs and other lipid-based ready-to-use products. Demand and production of RUTF have greatly expanded during the last two years (*see Box 6*). UNICEF the biggest buyer placed approximately 750,000 orders, costing around US\$40 million and delivered to around 50 countries in 2008 and 2010. During that period the proportion of locally made RUTF purchased by UNICEF increased from three to 37%. The objective was to bring the products closer to the final beneficiary and thus facilitate transfer from UNICEF/NGO management to the national authorities.

UNICEF forecasts a 40% annual increase in demand for the product in the next 2 years alone; planning an expansion of SAM children from 1.8 million to 6.1 million.⁶⁵



Box 6: UNICEF Global Procurement of RUTF 2000-2010

Source: Jan Komrska UNICEF Supply Division, 2010

WFP

RUSFs form a negligible part of WFP's overall food aid supply. In contrast, WFP distributes approximately 400,000 tons of FBFs, around half of which is procured from low income countries⁶⁶. WFP has been or is distributing RUSF's in about 23 countries. A total of 64% of what has been provided has gone to sub-Saharan Africa, 23% to Asia, 2% to Europe and CIS, 6% to Middle-East and North Africa and 5% to Latin America and the Caribbean. WFP India has started production of a ready-to-use complementary food known as Indian RUFC.

⁶⁵ **UNICEF** (July 2010) *Presentation at Global Nutrition Cluster meeting* (personal communication)

⁶⁶ **de Pee, S.** (2010) WFP (personal communication) August 2010

4.4 Nutrient composition, generics and brands

The formulation of RUTF is designed to deliver the same nutrient composition as F-100, the standard therapeutic milk (based on the WHO specifications). RUTFs use some of the same ingredients, including a specially formulated powdered mix of vitamins and minerals with the addition of peanut butter (e.g. *plumpy'nut*TM) another pulse and/or oilseed like chickpeas and/or sesame (e.g. *VN* in Malawi) as well as other components to give the lipid based paste consistency. This changes the physical properties of the food to a nutrient-dense viscous liquid or paste product instead of a powder. Additionally, the moisture content is reduced significantly (compared to *F100* milk) which lowers the risk of bacterial contamination. The new viscous liquid can be packaged in individual packets and consumed as is, straight from the sachet.

Because the nutrient composition of RUTF is well defined, it is possible to change the ingredients in order to ensure that they are suitable in different environments while ensuring that the nutrient content is maintained. This increases the potential for local production and for generic products to be produced when the Nutriset patent has ended.

The same is true for MNPs. Two *sprinkles*TM formulations have been developed; a nutritional anaemia formulation delivering iron and folate and a multiple micronutrient formulation based on WHO recommended nutrient intakes to deliver a spectrum of micronutrients. Other MNPs vary slightly, but generally contain approximately the same amounts of micronutrients.

There is no set formulation for other nutrition products (i.e. specifications agreed to by experts or international norm-setting bodies such as WHO), however. This means that individual manufacturers can produce a nutrient product with a range of ingredients and nutrients. If standard nutrient compositions for particular nutrition products could be agreed upon, it would mean that companies would produce the same standard nutrition product based on procurement specifications of the buyer and the product would only vary in price and ingredient composition. Developing performance based standards (that include a finished product nutritional profile and quality standards and guidelines for ingredients) would open the door for production of generic products as opposed to branded products which are generally more expensive.

There is no "one size fits all" product, and specifications would need to be tailored to different settings and local ingredients (i.e. whether local ground nuts or sesame). In order to promote local production, there would likely be a family or line of products that would meet the needs specified locally or regionally. Procurement documents can be crafted to include various (interchangeable) ingredients, such as "nuts or oilseeds" instead of "peanuts or groundnuts" or include a list of approved "dairy protein ingredients" instead of just one; specific quality assurance and microbiological standards would need to be included based the specification modifications. Developing specifications would need to be part of the harmonisation efforts. Procurement arms of the UN and bilateral donors (e.g., USAID/SCMS for food and medicine purchased under PEPFAR) already work with multiple specifications adapted to different country needs and Government requirements.

In the more mature supplement market (i.e. multi and individual vitamin pills, powders and fortified products) in the US, the EU, and middle income segments of Asia or India for example, there are many companies competing to produce similar products. The technology, safety standards and commercial market place have allowed the development of generic brands and premium brands for different consumer segments, with the expectation that similar products are safe and equally efficacious. The nutrition products being discussed in this report represent an international market that has potential for some growth but that is somewhat self-limiting since the products are controlled by a small number of producers and an even smaller number of volume buyers.

4.5 Conclusion

Nutriset and its franchisees are the bigget producers of RUTFs and the growing range of RUSFs. Though Nutriset has patented all of its RUSF products in the plumpy line and others, the company has recently relaxed its patent licensing process (Nutriset Press Release, October 14, 2010), to allow companies to manufacture local variants of LNS, RUTF and RUSF products that use the patented approach and market them under local names and brands. This could lead to a proliferation of local production of products, making the need more urgent for standardisation and harmonisation of ingredients options, finished product nutrient specifications, quality assurance, and procurement processes.

Local production in developing countries has the potential of stimulating the local economy, contributing to self-sufficiency and reducing environmental waste linked with international transportation. It does not guarantee lower prices, however, largely because of the high cost of some ingredients that have to be imported. There are various initiatives

to develop local production sites and experiment with new formulations for RUTFs. More and more FBF's and MNPs are also being produced in developing countries. Nevertheless, local production can be costly.

Ready to use food products are mainly bought by international agencies (UNICEF and WFP) and are not widely available for retail purchase directly by consumers.

Nutrient composition is standardised for RUTFs and for the MNPs delivering the iron and folate content developed for *sprinkles*TM. Nutrient composition has not been set for other nutrition products, however. Setting standard specifications for each nutrition product to specify purpose, standard nutrient composition and appropriate safety and quality controls would allow different companies to offer generic products to meet set generic specifications in terms of ingredients and nutrient profile of the finished product that would differ mainly in terms of price and ingredient composition.

Delivery Systems

The majority of interventions listed in *Box 3* are delivered using a variety of platforms. The appropriateness and cost of the delivery system in a given country (or region) varies depending on the type of intervention and available infrastructure and capacities. This chapter will consider the following systems: health systems; community nutrition programmes; social marketing and private delivery; voucher programmes; and conditional cash transfer programmes.

5.1 Health System: primary health care, child health days and CMAM

Within a functioning health system, there are various contact points that offer an opportunity to deliver nutrition products including antenatal and postnatal care, growth monitoring and during other visits to health posts. In Latin American countries, there is a long tradition of delivering nutrition programmes (including nutrition products) through the health system,. It has been shown that these are only successful if securely situated in the Ministry of Health and with clear goals, strategies and resources. Otherwise, workers become over-loaded and there is a potential risk that by giving them a product to hand out, other preventative tasks get left out. Hampshire *et al* (2004), argues that some African health systems miss opportunities to deliver nutrition services during routine prenatal, postnatal and child-care consultations because of the lack of a clear framework for nutrition programming⁶⁷.

In the context of poorly functioning health systems, low coverage and high burden of undernutrition (e.g. in parts of sub-Saharan Africa and South Asia), child health days (CHDs) are currently used as the preferred approach to reaching children. These are usually carried out twice a year and are used to provide vitamin A supplements, deworming tablets, insecticide-treated bed-nets, and immunizations, among other interventions. CHDs often are used to screen individuals for SAM and make referrals to clinical settings for their treatment. These CHDs can be a window of opportunity for the delivery of nutrition products alongside a comprehensive package of interventions⁶⁸.

Integration of CMAM into government health systems is gradually being rolled out. Integration requires incorporating community components of outpatient care, inpatient care, and community mobilization and outreach activities into national primary health care systems. The USAID funded Food and Nutrition Technical Assistance Project (FANTA) has described the experience of integration in Malawi, Ethiopia, Niger, Sudan, and Bangladesh and demonstrates the breadth of challenges of attempting to integrate community activities within different contexts⁶⁹. If CMAM is to expand into development contexts and be sustainable, RUTF needs to be more easily accessible and affordable.

 ⁶⁷ Hampshire, Rachel D 1,*; Aguayo, Victor M 2; Harouna, Hamani 3; Roley, Julie A 4; Tarini, Ann
 1; Baker, Shawn K 5 Delivery of nutrition services in health systems in sub-Saharan Africa: opportunities in Burkina Faso, Mozambique and Niger.
 ⁶⁸ Doherty, T et al (2009) Moving from vertical to integrated child health programmes: experiences from

⁶⁸ **Doherty, T** *et al* (2009) Moving from vertical to integrated child health programmes: experiences from a multi-country assessment of the Child Health Days approach in Africa Trop Med & Intl Health.

⁶⁹ **Deconinck, H. Swindale, A, Gran,t F and Navarro-Colorado, C** (2008) *Review of community based management of acute malnutrition (CMAM) in the post-emergency context: synthesis of lessons on integration of CMAM into national health systems.* FANTA Project: Washington

Gatchel *et al*⁷⁰ emphasize that strong community participation, and active screening linked to health service provision at the local level are paramount to ensure sustainable assessment and referral of SAM. At the national level, a commitment to address outpatient treatment of acute malnutrition is needed and at the local level, available and affordable RUTF is required. If the nutrition products are not available the integration does not work.

In emergency settings, the health service is disrupted and unlikely to be the best system for providing nutrition products. International and national agencies may be better placed to deliver products as part of a more comprehensive programme. However, where CMAM has been integrated into a country's health system, it is preferable for agencies to support the Government system to maintain delivery via health centres.

5.2 Community nutrition programmes

Community nutrition programmes provide an opportunity for one-to-one delivery of services. Activities take place outside the health facility, in the home or at a community central point, and may be supported by health staff based in health facilities. Community health and nutrition programmes are often initiated and run by the health sector, but sometimes a separate ministry (e.g. in India and Indonesia) or service (e.g. in Bangladesh) is set up^{71} .

However, community-based programmes have been shown to require high literacy, empowerment of women, community organizational capacity and appropriate legislation. Unfortunately, these tend to be lacking in many settings⁷² and this could limit the scope for community programmes as a platform for delivering nutrition products.

5.3 Social marketing and private delivery

Nutrition products that target children with acute malnutrition are largely distributed free of charge as part an emergency response or because UNICEF has provided funding for the product. Scale-up of MNPs in large programmes in South Asia and Latin America has involved a mix of distribution models, including public sector distribution at no cost for vulnerable groups, NGO-operated subsidized distribution and private sector social marketing⁷³. Each model is tailored to the country's requirements. The usual mode of delivery is through the public health system in development settings and by national and international agencies in emergencies. The UN currently recommends providing MNPs for children and pregnant women as part of emergency operations⁷⁴.

The social marketing model combines private and public sectors. MNPs are made available via the existing commercial sector at an affordable, partially subsidized cost and promoted using social marketing strategies. In addition to creating value for the

⁷⁰ Gatchell V, Forsythe V, and Paul-Rees T. (2006) The sustainability of community-based therapeutic care (CTC) in nonemergency contexts. Food and Nutrition Bulletin, vol. 27, no. 3 (supplement).

Mason, J, Sanders, D, Musgrove, P, Galloway, R Community Health and Nutrition Programs in Disease Control Priorities in Developing Countries ⁷² Mason, J, Sanders, D, Musgrove, P, Galloway, R. Community Health and Nutrition Programs in

Disease Control Priorities in Developing Countries⁷³ Micronutrient Initiative, International Nutrition Foundation and the Sprinkles Global Health

Initiative at Sick Kids (Joint Statement)

⁴ WHO, WFP and UNICEF (2007) Preventing and controlling micronutrient deficiencies in populations affected by an emergency.

product among consumers, the subsidized cost allows increased coverage to vulnerable populations.

In Bangladesh, community health workers employed by BRAC advise families on health issues and earn money from the medicines they sell in their communities, including MNPs. GAIN funding enables BRAC to train its community health workers in selling and marketing the product in their villages⁷⁵.

5.4 Voucher programmes

A food voucher or food coupon is a credit against the purchase or cost of food to be made in the future. Food vouchers can support nutrition objectives when the voucher exchange is tied to the purchase of nutritious food items through local markets. Vouchers can help meet needs in a timely and flexible manner where nutritious food products are available on the market. WFP launched a first food voucher operation in Africa in 2009, selecting an urban area of Burkina Faso where food was available but beyond the reach of many because of the high food prices (see *Box 7*). They have since piloted a 'nutrition-friendly' voucher programme in Pakistan and are planning to expand the approach to other countries. UNICEF has been adding coupons in exchange for fortified food to their maternal health benefits package in Bangladesh that targets pregnant women. MSF used coupons in Niger for providing mothers with their one-month ration of RUSFs.

Proponents of voucher-based approaches argue that they can be more cost-effective and timely, allow recipients greater choice and dignity, and have beneficial effects for local economic activity. Instruments such as food coupons or vouchers while politically popular have higher administrative costs than cash⁷⁶. Additionally, critics fear that cash and voucher approaches add risks of insecurity and corruption, and that targeting cash may be more difficult than commodities.

Box 7: WFP voucher programme in Burkina Faso

The WFP voucher programme targeted 120,000 people in urban Ouagadougou, where the prices of basic staples such as millet and sorghum were more than 25 % higher than the previous year. Households were given a voucher worth 1,500 francs CFA (US\$3) which could be used in shops that have signed a contract with WFP. In exchange for the voucher, people received maize, cooking oil, sugar, salt and soap. Each family received up to six vouchers per month for 6 months. The retailer is able to redeem food vouchers through an arrangement WFP has made with MICROFI, a local micro finance company.

Source: Burkina Faso: WFP launches first food voucher operation in Africa (accessed August, 2010) http://www.reliefweb.int/rw/rwb.nsf/db900SID/MUMA-7Q5ALJ?OpenDocument

5.5 Cash transfer programmes

Cash transfer programmes provide money directly to poor families. Sometimes they are conditional upon the beneficiaries' actions (e.g. bringing their children to the

⁷⁵ Global Health Alliance for Improved Nutrition. BRAC Community Health Workers to Play a Key Role in Reducing Child Malnutrition in Bangladesh

⁷⁶ The World Bank. (2008). Rising Food and Fuel Prices: Addressing the risks to future generations

health centres for regular checkups). These programmes have also been used to distribution nutritional products.

There is substantial evidence to show that transfers (conditional or unconditional) are spent on more and better food, but that this is not always translated into improved child growth. Nutritional supplements provided with the cash transfer seem to significantly enhance the nutritional impact of these programmes⁷⁷.

5.6 Conclusions

Nutritional products can be delivered through a range of routes though in almost all instances this will require the integration of their distribution into existing programmes (such as those delivered within the health, emergency relief or social protection sectors), or into commercial channels. This integration is important for the streamlining of delivery systems but also important because nutrition products should be seen as one of several complementary interventions being adopted to prevent or treat undernutrition.

Cost and cost-effectiveness of different interventions

6.1 Nutrition-health interventions

This chapter presents cost and cost-effectiveness studies of nutrition interventions for rehabilitating children 6-24 months of age suffering from SAM, food-based interventions for addressing MAM, and interventions for PLW. As there is little information on the cost-effectiveness of using nutrition products to prevent chronic malnutrition, this is not covered.

Definition of costs and cost-effectiveness

The costs and cost-effectiveness of selected interventions are given in *Box 8*. All costs are expressed in international dollars for the year 2010. The unit costs correspond to the cost per treating/rehabilitating one child, or the cost of preventing malnutrition or micronutrient deficiency in one child or one pregnant woman, and where possible, the costs of preventing a child death or saving a DALY. Studies are from scientific and grey literature (*See Annex 6*).

Cost studies include costs of staff (professional and supporting staff), maintenance of facilities and products or food prices at the delivery point (transportation plus taxes). Some of the costs quoted in *Box 8* are for the product alone. The costs of distribution are generally double the cost of the product alone. The studies done in emergency settings or in a new programme include installation costs such as offices, operations and maintenance, and new vehicles and their maintenance. Finally, costs vary between the initiation phase of a new programme (where training is required) and that of an established programme.

Cost-effectiveness analysis aims to inform policy makers about the economic attractiveness (or returns on investment) of interventions to reduce disease-related mortality and morbidity. By assessing costs and effectiveness of an intervention, a "value for money" estimate is provided. The cost-effectiveness of a given intervention is typically expressed as costs per unit of effectiveness, with costs measured in monetary terms and effectiveness measured in years of life saved or gained. The

⁷⁷ **Dewey, K; Adu-Afarwuah, S,** (2008) *Systematic review of the efficacy and effectiveness of complementary feeding interventions in developing countries.* Blackwell Publishing Ltd. Maternal and Child Nutrition, 4, pp. 24–85

impact of an intervention on the quality of life (morbidity) and length of life (mortality) of a population is measured and expressed as a single number such as disability adjusted life year or DALY. Interventions with a favourable cost-effectiveness ratio (e.g. low US\$ per DALY) are eligible for implementation, at least in economic terms.

Small differences in cost effectiveness are not meaningful. WHO classifies a child health intervention as "cost-effective" if its ratio is less than three times the country's gross domestic product (GDP) per capita and highly cost effective if it is less than the GDP per capita. Using these criteria, any intervention that can save a DALY for less than US\$400 is cost-effective (US\$138=lowest GPD per capita in Africa x 3=US\$414) and less than US\$138, very cost-effective.

Interventions for pregnant and lactating women

Box 8 presents the costs and cost effectiveness of iron-folate supplementation for pregnant women and breastfeeding promotion (initial, exclusive, continued) for women delivering in a public hospital setting.

Interventions for treatment of severe acute malnutrition

Children suffering from SAM are treated through the following types of programmes: Firstly, traditional programmes (before the introduction of CMAM) that include personalized advice on the right diet with local ingredients, plus the delivery of fortified food or micronutrients. The studies include cost estimates for inpatient care for children who have medical complications, outpatient care for those without medical complications, and community care for children with no medical complication who are provided with take home rations. Secondly, CMAM programmes where children without medical complications receive RUTF and other health services at outpatient sites.

Intervention	Estimated Cost per beneficiary 2010 (US\$)	Cost/ DALY (US\$)	Source
Pregnant and lactating	ng women		
Iron-folic acid Supplements	US\$11-US\$24	US\$66– US\$115	Baltussen <i>et al</i> 2004
Breastfeeding support hospital- based	US\$0.4-US\$0.55 per birth	US\$3–US\$7	Horton <i>et al</i> 1996
Breastfeeding promotion	US\$3.8-US\$5.7 per child	US\$11	Ross, Loening, and Mbele 1987
Breastfeeding promotion	US\$19 per child; US\$6-US\$70 per adopter of exclusive breastfeeding	US\$7.80	Chee, Makinen, and Sakagawa 2002
Children with severe acute malnutrition (SAM) receiving treatment			
Nutritional advice	US\$221 (inpatient) US\$83 (outpatient) US\$41 (community/home)		Khanum <i>et al</i> . 1994, 1997, 1998
Nutritional advice	US\$91 (inpatient) US\$26 (outpatient) US\$25 (home based)		Ahmed <i>et al</i> . 2002

Box 8: Costs and cost-effectiveness of nutrition interventions for women and children

Community-based Therapeutic Care	US\$63 (imported) US\$25 (local)		Sandige <i>et al.</i> 2004
Community-based Therapeutic Care	US\$37 (HIV+ children)		Ndekha <i>et al</i> . 2005
Community-based Therapeutic Care	US\$204 per case (US\$73=RUTF)	US\$53	Bachmann 2009
Community-based Therapeutic Care		US\$12 – 132	Collins S 2001, Sadler K at al 2005
Community-based Therapeutic Care	US\$322		Emergency Nutrition Network 2004 as cited by Horton 2010
Children with mode	rate acute malnutrition (M	AM) receiving	food-based interventions
Fortified complementary foods	US\$40-80 US\$200	US\$500– US\$1,000	Horton 2009
FBF (CSB)	US\$22-US\$43 (product alone for 3-6 months)		Save the Children 2010
RUSF (<i>nutributter</i> ™)	US\$18-US\$36 (product alone for 6 months)		Save the Children 2010
RUSF (<i>plumpy'doz™</i>)	US\$52 (product and distribution for 7 months)		Gadot, Médecins Sans Frontières, as cited by Horton 2010
RUSF (<i>supplementary</i> <i>plumpy</i> [™])	US\$30 (product alone for 3 months)		Save the Children 2010
Children at risk of micronutrient deficiency			
Vitamin A Supplements (twice per year)	US\$1.57-US\$1.03	US\$11– US\$12	Fiedler 2000 Rassas, Hottor <i>et al</i> 2004 Rassas, Nakamba <i>et al</i> 2004
MNPs (<i>sprinkles</i> [™]) to deliver iron and folate	US\$3.6 per year	US\$12	Sharieff <i>et al</i> 2006 as cited Horton 2010

Source: Annex 6

Interventions for prevent micronutrient deficiency

Micronutrient supplements can be delivered at the health facility for all children under 24 months to prevent specific micronutrient deficiencies. This includes a take home supply of multiple MNPs and micronutrients supplements, iron-folic acid, and iodine supplements.

Interventions to address moderate acute malnutrition

While there are potentially many types of programmes that can address MAM at different levels, cost and cost-effectiveness information is only easily available and comparable for food-based interventions. *Box 8* is therefore confined to supplementary feeding interventions that provide micronutrient-fortified FBFs or RUSFs.

6.2 Very cost-effective interventions

Breastfeeding promotion with a cost per DALY of US\$3-US\$11 is one of the most cost-effective interventions. Vitamin A supplementation and MNPs with cost per

DALY of approximately US\$12 are also cost-effective. These interventions have a similar cost effectiveness to other priority child health interventions, such as immunisation and treatment of pneumonia and diarrhoea.

The use of RUTFs for treatment of SAM has a cost per DALY between US\$12 and US\$132. Traditional food fortification programmes reported by WHO during the early 2000's have a cost per DALY of around US\$41-US\$43. The high cost-effectiveness of the RUTF programme is due to the precise targeting of the programme. Iron-folate supplements for pregnant women is also a highly cost-effective intervention with a cost per DALY of US\$66-US\$115.

6.3 Less cost-effective interventions

Traditional programmes providing fortified complementary and supplementary food to children and the RUSFs for MAM children show low cost-effectiveness ratios. The cost for the delivery of RUSFs for MAM children are reported at around US\$36-US\$72, which probably underestimates the cost of introducing a new product in the health system. A more realistic figure would be around US\$50-US\$100 or close to the cost of traditional programmes providing fortified complementary and supplementary food. There are no estimates available of the cost per DALY for RUSFs. If it is assumed that receiving RUSFs (*nutributterTM*, *plumpy'dozTM*, *supplementary plumpyTM*) is as effective as a traditional programme providing fortified complementary fortified complementary and supplementary foods, and their prices are similar they will have a similar median cost per DALY of US\$750. This is not cost-effective for the lowest income countries of Africa. and their prices are similar they will have a similar median cost per DALY of US\$750. At this cost per DALY saved, in low income countries of Africa with GDP per-capita under USUS\$750, both types of interventions are not very cost-effective.

Finally a note of caution, cost-effectiveness analyses are very sensitive to assumptions about mortality rates in the scenario of no treatment and the cost of the products at the delivery point. In other words, the higher the mortality rate and the lower the unit price of the product or food ration, the lower the cost per DALY saved per intervention and the higher the cost-effectiveness. This means that in a country with a high mortality rate attributed to malnutrition, interventions become comparativey more cost-effective in comparison.

6.4 Conclusions

There are limited data on the cost-effectiveness of using nutrition products while cost data has to be carefully interpreted as costs vary depending on whether the product alone or the product and distribution costs are being included. Initial data indicate that MNPs are very cost effective as are RUTFs for treatment of SAM, while RUSFs, and FBFs to address MAM are less cost-effective and similar to traditional programmes using fortified foods.

Policies, strategies and operational guidance

Ten years ago, two new products, *plumpynut*TM and *sprinkles*TM were being piloted, now there are numerous products on the market. Policy-makers have lagged behind and have not yet developed guidance or consensus on the use of products. Currently, there is a plethora of products with no agreed criteria set for nutrient composition, objective, use or safety; nor clarity around terminology. As a consequence different governments and agencies have adopted different approaches to using nutrition products. The gap in guidance has contributed to a polarisation of views about their role.

Supporters note that RUTFs represent a "revolutionary change" in the treatment of SAM by allowing outpatient care. They argue that the bulk of acute malnutrition is in stable countries and particularly affects children aged 6-24 months during the 'hunger period'. A strategy for early treatment of these children is needed but national health systems cannot cope with the extent of the problem. One response is to provide suitable nutrition products for young children. This curative, medical approach is concerned with immediate gains in growth and is impatient with perceived "conservatism against new innovations".

Others are concerned about the economic and public health impacts of products and "commercializing the feeding of young children." There are concerns about providing 'magic bullet' items that suggest to caretakers that their children's health is out of their hands. The medicalisation of nutrition moves away from a holistic approach to tackling the causes of undernutrition, to focusing on specific nutrients and specific products. For a family to have good nutrition, one product or even a few products cannot provide a long-term answer. Appropriate caring practices such as breastfeeding, complementary feeding the correct amount of locally available foods at the right time, proper sick care, hygiene and access to medical care. Proponents of the whole-problem approach view these new products with concern, seeing them as temporary 'band-aids' for chronic undernutrition in these countries which fail to address the complex underlying causes. Moreover, focusing on the delivery of these products risks detracting from developing long-term sustainable approaches that would ensure nutrition and food security over the long term.

There is a need to get away from debate based on ideological differences and to develop consensus for guidance based on sound evidence.

Nutrition products are at different stages in terms of research and development. Some, such as *sprinkles*TM and *plumpy'nut*TM have been available for 10 or more years and are now being rolled out on a large-scale. Joint statements concerning their use have been issued by UN agencies though there remain areas of controversy and lack of clarity. Other newer products, such as *nutributter*TM to prevent chronic undernutrition, are still in the research phase. Yet others, such as *plumpy'doz*TM and supplementary *plumpy*TM are being distributed in an ad hoc fashion. Finally, there are many new products (both locally and internationally produced) that are beginning to be tested and will add to the evidence base in the next few years.

The lack of clear international guidance and an agreed strategic framework is causing some confusion in terms of programming. An example of this can be seen in Niger (see *Box 9*).

Box 9: Lack of guidance on nutrition supplements in Niger

Niger is the grips of a crisis brought on by drought in 2009. An estimated 7.1 million people are classified as severely or moderately food insecure. In total, some US\$68 million has been provided in aid from January to August 2010. A nation-wide survey conducted in May to June 2010 indicated a significant deterioration in the overall nutritional level of children under 5 years of age compared to 2009. The survey found that 16.7 % of children under the age of five suffer from acute malnutrition countrywide - a 35 % increase from the 2009 rate of 12.3 %.

Distribution of general rations targeted at vulnerable households is being carried out simultaneously with blanket supplementary feeding in selected regions to children aged 6 to 23 months and their mothers. There is a 20-60 % overlap in targeted households (i.e. households receiving both a general ration and a supplementary ration for their child aged 6 to 23 months). WFP decided to provide CSB++ (equivalent to 1,000kcal per day which allows for sharing within the family) in November 2009 but couldn't procure it so is providing CSB+. MSF wanted to give $plumpy'doz^{TM}$ (equivalent to 250kcal per day for individual child only) but initially the Government of Niger was not prepared to import products.

Subsequently *plumpy'dozTM* was permitted. WFP's distribution of CSB+ was scheduled for March to June (the most food insecure period) while MSF's distribution of *plumpy'dozTM* was scheduled for June to September (period of highest malnutrition rates). Efforts are being coordinated at country level, in particular to ensure coverage as wide as possible so that eligible children receive at least one of the commodities.

Lack of clear guidance on which nutrition supplements were most appropriate and issues with their accessibility and permission for distribution, as well as differences in INGO approach and product preference, have led to two products being deployed with the potential for confusion.

7.1 Agency positions

Annex 7 sets out the mandates and general strategies of donors and major development agencies including their strategies with respect to nutrition products. The current positions of these agencies are as follows:

USAID/Office for Foreign Disaster Assistance (OFDA)

OFDA provides funding for procurement of RUTFs (on a large scale) and RUSFs (on a small scale) in emergency operations. Funding is generally provided to NGOs who purchase the RUTF or RUSF from UNICEF. OFDA has no documented position or guidelines on the use of nutrition products at present. While OFDA supports the use of RUTFs for treatment of SAM in emergencies there is less clarity around products to address MAM because of the lack of evidence.

USAID Food for Peace Office is in the process of reviewing its food aid commodity needs and considering the addition of RUTF and RUSF to the list of eligible commodities for in-kind direct distribution programmes, which would mean that it could purchase the products directly through US Government procurement mechanisms. As part of this two-year Food Aid Quality Review conducted by Tufts University (2010, www.foodaidquality.org), USAID is also reviewing its programming and products specifically with respect to improving its line of FBFs including CSB and WSB.

European Union/European Commission Humanitarian Office (ECHO)

ECHO provides funding for FBFs and RUTFs on a large scale. In response to a growing number of proposals from implementing partners requesting RUSFs at the end of 2008, ECHO introduced a criterion for funding that made it contingent on including a research component endorsed by an independent research institution. Few partners were able to comply with this criterion. ECHO is now lowering the criterion to be more permissive with respect to applications for funding RUSFs though documents are not yet available.

World Bank (WB)

The WB is not a technical agency and typically does not procure therapeutic or supplementary food products. It follows normative guidance from WHO and UNICEF. However, it would advocate for evidence-based products including those for treatment or prevention of SAM and MAM, as long they have been approved and certified by WHO and UNICEF. WB supports the expansion of eleven proven high impact nutrition interventions to children and their mothers⁷⁸

World Food Programme (WFP)

WFP has the mandate to address moderate malnutrition and supports supplementary feeding targeted at young children and women. FBFs are the main nutrition product procured by WFP.

A joint consultation meeting in January 2010 between ECHO, WFP, WHO, UNICEF and others agreed that for prevention of MAM, CSB++ should be promoted over and above RUSFs. The reason was that addressing MAM with RUTF is very costly and could potentially cause confusion, while other RUSFs are still in the process of development.

WFP procures RUSFs (supplementary $plumpy^{TM}$ and $plumpy'doz^{TM}$) on a small-scale for particular situations. The choice of product is situation-specific but at the present time, CSB++ is anticipated to be WFP's major nutrition product procured, once the pilot phase testing is completed. Pilot projects on the use of MNPs in different contexts are being conducted in partnership with the Dutch company DSM. WFP has developed a decision-tree on the use of nutrition products. This is still in draft form and can be found in *Annex 8*.

United Nations Children's Fund (UNICEF)

UNICEF has the mandate to provide therapeutic food for the treatment of SAM. UNICEF supports CMAM⁷⁹ and is currently the largest global purchaser of RUTF. In a few cases, UNICEF supplies RUSFs like *plumpy'dozTM* and supplementary *plumpyTM*. UNICEF is scaling up distribution of MNPs for children. UNICEF is joint signatory on a number of formal documents concerning different nutritional products (*See Box 10*).

⁷⁸ **World Bank** (2009) *Scaling Up Nutrition: How much will it cost.* World Bank, Washington.

⁷⁹ The World Health Organization, the World Food Programme, the United Nations System Standing Committee on Nutrition and the United Nations Children's Fund. (May 2007) *Community-based management of severe acute malnutrition.*

United Nations High Commission for Refugees (UNHCR)

UNHCR has recently developed a strategy to reduce anaemia and micronutrient deficiencies among refugee populations using, among other interventions, nutrition products including MNPs and RUSFs⁸⁰. Project activities were started in seven countries during 2008 and 2009 and will expand to additional countries during 2010. An operational guidance is currently under development to be used as an aid to intervention planning, risk assessment, quality assurance, assessment of acceptability and setting up monitoring and evaluation systems in project countries. The operational guidance on anaemia interventions using nutrition productss contains seven stages as shown in *Annex 9*.

World Health Organisation (WHO)

WHO has the mandate to set norms and standards for health. Nutrition products used for therapeutic purposes fall clearly within this mandate. In this respect, WHO is signatory to a number of relevant documents as shown in *Box 10*. WHO has set up a technical group to define specifications of diets or food products suitable to promote recovery of children with moderate acute malnutrition. This Nutrition Guidance Expert Advisory Group is discussed below.

7.2 Operational guidance

There is no internationally accepted operational guidance describing and/or regulating the use of nutrition products. There are a number of documents that provide guidance on particular areas as shown in *Box 10* but comprehensive guidance is lacking.

This has led some agencies to develop their own guidance. Save the Children (SC) US has developed its own guidance note and decision-tree that sets out the SC US position on the use of specialised products and clarifies context, purpose, target group and recommended use for different nutrition products⁸¹. WFP has also developed a decision tree while UNHCR is in the process of developing operational guidance. USAID is reviewing existing guidance and will be issuing new guidance to incorporate the safe use and programming surrounding the enhanced FBFs and new nutritional products (Tufts FAQR, 2010).

The Global Nutrition Cluster does not have global guidelines but the Nutrition Cluster in Somalia has developed its own guidance on approaches for management of acute malnutrition, providing different scenario options and recommendations for the use of nutrition products in these scenarios⁸².

In terms of marketing of products, GAIN has produced a working paper giving guidance to governments, private companies and others on the appropriate marketing of complementary foods and products⁸³. An ad hoc group of NGO and UN

⁸⁰ **UNHCR** Strategic Plan for Anaemia Control and Reduction 2008 - 2010: Reducing the global burden of anaemia in refugee populations

⁸¹ Save the Children. (2010) Guidance Note on Specialized Products for the Treatment and Prevention of Undernutrition.

⁸² Acute Malnutrition Management Taskforce – Nutrition Cluster. (October 2008) Guidance for Approaches for Management of Acute Malnutrition

³ Quinn V, Zehner E, Schofield D, Guyon A, Huffman S. (2010) Using the Code of Marketing of Breast-milk substitutes to guide the marketing of complementary foods to protect optimal infant feeding practices. GAIN Working Paper No. 3.

staff together with academics are drafting guidelines for the marketing of ready-touse supplemental foods for children⁸⁴.

While these initiatives represent a starting point in setting guidance, they are unable to be too prescriptive given the lack of evidence on various aspects of nutrition products and the lack of international consensus in this area.

7.3 Development of guidelines and systematic reviews of the evidence

There are three initiatives looking at the evidence base for programming that include nutrition products and the development of guidelines.

WHO Nutrition Guidance Expert Advisory Group

The WHO Nutrition Guidance Expert Advisory Group (NUGAG) has recently been set up to introduce more rigorous processes for using research evidence in the development of recommendations, including guidelines and policies⁸⁵. NUGAG consists of experts from various WHO Expert Advisory Panels and external experts who will work together over the next two years. There are three sub-groups: 1) micronutrients, 2) diet and health, and 3) nutrition in life course and undernutrition.

The NUGAG will provide advice on the following:

- The scope of the guidelines and priority questions for which systematic reviews of evidence will be commissioned
- The choice of important outcomes for decision-making and developing recommendations
- The interpretation of the evidence with explicit consideration of the overall balance of risks and benefits
- The final drafting of formulated recommendations, taking into account existing evidence as well as diverse values and preferences

Priority areas for systematic review are being identified. One of five priorities for addressing MAM is to examine the effectiveness and safety of a food product. The draft parameters set for the systematic review are shown in *Annex 10*. The parameters could be broadened to include more outcomes such as adverse effects on dietary habits. The review is expected to be completed by the end of 2011.

A recent WHO consultation on strategies to address MAM suggested that while randomized control studies are optimal for establishing the evidence base, they are frequently not possible in many field contexts. Non-randomized comparative studies can contribute significantly to the evidence base about the impacts of various nutrition products, interventions, and delivery mechanisms for the management of MAM. Observational studies can also add to the body of knowledge in this area⁸⁶.

⁸⁴ Guidelines for the Marketing of Ready-to-Use Supplemental Foods for Children (2010) (in draft)

 ⁸⁵ WHO (2010) Meeting of the WHO Nutrition Guidance Expert Advisory Group (NUGAG): Subgroup on Nutrition in Life course and Undernutrition, 2-4 June 2010: Geneva
 ⁸⁶ WHO, UNICEF, WFP and UNHCR (2010) Consultation on the Programmatic Aspects of the

^{oo} WHO, UNICEF, WFP and UNHCR (2010) Consultation on the Programmatic Aspects of the Management of Moderate Acute Malnutrition in Children under five years of age. 24-26 February 2010, WHO: Geneva

GAIN Home Fortification Technical Advisory Group (HF-TAG)

A Home Fortification Technical Advisory Group (HF-TAG) has been formed for which GAIN provides a secretariat function. It is composed of 'thought leaders' from international agencies, research/academic institutions, and suppliers. The purpose of the group is to manage technical knowledge, pull together technical documents and to develop consensus on guidance to governments and others. HF-TAG is mainly concerned with MNPs.

Cochrane Collaboration

Three relevant titles for systematic reviews have been registered87 through the Cochrane collaboration. These are:

- "Ready-to-use therapeutic food for the treatment of undernutrition in young children" (November 2009),
- "Home fortification of foods with multiple micronutrient powders for health and nutrition in children under two" (September 2009),
- "Supplementary feeding with nutritional education for caregivers for promoting growth and development in young children in developing countries".

None of the titles registered so far will explicitly look at LNSs foods for prevention of acute or chronic undernutrition (i.e. effectiveness of products such as *plumpy'dozTM*, *nutributterTM* and other LNS products etc.) though this could be incorporated into the third title registered above.

7.4 Conclusion

Fifteen years ago, two new products, *plumpynut*TM and *sprinkles*TM were being piloted, now there are numerous products on the market. Policy-makers have lagged behind and have not yet developed guidance or consensus on the use of products. Currently, there is a plethora of products with no agreed criteria set for nutrient composition, objective, use or safety. There is not even clarity around terminology. The result is that different governments and agencies have adopted different approaches to using nutrition products. Development of internationally agreed guidance for nutrition products is a priority.

⁸⁷ Cochrane reviews involve a multi-stage process. The first stage is for a Review Group to identify a review title which is registered. A protocol is then developed that sets out how the review will be done.

Public and private sector roles in marketing nutrition supplements

8.1 Global food sales and the future of the food industry in developing countries

The US, the EU and Japan account for over half of the total sales of packaged foods worldwide. In developing countries, intermediate products, such as vegetable oils, dry pasta and other dried products, account for the bulk of retail sales. Market trends indicate strong growth in sales of packaged foods in developing countries. This growth involves three quarters of the world's consumers and is partly due to rapidly growing income levels in some countries. Consumption of manufactured foods is growing in many developing countries. India had an annual retail food sales growth from 2003 to 2008 of 26.9% in ready meals, 15.2% in dried foods, 14.7 % in dairy products, 11.7 in breakfast cereals, and 8.1% in oil and fats. In Vietnam, the % increases were 13.2, 18.5, 13.3, 21.7, 18.6 respectively in these same categories.

Many companies making nutritious products, drinks and snacks are marketing to the world's poor. For example, 42% of Danone South Africa's global sales are now in low income countries and market segments, in large part because it developed cheap "on the go" drinkable yogurts. Danone South Africa has set up partnerships with local producers in Indonesia, Bangladesh and Senegal to manufacture and sell local variants. Pepsi Co. and Nestlé South Africa are also entering the fortified drink and food markets in low income countries.

Dominant companies marketing to the poor

Annex 12 describes food companies active in production and promotion of nutrition products in developing countries. The section below uses the example of Nestlé to highlight the range of products being promoted by one international company.

Nestlé SA (Nestlé) dominant in local manufacture and marketing products to low income consumers. Headquartered in Switzerland, Nestlé employs around 280,000 people and has factories or operations in almost every country in the world. The company plans to invest US\$138 billion in developing plants in Africa in the next three years. Sales for 2009 were CHF 108 billion (www.nestle.com). Working in line with its philosophy of Creating Shared Value, which emphasizes value creation between societies in which the company operates and its shareholders, Nestlé has developed a range of locally adapted, nutritionally valued foods for lower income brackets worldwide. These "popularly positioned products" are relatively low cost, packaged in appropriate serving sizes, and combat micronutrient deficiencies in iron, iodine, vitamin A and zinc. The product range includes: Iodine-enriched Maggi products (bouillons, seasonings and noodles), globally-branded milk products (specially fortified with iron, zinc, vitamin A and other micronutrients according to specific deficiencies in target markets), fortified cereals, baby foods, and powdered drink mixes.

Examples of Nestlé's affordable fortified milks include Ideal, sold in Brazil and Indonesia, Nespray (Malaysia and Sri Lanka), Bear Brand (Philippines), Klim (The Caribbean), and Nido Essentia (Central and West Africa – Guinea). Other Nestlé PPPs are country specific, such as its line of products in Indonesia: Dancow Batita (milk powder for toddlers), MILO Choco Blazz (chocolate powder, fortified with iron), Nestea (tea mix), Koko Krunch (cereal, fortified with iron, 8 vitamins, calcium and

whole grains), and Nescafe Tubruk (coffee). The first examples of affordable fortified milks could be used as breast milk substitutes.

8.2 Structure of the RUTF/RUSF market and its stakeholders

There is a growing demand for RUTFs and RUSFs, as more agencies seek ways to prevent undernutrition in children under 2 years of age. This market's potential is estimated at about US\$200 million⁸⁸. Compare this to the US\$25 billion dietary supplement market in the US, where 65% of adults label themselves as supplement users⁸⁹. Development of nutrition products for undernutrition has been largely supplier driven, dominated by Nutriset and its franchise model of global expansion. While there are more suppliers entering the market every year, sales are limited to a small number of large volume institutional buyers, because the products are mostly distributed through the public health system and international agencies.

To date, RUTFs and RUSFs have not become retail products. These products are more like medicines or health foods in terms of their therapeutic and preventive objectives, and so universities, research institutes and foundations play a role in advancing the evidence base and products are promoted through social marketing channels.

As discussed in Chapter 7, public sector entities play a significant role in developing policies to orient the further R&D of products to meet the needs of malnourished children and nutritionally vulnerable adults. The development of nutritional products in the future will require more public sector involvement at the international and national levels to develop the policies, frameworks, norms and quality assurance systems to protect consumers and ensure global harmonization around nutrition products. It should be noted that nutrition products do not exist in isolation from their use and must be considered in terms of how they are programmed when distributed in public health programmes and how they are marketed when sold through commercial channels.

The private sector, too, plays a critical role. It is best placed to understand what nutrition products are possible to produce from an R&D perspective, what is a profitable return on investment and what risks are tolerable in order to invest in R&D for new products. Obviously there is a profit to be made since there is an explosion of new companies entering the market, as described in earlier sections of this report.

Today, most preventative and curative nutrition products are procured and provided gratis through international or national food assisted development or emergency programmes. It is debateable whether there is a commercial potential for preventative nutrition products at price points low enough to attract low-income retail consumers. Incomes of households most at risk for malnutrition are invariably extremely low and nutritionally adequate diets are already unaffordable for a significant proportion.

8.3 Successful partnerships targeting nutrition products to the poor

Developing commercial food products for the public good is being accomplished through a variety of partnerships. Some PPPs advance the science and evidence base, while others concentrate on product R&D and marketing affordable nutritional

 ⁸⁸ Rice, A. (2010) *The Peanut Solution*, New York Times Magazine, September 5, 2010
 ⁸⁹ Dennis, J. (2010) *Dietary Supplements 2010*, Nutraceuticals World, http://www.neutraceuticalsworld.com/contents/view/17971).

products for low-income consumers. The following sections highlight types of partnerships.

Franchising and intellectual property transfer: Nutriset and PlumpyField

Nutriset, and its Plumpy Field model is an example of a successful PPP. In spite of the obstacles the patent creates for new suppliers, this model promotes good manufacturing practices, quality assurance and food safety standards. It is described in detail in Section 4.1.1.

Advancing the research and evidence base: The International Lipidbased Nutrient Supplements Project (iLiNS)

iLiNS, led by Kay Dewey at the University of California at Davis, with support from the Bill and Melinda Gates Foundation, is an example of a public private research partnership with the mission to "develop and test new solutions to help prevent malnutrition in vulnerable populations, and to share the knowledge and experience gained." The current project builds upon "recent research addressing the use of lipidbased nutrients for prevention of malnutrition and identifying formulas that have optimal nutrient content and energy doses while still remaining cost-effective." Partners include University of California Davis, University of Malawi, Nutriset, Institut de Recherches en Sciences de la Santé in Burkina Faso, University of Tampere in Finland, Project Peanut Butter in Malawi, University of Ghana, and Helen Keller International. When the research is completed in 2013, results will help determine the best nutritional profile for products to prevent and treat MAM. See the Project Overview: www.ilins.org/about-ilins.

Transferring technology: Insta-Pro and General Mills

Another model is the newly formed partnership of Insta-Pro International, a technology leader in low cost, high shear extrusion, with a presence in Africa for over 20 years, with General Mills Inc., a global cereal and food manufacturing company. The two companies have teamed up to provide low-cost efficient technology, technical assistance and relationship support to food manufacturers in developing countries, leveraging their expertise in good manufacturing practices. According to a recent press release, "Insta-Pro International has been successful for many years in providing food and feed processing solutions which meet the needs of many producers in...African countries." The company will provide the equipment, and know-how to use it, within General Mills' volunteer initiative to assist small to medium sized processors in Africa. In turn this will provide General Mills with the opportunity to expand their initiative through Insta-Pro's many current relationships in Africa⁹⁰. (www.insta-pro.com, August 20, 2010)

Combating iron deficiency: Britannia and GAIN

GAIN and the Indian food company Britannia, manufacturer of the Tiger biscuit, partnered in 2007 to fortify it with iron. Naandi Foundation, an organization based in Hyderabad, India dedicated to the eradication of Indian poverty, joined the partnership after realizing the potential nutritional impact the fortified biscuit could have on their beneficiaries.

In 2008, the partnership achieved health improvements in 150,000 children. A grant from GAIN enabled the biscuits to be purchased from Britannia and the project has continued in the mid-day meal programmes in Hyderabad schools. The success of this partnership has encouraged Britannia to fortify almost 55% of its commercial line

⁹⁰ <u>www.insta-pro.com</u>, August 20, 2010

with micronutrients, which includes other biscuit brands for children. Today, the Tiger brand sells nearly 3.5 billion units annually.

Improving nutrition and business practices: USAID Public-Private Partnerships in Namibia

In February 2008, USAID partnered with Africa's largest bank, Standard Bank, the subsidiary of the diamond company De Beers, Namdeb, Namibia Dairies, and the Namibia Business Coalition on AIDS to provide Namibian children with a 500 kcal nutritious yogurt and education on HIV/AIDS prevention. The partnership achieved a twofold increase in the number of children receiving the vogurt and education, from 400 to 800, by the second month of the partnership in March 2008. USAID and Standard Bank further cooperated in October 2007 in another project to assist the NGO Child Welfare of South Africa with the development of efficient business practices. In May 2010, Standard Bank was lending its personnel to Child Welfare in efforts to help the organization fulfil its mission of helping children. These projects show how the success of one PPP can be the impetus for another.

Unilever and WFP: Together for Child Vitality

In December 2006, Unilever and WFP partnered to tackle child malnutrition around the world⁹¹. In 2007, Unilever first donated EURO€ two million for WFP to use in its nutrition assistance programme for children in Kenya, Colombia, Ghana and Indonesia⁹². The partnership helped the WFP provide 16 million school meals to 76,000 children in Indonesia, Pakistan, the Philippines, Colombia, Kenya and Ghana in 200893. Unilever's cause-related marketing activities, "where for example one of Unilever's margarine brands donates the cost of a school meal to WFP for every tub of margarine bought, are a cornerstone of Unilever's partnership with WFP," and contributed to up to a 20% sales increase in Unilever's margarine brands in 2008⁹⁴. In 2010, the partnership will be involved in five countries; namely, Kenya, Indonesia, Ghana, Colombia and the Philippines⁹⁵.

8.4 Marketing – what can we learn from private sector experience

Key to marketing nutritional products is developing a desirable product at an affordable price, often meaning that it is packaged in small or individual sizes, as this consumer segment does not have a lot of cash or refrigerated storage to buy perishable products in bulk. Two examples of what the private sector can teach us about marketing nutritional products to low income populations are presented here.

Grameen Danone Foods Ltd.

In March 2006, the Danone SA food company and Grameen Bank (the "Bank of the poor") founded Grameen Danone Foods Ltd. as a business with a social orientation. One of the organization's four objectives is to develop a product that has high

⁹⁵ Information on Unilever and WFP partnership (2010), Unilever website

http://www.unilever.com/brands/nutrition/workingwithothers/wfp/, accessed August 25, 2010

⁹¹ Unilever and WFP (2010) Together for Child Vitality Annual Report 2008,

http://www.unilever.com/images/iv-icn09 Together-child-vitality-annual-report-2008 tcm13-189949.pdf, p.1, accessed August 25, 2010 ⁹² Press Release WFP-Unilever Partnership (2010):

http://www.unilever.co.id/ourcompany/newsandmedia/pressreleases/ 2007/UnileverWorldFoodProgram meWFPincooperationtofighthungerinchildren.asp, accessed August 25, 2010

Unilever and WFP (2010) Together for Child Vitality Annual Report 2008,

http://www.unilever.com/images/iv-icn09 Together-child-vitality-annual-report-2008 tcm13-189949.pdf, p.1, accessed August 25, 2010 ⁹⁴ **Unilever and WFP** (2010) *Together for Child Vitality* Annual Report 2008, p.6, accessed August 25,

²⁰¹⁰

nutritional value and is affordable for the poorest individuals. "Shokti Doi" yogurt ("that which builds strength" in Bengali) was developed according to the nutritional needs of Bangladeshi children with the help of nutritionists from GAIN. Made with cow's milk, date molasses and sugar, this product is a natural source of calcium and protein, contains live fermenting cultures that can reduce the severity of diarrhoea, and is enriched with micronutrients. Shokti Doi yogurt is sold in small sizes for € six cents. Studies have found this to be an affordable price for poor families. Initially, Shokti Doi was to be sold door-to-door by local sales women on commission. Now significant sales come from urban stores, not rural villages as planned.

Grameen Bank will assist local farmers with micro-credit, jumpstarting the flow of raw materials used in the yogurt's production. Grameen Danone is focused on social impact, and therefore, a contract between Grameen Danone and these farmers will guarantee a fixed sale price for the farmers' crop throughout the year and any profit from the sale of Shokti Doi yogurt will be reinvested in the maintenance or expansion of the Grameen Danone business.

Nutriset and social marketing in Niger

Nutriset employed social marketing techniques to low income mothers in Niamey, Niger, for a micronutrient supplement for 1-5 year olds⁹⁶. The product, "Grandbien," was named following focus group interviews because it was easy to understand and it emphasizes the product's benefits. Specially designed graphics were included on the package to communicate an affordable product to consumers who were likely to be illiterate.

Pricing the product was difficult, as Nutriset wanted to make it affordable to lowincome mothers. The price was fixed, to ensure the affordability of "Grandibien" based on studies of the amount of money needed for mothers to complement the diets of their children over a two week period. The retail price covers the production costs of the product only, while Nutriset covers the other variable marketing costs, such as communication and distribution, thereby subsidizing the cost to the consumer.

8.5 Current issues, obstacles, opportunities for future market development

Government bureaucracy

Just as with any business venture, government bureaucracy and country-specific laws can be barriers to entry for new products. An example of this in the context of nutrition products has been companies DSM Nutritional Products Ltd. and Renata Ltd. in Bangladesh, and their respective *sprinkles*TM products, *mixMe*TM and *magix*TM. The Bangladeshi government refused to acknowledge the products as food supplements, instead categorizing them as a pharmaceutical. Thus, these MNPs are only sold in Bangladeshi pharmacies and may not be as accessible to the Bangladeshi people as the companies originally hoped. In such cases, it is important for these companies to partner with organizations that have the know-how and capability of acquiring product approvals.

⁹⁶ Information on Unilever and WFP partnership (2010), Unilever website <u>http://www.unilever.com/brands/nutrition/workingwithothers/wfp/</u>, accessed August 25, 2010

Patents

Nutriset is being sued by two American not-for-profit organizations for the patent on its *plumpy'nut*TM brand. As the patent was filed in the US in 2002, Nutriset is able to prevent any US company from producing the RUTF without its consent. Nutriset gives several reasons for its filing for the US patent⁹⁷, one of them being the prevention of "cheap US surpluses" from entering the market that would diminish the quality of the RUTF product currently being distributed (i.e., *plumpy'nut*TM). Another reason given is that Nutriset patented *plumpy'nut*TM s to protect the network of partnerships and franchises in Africa that produce plumpy'nutTM with locally-grown raw materials⁹⁸.

Mike Mellace, president of the not-for-profit Mama Cares Foundation and co-owner of Mellace Family Brands, has joined forces with the Texas not-for-profit Breedlove Foods to challenge Nutriset's patent⁹⁹. Mellace says that global demand for RUTFs cannot be met by Nutriset alone. He notes that only one to two million of the world's 26 million malnourished children are receiving *plumpy'nut*TM or its equivalent, and thus, worldwide demand can only be fulfilled through an open supply chain. In this regard, he emphasizes the potential of the massive peanut industry in the United States, which feeds into Nutriset's argument about competition with US products. If the patent is overturned, Mellace believes the production capacity of this industry could save millions of children.

According to Remi Vallet, Nutriset's communications manager, the problem "is not lack of production." Rather, "there is neither the international funding nor the systems in place to provide RUTFs." Meanwhile, Nutriset believes African governments need to manage the issue of nutrition in their own countries, free of any foreign obstruction¹⁰⁰. Thus, the company's efforts to safeguard local African producers are not only for the economic development and wellbeing of the producers and surrounding regions, but also for the eventual ability of African governments to effectively manage the issue of nutrition in their respective countries. From one perspective, Nutriset's efforts towards this end are commendable. From another, expansion of RUTF production in the US and around the world could help meet the needs of millions of malnourished children not being reached by Nutriset.

Regardless, the patent clearly serves as a barrier to future market development of nutritional products and many food companies are likely awaiting its abrogation.

8.6 Conclusions

What can we learn from the private sector and their experience marketing nutrition products and other foods to the poor? First, it is essential to respect and consult the consumer. Secondly, size matters. Packaging the product in individual servings, often for immediate consumption, is preferred and allows for distribution to corner markets which is desirable. Thirdly price is key. It is critical to find the price point

⁹⁷Nutriset's patent from the U.S. Patent and Trademark Office database:

http://patft.uspto.gov/netacgi/nph-

Parser?Sect1=PTO2&Sect2=HITOFF&p=1&u=%2Fnetahtml%2FPTO%2Fsearch-

bool.html&r=1&f=G&l=50&co1=AND&d=PTXT&s2=nutriset.ASNM.&OS=AN/nutriset&RS=AN/nutriset, accessed August 23, 2010

⁹⁸ Schofield, H. (2010) Legal *fight over Plumpy'nut, the hunger wonder-product* 8 April 2010, <u>http://news.bbc.co.uk/2/hi/europe/8610427.stm</u>, accessed August 23, 2010

⁹⁹ Lavelle, J. Child malnutrition center of legal battle, 16 January, 2010 Union-Tribune, <u>http://www.signonsandiego.com/news/2010/jan/16/child-malnutrition-center-legal-battle/</u>, accessed August 23, 2010
¹⁰⁰ Schofield, H. Legal fight over Plumpulant the hunger mandatum start of the H 0010

¹⁰⁰ Schofield, H. Legal fight over Plumpy'nut, the hunger wonder-product, 8 April 2010, <u>http://news.bbc.co.uk/2/hi/europe/8610427.stm</u>, accessed August 23, 2010

which will allow the low income consumer, with little disposable cash, to purchase the product on a regular basis.

It is possible to market nutritious, quality food products to low income consumers.

Should nutrition products be marketed for the public good or as retail products? It is important to determine from the start if a nutrition product will be distributed through public channels as a treatment for free or at a significant discount or whether it is marketed at the "right price". It is very difficult to shift from distributing a nutrition product as a "medicine" gratis to distribution as a retail product. There might also be a deterioration in the effectiveness of therapeutic products if they lose their 'medicine' label.

There is potential for PPPs in contributing to addressing hunger through distribution of nutritious products. These partnerships are only effective, however, if all parties have a shared goal.

Finally, it will be important to plan for the entry of baby food, drink and snack food companies into the RUSF market space. Companies like Coke, Pepsi and Nestlé are important marketing forces in the global food industry but have yet to enter into the field of nutrition products for undernutrition. As the marketplace expands beyond treatment of SAM and MAM into prevention of undernutrition, it will be important to make sure the pitfalls of Nestlé (and other companies') approaches to marketing infant formula are avoided.

The way forward: future priorities

Throughout this report there are areas highlighted that are in need of increased attention by governments, development actors and the private sector. The key priorities for future action are detailed below.

9.1 Support research to address identified evidence gaps

Guidance on nutrition products cannot be developed without a strengthening of the evidence base. Much of the research on nutrition products has been linked to the food industry raising concerns about conflict of interest. This argues for research support from non-interested parties. Specific priority areas for research are:

- (a) Strategies to address MAM, chronic malnutrition, maternal malnutrition and low birthweight (with or without nutrition products) in different settings and adopting a multi-sectoral approach.
- (b) Efficacy and effectiveness of different nutrition products on nutrition outcomes (acute malnutrition, chronic malnutrition and micronutrient status) in diverse contexts. Potentially adverse effects of nutrition products (IYCF, later obesity and chronic disease, dietary habits) among different populations. Operational implications (sustainability, acceptability, cost-effectiveness) of including nutrition products for different purposes and among different populations.

9.2 Support development of international guidance

Guidance is needed in three key areas:

- (a) Internationally accepted operational guidance regulating the use of nutrition products through galvanising the four key nutrition UN agencies (FAO, UNICEF, WFP and WHO) to work together to build consensus and develop normative guidelines.
- (b) Interim guidance to support programme decisions as described in *Annex 11* to allow informed decisions on a case by case basis with regard to the use of nutrition products. While guiding principles have to remain general and unspecific given the current lack of evidence, they can help to orientate decisions. The guidance is short-term it should be updated as new evidence is established.
- (c) Support development of guidance on operational research methods for research into nutritional products. Since these products are in widespread use, full opportunity for learning about their use should be seized and the evidence generated should meet minimum research standards.

9.3 Support engagement with the food industry

Given the skills and interest of the private sector in the market there is ample to forge constructive relationships across the public and private sectors. The challenge will be to work together collaboratively on new product ideas and innovations while providing sufficiently high quality assurance standards and a level playing field in the procurement process. Engagement with the food industry goes beyond a narrow focus on nutrition products and could encompass a broader range of interventions aiming to reduce the global burden of malnutrition.

There are three priorities for this engagement:

- Development of nutrition products with set nutrient contents, suitable for clearly defined uses in addressing specific aspects of undernutrition in poor countries. These produced can then be produced as generic non-branded products. PPPs would be one effective mechanism for achieving this aim.
- Development of transparent harmonized international procurement and quality assurance standards, projections of global estimates based on structured demand for the products and their uses, and long-term contracting that would be attractive to manufacturers.
- Development of guiding principles and a framework for how to engage with the private sector, in particular to help the global process to evolve from a supply driven solution (as currently is the case of nutrition products for preventing and treating SAM and MAM) into one that draws on the best elements of private sector competitiveness and manufacturing good practices.

In addition greater engagement with national governments to bring together key people from several sector ministries (e.g., trade, finance, planning, agriculture, health, education, social welfare/safety nets) to help set in place policies that will attract private sector investment (i.e., as was done to attract the private sector to fortify salt, flours and other foods) and the partnerships to strengthen and/or build local companies to produce the needed products and develop a national framework that will ensure quality control and safety in manufacturing and quality assurance throughout the supply chain, without pipeline breaks (especially important in emergency situations).

9.4 Support local production of nutrition products

The arguments for supporting local production are strong and headway is being made in setting up local production sites. Nevertheless, huge challenges remain. Set up investments are high for updating production sites, equipment, capacity development, monitoring and evaluation mechanisms. Quality control for local production sites is essential because of the stringent hygiene and other requirements, particularly difficult to maintain in hot, humid environments. Development partners could consider funding the setup of local production sites for RUTF and MNPs for use in emergency-prone regions and provide a framework and training for improved quality assurance standards. Consideration would be contingent on a careful analysis of cost, quality assurance and sustainability in comparison with imported products.

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