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Improving the Nutritional Quality of U.S. Food Aid: Recommendations for Changes to Products and Programs

FINAL REPORT

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FOOD AID QUALITY REVIEW OVERVIEW

Broad Conclusions

- ❖ Putting nutrition at the heart of the food aid agenda will enhance the impacts and credibility of USAID
- ❖ Existing products have an important value, but they can and should be enhanced
- ❖ Quality food aid means enhanced products, but also upgrades in processes along the value chain
- ❖ “Smart” programming of food aid will dovetail with whole-of-government global initiatives

Quick Wins

- ❖ Adopt new specifications for FBFs in Title II (not only Corn–Soy Blend [CSB] and Wheat–Soy Blend [WSB]); explore new products beyond existing formulations (new grains or legumes in blends; lipid-based products)
- ❖ Promote new program guidance (decision tools) to facilitate improved matching of products to purposes having nutritional intent
- ❖ Revise micronutrient profile of premixes for milled grains; add bulk premix to commodities list for in-country fortification where feasible and cost-effective
- ❖ Update reference guidance in real time, including the Commodity Reference Guide
- ❖ Convene a new Interagency Food Aid Committee (IFAC) to provide a “one-stop shop” for whole-of-government technical actions in food aid (coordination of products, processes) and interface with industry and implementing partners
- ❖ Establish public–private partnerships to accelerate development and testing of products

Other Priorities for Action

- ❖ Explore and test options for improved packaging and storage of products, to improve shelf life and promote recommended usage by intended beneficiaries
- ❖ Pursue common (multiagency) process for review of new products, approval/certification of vendors, and quality assurance standards, with transparent industry-friendly interface
- ❖ Undertake reforms in commodity acquisition and supply chain management, drawing on best commercial practices for vendor selection, quality assurance standards, and auditing
- ❖ Identify incentives to enable industry to invest in, and commit to, quality production and innovation of enhanced products
- ❖ Issue “innovation challenges” to industry to develop cost-effective means to a) fortify cereals outside the U.S., working closely with other relevant initiatives, b) extend the shelf life of processed products, and c) produce blended foods on site, using mobile technologies in emergency response situations
- ❖ Establish a multistakeholder working group to oversee development of new programming guidance and coordinate field-testing of products
- ❖ Develop clear guidance, in coordination with the Office of the Global AIDS Coordinator and President’s Emergency Fund for AIDS Relief in Africa (PEPFAR), to support allocation of funds for nutrition support in HIV programming, using standardized indicators of impact.
- ❖ Establish process and system-wide protocols for strengthening evidence base on programming effectiveness and cost-effectiveness

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EXECUTIVE SUMMARY

Food aid provided by the United States has saved the lives of vulnerable people in dire need of assistance for almost two centuries. The volume of such aid, and the scope of the interventions it supports, dramatically increased in the 1950s with the enactment of Public Law 480. Billions of dollars have been invested since then in protecting life during conflicts and natural disasters and in enhancing the diets of chronically undernourished people in development settings. This review is part of a long-standing USAID effort to improve the quality of food aid products and programs as priorities and needs evolve.

Today, however, food aid is at a crossroads. Severe resource constraints, reduced volumes of food aid shipped globally, and questions posed about whether products used are “fit for purpose” all represent challenges to current food assistance practices. A spotlight has been turned on the U.S. food aid agenda.

Recognizing the need for a thorough review of product formulations and specifications, USAID commissioned a two-year assessment of quality issues relating to Title II food aid products. This report presents the findings and recommendations of that review.

Although the work was initially focused on cereal-based blended products enriched and/or fortified with micronutrients, it became clear that the bigger picture had to be taken into account (including attention to noncereal products), and that a focus on food products alone would not suffice. Thus, the report addresses not just the nutritional quality (composition) of food aid, but also the nature of programming and the processes that support programming, from procurement through to delivery.

A number of broad conclusions emerge. First of all, USAID and its partners on the ground already achieve remarkable impacts under the most challenging of circumstances imaginable. Most food aid now responds to humanitarian crises, and specification of products has to be framed in that context, without ignoring the valuable food-assisted work conducted outside of emergencies.

But there is much scope for improvement. Smarter programming, more careful targeting, greater attention to cost-effectiveness (in relation to planned human outcomes, not just numbers of people “fed”), enhanced coordination and streamlining of U.S. Government interagency processes, enhanced policy harmonization among international players, and application of best practice in product formulation and production can markedly increase the impact of U.S. food aid resources.

Second, the needs of food aid beneficiaries are not homogeneous—there is no one food product that can meet every kind of programming goal, and no one programming approach that fits all needs. The right tools have to be available for specific jobs on the ground, and new products that demonstrably meet defined needs in a cost-effective manner are to be welcomed. But combinations of foods are always

more appropriate to the needs of beneficiaries than are combinations of nutrients in a single food.

Third, improving food aid quality is more than just fine-tuning the composition of products; it is as much about ensuring appropriate programming of all products.

Specific recommendations include the following:

1. **Improve the formulation of Fortified Blended Foods (FBFs) used in Title II programming.** This includes upgrading the composition of cereal-based fortified foods targeted mainly to children 6 to 24 months of age, pregnant and lactating women, wasted children 6 to 59 months of age, and wasted individuals undergoing HIV/AIDS treatment. Enhancements include the addition of a dairy source of protein; enhancing their micronutrient profile; the development of new forms of cereal-based blends, particularly focusing on different grains that are nutritionally and culturally appropriate for use in Africa, allied with alternative sources of plant-based protein, such as legumes; and exploring ways to reduce phytates, which inhibit iron and zinc absorption, via processing. New packaging is needed to support more effective targeting and shelf life.
2. **Upgrade the vitamin and mineral mixes used and diversify approaches to addressing micronutrient needs.** Enhance the composition of premixes used to fortify blended foods as well as milled grains and vegetable oil; facilitate shipping of fortificant premix with bulk cereals for in-country fortification; and develop micronutrient powders (sachets) and other point-of-use fortification options.
3. **Develop or adopt non-cereal-based (e.g., lipid-based) products for the management of nutritional deficiencies.** A wider range of products should be available offering varying quantities and types of nutrients for different programmatic contexts. This is an argument for more choice among appropriate tools, not for discarding products that have already shown their value over many years. It also does not reduce the need to maintain a focus on supplying high volumes of quality grains as the main staple in food aid baskets.
4. **Provide clearer programming guidance.** Improved decision tools are needed to enable implementers to match products to specific consumption and nutrition goals (product-for-purpose). New guidance is needed on nutrition support for HIV/AIDS programming, home preparation of FBF products (enhanced as proposed) with vegetable oil for nutritionally vulnerable beneficiaries, and planning for delivery of nutrients across a basket of commodities rather than via single products. Additional investments are also essential to support Behavior Change Communication (BCC) and programming that support global infant and young child feeding principles.

5. **Establish an interagency committee to oversee all government interests in the food aid agenda.** Such a U.S. cross-agency committee would oversee ongoing review of products (improvement in existing, and introduction of new, products as needed) and programs (including careful testing of changes recommended here), progressive harmonization of products and policies among global food aid agencies, and effective integration of food aid in food security initiatives.
6. **Enhance processes along the product value chain.** Effective interaction with the private sector is needed to bring industry best practice to bear on food aid supply, food safety and quality assurance, and public–private partnerships to promote product innovations. Performance specifications should be established that allow for high-quality products that can be used in a variety of programmatic circumstances, but supportive of more clearly defined nutritional objectives.
7. **Strengthen the evidence base for innovations in products, programming approaches, and institutional processes.** Successful programming has to be evidence-based, not driven by simple data on tonnages and “hungry people fed,” but by an understanding of the unit cost of impact. Empirical rigor is essential to determine the role of alternative programming approaches, the cost-effectiveness of different products, and the relative efficiencies of using food versus other resources to achieve defined goals. The evidence base for people living with HIV/AIDS (PLHIV) is particularly limited and warrants further investigation. Any significant program changes, including those recommended here, should be tested and monitored.

Putting nutrition at the heart of the food aid agenda will enhance the impact and credibility of Title II programming. Innovations must be carefully tested and processes defined to support ongoing improvements across the food aid system. The ultimate goal of high-quality food aid programming should still be an end to the need for food assistance. USAID should champion smart programming, prioritize evidence-based cost-effective strategies, and advocate for a global convergence toward quality—not just in terms of products, but in terms of the way in which business is conducted.

“The question is not whether we can end hunger,
It’s whether we will.”

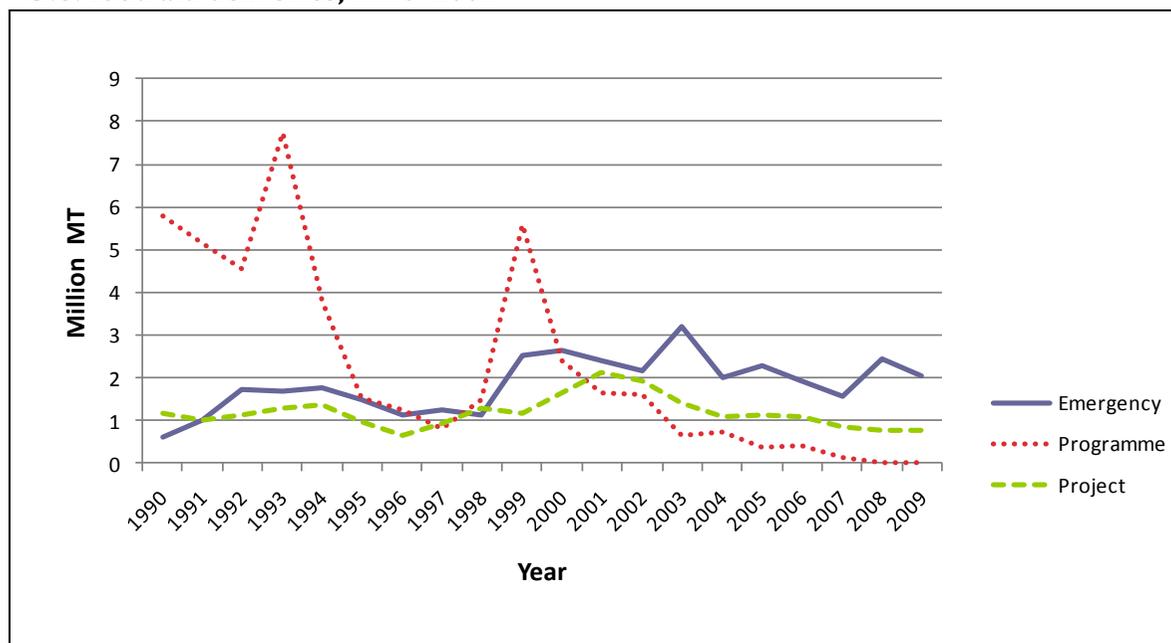
Secretary of State Hillary Rodham Clinton

I. INTRODUCTION

USAID’s food aid programming, through the FFP under Title II of Public Law 480, has been, and remains, an important instrument in tackling the multifaceted problems of food insecurity around the globe. Demands on food aid continue to grow, with increased frequency of natural disasters, increased numbers of people affected by such shocks, and upward pressures on food prices since 2007 leading to more people unable to meet minimum food requirements—all contributing to what has been called “the growing problem of hunger” (USAID, 2010).

That said, the total volume of food aid delivered by the United States has been falling since the later 1990s, mirroring patterns globally (Figure 1.1). During that time, the importance of emergency food aid grew relative to development project and program (balance of payment) support activities.

FIGURE 1
U.S. food aid deliveries, 1990–2009



Source: WFP (2010a).

A range of foods is used in both emergency and nonemergency settings. Based on United States Department of Agriculture (USDA) annual reports from fiscal year 2004 to 2008, 15 commodities accounted for 96% of the volume and 94% of the cost of all Title II food aid (USDA, 2008). Prices ranged from \$137 to \$298/metric ton (MT) for basic grains, from \$275 to \$314/MT for milled flours, from \$368 to \$473/MT for fortified blended milled products, and from \$486/MT for pulses to more than \$1000/MT for value-added products, such as Fortified Vegetable Oil (FVO). Nutritionally enhanced products, such as Corn–Soy Blend (CSB), micronutrient- and/or soy-fortified milled cereals, and FVO, represented 25% of the volume but 44% of the cost of Title II commodities purchased.

In the design and distribution of food rations, Title II programs implement activities in a similar range of technical sectors in both emergency and nonemergency settings: Maternal and Child Health and Nutrition (MCHN), agriculture and natural resource management, education, and water and sanitation. A key difference, however, is that emergency programs provide food rations that are often designed to meet a significant proportion, if not all, of a household’s nutritional needs.

In nonemergency programs, Title II commodities are also used as an incentive or as pay or compensation for participation in activities such as training or labor (land clearing or preparation, construction of roads or other physical assets, construction of irrigation or potable water systems, construction of latrines, etc.) and not necessarily, or primarily, for health or nutritional improvement.

In contrast, Title II food is used *primarily* to prevent or treat malnutrition in the context of MCHN activities (including the Prevention of Malnutrition in Children under Two Approach [PM2A]), in programs supporting HIV/AIDS and tuberculosis treatments (often used to promote care-seeking behavior and retention in care), and in programs managing wasting (low weight-for-height) or promoting healthy birth outcomes. Foods used in this way—such as CSB, Wheat–Soy Blend (WSB), or lipid-based nutrient-dense products—should be designed with the physiological demands of the target group in mind. Rations intended to provide a basic food basket to food-insecure households should be nutritionally adequate, but often do not need to include specialized, nutrient-dense food unless a nutritionally vulnerable individual is explicitly targeted. Food intended for monetization (sale on the open market) need not be formulated to meet specific nutrient needs of target groups; highly fortified foods are unlikely to command a premium on the market that would match the cost of producing them, and, if sold, their nutritional value is effectively “lost” to the intended consumer groups.

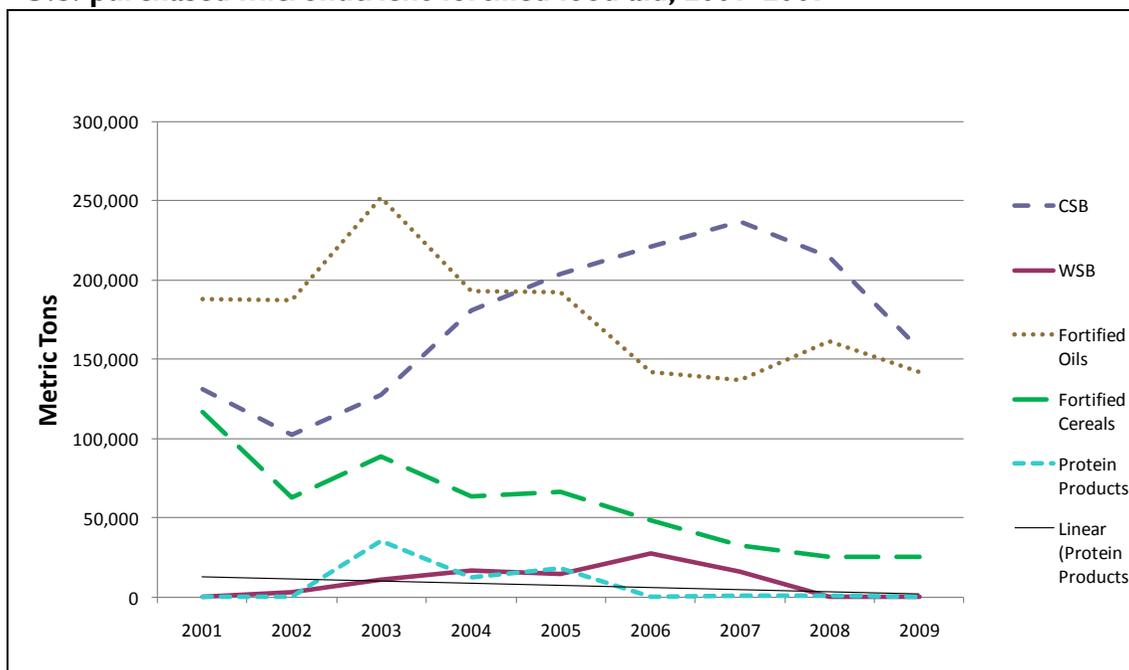
Recently, there has been a renewed focus in Title II programming on the prevention of chronic malnutrition (stunting, or low height-for-age), the treatment of moderate wasting, and the supplementation of pregnant and lactating women. For example, PM2A is being promoted by FFP as a strategy of choice for preventing child malnutrition in food-insecure environments. The approach is based on the concept of preventive “blanket feeding,” that is, providing rations to all members of the target

group (defined by age and physiologic status) in a given geographic area, irrespective of their *current* nutritional status, along with a family ration intended to ensure that the specialized, nutrient dense food reaches its intended target individuals. The approach is a conditional food transfer program that requires a strong BCC component to improve infant and young child feeding and nutrition practices along with the blanket feeding.

Title II commodities currently used in such activities include precooked FBFs such as CSB and WSB, pulses or legumes, enriched cereal blends (e.g., Soy-Fortified Bulgur [SFB]), and FVO, coupled with staple grains (whole or milled), all of which also are fortified with some combination of micronutrients. Title II foods that were fortified accounted for just over 300,000 MT of Title II deliveries in 2009 (Figure 1.2).

In fiscal year 2011, novel forms of nutrient delivery were introduced or pilot tested in some U.S. food assistance programs, such as Nutributter™—a 20-g foil sachet containing a micronutrient-fortified lipid paste used for at-home fortification of meals for young children. Similarly, USDA is pilot testing novel products to deliver micronutrients in its McGovern–Dole International Food for Education and Child Nutrition program (FFE).

FIGURE 2
U.S.-purchased micronutrient-fortified food aid, 2001–2009



Source: Data provided by USDA at USAID/USDA International Food Aid (and Development) Conferences, Kansas City, 2011–10.

Although this range of nutritionally enhanced food products is used in diverse settings, USAID's FFP commissioned a review to address mounting evidence that a)

the formulation of some Title II products is not up to date with current science; b) some Title II programs do not apply best practice in matching products to defined purposes; and c) the product value chain is not protected using industry best practice. This report presents the findings, conclusions, and recommendations of that two-year study. The focus of activity was on fortified and/or enriched blended foods rather than bulk commodities—that is, on processed food products that are designed to be nutritionally enhanced. Such products are typically designed to meet specific needs of defined beneficiary groups and the operational goals of field-level programming. However, to address the composition and functions of Title II blended foods, the role and usage of bulk commodities also had to be considered, as did food aid programmed outside of Title II.¹

The review addressed three core issues relevant to the quality of Title II food aid:

1. **Product quality**—that is, the characteristics of foods used in terms of nutrient composition, product acceptability (ease of usage, sensory properties), etc. The core question addressed was, Are current commodity specifications for enriched FBFs appropriate in light of evolving nutritional science and food fortification technology, or do they need to be updated?
2. **Programming quality**—how are food products currently used? Are interventions appropriately designed and implemented to achieve nutrition objectives consistent with the products used? The core question addressed was, Could nutrition targets be met more cost-effectively if different products were available and if nutritionally enhanced foods were programmed differently?
3. **Process quality**—do the systems that govern and oversee processes for the approval of product introduction and modification, for procurement and transportation, for quality control and assurance, and for interagency coordination optimally support a whole-of-government, multiagency food aid agenda? Can USAID respond better and more cost-effectively to the nutrition needs of its beneficiaries through changes in product formulation, the range of products provided, and/or modes of product approval, processing, procurement, and distribution?

A reformulation of products cannot be based on nutritional considerations alone. The technological feasibility of modified fortification specifications, the cost of new packaging, the review of new products or reformulations, the stability of nutrient levels during shipping and storage, and the assumptions made by implementing agencies about food sharing among beneficiaries and their households are critical. Ultimately, the more tailored and targeted a product, the smaller the quantity of each one that will be needed, but the higher the cost. What are the implications for FFP's

¹ Including food aid provided by the McGovern–Dole International Food for Education and Child Nutrition Program, PEPFAR, the World Food Programme (WFP), and the United Nations Children's Fund (UNICEF).

budget and its ability to reach its strategic goals? As USAID administrator Rajiv Shah recently put it, the overall aim is to transform the U.S. food assistance program “to make it more effective” (Shah, 2010).

1.1 CONTEXT AND APPROACH

The review comes at a time of heightened attention to undernutrition globally and at a time of increased attention to the potential for nutritionally enhanced food products to achieve significant life-saving and life-enhancing impacts. On the one hand, the international nutrition community has been galvanized during the past decade around an increasingly unified agenda for action. Important efforts to collate and summarize empirical evidence of programmatic and policy effectiveness (and sometimes cost-effectiveness) have included the *Lancet* series on maternal and child undernutrition (2008), the Copenhagen Consensus work (2004, 2008), the World Bank’s costing exercises (World Bank, 2006; Horton et al., 2009), and related nutrition landscaping exercises (the World Health Organization [WHO] and the Bill and Melinda Gates foundation). These increasingly convergent activities have fed into policy-based initiatives, including the *Scaling Up Nutrition* activity (2010), the Road Map to End Global Hunger (2009), and, most recently, attention to nutrition–agriculture links in the U.S. Government’s Feed the Future Initiative (2010).

Moving in parallel with these nutrition agendas has been increased attention to the quality (effectiveness, relevance, and appropriateness) of humanitarian action in general, and related scrutiny of quality (including nutritional quality) of food aid, in particular (GAO, 2011). The United Nations’ humanitarian reform agenda paid close attention to how well “need” is assessed in crisis situations and how effectively that need is met through existing funding and programmatic channels (Maxwell et al., 2010). That has increasingly included a focus on nutrition; as noted already in 2000, “nutritional considerations are an inescapable element of any major emergency” (WHO, 2000). The effort to define and calibrate “need” has paid close attention to how undernutrition interacts with other humanitarian problems, such as lack of water, disease, livelihood threats, etc. (Young and Jaspers, 2006).

In this broader context, the FAQR was not a stand-alone activity. USAID and USDA have long supported activities aimed at enhancing product choice under Title II, improving quality control (of both processes and products), and updating technical guidance on programming approaches. Table 1.1 illustrates a timeline of USDA- and USAID-supported work on food aid quality leading to the present review. Numerous studies and review activities have tackled a variety of complex issues that affect the success of the U.S. Government’s food aid agenda. The Tufts review elaborates on prior efforts to single out constraints to greater efficiency and impact, focusing in this instance on the intended nutritional impacts of Title II food aid operations, and the appropriateness of existing and proposed nutritionally enhanced products in that endeavor.

This report builds in particular on work supported by FFP since the mid-1990s, focused on micronutrient quality and contents of food aid, revising and rationalizing specifications for Title II processed products (including updates of the Commodities Reference Guide [CRG] and USDA food aid commodity product and procurement specifications), and issues relating to U.S. Government processes involved with the identification and review of new or modified commodities and with food safety and quality control (SUSTAIN, 2008b).

As noted by Harvey, “the resurgent interest in nutrition has an important influence on food assistance debates. This has led to calls for a stepped up focus on the nutritional outcomes of food assistance, and on the quality as well as the quantity of assistance provided” (Harvey et al., 2010). Attention to the nutritional quality of food aid is not new; considerable effort went into formulating and fine-tuning the specifications of the early FBFs during the 1960s and 1970s (Combs, 1967; Senti, 1972; Bookwalter, 1977).² However, what started out as a narrow focus on the nutritional needs of young children expanded during the 1990s to include the micronutrient and energy needs of all household members in emergencies (primarily refugees, at first) and has since become a lens through which all food aid is assessed. This does not mean that all food aid commodities can or should be nutritionally enhanced, rather that food aid policies and programs have put nutrition concerns closer to the center of the agenda than ever before.³ As Dworken (2010) argued, “food aid is no longer just about tonnage and logistics.” This has important implications for the U.S. Government’s food aid activities.

² It should be pointed out that the early cereal blends designed to serve as enhanced products for children were developed in close collaboration between USDA and private industry (including the North American Millers Association), as well as the scientific community, represented in this case by the Interdepartmental Committee on Nutrition for National Defense (which later became a section of the National Institutes of Health).

³ The INTERFAIS website now presents food aid data not just in terms of volume, but in terms of individual nutrients donated and delivered (<http://www.wfp.org/fais/nutritional-reporting>) (WFP, 2010a). Delegates to the Food Aid Convention negotiations have been considering a requirement for donor targets to be set in some form of nutritional equivalency, not just the conventional wheat equivalents (TAFAD, 2010).

TABLE I.1
Milestones in U.S. Government food aid quality initiatives since 1993

Date	Key activity or report
1993	U.S. Congress appropriations committees urged USAID to increase vitamin C content of CSB and WSB
1994	USAID–OMNI report on opportunities and challenges to fortification and enrichment of Title II commodities (Combs et al., 1994)
1997	IOM report on vitamin C fortification of food aid (IOM, 1997)
1999	USAID–SUSTAIN report on fortification of food aid (SUSTAIN, 1999b)
2001	SUSTAIN’s micronutrient compliance review (SUSTAIN, 2001b)
2002	GAO testimony on food aid (opportunities for improvement) (GAO, 2002)
2007	GAO testimony on efficiency and effectiveness of U.S. food aid (GAO, 2007) USDA Commodity Concerns Feedback Guide USDA Standardizing Existing Commodity Specifications
2008	USDA Commodity Sampling and Testing Protocol USDA–SUSTAIN final report on developing new template specifications for food aid products (SUSTAIN, 2008b)
2009	GAO testimony on local and regional procurement (GAO, 2009)
2009–11	USAID–Tufts FAQR Food Aid Quality Review
2010	New product calls put out by NIFA and the McGovern–Dole International Food for Education and Child Nutrition program
2011	GAO report on nutritional quality of U.S. food aid (GAO, 2011)
2011–13	Field testing of product modifications and other operations research around food aid programming

Note: CSB, Corn–Soy Blend; FAQR, Food Aid Quality Review; GAO, U.S. Government Accountability Office; IOM, Institute of Medicine; NIFA, National Institute of Food and Agriculture; SUSTAIN, Sharing and Utilizing Science and Technology to Aid in the Improvement of Nutrition; USAID, United States Agency for International Development; USDA, United States Department of Agriculture; WSB, Wheat–Soy Blend.

Several new products were approved for the Title II commodities list in the decade prior to 2010, and more are likely to be proposed in the coming years. Partners in the field are aware of the proliferation of new products (such as the new class of lipid-based products referred to as Ready-to-Use Foods [RUFs]). In addition, there is continued debate surrounding the appropriateness of foods that do not contain animal-source proteins to support infant growth and recovery from Severe Acute Malnutrition (SAM). Finally, there have been some questions about food safety, in light of a small number of “problem batches” of commodities delivered to the field. All such issues pointed to a need for a more comprehensive approach to reviewing

product suitability, encouraging appropriate operational practices, and overseeing the many processes in the U.S. Government food aid supply chain.

The findings presented here derive from analysis of empirical data, where available, and on expert opinion where the evidence is limited. The review was conducted over a 24-month period by a core team of 11 authors, with seven research assistants. The findings of the review rest on empirical evidence, on the one hand, and on eminence, on the other.

Empirical data were derived from a number of sources, including a survey of implementing partners, qualitative interviews with operational agency heads and program and logistic experts, and review of existing literature, program documents, and reports. Expert views were gathered from numerous consultations with scientists, U.S. Government employees and contractors, academics, donor agency staff from many countries around the world, United Nations personnel, and field-level food aid programming technical staff. For example, a survey of USAID implementing partners was conducted among 64 responding offices in 40 countries. The survey targeted program and logistics officers from every implementing partner distributing Title II food during the period from January to September 2010. The response rate was 81%. This survey gathered data on the use and effectiveness of enriched, fortified, or blended Title II commodities in programs, the use of new commodities, and procurement or logistics aspects.

The survey consisted primarily of closed-ended questions arranged under four headings: 1) Food Commodities, 2) The Use of Food Commodities According to Technical Sector, 3) New Commodities, and 4) Logistics and Procurement. As a computer-assisted telephone interview, the survey was conducted by telephone with the opportunity for joint follow-along online. This allowed respondents to both hear and view the questions and gave them the chance to receive extra explanation of the questions or to discuss their responses. The respondents also had the opportunity to give general comments at the end of each section. To gain additional information pertaining to a given response, FAQR staff followed up with implementing partners through individual e-mail or telephone contact after the survey.

In addition to the Implementing Partner Survey, which targeted field-level respondents, a series of qualitative interviews was conducted with heads of implementing partner organizations. This allowed the author team to cover the same topics as the Implementing Partner Survey but to receive policy- or administration-level perspectives and insights. In total, the team carried out 15 qualitative interviews.

Simultaneously, a formal process of consultation was put in place to engage scientists, industry, implementing partners, civil society, and donor organizations, which was integral to the preparation of this final report. A dozen well-attended meetings were organized around the world with groups of stakeholders, and well over 100 meetings were held with individuals and small groups. More than 500 individuals registered and accessed the dedicated website set up to promote knowledge about,

and discussion of, the review's focal tasks. A panel of experts from the fields of food technology and science, policy, law, industry, medicine, development and humanitarian work, and the maritime industry was consulted throughout the review process, in both individual consultations and collective gatherings. The expert panel, divided into technical and programming subgroups, reviewed and critiqued findings and recommendations, offering professional peer review from numerous relevant perspectives. In addition, an interagency panel composed of key staff from USDA and USAID agencies was set up and consulted individually, and through formal meetings of the group, to provide input throughout the process and feedback on recommendations.

A number of literature reviews and data analyses were conducted, including reviews of rations and programming in Title II program proposals and end-line evaluations; policy documents on U.S. and international nutrition and food aid; ongoing and published trials comparing various combinations of FBFs, fortified foods, and Lipid-Based Nutrient Supplement (LNSs) as well as different program models and BCC approaches; USAID/FFP guidance documents for implementing partners; previous reports and recommendations to USAID on the product, process, or programming of Title II enriched, fortified, and/or blended foods; Annual Estimate of Requirements (AER) data across multiple countries and programs; relevant academic publications; and USAID procurement system information. This process of literature review and analysis provided the author team with empirical evidence on which to base recommendations.

The draft findings and recommendations were widely shared and posted on the review website for public comment during March 2011. Twenty organizations and individuals shared comments on the draft in addition to the views of the expert panels. These comments were taken seriously and incorporated as appropriate into this final report.

2. THE NUTRITIONAL ENHANCEMENT OF FOOD AID –OPTIMIZING PRODUCTS

Reacting to a new formulation of cereal-based FBFs that has been proposed by Golden (2010b) for children with moderate wasting, Greiner (2010) stated that “much of what Dr. Golden posits has little or no true evidence base.” Greiner went on to say that “this is not his fault, but [is] a comment on the sad state of research on malnutrition in developing countries.” In response, Golden (2010 a) agreed, stating that “there is undoubtedly insufficient evidence and many questions remain to be even addressed meaningfully.”

That exchange in the letters pages of the *Food and Nutrition Bulletin* in the middle of 2010 illustrates a problem that is widely known in health sciences circles, but less so among field-based professionals; namely, that “the evidence base for treatment guidelines of...malnutrition is weak” (Brewster, 2006). If the evidence base for treatment is weak, then the basis for formulating foods to be used in the management of the many different forms of undernutrition is weaker still. This chapter makes recommendations on modifying the nutrient composition of Title II enriched foods or FBFs using what published information is available, as well as unpublished expertise: evidence and eminence together.

There *have* been adjustments made over time, both in product composition and in usage. What is needed today is acknowledgment that a) further change is necessary and desirable and b) a more systematic approach to assessing needs and product development is needed so that future modifications can be evidence-driven and carried out more swiftly and transparently than in the past.

FBFs are defined here as a category of cereal–legume–oil admixtures fortified with a range of vitamins and minerals, with the possible addition of a dairy-based source of protein. The grains and legumes are partially precooked to enhance their digestibility, denature antinutritional factors, and reduce the cooking time required (Wood et al., 2008). According to the United Nations Inter-Agency Standing Committee’s Nutrition Cluster, such foods need to be a) energy-dense and “rich in micronutrients,” b) easily digestible and palatable, and c) able to be prepared relatively quickly, i.e. with minimal cooking (IASC, 2009). The most significant adaptations (or recommendations for change) in the fortified cereal blends are noted in Table 2.1.

TABLE 2.1
The evolving formulation of Title II fortified cereal blends

Date	Changes or recommendations
1966	Formula Food No. 2 ⁴ (CSM) included on FFP's commodity list for Title II
1967	Minimum fat content increased from 2% to 6%
1975	Calcium carbonate replaced with tricalcium phosphate
1989	Vitamin A added to the premix of FBFs. Dried milk powder removed from cereal blends (CSM and WSM) due to supply shortage and price; not reintroduced until early 2000s
1994	OMNI report recommends a) 67% cut in vitamin B ₁₂ , b) 114% rise in riboflavin, c) 1000% rise in zinc (with move from zinc sulfate heptahydrate to sulfate monohydrate), d) no change in vitamin C, e) consider 50% rise in iron (as ferrous fumarate rather than hydrogen-reduced iron), and f) consider 25% cut in calcium
1996	USDA Task Group on Nutrient Standards recommends a) 500% rise in zinc, b) add selenium and magnesium to premix, c) 67% cut in vitamin B ₁₂ , d) 25% rise in iodine, e) consider use of NaFeEDTA as source of iron, f) consider 25% cut in calcium, g) maintain level of vitamin C, and h) raise protein to 20% and fat to 12%
1997	IOM recommends no change in vitamin C level in FBFs
1998	Magnesium added, zinc increased, and vitamin B ₁₂ reduced in FBFs
1999	Micronutrient Assessment Project study recommends increase in level of vitamin A and its use as a marker for fortification compliance in processed foods
2001	SUSTAIN report recommends a) enhanced stability specifications for vitamin A in premix, b) identification of more heat-stable forms of vitamins A and C, and c) identification of a more stable form of vitamin A
2008	SUSTAIN report recommends a) add folic acid to premix at levels defined as DRIs, b) not to use vitamin A as the marker for fortification compliance, c) combine vitamin and mineral premixes (into one)

Source: Anderson et al. (1970), Combs et al. (1994), Senti (1972), Bookwalter et al. (1971, 1991), Crowley (1975), Atwood et al. (1995), Dexter (1995), USDA (1996), IOM (1997), Marchione (2002), SUSTAIN (1999b), SUSTAIN (2001b, 2008b).

Note: CSM, Corn–Soy Milk; DRI, Dietary Reference Intake; FBF, Fortified Blended Food; FFP, Food for Peace; IOM, Institute of Medicine; NaFeEDTA, sodium iron ethylenediaminetetraacetate; SUSTAIN, Sharing and Utilizing Science and Technology to Aid in the Improvement of Nutrition; USDA United States Department of Agriculture; WSM, Wheat–Soy Milk.

The current review sought to assess what further changes are necessary, and how to pursue such changes in ways that are evidence driven and can be carried out more swiftly and transparently than in the past. The initial focus, as mandated by contract, was on cereal-based FBFs as defined above

Are these kinds of FBFs and other nutritionally enhanced products “fit for purpose”? One can only answer that question in relation to a) what a product was designed to achieve, b) how it is programmed and for whom, and c) what has changed in our understanding of nutrient needs and product formulation since the last revision of specifications.

⁴ Formula No. 1 was the prototype Ceplapro.

An appropriate balance of nutrients matters in ration design. The delivery of essential macronutrients (i.e., kilocalorie-generating carbohydrates, protein, and fats) and micronutrients is key to the management of undernutrition, whether in the treatment of wasted individuals in hospitals or in the specialized therapeutic feeding centers that are increasingly a feature of humanitarian action, in supplementary feeding, or in more general ration feeding, where delivery of micronutrients matters as much as delivery of kilocalories to prevent outbreaks of deficiency disease.

The original formulations of FBFs—Corn–Soy Milk and Wheat–Soy Milk (CSM and WSM)—were high in protein (17.8 g/100 g dry weight, compared with 5.9 g/100 g in the current CSB13) and relatively low in fat (6.3 g/100 g, compared with 8.7 g/100 g in CSB13). They were fortified with 11 vitamins and minerals and contained dried skimmed milk powder (DSMP). CSM and WSM cost roughly \$0.40 per 1000 kilocalories in 1971, compared with \$0.08 per 1000 kcal for CSB13 (using 2010 prices and gross domestic product [GDP] deflator to derive constant 2010 dollars). The lower cost of energy delivered in today’s products is due to lower real food prices compared with the late 1960s, even allowing for the recent world food price hikes. In the 1980s, FBFs were reformulated to omit the DSMP for reasons of cost and availability.

The original formula was prepared on the assumption that a single daily ration would meet roughly 25% of energy needs, with a view to “overcoming malnutrition in the pre-school-age child” (Combs, 1967). The dairy protein was considered to be appropriate to support the recuperation of children in, for example, the Biafra crisis (during the late 1960s). That humanitarian context convinced the United Nations Children’s Fund (UNICEF) that specific products were needed to support the treatment of wasting. However, a criticism leveled at CSB recently has been that its composition no longer includes animal-source protein (typically meaning a dairy source) to meet the needs of wasted children or (a new focus) to prevent stunting among infants under two. Indeed, the focus of use shifted over time from the needs of “small children” to older children, and then to adults (in emergencies or with HIV/AIDS). This shift has led to the “one size fits all” criticism often leveled against the programming of FBFs during the second half of the 2000s (SUSTAIN, 2007; Fleige et al., 2010a).

However, meeting the macro- and micronutrient needs of all beneficiaries is a challenge if a single product is to be the delivery mechanism. The appropriate formulation of any food product depends on its use—by whom, for what purpose, and for how long? It is these questions that led Beaton (1998) to argue that blended food products cannot meet *all* the needs of *all* beneficiaries (he used the term “mismatch”) and that much more attention needed to be paid to the potential for differing nutrient composition profiles “for different planned uses.”

Thus, in specifying the composition of upgraded FBFs and other nutritionally enhanced products, all depends on the assumptions made regarding the quantity of

product to be consumed daily by target beneficiaries, the contribution of nutrients consumed from that product to the overall diet, the bioavailability of nutrients (depending in part on the presence of antinutrients in the rest of the diet), the health status of the target consumer, intrahousehold sharing of the product, and more. The resulting formulations cannot be a perfect match for each beneficiary in every circumstance. Hence, the importance of a) tailoring product choice and combination (i.e., the ration mix) to programming intention (the role products can be expected to play in attaining specific outcomes), and b) understanding that nutrient needs should be met across the diet, not in single products; that is, most beneficiaries do not consume *only* a single food aid item, nor do most rely *only* on food aid (for example, the diet of children 0 to 24 months of age typically includes breast milk and/or complementary foods).

2.1 DEFINING NUTRITIONAL TARGETS

The delivery of essential nutrients is key to the management of undernutrition, in the treatment of wasted individuals either in hospitals or in the specialized therapeutic feeding centers that are increasingly a feature of humanitarian action, in supplementary feeding aimed at preventing stunting, or more general ration feeding where delivery of micronutrients matters as much as delivery of kilocalories to prevent deficiency disease outbreaks. In other words, an appropriate balance of macro- and micronutrients matters in ration design.

The original formulations of FBFs used to meet the needs of nutritionally vulnerable beneficiaries were high in protein (17.8 g per 100 g dry weight, compared with CSB13, which is designed with 15.9 g), and relatively low in fat (6.3 g per 100 g versus 8.7 g in CSB13). They were fortified with a set of 11 vitamins and minerals. Although copper and manganese were included in the prototype (Ceplapro), they were removed to improve the stability of labile vitamins, especially vitamin A, while vitamin C was also removed due to uncertainty about its stability. According to Combs (1967), these early formulations were not field tested for efficacy, but they underwent extensive laboratory testing as well as testing on rats to determine that the mixture of ingredients delivered a sufficiently high quality of protein and that nutrient ratios were acceptable. Batches were field tested for acceptability in child feeding programs in India (1966), Peru, and Taiwan (both 1967), and the product was deemed acceptable for use as food aid, requiring “only about 1 or 2 minutes of boiling prior to consumption.” The product cost US\$0.09 per pound (1966 prices) and roughly \$0.40 per 1000 kcal in 1971, compared with \$0.08 per 1000 kcal for CSB13 (using 2010 prices and GDP deflator to derive “constant” dollars). The lower cost of energy delivered in today’s CSB is due to lower real food prices (compared with the late 1960s) and the removal of milk powder, which was already escalating in price in the 1960s.

The CSM formula was prepared on the assumption that a single daily ration meeting roughly 25% of energy needs would also meet a high percentage of a preschool

child's protein, fat, and micronutrient needs (except for vitamin C and the minerals not included).⁵ The purpose of this product was, according to Combs (1967), "to adequately supplement the diet of children with respect to the potentially limiting essential nutrients, including amino acids," with a view to assisting "in overcoming malnutrition in the pre-school-age child"—also defined by Combs as "preventing severe malnutrition in young children."

Combs later recommended that FBFs (and/or enriched commodities) be used in emergency situations "to provide limited nutrients" (Combs et al., 1994). In the latter circumstance, the purpose of FBFs was to serve as a vehicle for delivering micronutrients to populations that were facing nutritional stresses and that were likely to have already been deficient in multiple micronutrients. The goal of recommendations by Combs et al. (1994), Beaton (1995), and others in the 1990s was to protect emergency-affected populations from debilitating (often life-threatening) deficiency diseases. Numerous outbreaks of micronutrient-based disorders were identified in that period, from beriberi among Cambodian refugees in the mid-1980s, to scurvy in East Africa, to pellagra among southern African refugees in the mid-1990s (Webb and Thorne-Lyman, 2008). The common wisdom of the time was to provide micronutrients to all affected people (not just nutritionally vulnerable subgroups) through fortified cereals and/or FBFs—even if these had been formulated to meet the needs only of small children. As Combs (1967) himself noted, CSM "could be used satisfactorily as a food supplement for other age groups." This phrase reflects how FBFs came to be used for practically every type of food aid program, leading to the "one size fits all" criticism commonly leveled at FBFs during the second half of the 2000s (SUSTAIN, 2007; Fleige et al., 2010a).⁶

Table 2.2 summarizes some of the stated purposes of FBFs since their inception, ranging from treatment through prevention, and from macronutrient to micronutrient concerns.

⁵ In Combs's words, "It is believed that this infant food packs a real nutritional 'wallop' "(Combs, 1967).

⁶ According to Dexter (1995), by the late 1980s more than 50% of the blended foods provided through Title II were used to support the Integrated Child Development Service (ICDS) in India.

TABLE 2.2
Purposes of FBFs in food aid programming

Source	Purpose of FBFs
Combs (1967)	CSM is for “prevention of severe malnutrition in small children.”
Graham et al. (1971)	CSM is used in the dietary management of “infants with severe marasmus.”
Senti (1972)	CSM is “designed as vehicles to transport high quality protein, vitamins and essential minerals to infants and children.”
Bookwalter et al. (1968)	CSM is “a supplement for preschool children of low-protein status.”
Bookwalter et al. (1971)	CSM was developed “to supplement the diets of recently weaned infants and preschoolers in areas of the world that need greater amounts of dietary protein.”
Katona-Apte (1993)	CSB and WSB included in emergency rations “to prevent deficiency symptoms from developing.”
Hertz (1997)	FBFs are for supplementary feeding of “children below 5 years and lactating mothers [and] where general ration deliveries have failed.”
Wadud et al. (2004)	“Blended foods, e.g. corn soy blend...have been specially developed as nutritional supplements for the diets of weaning infants.”
USDA (2005)	CSB “has proven especially effective in saving the lives of some of the most vulnerable and malnourished populations, particularly children.”
Wood et al. (2008)	CSB is designed to meet “the micronutrient requirements for malnourished children and adults.”
SUSTAIN (2008a)	CSB is a “supplemental food in emergency rations for children,” and a “weaning food in MCH and other development programs.”
WFP (2008b)	CSB “is a highly-nutritious fortified food used...as a supplement to nurse moderately malnourished children back to health.”
de Pee (2010) ⁷	The intent of improved CSB is to “meet the nutritional needs of moderately malnourished under 5s (targeted supplementary feeding) and under 2s (blanket feeding).”

Note: CSB, Corn–Soy Blend; CSM, Corn–Soy Milk; FBF, Fortified Blended Food; MCH, Maternal and Child Health; WSB, Wheat–Soy Blend.

A few important points deserve to be highlighted. First, early uses of FBFs (particularly WSM) included attention to wasting. The relatively high protein content derived from a dairy source was considered to be appropriate to support the recuperation of children in, for example, the Biafra crisis. The latter context convinced UNICEF that specific products are needed to support treatment of wasting on a large scale at relatively short notice. It was in that context that UNICEF promoted development of PKFM (post-kwashiorkor feeding mixture) and subsequent cereal blends, such as Mx-42 and Mx-86. These developed into the composite term UNIMIX (Graham et al., 1971; Dexter, 1995).⁸ One of the main criticisms leveled at

⁷ Personal communication, March 2010.

⁸ As with U.S. CSB, the type and levels of micronutrients used to fortify UNIMIX changed over time, including a variant in the mid-1990s called Super UNIMIX, manufactured in Kenya for use in Somalia (Dexter, 1995). Alternative cereal blends with different forms of micronutrient composition were also

CSB during recent years has been that its composition no longer includes an animal-source protein to enable it to meet the needs of wasted children, or to prevent stunting among infants.

Second, the focus shifted over time from the needs of “small children” to older children—the bulk of CSB shipped during the 1980s supported school feeding in India—and then to adults (with HIV/AIDS or in emergencies). Third, claims have been made that FBFs have the ability to *both* treat and prevent undernutrition, while meeting nutrient deficiencies of multiple kinds (protein, micronutrients, fat). As concluded by Navarro-Colorado et al. (2007) in their review of supplementary feeding, there is a “marked lack of consensus over the objectives,” which spills over into a lack of consensus over the appropriate products to be used in different operations on the ground.

The wide range of proposed purposes complicates current concerns about the viability of FBFs to achieve *any* of them well. As Beaton underlined, the goal of food aid programming “must be known in advance” (MI/OXFAM, 1998). Is it to prevent classical deficiency diseases, or is it to meet all known functional needs, or is it to build and maintain normative stores?” In other words, the intention of a food-supported program must be clear at the outset, and the products selected for the intervention should be appropriate to the task.

TABLE 2.3
Milestones in the development of nutritionally enhanced food aid products

Date	Product
1964	Cereal–plant–protein (Ceplapro) prototype FBF developed for FFP
1966–1970s	Corn–Soy Milk (CSM), Corn–Soy Blend (CSB), UNIMIX
1980s	High-Energy Biscuits (HEBs)
1980s/1990s	Therapeutic milk products (F100, F75, SP450, etc.)
1990s	Emergency/survival rations (BP5, HDRs)
1990s/2000s	Home fortificant powders (HFPs)
2000s	Ready-to-Use-Therapeutic Foods (RUTFs) Ready-to-Use-Supplementary Foods (RUSFs), Lipid-Based Nutrient Supplements (LNSs), other fortified-soy flour supplements (RUNs)
2010s	Enhanced variants of Corn-Soy Blend and Wheat-Soy Blend, emergency survival bars/pastes, reformulated high-energy biscuits

The success of RUTFs has been based on their ability a) to take treatment outside of hospital facilities and into affected communities, thereby greatly increasing coverage rates; and, importantly, b) to demonstrate to the world that “something can be done” to resolve undernutrition. A growing body of evidence has shown that RUTFs are

proposed and tested during the 1990s, including Nutrifil (used in Cameroon and Zaire) and Weanimix (used in Ghana) (Mathias and Byrne, 1995; Lartey et al., 1999).

efficacious; that is, they work as intended (Chaparro and Dewey, 2010; Gera, 2010).⁹ Field trials using locally produced variants of RUTFs have reported satisfactory weight gain (Patel et al., 2005, in Malawi), reduced rates of mortality and post-treatment complications (Ashraf et al., 2007, in Bangladesh), and adequate child recovery (Scherbaum et al., 2009, in Indonesia).

In addition to RUTFs, a range of lipid-based products have become available in varying doses, with differing micronutrient profiles, and used for different programmatic purposes—from prevention of stunting to management of moderate wasting, to supplementation of small children with daily doses of 1 Recommended Dietary Allowance (RDA) of key micronutrients. Research is under way on the supplementation of nonwasted children with RUTFs aimed at reducing (flattening out) increases in population-wide prevalence during the hungry season (Isanaka et al., 2009, and Defourny et al., 2009, in Niger), as well as blanket supplementation of young children with a view to preventing stunting and wasting from taking hold (Ruel et al., 2008; Chaparro and Dewey, 2010).

While the arrival of these new products served to stimulate debate about the appropriateness of different food aid products for various nutritional goals, the focus on lipids quickly cast FBFs in a poor light.¹⁰ For example, in Malawi, Sandige et al. (2004), Maleta et al. (2004), Ciliberto et al. (2006), Linneman et al. (2007), Phuka et al. (2009b), and Ndekha et al. (2005) all reported that home-based therapy with RUTF was associated with more rapid weight gain than treatment with a maize–soy blended food and a higher likelihood of attaining catch-up growth and was associated with no more medical complications or deaths than inpatient care.

Arguments that FBFs are “not optimal for treating young children with malnutrition” (Skau et al., 2009), that they have shown “limited effectiveness” (Matilsky et al., 2009), or at least that they are “less effective” than lipid-based products in promoting nutrition outcomes (Patel et al., 2005; Ndekha et al., 2005) proliferated during the 2000s. The “case against” CSB (and, by extension, against cereal-based blended foods more generally) has been framed in four principal ways. First, the composition of CSB (relatively low levels of fat, low energy density, and no animal-source protein) does not perform well in the management (or prevention) of wasting. Second, the lack of growth factors available in RUFs and the less dense micronutrient composition are not effective in promoting growth (preventing stunting) or in meeting the elevated needs of pregnant or lactating women. Third, the micronutrient composition is inadequate and the food matrix itself impedes physiological absorption

⁹ Although Bhutta et al. (2008) stated in the *Lancet* series that it was not possible to offer supportive statements on the role of RUTFs, since “community-based preventive and treatment strategies for severe acute malnutrition have been the subject of only a few studies.” Similarly, a review of the literature by Connelly and Ashworth-Hill (2008) noted that the evidence that home-based care with RUTFs was superior to inpatient management “remains incomplete.”

¹⁰ Already in the mid-1990s there were clinical trials comparing rates of recovery from severe wasting in patients receiving either a cereal product-based diet or a milk-based diet. For example, Brewster et al. (1997) compared a WHO F100-based diet with a milk-free, maize-based diet and found that “milk was superior to cereal.”

of nutrients (due to the presence of phytates and other antinutrients and high fiber content). Finally, it is difficult to meet the caloric needs of the infants with FBF, even as complementary with breast-feeding.

There are dozens of recent efficacy, effectiveness, and acceptability trials comparing some combination of LNSs, multiple micronutrient fortified powders, and some form of FBF (typically a local variant of CSB) (see Appendix 13). These studies vary widely in terms of outcomes measured, duration of trial, degree of instruction on product use, degree of compliance supervision, setting, and follow-up. In addition, there are at least 70 still-ongoing trials (as of November 2010) comparing products in clinical and community settings.¹¹ Many of the studies argue that RUFs result in faster weight gain (among wasted children, and also in adults living with HIV or AIDS), reduced default rates, and reduced treatment time compared with FBFs. Ndekha et al. (2009b), for example, noted that CSB is “associated with disappointing results in supplementary feeding programs among children, pregnant women, and adults with HIV in sub-Saharan Africa,” while Mates et al. (2009) reported that implementing agencies in Sudan have expressed doubts “about the effectiveness of CSB for the rehabilitation of moderately malnourished children.” As a result, the United Nations Inter-Agency Standing Committee’s Nutrition Cluster reported that “rations based on fortified blended foods do not address mild and moderate malnutrition as effectively as specially designed foods such as...RUTF” (IASC, 2009).

A second criticism of FBFs relates to their potential for reducing stunting. Linear growth promotion is a key focus of USAID’s PM2A model, which builds on the growing international consensus that prevention of undernutrition should occur as early as possible in the life cycle—ideally in the so-called “1000-day window” running from pregnancy through the first 24 months of a child’s life. Current FFP guidance to implementing agencies states that if an applicant for nonemergency funding proposes maternal-child nutrition activities, “FFP strongly encourages applicants to focus specifically on preventing malnutrition in pregnant and lactating women and children under the age of two years” (USAID/FFP, 2010). It has been argued by Menon et al. (2007), MSF (2008), Defourny et al. (2009), Zlotkin et al. (2009), Fleige et al. (2010a), and many others that FBFs are not designed to promote growth since they lack key ingredients, including animal-source protein, adequate zinc, and sufficient energy density. Thus, the European Community has stated that “CSB in its current form is not ideal for children less than 2 years old [and that] there is an urgent need to develop new affordable and effective products to address malnutrition of children of this age group” (ECHO, 2009). One such new product, Supplementary Plumpy® (one of Nutriset’s RUSFs), was designed with the intention

¹¹ Information about some of these trials may be found at the ILINS website (<http://ilins.org>).

of “reversing stunting” (Briend, 2001).¹² It was promoted as a product superior to CSB, mainly because of its higher lipid and lower protein contents.¹³

The third (related) criticism is that the form of FBFs (containing high fiber content and considerable amounts of phytates) and the micronutrient composition do not serve any beneficiary well. Skau et al. (2009), for example, argued that “CSB contains inadequate quantities of some micronutrients; has low nutrient density, especially when made into porridge; and contains high levels of antinutrients, especially phytates which inhibit the absorption of many micronutrients, including iron and zinc.” Huffman (2009) also noted that “CSB is unable to efficiently improve child nutrition, *both* for malnourished children and those at risk of malnutrition [because] the high fiber content increases the bulk of the food, filling up the child and reducing its ability to consume sufficient energy.”¹⁴ Ruel et al. (2003) and others have also noted that FBFs are unable at present to “close the iron and zinc gaps at current fortification levels.”

Fourth, it has been argued that, due to the volume of diluted CSB and the stomach capacity of the infant child, it would be difficult to meet the caloric needs of the child with FBF, even as complementary with breast-feeding. (The proposal that follows argues that the nutritional needs can be met with FBFs plus oil.)

Most critiques in all three domains end with a statement offering support for alternative products, be they RUFs, home fortificant powders, or other forms of energy-dense foods (such as High-Energy Biscuits [HEBs]). It is important, however, to underscore two points. On the one hand, a surprisingly large number of published studies that purport to compare FBFs with an alternative product do so on a basis that is not, in fact, comparable. Most existing studies fail to capture major elements inherent in community-based feeding programs on three fronts. First, the trials make repeated assumptions about intrahousehold sharing but generally offer no real evidence to support these assumptions. Second, many, if not most, studies fail to monitor compliance, which is a key factor in recovery with the use of nutritionally enhanced products.¹⁵ And third, few, if any, trials have so far focused on the roles of packaging and programming in determining outcomes.¹⁶

¹² The first field-based efficacy trial of what was at first called the Highly Nutrient Dense Spread (HNDS) was carried out among refugees in Algeria, focused on stunting among anemic children (Branca et al., 1999).

¹³ Lower protein in terms of quantity rather than quality.

¹⁴ Personal communication, May 2009.

¹⁵ Studies that do not track and report on compliance include widely cited studies such as Manary et al. (2004), Ciliberto et al. (2005), and Nackers et al., (2010).

¹⁶ The generalized criticisms of CSB of recent years echo the generalized criticism of supplementary feeding activities during the 1980s. Beaton (1993) pointed out that his review of supplementary feeding (Beaton and Ghassemi, 1982) was widely misinterpreted as concluding that supplementary feeding “had little or no effect.” In fact, it suggested that supplementary feeding *did* have an impact on immediate malnutrition, but that there was limited evidence of impact on chronic undernutrition (linear growth). Beaton argued that there were many operational issues not taken into account in most of the studies reviewed, which left large gaps in the evidence base and constrained the conclusions they could draw.

In other words, much of the evidence base used to support criticisms of FBFs does not compare “like with like” and mixes efficacy studies with effectiveness trials. Comparing the efficacy of two or more products is much more reliable than comparing effectiveness, since the latter is comparing all the elements, including delivery and compliance, and is therefore not simply a product comparison. Most trials do not package or program compared products identically, leading to many questions about the “greater effectiveness,” reduced sharing, higher acceptability, and countless other assertions made in favor of novel products. Not only do the products differ, but the mode of distribution, degree of supervision, instructions to the caregivers, and other factors vary as well, meaning that conclusions about the relative effectiveness of one or another product are questionable.

On the other hand, not every commentator is as negative about FBFs as some of the authors quoted above—particularly when they have studied these products closely in operational settings. Mourey (2008), for example, drawing on the field experience of the International Red Cross, argued that “CSB...is not specifically adapted for the treatment of moderate malnutrition, but is nevertheless suitable,” while Castelman (2008) proposed that “reports of CSB’s demise may be exaggerated. FBF products can help achieve nutrition and health objectives for some target groups.” It is important to note that there are many less-often-cited studies that report little (modest) or no statistically significant difference in certain nutritional outcomes when comparing use of FBFs and lipid-based products, including Maleta et al. (2004), Galpin et al. (2007), Phuka et al. (2009b), and Lagrone et al. (2010), whereas others note that programming effectiveness matters at least as much as the product delivered (including Ashworth, 2006; Mates et al., 2009; Ndekha et al., 2009b; and Flax et al., 2009).

Thus, it is concluded here that lipid-based preparations should indeed be included in Title II programming when appropriate, in addition to (rather than substituting for) a range of enhanced cereal-based products. It is important that FFP focus on making available a suite of products that are fit for defined purposes, used in appropriate contexts, and supportive of a range of defined outcomes in cost-effective ways. Continued usage of FBFs will allow for more choice for implementing agencies, since no single product can do everything, and no two equally viable products will function equally well in every circumstance, a) modified (upgraded) FBFs will cost less per ton than comparator RUFs, and b) future choices around products (cereal versus lipid-based) must rely on sound assessments of cost-effectiveness relative to achievement of intended outcomes.

The landscape of targets, needs, and approaches for prioritization of food aid has undergone substantial change. Along with recognition of changing priorities, not least the shift toward emergency response, there has been a growing consensus during the 2000s on a) the imperative for targeting wasted children, b) the need for increased attention to micronutrient deficiencies, and c) the importance of promoting linear

growth in children, which requires attention to children from conception up to 2 years of age (often referred to as “the first 1000 days”).

The past 15 years or so have seen considerable advances in the biological sciences, particularly in understanding why micronutrients are so important in protecting and enhancing health (Webb and Thorne-Lyman, 2008), and which micronutrients are relatively more important than others. Such advances have been mirrored by increasing recognition among humanitarian practitioners that micronutrient deficiencies are also a contributor to mortality in emergencies and that an appropriate formulation of products is essential when seeking to address wasting, as opposed to stunting or individual nutrient deficiencies (Van den Briel et al., 2006; WFP, 2010b).

A still unresolved and important issue in food assistance and feeding relates to the relative merits of targeting and treating malnourished or underweight children (stunted or wasted) versus broader programs of prevention of stunting and wasting in the larger population. The recent series in *Lancet* on maternal and child health and nutrition culminated in the report of Ruel et al. (2008), showing that a preventive program in Haiti was more effective for the reduction of childhood stunting than the traditional targeting or recuperative model.

However, as noted by the United Nations Standing Committee on Nutrition (UNSCN), while “there has been more and more recognition of the importance of improving the micronutrient content of the ration...debate still continues on whether all of the micronutrients...should in fact be included or, indeed, whether others should be added” (Seal and Prudhon, 2007). Part of the continued debate around what should, or should not, be included in the formulation of food aid products is a result of the rapid evolution of scientific understanding of individual macro- as well as micronutrient needs. As noted above, there is a trend toward tailoring of rations and commodities to more specific desired outcomes, such as nutritional status, reduced diarrhea, or support for HIV/AIDS therapy. However, in the absence of rigorous assessment of needs and operational possibilities on the ground, or of the impact of different formulations in multiple contexts, a clear understanding of optimal product design remains elusive. As Seal and Prudhon (2007) noted, assessments of nutritional need in settings where food aid is delivered, or of nutritional impact, “have remained scarce.” Similarly, a recent review of nutrition support for HIV/AIDS programming in East and Southern Africa concluded that although many programs address nutritional concerns (including provision of food aid), “there has been no evaluation as to whether these programs are sufficient to cover the needs of individuals and households, or whether they have nutritional impacts” (Panagides et al., 2007).

New understanding of nutritional requirements during pregnancy and lactation to nourish fetal development and growth and to prevent low birth weight, and of the increased needs for growth and prevention of stunting, comes from a series of expert meetings—including those underpinning the Food and Agriculture Organization (FAO)/World Health Organization (WHO) report on energy requirements (2004), a WHO/FAO/UNICEF report on protein requirements (2007), the FAO/WHO report on

human vitamin and mineral requirements (2001), and the Dietary Reference Intake (DRI) reports by the United States and Canada of requirements for macronutrients, vitamins, and minerals (IOM, 2002, 2004).

The major underlying principles supporting the current review's recommendations can be summarized as follows:

First, energy-dense foods with good protein content and an appropriate inclusion of essential micronutrients are necessary (albeit not always sufficient) to achieve defined nutrition goals among vulnerable populations. Staple foods must be available in sufficient quantity to ensure that nutritionally enhanced (value-added, usually processed) food products are adding to rather than replacing other sources of energy in the local food supply.

Second, there is increasing recognition that vulnerable children in countries where there is a high prevalence of undernutrition usually have a high exposure to infectious diseases and poor quality of hygiene and sanitation. The nutrient requirements for *preventing* malnutrition (as well as treating it) under such conditions are higher than those in a healthy environment with low rates of undernutrition.

Third, for the prevention of stunting (promotion of linear growth), a growing consensus gives priority to children under 2 years of age, along with the needs of pregnant and lactating women (Horton et al., 2009; Scaling-Up Nutrition Roadmap Task Team, 2010). This poses a challenge in dealing with infants around six months old who may still be breast-fed, but for whom the contribution of milk in the diet is unknown, and who should consume complementary foods that not only are of sufficient quality (to meet the high demands for key nutrients) and quantity but also meet high food safety standards.

Fourth, with regard to wasting, the prevention and treatment of Moderate Acute Malnutrition (MAM) should be a special focus of food aid, given the high prevalence rates of MAM in regions and target areas where Title II delivers most food, especially in emergency settings, with its accompanying high risk of mortality and permanent developmental deficits and physical delay. Treatment of Severe Acute Malnutrition (SAM) with Ready-to-Use Therapeutic Food (RUTF) (i.e., nutrient-dense, lipid-based food products formulated for treatment of SAM) has been a success story, leading to the wider use of such foods, sometimes in programs for which they were not intended—a reflection of demand for effective *products* in interventions around the world.

Fifth, HIV/AIDS is a special case in which the burden of HIV infection is often compounded by the presence of additional (opportunistic) infections that further increase metabolic demands. Although it is generally accepted that individuals with HIV have increased energy demands, the precise amount of additional demand is not clearly defined by currently available data. In addition, specific requirements for individual macro- and micronutrients have not been studied sufficiently, particularly

with regard to the response to antiretroviral therapy (ART). The appropriate criteria for initiation of (and graduation from) food aid need to be defined, as the altered nutritional demands do not abate in this population. Much more needs to be known about the nutritional requirements for different groups of PLHIV.

Despite these limitations, we used the best current evidence and sought insight from leaders in the field to define nutrient target levels for vulnerable target groups, in particular for infants 6 to 11 months of age, children 12 to 36 months of age, and pregnant and lactating women. The target micronutrient contents and macronutrient densities built on the in-depth work by Lutter and Dewey (2003), Golden (2009, 2010b), Chaparro and Dewey (2010), and Fleige et al. (2010a, 2010b), in addition to consensus recommendations from a wide range of experts. The targets presented here (Table 2.4) derive from the widely accepted vitamin and mineral requirements promulgated as Recommended Nutrient Intakes (RNIs) by FAO/WHO (2001), supplemented by more recent recommendations for some nutrients in the Dietary Reference Intakes of the U.S. Institute of Medicine (IOM) report of 2004. Nutrient target levels are set at about 115% of the recommended amount to cover extra needs of the target population, which suffers systematically from poor absorption induced by intermittent infection and food and water contamination (Golden, 2009).

Safe Upper Levels (ULs) were taken into account, especially where nutrients added as fortificants could theoretically reach levels with adverse effects when ingested regularly over long periods. Where no ULs have been established by the IOM, the No Observed Adverse Effect Level (NOAEL) or the Lowest Observed Adverse Effect Level (LOAEL) has been used. These are defined as part of the process of determining ULs and have been established for a few nutrients that currently do not have ULs. For ease in labeling tables, we refer to all of these levels as “ULs.”

TABLE 2.4
Daily nutrient needs by selected age and demographic groups for
moderately malnourished populations (115% RNI or DRI)

Nutrient	Infants 6–11 mo	Children 12–36 mo	Pregnant women	Lactating women
Macronutrients				
Energy (kcal)	675	1000	2385	2600
Protein (g)	16	23	71	71
Fat (g)	31	30	20–35	20–35
Minerals (mg)				
Calcium**	299	700	1150	1150
Chromium	0.0115	0.01265	0.035	0.052
Copper†	0.253	0.391	1.15	1.495
Iodine‡	0.104	0.104	0.230	0.230
Iron‡	10	10.35	31	23
Magnesium‡	62.1	69	253	310.5
Manganese	0.69	1.38	2.3	2.99
Molybdenum†	0.00345	0.0196	0.0575	0.0575
Phosphorus†	316.25	529	805	805
Potassium	805	3450	5405	5865
Selenium†	0.012	0.020	0.035	0.048
Sodium	425.5	1150	1725	1725
Zinc‡	5.75	7.13	8.05	9.2
Vitamins (mg)				
Vitamin A (RE)‡	0.460	0.460	0.920	0.978
Vitamin B ₁ (thiamin)‡	0.345	0.575	1.61	1.725
Vitamin B ₂ (riboflavin)‡	0.46	0.575	1.61	1.84
Vitamin B ₃ (niacin)‡	4.6	6.9	20.7	19.6
Vitamin B ₅ (pantothenic acid)‡	2.07	2.3	6.9	8.05
Vitamin B ₆ ‡	0.345	0.575	2.19	2.30
Vitamin B ₇ (biotin)‡	0.0069	0.0092	0.0345	0.0403
Vitamin B ₉ (folic acid)‡	0.054	0.101	0.406	0.338
Vitamin B ₁₂ ‡	0.000805	0.00104	0.00299	0.00322
Vitamin C‡	34.5	34.5	63.25	80.5
Vitamin D ₃ **	0.0115	0.0173	0.0173	0.0173
Vitamin E‡	5.75	5.75	11.5	8.63
Vitamin K‡	0.0115	0.0173	0.0633	0.0748

All unmarked nutrients are the Adequate Intakes (AIs), as established by IOM.

** There are RNIs established for calcium and vitamin D₃, but we chose to follow the new IOM guidelines released in 2010.

† These nutrient amounts are the Recommended Dietary Allowances (RDAs) for children 12 to 36 months of age and pregnant and lactating women.

‡ These nutrient amounts are based on Recommended Nutrient Intakes (RNIs).

It should be understood that the ULs in the IOM report were focused, by definition, on diets and supplements of *healthy* individuals in North America in order to prevent excessive intakes of vitamins or minerals, especially in the form of fortified foods or as dietary supplements. In some tables, ULs refer to the total amounts of nutrients *added* to a fortification premix, not to the total amounts *in* the food, which include intrinsic levels and those from the premix.

As such, the ULs do not pertain to the operational settings in which USAID’s implementing partners typically work. In these contexts, high levels of undernutrition and multiple micronutrient deficiencies are present, in contrast to a “generally healthy population.” As Golden (2009) puts it, “The [UL] levels explicitly do not apply to deficient individuals or to therapeutic treatment of nutritional diseases and could argue therefore that such limits do not apply to FBFs and other supplementary foods for the malnourished child.” We are therefore in strong agreement with both Golden (2009) and Dewey and Huffman (2009) on the importance of giving higher priority to essential nutritional needs for growth than to theoretical concerns about population-wide excess.

2.2 RECOMMENDATIONS FOR PRODUCT CHANGES

The reformulation of FBFs recommended here is intended to meet the needs of multiple nutritionally vulnerable beneficiaries, including, but not limited to, breast-fed children (as a complementary food). That said, FBF is *not* intended to serve as a generic vehicle for “nutritional quality” (delivering micronutrients) to *all* household members or for use in any undifferentiated setting.

The promotion of breast-feeding (and optimal complementary feeding) is underscored here; the recommendations include estimates of the contribution of breast-feeding to a small child’s diet. A formulation based on an intake of 50 g per day (when served as recommended with 15 g of FVO) would meet most nutrient needs of a breast-feeding infant aged roughly 6 to 12 months, with 30 g of FVO per 100 g meeting nutrient needs of 12-24 month olds. Additional quantity increments of the same product will similarly contribute to nutrient needs of other target consumers, be they wasted children up to 5 years of age, underweight pregnant or lactating women, or wasted adults with HIV/AIDS.

TABLE 2.5
Primary beneficiary groups (model for FBF reformulation)*

Prevention of stunting (linear growth promotion) among children 6–23 months of age
Management of moderate wasting among children 6–59 months of age
Meeting the elevated protein and micronutrient needs of nutritionally vulnerable pregnant and lactating women
Management or prevention of moderate wasting among people (including adults) living with HIV or AIDS

*The amount of FBF served to each group will be determined according to local context and needs, but guided by amounts proposed for each age group and condition.

For the 6- to 11-month-old breast-feeding child, the 50 g of CSB14 (the proposed new variant) as a daily complement to breast-feeding will be further complemented, not only by 15 g of fortified vegetable oil (FVO), but by the fat content of breast

milk. In the 6- to 11-month-old child, we have chosen to make a conservative estimate of 444 g of breast milk per day,¹⁷ which carries calories as carbohydrate and fat, high-quality protein, and its own complement of micronutrients and minerals to contribute toward the target requirements. As emphasized by Fleige et al. (2010a), the blended foods require adequate dilution (with water heated to boiling for safety) in order to meet the newly promulgated requirements for viscosity. The added oil at the ratio of 15 g of oil to 50 g of dry blended food, with the appropriate amount of boiled water, should further enhance the target viscosity, as well as the palatability of the blend. Combined with projected intake from breast milk, CSB14 provides more than two thirds of fat and nearly 80% of energy requirements and 100% of gross protein requirements for 6- to 11-month-olds. With additional fat and calories from vegetable oil, 6- to 11-month-olds reach greater than 100% of recommended fat intake and 91% of total daily energy needs, as well as the energy needs to ensure utilization of the added protein.¹⁸ Therefore, along with this proposed CSB14 formulation, vegetable oil continues to be a critical input for nutrition protection of 6- to 11-month-old children.

We recommend a ration of around 100 g of CSB14 per day for the 12- to 23-month-old child and 150 g for the 24- to 35-month-old child, with FVO added at the same ratio to the dry weight of CSB14, i.e., 30 g or 2 tablespoons for the 12- to 23-month-old child and 45 g or 3 tablespoons for the 24- to 35-month-old child.¹⁹ The added FVO, described below, will add fat-soluble vitamins and act as a source of essential fatty acids, which are known to be necessary for growth and development of nervous tissue, and will provide the essential amount of fat calories to meet the established needs for growth.

Adding calories as oil will not only contribute essential calories required for growth and spare the valuable protein, but also provide essential fatty acids, both linoleic (omega 6) and linolenic (omega 3). Table 2.8 shows the quantities of these essential fatty acids in two of the oils most commonly used in food aid, soybean and canola oil. When the recommended amount of oil is ingested, it should meet the needs of the children for omega 3 and 6 fatty acids. Fifteen grams of soybean oil or canola oil provides 0.98 and 1.37 g of omega 3 fatty acids, respectively. These quantities exceed safely the recommended 0.5 g recommended for infants 6 to 11 months of age (IOM, 2005). The 2008 FAO/WHO interim summary of conclusions on fatty acids states that the ratio of omega 3 to omega 6 fatty acids is not a significant factor when intakes are at or near required levels (FAO/WHO, 2008).

Described below is the recommended content of a modified FBF (focusing for this report on CSB as an example, which we call CSB14 since the current formulation is CSB13). It includes levels of micronutrients and high-quality protein (i.e., delivering

¹⁷ See Appendix 6

¹⁸ This is using our conservative, and most likely low, estimated breast milk intake for this age group. See Appendix 6 for more information.

¹⁹ Again, it must be emphasized that these are notional “target” servings that would be adjusted locally when detailed knowledge of consumption patterns and needs are available.

adequate essential amino acid levels), so that a 50-g ration of reformulated CSB, WSB, or other FBF (potentially based on a different staple grain, such as a sorghum–soy, rice–soy, potato–soy, or rice–lentil blend), would satisfy the needs of a 6- to 12-month-old infant. For example, 50 g of CSB14 prepared with 15 g of FVO would allow infants aged 6 to 12 months who are still breast-fed to meet roughly 100% of their protein, energy, and micronutrient daily needs.

Of course, many assumptions have to be made about the contribution of food aid products to the overall diet of target consumers. As noted long ago, “in assessing nutritional benefits to be derived from the modification or the formulation of foods, the composition of the overall diet must be considered” (AMA/CFN, 1968). Unfortunately, detailed knowledge of local diets and dietary practices in locations where FFP supports programming is often extremely weak. This was noted in the mid-1990s, when Dexter (1995) pointed out that although calculations indicate that FBFs make an important contribution to nutrient needs, “information on actual food intakes is limited.” And it remains true today, as revealed in the FAQR Implementing Partner Survey and through consultations with implementing partners and WFP. Thus, assumptions about the share of the diet to be delivered via FBFs have varied widely.

The original CSM was designed so that a daily 50-g ration would meet 10% of the Recommended Dietary Allowance (RDA) for energy and 25% of RDAs for micronutrients of infants (Wood et al., 2008), but Dexter (1995) noted that later versions of CSB met 25% of the energy needs of “young children *and pregnant and lactating women*” [emphasis added]. Fleige et al. (2010b) more specifically suggested that FBFs be fortified “at a level that would supply 75% of the Recommended Nutrient Intake (RNI) or Adequate Intake (AI) for most micronutrients if consumed to supply 25% of daily energy.”

The FBFs formulated by WFP and UNICEF align themselves with the 1991 Codex Alimentarius *Guidelines on Formulated Supplementary Foods for Older Infants and Young Children*, which indicate that 100 g should provide at least two thirds of the RNI for essential nutrients (Codex Alimentarius, 1991). Section 6.2.4 of the Codex’s *Guidelines* also recommends a daily ration of 100 g, although Zlotkin et al. (2010) point out that “new evidence suggests that breastfed children do not need such large amounts of energy ... [and that 100 g] would exceed the requirements for breastfed infants 6 to 11 months of age” and hence could inhibit breast-feeding.

Four changes are recommended here for reformulations of existing products:

1. Upgrade the macronutrient contents of the precooked, fortified cereal blends (CSB, WSB, and similar FBF products)
2. Upgrade the micronutrient composition of those same FBFs
3. Upgrade the micronutrient composition of soy-fortified enriched blended cereals (SFB, Soy-Fortified Grits [SFG], and similar products) and of fortified milled grains

4. Upgrade the micronutrient profile of currently used vitamin A–fortified vegetable oil

Throughout this chapter, there are numerous proposed changes to different products currently used in Title II. It is the recommendation of the review authors that all changes be piloted and tested as appropriate.

The specific micronutrient amounts required for catch-up growth and treatment of moderate malnutrition are not as well defined as are the macronutrient needs in the form of adequate calories, quality protein, and necessary intake of fat in the form of oil. For example, Doak et al. (2008, p 8) suggested that “15 micronutrients are identified as most important to the context of emergency food aid...[and that] food aid quality should be assessed based on how well food aid deliveries contribute to these 15 micronutrients.” By contrast, Dewey et al. (2009) stated that the number of nutrients used to fortify complementary foods and supplements has “ranged from 5 to more than 20,” while Golden (2009) talked of “40 or so essential nutrients.”

The approach adopted by this review has been to recognize the importance of FBFs that have not only an improved micronutrient profile, but also a higher-quality protein and increased calorie density as provided by oil at the time of preparation. The premix proposed here for the family of FBFs in Title II contains 20 minerals and vitamins. Zlotkin et al. (2009) point out that the revised Codex *Guidelines* should include magnesium, phosphorus, and potassium (which are noted in the 1991 list of essential nutrients to be added to processed complementary foods)—and each of these is included in the recommended premix. We do not, however, include in our recommendations adding biotin (vitamin B₇), chromium, copper, manganese, or molybdenum. In the absence of more compelling empirical evidence of their essentiality to the nutrition goals as defined, and documentation of deficiencies among targeted beneficiaries, we have decided not to add them to the premix. However, biotin, chromium, and molybdenum are all found in the ingredients that make up CSB or WSB and other FBFs, and hence their intrinsic values will be present in the final product. Despite not adding these nutrients to our premix, we will still measure against our nutrient target levels (115% RNI or DRI) in the following sections looking at the adequacy of the proposed premix.

Described below is the recommended content of this modified FBF. It is the recommendation that the provision of additional calories with FVO at the time of consumption of the fortified blend will help meet the extra requirements for growth. Provision of 30% to 45% of calories in the form of oil for these young growing infants and children is essential, not only for growth, but for the accretion of lean mass as opposed to adipose mass, where the latter might increase with provision of carbohydrate calories alone.

The FBF has been designed with generally increased levels of micronutrients and high-quality protein (adequate amino acid levels), so that a 50-g ration of

reformulated CSB, WSB, or other FBF²⁰ served with 15 g of FVO would satisfy the micro- and macronutrient needs of a 6- to 11-month-old child when combined with a conservative estimate of the amount of breast milk intake. There is increasing recognition that essential micronutrients should be provided to the fetus through provision of pregnant women. As such, it was our ambition that FBFs be fortified to provide the widely accepted set of vitamins and minerals in sufficient amounts so that ingestion of the blend as directed for the age/target group will provide an important share of the nutrient needs of older children, pregnant and lactating women, and wasted adults across the life cycle.

Upgrade Macronutrient Composition of CSB and WSB

The tables that follow provide recommendations for the composition of CSB14 as well as the micronutrient premix to be added to nonprecooked FBFs and to milled grains. With a few exceptions, the goal of the formulation is to meet the aforementioned nutrient targets, which are about 115% of the RNI or DRI when combined with oil and breast milk²¹ for a 6- to 11-month-old child. This formulation in incremental amounts attains 50% to 100% of the 115% RNI or DRI targets, when combined with breast milk, for children 12 to 23 months old, and 50% to 100% of the 115% RNI or DRI targets for pregnant and lactating women, without exceeding the ULs). Exceptions to attaining the 115% RNI or DRI objective include vitamin C, sodium, and potassium. To reiterate, this does not mean that CSB14 is designed *only* for children under 12 months of age, rather that the product is appropriate for consumption (when prepared and used as indicated) by that age group.

Although the focus of the tables and text is on CSB, it should be understood that these recommendations are meant for additional forms of FBF that could also be developed using sorghum, millet, or rice as the core cereal, mixed with peas, pulses, or other legumes as feasible and appropriate. Given that the bulk of emergency food aid currently goes to Africa, the use of cereals that match local tastes (such as sorghum and millet) and that are approved for use in each country represents an opportunity to generate new forms of blended foods. In providing food, whether for emergency, treatment, prevention, development, or any of the other reasons food is distributed in low- and middle-income countries, we felt it was important to try and match the local diets.

Table 2.6 shows the proposed ingredients list to improve the two FBFs currently in production.

²⁰ FBFs using a different staple grain, such as a sorghum–soy blend, a rice–soy blend, a potato–soy blend, or potentially a rice–lentil blend.

²¹ Kimmons et al. (2005) found in Bangladesh that breast milk contributed 78% of energy intake to 6- to 8-month-olds and 75% of energy intake to 9- to 12-month olds . Complementary foods supplied 22% and 25% of total energy intake at 6 to 8 and 9 to 12 months, respectively. Here, we estimate breast milk consumption for ages 7 to 12 months using the WHO publication *Complementary Feeding of Young Children in Developing Countries* (WHO, 1998). Details of our calculations can be found in Appendix 6.

TABLE 2.6
Recommended ingredients for new FBFs²⁴

Ingredient	CSB14	WSB16
	percent	
Maize meal	67.50	
Bulgur		53.00
Gluten		16.50
WPC80	3.00	3.00
Soy flour	21.00	19.00
Vegetable oil	5.50	5.50
	per 100 g	
Energy (kcal)	387	350
Protein (g)	17.7	28
Fat (g)	9	6.8

Note: CSB14, Corn–Soy Blend Version 14; FBF, Fortified Blended Food; WSB16, Wheat–Soy Blend version 16; WPC80, Whey Protein Concentrate with 80% protein content.

CSB14 provides roughly 400 kcal in a 100-g ration (dry weight), which conforms to the Codex *Guidelines* (Section 6.2.3). When CSB14 is served with the defined volume of oil (30 g of FVO to 100 g of FBF), the total energy rises to over 650 kcal. The importance of providing sufficient supplemental energy in itself should not be discounted. Meeting the need for calories needed for growth by a mix of calorie sources so that fats, oils, and lipids provide 30% to 45% of calorie intake is central to the goal of linear or catch-up growth or weight restitution and for utilization of protein and amino acids for lean mass accretion (see Golden 2010b). Habicht and Martorell’s (2010) careful assessment of the evidence of impact of nutritional supplementation in Central America found “evidence for a causal effect of energy,” while they could not identify the contribution of other specific nutrient(s) responsible for measured impacts. Consumption of the full recommended daily serving matters greatly to achieving desired impacts, and therefore sharing (leakage of product to nontarget consumers) can be an issue (see Chapter 3) (Habicht and Martorell, 2010).

To better support defined nutritional goals while promoting optimal breast-feeding and infant feeding practices, the macronutrient profile of CSB and WSB and similar products should be adjusted in four main ways:

Recommendation 1: The quantity of protein should be increased, and Whey Protein Concentrate (WPC) should be added. The inclusion of 3 g of Whey Protein Concentrate with 80% protein content (WPC80) per 100 g dry product of CSB or WSB will increase the protein available in these products and provide essential growth factors derived from an animal source, thereby improving their effectiveness in the management of moderate wasting, as well as in meeting the enhanced nutritional needs of children 6 to 24 months of age, thereby promoting

linear growth. The addition of an animal-source protein acknowledges new evidence that animal-source proteins matter in the accrual of lean tissue during recovery from wasting and in linear growth of children (Murphy and Alle, 2003). Animal-source proteins, in particular those from milk sources, contain (as yet incompletely defined) growth factors such as insulin-like growth factor 1 (IGF-1) and anti-infective agents such as lactoferrin (Hoppe et al., 2006; Michaelsen et al., 2009).

Healthy linear growth requires not only adequate energy but also *quality* protein. *Guiding Principles for Complementary Feeding of the Breastfed Child* states that "it is advisable to include meat, poultry, fish or eggs in complementary food diets as often as possible. Dairy products are a good source of some nutrients, such as calcium, but do not provide sufficient iron unless they are fortified....it may be more appropriate during the first year of life to choose dairy products such as cheese, yogurt and dried milk (mixed with other foods, e.g. in a cooked porridge)" (PAHO/WHO, 2002). However, in the populations we are targeting, regular access to these foods is difficult, if not impossible. It is therefore imperative that breast-feeding be continued and that the complementary food offered be a source of quality protein.

The current preferred measure of protein quality is the Protein Digestibility Corrected Amino Acid Score (PDCAAS), which takes account of digestibility as well as protein quality by assessing the limiting amino acids in a food source. Michaelsen et al. (2009) concluded that "children receiving a diet with a low PDCAAS would benefit from addition of animal-source foods to the diet. It is suggested that about one-third of the protein intake should come from animal-source food to make a significant impact on growth." Foods with a PDCAAS above 0.80 are considered a quality source of protein, and by some a PDCAAS of above 0.70 is satisfactory for moderate malnutrition (Michaelsen et al., 2009). If they are provided together with adequate calories from fat or oil for full utilization of the high-quality protein, CSB and WSB have a high PDCAAS due to amino acid complementarity, as defined by WHO/FAO/UNICEF (2007). The addition of 3% WPC80 brings the PDCAAS up to 0.88 (Table 2.7).

CSB13, the current FBF in use, has a PDCAAS of 0.85, which is above the minimum level recommended for treatment of moderate malnutrition. According to current standards, there is no need for additional animal-source protein to improve on a diet with FBFs, as the complementarity of cereal and pulse provides a sufficient quality of protein for growth. Table 2.7 below shows the PDCAAS scores for various FBFs.

Although existing FBFs composed with soy protein already have a good protein profile, empirical evidence suggests that an animal-source protein will contribute further to appropriate utilization and lean mass accretion (Grillenberger et al., 2003). This has led to the addition of milk powder or other dairy derivatives to CSB++ (WFP's own upgraded specification for CSB dating from 2009) and to most LNSs. Dairy proteins provide growth-promoting content, including higher contents of branched-chain amino acids (BCAAs) and growth-promoting IGF-1 and other growth factors shown to affect bone accretion and lean mass accretion (see Appendix 14). A

recent study by Oakley and colleagues (2010) in Malawi showed that children with kwashiorkor had a higher recovery rate after 8 weeks of treatment with an LNS designed for severely malnourished children with a 25% content of DSMP than did children with kwashiorkor treated with an LNS with 10% DSMP. There was no difference in recovery rate between treatment groups among marasmic children. This study was done only with children who were suffering from SAM; however, a case is building for the plausible importance of dairy protein in linear growth. One of our recommendations is that research such as this needs to be carried out in moderately malnourished populations that are the target of this document. The authors of the study do point out that their findings “emphasize that clinical evidence should be examined before recommending any changes to the formulation of [Ready-to-Use Therapeutic Food].” It is evident that further research is needed on the minimum amount of dairy-source protein that is needed for maximum impact on catch-up and linear growth of severely malnourished, moderately malnourished, and healthy children.

The current CSB13 provides quality protein when measured by the PDCAAS (0.85), and adding dairy will not increase the quality through addition of amino acids, but rather increases the digestibility, thus increasing the PDCAAS score. For both cost and supply reasons, WPC80 was chosen over DSMP, since its protein quality as measured by PDCAAS score is equivalent to that of DSMP. Indeed, WPC80 is slightly richer in growth-promoting substances and lactoferrin than DSMP. WPC80 is recommended over WPC34 (Whey Protein Concentrate with 34% protein content) for quality and cost reasons. WPC is essentially free of any fat, so concerns about shelf life are minimal. It is acknowledged that in the coming years research and markets can develop and change, and the best ingredients for FBFs may need to change with these developments.²² When provided with adequate calories to meet the needs for growth, so that the protein can be utilized for maximal benefit, this calorie–protein–fat combination with adequate micronutrients is expected to be effective for healthy linear growth, reversal of wasting, and catch-up growth in stunted children below 36 months of age.

CSB14, with the addition of WPC80, has a PDCAAS of 0.88 and provides 17.7 g of protein per 100 g.²³ When it is consumed with the recommended amount of oil, the protein/energy (P/E) ratio for CSB14 is 11%, in line with the recommendation that complementary foods for moderately malnourished children should have a P/E ratio of 12% (Hoppe et al, 2008). WSB15, which is the current product used, and WSB16 (with the additional WPC80 at 3%) have lower PDCAAS scores, even with the addition of animal-source protein, because the amino acid profile of wheat is poorer than that of

²² See Chapter 4 for a discussion of recommendations for changes in the system to be able to incorporate new findings in science and market needs more quickly into the products produced for FFP.

²³ Section 6.3.5 of the Codex’s Guidelines for Formulated Supplementary Foods states that the protein content of the product should be in the order of 15 g per 100 g dry matter (Codex Alimentarius, 1991). But Zlotkin et al. (2009) argue that “100 g of a supplement providing 15 g of protein is too much.” This is another area of limited consensus that the Codex will need to resolve in the process of updating the Guidelines during 2011.

corn. As other FBFs are developed, the formulations and nutrient levels should be assessed to best establish the level of WPC80 or other dairy source of protein to maximize nutritional benefits.

The addition of WPC80 makes the protein quality of CSB13 comparable to that of WFP’s CSB Plus Plus (CSB++), which has added DSMP. The total protein-to-total energy ratios of CSB14 and CSB++ (18% and 15%, respectively), without the addition of oil, are about the same as that of CSB13 (18%). WSB15, which is the current version listed among the products approved for use in Title II, and WSB16 (with additional WPC80 at 3%) have lower PDCAASs than CSB, even with the addition of animal-source protein, because the amino acid profile of wheat is poorer than that of corn. As other FBFs are developed, the formulations and nutrient levels should be assessed to best establish the level of WPC or other dairy source of protein to maximize nutritional benefits.

Field trials are ongoing aimed at understanding the optimum levels of protein enhancer to be included in such blended products (i.e., how little of the product can provide adequate nutritional content, thereby keeping costs to a minimum). Although the unit price of WPC80 is relatively high, the addition of just 3% (bringing with it important nutritional value) would represent 15% of the total ingredient cost of CSB14. Tests should be conducted to assess if 3% is the optimal level for CSB or WSB to achieve desired nutritional goals at the lowest price (sensitivity analysis around the current recommendation). FFP should also be open to alternative sources of animal-source protein that meet at least equivalent performance specifications.

TABLE 2.7
Protein quality of selected FBFs

Measurement	CSB14	CSB13	CSB++*	WSB16	WSB15
PDCAAS	0.88	0.85	0.89	0.72	0.63
Total P/E ratio**	18%	18%	15%	30%	35%

Note: CSB, Corn–Soy Blend; FBF, Fortified Blended Food; P/E, protein/energy; PDCAAS, Protein Digestibility Corrected Amino Acid Score; WSB, Wheat–Soy Blend.

* The new version of CSB following World Food Programme specifications.

** Without oil added at time of consumption.

The amount of WPC to be added to CSB and WSB recommended here (3 g per 100 g) meets the target levels for high-quality protein at a ration size adjusted by target group, but the possibility of keeping quantities as low as possible would also have to be tested against desired operationally relevant nutrition outcomes, given the possibilities for sharing and other leakage. Although DSMP is a potential source of such protein (as in the original CSM and in WFP’s new form of CSB), we recommend WPC for three reasons: a) it delivers significant nutrient value in small quantity (avoiding “bulking up” the final product at the expense of other nutrients); b) its price in the United States has been more stable (variable within a narrower band) than that of DSMP during the past decade, which offers the advantage of more

predictable pricing; and c) it contains no fat, thereby not impairing the shelf life of the finished product. WPC80 is already on the approved commodities list.

Recommendation 2: Increase the fat content. Some fat derives from the cereal blend, but it is our recommendation that such products be prepared and served with an appropriate quantity of FVO. Much of the nutritional value added offered by lipid products derives from the higher fat and energy content per daily dose or ration. The recommended CSB or WSB should be prepared and consumed with FVO at defined volumes (15 g oil per 50 g dry matter, and in increments of that ratio), resulting in higher fat and energy, meeting essential fatty acid (n-3 and n-6) needs, and also oil based micronutrients delivered; all important for management of wasting and for supporting child growth.

This recommendation is not without historical precedent and scientific support. Dewey et al. (2004) discuss feeding of non-breast-fed children 6 to 24 months old and recommend a maximum amount of 35 g oil per day for this group if animal-source proteins are not consumed. The International Federation of Red Cross and Red Crescent Societies' (IFRC's) *Nutrition Manual for Humanitarian Action* (Mourey, 2008) recommends preparing the following ration for supplementary feeding where CSB is not available: 60 g flour, 40 g DSMP, 30 g oil, 10 g sugar, and ~400 mL water. This is in line with this report's recommendation to prepare 100 g CSB with 30 g oil and 400 mL water. Similarly, the United Nations High Commissioner for Refugees' (UNHCR's) 1982 *Handbook for Emergencies*, Save the Children's 1987 *Drought Relief in Ethiopia: Planning and Management of Feeding Programmes*, and WFP's 2000 *Food and Nutrition Handbook* all recommend similar recipes for supplementary feeding that include a mixture of some type of flour, a protein (typically DSMP), and oil at roughly the same ratios (Appleton, 1987; UNHCR, 1982; WFP, 2000). The improved fat profile from combining products (CSB or WSB with oil) at the point of consumption will allow the attainment of nutritional goals similar to those attained with the use of alternative lipid-based products. This will require greater programmatic guidance and investments in enhanced social marketing and behavior change communication (BCC) to promote adherence. This change will benefit PLHIV, as dyslipidemia in this group, fostered in part by inadequate dietary intake, is frequent.

When combined with breast-feeding, CSB14 will provide two thirds of fat requirements, nearly 80% of energy requirements, and 100% of gross protein requirements for 6- to 12-month-olds. The addition of calories as oil should also provide required levels of essential fatty acids, linoleic (omega 6) or linolenic (omega 3).

Brown, Dewey, and others have emphasized the importance of energy density of complementary feedings for children who are at risk for malnutrition or malnourished from 6 months on to meet energy needs and prevent stunting, given the limited gastric capacity of infants. Their studies demonstrate the importance of divided and multiple feedings to achieve enhanced energy intake (Brown et al., 1995; Islam et al., 2006;

Bennett et al., 1999; Dewey et al., 2004). Our recommendation that CSB be ingested by infants at a ratio of 50 g CSB to 15 g oil with about 200 ml boiled water in three or four feedings per day would enhance the calorie value of feedings (by the use of oil) by roughly 50%. This additional calorie contribution would permit the intake of enough energy (with associated nutrients) to meet the needs for growth or growth recovery, which could not be achieved by CSB alone. The gastric capacity of the 6-month-old infant is estimated as 40 g per kilogram of weight (adapted from Brown et al., 1995); for a 6-month-old girl weighing 7.3 kg (WHO, 2006), the gastric capacity would be nearly 290 mL, well within the capacity to ingest the 86 mL of CSB porridge with oil in four divided feedings of the 50:15:200 ratio recommended for the 6- to 12-month-old infant. In addition, the oil can be expected to improve the palatability and texture of the porridge.

TABLE 2.8
Essential fatty acids in soybean oil and canola oil

Fatty acid	Soybean oil		Canola oil		RDI or AI (g/day)	
	g/15 g	g/30 g	g/15 g	g/30 g	7–12 mo	1–3 yr
Omega 3 (ALA)	0.98	1.96	1.37	2.74	0.5	0.7
Omega 6 (LA)	7.50	15.0	2.8	5.59	4.6	7.0

Source: IOM (2005); USDA/ARS (2010).

Note: AI, Adequate Intake; ALA, alpha-linolenic acid; LA, linoleic acid; RDI, Recommended Dietary Intake.

Recommendation 3: Increase the energy content. The proposed reformulation is such that a significant share of the nutrient needs of children and adults could be met by increasing the quantity in increments according to age. Infants 6 to 11 months of age would meet 50% of their energy requirements and most of their micronutrient requirements if they consumed 50 g of FBF with 15 g (~1 tablespoon) of vegetable oil (during one day, not at a single sitting); children 12 to 24 months of age would meet around two thirds of their energy requirements and most of their micronutrient requirements if they consumed 100 g of FBF with 30 g (~2 tablespoons) of oil. If 100 g of CSB or WSB, for example, is appropriately prepared with 30 g of oil, the energy content increases by roughly two thirds over that of the currently used CSB13 (which is often not prepared with oil at the time of consumption). In combination with energy from breast milk (at younger ages) or other foods (at older ages), the energy provided would meet most needs of nutritionally vulnerable and/or compromised children.

Recommendation 4: Add a flavor enhancer to formulations of FBFs. The addition of a sweetening additive would enhance taste and acceptability, which is particularly important when seeking to increase consumption among sick, undernourished children. UNICEF's version of CSB (UNIMIX) includes sugar, which is not recommended here. It has been suggested by industry that toasting the corn germ would provide a flavor that suggests sweetness. We urge exploration of innovations in processing by the private sector that would increase palatability (particularly for undernourished children) without significantly increasing cost.

Upgrade the Micronutrient Composition of CSB and WSB

Overall, micronutrient levels should be set higher than in the past, with a target of 115% of RNI across the diet to account for disease-intense (low-hygiene) environments and assumptions regarding prior nutritional deficits and likely current dietary deficiencies. The micronutrient content and nutrient density settled upon drew from the work of Lutter and Dewey (2003), Golden (2010b), Chaparro and Dewey (2010), and Fleige et al. (2010a, 2010b), among others, as well as on consensus recommendations from a wide range of experts consulted as part of this review. Target levels are adjusted taking into account intrinsic levels of food ingredients, updated knowledge of fortificant stability (losses due to length of storage, sunlight, and cooking), assumed breast milk consumption of infants, and other factors.

These targets derive from the widely accepted Recommended Nutrient Intakes (RNIs) for vitamins and minerals promulgated by FAO/WHO (2001) or, for some nutrients, the more recent Dietary Reference Intakes (DRIs) from the 2004 U.S. Institute of Medicine report (see beginning of Section 2.3.1) (IOM, 2004). For children up to 36 months of age, we have set the nutrient target levels at about 115% of the recommended RNI or DRI to cover additional needs of the target population, which suffers systematically from poor absorption induced by intermittent infection and food and water contamination (Golden, 2009).²⁴ These nutrient targets for children (as well as other malnourished groups) are presented in Table 2.4. An exception to the 115% rule is iron. For children 6 to 11 and 12 to 35 months of age, we chose a bioavailability of 12% for iron and did not increase the target level to 115% of RNI or DRI.

Whereas there is limited evidence for the needs of infants and children who are moderately malnourished, there is even less information about the levels of nutrients needed for pregnant and lactating women who are moderately malnourished or at risk for undernutrition. However, as with the children, we needed to set a target. We followed the same pattern, assuming an increased need of 115% above the established RNI or DRI. The nutrient targets for these groups are presented in Table 2.4. However, because of the special needs of pregnant women, both in obtaining adequate quantities of various micronutrients and in the risk of high amounts of certain micronutrients, the tables throughout this report compare product formulation recommendations in terms of requirements of a pregnant woman. The amounts in the tables will be labeled 115% RNI or DRI, as with the children and infants.

²⁴ Lartey et al. (1999) fortified their local variant of CSB (Weanimix) “to meet or exceed the vitamin and mineral requirements of infants when consumed with typical volumes of breast milk.” Similarly, Mathias and Byrne (1995) fortified Nutriful to provide “up to 100% of reference nutrient intakes (RNI) for vitamins and minerals for children under 5 years of age.” Several analysts have also argued that given the type of beneficiaries targeted by food aid, and the environments in which they live, fortification levels should be established in such a way that they would exceed the “normal” RNIs for healthy consumers in healthy contexts (Chaparro and Dewey 2010; Golden, 2009).

Aside from assessing the minimum requirements for nutrients, it is necessary to take into consideration the ULs, which were estimated in the DRI document to take account of the need for providing diets that were not only adequate in nutrient content, but included safe levels in the face of the possibility that some nutrients, especially when added as fortificants, might reach levels with adverse effects when ingested regularly over prolonged periods of time.

There are special considerations to be taken into account in the case of safe iron supplement levels for children in areas of heavy malarial infestation who are significantly undernourished. Safe supplement levels of zinc need to take into account nutrient–nutrient interactions, such as those with copper, where large amounts of zinc may compete for absorption with copper as well as with some other mineral nutrients, including iron. When FBFs are used in supplementary feeding for adults who are pregnant or lactating, or wasted as a result of HIV/AIDS, it would be prudent not to exceed amounts of folic acid fortification that may be associated with adverse effects in those with vitamin B₁₂ deficiency or marginal status. Where such risks exist in the use of the formulated products described below, the basis for the decision will be emphasized.

Recommendation 5: Increase the levels of vitamins B₁ (thiamin), B₂ (riboflavin), B₃ (niacin), B₅ (pantothenic acid), B₁₂, D₃, and E. Scientific consensus is moving toward an understanding that each of these vitamins is important in its own right. Increased levels will render the FBFs more effective, will not pose undue technical difficulties for producers, and should not have adverse organoleptic impacts on the final product. Levels of vitamins D and E are increased in line with recent recommendations by the IOM and other expert consultations.

Recommendation 6: Maintain vitamin C at the current level. Vitamin C is kept in the formulation to serve as an “enabler” to improve absorption of other nutrients and possibly as a future marker to replace vitamin A. Losses of vitamin C are known to be high, but its cost is no longer a major component of the premix price. It is therefore recommended that target levels of vitamin C remain at the status quo until future testing shows that a) its removal from the premix would not impair iron absorption, or b) it could not be delivered in alternative forms that would be more stable and thus deliver vitamin C more reliably, for example, in home fortificants. If more stable forms of premix-bound vitamin A and field-friendly spot tests for vitamin A levels in premixes become viable and cost-effective in coming years, the rationale for retaining vitamin C (as a marker in the premix) would be further weakened.

We kept ascorbic acid content at the CSB13 level for the time being—potentially as a preferred marker for assessing compliance with fortification specifications (rather than vitamin A, although this option has to be explored further). For potassium and sodium, it was decided to only aim for 50% of the recommended adequate intake for children 6 to 11 months of age. The potassium level recommended here is around 40% lower than in CSB++, largely due to concerns over potential organoleptic properties (to be tested) and cost. It should be noted that potassium, along with

phosphorus and vitamin E, accounts for almost 57% of the premix cost (or more than \$50/MT). Sodium levels are lowered on the basis of current expert opinion, which is focused on limiting daily intake by children at risk for fluid retention and edema, as well as the food technology challenge that meeting the daily RNI for sodium by providing it in salt would require such a large amount of salt that it would be too bulky (i.e., take up too much volume in relation to the final product).

Recommendation 7: Reduce levels of vitamin A. With vitamin A in vegetable oil, the amount in FBFs should be reduced not only to save cost, but, more importantly, to avoid any potential for exceeding ULs among nutritionally vulnerable consumers (particularly pregnant women). The recommended combination of 50 g of upgraded CSB or WSB with 15 g of FVO *and* breast milk meets 90% of the RNI of vitamin A for an infant 6 to 11 months of age. Similarly, 200 g of upgraded CSB or WSB with 40 g of FVO meets 76% of the RNI of vitamin A for pregnant women and only 23% of the UL.

Vitamin A is an important nutrient for appropriate growth and a strong immune system. A fat-soluble vitamin, it plays an important role in the immune system, but when given in high doses to pregnant women it can cause irreversible birth defects. In analyzing the current levels of fortification in FBFs, oil, and milled cereals, we determined that if a woman were to receive all three, which is a possibility, she could easily exceed the Safe Upper Level (UL) for vitamin A. For example, if she ate 440 g of fortified flour, 200 g of CSB13, and 40 g of oil, she would consume 119% of the UL in just those foods. For this and other reasons (elaborated upon below), we chose to decrease the levels of vitamin A in milled cereals and FBFs. The recommended premix for FBFs will attain 100% of our 115% RNI for vitamin A for children 6 to 11 months of age when 50 g is consumed with 15 g of oil.

Recommendation 8: Add vitamin K to the premix provisionally. Acknowledging recommendations by several nutrition scientists, and following WFP's lead, we propose adding vitamin K. Although widespread deficiency of this vitamin is rare, it can occur when the body is unable to absorb nutrients via the intestinal tract. Deficiency is therefore possible in unsanitary environments and where dietary sources of vitamin K (leafy green vegetables and fruits) are few, as in refugee camps or where markets are disrupted in emergencies. Adding vitamin K to the premix represents 2% of the cost. The stability of this new nutrient should be confirmed through testing, and its value should be assessed in field settings. If it is decided to continue including vitamin K, the potential cost savings from its addition to the oil versus its addition to the premix should also be examined.

The addition of other "new" vitamins (not currently included in the premix) should be based on evidence of deficiency among target populations or risks associated with potential deficiency. The potential inclusion of certain nutrients, such as biotin, selenium, molybdenum, manganese, and chromium, was considered, but their inclusion was not recommended until convincing data emerge on their functionality in relation to beneficiary needs and programming goals. There is a lack of strong

empirical evidence that they should be included, beyond the assumption that since they are “required nutrients” they should be added. Actual evidence of a significant risk associated with absence from the premix should determine whether or not these and other nutrients should be included, rather than an argument based on “negligible” cost.

When approximating the quantities of macro- and micronutrients needed even by the general population, there is a wide range within the recommendations for various nutrients. Two such nutrients of vital importance that are commonly deficient in diets are iron and zinc. Table 2.9 shows the recommendations for iron and zinc for healthy 6- to 11-month-old and 12- to 35-month-old children. The dietary source of iron and zinc affects the quantity prescribed. However, it is unclear how these numbers take into consideration the types of fortificants we are recommending for FBFs, milled grains, and improved cereals. For example, there are two general forms of iron, heme or animal-source iron and nonheme or plant-source iron. With the options for fortificants, there is a substantial difference between ferrous fumarate and sodium iron ethylenediaminetetraacetate (NaFeEDTA), with the latter more readily absorbed and closer to the absorption levels for heme iron. As the note following Table 2.9 suggests, understanding the quantity needed by even the healthy population for whom the RNIs and RDA’s were created is difficult, and even more so for the populations with or at risk for moderate malnutrition where research is still ongoing.

TABLE 2.9
Varying recommendations for iron and zinc (mg) by WHO
and IOM for healthy infants and children

Unit	Micronutrient	Infants 6–11 mo	Children 12–35 mo
RNI (by bioavailability)	Iron 15%	6.2	3.9
	Iron 12%	7.7	4.8
	Iron 10%	9.3	5.8
	Iron 5%	18.6	11.6
	Zinc high	2.5	2.4
	Zinc moderate	4.1	4.1
	Zinc low	8.4	8.3
RDA	Iron	11	7
	Zinc	3	3

Note: IOM, Institute of Medicine; RDA, Recommended Dietary Allowance; RNI, Recommended Nutrient Intake; WHO, World Health Organization.

RNIs for iron and zinc vary according to their bioavailability in the diet. For RDAs, only one number is given for each age group. RDAs for iron assume that the iron source consists of 75% heme iron. RDAs for zinc should be doubled for vegetarians. However, none of these recommendations take into account the form of iron used in fortification.

Iron is of vital importance for growth and health during the 1000-day window; however, controversy over the recommended quantities of iron supplementation has grown over the years. Although high supplement doses have been shown to increase mortality among non-iron-deficient children and women living in malaria endemic zones, such adverse affects have not been reported for iron in foods (Michaelsen et al., 2009). We determined to aim for 13 mg per 100 g of FBF. This is the upper level recommended by Golden (2010b) for FBFs for the treatment of MAM. However, palatability tests will need to be run to ensure that the food will be acceptable with this high level of iron as well as our other changes in the premix. The RNI is based on the bioavailability of the nutrient, and for iron in children 6 to 11 months it is between 6 and 19 mg per day. Our target, is 7.7 mg per day of iron at 12% bioavailability, and it is not increased to 115% of RNI or DRI as it is for the other nutrients. At our recommended dosage of 50 g of FBF and 15 g of oil, a 6- to 11-month-old will receive 7.75 mg of iron. In the tables that follow, this amount of iron is compared with the needs of 12- to 35-month-old children and pregnant and lactating women.

Less than half of the iron in the recommended premix is the NaFeEDTA form, which is more bioavailable than ferrous fumarate and has been proposed as the preferred compound in fortificant premixes for some time (INACG, 1993; Dexter, 1995; Trinidad et al., 2002; Serdula, 2010). Current WHO recommendations limit the amount of NaFeEDTA to 1.9 mg per kilogram of body weight in children under 5 years of age (WHO, 2007). It is argued that this limit should be reassessed and possibly increased, once appropriate clinical trials have been conducted.

Recommendation 9: Combine two forms of iron, NaFeEDTA and ferrous fumarate, in the premix to enhance iron absorption. Reduce the level of ferrous fumarate and add NaFeEDTA to levels currently permitted for children by the Codex Alimentarius (pending revisions to the *Guidelines*). Ferrous fumarate has limitations in terms of its bioavailability. A combination of ferrous fumarate and NaFeEDTA will enhance the impact of CSB and WSB by making more iron available to the beneficiary. The amount of NaFeEDTA to be included is restricted by current WHO limits (1.9 mg per kilogram of body weight for children). The increased effectiveness of the product justifies the increased cost of the micronutrient premix. Iron levels overall are set lower than in the past because of concerns over potential toxicity effects in seriously undernourished children.

Recommendation 10: Increase levels of zinc and add potassium. These two minerals play important roles in child growth, as well as supporting recovery from wasting. Zinc is separately important for enhancing iron absorption and combating diarrheal disease. We recommend that zinc oxide be included in all product specifications henceforth. Current FBF specifications are confusing, since both $ZnSO_4 \cdot H_2O$ and $ZnSO_4 \cdot 7H_2O$ are quoted in guidance as the zinc compound to be used. The level of zinc recommended is not as high as would be required to meet the 115% RNI or DRI target set for other nutrients, mainly due to uncertainty about its organoleptic properties. It is recommended that levels be increased from current targets to half of what has been suggested by some analysts (and

roughly the same as for WFP's CSB++). Testing should be carried out to ascertain if higher levels of zinc in FBFs would be feasible without affecting product acceptability.

Zinc deficiency has received increased attention over the years because of its link to poor growth. Diets in most low-income countries are low in zinc, and diseases such as diarrhea deplete body stores. The bioavailability of zinc also varies according to the source, as discussed earlier. Zinc from animal sources tends to have higher bioavailability than zinc from plant sources, as in the case of iron. Since most diets in low-income countries are plant based, it is important that children and women receive sufficient zinc to make up for poor intake and low-bioavailability sources. However, the chemical properties of zinc make it difficult to fortify foods with zinc, since zinc greatly affects taste and may alter color (see Appendix 15 for more information). The levels we are recommending are lower than the 115% RNI or DRI, but at this point in time they are the highest known not to cause organoleptic problems in FBFs. We recommend further research on the feasibility of increasing the quantity of zinc in enriched grain products.

TABLE 2.10
Target levels of nutrients for upgraded CSB plus oil

Nutrient	FVO	Fortification (premix)	CSB14 product total*	CSB14 + oil	Fortificant form
	30 g	per 100 g	100 g	100 g + 30g	
Macronutrients					
Energy (kcal)	265		387	652	
Protein (g)	—		18	18	
Fat (g)	30		9	39	
Minerals (mg)					
Calcium		279.08	352.89	352.9	2% tricalcium phosphate
Copper		—	0.39	0.39	N/A
Iodine		0.23	0.23	0.228	Potassium iodide
Iron		13	15.5	15.5	EDTA and ferrous fumarate
Magnesium		9.47	94.06	94.1	Magnesium oxide
Manganese		—	0.79	0.787	N/A
Phosphorus		290.97	513.31	513.3	2% tricalcium phosphate
Potassium		163.19	707.07	707.1	Potassium monophosphate (monocalcium phosphate)
Selenium		—	0.02	0.02	N/A
Sodium		225.67	239.19	239.2	Sodium chloride
Zinc		5.5	6.85	6.85	Zinc sulfate monohydrate
Vitamins (mg)					
Vitamin A	0.378	0.110	0.154	0.532	Vitamin A palmitate
Vitamin B ₁ (thiamin)		0.652	0.746	0.746	Thiamin mononitrate
Vitamin B ₂ (riboflavin)		0.933	0.967	0.967	Riboflavin
Vitamin B ₃ (niacin)		9.07	9.74	9.74	Niacinamide
Vitamin B ₅ (pantothenic acid)		3.34	3.53	3.53	Calcium D-pantothenate
Vitamin B ₆		0.619	0.752	0.752	Pyridoxine hydrochloride
Vitamin B ₉ (folic acid)		0.087	0.095	0.095	Folic acid
Vitamin B ₁₂		0.0015	0.0015	0.0015	Vitamin B ₁₂ 0.1% (water soluble)
Vitamin C		40	40	40	Coated ascorbic acid Type EC
Vitamin D ₃	0.0042	0.025	0.025	0.030	Vitamin D ₃ 100,000 IU/g
Vitamin E	2.454	10.77	10.88	13.34	Vitamin E 50% CWS
Vitamin K		0.033	0.033	0.033	Dry vitamin K ₁ 5% (spray dried)

CSB, Corn–Soy Blend; FBF, Fortified Blended Food.

*Including intrinsic values in CSB. These numbers will be slightly different, depending on what FBF is being fortified, as the premix is the same for all FBFs.

Recommendation 11: Decrease levels of magnesium, calcium, iodine, and sodium.

The levels of these minerals in current premixes are considered excessive. The sodium level was high in earlier CSBs because iodized salt was the source of iodine, which can now be added independently. High sodium can be a factor in renal overload and edema. Calcium levels are reduced in line with the new IOM recommendations, dropping from 400 to 260 mg per day.

The estimated cost of a reformulated CSB14 would be around \$833/MT from the mill (although as with all FBFs the price will change over time depending on variability in ingredient and other costs). This reflects an increase in unit price of around 18% over CSB13. The drivers of the increase include a higher macroingredient cost due to addition of WPC80 and an estimated rise of 11% in “upcharge” from producers due to the increased complexity of mixing (since the processors would need to procure and store more ingredients and might need to make special arrangements for handling WPC80). Overall, CSB14, with its reformulated micronutrient premix profile, is moderately *less* expensive than CSB13 (\$73.57/MT versus \$76.20/MT).

However, further cost factors need to be considered. In terms of food technology, it is recommended that when premixes are prepared, iron and zinc should be combined with the vitamins and calcium and phosphorus added separately. The bulkiness of calcium and phosphorus can cause problems in mixing (clumping and nonhomogeneity). The possibility should be explored of moving from one premix for vitamins and another for minerals, to one premix for vitamins *plus* the iron and zinc (which are now stable and less likely to interact with the vitamins) and a separate premix for the bulky minerals. An additional food technology issue is that the potential should be explored of processing that can reduce the antinutrient content of such foods, including extrusion and the use of phytase once it has been granted Generally Recognized as Safe (GRAS) status. There are many more options to be considered, in collaboration with industry, to enhance the nutrient and energy density of FBFs, reduce phytates and fiber, improve product quality, and enhance shelf life. For example, WFP has carried out extrusion trials using high moisture and coextrusion that have demonstrated improvement in the shelf life of CSB products.

A further cost issue relates to changes in packaging size and composition. It is argued here that improved packaging materials and smaller-sized units should both be urgently explored. Given the costs involved in improving FBFs outlined above, it is believed that improved packaging of the enhanced product would support BCC at the field level to reduce sharing within the household (by focusing products on the actual intended consumer) and would potentially also improve storability. Many agencies and experts have suggested that providing recipients with a closed package reduces the potential for contamination and is also a more dignified method of distribution. Smaller packaging is recommended, down from current delivery in 25-kg sacks to monthly ration sizes, perhaps in the 6- to 10-kg range (based on 100 g/day for 60 days for a total of 6 kg). However, the actual size, form, and mode of sealing all remain to be appropriately determined, as well as the cost relative to enhanced targeting effectiveness.

Metal (foil) package specifications for vegetable oil should be reassessed in the light of potential alternatives and frequent reports of breakage. A “best if used by” date or an expiry date should be included on all Title II packaging, particularly for new formulations of CSB and WSB, after testing for shelf life. Greater flexibility in packaging size should be allowed, given differences between U.S. and international metrics. Current requirements stipulate 50-lb bags, and since those specifications would have to be changed to allow for smaller bags, it would allow vendors more flexibility if metric-based alternatives were possible (i.e., kilograms as alternatives to pounds). The feasibility of “front-of-package” messaging must be fully explored in relation to costs and the viability of improving intrahousehold targeting and correct use. The impact of smaller, more targeted packaging on consumption by target consumers (reduced sharing) as well as shelf life and storability will have to be tested under field conditions.

It is also recommended that product (ingredient) and nutrition composition be described in a user-friendly manner on a label on the product container of all nutritionally enhanced products (FBFs, lipid-based products, home fortificants, etc.). The U.S. Government already requires such labeling for processed food products sold in the U.S., and implementing partners and recipient governments would welcome this information.

The new CSB provides roughly 400 kcal in a 100-g ration (dry weight), conforming to Codex Alimentarius *Guidelines*. When it is served with the prescribed amount of oil, the total energy provided rises to more than 650 kcal. The importance of providing sufficient supplemental energy in itself should not be discounted. Meeting the need for calories through a mix of sources (so that fats, oils, and other lipids provide 30% to 45% of calorie intake) is central to the goals of restitution of linear or catch-up growth or weight and utilization of protein and amino acids for lean mass accretion (Golden, 2009, 2010a).

The recommendation that Title II stay with a single improved CSB to meet explicitly defined nutritional goals (rather than multiple variants, some with animal protein added and others without) rests on two principles: first, that nutrient-dense, value-added foods should not be used as a generic vehicle for the delivery of “nutrient quality” in an untargeted fashion when nutrient value can be delivered in other, less expensive and more appropriate ways; and second, that the ability to promote the enhanced FBF as a food designed to support specific nutrition outcomes among clearly identified target demographics would be compromised. Voices for and against this position were listened to during the review process, with as many people arguing for a single version (“to avoid confusion in the field,” “to keep programming logistics as simple as possible,” “to focus more attention on the prescribed uses of CSB”) as against (“there should be harmonization with the practice of UN agencies,” “implementing partners working with both USAID and WFP will be confused”).

Nutrients should be delivered across the food basket, and wherever possible a range of foods should be programmed. The goal of ensuring adequate micronutrient content of a family ration can be met in a cost-effective manner more by improving the cereal component than through the use of CSB or WSB. Sharing is common, but unless targeted to specific individuals, the CSB or WSB will not achieve intended goals. Although most implementing partners recognize the potential value of having different versions of CSB for different nutritional purposes (mainly supporting a CSB without animal protein for use in school feeding activities), the majority also stated that they would not want to program two different versions because of the logistical and programming challenges involved. Although it is not based on these survey responses, the recommendation here for a single enhanced FBF does address such concerns, in addition to accounting for cost, cost-effectiveness, and programming priorities in Title II programs.

Table 2.11 illustrates the nutrient targets that would be achieved for three key beneficiary groups were they to consume the recommended amounts of the proposed new formulation of CSB plus the recommended amounts of vegetable oil. It underlines the fact that since the nutrient requirements of individuals are constantly changing through the life cycle, a single product cannot be expected to achieve the same goals for every consumer or for every nutrient. However, the formulation proposed does allow Title II to achieve at least minimum goals for most nutrients for key nutritionally vulnerable beneficiaries.

TABLE 2.11
CSB14 and oil with ~115% RNI or DRI for three groups of target beneficiaries

Nutrient	Infants 6–11 mo		Children 12–36 mo		Pregnant women	
	50 g CSB14 + 15 g oil	50 g CSB14 + 15 g oil + 444 g breast milk	100 g CSB14 + 30 g oil	100 g CSB14 + 30 g oil + 362 g breast milk	200 g CSB14 + 40 g oil	
	Percentage of 115% RNI or DRI					% of UL
Macronutrients						
Energy (kcal)	48	91	65	89	47	
Protein	55	84	77	93	50	
Fat	63	118	129	176	192	
Minerals						
Calcium	58	100	50	64	61	28
Copper	76	120	99	122	67	1
Iodine	53	100	106	144	95	20
Iron	99	101	319	321	99	68
Magnesium	75	100	135	153	74	
Manganese	56	57	56	57	68	14
Phosphorus	80	100	96	106	126	29
Potassium	43	72	20	26	26	
Selenium	87	165	103	139	116	10
Sodium	28	43	21	25	27	21
Zinc	59	59	95	95	168	34
Vitamins						
Vitamin A	52	100	103	143	76	23
Vitamin B ₁ (thiamin)	73	100	88	101	63	
Vitamin B ₂ (riboflavin)	66	100	106	128	76	
Vitamin B ₃ (niacin)	86	100	114	122	76	45
Vitamin B ₅ (pantothenic acid)	61	100	111	139	74	
Vitamin B ₆	88	100	106	111	56	1
Vitamin B ₉ (folic acid)	58	100	62	81	31	13
Vitamin B ₁₂	46	100	72	106	50	
Vitamin C	17	68	34	76	37	1
Vitamin D ₃	98	100	130	131	245	84
Vitamin E	102	120	204	219	190	2
Vitamin K	92	100	122	127	67	

CSB, Corn–Soy Blend; DRI, Dietary Reference Intake; RNI, Recommended Nutrient Intake; UL, Safe Upper Level.

Table 2.12 compares components of CSB13, CSB14, and WFP’s CSB++ per 100 g, the amount suggested for children 12 to 36 months of age, and considers the nutrient sufficiency of the formulations in comparison with our aforementioned nutrient targets. There are some differences in the formulations, such as for calcium. The IOM has released new recommendations for calcium, resulting in our decreased level. Note that the current reformulation is not the final word on FBF product composition; we recommend the creation of a mechanism for ongoing review of appropriate evidence that would allow for periodic updating of formulation as required.

TABLE 2.12**Macro- and micronutrient contents of CSB13, CSB14, and CSB++ in serving size recommended for children 12 to 36 months of age (100 g)**

Nutrient	CSB13	CSB14 + oil	CSB++
	100 g	100 g + 30 g	100 g
Macronutrients			
Energy (kcal)	386.1	652.2	397
Protein	15.9	17.7	15.3
Fat	8.7	38.8	9.59
Minerals (mg)			
Calcium	650	352.9	755
Copper	0.403	0.39	0.497
Iodine	0.568	0.228	0.40
Iron	10.6	15.5	12.54
Magnesium	168.0	94.1	138
Manganese	0.815	0.787	0.756
Phosphorus	522	513.3	334
Potassium	563	707.1	1045
Selenium	0.021	0.02	0.015
Sodium	326	239.2	65
Zinc	5.94	6.85	7.58
Vitamins (mg)			
Vitamin A	0.819	0.532	0.825
Vitamin B ₁ (thiamin)	0.61	0.746	0.557
Vitamin B ₂ (riboflavin)	0.481	0.967	0.856
Vitamin B ₃ (niacin)	6.29	9.74	7.42
Vitamin B ₅ (pantothenic acid)	3.285	3.53	7.39
Vitamin B ₆	0.532	0.752	2.18
Vitamin B ₉ (folic acid)	0.247	0.095	0.110
Vitamin B ₁₂	0.0013	0.0015	0.0023
Vitamin C	40.2	40	101.6
Vitamin D ₃	0.0050	0.03	0.005
Vitamin E	0.98	13.34	8.7
Vitamin K	0.0009	0.033	0.114

Note: CSB, Corn-Soy Blend.

Upgrade the Premix for Cereal Blends and for Milled Cereals

Currently Title II has five different fortification standards applying to cornmeal, wheat flour, and soy-fortified products, including bulgur, sorghum grits, and corn masa flours. A single upgraded premix is recommended. Having a single version will reduce confusion and allow cost savings to the miller. In this case, however, the intention is not to meet 115% of micronutrient requirements; instead, goals are set at between 55% and 100% of RNI for adult women (depending on the nutrient), with a view to balancing nutrients delivered via other food sources.

Recommendation 12: Cut levels of vitamin A, vitamin B₁, vitamin B₃, and iron, but increase vitamins D₃ and B₆. The recommended level of vitamin A in the new premix is much lower than the previous recommendation. Given the levels proposed for vegetable oil and FBFs, it is recommended that the vitamin A level in cereal flours be reduced from 6.6 ppm (required for wheat flour) to 1.1 ppm. This lower level will provide 100% of the RNI for women, assuming consumption of 400 g, and for children 2 to 5 years of age, assuming consumption of 300 g—with added CSB and fortified oil providing a margin of safety in both cases. For children 1 to 3 years of age, 100 g of fortified cereal flours provides about one third of the RNI, with CSB and oil (and supplementation with high-dose capsules) providing the remainder. Additionally, the stability of vitamin A compounds used in cereal fortification needs to be improved. Vendors of vitamin A should be challenged to improve the stability of vitamin A in premixes. To be able to determine improved stability, it will be important to secure approval (or other official status) for a vitamin A stability test (i.e., from AOAC International or the American Association of Clinical Chemists [AACC]).

Recommendation 13: Change the form of iron in the premix to NaFeEDTA (as in the CSB or WSB reformulation) to enhance bioavailability, which allows for slightly lower levels to be added, thereby containing costs.

Recommendation 14: Add zinc and vitamin B₁₂ at levels recommended by WHO (WHO, 2009)

Recommendation 15: Remove calcium from the premix. This nutrient is both bulky and costly, causing problems at the point of mixing, and it would require a threefold increase in calcium in the premix to reach target levels of 115% of RNI—at which point its cost would become prohibitive. At current levels, calcium already represents 16% of the premix cost. Taking food technology and price factors into consideration, weighed against the role of calcium in a generic premix (for household use as opposed to being targeted to specific consumers), its removal from this particular premix is the efficient option.

Tables 2.13 and 2.14 show the quantity and form of each nutrient recommended for the FBF premix. Further discussion of these can be found in Appendix 15.

TABLE 2.13**Bulk mineral compound forms and quantities recommended for FBF premix**

Nutrient	Fortification level	Fortificant compound
	mg/kg (ppm)	
Sodium	2257	Sodium chloride
Phosphorus	2910	2% tricalcium phosphate
Calcium	2791	2% tricalcium phosphate
Potassium	1632	Potassium monophosphate

TABLE 2.14**Fine vitamin and mineral compound forms and quantities recommended for FBF premix**

Nutrient	Fortification level	Fortificant compound
	mg/kg (ppm)	
Vitamins		
Vitamin A	1.1	Vitamin A palmitate
Vitamin B ₁ (thiamin)	6.5	Thiamin mononitrate
Vitamin B ₂ (riboflavin)	9.3	Riboflavin
Vitamin B ₃ (niacin)	90.7	Niacinamide
Vitamin B ₅ (pantothenic acid)	33.4	Calcium D-pantothenate
Vitamin B ₆	6.2	Pyridoxine hydrochloride
Vitamin B ₉ (folate)	0.874	Folic acid
Vitamin B ₁₂	0.015	Vitamin B ₁₂ 0.1% (water soluble)
Vitamin C	400	Coated ascorbic acid. Type EC
Vitamin D	0.254	Vitamin D ₃ 100 kIU/g
Vitamin E	108	Vitamin E 50%
Vitamin K	0.33	Dry vitamin K ₁ 5% (spray dried)
Minerals		
Iodine	2.28	Potassium iodide
Iron	40	NaFeEDTA
Iron	90	Ferrous fumarate
Magnesium	94.65	Magnesium oxide
Zinc	55.04	Zinc sulfate monohydrate

Note: NaFeEDTA, sodium iron ethylenediaminetetraacetate.

Table 2.15 compares levels of fortification proposed for milled cereals with current Title II specifications, as well as the nutrient form. The lower amounts of thiamin and niacin in the recommendations are not considered to be nutritionally significant. Higher vitamin D fortification takes account of newer recommendations in the face of increasing evidence of vitamin D deficiency as a global problem in nutrition.

Similarly, the higher amounts of vitamin B₆ represent a reaction to evidence of the importance of this nutrient to protein metabolism, growth, and disease resistance.

The cost of the recommended fortification profile is approximately \$6.68/MT (based on the 2010/11 micronutrient cost of \$8.89/kg, an addition rate of 600 g/MT, and a 20% increase in the cost of premix). This compares favorably with the current cost of \$10.12/MT. NaFeEDTA accounts for about one third of the cost and is considered essential because of its superior bioavailability. The new fortification profile may be significantly less expensive than the current one, possibly one third less. This is largely the result of significantly lower vitamin A levels as well as the elimination of calcium in the proposed fortification profile. Although the cost of iron is significantly higher in the proposed profile due to the addition of NaFeEDTA, cost savings are still achieved by lowering vitamin A and eliminating calcium from the premix.

TABLE 2.15
Fortification of milled and blended cereals (premix composition)

Nutrient	Current Title II fortification level	Recommended level	Fortificant form
	mg/100 g	mg/100 g	
Vitamin A	0.66	0.11	Vitamin A palmitate 250 (spray dried)
Vitamin B ₁ (thiamin)	0.638	0.4	Thiamin mononitrate
Vitamin B ₂ (riboflavin)	0.396	0.4	Riboflavin
Vitamin B ₃ (niacin)	5.28	4	Niacinamide
Vitamin B ₆		0.4	Pyridoxine hydrochloride
Vitamin B ₉ (folic acid)	0.154	0.154	Folic acid
Vitamin B ₁₂		0.011	Vitamin B ₁₂ 0.1% (water soluble)
Vitamin D ₃		0.002	Vitamin D ₃ 100,000 IU/g
Iron	4.4	4	NaFeEDTA
Zinc		2.4	Zinc oxide

Note: NaFeEDTA, sodium iron ethylenediaminetetraacetate

Upgrade the Micronutrient Composition of Vegetable Oil

With an average distribution of 170,000 MT per year, oils make significant contributions to fat and calories in the food basket, and they represent the least expensive vehicle for vitamin A. At the current vitamin A fortification level of 20 ppm, vegetable oil in the quantities provided is generally sufficient to provide substantial levels of vitamin A protection for most people. Assuming 60% retention, 20 g provides more than half of the RNI for children 1 to 3 years old, and a 40-g ration offers nearly full RNI for adult women.

In addition to serving as a vehicle for vitamins, oil is needed in the diet for other reasons. Essential fatty acids—“essential” because our bodies cannot produce them—

are important in the diets of growing children and pregnant and breast-feeding women. They play a crucial role in the development of the nervous system. As well as essential fatty acids, oil provides the necessary caloric density to spare the vital protein. For all of these reasons, our recommendation that CSB be served with oil is a necessary and important change in programming (see Chapter 3 for further discussion). Moreover, it is important to recognize that all three reasons given above for serving CSB with oil have the same level of importance.

Recommendation 16: Maintain level of vitamin A in oil and add vitamin D.

Reaching desired (target) levels of oil-soluble micronutrients for child beneficiaries is considerably less expensive when these nutrients are included in the food specifically targeted to children. On the grounds of cost-effectiveness, therefore, the recommendation that CSB and WSB (and future analogues) be prepared or served with vegetable oil at the point of consumption suggests that there should be an appropriate level of vitamin A in the FBF as well as in the oil (which is shared across the entire household). For household consumption targets, vitamin A is recommended for inclusion in the premix intended to fortify milled cereals.

In addition to vitamin A, oils can be effective fortification vehicles for oil-based vitamins such as vitamins D, E, and K. The full food basket includes vitamins E and K from oil and legumes. However, there are no sources of vitamin D. Therefore, we recommend vitamin D fortification at 0.425 ppm to provide 100% of the RNI for adult women in a 40-g ration. With vitamin A at 18 ppm and vitamin D at 0.425 ppm, the legumes and oil provide virtually full protection for vitamins A, D, and K and about one third the RNI of vitamin E. The oil used in the manufacture of FBFs should be nonhydrogenated, rather than hydrogenated, which will be more in line with current industry practice and thereby keep costs down.

2.3 MEETING NUTRITIONAL TARGETS

This section presents the share of target nutrients for our three main target groups: 6- to 11-month-old infants, 12- to 35-month-old children, and pregnant and lactating women. For 6- to 11-month-old infants, as mentioned, we are assuming a conservative breast milk intake of 444 g. For children 12 to 36 months of age, we conservatively estimate an intake of 362 g of breast milk. For more on these assumptions, see Appendix 6. The nutrient targets of ~115% of RNI or DRI for 6- to 11-month-old infants are achieved with 50 g of CSB14 plus 15 g of oil provided as complement to breast-feeding, with the exception of manganese, potassium, sodium, zinc, biotin, and vitamin C (see Table 2.16 below). As explained earlier, we chose not to add biotin and manganese to the premix and decided on lower levels for potassium and sodium. Zinc and vitamin C, although recognized as vital, are not at the 100% of RNI/DRI level because of food technology issues. As was explained, vitamin C loss is substantial, and for the moment we felt it was best to leave it at its current level until further research can allow higher retention rates to be attained. Zinc is at the current maximum allowable level due to organoleptic issues. With further research, it

is hoped that the quantity of zinc can be brought up in FBFs, but for now we can only attain 60%.of requirement

The last column in Table 2.16 shows the percentage of the ~115% RNI or DRI achieved by the *total product*. The levels of the nutrients were raised according to our estimates of losses in transport, storage, and cooking. These assumptions are outlined in Appendix 16.

TABLE 2.16
Comparison of CSB14 + oil with breast milk for infants 6 to 11 months old

Nutrient	50 g CSB14 + 15 g oil—less assumed losses	50 g CSB14 + 15 g oil + 444 g breast milk*—less assumed losses	100 g CSB14 + 15 g oil + 444 g breast milk*—less assumed losses	50 g CSB14 + 15 g oil + 444 g breast milk*—total product
	Percentage of 115% RNI or DRI [‡]			
Macronutrients				
Energy (kcal)	48	91	139	91
Protein	55	84	140	84
Fat	63	118	181	118
Minerals				
Calcium	58	100	158	101
Chromium	0	193	193	193
Copper	76	120	196	121
Iodine	53	100	153	157
Iron	99	101	201	102
Magnesium	75	100	175	101
Manganese	56	57	113	57
Phosphorus	80	100	180	101
Potassium	43	72	116	73
Selenium	87	165	252	165
Sodium	28	43	71	44
Zinc	59	59	118	60
Vitamins				
Vitamin A	52	100	152	106
Vitamin B ₁ (thiamin)	73	100	173	135
Vitamin B ₂ (riboflavin)	66	100	166	139
Vitamin B ₃ (niacin)	86	100	186	120
Vitamin B ₅ (pantothenic acid)	61	100	161	124
Vitamin B ₆	88	100	188	121
Vitamin B ₇ (biotin)	0	26	26	26
Vitamin B ₉ (folic acid)	58	100	159	130
Vitamin B ₁₂	46	100	146	145
Vitamin C	17	68	85	109
Vitamin D ₃	98	100	198	131
Vitamin E	102	120	222	134
Vitamin K	92	100	192	152

Note: CSB, Corn–Soy Blend; DRI, Dietary Reference Intake; RNI, Recommended Nutrient Intake.

* Quantity of breast milk is estimated. See Appendix 6 for details.

‡ See defined nutrient targets in Table 2.4.

Comparing FBF Recommendations to Existing Formulations

The following section compares the profile of the current title II CSB13 and WFP's CSB++ with our recommendations for new FBFs, such as CSB14. WFP has two new FBFs, CSB+ and CSB++. After much discussion and exploration of the possibility of using two CSBs, it was decided that a single formulation used as recommended would serve USAID better and be more cost-effective. The programmatic implications of our choosing one CSB while WFP uses two should be further explored. Ideally, standardization of formulation and policy should be pursued as a principle, but cost-effectiveness and differential usage of products among different agencies may require flexibility rather than standardization.

Table 2.17 compares the components of CSB13, CSB14, and WFP's CSB++ per 100 g, the amount suggested for children 12 to 35 months of age, while Table 2.18 considers the nutrient sufficiency of the formulations in comparison with our aforementioned nutrient targets (~115% RNI or DRI). As was noted above, due to losses in transport and cooking, these amounts are higher than those that will be consumed. However, as we cannot estimate losses for CSB++ (and other products, as shown later in this section), we are comparing total levels added to the product only.

There are some clear differences in the formulations, for example, that for calcium. IOM has released new recommendations for calcium, resulting in our decreased level (IOM, 2010).

TABLE 2.17

Comparison of total product for three FBFs: macro- and micronutrient content of CSB13, CSB14, and CSB++ in serving size recommended for children 12 to 35 months old (100 g)

Nutrient	CSB13	CSB14 + oil	CSB++
	100 g	100 g + 30 g	100 g
Macronutrients			
Energy (kcal)	386.1	652.2	397
Protein (g)	15.9	17.7	15.3
Fat (g)	8.7	38.8	9.59
Minerals (mg)			
Calcium	650	352.9	755
Copper	0.403	0.39	0.497
Iodine	56.8	0.228	40
Iron	10.6	15.5	12.54
Magnesium	168.0	94.1	138
Manganese	0.815	0.787	0.756
Phosphorus	522	513.3	334
Potassium	563	707.1	1045
Selenium	0.021	0.02	0.015
Sodium	326	239.2	65
Zinc	5.94	6.85	7.58
Vitamins (mg)			
Vitamin A	0.819	0.532	0.825
Vitamin B ₁ (thiamin)	0.61	0.746	0.557
Vitamin B ₂ (riboflavin)	0.481	0.967	0.856
Vitamin B ₃ (niacin)	6.29	9.74	7.42
Vitamin B ₅ (pantothenic acid)	3.285	3.53	7.39
Vitamin B ₆	0.532	0.752	2.18
Vitamin B ₉ (folic acid)	0.247	0.095	0.110
Vitamin B ₁₂	0.0013	0.0015	0.0023
Vitamin C	40.2	40	101.6
Vitamin D ₃	0.0050	0.03	0.005
Vitamin E	0.98	13.34	8.7
Vitamin K	0.0009	0.033	0.114

Note: CSB, Corn–Soy Blend.

TABLE 2.18
Comparison of percentage of nutrient target (115% RNI or DRI) for children 12 to 35 months old in 100 g of three FBFs (plus 30 g oil for CSB14, as recommended)

Nutrient	Percentage of 115% RNI or DRI		
	CSB13	CSB14 + oil	CSB++
Macronutrients			
Energy (kcal)	39	65	40
Protein	69	77	67
Fat	29	129	32
Minerals			
Calcium	93	50	108
Copper	103	100	127
Iodine	55	220	39
Iron	220	322	261
Magnesium	243	136	200
Manganese	59	57	55
Phosphorus	99	97	63
Potassium	16	20	30
Selenium	107	104	77
Sodium	28	21	6
Zinc	83	96	106
Vitamins			
Vitamin A	178	116	179
Vitamin B ₁ (thiamin)	106	130	97
Vitamin B ₂ (riboflavin)	84	168	149
Vitamin B ₃ (niacin)	91	141	107
Vitamin B ₅ (pantothenic acid)	143	153	321
Vitamin B ₆	93	131	380
Vitamin B ₉ (folic acid)	245	94	109
Vitamin B ₁₂	127	141	223
Vitamin C	117	116	294
Vitamin D ₃	29	171	29
Vitamin E	17	232	151
Vitamin K	5	192	660

Note: CSB, Corn–Soy Blend; DRI, Dietary Reference Intake; RNI, Recommended Nutrient Intake

Energy content is roughly equivalent across the three forms of CSB compared above: CSB13, CSB14, and WFP's CSB++. CSB++ includes lower levels of oil than CSB13 and adds 8 g/100 g of DSMP (for protein) and 9 g/100 g of sugar (presumably for taste). Although CSB14 offers the highest levels of protein, CSB ++, with 8% DSMP, has a marginally higher quantity of animal-source protein, at 2.9 versus 2.4 g/100 g. However, all three have PDCAAS scores of sufficient quality, as defined by Michaelsen et al. (2009).

TABLE 2.19
Comparison of macronutrient profiles of CSB14, CSB++, and CSB13 per 100 g of product

Variable	CSB14*	CSB ++	CSB13
Energy (kcal)	387	375	386
Protein (g)	17.7	15.7	15.9
PDCAAS	0.87	0.89	0.85
Utilizable protein** (g)	15.4	14	13.5
Animal-source protein (g)	2.4	2.9	0
Protein/energy ratio (%)‡	16 [§]	15	14
Fat (g)	8.8	9.6	8.7

Note: CSB, Corn–Soy Blend; PDCAAS, Protein Digestibility Corrected Amino Acid Score.

*These numbers do NOT include the recommended addition of oil at time of preparation, just the CSB14.

**Adjusted for digestibility and quality, based on PDCAAS.

‡Protein/Energy ratio is calculated for only utilizable protein, unlike Table 2.11, which uses the value for total protein.

§ With the recommended oil, P/E ratio is 9.4%.

Table 2.20 compares recommended nutrient contents in 50 g of FBF for treatment of MAM among CSB13, CSB14 (plus FVO), CSB++, SUSTAIN’s recommendations (Fleige et al., 2010a), and Golden’s (2009) recommendations. If the assumption is that the CSB14 and oil are provided to 2- to 3-year-olds who are not breast-feeding, then the micronutrient amounts tend to be lower than those proposed by Golden and, in some cases, are higher or lower than those proposed by Fleige et al. (2010a). These differences are much smaller if one assumes that CSB14 and oil will be presented while the child continues to breast-feed at a lower rate in the second year of life. Evidence is lacking that the larger amounts of micronutrients recommended by Golden (2009) are necessary for treatment of MAM if adequate calories, protein, and fat are provided. Still, this is a significant gap in our knowledge with respect to the requirements of individual micronutrients for growth promotion or nutritional recovery beyond the amounts embedded in the RNI for that age group, with an additional cushion to cover malabsorption and underutilization.

TABLE 2.20
Comparison of proposed and recommended nutrient levels in FBFs for MAM in infants 6 to 11 months old

Nutrient	Content of proposed profiles for FBFs and CSB13			Fleige et al. (2010a) recommendations for Premix*	Golden (2009) recommendations for treatment of MAM*	Percentage of 115% RNI or DRI for 6- to 11-mo infant per day
	CSB13	CSB14 + oil	CSB++			
	50 g	50 g + 15 g	50 g			
Macronutrients						
Energy (kcal)	193	326	198.5	168.75	175	675
Protein (g)	8.0	8.8	7.7	8.9	5	16
Fat (g)	4.4	19.4	4.8	4.9	8	31
Minerals (mg)						
Calcium	325	176.4	377.5	346.5	560	299
Copper	0.202	0.195	0.249		0.6	0.253
Iodine	28.4	0.114	20	0.082	0.8	0.1035
Iron	5.28	7.74	6.27	7.7	12	7.7
Magnesium	84.0	47.0	69	16.5	200	62.1
Manganese	0.4075	0.394	0.378		0.8	0.69
Phosphorus	261	256.7	167	169.5	0.135	316.25
Potassium	281.5	353.5	522.5	1327	1,050	805
Selenium	0.011	0.010	0.0076		0.035	0.0115
Sodium	163	119.6	32.5	109.5	370	425.5
Zinc	2.97	3.42	3.79	7.5	13	5.75
Vitamins (mg)						
Vitamin A	0.410	0.266	0.413	0.367	1.28	0.46
Vitamin B ₁ (thiamin)	0.305	0.373	0.2785	0.18	0.67	0.345
Vitamin B ₂ (riboflavin)	0.241	0.483	0.428	0.33	1.2	0.46
Vitamin B ₃ (niacin)	3.15	4.87	3.7	3.2	12	4.6
Vitamin B ₅ (pantothenic acid)	1.64	1.77	3.6955	1.4	2	2.07
Vitamin B ₆	0.266	0.376	1.0915	0.175	1.2	0.345
Vitamin B ₇ (biotin)	0	0	0		0.0085	0.0069
Vitamin B ₉ (folic acid)	0.124	0.047	0.0432	0.0498	0.144	0.054
Vitamin B ₁₂	0.00066	0.00073	0.00116	0.00065	0.0018	0.000805
Vitamin C	20	20	50.8	27.5	60	34.5
Vitamin D ₃	0.00248	0.0148	0.0025	0.0046	0.007	0.0115
Vitamin E	0.49	6.67	4.35	2.55	15	5.75
Vitamin K	0.00045	0.017	0.2071		0.025	0.0115

Note: CSB, Corn–Soy Blend; DRI, Dietary Reference Intake; FBF, Fortified Blended Food; MAM, Moderate Acute Malnutrition; RNI, Recommended Nutrient Intake.

*Adjusted to a 50-g portion, as is recommended for a 6- to 11-month-old. Original recommendations were per 100 g.

2.4 INTRODUCTION OF NEW PRODUCTS

Three recommendations for new products are also made:

1. Include in the commodity list a range of lipid-based fortified products
2. Explore the development and introduction of new forms of cereal-based blends (particularly focusing on cereals that are nutritionally and culturally appropriate for use in Africa, and/or using alternative sources of plant-based protein, such as legumes or vegetables)
3. Consider new vehicles for micronutrient delivery, including shipping premix for bulk grains and point-of-consumption (i.e., at home) fortificant powders

Introduce a Range of Lipid-Based Ready-to-Use Foods

There is an increasing interest in and acceptance of ready-to-use lipid-based nutrient supplements (LNSs). LNSs were initially envisaged as a method to treat uncomplicated cases of SAM in communities, rather than hospital or clinic settings; to date this is their main purpose. The joint statement by WHO, WFP, UNSCN, and UNICEF (2007) on community-based management of SAM states “children with severe acute malnutrition need safe, palatable foods with a high energy content and adequate amounts of vitamins and minerals” (WHO/WFP/UNSCN/UNICEF, 2007). These Ready-to-Use Therapeutic Foods (RUTFs) with a lipid base of peanuts were designed with a similar nutrient composition to the current therapeutic milk used in hospital settings, F100, and fill the role of safe at-home foods as described by the statement. The effectiveness of these LNSs for the treatment of SAM has been established in numerous field trials. There are numerous benefits to their use, including no need for cooking, low water content (so they cannot support bacterial growth), and single-serving packaging. However, because RUTFs do not contain water or need water in preparation, children still need water and must be offered safe drinking water according to their thirst, so access to potable water is still important.

Following on their successes, LNSs have also been proposed for supplementary feeding and for treatment of MAM. They are generally referred to as Ready-to-Use Supplementary Foods (RUSFs) or just Ready-to-Use Foods (RUFs). At present, the FAQR authors feel that the effectiveness of these LNSs has not been adequately established for the treatment of MAM. Further studies assessing the new proposed FBFs in this report, use of home fortificants, and other innovations will also need to be carried out along with LNS studies. This is another reason we support changes (proposed below) in the approach to new product review, such that improvements in the management of malnutrition can be incorporated as advances are documented.

Given the centrality of meeting calorie and high-quality protein needs in the treatment of moderate wasting, and the prevention of wasting and stunting, the most relevant comparisons are between CSB14 plus fortified oil and Supplementary Plumpy®,

although the latter provides 25% fewer calories in 92 g than the combination of CSB14 and oil at levels recommended in this report. The levels of protein and fat provided are similar when expressed per 1000 kcal, and it is expected that the quality of protein will be similar, as both products have both vegetable and additional animal protein in the form of milk products, although we do not have the exact information to calculate the PDCAAS for Supplementary'Plumpy®.

The amounts per serving of iodine, iron, phosphorus, and vitamins B₆ and D are higher in CSB14 plus oil than in Supplementary'Plumpy®. The zinc content of CSB14 is about two thirds that of Supplementary'Plumpy®. Thiamin and riboflavin contents are higher in the LNSs, and niacin is higher in CSB14. Folic acid and vitamin B₁₂ contents are slightly lower, as are the contents of vitamins C and E. Evidence to favor the amounts in either of these products is lacking. Our contention is that the critical nutrient requirement for treatment of MAM and for supporting growth is in the adequate provision of calories, high-quality protein, and fat, with adequate, but not excessive amounts of micronutrients. We consider the combination of CSB14 and oil in amounts of 100 g CSB14 plus 30 g of oil to have excellent content for prevention and treatment of MAM in children and for supplementation of diets in pregnant and lactating women.

Arguably the most significant change in food aid during the 21st century has been the arrival of a new family of products in the form of lipid-based spreads. In terms of composition, these were originally solid-form analogues of the therapeutic milks already used for inpatient treatment of severe wasting. These RUTFs are “high-energy, high-protein milk feeds” designed explicitly to meet WHO recommendations for treatment during rehabilitation after severe wasting. They can be consumed without cooking or other preparation, and their lower water activity means a lower risk of bacterial contamination.

There is an increasing interest in variants of such RUTFs for use beyond the treatment of SAM. What are now widely called Lipid-Based Nutrient Supplements (LNSs) are already being used in the management of *moderate* acute malnutrition, in the prevention of stunting, and as a form of home fortificant used to deliver micronutrients and small amounts of fat, energy, and protein. That said, there is already sufficient practical evidence that such products can, appropriately programmed, be a useful complement to other food products in operations seeking to have nutritional impact, with the knowledge that their nutrient and ingredient profiles may need to be modified in the coming years on the basis of emerging data.

Recommendation 17: Lipid-based products should be available for use by Title II implementing partners. Such products should be assessed for their value to Title II operations and applied in relevant settings. It is likely that certain LNS products will be cost-effective when specific nutrition goals are explicitly defined. However, it is also recommended that FBFs continue to play an important role as part of a suite of products available to Title II implementing partners. Rather than argue for dispensing with FBFs, which have served relatively well for decades, we argue for including

enhanced FBFs and LNS products in the set of food aid options available. Lipid-based products and cereal blends offer price-, taste-, and acceptability-differentiated options that can be taken into consideration when designing a ration based on local programming needs.

For comparative purposes, Table 2.21 presents the nutrient composition of the proposed CSB14 (100 g plus 30 g of vegetable oil as recommended), with 46 g of Plumpy'Doz™, 92 g of Supplementary Plumpy™, and 20 g of Nutributter™. They are compared in this fashion, with varying quantities, because these are the recommended daily serving sizes. FFP should continue to identify appropriate lipid-based products for inclusion in its approved commodity list and field operations. Cost-effectiveness studies in the field will be critical to determining which products offer impacts at best value.

TABLE 2.21
Composition of CSB14 and oil compared with LNS units

Nutrient	CSB14 + oil	Plumpy' Doz™	Supplementary' Plumpy™	Nutributter™
	100 g 30 g	46.3 g	92 g	20 g
Macronutrients				
Energy (kcal)	652.6	247	506	108
Protein (g)	17.7	5.9	13.8	2.6
Fat (g)	38.8	16	34.96	7.1
Minerals (mg)				
Calcium	352.89	387	303.6	100
Copper	0.39	0.3	1.84	0.2
Iodine	0.23	0.09	0.1012	0.09
Iron	9	9	11.592	9
Magnesium	94.1	60	92.92	16
Manganese	0.787	0.17	0	0.08
Phosphorus	513.3	275	303.6	82.1
Potassium	707.1	310	1124.24	152
Selenium	0.02	0.017	0.03036	0.01
Sodium	239.2	0	266.8	
Zinc	11.6	9	13.8	4
Vitamins (mg)				
Vitamin A	0.532	0.4	0.92	0.0004
Vitamin B ₁ (thiamin)	0.7	0.5	1.104	0.3
Vitamin B ₂ (riboflavin)	0.967	0.5	1.84	0.4
Vitamin B ₃ (niacin)	9.7	6	5.336	4
Vitamin B ₅ (pantothenic acid)	3.53	2	3.128	1.8
Vitamin B ₆	0.8	0.5	0.644	0.3
Vitamin B ₉ (folic acid)	0.2	0.16	231.84	80
Vitamin B ₁₂	0.0015	0.0009	1840	0.5
Vitamin C	40	30	121.44	30
Vitamin D	0.03	0	20.608	
Vitamin E	13.4	6	23	
Vitamin K	0.033	0	23	

Note: CSB, Corn–Soy Blend; LNS, Lipid-Based Nutrient Supplement.

Introduce New Forms of Cereal-Based Blended Foods and Other Products

In addition, we propose to enhance the nutritional quality of the entire food ration package by improving fortification levels of the bulkier (unprocessed) commodities, in recognition of the fact that not only will there be some sharing of the FBFs with other family members, but that their use will be embedded in the larger complement of food aid products that compose the family ration. The composition of these products is detailed in the tables that follow, along with comparisons with target intakes for growth promotion and comparisons with former and contemporary products that are in use in the field.

As mentioned earlier, Title II has five different fortification standards applying to cornmeal, wheat flour, and soy-fortified products, including bulgur, sorghum grits, and corn-soy masa flours. We propose that once the micronutrient profiles of these various milled and enriched blended cereals are improved, their use should be advocated for in family rations and other places where FBFs have been used historically. Often FBFs are used as a way to deliver micronutrients, whereas it is proposed here that milled grains and enriched blended cereals, as well as whole grains, with perhaps use of home fortificants, can replace and better meet the needs of mass distribution or family ration situations. FBFs, as discussed earlier, and later in Chapter 3, should be viewed as tailor-made for specific beneficiaries with higher needs, namely children under two, pregnant and lactating women, and People Living with HIV and AIDS.

TABLE 2.22
Current fortification standards for Title II milled cereals

Nutrient	SFG13	BWSF13	CSMasa	SFCM3	WFBF6	CM4
	Minimum mg/lb					
Thiamin	2	2	2	2	2.9	2
Riboflavin	1.2	1.2	1.2	1.2	1.8	1.2
Niacin	16	16	16	16	24	16
Vitamin A	8,800	8,800	10,000	10,000	8,800	8,800
Calcium	500	500	500	500	500	500
Iron reduced	13	13	13	13	20	13
Folic acid					0.7	

Note: BWSF13, Bulgur Wheat Soy Fortified; CM4, Cornmeal; CSMasa, Corn–Soy Masa; SFCM3, Soy–Fortified Cornmeal; SFG13, Soy-Fortified Grits; WFBF6, Wheat Flour or Bulgur Flour.

We recommend a single enhanced cereal fortification profile for wheat flour, cornmeal, and the other milled cereals. The proposal is based on a) providing between 55% and 100% of RNI for adult women, b) adding zinc and vitamin B₁₂ at levels recommended in the *WHO Recommendations on Wheat and Maize Flour Fortification* (WHO, 2009), and c) lowering vitamin A.

It should be noted that there are arguments in favor of tailoring a standard to each vehicle. First, there are differing intrinsic values of nutrients and deficiencies across the milled cereals. Second, wheat and masa flours, which are baked, may have superior retention of vitamins and may require a “lower overage” than other cereals, which suffer higher losses when cooked in a gruel or porridge. However, the variation in intrinsic micronutrient nutrition content and retention is relatively minor, and nutrition protection is much more related to the variation in ration amounts actually delivered. A single fortification profile or standard means simplicity for suppliers and a larger premix market volume for a single formulation and offers efficiencies of scale, lower pricing, and possibly higher quality. The premix profile proposed is presented in Table 2.23.

TABLE 2.23
Proposed unified milled cereals fortification profile

Nutrient	mg/kg (ppm)	Compound
Thiamin	4	Thiamin mononitrate
Riboflavin	4	Riboflavin
Niacin	40	Niacinamide
Folate	1.54	Folic acid
Vitamin B ₆	4	Pyridoxine hydrochloride
Vitamin B ₁₂	0.011	Vitamin B ₁₂ 0.1% (water soluble)
Vitamin A	1.1	Vitamin A palmitate 250S/N
Vitamin D	0.02	Vitamin D ₃ 100 kIU/g
Iron	40	NaFeEDTA
Zinc	24	Zinc oxide

Note: NaFeEDTA, sodium iron ethylenediaminetetraacetate.

Recommendation 18: Encourage the development of new cereal-based FBFs beyond wheat and corn as the cereals and soy as the current legume sources, including bars and other products. Several cereals offer potential as variants of CSB or WSB. One example, sorghum, could be well suited, given its acceptability in Africa, its relatively low price, and its acceptability among host governments. A sorghum–soy (or indeed sorghum–pea or other pulse) blend could be envisaged, as could millet–soy, rice–soy, or other cereal or even potato–soy (or other pulse) blends, offering new choices for programming, potentially including new forms of fortified biscuits used in schools or for emergency response. The establishment of performance-based specifications should free up vendor initiative to explore the most cost-effective approaches to meeting better-defined nutritional product characteristics. Enhanced formulations of so-called High-Energy Biscuits (HEBs), typically used in early phases of emergencies or as snacks in schools, should also be explored, tested, and costed. HEBs have not been reviewed or reformulated for many years.

Recommendation 19: Establish public–private partnerships to accelerate development, testing, and implementation of new products. Innovation in product development should be encouraged and supported. There are many food technology issues and challenges still needing to be addressed. These include processing, allergen concerns, packaging requirements, potential micronutrient interactions in both the premixes and the fortified foods, and organoleptic properties of FBFs. The food manufacturing industry has the know-how and experience to identify and solve many of them. There is a need for transparent mechanisms for a) USAID and USDA to consult with industry and solicit industry input and expertise in a timely manner regarding, for example, new and modified products, technology, and safety; and b) industry to consult with USDA and USAID as needed to bring up and resolve issues related to manufacturing, product safety, etc. U.S. agencies, in collaboration with the United Nations, should join forces with the private sector to fast-track the improvement of nutritionally enhanced products of all kinds. Input from industry is critical to ensuring the feasibility and cost-effectiveness of improved products; the appropriate approach would involve a public–private partnership. USAID should provide funding to launch an initiative to develop practical specifications for novel products and test them for program applicability and cost-effectiveness.

Recommendation 20: Establish a Micronutrient Fortification Program for pursuing innovations in micronutrient delivery. To ensure that USAID stays at the cutting edge in delivery of micronutrients through food aid, it should take the mandate for leadership in micronutrient programming offered by the 2008 Food for Peace Act and play a strong role in global efforts to set standards (including safety and quality assurance), establish premix norms, consider alternative measures of fortification effectiveness, and assess the cost-effectiveness of alternative ways to deliver micronutrients.

Recommendation 21: Ship micronutrient premix and home fortificant powders as Title II products. If milled or fortified cereals cannot be shipped or procured locally, FFP should establish the practice of allowing bulk premix packages to be shipped along with bulk grains for addition to cereals milled close to the operation (within the recipient developing country). A budget will be required to support the added local costs of milling, break-bulk bill of lading,²⁵ and rebagging (Maritimeknowhow, 2011). However, costs will be saved from the reduced volume of FBFs delivered when aimed at meeting micronutrient needs at the household level (that is, untargeted as opposed to focused on meeting the needs of defined beneficiary groups). Support for in-country milling and fortification capacity (training, contracting, technology development, quality assurance, etc.) in the vicinity of emergency operations will overlap with other USAID development goals, as elaborated in the Feed the Future Initiative. Joint ventures and industry-to-industry exchanges (along the lines of farmer-to-farmer programs) could allow U.S.-based millers and manufacturers to partner with FFP in enhancing the capacity of

²⁵ Break-bulk bill of lading is the carriage (transportation) at sea of conventional goods not in containers, i.e., in-the-liner shipping as it existed before containerization.

developing countries for local fortification and processing, thereby promoting modernization of their staple grain value chains.

3. PRODUCT SELECTION AND USAGE— OPTIMIZING PROGRAMMING

Improved programming is as important as improved products, as FFP seeks to achieve greater impacts in nutrition through food-based interventions, and these changes are essential to accelerate efforts to reduce malnutrition and food insecurity in the long term. Enhanced programming has several dimensions: a) better choice of products and program design (following enhanced guidance); b) changes in the way products are used (addition of oil at the point of food preparation); c) changes in packaging of products, designed to reduce sharing and improve correct use; d) improved approaches to delivery; e) more effective BCC; and f) consideration of ancillary services to improve health on the one hand and food security on the other, all supported by more specific technical guidance and an enhanced evidence base for decision making. This section makes recommendations on the matching of products to purpose, enhanced operational guidance to implementing partners, and the evidence needed for programming, and explores the special case of nutritional support to HIV/AIDS treatment.

Despite improvement in efforts to manage Title II foods and ensure appropriate targeting of rations, delivery of defined quantities of supplementary food cannot be guaranteed, nor is it always possible to target food distribution only to food-insecure households and communities. Yet, targeting within the household is even more challenging: the sharing of food intended for a specific individual in the household is widely recognized but rarely quantified. Programs often design their rations to account for such leakage, but in widely varying ways, assuming that from 100% to less than 20% of the food provided will reach the intended beneficiary (and adjusting the ration quantities accordingly). This review found that the quantities programmed for a specific individual vary widely, even within a technical sector and a specific target group defined by age, sex, and physiologic or disease status. Because they typically lack detailed local consumption data, the majority of programs design rations based on national-level data and assumptions about food gaps and nutritional need. Rations are rarely adjusted on the basis of monitoring either before or during implementation to see how local consumption patterns and opportunities affect the need for and use of the food aid products.

Beyond the uncertainty about quantities consumed, the quality of the programming is critical to product effectiveness. Title II food assistance programs have a range of goals, including improving household food security, improving access to an adequate diet, and protecting and, in certain cases, improving the nutritional status of vulnerable groups. Targeting, and the implementation of complementary interventions, cannot be separated from the simple provision of food to achieve short-term nutritional improvements and, equally importantly, improvements in nutritional status and household food security that are sustainable over the long term.

3.1 CURRENT PROGRAMMING APPROACHES

In both emergency and nonemergency settings, Title II food is used in a range of programmatic areas or technical sectors. In the design and implementation of food rations, Title II emergency and nonemergency programs implement activities in a similar range of technical sectors: maternal and child health and nutrition (MCHN), agriculture and natural resource management, education, and water and sanitation. A key difference, however, is that emergency programs provide general food rations to households as direct distribution and are often designed to meet a significant proportion if not all of the entire household's nutritional needs.

In nonemergency programs, under most technical sectors (including agriculture and natural resource management, income generation, water and sanitation, and infrastructure construction), Title II commodities are used as an incentive or as pay or compensation for participation in activities such as training (as trainers or as participants) or labor (land clearing or preparation, construction of roads or other physical assets, construction of irrigation or potable water systems, latrines, etc.) and not specifically for health or nutritional improvement. Provision of general food rations to households in nonemergency programs is limited to those implementing Vulnerable Group Feeding/Social Safety Net programs aimed at highly food-insecure households and to the family ration provided as part of the Prevention of Malnutrition in Children under Two Approach [PM2A], though similar rations are often provided as Food for Work (FFW) or Food for Training (FFT), in amounts linked to work performed and not intended to provide all of the recipient household's needs.

Only in MCHN and in programs to provide food to persons with HIV or tuberculosis is Title II food used primarily to prevent or treat malnutrition in vulnerable groups, including infants and young children (because of their elevated nutritional needs due to rapid growth), pregnant and lactating women (again, because of the elevated nutritional demands of pregnancy and lactation), and persons infected with HIV or tuberculosis. Food used in this way needs to be designed with these physiological demands in mind, and the most commonly used commodity for this is CSB. Indeed, CSB was originally designed to meet the elevated nutrient needs of infants and young children and has been used for these other target groups as well. More recently, other novel lipid-based supplements have been developed and are being used to treat and prevent undernutrition, but CSB continues to be the primary product of choice for the vast majority of programs.

A review was conducted of all the development and emergency program proposals for programs that were operational in fiscal year 2009 and all the endline evaluation reports available for programs ending in fiscal year 2009. In addition, a telephone survey was conducted with senior programming and logistics or procurement managers in all of the implementing partner agencies carrying out programs using

Title II foods during fiscal year 2009 (FAQR, 2010).²⁶ The survey showed that the use of FBFs varies between emergency and development programs: 50% of emergency programs and 40% of development programs (where a program means an activity in one technical sector) reported using CSB or WSB. Sixty-nine percent of health programs and roughly half of education and emergency preparedness programs used FBFs in emergencies, compared with 61% of health programs, 63% of vulnerable group or social safety net programs, and 25% of education programs.

When CSB or WSB is *not* included in the ration, the commonest reasons are that a) beneficiaries are not familiar with the product or it is not culturally accepted, b) there are national restrictions on use of the food (in particular relating to genetically modified content), c) the programs do not deal explicitly with nutrition, and d) the cost is high compared with that of bulk commodities.

This review's analysis of rations used in Title II programs found that 12 of 30 development programs and 28 of 54 emergency programs planned to provide CSB or WSB. In both types of program, all but one of these also planned to include oil in the ration. Among programs included in the Implementing Partner Survey, 30 of 76 nonemergency programs provided CSB or WSB, and 67 provided oil as part of the ration. Of 56 emergency programs surveyed, 28 provided a precooked FBF, and 51 included oil in the ration. In fact, both the survey of implementing partners and the review of rations found that vegetable oil is the most widely used commodity across the span of Title II programs because of its versatility and acceptability. Virtually all of the rations that include CSB or WSB also provide vegetable oil, which indicates the feasibility of ensuring that enhanced FBFs be distributed with oil. This supports our recommendation that CSB and WSB be prepared with oil. Of programs currently using FBFs, 76% instruct the beneficiaries to prepare the product with another food; of these 38 programs, 11 instruct the beneficiaries to prepare the product with oil and 7 to prepare it with sugar (FAQR, 2009, 2010).

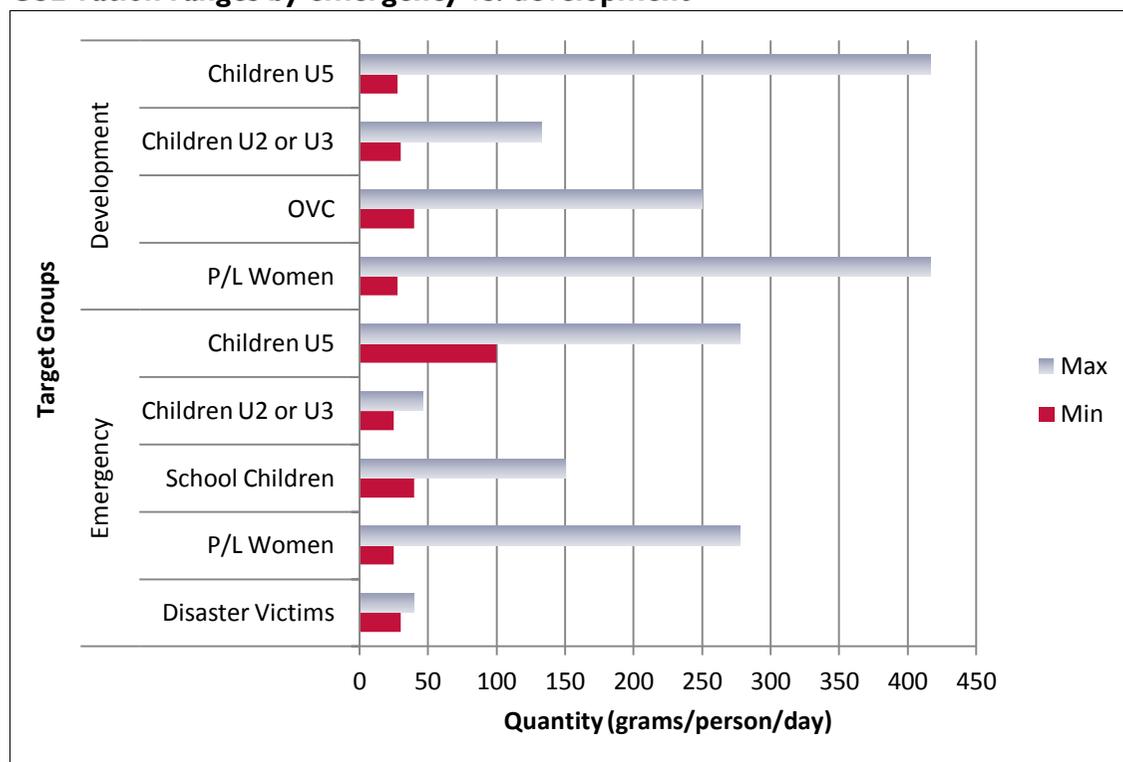
Among these programs, the majority of maternal and child programs (92%) use FBFs for explicit nutritional goals; 88% cite maintenance of adequate growth, and several cite treatment of moderate malnutrition (sometimes not distinguishing between moderate forms of wasting or stunting); only 4% mention treating but 8% mention preventing micronutrient deficiencies. Half of the programs using FBFs for emergency preparedness and vulnerable group feeding or social safety nets also cite specific nutritional goals, such as maintaining adequate growth. In the case of educational programs, use of the ration as an incentive was cited 27% of the time, and in vulnerable group feeding or social safety net programs, "ensuring the adequacy of a general ration" was also cited as a reason for using FBFs. Overall, 20% of programs

²⁶ Implementing partner survey, FAQR (2010): The results are based on responses from 64 agencies in 40 countries, of 82 agencies initially contacted (79 of which were appropriate for interviewing, i.e., implemented at least one program making use of Title II foods). Programs that use food only for monetization were excluded. The agencies were interviewed about a total of 133 programs, where a program was defined as an activity in a particular technical sector, so that one agency in a country could represent several programs. The response rate was 81%, and the respondents were willing to be contacted by telephone or e-mail for follow-up.

reported using FBFs as a wage or incentive, but of these, 80% said that the goal was explicitly related to nutritional improvement (FAQR, 2010).

One of the most striking results to emerge from the review of rations was the wide variability in the amount of FBFs included in the rations for various target groups. These results were confirmed in the Implementing Partner Survey. Figures 3.1 and 3.2 show the range in the amount of FBFs included in the rations from lowest to highest for each target group, aggregated as well as broken down by the kinds of programs in which the product is delivered.

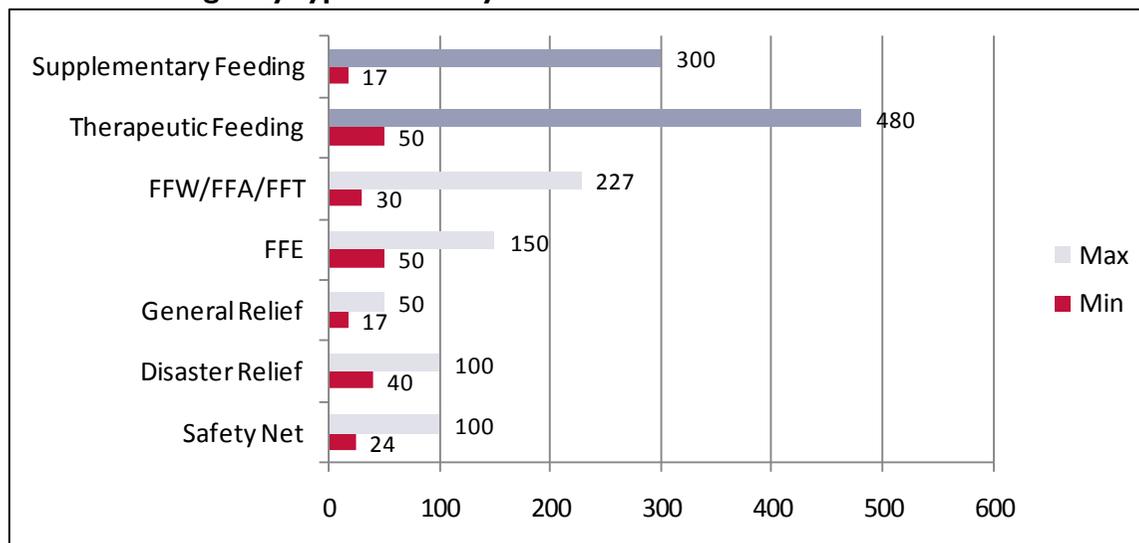
FIGURE 3.1
CSB ration ranges by emergency vs. development



Source: FAQR (2010).

Note: CSB, Corn-Soy Blend; OVC, orphans and vulnerable children; P/L, pregnant or lactating; U2, U3, U5, under 2, 3, or 5 years of age.

FIGURE 3.2
FBF ration ranges by type of activity



Source: FAQR (2009).

Note: FFA, Food for Assets; FFE, Food for Education and Child Nutrition; FFT, Food for Training; FFW, Food for Work.

The variability is somewhat less for emergency programs, probably due to the fact that the majority of emergency programs are administered by WFP, and WFP provides systematic guidance on the programming of rations. USAID provides guidance on the contents of the overall ration, but not on the amounts of specific components of the ration. Still, the ranges are quite large. At the high end, these quantities are greater than one person would be likely to consume in a day. These variations do not represent only one or two outliers: the distribution of ration quantities is relatively even. We followed up with all of the agencies reporting ration quantities above 250 g/person/day and below 25 g/person/day and verified that these had been reported correctly.

One reason for the variability in programmed quantities of CSB is that each agency makes different assumptions about the degree to which the commodity is likely to be shared. Many WFP programs routinely double the amount of CSB provided to a household, on the expectation that the food will be shared with another household member. In the development program proposals, assumptions about sharing that are built into the program range from zero sharing (all is assumed to reach the target individual) to equal sharing among all household members (so that the amount intended for a target individual is multiplied by the average household size of 5 to 5.5 people). In program documents, however, and in the FAQR survey, the ration is reported as intended for one target individual. On the lower end, in some cases, it appears from the development program proposals that agencies used the Commodities Reference Guide (CRG) Ration Calculator to identify a mix of foods that would achieve a certain level of calories, protein, and key micronutrients, and the calculator returned a ration containing quite small quantities of CSB. In many of the program

planning documents, the nutritional composition of the ration is reported, but the basis for making the calculation is not explained.

Both CSB and FVO are often programmed with the intention of reaching one individual within the household. In some cases, as in MCHN and the provision of food to persons with HIV or tuberculosis, the ration is provided to one target individual. In about half (45%) of the cases, the agencies reported that instructions were given about particular foods intended for one individual. In about 28% of these cases, the food that was intended for only one individual within the household was CSB; in about 30% of cases it was FVO; and in about 30%, the restriction was applied to some other food.

In all of these cases, about 60% of respondents reported that the food was shared anyway. There was no difference in the proportion of respondents reporting sharing according to whether the question referred to an individual ration or a single food within a household ration. CSB is reported to be shared 56% of the time; not surprisingly, oil is shared about 71% of the time. In almost all cases of sharing (87.6%), the food is reported to be shared with all household members, not just with other children. Sharing was very widely acknowledged, not only in the survey, but in all of the qualitative interviews we conducted. Personal experience of the FAQR team confirms the observation that mothers and caretakers in MCHN programs, as well as community health volunteers who conduct growth monitoring and health or nutrition counseling, commonly acknowledge that the food provided for vulnerable target members (children under 24 months of age and pregnant or lactating women) is shared within the household. As mentioned earlier, the expectation of sharing is built into the calculation of ration commodities in widely varying ways across programs, technical sectors, and target groups, and little is known about the actual use of commodities in beneficiary households. Of course, not all food that is shared is wasted, as other family members may also be in nutritional need. But the principle of targeting is to fit the ration to the intended beneficiary.

TABLE 3.1
Sharing of commodities intended for a target individual

Commodity intended for individual or in family ration that is intended for a single individual	% of cases (of all foods intended for specific individual)—% (no.)	% of times intended individual is child < 2 or < 3 yr—% (no.)	% of times intended individual is pregnant or lactating woman—% (no.)	Of all cases where food is intended for a defined individual, % reporting food is shared anyway—% (no.)	No. of cases (of food intended for a specific individual in the household)
CSB	28.1 (62)	12.9 (8)	29.0 (18)	56.4 (35)	62
FVO	29.5 (65)	7.7 (5)	23.1 (15)	70.7 (46)	65
Other food (not fortified)	30.4 (67)	6.0 (4)	19.4 (13)	50.7 (34)	67

Source: FAQR (2010).

Note: CSB, Corn–Soy Blend; FVO, Fortified Vegetable Oil.

Little empirical study of sharing has been conducted, although it is widely assumed to occur (Fleige et al., 2010a). We reported above that one of the randomized, controlled trials comparing LNS with a CSB-type product found evidence of sharing of both

commodities: 30% of the LNS and about 43% of the CSB was consumed by the target child (Maleta et al., 2004). A report of a program evaluation in Ethiopia is one of very few to address sharing using primary data (Belachew and Tiyu, 2009). The report found that most children who were intended to receive the supplementary food ate less than the amount programmed, and over 50% ate less than half. On average, 61% of respondents reported sharing the CSB, most commonly with other children, but also with older children and mothers. The commonest reasons given were that sharing is a cultural practice and that other children asked for it. There was no measure of the amount distributed to other household members.

Culturally, sharing will be difficult to eliminate, no matter what kind of BCC is implemented. Mothers are unlikely to withhold a valuable food from their children, and individuals in highly food-insecure households are unlikely to refuse to share their food with others in the household. One evaluation report from Rwanda World Vision in 2008 stated that no person living with HIV/AIDS is going to reserve the ration only to him or herself. The logic of providing food supplements in a clinical context (as in Food by Prescription [FBP] or Community-Based Management of Acute Malnutrition [CMAM] programs) is to present the food as medicine rather than as an ordinary food. Many of the recipes provided by implementing agencies for the use of CSB are for family foods such as dumplings or flat breads, communicating the appropriateness of CSB as a food for the whole family. Although it is widely asserted that the packaging and mode of distribution of RUFs make these foods much more self-targeting than CSB, this has not been widely studied. The published trials comparing RUFs with precooked FBFs have not been structured in such a way that the messaging and packaging accompanying the two commodities and their modes of distribution were comparable. The one study to quantify sharing found it to be common for both CSB and RUF (Maleta et al., 2004), and of course the effect of better education and different packaging of CSB has not been measured. A realistic goal for the programming of nutritionally dense foods is probably not to eliminate sharing completely but to ensure that these foods reach the target individuals in sufficient quantities to make a nutritional difference.

The unarguably widespread practice of intrahousehold sharing of individual rations and the wide range of ration quantities of nutrient-dense, precooked FBFs programmed in the field suggest that the fine-tuning of micro- and macronutrient content to meet the nutritional needs of specific target groups needs to be balanced against the need to allow for fairly wide tolerances in the composition of these foods. Careful programming, improved communication, and alterations in the packaging may reduce the degree of leakage, but these are unlikely to eliminate sharing completely, given the cultural and maternal inclination to provide for the whole family. Any new product, FBF or LNS, needs to be designed with the expectation that the quantities consumed cannot be completely managed and controlled by the implementing agency. Further study of the factors that influence intrahousehold distribution and consumption is sorely needed. However, there is also a need for better sharing of information currently available on food aid programming realities

(based on evidence from the field); this could allow for potential replication of innovations.

Recommendation 22: The capacity for rigorous evaluation of program innovations should be strengthened. When new products or new program elements are introduced, evaluation of these products or elements should be required in at least two different country contexts before the innovation is accepted as a permanent part of the Title II program. Evaluation of any new product (including those we recommend in this report) must take into account the complementary program elements discussed above and must assess effectiveness by comparing “like with like,” that is, using the different products in comparable program contexts. Investment in the provision of technical assistance and resources to conduct studies will be returned in their contribution to more effective and cost-effective programs. Not every implementing partner will have the capacity to design and implement such studies, and technical assistance and, in many cases, external support will be needed to implement the kinds of evaluations that genuinely contribute to an understanding of what works, and why.

The Current Food Basket

The basic family ration typically includes a grain or cereal, a pulse (legume), and oil. A basic or general ration is given in several programming contexts: humanitarian crises, food for work or training, food for education, as a take-home “protection” ration (i.e., to discourage intrahousehold sharing of a targeted supplementary ration such as CSB in nutrition programs), or as an incentive to encourage parents to continue to send their daughters to school. In most humanitarian crisis situations, short-term or long-term, a general family ration is given at the household level to cover basic food needs during or after a shock.

Title II also ships an array of FBFs, including a) soy-fortified processed foods, such as corn masa flour, cornmeal, sorghum grits, bulgur, and others; b) precooked blended foods, such as CSB and WSB; and c) fortified, refined vegetable oil (FVO)(USAID, 2000). These blended foods are primarily intended for use in health and nutrition programs; however, the FAQR field survey found the next most common uses are in vulnerable group feeding, social safety net, or emergency programs (see Table 3.2 below).

Food for Education and Child Nutrition (FFE) and FFW programs also use CSB. Occasionally they are used in programs where the food is intended as an incentive or pay, to compensate for the generally low nutritional quality of the local diet.

CSB and WSB are typically packaged and shipped in bulk, 25-kg bags and then distributed to recipients through a variety of programs by repackaging, scooping into carry-home containers, or serving on site. Other FBFs are also shipped in bulk 25- or 50-kg bags and then may be separated out into small portions, depending on the needs

of the distribution (USAID, 2000). CSB is typically served by mixing it with water and/or FVO and sometimes sugar (if it is not already in the premix) and then cooking; however, private voluntary organizations report a wide range of preparations depending on cultural context, including some, such as tortillas and dumplings, that are clearly appropriate for adult feeding.

The Use of Commodities by Technical Sector

The class of precooked, micronutrient-fortified FBFs such as CSB and WSB was developed to meet the specific elevated nutritional needs of rapidly growing small children and is recommended for use in programs with specific nutritional objectives. About 64% of MCHN programs make use of CSB; the next highest percentage of CSB users (61%) is found in programs for vulnerable groups and social safety net programs (which include programs for people with HIV/AIDS or tuberculosis). Only a few programs in the other sectors provide CSB as part of the ration, with the highest proportions being among emergency preparedness or disaster mitigation and education programs.

Table 3.2 shows the distribution of programs making use of the precooked FBF in the ration. Use of CSB varies between emergency and nonemergency programs: 50% of emergency and 39.5% of nonemergency programs (where a program means an activity in one technical sector) reported using CSB. In emergencies, 69% of health programs and roughly half of education and emergency preparedness programs (50% and 55.5%, respectively) use CSB, compared with 61% of health programs, 63% of vulnerable group or social safety net programs, and one quarter of education programs that use CSB in nonemergency programs.

The distribution of rations according to target group was also reviewed. Most or all (60% to 100%) of the rations intended for children under 5, 3, or 2 years of age and 71% of the rations intended for pregnant or lactating women included CSB (see Table 3.4 in the Ration Composition section below).

TABLE 3.2
Programs providing CSB according to technical sector

Technical sector	% of programs in this technical sector providing a food ration	% of those programs providing CSB in the ration	% of nonemergency programs providing CSB	% of emergency programs providing CSB
Agriculture/natural resource management	24.0	4.2	0.0	11.1
Education	22.0	41.0	25.0	50.0
Emergency preparedness/disaster mitigation	19.0	42.1	30.0	55.5
Health and nutrition	39.0	64.1	60.9	68.7
Vulnerable group feeding/social safety net	23.0	60.9	62.5	57.1
Water and sanitation	5.0	20.0	25.0	0.0
Nonagricultural income generation	0.0	0.0	0.0	0.0

Source: FAQR (2010).

Note: CSB, Corn–Soy Blend.

In response to an open-ended question about the reasons why CSB or WSB was *not* included in the ration, some of the commonest responses were that the beneficiaries were not familiar with the product or it was not culturally accepted, there were national restrictions against the food (in particular relating to genetically modified content), the program did not deal explicitly with nutrition, and the cost of CSB and WSB was high compared with that of bulk commodities. By contrast, CSB does have a high level of acceptability where it is used, according to the perception of the program implementing staff. Table 3.3 shows the perception of CSB compared with attitudes toward the other commonly used fortified foods.

TABLE 3.3
Beneficiary attitudes toward fortified foods as reported by program staff

Food	Tastes good—% (no.)	Easy to prepare—% (no.)	Easy to use—% (no.)	Liked by all—% (no.)	Easy to transport—% (no.)	Easy to store—% (no.)
CSB (<i>n</i> = 38)	52.6 (20)	89.5 (34)	89.5 (34)	65.8 (25)	76.3 (29)	42.1 (16)
FVO (<i>n</i> = 54)	85.2 (46)	87.0 (47)	88.9 (48)	83.3 (45)	83.3 (45)	87.0 (47)
SFB (<i>n</i> = 11)	72.7 (8)	90.9 (10)	90.9 (10)	81.8 (9)	81.8 (9)	72.7 (8)

Source: FAQR (2010).

Note: CSB, Corn–Soy Blend; FVO, Fortified Vegetable Oil; SFB, Soy-Fortified Bulgur.

The Composition of the Ration

Vegetable oil aids in the absorption of fat-soluble vitamins contained in the precooked FBFs. Table 3.4 shows the percentage of rations for each target group that include CSB and FVO, derived from the FAQR Implementing Partner Survey. Where CSB is provided to nutritionally vulnerable individuals (young children, pregnant and lactating women, and “other adults” who are typically persons with HIV/AIDS or tuberculosis), in all but one case oil is also part of the ration (although we cannot say they are always consumed together).

The Review of Rations in 2009 Title II development and emergency program proposals found that of 30 nonemergency programs, 12 provided CSB or WSB, and all but one provided oil as part of the ration. Out of 54 emergency programs 28 provided a precooked FBF, and again, all but one also included oil in the ration. The FAQR Implementing Partner survey found that of 76 nonemergency programs, 30 provided CSB or WSB, and 67 provided oil as part of the ration. Of 56 emergency programs surveyed, 28 provided a precooked FBF, and 51 included oil in the ration. In fact, both the FAQR field survey and the Review of Rations found that FVO is the most widely used commodity across the span of Title II private voluntary organizations due to its versatility and acceptability. Oil is included in most household rations along with a cereal and a pulse, and it is included in most of the rations targeted toward nutritionally vulnerable groups, along with CSB.

TABLE 3.4
Breakdown of rations according to target group

Target group	No. of cases	% (no.) of rations with CSB	% (no.) of rations with FVO	% (no.) of rations with grain	Of those with CSB, % (no.) with FVO*	Of those with CSB, % (no.) with “family foods” (grain, pulse)*
Children < 5 yr	27	77.8 (21)	88.9 (24)	18.5 (5)	100.0 (21)	33.3 (7)
Children < 3 yr, < 2 yr	5	100.0 (5)	100.0 (5)	80.0 (4)	100.0 (5)	100.0 (5)
Children < 2 yr	5	60.0 (3)	80.0 (4)	0.0 (0)	66.7 (2)	33.3 (1)
School-age children	25	36.0 (9)	84.0 (21)	48.0 (12)	100.0 (9)	66.7 (6)
OVCs	7	42.9 (3)	85.7 (6)	28.6 (2)	100.0 (3)	66.7 (2)
PM2A households	3	66.7 (2)	100.0 (3)	33.3 (1)	100.0 (2)	50.0 (1)
Pregnant and lactating women	34	70.6 (24)	91.2 (31)	41.2 (14)	95.8 (23)	45.8 (11)
Adult workers	41	4.9 (2)	80.5 (33)	65.9 (27)	100.0 (2)	100.0 (2)
Internally displaced people	18	38.9 (7)	94.4 (17)	55.5 (10)	100.0 (7)	100.0 (7)
Elderly disabled	5	20.0 (1)	60.0 (3)	0.0 (0)	100.0 (1)	100.0 (1)
Caretakers	3	100.0 (3)	100.0 (3)	0.0 (0)	100.0 (3)	100.0 (3)
Other adults	31	41.9 (13)	90.3 (28)	22.6 (7)	100.0 (13)	53.8 (7)
Disaster victims	8	37.5 (3)	87.5 (7)	75.0 (6)	100.0 (3)	100.0 (3)

Source: FAQR (2010).

Note: CSB, Corn–Soy Blend; *FVO, Fortified Vegetable Oil; OVCs, orphans and vulnerable children; PM2A, Prevention of Malnutrition in Children Under Two Approach.

Table 3.5, based on the FAQR Implementing Partner Survey, shows how programs instruct beneficiaries on the use of fortified commodities. Virtually all of the rations that provide CSB also provide FVO, but this does not necessarily mean the oil is

intended to be mixed with the CSB; CSB is typically given to one target individual, whereas oil is often part of a family ration intended for use by the whole household. It does, however, indicate the feasibility of ensuring that CSB be distributed with FVO. Currently in programs using CSB, 76.3% of beneficiaries are instructed to prepare CSB with another food; of these 38 programs, 11 are told to prepare it with oil, 7 with sugar, and 18 with their regular family food.

Title II programs provide instructions on the preparation of CSB, and recipes that make use of the commodity are commonly provided as well. It used to be standard practice to prepare CSB with oil, until a report recommended eliminating the oil because it would reduce the nutrient density (per 100 kcal) of the product. But CSB is always mixed with water, so the volume of CSB as prepared is always greater than the volume of dry product, and adding oil should add to palatability as well as increasing the calorie content of the CSB as consumed.

TABLE 3.5
How programs instruct beneficiaries in use of fortified foods

Food	No. of cases	Programs that tell beneficiaries to prepare fortified foods with another food—% (no.)	Prepare with oil — % (no.)*	Prepare with sugar—% (no.)*	Prepare with “regular family diet”—% (no.)*	% of programs indicating who in the household should consume the food
CSB	38	76.3 (29)	37.9 (11)	24.1 (7)	62.1 (18)	86.8 (33)
FVO	54	53.7 (29)	N/A	13.8 (4)	51.7 (15)	48.1 (26)
SFB	11	81.8 (9)	11.1 (1)	11.1 (1)	100.0 (9)	72.7 (8)
Enriched wheat flour	10	40.0 (4)	50.0 (2)	0.0 (0)	100.0 (4)	40.0 (4)
Enriched cornmeal	6	33.3 (2)	0.0 (0)	0.0 (0)	50.0 (1)	33.3 (2)

Source: FAQR (2010)

*Percentages are based on the number of programs telling beneficiaries to prepare the fortified food with another food.

3.2 THE CASE OF HIV/AIDS PROGRAMMING

Not identified separately in Figure 3.2 are programs that offer foods in support of HIV/AIDS programming. Programs delivering ART continue to expand and reach increasing numbers of infected individuals. However, although there have been advances in HIV treatment, equivalent advances in the programming of nutritional support to ART activities remain limited.

The scientific literature suggests that weight loss, which is common in HIV infection, is independently associated with increased risks of disease progression, opportunistic infection, and death. Studies in which macronutrients were given in a variety of formulations were consistently able to demonstrate an increase in weight or body mass index (BMI) (Clark et al., 2000; de Luis et al., 2003; Ndekha et al., 2005;

Schwenk et al., 1999; Swaminathan et al., 2010). The inclusion of food rations in ART programs suggests that the availability of rations increases adherence to ART and also results in an increase in BMI that does not persist, however, after discontinuation of the ration. Although dietary interventions are often able to improve BMI, they do not return it to a normal or pre-morbid level. Taken together, these data strongly suggest that both food access issues and altered metabolism play a role in weight loss and nutritional compromise in HIV-infected individuals. RUTFs appeared to be linked to more rapid gain in weight. None of these studies was able to demonstrate any impact on CD4 count or viral load, although these were not included as endpoints in most studies.

A telephone survey was conducted with all country coordinators for the President's Emergency Plan for AIDS Relief (PEPFAR), as well as a review of both the gray and the published literature for descriptions and evaluations of programs that have delivered food specifically for people infected or affected by HIV. This survey is referenced in the following section.

Title II has used food in HIV programming since 1999, focusing on meeting the needs of HIV-affected, food-insecure households. PEPFAR-funded programs have used food only since 2006, and the priorities of these programs center on meeting individual needs: HIV-positive pregnant and lactating women, orphans and vulnerable children (OVCs) born to HIV-positive parents, and HIV-positive adults in care and treatment programs. Support is delivered largely through Nutrition Assessment, Counseling, and Support (NACS) programs that include, as one component, provision of food supplementation, otherwise known as Food by Prescription (FBP). These programs emphasize the nutritional rehabilitation and/or support of the HIV-positive individual to improve well-being and treatment outcomes. However, there is limited guidance on priority beneficiary targets for nutrition support through such programming.

Recommendation 23: USAID and the office of HIV/AIDS should develop guidance on priority demographics for nutrition support and food assistance.

Recommendations from PEPFAR suggest that OVCs and HIV-positive pregnant and lactating women are most vulnerable and that they should be prioritized for food assistance. However, in practice the most commonly targeted groups are HIV-positive nonpregnant women and other adults (along with adolescents). To achieve a switch or broadening of target emphasis would require that programs develop a stronger link with ongoing antenatal, Prevention of Mother-to-Child Transmission (PMTCT), and Maternal and Child Health (MCH) services and with programs that treat wasting among children. Those individuals with HIV in any group (pre- or post-ART, and of any age) who are moderately to severely malnourished should be prioritized for nutrition intervention.

Articulating the objectives of the use of food in HIV programming is important; as with all other food programming, we need to ask the question “for what?”

Interventions with Micronutrients in ART-Naïve PLHIV

Micronutrient deficiencies have been documented to have adverse effects on HIV disease progression, which may be related to the independent association of micronutrient deficiencies with immune deficiency in non-HIV-infected individuals or, as in the case of zinc, with loss of intestinal integrity and presumably absorptive function (Tang et al., 1996, 1997, 2005; Semba et al., 1995; Baum et al., 1995; McClelland et al., 2004). There is concern that supplementation with iron may contribute to increased viral replication. Micronutrient deficiencies have also been associated with an increased risk of morbidity and mortality in studies done in treatment-naïve populations.

The table in Appendix 11 describes clinical trials of both micronutrients and macronutrients that were performed in PLHIV who were naïve to ART, thus examining the impact of micro- or macronutrient status on the progression or outcome of untreated HIV disease. The trials varied widely in study design, whether or not deficiency was documented prior to intervention, the intervention used, the dose as well as the combination of nutrients, duration of intervention, sample size, and population studied.

However, the majority of trials that used vitamin A demonstrated a reduction in mortality without any associated change in CD4 count or viral load (Fawzi et al., 1999, 2004; Coutoudis et al., 1995; Kelly et al., 1999; Baeten et al., 2002; Semba et al., 1998). Two trials of iron, using different doses and different durations, did not find an impact on viral load. Multivitamin complex studies demonstrated a reduction in morbidity among children, as defined by hospitalization, but the trials were not consistently able to demonstrate that supplementation improved levels of micronutrients in the context of inflammation due to HIV or comorbid conditions. One trial of selenium demonstrated an increase in vaginal shedding in HIV-infected women, and one trial of vitamins A, B, and C demonstrated an increase in shedding of HIV in breast milk of HIV-infected women (Villamor et al., 2010).

Interventions with Macronutrients in ART-Naïve PLHIV

Although the expectation when treating infectious diseases with effective therapy is that any nutritional compromise associated with the infection will resolve, for reasons discussed previously, it is clear that even effectively treated HIV infection may still be accompanied by weight loss or by weight gain that does not return the infected individual to a premorbid weight. In a study of HIV-infected individuals in the U.S. who were initiating their first Highly Active Antiretroviral Treatment (HAART) regimens, 24% had significant weight loss (5% over 6 months or 10% total) after the initiation of the first HAART regimen (Wanke et al., 2002). In South India, HIV-infected individuals who started their first Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTI)-based ART regimen, 55% gained weight, 27% had no change in

weight, and 24% continued to lose weight in the first 12 months of therapy, even though CD4 count improved and viral load decreased, but this study did not have data on adequacy of dietary intake to understand why patients whose weight decreased or remained stable may not have gained weight (Saghayam et al., 2007).

Micronutrient Interventions in PLHIV receiving ART

There are studies done in HIV-infected individuals after the introduction of ART that suggest that fewer HIV-infected individuals receiving ART suffer from micronutrient deficiencies than those who were studied before they were given ART. Unfortunately, these studies have not been done longitudinally in cohorts as they are initiated on ART, but rather they have most often been cross-sectional. It is therefore difficult to assess what role the ART and the control of the virus are playing in the micronutrient levels. The impact of supplementation with either micro- or macronutrients on the response of PLHIV to ART has been of great interest. Studies that have been done to examine aspects of this question are detailed in Appendix 12 (Shor-Posner et al., 2003; Batterham et al., 2001; Spada et al., 2002; Jensen-Fangel et al., 2003; Burbano et al., 2002; McComsey et al., 2003; Jaruga et al., 2002; Hurwitz et al., 2007).

Additional studies to clarify the risk/benefit status of the use of micronutrients and total nutrient intake are urgently needed, and these studies should be done systematically to answer the questions that have been raised.

The studies that have been done with selenium most consistently suggest a small increase in CD4 count with selenium supplementation (Hurwitz et al., 2007). More mixed results are found in studies examining the effect of vitamins A, C, and E on CD4 count. Niacin was studied in one trial and demonstrated the ability to decrease both triglyceride and total cholesterol levels (Gerber et al., 2004). At this point in time, there are no data to suggest that RNIs of micronutrients for HIV-infected individuals should be different from those for the general population, and the RNIs for HIV-negative individuals also apply to the HIV-infected.

Macronutrient Interventions in PLHIV receiving ART

Studies of food rations, as outlined in Appendix 12, suggest that the availability of rations increases adherence to ART and also results in an increase in BMI that does not persist after discontinuation of the rations. Studies showed that macronutrient supplementation in a variety of forms consistently led to an increase in weight. Studies done in Kenya suggest that provision of food, as RUTF, is able to more rapidly improve malnutrition in HIV-infected individuals initiating ART than provision of less convenient or complete nutritional interventions. The ideal formulation of the macronutrient intervention in terms of nutrients, nutrient density, and acceptability is not clear (Castelman, 2008; Ahoua et al., 2011; Cantrell et al., 2008; Ndekha et al., 2009a; Ndekha et al., 2009b).

However, since weight loss in HIV-infected individuals may be expected to be multifactorial, interventions to improve nutritional status ideally should identify the etiologies of weight that are operative in the individual and address the correctable reasons for weight loss to most efficiently improve nutritional status. In much of the resource-limited world, food insecurity may well contribute to a substantial part of the nutritional compromise seen in HIV. However, it would be simplistic to assume that the complexities that are involved in weight loss and nutritional compromise in HIV can all be alleviated by availability of food (Frega et al., 2010). Often dietary interventions are able to improve BMI but not to return it to a normal or pre-morbid level. And although initiation of ART is also noted to improve BMI, it rarely increases BMI to the “normal” or pre-morbid level. Taken together, these data strongly suggest that both food access issues and altered metabolism play a role in weight loss and nutritional compromise in HIV-infected individuals.

The use of dietary advice has been convincingly demonstrated in resource-sufficient populations to lead to improved weight and lean body mass (most studies were done in the U.S. in the early part of the HIV epidemic) (McDermott et al., 2005; McDermott et al., 2003; Ivers et al., 2010). Thus, this approach may be anticipated to be effective only if the individuals counseled are food secure and able to modify their diet as suggested during the nutritional counseling.

In other studies done in the U.S. in the early part of the HIV epidemic, specific types of nutrients were utilized to overcome defects in nutrition or metabolism induced by HIV. For example, in advanced HIV and HIV enteropathy, fat malabsorption was frequent. The use of medium-chain triglyceride products reduced the amount of fat malabsorption and led to a decrease in the amount of diarrhea in HIV-infected patients with fat malabsorption, and these patients were able to gain weight during the intervention (Wanke et al., 1996). More recently, a study done with diets high in omega 3 fatty acids was able to demonstrate that lipid parameters improved with alteration in the quality of fat in the diet while weight remained stable (Woods et al., 2009). Specific dietary interventions are therefore able to have a beneficial impact, whether on weight or BMI or on metabolic parameters, when the specific nutritional insult is defined and the diet can be appropriately formulated to overcome this.

Other strategies have allowed other defined barriers to appropriate nutrient intake to be addressed. As anorexia may be common in HIV, the stimulation of appetite by pharmacologic means has proven to be successful in HIV-infected individuals with anorexia resulting from HIV infection, comorbidities associated with HIV, or treatment with ART.

Recommendation 24: Better indicators of nutritional need and cutoffs are needed to determine eligibility for food assistance in HIV programming. Because HIV programming largely deals with adults, questions about nutritional assessment and appropriate indicators and cutoffs for eligibility are particularly pertinent. Moderately malnourished individuals and those being monitored pre-ART should be

included where possible. There is emerging evidence to suggest that the earlier malnutrition is detected and treated, the more likely it is that food will slow progression of the HIV disease. However, food supplementation should be time limited, with specific graduation or exit criteria for program participants. This is usually achieved with an anthropometric criterion, such as BMI greater than 18.5, or with some kind of socioeconomic criterion.

Of the 48 programs reviewed, 94% delivered food for a nutritional objective, 45% aiming to achieve both nutritional and non-nutritional objectives, with 8% seeking to achieve *only* non-nutritional objectives. FBFs were used by all programs that specified nutritional objectives, i.e., that aimed to prevent deterioration or to treat undernutrition. Most of those programs (75%) also used other basic commodities, such as cereals and grains, oil, and pulses. Of the 25 programs that specifically aimed to treat adults or children suffering from moderate or severe wasting, 72% used a ration that included FBF with other basic commodities, including oil. Of this group, 50% also added an LNS to the ration.

Recommendation 25: A strong signal is needed from PEPFAR supporting allocation of funds for food in HIV programs. PEPFAR country coordinators report that requests for approval of the use of funds for food are still commonly met with caution. This contributes to low coverage of food assistance within programs. Coordinated work between PEPFAR, Title II, and Feed the Future should create a clear agenda and strategy for enhancing the use of NACS in HIV programming. A continued effort is required to expand Title II targeting mechanisms to use clinics, PMTCT, and other HIV service delivery sites. In addition, programs that implement stronger “wrap-around” mechanisms, such as economic strengthening and social assistance, express higher levels of confidence in their ability to graduate clients. Support for ongoing initiatives such as the Livelihood and Food Security Technical Assistance (LIFT) Project, which aims to enable U.S. Government-funded programs to support the improvement of food security of HIV-affected families through livelihood assistance and economic strengthening activities, will be beneficial. For PEPFAR and FBP programs, the need for such support also reinforces a need to link with Title II and other food security support programs through “hybrid” agreements and proposals. Documentation of successes in this area remains scarce and is needed.

The PEPFAR survey highlighted demand for increased access to a wider variety of products, such as LNS. The reasons varied from recognizing the need for products that provide protein and micronutrient density for people with increased nutritional requirements, to “ease of programming” compared with bulky flours. Many acknowledged that funding would be a limiting factor. As a result, increasing numbers of programs are combining the use of an FBF with an LNS, particularly for severely wasted HIV-positive adults and moderately wasted HIV-positive adults and children. The thinking behind this combined ration is that it supports higher nutrient intake and improved effectiveness of programs that aim to rehabilitate wasted individuals while keeping costs down and diet diversity more acceptable. There is

increasing anecdotal evidence that adults do not like eating only the sweet LNS pastes.

Enhanced versions of CSB and WSB that, with the addition of oil, could meet the generally increased requirements of PLHIV to maintain or improve the nutritional status of non wasted individuals or to address moderate acute wasting in this group without the need for combining products would be useful. A Ready-to Use Supplementary Food (RUSF) would also be appropriate for addressing the latter. There is a need to conduct both effectiveness and cost-effectiveness studies to examine the advantages of using each commodity for these objectives. In many countries, very large numbers of HIV-positive adults with mild-to-moderate malnutrition are being identified, and the cost of providing nutritional support to these adults (particularly with an imported LNS) is a commonly voiced concern. An improved, locally produced FBF has the potential to be more cost-effective.

Second, fortified cereals (flour and meal) or fortified cereal blends (such as FBFs) also fulfill an important role in combined rations where they improve acceptability (particularly for adults) and protect the ration of nutrient-dense spreads for the treatment of severe acute wasting. In programs that do not have a nutrition rationale, there is no need to provide products that are designed with nutrient density in mind. Issues such as ease of use and acceptability become more important for PLHIV, who may not have the resources, social support network, or good health to support ration collection, use, and consumption by program participants.

Where there *is* a defined nutrition rationale, improved data collection is essential in order to determine best practice in food support. Of the 48 programs reviewed, 20 detailed a list of indicators that they planned to use to monitor program progress and outcomes. Of these 20 programs, only 7 documented nutritional outcomes (quantitative and/or qualitative measures) in their own monitoring and evaluation. Where programs attempt to measure impact, neither eligibility and graduation criteria, rations provided, nor the indicators used are standardized; thus, it is impossible to compare outcomes across programs.

This section reviews current uses of food aid in HIV programming and particularly how food is meeting the needs of HIV program beneficiaries in programs funded by Title II (including those implemented by WFP) and PEPFAR. In order to do this, several data collection methods were used:

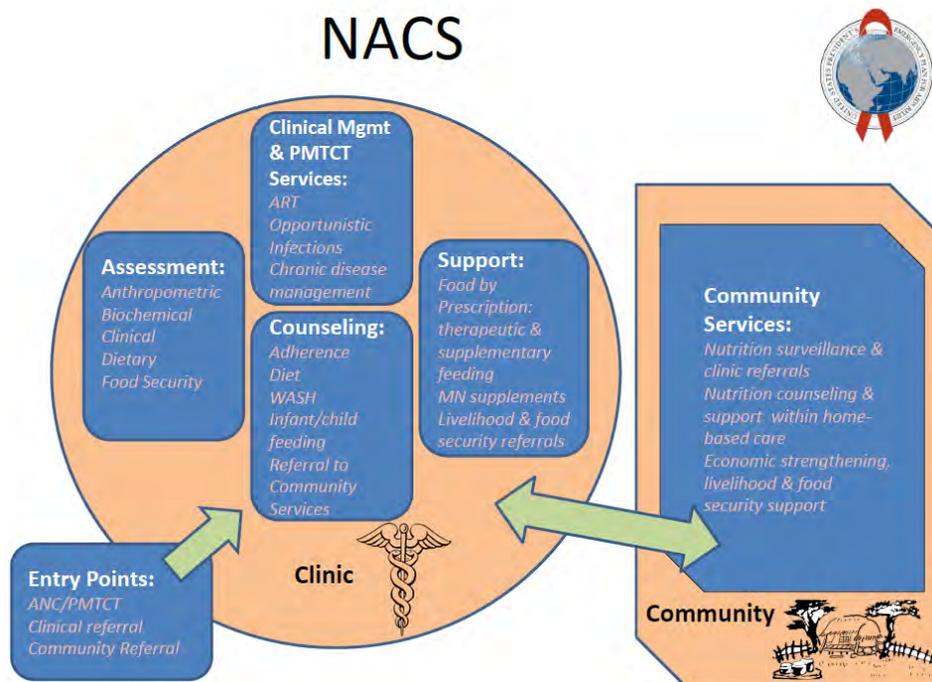
- A search of both the gray and the published literature for descriptions and evaluations of programs that have delivered food specifically for people infected or affected by HIV. This involved requesting program information from all relevant agencies and searching online databases (PubMed) for articles that described relevant *programs*. A discussion of the published *studies* in this area is limited to the previous sections.
- A telephone-administered survey with all PEPFAR country coordinators that asked a series of questions about current programming of food for PLHIV.

- Compilation of data that specifically referred to the target group “HIV-positive or -exposed,” where it was available, from the review of Title II–funded programs described in Chapter 3.
- Interviews and requests for information from a range of stakeholders involved in the support and implementation of programs that deliver food to people infected or affected by HIV.

Our review of Title II, PEPFAR, and WFP programs found information on 48 programs that currently use (or have used in the recent past) food supplements in HIV programming (see Appendix 3: Title II and PEPFAR Programs That Are Currently Using or in the Recent Past (Since FY08) Have Used Food for PLHIV and HIV/Food Insecurity Rankings). These include 30 programs funded by Title II/FFP, 9 funded by PEPFAR, and 10 implemented (and funded through various mechanisms) by WFP. This is unlikely to be a complete list but represents those programs on which some information (however small) was available for this review.

It is important to note that the introduction of food into programs that aim to support PLHIV is relatively new. These programs emphasize the nutritional rehabilitation and/or nutrition support of the individual to improve well-being and treatment outcomes (see Figure 3.3).

FIGURE 3.3
The NACS program model as supported by PEPFAR



Courtesy of T. Quick, USAID Office of HIV/AIDS

Note: ANC, antenatal care; ART, antiretroviral therapy; PMTCT, prevention of mother-to-child transmission; WASH, Water and Sanitation Hygiene.

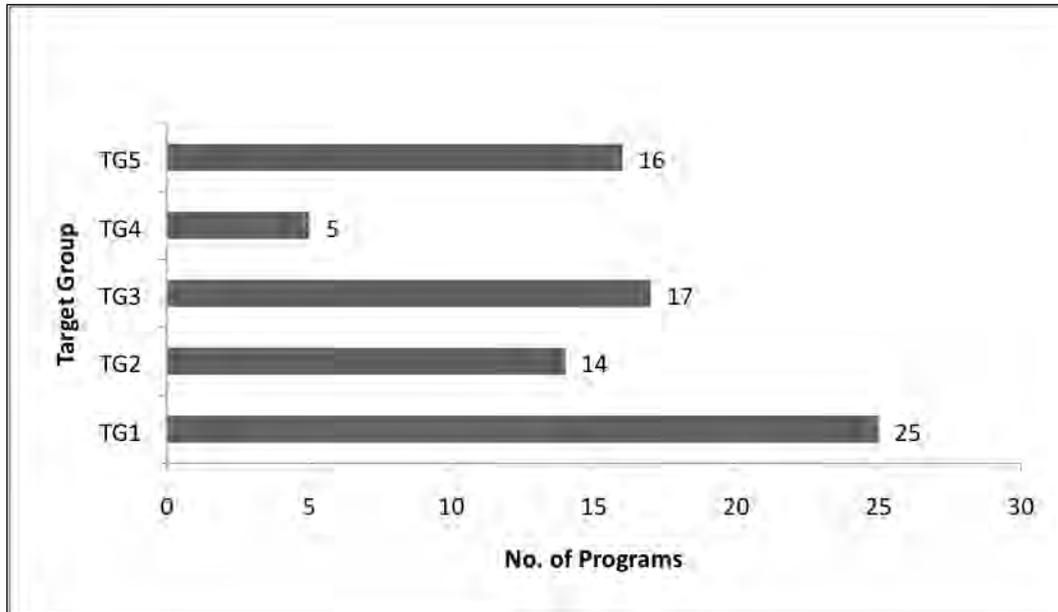
Targeting in the HIV/AIDS Context

Most of the program descriptions reviewed and all of the PEPFAR country programs surveyed targeted nutritional support according to the priority target groups laid out in the 2007 Title II-PEPFAR conceptual framework. These are:

- Target group 1: HIV-positive acutely malnourished and/or food-insecure nonpregnant adults and adolescents (ART and pre-ART clients)
- Target group 2: HIV-positive pregnant and lactating women (this group is assumed nutritionally vulnerable)
- Target group 3: HIV-infected or -affected OVCs (this group is assumed nutritionally vulnerable)
- Target group 4: Food-insecure households in HIV-affected communities

Many programs targeted more than one group, often with a different ration quantity or commodity mix, within the same program. Target group 1 in Figure 3.4 (acutely malnourished and/or food-insecure nonpregnant adults and adolescents on ART or pre-ART) were most commonly targeted for food (25 of 48 programs). Target groups 2 and 3 in Figure 3.4 were targeted for food by a similar number of programs (around 15 of 48 programs), and target group 4 (food-insecure, HIV-affected households) were least commonly targeted (5 of 48 programs). In the sample of programs reviewed, there was a significant proportion (16 of 48 or 33% of the total) that targeted food to the HIV-infected or -affected regardless of food security or nutritional status (target group 5 in Figure 3.4 below).

FIGURE 3.4
Frequency of target groups included in programs for people living with HIV/AIDS (PLHIV)*



*Note: Several programs targeted more than one group. The target groups are defined as follows: TG1, HIV-positive acutely malnourished and/or food-insecure nonpregnant adults and adolescents (ART and pre-ART clients); TG2, HIV-positive pregnant and lactating women (this group is assumed nutritionally vulnerable); TG3, HIV-infected or -affected OVCs (this group is assumed nutritionally vulnerable); TG4, Food-insecure households in HIV-affected communities; TG5, targeted food to the HIV-infected or -affected regardless of food security or nutritional status.

The entry points for identifying individuals or households eligible for food included primarily the ART treatment facility for PEPFAR-funded programs that provide NACS only to those identified as HIV-infected or -affected through ongoing HIV care and treatment programs. Title II (and WFP) programs also use the ART facility to identify participants where the target group is HIV-infected individuals but also work with home-based care programs and use community-based targeting mechanisms to target households affected by food insecurity and HIV. Twenty-four of 48 (50%) of the programs reviewed here were “piggy-backed” onto broader food security programs; i.e., it was not just HIV-infected or -affected individuals and households that were eligible for support.

Prioritizing Groups for Nutritional Support

The most commonly targeted group in this review was HIV-positive, acutely malnourished and/or food-insecure nonpregnant adults and adolescents (ART and pre-ART clients). PEPFAR would like to see the priority for NACS shift to infected or affected OVCs, because they see these groups as being the most vulnerable to the effects of HIV in combination with poor nutritional status and food insecurity. Guidance on prioritization for NACS needs to be explicitly given. Adolescents were

rarely specified as a target group with their own particular nutritional needs. They were almost always included in the same group with adults. This reflects a severe lack of guidance on how to treat this group, which needs to be developed.

The Need to Use Food Security and/or Nutrition Criteria

How to target food assistance in programs for people living with or affected by HIV is a challenging area. It has been noted in previous reviews (Bonnard et al., 2006) that commonly, targeting criteria have focused only on HIV status, with the assumption that HIV infection implies hunger and food deficits. The recent international consensus, such as that found in the Title II/PEPFAR conceptual framework, challenges this and states clearly the need to target food assistance with explicit food insecurity or nutritional vulnerability criteria. This is in light of an emerging evidence base that shows that not all HIV-positive individuals are food insecure or malnourished. It is also clear that attempting to target everyone with food is not feasible in the current resource environment and can cause problems at the field level.

Targeting Mechanisms

The current focus on nonpregnant adults would seem to reflect the most commonly used entry point (certainly for PEPFAR programs) for introducing NACS into HIV programming. This is the ART facility, which often serves a larger proportion of men than women. Identifying children and pregnant and postpartum women infected or affected by HIV who are in need of nutritional support needs a much stronger link with ongoing PMTCT, antenatal, and MCH services at the community level. This may serve to highlight the fact that children infected or affected by HIV are receiving support from programs that use nutritional and/or food security status as a targeting criterion, regardless of HIV status. In Ethiopia, for example, where a national CMAM program has now been rolled out to a large proportion of health facilities, a large number of HIV-infected or -affected children are likely to be covered if they have SAM or MAM. These children need linking to HIV treatment services where they exist.

Household and individual targeting can be done through community health centers, home-based care networks, support networks, and PLHIV networks, as well as through ongoing MCH programming and facility-based care systems. These are all structures that Title II–funded programs are beginning to utilize and that recent guidance covers in detail (FANTA and WFP, 2007).

In high HIV contexts, the key challenge for targeting vulnerable households is to ensure that targeting mechanisms capture HIV-related vulnerabilities in addition to other food insecurity risks and vulnerabilities. Best practice suggests that using multiple criteria for targeting is especially helpful, considering the dynamic interaction between food security and HIV. Several of the Title II programs reviewed

here have used this approach, in combination with community-based targeting mechanisms, in order to increase awareness and understanding of HIV and promote ownership of the intervention. For example, WFP Malawi used the community-identified criteria in Box 3.1 to select areas of operation and beneficiary households.

BOX 3.1
Targeting Criteria

<i>Geographic targeting (district and community levels)</i>
<ul style="list-style-type: none"> • High food insecurity as determined by the 2005 Malawi Vulnerability Committee Report • High HIV prevalence based on the 2003 HIV/AIDS Surveillance Report by the NAC • High population density
<i>Household targeting (households must meet at least three criteria)</i>
<ul style="list-style-type: none"> • Own less than 2 acres of land and be unable to hire it for food or cash • Own no major common livestock (e.g., cattle, goats, sheep, pigs) • Receive no formal wages • Do not participate in regular income-generating activities • Rely on piecework to meet daily food needs • Have less than 3 months of food stock starting from harvest time
<i>HIV-affected households targeted to receive food assistance must also meet one or both of these social criteria</i>
<ul style="list-style-type: none"> • Household must be caring for chronically ill member(s) • Household must be caring for OVCs
<i>These households are prioritized in this order</i>
<ul style="list-style-type: none"> • Child-headed household with more than two orphans who have lost both parents • Elderly-headed households with more than two orphans who have lost both parents • Female-headed households with more than two orphans who have lost one parent • Any other households with more than two orphans who have lost both parents.

In highly food-insecure areas, the practice of “piggy-backing” food assistance for PLHIV onto broader Title II food security programs is seen as best practice. In these cases, targeting mechanisms would include those used more generally for identifying food-insecure households and individuals as well as criteria more specific to HIV vulnerabilities, as discussed above.

Inclusive vs. Exclusive Programming

Twenty-four of 48 (50%) of the programs reviewed here (>50% of the Title II funded programs) were “piggy-backed” onto other programs, reflecting a consensus among the international community that in areas of chronic food insecurity, targeting interventions that aim to improve food security and nutritional status should not be restricted to the HIV-infected or -affected alone but should support all those that need assistance. For PEPFAR-funded programs, this is challenging in the context of programming priorities that by default work specifically with HIV care and treatment programs. A recent review of FBP programming noted that this remains contentious at the community level and that health care providers felt that PEPFAR-funded programs set PLHIV apart from people with other diseases who would benefit from nutritional support. Synergizing support with tuberculosis programs is particularly crucial here, given the considerable overlap in the target groups (Semba et al., 2010). What this reinforces is the need for harmonization of eligibility and targeting criteria for nutritional support across programs to ensure that all those in need of nutritional support have access to it. NACS is a model that can be applied to clinical care as delivered for any condition and at any level of facility. What is needed is funding to extend NACS more broadly within MCH. There are examples of countries included in this review that have been able to implement this approach quite successfully. Malawi routinely applies nutrition criteria to establish primary eligibility for nutritional supplementation regardless of HIV status. This means that, in theory, people undergoing treatment for any sort of illness have access to nutritional rehabilitation (Greenaway, 2009a).

Most of the program descriptions reviewed and all of the PEPFAR country programs surveyed articulated program objectives that could be classified according to the three broad goals—treatment, care and support, and prevention and mitigation—that are outlined in the main international frameworks that list objectives for the use of food in HIV programming (see Appendix 3). There are two main groups of programs considered by this review— PEPFAR-funded and Title II–funded. Each of these allows the use of food only for specific objectives: PEPFAR for nutritional care and support and rehabilitation and Title II for broader nutrition, food security, care, and support. The types of food most appropriate to meet these different objectives are very different. Therefore, in the context of this review it is useful to group program objectives into “nutritional” (i.e., those that aim to use food to maintain or improve the nutritional status of HIV-infected or -affected individuals) and “non-nutritional” (i.e., those that aim to use food to support participation in services, to impact health outcomes such as the progression of HIV itself ,or to improve food security).

The range of commodities used across the programs reviewed included the following:

- Fortified blended flours (FBFs), including Corn–Soy Blend (CSB) and Wheat–Soy Blend (WSB)
- Other cereals and grains, including whole grain maize and/or flour, whole grain wheat and/or flour, whole grain sorghum and/or flour, and rice
- Pulses and nuts, including lentils, peas, beans, and groundnuts

- Oil, including fortified and unfortified vegetable oil and palm oil
- Lipid-Based Nutrient Supplements (LNSs), such as Ready-to-Use Therapeutic Foods (RUTFs)
- Other (locally produced) high-energy and/or protein supplements

Three programs included in this review did not specify the type of food supplement provided.

TABLE 3.6
Treatment, Care and Support, Prevention and Mitigation for Target Groups

Target group	Objective
Malnourished and/or food-insecure PLHIV (ART and pre-ART clients), including children	<p>Treatment</p> <ul style="list-style-type: none"> To treat acute malnutrition To support adherence to ART To improve ART efficacy To help manage ART side effects
	<p>Prevention or mitigation</p> <ul style="list-style-type: none"> To prevent or reduce high-risk behaviors and reliance on negative coping strategies To encourage uptake of voluntary testing and counseling To encourage participation in PMTCT
Food-insecure PLHIV and affected households; HIV+ pregnant and lactating women	<ul style="list-style-type: none"> To encourage participation in HIV/AIDS awareness and behavior change programs To encourage uptake of voluntary testing and counseling To prevent or reduce high-risk behaviors and reliance on negative coping strategies
Food-insecure households in HIV-affected communities	<ul style="list-style-type: none"> To encourage participation in HIV/AIDS awareness and behavior change programs To encourage uptake of voluntary testing and counseling To prevent or reduce high-risk behaviors and reliance on negative coping strategies
Food-insecure PLHIV; HIV+ pregnant and lactating women	<p>Care and support (including nutrition, caregiving, and livelihoods)</p> <ul style="list-style-type: none"> To supplement daily nutritional requirements and special dietary needs, such as increased energy requirements To support nutritional management of symptoms of opportunistic infections (e.g., anorexia, diarrhea, nausea) To provide income transfer and asset protection To support participation in training in life skills, life planning, and alternative livelihood strategies
	<ul style="list-style-type: none"> To improve food and livelihood security To supplement daily nutritional requirements of OVCs and other affected household members To provide income transfer and asset protection To encourage school attendance To support participation in training in life skills, life planning, and alternative livelihood strategies To support adoption of new technologies and practices or new livelihood strategies
OVCs	<ul style="list-style-type: none"> To improve food and livelihood security To supplement daily nutritional requirements of OVCs and other affected household members To provide income transfer and asset protection To encourage school attendance To support participation in training in life skills, life planning, and alternative livelihood strategies To support adoption of new technologies and practices or new livelihood strategies
Food-insecure households in HIV-affected communities	<ul style="list-style-type: none"> To provide income transfer or to cover opportunity costs to voluntary care providers To support participation in training voluntary care providers To support establishment of community-based social safety nets (food banks) and care and support services To support the use of food as an income transfer and asset protection To prevent or reduce high-risk behaviors and reliance on negative coping strategies

Source: PEPFAR

FBF was used by all programs that specified *nutritional objectives*, i.e., that aimed to either prevent deterioration of nutritional status or to treat undernutrition in the target group. Most of these programs (about 75%) also used other basic commodities such as cereals and grains, oil, and pulses.

Although the majority of programs reviewed aimed to impact nutritional outcomes, for most nutrition intervention was synonymous with food distribution that usually consisted of a food basket containing FBF, other cereals, pulses, and oil. There was little variation in the commodity mixes provided by programs that aimed to impact food security or other non-nutritional outcomes, unlike those provided by programs that aimed to maintain nutritional status or treat malnutrition. In some cases, there appeared to be little consideration of the particular nutritional requirements of the target group. The exceptions to this were some of the new PEPFAR-funded NACS (previously Food-by-Prescription) programs that have had significant technical input from agencies like FANTA2 and that have designed nutrition protocols with requirements in mind and introduced products like LNS to meet the special needs of moderately and severely malnourished adults and children. Generally, there is certainly a need for programs that have explicit nutritional intent to design rations more precisely.

Some guidance is available to support this. The relatively new WFP ration design guide (WFP, 2008a) and the FANTA/WFP “Food Assistance in the Context of HIV” Guide (FANTA and WFP, 2007) give some direction on the steps involved in the design of appropriate rations for different target groups and different objectives, and at the country level some well-thought-through national guidelines are beginning to appear,²⁷ particularly in relation to the PEPFAR programs that have benefited from the technical support of agencies like FANTA2. However, this guidance currently suffers from the general lack of scientific evidence on the specific macro- and micronutrient requirements of different HIV-infected groups. In the absence of knowledge here, guidance is conflicting. On the one hand, WHO recommends increasing energy intakes by up to 50% in symptomatic adults and 100% in symptomatic children, while on the other, guidance regularly states that HIV-positive adults and children with MAM and SAM should receive exactly the same nutritional protocol as HIV-negative adults and children with MAM and SAM (Valid International, 2006; WHO, 1999). The latter recommendation is well established with an evidence base for HIV-positive children with SAM but is less established for HIV-positive children with MAM, although WHO is working on establishing guidance for treatment of HIV-positive children with MAM through recent consultations (Briend and Prinzo, 2009). There is only a very weak evidence base for the nutrient requirements of HIV-positive adults with MAM and SAM. There is a huge gap in the evidence that guidance can draw on here, as discussed previously.

²⁷ At the time of this review, national guidelines for FBP programs were available in Ethiopia, Kenya, Zambia (draft), Uganda (draft), Malawi (draft), and Tanzania (draft).

There is less convergence around graduation criteria in programming than there is around eligibility criteria. This is reflected by the wide range of indicators used for graduation in the programs reviewed here. Best practice does suggest that food supplementation should be time limited and that graduation should be linked to the program's overall purpose. The latter most often includes using improved anthropometric status to graduate clients who have been targeted based on poor nutritional status (see Appendix 5) and improved socioeconomic and food security status for programs with non-nutritional objectives.

Generally, of the programs reviewed here, those with stronger “wrap-around” mechanisms such as economic strengthening and social assistance expressed higher levels of confidence in their ability to graduate clients. This is a challenging area of programming. For PEPFAR programs at least, this reinforces the need to link with Title II and other food security support programs through “hybrid” agreements and proposals. Although most PEPFAR programs reviewed here did aim to provide links to livelihood and food security partner programming, documentation of success in this area was scarce. As discussed above, PLHIV will have evolving nutritional needs along the life course, and programs will need to be able to respond to the demands as they occur.

Generally, there was evidence of very wide use of FBFs across programs. This reflects the general consensus in HIV programming that the target group (whatever their nutritional status) requires a ration that is of better nutritional quality than the standard fare and that is easy to prepare and consume. There were many examples found in this review of FBF being used as part of a ration to maintain the nutritional status of a target group and examples of it being used to address SAM, with little impact on weight gain and recovery (Greenaway, 2009b).

3.3 ENHANCING PROGRAM GUIDANCE TO IMPLEMENTING PARTNERS

A range of guidance is provided to USAID implementing partners as they prepare their proposals. A review of the available guidance demonstrates some problems. One is that there are multiple sources of guidance, some quite lengthy, all of which need to be considered in agencies' responses. The length and complexity of guidance for Title II programs exceed that for other U.S. food assistance programs. A more serious problem is that the guidance is at times inconsistent, providing conflicting advice in different places, and the sources of information on ration composition (in particular the CRG) contain information about the nutritional composition of foods that is in places out of date and/or incorrect. A comprehensive review of program guidance provided to Title II implementing partners should be conducted, with a view to simplifying and harmonizing the guidance provided and ensuring that it is up to date, correct, and consistent.

A recent change is that USAID now provides food security analyses through FANTA-2 for agencies applying to implement development programs. These analyses do not offer guidance on program design, but they do provide a detailed analysis of the food security situation and its determinants, based on available data. This level of analysis of national food security context is probably beyond the technical capacity of many of the individual implementing partners, so having it done by an outside agency is a positive development. However, where implementing organizations are designing programs that do have nutritional intent, their capacity to identify problems to be tackled, understand local diets needing to be changed, and document the impact of interventions needs to be considerably improved.

For the 2011 program cycle, the following directives or pieces of guidance are required for the preparation of a Multi-Year Assistance Program (MYAP) proposal. To be clear, only four items listed below—the Request for Applications (RFA), the 2010 Program Guidance, the Country Specific Guidance, and the Pipeline and Resources Estimate Proposal (PREP) Guidance—are officially called “guidance.” An understanding of the other listed documents is, however, essential for the development of a competitive MYAP proposal.

TABLE 3.7
Mandatory guidance

RFA (Request for Applications) for Fiscal Year 2011 Non-Emergency Food Aid Programs (22 pages)	Outlines the content, format, and timing of submission of MYAP proposals, and provides recommendations for and links to additional proposal development resources. The expressed goal of this new 2011 RFA was to “streamline” the application process, but in fact, the FY2011 RFA is additional to the FY2010 RFA, so that both documents must be used in preparing a program proposal.
FY 2010 Proposal Guidance and Program Policies (72 pages)	Guidance issued for 2010 MYAPs. It provides a detailed and comprehensive explanation of all items to be addressed in the design of a Title II program and proposal. Based on the RFA cited above, the 2010 guidance is critical to the development and preparation of 2011 MYAP proposals.
Country-Specific Guidance: Title II Proposal Guidelines and Program Policies (2 pages)	Serves as a cover for and recap of the salient points of the Food Security Country Framework (see below); highlights the underlying causes of food insecurity in a given country; recommends priority intervention areas; and provides links to technical resources and publications.
Pipeline and Resources Estimate Proposal (PREP) Guidance	A package of about twenty (20) assorted tables, lists, spreadsheets, and forms that are required for, among other things, budgeting, calculation of rations, Annual Estimate of Requirements (AER), Certifications and Assurances, and Environmental Compliance.

TABLE 3.8
Additional guidance

<p>BEST Study (Bellmon Estimation Study Title II) (~100 pages, length varies with country)</p>	<p>Formerly known as the Bellmon Analysis, the BEST Study is designed to determine: a) that there exists sufficient adequate storage for the commodity to be imported, and b) that the imported commodity will not disrupt local production of that commodity and local markets. This analysis was previously conducted by each applicant private voluntary organization or private voluntary organization consortium, and is currently performed by an external contracted agent. While it is important to commodity selection for direct distribution programs, it is required if monetization, i.e., sale, of the commodity is intended.</p>
<p>FFPIB (Food for Peace Information Bulletin)-07-01: Indicators and Reporting Systems (4 pages)</p>	<p>Describes the five (5) sets of reporting requirements applicable to all MYAPs.</p>
<p>FFPIB-07-02: New Reporting Requirements for Food for Peace (5 pages)</p>	<p>Lays out reporting requirements designed to enable FFP to better track progress toward the objective(s) and intermediate results (IRs) of the FFP Strategic Plan.</p>
<p>FFPIB-09-02: New Procedures to Determine Compliance of Title II Food Aid Proposals with the Conditions of the Bellmon Amendment (5 pages)</p>	<p>Clarifies the responsibilities of Cooperating Sponsors concerning local and regional markets and their relevance to both direct distribution and monetization projects in addition to the information provided by the BEST Study.</p>
<p>FFPIB-09-06 Monitoring and Evaluation Responsibilities of Food for Peace Multi-Year Assistance Programs Awardees (7 pages)</p>	<p>Describes the key monitoring and evaluation (M&E) responsibilities of Title II awardees and potential awardees and provides additional detail to existing policies.</p>
<p>FFPIB-08-03: Eligible Uses of Section 202(e) and ITSH Funding (8 pages)</p>	<p>Provides information for the determination of funding required to cover the costs of administering a Title II program and the costs of internal transport, storage, and handling of the commodity.</p>
<p>FFP Paper No. 5: Trigger Indicators and Early Warning and Response Systems for Multi-Year Title II Programs (20 pages)</p>	<p>Explains the need for inclusion in MYAPs of early warning and response mechanisms in order to respond to increased food needs caused by a shock affecting the beneficiaries of the MYAP.</p>
<p>Title II Technical Resource Materials (TRM)-01: Preventing Malnutrition in Children Under 2 Approach (PM2A): A Food Assisted Approach (51 pages)</p>	<p>A comprehensive guide to the planning of PM2A programs.</p>

Program Graduation and Exit Strategies: A Focus on Title II Food Aid Development Programs: FANTA Technical Note No. 9 (12 pages)	Discusses the methodology for the design of a strategy for the continuation of a program after the termination of the program and/or when external assistance is no longer available.
Guidance for programs involving monetization	
Monetization Field Manual (27 pages)	Explains the need for market analysis, the conditions and related justifications, and the procedures to be employed in the sale, i.e., monetization, of Title II food commodity, and outlines the elements of a plan for the monetization required to be included in the MYAP.
Additional technical guidance	
Food Security Country Framework (~125 pages, length varies with country)	A comprehensive document that: a) provides an overview of the food security situation and its underlying causes in a given country; b) identifies the most food-insecure populations within that country and their geographical location(s); c) outlines strategies and interventions appropriate for addressing food insecurity in the country; and d) recommends programming priorities, objectives, and overall program and proposal design considerations. These frameworks represent an innovation in the provision of program guidance, allowing implementing partners to access relevant information on the local food security context in a single source.
Commodities Reference Guide (CRG)	A long-standing resource that provides information on: a) the content of food commodities eligible for use in Title II programs, and b) the formulation of rations for specific types of program beneficiaries. It provides a ration calculator, but the information on individual commodities is not always consistent with the latest science.
USAID Performance Monitoring and Evaluation TIPS, 2000, Number 13, Building a Results Framework	Provides information on the key elements of and methodology to be employed in designing a Results Framework.
Initial Environmental Examination Guidance and Compliance Information For Title II Programs	Provides information on the preparation of an IEE required in the submission of MYAPs with the aim of demonstrating that any impact the proposed Title II activity might have on the environment has been taken into consideration, and that a plan is in place to mitigate any negative environmental impact. Compliance with the foregoing guidance is facilitated through use of <i>A Cooperating Sponsor's Field Guide to USAID Environmental Compliance Procedure</i> (69 pages), published by Catholic Relief Services (CRS) and the now defunct organization Food Aid Management (FAM).
Background resources that define and expand upon the “food security” concept and that are important for an understanding of all Title II programming	

The Food Aid and Food Security Policy Paper (36 pages)	First issued by USAID in 1995, this document represents a milestone in the conceptualization of food aid programming and explains the basic tenets or pillars of the food security paradigm, i.e., availability, access, and utilization (it was subsequently updated to include a fourth pillar—risk and vulnerability) and, therefore, it is essential to understanding “food security,” the overarching objective of all Title II programming and MYAPs.
Food for Peace Strategic Plan 2006-2010	

Sources: USAID 1995, 2000, 2005.

This extensive list poses a challenging task for the implementing partners responding to Title II RFPs. Given the similarity between Title II programs and some other programs that make use of food aid, such as McGovern–Dole Food for Education and Food for Progress, PEPFAR’s Food by Prescription, as well as the new Feed the Future initiative, it is noteworthy that the requirements for responding to RFPs relating to these latter programs are considerably less than those for Title II. FFP should take a critical look at the guidance documents now in use for Title II programs and consider the possibility of harmonizing them with the requirements of these other food assistance programs.

In addition to the required baseline, midterm, and endline evaluations of their programs, agencies face annual reporting requirements relating to specific performance indicators. All of the information from these reports is centralized in a repository run by a contractor, Amex, which is responsible for collecting, storing, and reporting on the information. Amex is responsive to requests for information, as the FAQR has found in the course of the present study. Still, it is not clear what use is made of all the data collected from all the implementing partners, and whether these data could be used more effectively to make cross-program comparisons and identify best practices and most successful interventions. A review of the FFP information system, with a view to identifying ways in which it can be made more useful for cross-country and cross-program comparisons and for identifying successful program approaches, would be a valuable contribution.

Recommendation 26: Support implementing partners to incorporate data on local consumption and food availability into the design of rations and programs.

Few, if any, programs design their rations based on empirical data about local diets and consumption patterns. The majority of plans reviewed make reference to calorie gaps estimated from FAO food balance sheets or, in some cases, from needs assessment missions. The paucity of information has meant that food-assisted programs and the choice of both quantity and quality of the commodities in the rations have not always supported the specific needs of the most nutritionally vulnerable, nor always accounted for food resources present in the community and diet practices. We do *not* recommend that each agency undertake primary data

collection on dietary consumption prior to designing its own programs. However, we recommend attempts to narrow the gaping chasm between knowledge of dietary realities and program design. Many agencies implementing programs using Title II foods have been working in the same area for many years; agencies should be encouraged and assisted to incorporate, explicitly, their knowledge of local food availability and food consumption in the design and justification for their programs, including the design of their food rations.

Recommendation 27: USAID should improve training on needs assessment and on monitoring and evaluation methods and tools with regard to nutrition. If programs are to be designed with appropriate reference to local conditions, new approaches must be more rigorously tested, and empirical support must be provided for common assertions about the effectiveness of specific program elements and their cost-effectiveness. To enable implementing partners to do this, USAID will need to improve their capacity to undertake the necessary studies. In addition, funds and sources of technical assistance to the agencies to support these activities should be identified.

Recommendation 28: USAID should systematically incorporate cost-effectiveness into the evidence base for nutrition programming. In nutrition interventions, the cost of programming (versus the cost of product) has had too little attention. As Ashworth (2006) noted in the mid-2000s, information on the cost of the products used is important, but the product does not deliver itself; equally important is clarity on the cost of “logistics of procurement and distribution.” The lack of costing data on programming is a common problem in the intervention literature. Enhanced evidence on the efficacy of food supplements, but especially on the effectiveness of food-based interventions as implemented, is urgently needed to establish policy and program options to deal with the coexistence of protein–energy malnutrition and multiple micronutrient deficiencies. A number of important program issues require empirical investigation to ensure that assumptions and assertions are justified. Similarly, program impact is commonly reported in midterm and endline evaluations using indicators such as the percentage of children under two who are malnourished (underweight [low weight-for-age z-score] or stunted [low height-for-age z-score]). Other, more process-oriented indicators include the number of individuals or households reached, the amount of food distributed, and other process-focused accomplishments. These numbers are of limited use in choosing among programs unless the cost of achieving a particular impact is included in the analysis. Therefore, some estimate of cost and cost-effectiveness should be incorporated as a routine element of program evaluations.

There is, as noted, a significant amount of programming that does not have explicit nutritional intent (although there are other, equally appropriate goals). For such operations, the selection of commodities and choice of ration sizes should not be guided by nutritional parameters, but by other priorities. FFP must provide clearer guidance to implementing agencies on the recommended compositions of food rations for different nutrition goals (matching product to purpose). Current practice allows

for a wide range of quantities to be programmed and requires little empirical support (i.e., based on current dietary and consumption patterns) for the choices made. Guidance should be framed and communicated through easy-to-use flow charts and decision trees accompanied by clear “how-to” guides. In all cases, rations should be tailored for, and appropriate to, clearly defined outcomes.

Recommendation 29: Enhanced guidance should be prepared (such as decision tree tools) to enable agencies to better select commodities for programming.

Appendix 1 presents a set of flow charts and decision trees to guide the selection of commodities for different kinds of emergency and nonemergency programs. These graphics provide a basis for making decisions about the composition of food aid rations for different purposes. They are intended as guidance and of course must be applied flexibly in light of the specific situation in which food is being used. They represent just a first step in the development of tools for improved programming decisions.

The foods developed for use under Title II should be appropriate to their defined objectives if they are to achieve cost-effectiveness. As noted, enhanced versions of CSB and WSB and other FBFs should be used primarily in support of interventions that have explicit nutritional goals. Rations used as an incentive or as pay (e.g., in Food for Work [FFW] or Food for Training [FFT] programs) should be based on the local value of commodities with respect to wages and on household (as opposed to individual) needs. In contexts in which targeted outreach to nutritionally vulnerable individuals is possible, the family ration should not automatically include nutritionally enhanced products. However, when it is deemed that a household ration will not meet the needs of vulnerable consumers (such as infants 6 to 12 months of age in an emergency setting where non-food-aid sources of food are limited), then enhanced products can be added to the general distribution.

We have argued that foods provided in Title II programs should be “fit for purpose.” Even among the specialized foods intended for specific nutritionally vulnerable target groups, the choice of food must be appropriate to the context. FBFs such as CSB have cost advantages over such foods as LNSs and HEBs, both in terms of the product itself and in terms of packaging. CSB is familiar to many beneficiary populations, and its taste and appearance are acceptable. In some settings where fuel is scarce, the need to cook CSB may be a disadvantage, and because it is prepared by the beneficiary, the preparation methods may not be standard. In terms of relative nutritional effectiveness, improved CSB as recommended here has not been tested. LNSs have been criticized for being too sweet, and, although they do not require water for preparation, they need to be consumed with water because the texture and sweetness make people thirsty. Some LNSs are provided in individual packages, which may be an advantage for targeting, though this has not been empirically demonstrated. Shelf life can be longer for the LNSs because of their enhanced packaging. The amount of packaging for a given amount of food supplement is a concern, however. Generally, a variety of local considerations will affect the specific food selected for a given set of conditions.

3.4 WHAT WILL IT COST? IMPLICATIONS OF PRODUCT AND PROGRAMMING CHANGES

CSB/WSB offers greater nutrient density than other fortified milled cereals in terms of macro- and micronutrients. Its relatively low cost is one reason CSB has served such a wide number of nutritional objectives. As indicated in Table 3.9, on a metric ton basis the commodity and freight costs for wheat flour, cornmeal, and soy-fortified milled cereals averaged only 15% to 25% less than those for CSB (although CSB has less flexibility in the distribution chain because of its shorter shelf life relative to milled cereals and grains). On the other hand, CSB is considerably less expensive, not only per metric ton, but also per ration and per beneficiary treated, than dried milks or a range of special formulated lipid-based foods and supplements designed to prevent and treat malnutrition. Table 3.9 shows the cost of a daily 100-g ration of CSB13 compared with the cost per daily ration of other commodities (400 g of milled flours or 440 of unmilled grains). The table demonstrates again that despite their lower cost per metric ton, many of the less expensive products are in fact more costly on a per-ration basis. Of course, these commodities are typically used for different purposes: CSB and RUSF for explicit nutritional objectives, and flours, meals, and the enriched soy-fortified cereals for general household rations and programs using food as incentive or pay.

TABLE 3.9
Comparison of cost of a daily ration of CSB13 with cost of a daily ration of soy-fortified and milled cereals

Food	Cost/MT vs. CSB13 (%)	Cost of daily ration (\$)
Corn–soy blend (CSB13)	100	0.09
Sorghum grits, soy-fortified	84	0.32
Flour	85	0.31
Bulgur, soy-fortified	84	0.31
Cornmeal	75	0.28
Cornmeal, soy-fortified	76	0.38

Cost of Reformulating Rations

Table 3.10 shows the estimated costs for a reformulated CSB14 at \$833/MT from the mill, and \$1021/MT when taking into account the added average cost of \$188 for freight to overseas ports. As shown in the table, this reflects an increase of \$187 or a cost around 18% more than that of CSB13.²⁸ The major driver of the increase is the

²⁸ In June 1969, 1 kg of Corn–Soy Milk (CSM) cost roughly 18 cents (Wood et al., 2008). That equates to roughly US\$0.35/kg for CSB13 at today’s prices, and a projected price of roughly \$0.5/kg for an enhanced form of CSB (CSB14), which in many respects is close to the formulation of the original CSM.

addition of WPC80 at \$162/MT (or \$150 when the associated lower volumes of cornmeal and soy flour are taken into account). A minor cost driver is a roughly projected increase of about 11% (from 18% to 20%) in the expected upcharge from producers due to the increased complexity of mixing, including added costs of procurement and storage and special arrangements for the handling of WPC80, since milk is a known allergen. Overall, the reformulated CSB14 is modestly less expensive than CSB13 in the narrow sense of cost per ton.

Table 3.11 compares the macroingredient costs for CSB14 with those for CSB13 and CSB++. This comparison underscores the projection that despite considerable enhancements in the nutritional profile, the cost increases from CSB13 to CSB14 (and WSB equivalents) are not expected to be substantial; indeed, the increase is less than for CSB++. It should of course be understood that prices of ALL food ingredients and commodities vary over time in absolute amounts and relative to each other. As a result, these price estimates, pertaining to early 2011 and based on actual and estimated costs confirmed by industry experts at the time, are merely indicative of what the actual cost would be at any given point in the future.

TABLE 3.10

Estimated cost of CSB14 components, CSB14 cost, and comparison with CSB13

Ingredient	Component unit cost	Cost of CSB14
Cornmeal	\$403/MT	\$272.03/MT
Soy flour	\$488/MT	\$102.48/MT
Vegetable oil	\$877/MT	\$48.24/MT
WPC80	\$5405/MT	\$162.15/MT
Micronutrients		\$73.57/MT
Bags	\$0.90/MT	\$36.00/MT
Estimated upcharge	20%	\$138.89/MT
Total purchase price		\$833.36/MT
Transport to overseas hub (average 2004–08)		\$188/MT
Total estimated cost		\$1021/MT

Note: CSB, Corn-Blend; DSMP, dried skimmed milk powder; WPC80, Whey Protein Concentrate 80%.

TABLE 3.11
Comparison of macroingredient costs for CSB13, CSB14, and WFP CSB++

Ingredient	Cost (\$/MT) ²⁹	CSB13		CSB14		CSB++	
		g/kg	Cost (\$/MT)	g/kg	Cost (\$/MT)	g/kg	Cost (\$/MT)
Cornmeal	403	69.55	280	67.27	272	62	249.86
Soy flour	488	21.85	107	21.13	103	14.9	60.05
Vegetable oil	877	5.5	48	5.50	48	3	14.64
WPC80	5405			3.00	162		
DSMP	2976					8	238.08
Sugar	1120					9	100.80
Ingredients cost (\$/MT)			435		585		663.43

Note: CSB, Corn-Soy Blend; DSMP, dried skimmed milk powder; WPC80, Whey Protein Concentrate 80%.

The fortification cost for CSB14 includes a recommended revision in the current specifications for adding micronutrients in separate vitamin and mineral mixes. For CSB13, specifications include two separate premixes, a mineral premix and a vitamin premix. The mineral premix includes both bulky heavy mineral components such as 16 kg/MT of tricalcium phosphate or 8 kg/MT of iodized salt, as well as micro components such as iron, zinc, and magnesium. Quality assuring this premix involves analysis to assure that the microingredients are accurately and homogeneously mixed in this bulky premix. This increases premixing costs and probably reduces quality as well.

Therefore, for CSB14 we recommend segmenting the fortificant compounds by bulk or volume, rather than by vitamin or mineral. Our recommended approach includes specifying a Fine Vitamin and Mineral Premix with 17 micronutrients added at about 2.1 kg/MT of CSB. This premix includes both vitamins and the microminerals, including iron, zinc, magnesium, and iodine (added as a micronutrient but not as a component of salt, as in CSB13). As calculated in Table 3.12 below, the cost of recommended Fine Vitamin and Mineral Premix is an estimated \$24.32 per kilogram of premix. Assuming a \$2.25/kg premixing upcharge and an addition rate of 2.1 kg/MT, the total fortification cost is estimated at \$51.08/MT.

²⁹ Ingredient Market Reports (2010), not including freight.

TABLE 3.12
Estimated cost of fine vitamin and mineral premix for CSB14

Nutrient	Fortification level	Fortificant compound	Fortificant compound activity	Fortificant compound in 1 MT CSB	Fortificant compound cost	Cost per component in premix
	ppm or mg/kg		%	g/MT	\$/kg	\$/kg
Vitamins						
Vitamin A	1.10	Vitamin A palmitate	7.50	14.73	40.00	0.28
Vitamin B ₁ (thiamin)	6.52	Thiamin mononitrate	81.06	8.04	24.50	0.09
Vitamin B ₂ (riboflavin)	9.33	Riboflavin	100.00	9.33	80.00	0.36
Vitamin B ₃ (niacin)	90.70	Niacinamide	99.00	91.62	11.50	0.50
Vitamin B ₅ (pantothenic acid)	33.40	Calcium D-pantothenate	89.25	37.43	28.50	0.51
Vitamin B ₆	6.19	Pyridoxin hydrochloride	82.00	7.54	33.00	0.12
Vitamin B ₉ (folic acid)	0.87	Folic acid	90.00%	0.97	195.00	0.09
Vitamin B ₁₂	0.01	Vitamin B ₁₂ 0.1% water soluble	0.10	14.68	42.00	0.29
Vitamin C	400.00	Coated ascorbic acid	100	400.00	26.50	5.05
Vitamin D ₃	0.25	Vitamin D ₃ 100 kIU/g	0.25	101.73	50.00	2.42
Vitamin E	107.75	Vitamin E 50% CWS	33.56	321.09	58.00	8.87
Vitamin K	0.33	Dry vitamin K ₁ 5% spray-dried	5.00	6.63	250.00	0.79
Minerals						
Iodine	2.28	Iodine	76	3.00	34.00	0.05
Iron	40.00	NaFeEDTA	13	307.69	7.50	1.10
Iron	90.00	Ferrous fumarate	32	281.25	6.50	0.87
Magnesium	94.65	Magnesium oxide	59	160.43	2.95	0.23
Zinc	55.04	Zinc sulfate monohydrate	36.44	151.05	5.20	0.37
Total fortificant compound				1917.21		
Excipient		Calcium carbonate		183	1.05	0.09
Addition rate (g/MT)				2100	Ingredients cost (\$/kg)	22.07
					Upcharge (\$/kg)	2.25
					Premix cost (\$/kg)	24.32
					CSB14 cost (\$/MT)	51.08

Note: CSB, Corn–Soy Blend; NaFeEDTA, sodium iron ethylenediaminetetraacetate.

There are several unknown cost implications to the recommended reformulation. First, the procurement and storage of additional components such as WPC80 will require process changes that may present some challenges, liabilities, and unforeseen costs. Second, WCP80 added at 3%—roughly the same rate as that in the micronutrient premix—might be considered a bulk ingredient to be mixed or another microingredient added via microfeeder. How individual mills incorporate these added ingredients will affect costs. Although these technical issues are not insurmountable barriers, the technical solutions and related costs will need to be addressed with the

involved industries—and individual companies may well apply different solutions. Discussions with CSB suppliers suggest there are no “off the shelf” solutions.³⁰

A third issue is perhaps more significant. Although the current CSB13 is more complex than most products processed at mills, it has still proven acceptable and feasible for processors to produce within the standard mill processing environment. However, the increased complexity of CSB14 and WSB16—including the addition of both the elements of the premix and the WPC80—means producers will need to assess whether the new product fits within their overall technical capacity and business model. Will the volume of milling and revenue from production of newly formulated precooked FBFs justify the capital investment and start-up costs needed? Discussions with current suppliers suggest that they would weigh a number of technical and business factors prior to determining whether they would invest in-house or send the milled product out for finishing to a blending and packaging operation.³¹ New processors have expressed interest in responding to tender offers if the product matches their technical capacity in the production of other food products.

Cost of FVO

The cost-effectiveness of delivering vitamin A through vegetable oil as opposed to CSB was discussed by Atwood et al. (1995), who determined that delivering vitamin A in oil is considerably less expensive than delivering it in CSB. By contrast, Fiedler and Afidra (2010) suggest that in Uganda’s case, delivering vitamin A in sugar can achieve higher rates of coverage than delivering it in oil. In other words, it should not be assumed a priori that fat-soluble vitamins would be better delivered in oil than in other products in the food aid basket.

The cost of the vitamin A fortificant at 20 ppm is estimated at \$3.96/MT of oil, as calculated in Table 3.13 below. The additional cost to fortify vegetable oil with the recommended level of vitamin D is estimated at \$2.13/MT. Currently vegetable oil is fortified only with vitamin A. With an average annual purchase of 170,000 MT of oil, this suggests an incremental cost of about \$2.13/MT, or a total of \$360,000 annually, to add vitamin D. In addition to providing for a sufficient level of these critical vitamins within the general food basket, this will also make an important contribution to the nutrition of children 6 to 59 months of age if it is provided in conjunction with the precooked FBFs, as we have recommended.

³⁰ Discussions held with representatives of current CSB producers.

³¹ Ibid.

TABLE 3.13
Cost of proposed vegetable oil fortification specifications

Vitamin	Ppm	Compound	% Activity	Cost (\$/kg)	Cost (\$/MT)
A	20	Vitamin A palmitate 1,000,000 IU/g	51	101	3.96
D	0.42	Vitamin D ₃ 1,000,000 IU/g	2.50	127	2.13
Total fortificant costs (\$/MT)					6.09

Cost of Fortified Milled Grains (Flours and Meal)

The cost of this proposed fortification profile is approximately \$6.97/MT based on a micronutrient cost of \$11.62/kg, an addition rate of 600 g/MT, and a premix upcharge of \$2.25 per kg. NaFeEDTA accounts for about one third of the cost and is considered essential due to its superior bioavailability. As noted by Gibson et al. (2010), “for the high-phytate, cereal-based, processed complementary foods...the potential for using ‘protected’ iron compounds such as NaFeEDTA should be explored, because this compound partially protects the fortificant iron from reacting with absorption inhibitors such as phytate (and polyphenols).” Another major difference from current specifications is that the recommended level of vitamin A is lowered to 1.1 ppm, so that vitamin A accounts for only 9% of the cost of fortifying milled cereals. In addition, calcium has been eliminated from the micronutrient profile (see Chapter 2).

TABLE 3.14
Cost of premix for new milled cereal fortification profile

Fortificant	Fortification level	Compound activity	Compound per MT of flour	Fortificant compound in 1 kg premix	Compound cost	Cost per component in 1 kg premix
	mg/kg	%	mg/kg	kg	\$/kg	\$/kg
Thiamin	4	81	4.93	0.0082	\$24.50	\$0.20
Riboflavin	4	100	4.00	0.0067	\$80.00	\$0.53
Niacin	40	99	40.40	0.0673	\$11.50	\$0.77
Folate	1.54	90	1.71	0.0028	\$195.00	\$0.56
Vitamin B ₆	4	82	4.88	0.0081	\$30.00	\$0.24
Vitamin B ₁₂	0.011	0.10	11.00	0.0183	\$42.00	\$0.77
Vitamin A	1.1	7.5	14.67	0.0244	\$40.00	\$0.98
Vitamin D	0.02	0.0025	8.00	0.0133	\$50.00	\$0.67
NaFeEDTA	40	13	307.69	0.5128	\$7.50	\$3.85
Zinc	24	36	65.93	0.1099	\$5.20	\$0.57
Nutrients subtotal			463.22	0.77		
Excipient			137	0.23	\$1.05	\$0.23
				Premix totals		
				Nutrient cost/kg		\$9.37
				Upcharge/kg		\$2.25
				Cost/kg		\$11.62
				Cost/MT @ 600 g/MT		\$6.97

Note: NaFeEDTA, sodium iron ethylenediaminetetraacetate.

Since there is a range of fortification profiles for current Title II milled cereals, to compare proposed and current specifications we use a composite profile for cornmeal, wheat flour, and other milled cereals, based on the higher amount in each case.

Cost Implications for New Programming Approaches

Proposed improvements in programming have several dimensions: a) changes in packaging designed to reduce sharing; b) improved approaches to delivery; c) more effective BCC; and d) consideration of ancillary services to improve health on the one hand and food security on the other, all supported by clearer, more specific technical guidance and the development of an enhanced evidence base for program decision making.

Targeting is a powerful driver of cost-effectiveness. But with the extent of sharing a variable of unknown quantity, it is difficult to establish the current success in targeting of CSB. It is known that CSB is typically shared in the family. It looks, tastes, and cooks much like local cereal staples and can easily be mixed into the family pot. Indeed, many implementing partner agencies provide recipes for using CSB in family meals. These are positive features that have a range of benefits, but repackaging may allow for cost savings due to reduced sharing of this commodity and greater reliance on other fortified products by the nontargeted beneficiaries of CSB and the like. Based on current industrial approach and class of suppliers, it is possible to continue the current packaging in 25-kg bags while building capacity among

private voluntary organizations for repackaging regionally or locally. This has several advantages. First, the current production and milling environment is not modified, and supplier relationships are sustained. Second, packaging size, language, and messaging can be localized. Third, with inexpensive labor available and employment at a premium, this may be less expensive than packaging at the point of production.

On the other hand, repackaging would involve capacity building and quality assurance of the repackaging done by private voluntary organizations, as well as defining financing responsibilities to address extra costs. It should be noted that repackaging is already happening on a serendipitous basis as groups in the field repack CSB due to damage during shipping and, in some cases, do so routinely for programmatic reasons. In some cases, CSB has been repackaged into smaller packs to better suit smaller CSB ration size and because programmers find it more efficient and better utilized and in many cases feel it provides the product with “more dignity.”³² These agencies may be able to provide some estimate of the staffing and management costs associated with repackaging.

For example, WFP in Pakistan reports that 50-kg bags of sugar and 25-kg bags of WSB are routinely repackaged in 3.75-kg bags in order to match planned monthly ration sizes as well as improve hygiene. The small bags cost \$0.05 each, and it takes about 15 days to repack 2100 MT of product at a cost of about \$36/ MT. Smaller bags from the international supplier were bid at about \$80/MT.³³ Similarly, a supplementary feeding program in Kenya reports repackaging into 7.5-kg bags in order to “avoid[ing] scooping at distribution points where beneficiary numbers are high, and ensuring beneficiaries get correct rations.” The cost was estimated at roughly \$31/MT. However, it was noted that “repackaging stopped in a number of districts due to challenges, tonnages were high and repackaging was not fast enough.”³⁴

A second approach to consider is repackaging at the port of entry or regional center. Related to the above option, the approach would continue to use the current class of suppliers and packaging, as well as possibly packaging in 1-MT containerized units or “totes” for repackaging locally. This has some advantages for localized branding and messaging, and may be more efficient. As well as addressing financing needs and liability responsibilities, this involves building capacity for private voluntary organizations receiving Title II shipments at the port and partnering with local industries. Management, quality control, and supervision on the part of the private voluntary organization will be needed.

A third option is domestic toll blending, using a new domestic (U.S.) industrial approach by specifying custom blending. Toll blending companies produce a variety of products, from special cereals to snack foods, and typically offer higher-quality services, quality control, and packaging than the current industrial milling operations.

³² Beatrice Lorge Rogers, personal communication regarding the Implementing Partner Survey.

³³ Jack Bagriansky/Amelia Reese Masterson Survey on Packaging.

³⁴ Jack Bagriansky et al., unpublished survey, 2010.

These companies are available both domestically and at a few key overseas destinations. However, rough estimates suggest these companies will charge \$300/MT more than current suppliers. Packaging in these instances may well require vacuum sealing to prevent damage in intercontinental shipping. Although this would have superior benefits in terms of preserving the product and retaining the nutrients, the cost might be high. WFP currently packages at least some CSB++ in "multi metalized foil" 1.5-kg bags with a supplier in Europe at an estimated incremental cost of \$200/MT.³⁵

Fourth, it is possible to consider upgrading current mill suppliers. Since current suppliers do not service the end consumer and do not have automated packaging equipment, expansion into this value-added area may or may not be possible. The feasibility of this added investment will depend less on the relatively small revenue stream from CSB and more on whether these companies see an opportunity in expanding their capacities and indeed their business model. As in the case above, packaging may well require vacuum sealing to prevent damage in intercontinental shipping. Another potential barrier is the slow throughput of packaging machines relative to the high volume of the milling operations. Investments in high-capacity automatic packaging or form-and-fill line may be as high as \$500,000 for a one-time investment.³⁶

Packaging is a key element in branding—a vehicle to shape perceptions of value about the product inside as well as educate consumers and change behaviors related to product utilization. Enhanced packaging and/or programming might improve the proportion of distributed products actually consumed by the target group.³⁷

We recommend working with partners to develop several focused research proposals, including:

- Pilot and evaluate local repackaging options
- Explore repackaging capacity as part of regional milling contracting
- Develop feasibility of working with a new class of domestic suppliers
- Work with current suppliers to develop feasibility of continuing in current industrial approach with appropriate modification

Based on the results of these R&D activities, it will be possible to undertake larger-scale testing to define improvements in targeting and effectiveness.

To estimate the effect of recommended changes in products and programming approaches on overall intervention costs, seven of the largest (in terms of tonnage) Title II emergency programs in fiscal year 2009 were compared to assess their overall costs under current program expenditures (using current prices) versus potential expenditures following the recommendations made here on upgraded products and

³⁵ Personal communication, Bertrand Salvignol, WFP

³⁶ Personal communication Bertrand Salvignol, WFP

³⁷ Some authors point to smaller packaging as a major factor in reduced sharing of lipid products, while others point to the “dissimilarity” of the food compared with normal diets (Matilsky et al., 2009).

changes to programming approaches (as captured in the decision trees laid out in Appendix 1). Fiscal year 2009 development programs operational in the same countries were also included in the calculation to get a sense of development program costs as well, which increased the number of programs assessed to 10.

Table 3.15 suggests that when rough estimates of actual versus projected costs of programs are used, the net impact of improved products and programs on costs is not hugely higher, despite the expected gains in nutritional benefit. The calculations are based on real commodity and freight prices drawn from averages of fiscal year 2009 commodity prices received from USAID and real ration quantities taken from a number of proposal narratives for each country or implementing partner.

Several factors cause program costs to increase in some countries under the FAQR scenario (i.e., FAQR-recommended rations and commodities per technical sector and target group). First, in programs where CSB13 (the current version) was used for nutritional purposes (i.e., in settings where beneficiaries are screened for malnutrition or where nutritional improvement is an explicit objective), the recommended versions of CSB and WSB raise the cost of product, though not necessarily of programming. Second, in programs that provide whole grains in the ration, the FAQR scenario recommends milling and fortifying those grains, incurring a cost relating to milling, fortification, and bagging. Since the quantity of whole grains provided in emergencies is high in the fiscal year 2009 scenarios considered, this element raises costs, while delivering needed micronutrients to very large numbers (millions) of beneficiaries. Third, because the review recommends serving enhanced FBFs with vegetable oil, the total amount of vegetable oil programmed is (in this calculation) increased if this is necessary to meet recommended preparation levels (15 g vegetable oil for 50 g enhanced FBF).

TABLE 3.15
Program (estimated) cost comparisons under recommended changes to products and programming approaches

Program	Original C&F (1000s)	New C&F with FAQR scenario (1000s)	% change in C&F
Emergency			
DPRK Mercy Corps	45,787.7	47,036.5	2.7
Ethiopia WFP	606,606.9	667,292.4	10.0
Guatemala WFP	25,141.0	25,512.3	1.5
Haiti WFP	71,671.1	88,916.4	24.1
Kenya WFP	87,734.4	87,936.1	0.2
Niger WFP	154,262.2	161,594.5	4.8
Somalia WFP	76,776.3	82,490.1	7.4
Development			
Ethiopia Catholic Relief Services	41,243.3	41,319.5	0.2
Guatemala Mercy Corps	19,295.7	20,884.1	8.2
Haiti World Vision	24,086.1	23,446.9	-2.7

Note: C&F, Commodity and Freight; DPRK, Democratic People's Republic of Korea; WFP, World Food Programme.

However, although some costs increase, a factor causing costs to decrease is the recommendation that enhanced FBFs be used only for nutritional purposes (i.e., in programs targeted to specific, nutritionally vulnerable demographic groups). Therefore, where CSB13 was used in fiscal year 2009 for non-nutritional purposes (e.g., as an incentive or pay), it was replaced in this exercise by less expensive fortified products, such as SFG, or by fortified milled grains (depending upon the country or region and the level of nutrient need determined by FAQR-established criteria). The average increase in cost for the nine programs seeing a rise was 6.6% (or 5.6% when the program seeing a reduced cost is included).

This estimate represents just a first step in what should be a serious process of assessing actual and likely costs of changes in product price and packaging, as well as costs relating to recommended changes in programming—that is, costs per outcome desired, not simply cost per ton of product delivered. Empirical assessment should be conducted of the change in program costs as these recommendations are implemented.

4. OPTIMIZING PROCESSES

How are products modified and new products introduced? This chapter discusses the USAID and USDA intra- and interagency processes involved in Title II food aid product introduction, modification, procurement, and quality assurance and what could be done to optimize and coordinate them more efficiently. The FAQR held multiple individual and group consultations with industry, USAID, USDA, and implementing partner stakeholders with respect to the process component of the FAQR. The input and insights derived from such consultations are reflected in this chapter.

Since the introduction of FBFs in 1964, there have been periodic cross-cutting reviews and recommended modifications to update FBFs and other fortifiable products. Not all recommendations have been adopted, for a variety of reasons.

BOX 4.1

Recommendations/modifications to USAID fortified blended foods 1964–98

December 1964	Ceplapro (formula #1) provided to FFP as an example prototype formula for preschool-age children to overcome malnutrition
Spring 1965	Original formula is revised to include defatted toasted soy flour instead of full-fat; 10% durum wheat flour was also included in this formula
Fall 1965	CSM (formula #2) is introduced, after the following modifications are made: <ul style="list-style-type: none"> • Durum wheat flour is removed • Supplemental copper and manganese are removed to improve stability of labile vitamins, especially vitamin A; • Vitamin C is removed due to uncertainty about its stability
1966	Vitamin C and soy oil are added, after stability tests have been conducted
May 1966	CSM is tested in child feeding programs in India and found to be a suitable supplement in the diets of young children (supplying approximately 25% of total dietary energy)
1966	Food for Peace Act amends P.L. 480, placing greater emphasis on the use of food commodities as nutritional supplements, especially for young children and pregnant and lactating women
1968	Specifications are developed for a wheat-based fortified food (WSM)
Late 1970s	Because of inadequate supply of nonfat dry milk, dried whey is substituted for nonfat dry milk
1980s	CSB and WSB are introduced. Most milk-based products are eliminated from blended food supplements because of high cost and low availability. Adjustments are made to nutrient levels
1988	Vitamin A levels are increased from 1100 to 2000 IU/100 g, based on

1997	recommendations of an expert panel convened by USAID Levels of iron and vitamin C are reviewed by an IOM expert panel, which recommends no change to vitamin C in FBFs
1998	Bagriansky et al. study the potential for fortification of vegetable oil with vitamin A
1998	Magnesium is added, zinc levels are significantly increased, and vitamin B ₁₂ is decreased in CSB and WSB
1998	Vitamin A is added to all refined vegetable oil for PL480

Sources: Bagriansky and Ranum (1998), Combs (1967), Combs et al. (1994), Marchione (2002).

This report reiterates some of these in its product specifications (Chapter 2), programming recommendations (Chapter 3), and process recommendations (this chapter). We will focus here on the USAID- and USDA-commissioned studies of food aid commodities over the past decade. A timeline of recommendations and modifications prior to 1999 is provided in Box 4.1.

The Micronutrient Assessment Project (MAP) (SUSTAIN, 1999b), a three-year study, investigated the stability (from production to consumption) and uniformity of the manufacturing process for key micronutrients added to processed Title II food commodities. The Project focused on vitamin A, niacin, and the mineral iron. Vitamin C was investigated by SUSTAIN and reviewed by the IOM Committee on Food Aid, which found that vitamin C levels were unreliable and concluded that it would not be cost-effective or useful to increase the levels of vitamin C, which therefore remained the same (IOM, 1997).

On the whole, recommendations to improve food aid quality since 1999 have focused on production and meeting micronutrient levels during production, uniformity of product quality and meeting specifications across manufacturers (promoting and enforcing quality assurance, combined addition of vitamins and minerals, and technical assistance to producers), setting minimum (not maximum) levels and markers for testing (for vitamins, vitamin A; for minerals, iron), and optimizing the stability of added vitamins. Most of the MAP report recommendations were met; the most significant in terms of quality assurance was the integration of FBFs in USDA's Total Quality System Audit (TQSA) for 10 years, which was ongoing until 2008 when there was a government-wide shift to make procurement more uniform in compliance with Federal Acquisitions Regulations (FAR).

Some recommendations from the 1999 report have *not* been implemented. These include combining vitamins and minerals into a single premix and enforcing stability specifications on vitamin A required in fortification. Many interests are involved in changes to Title II formulations or specifications, however, so the recommendations are not all easily adopted. For example, combining the vitamin and mineral premixes has not been adopted to date, due in large part to pushback from the U.S. mineral

premix manufacturers. However, new opportunities are emerging to translate proposed (including some past) recommendations into changes in practice.

From 2006 to 2008, SUSTAIN was commissioned by USAID to develop product specification templates, including changes in nomenclature to harmonize the Commodity Requirements documents (SUSTAIN, 2008b). Several templates were produced for different commodities (e.g., bulk grains and fortified blended cereals). However, implementation of suggestions from the report has been slow; it is taking time for the Commodity Requirements (CR) documents to be revised and moved to the USDA Kansas City Commodities Office (KCCO) for translation into bidding specifications. Also, since the report was issued, there have been (and continue to be) significant personnel and management changes, with retirements and reorganization within the USDA Farm Service Agency (FSA) in Washington and the KCCO that may have delayed the process. As of this writing, the first procurement of the Emergency Food Product(s) that USAID would like to purchase to preposition for emergencies is imminent.

4.1 ENHANCED COORDINATION ACROSS THE U.S. FOOD AID SYSTEM

A large number of agencies and stakeholders are involved in food aid today, including FFP, the Office of Foreign Disaster Assistance (OFDA), several agencies within USDA, the Department of Defense, the Food and Drug Administration (FDA), the State Department, USDA, and others, yet the lines of accountability are not always clear or transparent. Currently there is a division of roles and responsibilities between USAID and USDA for the provision and distribution of Title II foods. USDA is responsible for the development of food specifications and provides the quality assurance oversight for the production and shipment of foods. However, the foods are distributed under the oversight of USAID in the field. As nutrition science develops, there will be an increasing need for closer collaboration on a technical level between these two agencies and among other agencies to facilitate the development and review of new products, assess quality, and resolve concerns. This increased collaboration will benefit food aid administered by USDA, which increasingly is exploring the use of new products (e.g., for its McGovern–Dole International Food for Education and Child Nutrition Program).

There is a proliferation of FBFs around the globe (see Chapters 1 and 2), and there are many in use today that would benefit from harmonization. This has created some level of confusion for nongovernmental organizations (NGOs) and beneficiaries in the field. And now, more countries are developing their own local versions of these FBFs. WFP, the user of the largest volume of CSB and WSB, has spent the past several years improving its formulations based on advances in the field of nutrition and food technology to better meet nutritional needs. As a result, WFP and UNICEF have agreed to use the same improved product specifications. This FAQR is USAID's

effort to update its product mix and is recommending similar (but not identical) changes to the Title II versions of CSB and WSB and of other FBFs.

It is therefore recommended that an international effort be made to harmonize and standardize product specifications and profiles, and that the procurement and quality assurance processes be more consistent across sources. For example, USAID could adopt a singular quality system of ISO 2200 (2005) as the uniform standard, as do WFP, UNICEF, Médecins sans Frontières (MSF), and others. USAID could lead or cosponsor with WFP the development of a consultative body and process to bring in the various international stakeholders. This may take some time, as there is a different philosophy in the FAQR proposal for one enhanced CSB product compared with the two-product approach of WFP.

There is a need for a) a transparent mechanism for i) consulting with and soliciting industry input in a timely manner and for ii) industry to consult with USDA as needed to bring up and resolve issues in a timely manner, b) a systematic approach for the development of new FBF products suitable for provision under Title II programs, and c) new mechanisms to promote innovation. This system needs to take into account all aspects of new product development for foods covering both nutrition and food technology aspects. The IOM has put forth a methodology for evaluating the safety of new ingredients in infant formula, for example, that could serve as a model for setting safety standards and requirements when introducing new products designed with specific nutritional purposes (IOM, 2004).

More broadly, USAID should consider new approaches and mechanisms such as “innovations grants,” “open source grants,” and public–private partnerships or Global Development Alliances (GDAs) to solicit the best ideas and partnership from industry to help develop food products and approaches to address the problems of MAM and other priorities as they arise.

Recommendation 30: Establish an Interagency Food Aid Committee. An Interagency Food Aid Committee (IFAC), cochaired by USAID and USDA, is needed to facilitate all-of-government oversight of the increasingly complex food aid agenda. Made up of technical experts from USAID and USDA (as well as WFP and UNICEF), it would facilitate systematic reviews of products and quality assurance systems and would investigate and resolve complaints in a timely manner. Fragmentation of oversight responsibilities across the U.S. Government leads to confusion. It also weakens the potential for enhanced coherence with the U.S. Government’s various global initiatives, to which the FFP and its partners have a lot to contribute. What is needed is a “one-stop shop” for matters dealing with U.S. Government food aid. The FAQR has already begun to hold a series of interagency meetings to foster information exchange and lay the foundation for enhanced communication and collaboration among various agency stakeholders.

Committee representation should be broad, but participants would have expert technical knowledge. The committee would seek regular and substantive involvement of key

technical departments in both USDA and USAID, while also seeking formal representation of FDA, IOM, and the Food and Nutrition Board of the National Academy of Sciences. In addition, the committee would invite as observers key international food aid bodies, including WFP, UNICEF, UNHCR, and IFRC. The goal would be to promote policy alignment, share resources where appropriate (such as in promoting joint public–private partnership initiatives around new product development and testing), and establish a common product review and approval process.

The committee would oversee issues relating to food aid products *and* programming, with a mandate allowing it to a) convene expert panels to address critical questions as they arise; b) commission relevant reviews of the effectiveness of new products in the field (suppliers to demonstrate efficacy and acceptability, while users [implementing partners] should have a voice or a vote on proposals to formally adopt new products); c) support improved communication among industry or suppliers, stakeholders in the field, and other donors; d) play a role in coordinating responses to requests for information from Congress (including coordination of data used in the Foreign Assistance Coordination and Tracking System and playing a more proactive role in informing members of Congress about food aid issues); and e) contribute to the U.S. Government’s determination of “eligible” or “priority” countries (based on food aid needs and consideration of wasting and micronutrient deficiencies, not just the current focus on stunting as the single metric of malnutrition).

4.2 THE CHANGING MARKETPLACE: INCREASED AVAILABILITY OF NEW PRODUCTS

The marketplace is changing, in that there are many new food aid products available or in development. In addition to the family of enhanced CSB, WSB, and FBF products proposed in Chapter 2, there is a growing array of commercial products designed to meet the nutritional needs of, for example, wasted children, pregnant and lactating women, and adults with HIV/AIDS or tuberculosis and other illnesses, which might be of interest to USAID for Title II.

With the expanding use of RUFs for emergencies and blanket seasonal protection against hunger, led by MSF and other advocacy groups, and the increasing availability around the world of a new generation of locally made RUFs, there is pressure on USAID to expand its food aid basket to incorporate such products, especially now that they are being made in the U.S. and could be sourced under Title II. Nutriset certified its first U.S.-based franchisee, Edesia LLC, in 2009³⁸ to make the Plumpy® line of products (Edesia 2010), and other companies, such as Challenge

³⁸ Nutriset has 11 manufacturers in its Plumpy’field network. Edesia LLC. is Nutriset’s first U.S.-based franchisee (Edesia, 2010). A not for profit company based in Rhode Island, Edesia LLC started production of Plumpy’nut™ and Nutributter™ in 2010 and its Nutributter™ product has been approved by USAID for use in private voluntary organization grants under the special conditions of the International Food Relief Program (IFRP) starting in November 2010

Dairy Products Inc., Tabatchnick Fine Foods, Mama Cares, MANA Nutrition, OLAM, and Breedlove, have brought to market or are developing RUTFs and RUSFs in the U.S.

Similar products are being produced in many countries and can be sourced through USAID Title II resources and under PEPFAR (through its separate global supply chain procurement/management system). Nutriset has relaxed its patent licensing process (Nutriset and IRD, 2010), making licensing a simpler, one-stop, on-line process for qualifying local companies and/or joint ventures with at least 51% developing-country shareholders. This allows for North–South joint ventures and partnerships, with industrialized country companies able to hold up to a 49% share in the venture. This could open the door for creative alliances with companies that are expanding their nutrition product and drink markets overseas, with new nutritional products for low-income consumers. Danone SA, as just one example, already receives 41% of its revenue from developing-country sales—in part from its Grameen-Danone Foods Ltd. line of products such as Shokti Doi yogurt (“strengthening yogurt” in Bengali) in Bangladesh (Groupe Danone, 2009; Grameen Danone Foods Ltd., 2010).

Some new products would be desirable additions to the food aid basket today. For reasons described in earlier chapters, these would include product lines such as RUSF and LNS to complement the enhanced CSB and WSB and other FBF products, and point-of-use micronutrient fortificants. An enhancement of the grain value chain is also recommended (important in Feed the Future country initiatives), through small-to large-scale fortification of cereal flours. As evidence grows and USAID priority needs change or new ones arise in the future, it will be important for USAID (and USDA) to have the ability to rapidly introduce modifications or new products into their food aid baskets. The process of getting new products into the approved food aid basket and specified for procurement involves several agencies, many decision-making steps, and systems both bureaucratic and electronic that are not harmonized, up-to-date, or adequately resourced. They are a challenge for new U.S. suppliers to navigate and USAID to manage.

4.3 CURRENT PROCUREMENT PRACTICE

Title II food aid commodity procurement is carried out by USDA through the KCCO, while the PEPFAR program handles all of its procurement (food by prescription, medicines, and other supplies) through a separate mechanism using a private contractor.³⁹ Current Title II procurement practices have been on an open tender, per call-forward basis, meaning that each tender is a new order and any vendor (who finds out about it) can submit a bid. The solicitation and bidding process is electronic

³⁹ PEPFAR uses a private sector procurement mechanism managed by the Partnership in Supply Chain Management (SCMS) for global sourcing and purchase of all supplies, including medicines, equipment, and other supplies. Since 2008, foods such as CSB and WSB and special FBFs have generally been purchased from local vendors at the country level (i.e., not from U.S. suppliers).

(Freight Evaluations Bid Entry System Food Aid Request Entry System [FEBES, FARES]) and vendors must be registered with USDA to get a login and password. Dairy plants must be preapproved for the commodities containing a dairy ingredient in the composition of the product. Similarly, bulk grain vendors must have a Uniform Grain and Rice Storage Agreement (UGRSA) with the Commodity Credit Corporation's (CCC) List of Approved Warehouses, or have a put-through agreement or other means to assure timely delivery through an export elevator.

The number of CSB and WSB manufacturers in the U.S. participating in the program has dropped from ten to three in recent years. Consultations with industry, USAID, and USDA representatives all confirm that the main reason for this decline is the lack of predictability in orders, which does not allow vendors to plan production consistently. Although it is possible to estimate nonemergency needs in the call forwards over the fiscal year (implementing partners include their predicted pipeline needs and timetable in their proposals and reports to FFP) and USAID/USDA posts a schedule of call forward dates, procurements take place with each call forward, not in advance. Further, there are swings in the demand for FBFs. Current vendors consider the incremental business to be relatively low-volume and low-margin and orders for CSB and WSB to be incremental business. This means that they cannot always shift from their regular business to CSB and WSB. Current vendors who are members of the North American Millers Association advise that having a more consistent order requirement would allow them to supply a pipeline on a regular basis, and in cases of urgent need would allow them to meet extra demand in a timely manner.

One way of increasing the vendor base would be to investigate alternative vendors to produce FBFs using dry food blending manufacturers. These could include bakery premix suppliers, custom dry blenders, breakfast cereal manufacturers, and others. This will allow other suppliers to be included in the system. It will also allow USDA-certified suppliers who handle ingredients that are known allergens, such as milk powder products, to be able to supply new versions of CSB and WSB containing milk ingredients.

It is therefore recommended that USDA and USAID develop a broader list of potential vendors to include bakery premix suppliers, custom dry blenders, breakfast cereal manufacturers, etc. Expressions of Interest should be sent to the broad list to assess new potential vendors.

Appendix 10 depicts a five-part, multistep procurement process that begins with Project Approval (Part 1), in which the NGO prepares, submits, and receives approval for its proposal (USDA and USAID programs). Once the budget, commodity mix, and timetable for call forward are approved, the actual Procurement Process (Part 2) begins. Please see Appendix 10 for a detailed flow chart, with explanations, of this process.

There have been many changes within the U.S. Government procurement systems in recent years, some of which have had a major impact on commodity procurement and

quality assurance, affecting both USDA and USAID programs. This is in large part because one office, the USDA Kansas City Commodities Office (KCCO) is the procurement arm for *all* programs, purchasing processed products and bulk commodities for the domestic programs administered by the USDA Food and Nutrition Service (FNS), the USDA McGovern–Dole International Food for Education and Child Nutrition Program and the Food for Progress Program administered by the USDA Foreign Agriculture Service (FAS), and the USAID/FFP-administered Title II Program.

In 2008, KCCO continued to refine its processes and contract requirements based on Federal Acquisitions Regulations (FAR) policies and advice of counsel. These included modifications in vendor qualification requirements, including removal of the preaward Total Quality Assurance Systems Audit (TQSA), inclusion of trade agreements clauses for commodity packaging, and requirement of proof of delivery, rather than shipment, prior to invoice payment. Procurement Integrity Act considerations and advice of Department of Ethics Officers led to reduced communication with suppliers and industry representatives (including USDA Cooperators).⁴⁰ Utilization of other FAR-recognized procurement methods and contract types allowed for the move toward Request for Proposal (RFP) and Indefinite Quantity Contract (IQC) mechanisms.

In terms of quality assurance, FAR policies resulted in the replacement of the preaward TQSA program that had been implemented for food aid commodity manufacture and procurement, following the recommendations of SUSTAIN (1999 and 2001), and had been assuring the quality of food aid commodity production for 10 years (SUSTAIN, 1999b, 2001b)⁴¹ Under the TQSA program, vendors became approved once their plants had been certified by USDA (or FDA in some cases). They then needed only to provide a Certificate of Assurance indicating that they continued to meet those preapproved standards when they bid on a USDA invitation. If they did not meet the contract requirements, as determined by government audit, the vendor was penalized by a deduction from payment. No actual vendor disqualification criteria were applied, such as “zero tolerance” or “three strikes and you are out,” so it was particularly important to resolve quality problems that might arise. When the TQSA was dropped, government contract quality assurance was implemented after award of the contract, pursuant to FAR Part 46. In September 2009, USDA addressed this gap by changing the CSB quality assurance program and the testing methods. It went back to the government inspection process it had used prior to TQSA, which requires that a USDA inspector be present at the manufacturer’s plant when CSB is being produced.

⁴⁰ USDA Cooperators include agriculture and food industry trade associations such as the American Soybean Association, the North American Millers Association, and the many others representing stakeholders among food aid commodity producers and suppliers.

⁴¹ SUSTAIN (1999b, 2001b) made a series of recommendations to improve food aid quality that involved bringing the procurement of food aid commodities into compliance with the TQSA system. All of those recommendations were adopted and have been implemented successfully for 10 years.

Only CSB and WSB are subject to government sampling and testing at this time, but it could be required for potential new specialized nutritional products such as LNS (which would include dairy). Other products are not being inspected by USDA. USDA is relying on Certificates of Assurance (COAs) as the quality control for other FBFs and commodities. The draft RFPs that were out for comment move the Federal Grain Inspection Service (FGIS) back into the quality control process. Past experience has shown that vendors rely on FGIS for their quality control. There are a limited number of USDA inspectors who can perform such inspections, and this problem may need to be addressed as products with more stringent production requirements are added to the food aid basket. However, FSA does not have the funds to pay for government sampling and testing for product conformance. There needs to be a budget to go along with this change if quality is to be assured.

KCCO is moving toward the use of negotiated procurements and requests for proposals, as permitted by the FAR. The intention is to award indefinite delivery/indefinite quantity (ID/IQ) contracts and conduct competitions between contract holders for the award of delivery orders. The use of delivery order competitions will allow the government to utilize not only price, but also technical evaluation factors in providing contractors with the fair opportunity to compete for delivery orders. Food commodity prices are volatile, and the spot price for wheat or corn can change several times in a day, so the time during which a bid is required to be held is an issue for suppliers. The delivery order competitions to be conducted under the ID/IQ contracts are intended to be structured in a way that preserves the short time frame between the due date for the delivery order offer and the award of delivery order. According to USDA (Interagency consultations, KCCO and FSA communications, September 2010), this Indefinite Quality Contract (IQC) process will allow the USDA procurement office to be more stringent in terms of enforcement and exclusion of nonperforming suppliers, which should reduce problems of noncompliance. This system also paves the way for incorporating performance-based product specifications, once a procedure for developing them fairly and transparently is developed and instituted.

4.4 NEW PRODUCT INTRODUCTION AND MODIFICATION

The system for introduction and review of new Title II products involves many steps and several offices within USAID and USDA. Although new product introductions can be internally generated as needs arise, there continues to be external pressure on FFP to adopt “new” products. Most of the pressure is driven by suppliers and the food industry, with companies approaching FFP and USDA on an ad hoc basis with ideas for new products. It is not clear that these products respond to a felt need on the part of the agencies that will use them. Even when internally generated (within the community of U.S. Government food aid programs and implementing partners), the process of approval can take years. For example, it has taken 10 years (2001 to 2011)

from concept to procurement of an Emergency Food Product (EFP) line of paste and bars for early-stage emergencies. Many commercial products are already available or in development that could be of interest to Title II. There is, therefore, an urgent need for a more streamlined process for approval of new or modified products that is clear, straightforward, transparent, and timely. Further, there is a need to assess the nutrient compositions of approved food aid products in light of emerging scientific evidence and evolving target group needs. We recommend the establishment of a formal, systematic process for ongoing, rather than repeated, periodic ad hoc reviews of issues around product composition.

BOX 4.2
INTRODUCTION OF EMERGENCY FOOD PRODUCT (EFP)

Need: USAID/FFP wanted to develop a U.S.-made Emergency Food Product (EFP) to replace its dependence on foreign-made BP-5 bars and other emergency High Energy Biscuits used in the first weeks of emergencies.

Timeline: In 2001, FFP commissioned the IOM to develop specifications for such a product (IOM, 2002) and then asked the Department of Defense to develop three prototype EFPs, a rice-based bar, a wheat-based bar, and a paste, which it did in 2003/04. Acceptability studies were carried out by the Academy for Educational Development in 2005/06. Product specification documents were initiated by USDA in 2009, and the Commercial Item Description (CID) was developed in 2009/10. At the time of this writing, the Commodity Requirements (CR) document was under review, with the first procurement slated to take place in 2011.

In 2004, FFP introduced the New Commodity Proposal (NCP) process and updated its system for review as follows. Typically, a U.S.-based entity with a product it wants FFP to consider must make an inquiry to FFP that provides an NCP application and checklist within 5 days (it is not available on the Web). The applicant submits the NCP, which FFP forwards to the Technical Review Committee.⁴² The committee members include “representatives from the U.S. Department of Agriculture (USDA), USAID's nutrition advisors in FFP's Policy/Tech Division, the Office of Policy and Program Management (PPM), FANTA, the GH/HIDN Office, and the World Food Programme (WFP) Headquarters' Office in Washington, D.C.” (New Commodity Proposal Checklist, 2010; see Appendix 9). The application requests product information such as country of origin, ingredients, and packaging; processing method and manufacturing capability in the U.S.; composition, including all micronutrient and macronutrients; special packaging and shipping requirements; expected shelf life; assurance that process and formulations are not proprietary; reports on prior use; and expected price. It should be noted that all food products are required to be prepared solely from ingredients and raw materials of U.S. origin.

NCP applications are accepted ad hoc and are reviewed whenever they are filed. The Technical Review Committee reviews the proposal within 30 days of receipt, and the applicant is notified within 5 days of the review whether the proposal is accepted or rejected. The applicant may be requested to provide additional information, with ensuing back and forth communication until USAID's concerns are addressed

⁴² The USAID process was introduced in 2004 and modeled after the WFP process whereby new commodity proposals are submitted and reviewed by a Technical Advisory Group (TAG) process.

satisfactorily. Once a positive determination is made, the applicant receives a letter (within 5 days) from the head of FFP stating that its product has been accepted. At the same time, USAID notifies the FSA and KCCO to be ready to prepare the appropriate commodity specification documents (Commercial Item Description [CID] and/or Commodity Requirements [CR] documents) for eventual product procurement. There is no specified timetable for the completion of the CID and CR. Approved items are added to the Title II approved commodity list, which is updated annually and provided to private voluntary organizations as part of the Title II Emergency and Non-Emergency proposal guidance. Additionally, the vendor or industry group must provide a price per metric ton, projected over several years, for FFP to include in its price list of Title II products (which also is updated quarterly).

Once the commodity or product is approved, there is no guarantee that implementing partners will order it. The word needs to be spread to the implementing partner decision-makers that the product is available for inclusion in emergency and development program proposals; it needs to have all the USDA specification documents completed for procurement, and be appropriately listed and included in the Title II Ration Calculator. There is no systematic announcement to the field or posting on USAID's website that a new product is now available. In many instances, the company or industry trade group has not gotten sufficient prior backing of the private voluntary organizations in advance of its application and must "market" their product to the implementing partners to create demand. This is a costly and time-consuming effort. There are several criteria that implementing partners look for in a product, including (not in any special order of priority) a product "fit for purpose"; nutritional quality; price point; packaging (size, material, etc.); ease of shipping, handling, storage, and use; preparation requirements (e.g., fuel, water, and/or other resources and ingredients for preparation, if any); cultural appropriateness; and demonstrated successful use in similar programs. Several products have been approved but never purchased because of lack of demand, high price point, or lack of supplier response when the tender comes out. In the latter case, the implementing partner must select an alternative, which can cause delays and possible pipeline breaks. All these factors combine to create a situation in which implementing partners tend to opt for tried and true options for their commodity baskets, leaving out a variety of lesser-known alternatives that have been approved.

Recommendation 31: Establish a formal product review and approval process.

Under the auspices of the proposed IFAC (above), a new multistakeholder working group would deal with technical and scientific review of existing and proposed new and modified products. This technical subcommittee would ensure that scientific and technological advances, new developments in programming, and emerging nutritional and food security considerations are reviewed on a systematic, ongoing basis and applied to the design of food aid programs as appropriate. This process or system should be co-owned and cofunded with relevant United Nations agencies, with a view to moving toward convergence on specifications for, and guidance in the usage of, nutritionally enhanced food aid products.

The review and approval process would need to include the following elements: a) A jointly funded and “owned” external (outside the U.S. Government) Interagency Technical Advisory Group (ITAG) should be established that would serve the U.S. Government (including representation from key offices and divisions within USAID, USDA, the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and FDA, as appropriate, but also WFP and other relevant agencies) as a “one-stop global shop” mechanism for product (or ingredient) review and approval. b) The review and approval process should be of industry standard in terms of pace of response to interested parties. A transparent timeline (deadline) for decision making should be established and communicated. c) The ITAG would offer publicly accessible generic feedback (open guidance) relating to products reviewed and problems encountered. Reviews would be blind, but communication to applicants about why decisions were made, suggestions for avoiding delays in review, future challenges likely to be faced, etc. would be a valuable mechanism for public–private engagement around product development. The approval process for new products should be no more complex and cumbersome than that in the commercial sector and should be standardized with the approval processes of WFP and UNICEF, so that a single approval would be deemed sufficient by the other partners (and review of products already approved by one of the other agencies would be expedited). The process for approval of single ingredients should be distinct from the process for approval of multiple-ingredient (processed) products. A confidential, reciprocal approach to auditing of suppliers (plant and laboratory inspections) would allow for sharing of knowledge and costs (avoiding multiple audits or demands for information from the same suppliers) and identification of capacity gaps requiring attention.

Although it is desirable to develop specifications for the nutritional composition of finished products, performance-based specifications, with penalties for nonperformance, need to be developed based on industry standards of private-sector procurement processes. Steps should be taken, with input from industry, to move toward performance-based specifications and appropriate sanctions for noncompliance. Input from the field should be taken into account when new products are proposed, and a system should be established to facilitate such input, including comments on proposed products and a system for requesting the development of products or product modifications to meet the program needs of the agencies.

It is important, too, that USAID’s implementing partners be aware of these changes. There should be an announcement sent to all PL 480 stakeholders, possibly through the Food Aid Consultative Group (FACG) distribution list, when a new commodity has been approved, complete with timetable for possible procurement.

USAID should assist USDA to make the process of CID and CR document preparation more transparent, including setting up a one-stop shop on USDA’s website to provide information to vendors and industry about the specific steps and contact persons for the development of these product specification documents, and to provide links to them on the USAID website. A Frequently Asked Questions and a link to request more information on the USDA website would be useful. USDA

should set up a timetable for the development of the CID and CR documents (i.e., within 45 or 90 days of reception of the request by the USDA entity) and incorporate consultation with industry and manufacturers to make sure that composition, quality, packaging, and other processes are feasible and, where appropriate, meet industry best practices.

Recommendation 32: Establish performance-based specifications (i.e., basic nutritional profiles of final products) for nutritionally enhanced products.

Lowest cost is not always compatible with best value (when food safety or other quality problems arise), let alone with nutritional quality. “No tolerance” rules should be established for suppliers such that minimum quality is maintained. More than one third of complaints about commodities and products reported by SUSTAIN (2006) related to CSB; another 20% focused on oil, with 10% concerning SFB and fortified cornmeal. Complaints about CSB quality mostly concerned shelf life and organoleptic issues. Ingredient and nutrition composition should be described on labels affixed to product containers for nutritionally enhanced products to enhance transparency of information about food content.

Complaints about the quality of vegetable oil concerned the packaging strength of metal containers. A number of these issues have been resolved and prevented through new procurement specifications and quality control measures in recent years. Vendor specifications should include rigorous performance criteria with penalties for nonconformance, including potential exclusion from subsequent tender bids for a predetermined period (a “time-out” clause). The use of price discounts for substandard processed food should be discontinued.

The number of FBF manufacturers in the U.S. has fallen considerably in recent years. Consultations with industry, USAID, and USDA representatives all confirm that the main reason for this decline is the lack of predictability in orders, which does not allow vendors to plan production consistently. Current vendors who are members of the North American Millers Association note that having a more consistent order requirement would allow them to supply a pipeline on a regular basis, and in cases of urgent need would allow them to meet extra demand in a timely manner.

One way of increasing the vendor base would be to investigate alternative vendors to produce FBFs, such as dry food blending manufacturers. These could include bakery premix suppliers, custom dry blenders, breakfast cereal manufacturers, etc. Consideration should be given to the development of annual supply contracts for CSB and WSB that would include periodic regular delivery of foods into the pipeline and prepositioning of stockpiles for emergencies. These measures would apply to other FBFs and specialized products that are needed on a relatively small tonnage basis. It should be noted that once the effectiveness of reformulated FBFs used in enhanced programming contexts delivers improved outcomes, field demand for FBFs would increase, leading to a need for increased, not just enhanced, output.

Recommendation 33: Develop a planning model that would better predict demand for FBFs and support longer vendor contracts for value-added commodities. The current procurement system is widely perceived as lacking transparency and consistency. It is also seen as too short-term in the specification of contracts. A lack of predictability in demand, together with cost inefficiencies arising from unsecured contracts over the longer term, results in waning interest among vendors and leads to concerns about the supply of quality products. Planning is not easy for existing vendors, and new vendors are put off by their perception that procurement processes are unwieldy and inconsistent. Revising the procurement system to allow for 12- to 18-month contracts based on a fixed volume rather than batch-by-batch tenders and prepositioning of emergency stockpiles of FBFs for rapid deployment would permit more predictable contracts.

4.5 QUALITY ASSURANCE

Dealing with problem products is a lengthy process, involving many supply chain steps along the value chain. Recent negative experiences with certain products, the complexity of tracing responsibility, the lack of timeliness, and the cost of problem solving have all contributed to a less than optimal process. USAID and USDA have developed a feedback loop, but it is complicated and there is no definitive feedback to the companies or the implementing partners in the field that the problem has been resolved and that the supplier and product have been cleared; as a result, to industry and implementers alike, there seems to be no closure. Timing also has proven to be a constraint. Contract requirements are very tight, with vessels booked and penalties for late shipment. Any delay costs vendors dearly, and serious quality problems cause serious problems for all involved in the supply chain from vendor to recipient. Several of the recommendations made below have been made before by SUSTAIN.

Recommendation 34: Design and implement a comprehensive food aid quality assurance strategy and plan of action. With increasing public concerns about food safety, growing international scrutiny of food aid products, and continued problems with the quality of certain batches, it is important for USAID and USDA to work together to establish transparent and rigorous mechanisms for oversight of quality throughout the food aid commodity supply chain.

This should include the following elements. First, a raw materials quality assurance system has to be developed, including mycotoxin monitoring, with required testing by millers or required certificates of assurance from suppliers for susceptible products. Nutritionally enhanced foods should be manufactured in plants that use food-based quality systems such as Good Manufacturing Practices (GMP) and/or Hazard Analysis and Critical Control Points (HACCP) that are common in private sector food manufacturing. Standardized and transparent methods for batch and laboratory testing and reporting and guidance on how to deal with suspected problems are priorities. Second, vendor specifications should include rigorous performance criteria with penalties for nonconformance, including exclusion from future tender participation

until certain criteria are met. Third, a new approach is needed to quality control via site inspections, whereby plants producing value-added foods would be subject to FDA quality standards and inspections. Premix producers and analytical laboratories should also be audited. Fourth, clear sampling and testing procedures, with defined responsibilities for agencies and industries, are essential, including defined steps for the assessment of problem batches of products. Detailed sampling procedures and analytical parameters must be laid out clearly. Methods to achieve representative sampling of lots are critical, and sufficient quantities must be retained (separately, rather than mixed) to allow validation testing at accredited laboratories.

Recommendation 35: Update the Commodities Reference Guide (CRG) and establish a process for regular updating and communication. A major overhaul of the CRG is needed to correct inconsistencies and errors of fact, fill in missing data, and ensure that the guide serves the purpose for which it was intended. Responsibility for maintaining (updating and correcting) the CRG should be clearly defined. Commodity groups and industry, as well as scientific experts, should be brought into this process of overhauling current information. Inconsistencies between USDA's food reference database and alternative sources of nutrient composition should be investigated, and major differences should be clearly flagged and explained.

There are several lists of title II commodities, but they are not all complete and do not always match. These include the list of Title II Value Added Products in an Appendix to the MYAP guidance; the drop-down menu for the commodity calculator that is included in the proposal submission; the Price List of Title II Commodities; and the list of commodities in the CRG, FFP's major Web-based reference for Title II. Not all products procured by the programs are included, and new products that are approved generally do not make it to the CRG, so it is difficult for the implementing partners to know in full what is actually available under Title II. There is no system for new products to get on all lists simultaneously.

The CRG was introduced in 1988 with two sections: Part 1 on Commodities, including Commodity Fact Sheets on many, but not all, approved Title II commodities; and Part 2 on Programming. In 1999/2000, both sections were updated and turned into a Web-based document. The most recent update of many sections seems to have been in 2006, with some updated in 2008. The Commodities section (Part 1) was streamlined, harmonized, and expanded. Changes in specific commodities were included, e.g., "Peas and Beans" had been combined on one sheet in the original version. Peas were split into individual sheets for yellow peas and green peas. Individual sheets were introduced for each of the eight varieties of available beans, so it became possible to order the variety that is most culturally appropriate for the setting (e.g., Great Northern beans for Kosovo, where people like a large white bean, and black beans for Guatemala). In 2007/08 Corn-Soy Milk (CSM) and Wheat-Soy Milk (WSM) were added back to the CRG, after having been dropped for several years. However, products such as dehydrated potato flakes and granules, which were approved in 2005 and have been procured for Title II since 2007 (Africare was the first implementing partner to include 70 MT of dehydrated

potato flakes in its Title II project in Burkina Faso), were never added to the CRG. In 2010, several new products were approved, e.g., Whey Protein Concentrate 34 and 80 (WPC34 and WPC80), which have not yet been ordered under Title II.

When it was developed and first posted to the Web, the CRG served as a one-stop site for the implementing partners on Title II commodities and programming. The CRG is updated intermittently, when requested by FFP, to reflect commodity specification changes, new commodity additions, or program requirements (see Chapter 3 for a discussion of programming guidance and its evolution). Updates have been on hold while this FAQR was under way. However, as a go-to document on the USAID website, the CRG needs to have the most current information on product specifications and program guidance for the use of implementing partners and interested parties.

5. CONCLUSIONS

USAID and its food aid partners carry out very effective work around the globe in harsh and difficult settings. Food delivered is saving lives and promoting development in diverse contexts. The instances of serious systems failure are remarkably few, given the tonnage of food shipped, the range of implementing partners involved, and the number of beneficiaries reached. However, this does not diminish the importance of seeking to enhance all aspects of quality assurance and control and of ensuring that such efforts become systematized, rather than pursued periodically in an ad hoc manner. Improvements in products developed, modified, and used and in the ways that FFP carries out its business will be important for future success.

It is increasingly accepted that food aid has a part to play in addressing certain categories of nutrition problems in developing countries. Its role is not simply to “feed hungry people” in a generic sense, but to address specific needs of vulnerable people in both emergency and nonemergency settings where food is the optimal resource to use. High-quality bulk grains moved quickly to feed very large numbers of people in emergency contexts are, and will remain, important; so too are nutritionally enhanced products targeted to smaller numbers of particularly nutritionally vulnerable individuals. All need nutritionally appropriate foods of the best quality. Cost-effective programming requires the optimal delivery of appropriate *combinations* of foods so that defined nutrition goals can be achieved. In this sense, the measure of success relates less to tonnage of commodities moved than to desired outcomes achieved.

Upgraded FBFs, programmed appropriately and consumed in expected amounts, would support the programmatic goals of management of moderate wasting (targeted supplementary feeding); support for MCHN, including growth promotion and the prevention of stunting (PM2A and other operations reaching mother and infant pairs); and the management of nutrition among persons with HIV/AIDS or tuberculosis. Such programming goals cut across the conventional emergency/development funding envelopes. Other than lifesaving or life-supporting products intended for immediate response to humanitarian crises (such as humanitarian daily rations or emergency food bars), FBFs are not tailored for emergency or development settings but rather for specific goals within either setting.

That said, no one product can be effective for every purpose in every setting, regardless of how much it is enhanced and fine-tuned. Although products can be optimized in terms of a tradeoff between nutrient composition and cost, no food can fulfill all nutrient requirements of all potential beneficiaries over time. This necessitates tailoring of products to purpose and greater attention to the contribution of individual products in the context of whole diets.

As a result, improving food aid quality means not only fine-tuning the composition of products; it is equally about appropriate programming of those products. Not only must food aid be fit for purpose—nutritionally adequate for its intended purpose, safe, and culturally appropriate—but programming must also be appropriate to the products selected. Product formulation is not the only, or even always the most important, factor in achieving nutritional impact. This field has been characterized by debate over inclusion of one micronutrient over another, or levels of nutrients defined in micrograms, yet programming matters at least as much as product quality.

Finally, effective programming requires supportive institutional processes. Enhanced oversight of, and coordination across, the entire food assistance endeavor is needed, not simply to enhance and protect the quality of products delivered, but to generate value added from an all-of-government approach that sees food aid as one key instrument in a more united approach to increasing food security around the world and finally conquering hunger.

ABBREVIATIONS AND ACRONYMS

AACC	American Association of Clinical Chemists
ACDI/VOCA	Agricultural Cooperative Development International/Volunteers in Overseas Cooperative Assistance
ACF	Action Contre la Faim
ADRA	Adventist Development and Relief Agency
AER	Annual Estimate of Requirements
AI	Adequate Intake
AID TRANS	USAIDs Transportation Department
ANC	antenatal care
ART	antiretroviral therapy
BCAA	branched-chain amino acid
BCC	Behavior Change Communication
BMI	body mass index
CCC	Commodity Credit Corporation
CDC	Centers for Disease Control and Prevention
C&F	Commodity and Freight
CI	confidence interval
CID	Commercial Item Description
CMAM	Community-Based Management of Acute Malnutrition
COAs	Certificates of Assurance
CR	Commodity Requirements
CRD	Commodity Requirements Document
CRG	Commodities Reference Guide
CRS	Catholic Relief Services
CSB	Corn–Soy Blend
CSB+	Corn–Soy Blend Plus
CSB++	Corn–Soy Blend Plus Plus
CSB13	Corn–Soy Blend Version 13
CSB14	Corn–Soy Blend Version 14
CSM	Corn–Soy Milk
CWS	Cold Water Soluble
DCHA	Bureau for Democracy, Conflict and Humanitarian Assistance
DPRK	Democratic People’s Republic of Korea
DRI	Dietary Reference Intake
DSMP	dried skimmed milk powder
ENN	Emergency Nutrition Network
FACG	Food Aid Consultative Group
FAM	Food Aid Management
FAO	Food and Agriculture Organization
FAQR	Food Aid Quality Review
FAR	Federal Acquisitions Regulations (FAR)
FARES	Food Aid Request Entry System
FAS	Foreign Agriculture Service (USDA)

FBF	Fortified Blended Food (a generic term that includes CSB and WSB, but is not limited to those products. It also includes fortified cereal blends such as soy-fortified bulgur, for example)
FBP	Food by Prescription
FDA	Food and Drug Administration
FEBES	Freight Evaluations Bid Entry System
FFA	Food for Assets
FFE	Food for Education and Child Nutrition
FFI	Flour Fortification Initiative
FFP	Office of Food for Peace (USAID)
FFT	Food for Training
FFW	Food for Work
FSA	Farm Service Agency
FGIS	Federal Grain Inspection Service
FVO	Fortified Vegetable Oil
GAIN	Global Alliance for Improved Nutrition
GAO	U.S. Government Accountability Office
GDA	Global Development Alliance
GMP	Good Manufacturing Practices
GRAS	Generally Recognized as Safe
HAART	Highly Active Antiretroviral Treatment
HACCP	Hazard Analysis and Critical Control Points
HAZ	height-for-age z-score
HCV	hepatitis C virus
HDR	Humanitarian Daily Rations
HDV	Hepatitis delta virus
HEB	High-Energy Biscuit
HEPS	High Energy Protein Supplement
HOMA-IR	Homeostasis Model of Assessment - Insulin Resistance
HUB Zone	Historically Underutilized Business Zone
IBFAN	International Baby Food Action Network
ICDS	Integrated Child Development Service
ICRC	International Committee of the Red Cross
ID/IQ	indefinite delivery/indefinite quantity
IFAC	Interagency Food Aid Committee
IFPRI	International Food Policy Research Institute
IFRC	International Federation of Red Cross and Red Crescent Societies
IFRP	International Food Relief Program
IOM	Institute of Medicine
IQC	Indefinite Quantity Contract
IQR	Inter-quartile range
ITAG	Interagency Technical Advisory Group
KCCO	Kansas City Commodities Office
LAZ	length-for-age z-score
LBW	low birth weight
LGA	large for gestational age

LIFT	Livelihood and Food Security Technical Assistance
LNS	Lipid-Based Nutrient Supplement
LOAEL	Lowest Observed Adverse Effect Level
MAM	Moderate Acute Malnutrition
MCH	Maternal and Child Health
MCHN	Maternal and Child Health and Nutrition
MNP	Micronutrient Powder
MREs	Meals Ready to Eat
MSF	Médecins sans Frontières
MT	metric ton
MUAC	mid-upper-arm circumference
MYAP	Multi-Year Assistance Program
NCP	New Commodity Proposal
NACS	Nutrition Assessment, Counseling, and Support
NaFeEDTA	sodium iron ethylenediaminetetraacetate
NGO	nongovernmental organization
NIFA	National Institute of Food and Agriculture (USDA)
NIH	National Institutes of Health
NOAEL	No Observed Adverse Effect Level
NRU	Nutrition Rehabilitation Unit
OFDA	Office of Foreign Disaster Assistance
OR	odds ratio
OVCs	orphans and vulnerable children
PDCAAS	Protein Digestibility Corrected Amino Acid Score
P/E	protein/energy
PEPFAR	President's Emergency Fund for AIDS Relief in Africa
PHA	Phytohemagglutinin
PI	Principal Investigator
PLW	pregnant and lactating women
PLHIV	people living with HIV/AIDS
PM2A	Prevention of Malnutrition in Children Under Two Approach
PMTCT	prevention of mother-to-child transmission
PREP	Pipeline and Resources Estimate Proposal
RDA	Recommended Dietary Allowance (for meeting individual needs)
RDI	Recommended Dietary Intake.
RFP	Request for Proposal
RNI	Recommended Nutrient Intake
RUF	Ready-to-Use Food,
RUSF	Ready-to-Use Supplementary Food
RUTF	Ready-to-Use Therapeutic Food
SAM	Severe Acute Malnutrition
SCSM	Partnership in Supply Chain Management
SFB	Soy-Fortified Bulgur
SFCM	Soy-Fortified Cornmeal
SFG	Soy-Fortified Grits
SGA	small for gestational age

SFP	supplementary feeding program
SSL	steam ship lines
SUSTAIN	Sharing and Utilizing Science and Technology to Aid in the Improvement of Nutrition
SYAP	Single-Year Assistance Program
TAG	Technical Advisory Group
TQSA	Total Quality System Audit
UGRSA	Uniform Grain and Rice Storage Agreement
UL	Safe Upper Level
UNHCR	United Nations High Commissioner for Refugees
UNICEF	United Nations Children's Fund
UNSCN	United Nations Standing Committee on Nutrition
UNU	United Nations University
USAID	United States Agency for International Development
USDA	United States Department of Agriculture
WASH	Water and Sanitation Hygiene
WAZ	weight-for-age z-score
WBSCM	Web Based Supply Chain Management
WFP	World Food Programme
WHO	World Health Organization
WHZ	weight-for-height z-score
WLZ	weight-for-length z-score
WPC	Whey Protein Concentrate
WPC80	Whey Protein Concentrate 80%
WSB	Wheat-Soy Blend
WSB15	Wheat-Soy Blend version 15
WSB16	Wheat-Soy Blend version 16
WSM	Wheat-Soy Milk

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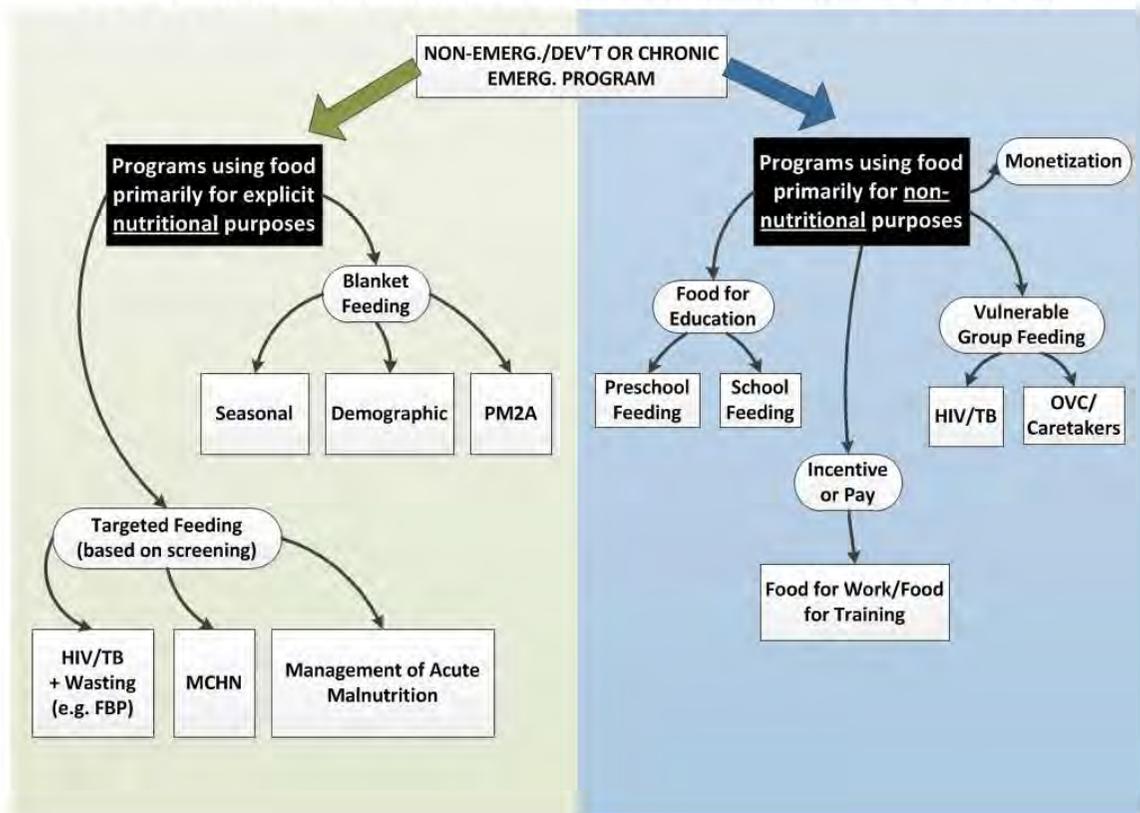
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APPENDICES

Appendix I: Enhanced Program Guidance: Decision Trees and Flow Charts

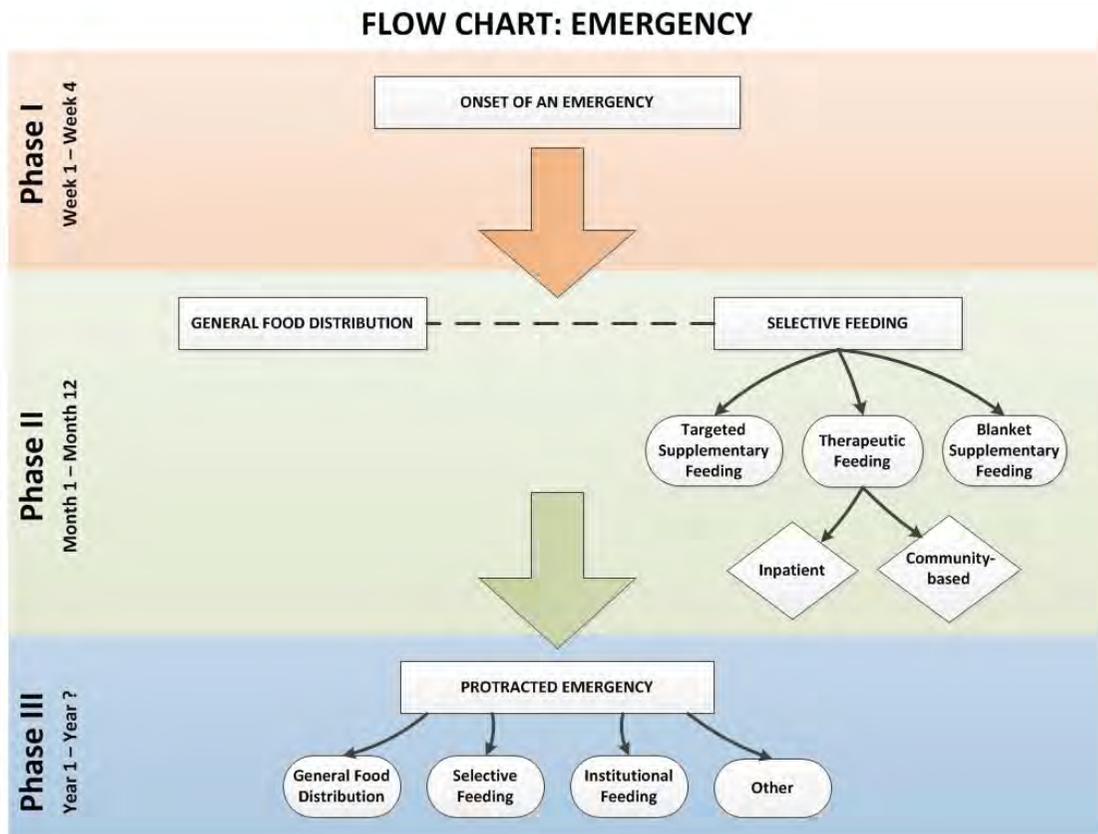
FLOW CHART: NON-EMERGENCY/DEV'T or CHRONIC EMERGENCY



Note: FBP, Food by Prescription; FFE, Food for Education and Child Nutrition; FFT, Food for Training; FFW, Food for Work; MCHN, Maternal and Child Health and Nutrition; OVCs, orphans and vulnerable children; PM2A, Prevention of Malnutrition in Children Under Two Approach.

This figure shows the decision-making process guiding the use of food in various types of nonemergency programs. Among these, we can distinguish between programs in which food is used primarily for nutritional purposes, that is, to prevent or address undernutrition (wasting, stunting, and, less often, the prevalence of deficiencies of micronutrients such as iron, vitamin A, and others) and those in which food is used as compensation, as incentive or pay, or to meet general household food needs in highly food-insecure households. In programs with explicit nutritional goals, blanket feeding is the approach that provides supplementary food to all individuals in the high-risk categories. In addition to blanket feeding as a preventive strategy, some programs use nutritional screening as a basis for the provision of supplementary food, due to the cost and intensity of treatment.

On the right of the diagram, the graphic describes programs in which food is used primarily for non-nutritional purposes. These uses include food for education, food as pay in FFW and FFT programs, and vulnerable group feeding, in which food is provided to households that are at exceedingly high risk for food insecurity. In these cases, use of specialized, nutrient-dense products such as CSB14 or LNS is not appropriate, and distribution of improved basic staples is recommended where possible.

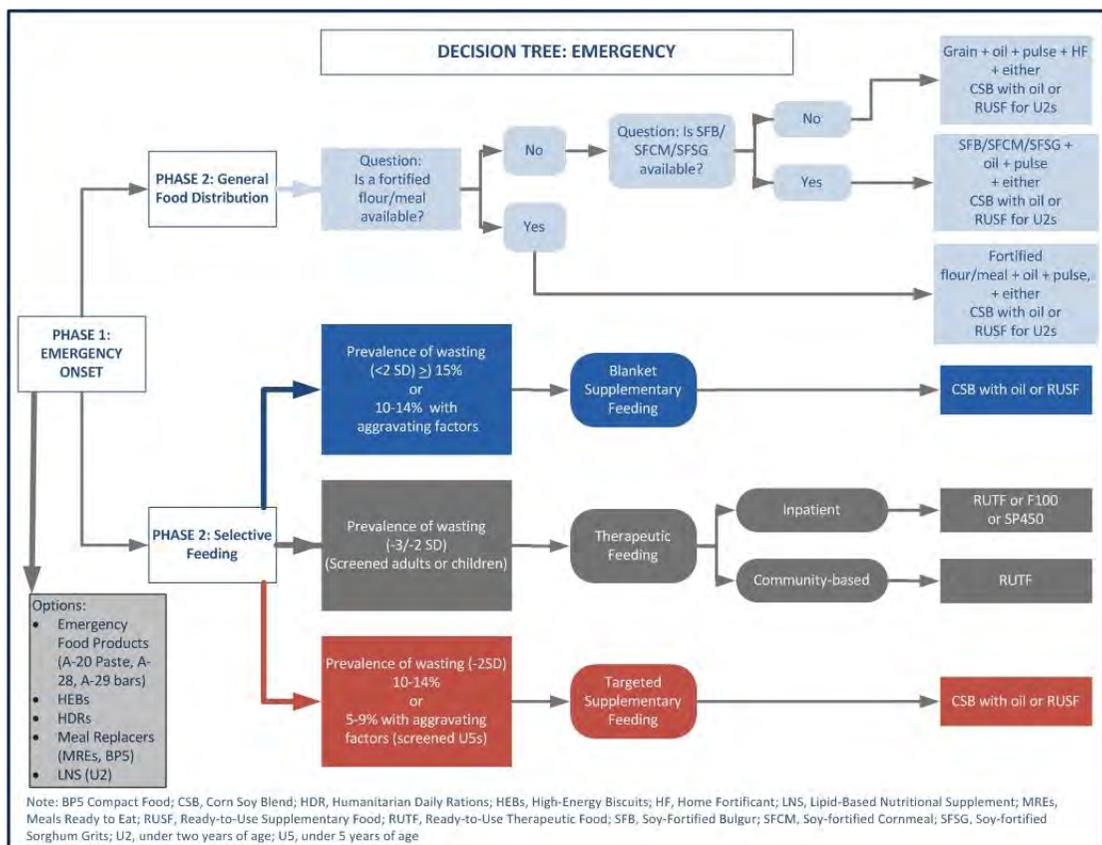


This figure emphasizes that the choices available in emergencies vary depending on the phase of the emergency. In the first few weeks of an emergency, whether due to conflict or natural disaster, the goal is to address immediate threats to survival. Provision of food is often restricted to easily transportable emergency rations. As the emergency situation stabilizes, maintenance of the threatened or displaced population becomes the priority, making use of general food distribution to households that have lost their access to food supplies and selective feeding of individuals at high risk for nutritional deficiency.

Selective feeding is feeding that is targeted on the basis of nutritional risk (defined in terms of age and physiologic or disease status) or nutritional condition. Blanket

feeding is based on risk category; it is targeted on the basis of age and physiologic or disease status, but not on the basis of anthropometric screening for wasting or stunting. Some programs make use of nutritional screening of these high-risk groups to determine who receives the specialized, nutrient-dense supplementary food, particularly in situations where resources do not permit blanket feeding based on risk category alone. Therapeutic feeding of children or older wasted individuals suffering from SAM is delivered according to a medical model of treatment, whether it is clinic or community based, and is by definition based on nutritional (anthropometric) screening.

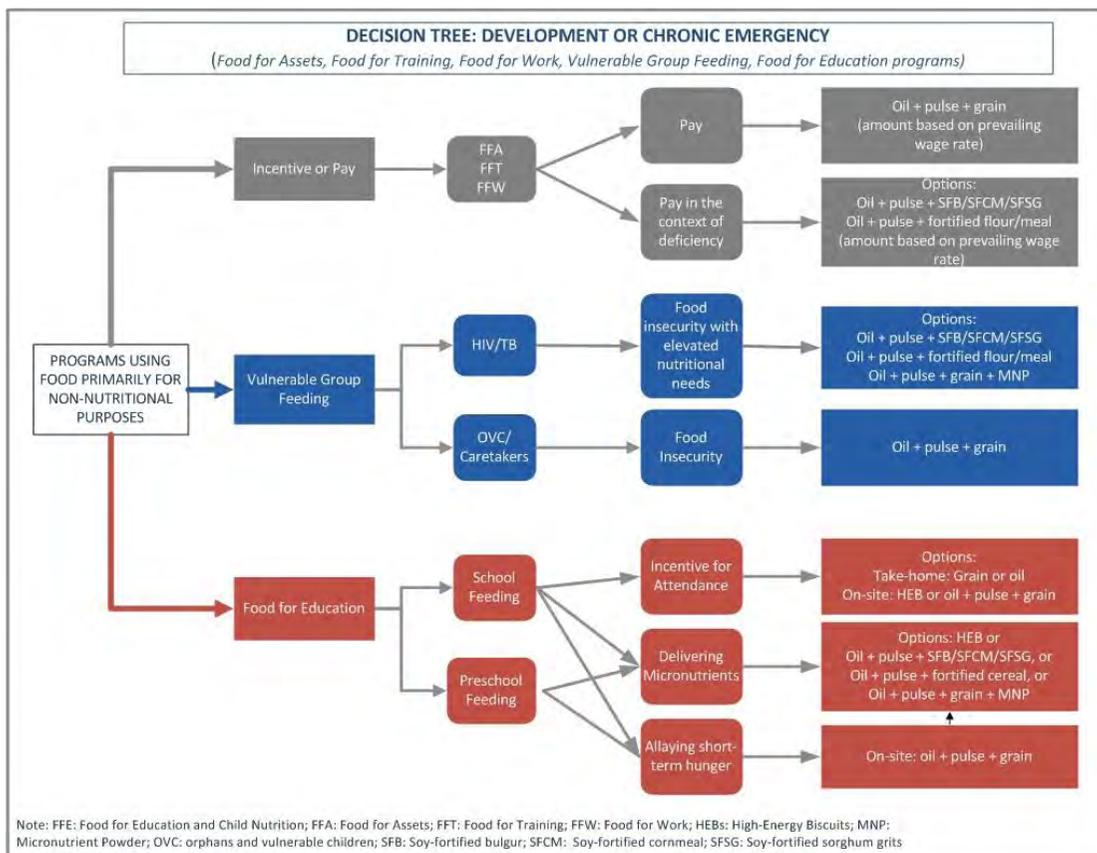
If an emergency becomes protracted, that is, lasting for years, the range of programs provided under the rubric of emergency comes to resemble those common in nonemergency programs.



This figure describes the range of rations commonly used in various phases of emergency programs. In Phase 1 (emergency onset), packaged products are used to promote survival and prevent starvation. In Phase 2 of an emergency, choices are made based on the availability of food products and prevailing nutrition situations. For general food distribution, we recommend a food basket of cereal, pulse, and oil, but with an enhanced nutrient profile for cereals.

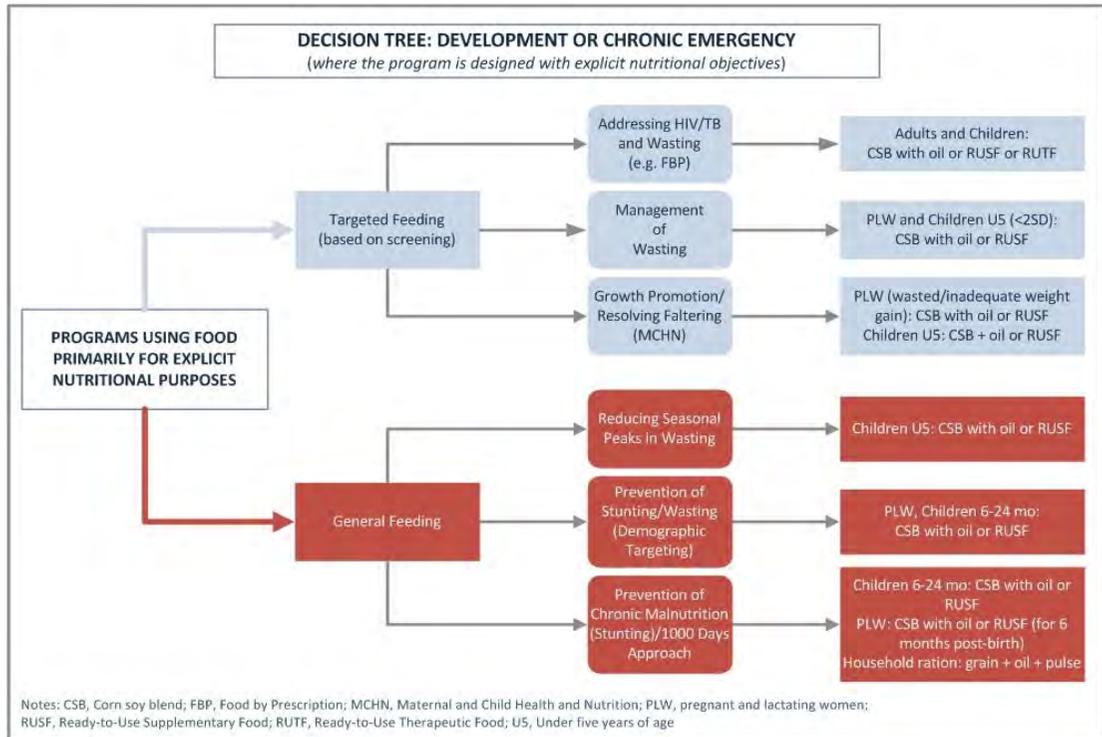
When the prevalence of wasting in children under five exceeds 15% (or is 10% to 15% with aggravating health factors), blanket feeding of high-risk groups is recommended. Virtually all children in this case are in need of nutritional improvement, even if they have not yet fallen below thresholds for stunting or wasting. If blanket supplementary feeding is not possible, distribution of supplementary food based on screening of individuals may be needed.

Therapeutic feeding has not normally been a part of nonemergency Title II programs but is now increasingly included. Therapeutic feeding must be based on screening and is directed at children with SAM, that is, weight-for-height z-score below -3 SD. Therapeutic feeding in a clinical setting may use LNS or F-100 (with careful oversight to avoid contamination), but in community-based therapeutic feeding programs, LNSs are recommended because of the lower chance of microbiological contamination (although drinking water quality still needs to be monitored carefully).



This figure describes food choices appropriate for the Title II programs listed. In the case of blanket feeding for prevention, it is appropriate to use an enhanced FBF, such as CSB combined with oil, or, depending on the circumstances, an LNS (developed as an RUSF). All of the above recommendations must be tested, including effectiveness, acceptability, efficacy, and feasibility of programming an enhanced CSB.

In the case of the PM2A approach, family food (cereal, pulses, oil) is provided as a protective ration, so that the more costly, nutrient-dense food is more likely to reach target individuals. Modifications to this approach are currently being tested, including the provision of LNS in place of CSB and the provision of a smaller protective ration.



This figure shows the ration choices recommended for programs in which nutrition is not explicitly included as an objective for the use of Title II food. When food is used as incentive or pay, or as a means of addressing household food insecurity, the preferred ration options should not include CSB or LNS, but rather a combination of fortified staples, oil, and pulses—the standard household ration.

We have recommended that all cereals distributed through Title II programs (not monetized) be fortified with a wider range of micronutrients than is currently the case, in order to assure adequacy of these key micronutrients without the need to rely on the addition of specialized, nutrient-dense foods to the household ration. The provision of FBFs or LNS is not ideal to assure the nutritional adequacy of the household ration. Where micronutrient deficiencies are prevalent at levels that may not be addressed with fortified cereal products alone, the use of home fortificants may be considered. Similarly, in school and preschool feeding programs, the grain/pulse/oil ration is most appropriate, with MNP added in cases where micronutrient deficiency is a significant issue. If on-site food preparation is not possible or there are other logistical constraints, HEBs are commonly used in place of a school meal.

Appendix 2: Food Aid Quality Review Authors

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Appendix 3: Title II and PEPFAR Programs that are Currently Using or in the Recent Past (Since FY08) Have Used Food for PLHIV and HIV/Food Insecurity Rankings

No.	Country	Title II/WFP (FFP programs with nutrition component)	Main WFP programs with food delivered for HIV programs	PEPFAR	USAID FFP awardees (MYAPs and SYAPs) that target HIV-affected	HIV prevalence ranking*	No. of people living with HIV/AIDS ranking	Food insecurity ranking**
1	Angola	✓					31	
2	Benin	✓				50	57	
3	Burkina Faso	✓	✓		✓	38	39	
4	Botswana	✓				2	22	
5	Burundi	✓			✓	32	43	3
6	Central African Republic	✓				11	34	
7	Chad	✓					28	
8	Congo	✓					50	
9	Democratic Republic of Congo	✓					9	
10	Djibouti	✓					82	
11	Dominican Republic	✓				51	58	
12	Eritrea					47	65	4
13	Ethiopia	✓	✓	✓		31	11	6
14	Gambia	✓				55	110	
15	Ghana	✓			✓	33	26	
16	Guinea	✓	✓	✓		34	47	
17	Guinea Bissau	✓					84	
18	Georgia	✓					132	
19	Haiti	✓	✓	✓		28	42	
20	Honduras	✓					70	
21	India	✓			✓	89	3	
22	Indonesia	✓				103	24	
23	Kenya	✓	✓	✓	✓	10	7	
24	Laos	✓					121	

No.	Country	Title II/WFP (FFP programs with nutrition component)	Main WFP programs with food delivered for HIV programs	PEPFAR	USAID FFP awardees (MYAPs and SYAPs) that target HIV-affected	HIV prevalence ranking*	No. of people living with HIV/AIDS ranking	Food insecurity ranking**
25	Lesotho	✓	✓			3	25	
26	Liberia	✓					67	
27	Madagascar	✓					87	
28	Malawi	✓	✓	✓		9	14	
29	Mali	✓					45	
30	Mozambique	✓	✓			8	4	
31	Myanmar	✓						
32	Niger	✓					59	
33	Peru	✓					52	
34	Romania	✓				127	86	
35	Rwanda	✓	✓	✓	✓	25	36	
36	São Tomé and Príncipe	✓						
37	Senegal	✓				54	56	
38	Sierra Leone	✓	✓			37	61	
39	Somalia	✓					74	
40	South Africa			✓		4	1	
41	Sudan	✓	✓		✓	45	21	5
42	Swaziland	✓					32	
43	Tanzania	✓	✓	✓		12	5	
44	Uganda	✓	✓	✓	✓	14	13	
45	Zambia	✓	✓	✓		7	10	
46	Zimbabwe	✓	✓			6	6	10

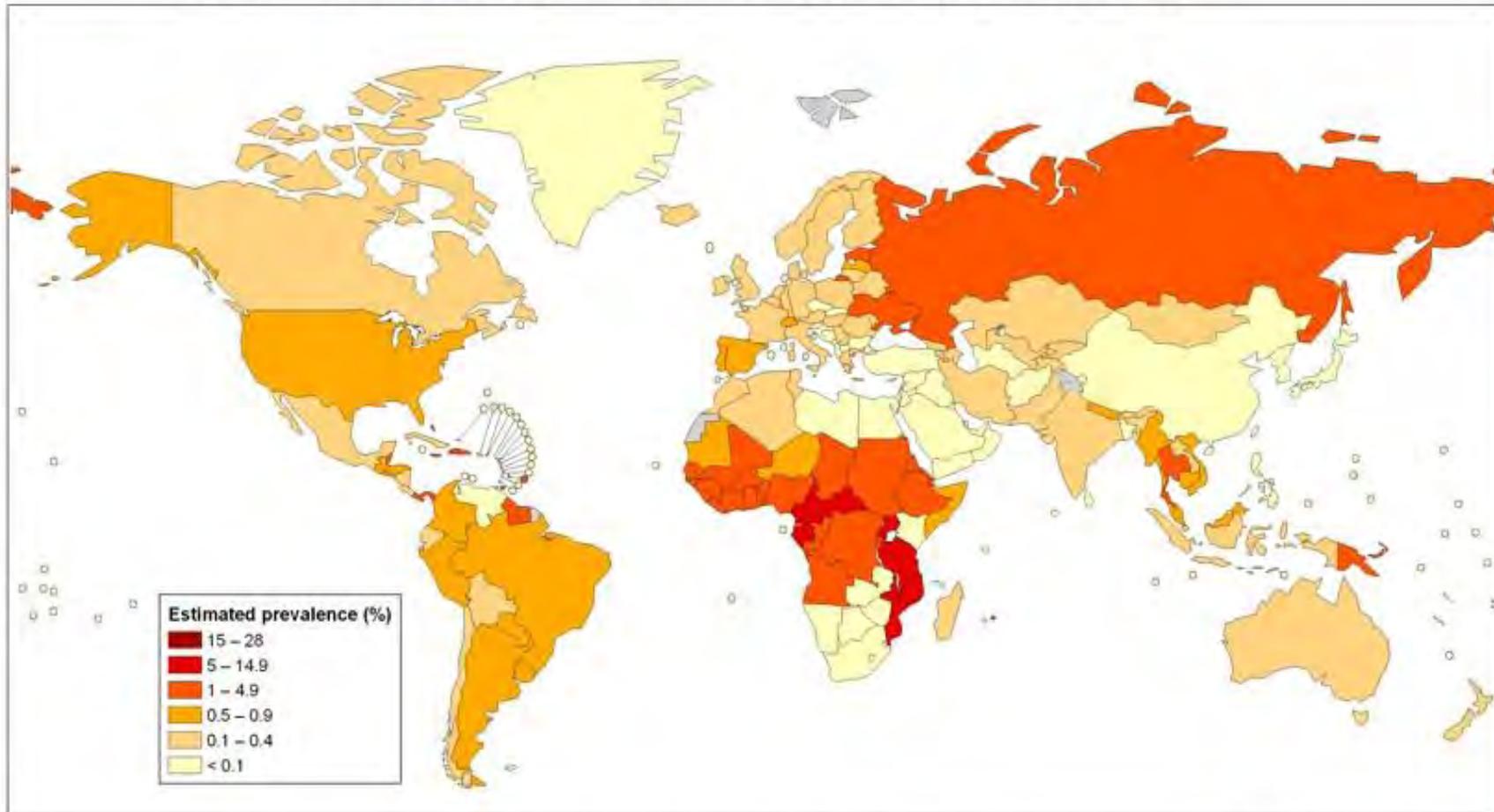
Note: FFP, Food for Peace; MYAP, Multi-Year Assistance Program; PEPFAR, President's Emergency Fund for AIDS Relief in Africa; SYAP, Single-Year Assistance Program; USAID, United States Agency for International Development; WFP, World Food Programme.

*HIV prevalence rankings are taken from the CIA World Factbook (2007).

**Food insecurity rankings are taken from the Maplecroft 2010 Food Insecurity Index, based upon 12 factors drawn up in collaboration with WFP. The criteria include cereal production, GDP per capita, risk of extreme weather events, quality of agricultural and distribution infrastructure, conflict, and effectiveness of the government. If no ranking appears, the country is not listed in the top 10 as ranked by Maplecroft.

Appendix 4: World Map of Distribution of HIV Prevalence and Food Insecurity

HIV estimated prevalence among population aged 15–49 years (%), 2007



The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

Data Source: UNAIDS/World Health Organization
 Map Production: Public Health Information
 and Geographic Information Systems (GIS)
 World Health Organization



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Appendix 5: Tables Summarizing Main Outcomes from Nutrition/HIV Program Evaluations

Out of 48 programs reviewed, only 7 had official evaluation documents available. These include the following:

No.	Program name	Country	Evaluator	Target groups	Food ration (per person/day)																				
1	CRS SUCCESS Palliative Care Nutritional Supplementation in Zambia	Zambia	CRS-Zambia	Chronically ill and food-insecure HIV+ clients of the home-based care program in 2 dioceses: Solwezi and Mongu. Only clients not yet receiving ART were selected for analysis. One group of similar clients in a 3rd diocese was selected for comparison.	Solwezi: 139 g HEPS, 13.3 g oil. Providing 609 kcal and 19.5 g protein. Mongu: 268 g bulgur wheat or sorghum, 67 g beans or peas. Providing 1214 kcal and 46.4 g protein.																				
2	Supporting Households, Women and Children Infected and Affected by HIV/AIDS (03-06)	Ethiopia	WFP	PLHIV receiving home-based care or taking ART, OVCs, and HIV-positive pregnant or lactating women and their under-two children attending PMTCT services.	<table border="1"> <thead> <tr> <th>Target group</th> <th>CSB</th> <th>Wheat</th> <th>Oil</th> <th>Pulse</th> </tr> </thead> <tbody> <tr> <td>PLHIV</td> <td>100 g</td> <td>300 g</td> <td>20 g</td> <td>50 g</td> </tr> <tr> <td>Pregnant women</td> <td>100 g</td> <td>300 g</td> <td>20 g</td> <td>50 g</td> </tr> <tr> <td>OVCs</td> <td>100 g</td> <td>500 g</td> <td>33 g</td> <td>50 g</td> </tr> </tbody> </table>	Target group	CSB	Wheat	Oil	Pulse	PLHIV	100 g	300 g	20 g	50 g	Pregnant women	100 g	300 g	20 g	50 g	OVCs	100 g	500 g	33 g	50 g
Target group	CSB	Wheat	Oil	Pulse																					
PLHIV	100 g	300 g	20 g	50 g																					
Pregnant women	100 g	300 g	20 g	50 g																					
OVCs	100 g	500 g	33 g	50 g																					
3	Kenya's Food By Prescription	Kenya	FANTA II	PLHIV receiving ART or pre-ART and OVCs.	FBF rations aimed at meeting 45% of clients' daily energy requirements, 50–78% of protein requirements, and 1 RDA of micronutrients.																				
4	Zambia's Food By Prescription	Zambia	CRS	Malnourished PLHIV, HIV+ pregnant or lactating women, and OVCs born to HIV+ women.	Adults and children with SAM prescribed both RUTF and HEPS to meet 100% of daily energy requirements. Those with MAM prescribed HEPS only to meet 50% of energy requirements.																				
5	NSART—Nutrition Support to Antiretroviral Therapy	Zimbabwe	WFP	Food-insecure PLHIV taking ART and their households in Bulawayo and Tsholotsho districts.	Households received a monthly ration of cereals (10 kg/person), pulses (1.8 kg/person), vegetable oil (0.5 kg/person), and CSB (3 kg/person).																				
6	Title II Feeding Program Targeting People Living with and Affected by HIV	Uganda	ACDI/VOCA	PLHIV who are vulnerable to chronic food insecurity and children orphaned by the death of parents from AIDS.	300 g CSB, 25 g oil.																				
7	The Academic Model for Prevention and Treatment of HIV/AIDS (AMPATH).	Kenya	IFPRI	PLHIV meeting one or more of the following criteria: insufficient food access, BMI < 19, household income < 3000 Ksh/mo, and CD4 count < 200.	Supplementary foods provided by the HAART and Harvest Initiative included eggs, milk, and fresh fruits and vegetables, as well as purchased food. Some patients also received a WFP ration consisting of maize, beans, CSB, and vegetable oil. Amounts not specified.																				

Main Outcomes from Nutrition/HIV Program Evaluations:

No.	No. graduated or recovered and length of stay	No. lost to death or default	Change in MUAC	Change in BMI	Change in weight	Quality of life	No. of meals/day	Food consumption
1	N/A	4.4% of those enrolled at baseline died in the intervention group. The same proportion of clients died in the comparison group.	MUAC significantly increased from baseline (mean 239 mm) to endline (mean 247 mm) in the intervention arm ($p < 0.001$), while measurements in the control remained statistically unchanged.	No significant change in any intervention arm. A small, nonsignificant increase in mean BMI was noted in the intervention arms (19.58, 19.71) and a small, nonsignificant decrease in BMI in the control arm.	No significant change noted.	<p>Physical and mental health quality of life index scores in the intervention arm significantly increased from baseline to endline ($p < 0.001$), while both scores in the control arm remained statistically unchanged.</p> <p>The severity and frequency of coping strategies used by the household in the previous 30 days, as measured by the Coping Strategy Index, decreased significantly in the intervention arm ($p < 0.001$) while increasing in the control arm ($p < 0.001$).</p> <p>The amount of time a home-based care client needed assistance per day from a family member or community volunteer caregiver decreased significantly in the intervention arm ($p < 0.001$) while increasing significantly in the control arm ($p < 0.05$).</p>	The number of meals eaten per day in the intervention arm increased by 13% ($p < 0.05$) in the intervention arms while decreasing by 11.5% in the control arm ($p < 0.05$).	Food consumption scores, which measure the nutritional quality and diversity of the household diet, decreased significantly in the control arm ($p < 0.001$) while remaining statistically the same in the intervention arm.

No.	No. graduated or recovered and length of stay	No. lost to death or default	Change in MUAC	Change in BMI	Change in weight	Quality of life	No. of meals/day	Food consumption
2	N/A	N/A	N/A	N/A	<p>46% of the patient beneficiaries on ART and food support for 6 mo or more gained at least 10% of their weight at baseline.</p> <p>Overall, > 75% of patient beneficiaries gained weight since the start of the food support. The majority gained 5 kg or less; about 20% gained 5–10 kg.</p> <p>15% of patients lost weight after the start of ART and food support. Only a small proportion lost more than 5 kg.</p> <p>Female patients were more likely to show improvement than males: 16% of female beneficiaries gained more than 10 kg, compared with 8% of male patients.</p>	<p>96% (compared with 65% at baseline) of beneficiaries self-reported that their health status was improving or stable.</p> <p>93% of beneficiaries reported improved functional status in the previous month.</p>	<p>52% of beneficiaries reported consuming foods from 4 or more food groups (out of 8) during the 24 h prior to the survey. There was no baseline for this indicator.</p>	<p>93% of beneficiaries reported that they regularly received the food ration on a monthly basis.</p> <p>95% of beneficiaries knew the amount of food they were entitled to.</p> <p>79% of beneficiaries reported that they always received the correct amount of food ration.</p> <p>There was no significant change in any of these indicators since baseline.</p> <p>As self-reported by recipients, 83% of the distributed food items were consumed.</p>

No.	No. graduated or recovered and length of stay	No. lost to death or default	Change in MUAC	Change in BMI	Change in weight	Quality of life	No. of meals/day	Food consumption
3	<p>6.5% of the exited client group reached the BMI discharge criterion of > 20 (i.e., graduated).</p> <p>Among exited clients who graduated, the overall median length of treatment was 105 days and 99 days for the ART and pre- ART groups, respectively.</p> <p>(Note: This evaluation grouped together graduation, attrition, death, and transfer to other facilities as one group).</p>	<p>Overall attrition due to loss to follow-up, deaths, and transfers to other facilities among PLHIV accounted for 50.1% of the exited client group. Loss to follow-up accounted for 98% of this attrition. The proportion of all clients who were lost to follow-up ranged from 36% to 64% in different facilities. It occurred more commonly in pre-ART than ART clients (56% vs. 38.5%, $p < 0.001$).</p>	<p>N/A</p> <p>At the time of review, MUAC data were recorded for only 57 clients (4%), although it is specified as a discharge criterion for the MCH program</p>	<p>Median BMI increase was 0.4 (IQR, -0.7, 1.2) kg/m², 0.3 (IQR, -1.7, 1.06) kg/m², and 0.3 (IQR, -0.75, 0.78) kg/m² during the 1st, 2nd, and 3rd months, respectively. The average rate of weight gain of 0.3 to 0.4 kg/m²/mo was low for clients with advanced malnutrition. This translated into an average of about 1 kg/mo. For most clients, this would require a length of stay of close to 5 mo to reach the endpoint as defined in this program (BMI > 20 kg/m²)</p> <p>On average, a decrease of 1 BMI unit was associated with a decrease in CD4 count of 28 cells/μl (95% CI, 21, 35; $p < 0.001$).</p>	<p>Upon supplementation, 60.8% of the clients gained weight during the 1st month. In the 2nd and 3rd months, 55.1% and 53.8% gained weight, respectively. These findings show that the largest weight gains were realized during the 1st month of food treatment.</p> <p>Among severely and moderately malnourished clients, the ratio of those who gained weight to those who lost was about 2:1. Among the mildly malnourished, this ratio was close to unity.</p>	N/A	N/A	N/A

No.	No. graduated or recovered and length of stay	No. lost to death or default	Change in MUAC	Change in BMI	Change in weight	Quality of life	No. of meals/day	Food consumption
				<p>The median BMI of clients who graduated was higher than that of clients lost to follow-up in both the pre-ART and the ART groups ($p < 0.001$) and higher than that of clients who died, but the difference was not significant ($p = 0.16$). Overall, on enrollment the median BMI of clients who graduated was higher than that of clients who died or were lost to follow-up ($p < 0.001$). This observation suggests that attrition (death and loss to follow-up) was more likely among clients who had poorer nutritional status at the time of enrollment.</p>				

No.	No. graduated or recovered and length of stay	No. lost to death or default	Change in MUAC	Change in BMI*	Change in weight*	Quality of life*	No. of meals/day*	Food consumption*
4	Of the 22% of clients discharged from the program, 997 (84%) graduated cured (BMI > 18.5).	127 (11%) died from various causes, 45 (4%) were unknown or lost to follow-up, and 18 (1%) were removed from treatment because of medical complications.	N/A	All 5 sites showed an increase in average and median BMI between the time the client entered treatment and was discharged from treatment. Average BMI on entry was 17.6 kg/m ² , ranging from 12 to 35 kg/m ² . Average BMI on discharge was 20.5 kg/m ² , ranging from 14 to 42 kg/m ² . The overall average increase in BMI was 2.9 kg/m ² .	Total weight gain ranged from 1.3 to 3.7 g/kg/day	According to the Eastern Cooperative Oncology Group (ECOG) performance scale, only 1% of clients were completely bed- or chair-ridden post-FBP, compared with 17% pre-FBP Results show an overall significant difference ($p < 0.0001$) between pre- and postintervention health status. There is no significant difference by gender pre-FBP and post-FBP ($p = 0.42$), indicating that the response to treatment was similar in males and females.	Average number of meals eaten in respondents' households in the previous 24 h by children and adults was 2.1 and 2.3, respectively.	Both active and discharged clients reported household food insecurity. For the 70 clients (77%) still on the program, 24 (34%) reported cultivating their own food. Most discharged clients were not benefiting from livelihood programs, economic strengthening programs, or other food security initiatives that would prevent them from relapsing and support long-term improved nutritional status. Food consumption ranged from 0 to 11 on the FANTA food consumption scale, with a mean score of 5.1, implying that, in the 24 h before review, clients consumed approximately 5 different types of food (top groups: cereals, dark green leafy vegetables, cooking oils/fats, sugar, and beans).

*Based on an analysis of only 94 sampled clients

No.	No. graduated or recovered and length of stay	No. lost to death or default	Change in MUAC	Change in BMI	Change in weight	Quality of life	No. of meals/day	Food consumption
5	No discharges based on impact or health changes have been made in the program.	N/A	No quantitative evidence available.	No quantitative evidence available.	No quantitative evidence available.	N/A	N/A	Key beneficiary feedback on the combination of food and ART has been very positive. The food basket meets national policy guidelines but varies in recommended calories by about 1 meal less a day due to its supplementary nature.
6	No quantitative evidence available.	No quantitative evidence available.	75% of primary adult beneficiaries showed increased MUAC. Results were statistically significant.	No quantitative evidence available.	44% of primary adult beneficiaries gained 0–3 kg after 8 mo of food support; 32% gained > 3 kg. 74% of primary orphan beneficiaries gained 0–3 kg; 22% gained > 3 kg. Weight gain was statistically significant.	No quantitative evidence available.	Beneficiaries reported an ability to consume more meals.	Majority of beneficiaries perceived food rations to be beneficial in increasing food availability in the home and improving the diet.
7	N/A	N/A	N/A	N/A	Majority of beneficiaries reported weight gain. No quantitative evidence available.	82% self-reported decreased worries over access to food for their households.	N/A	Participants self-reported increased dietary diversity and quality.

Note: ACDI/VOCA, Agricultural Cooperative Development International/Volunteers in Overseas Cooperative Assistance; ART, antiretroviral therapy; BMI, body mass index; CRS, Catholic Relief Services; CSB, Corn–Soy Blend; FBF, Fortified Blended Food; HAART, Highly Active Antiretroviral Treatment; HEPS, High Energy Protein Supplement; International Food Policy Research Institute; IFPRI, International Food Policy Research Institute; MAM, Moderate Acute Malnutrition; MCH, Maternal and Child Health; MUAC, mid-upper-arm circumference; OVC, orphans and vulnerable children; PLHLIV, people living with HIV/AIDS; PMTCT, prevention of mother-to-child transmission; RDA, Recommended Dietary Allowance; RUTF, Ready-to-Use Therapeutic Food; SAM, Severe Acute Malnutrition; WFP, World Food Programme.

Appendix 6: Assumptions on Nutrient Content of Breast Milk

Determining the quantity of breast milk consumed by infants is by its nature a difficult undertaking. Along with the difficulty of measuring quantity, the macro- and micronutrient levels found in breast milk can vary tremendously from woman to woman, depending on her diet as well as the known changes in breast milk over the course of the feeding and the life of the infant, in addition to genetic factors. Despite these challenges, it was necessary for our work to make assumptions about the quantities of nutrients found in breast milk as well as the average amount consumed by the child, in order to understand the quantity of nutrients required from complementary foods for healthy growth and development. The task of determining these numbers is even more difficult in rural settings of low-income countries, where the majority of our target population lives. However, in order to move forward with designing a complementary food that will be appropriate in numerous situations and settings for children of different ages, certain assumptions must be made.

We begin with an estimated breast milk intake from where we could build the nutrient profile needed for 6- to 11-month-old infants.⁴³ The quantity of breast milk consumed varies greatly from child to child, over the 6-month period specified, and depending on the mother's and child's health. Complementary food should be introduced at 6 months, while slowly decreasing the amount of breast milk and replacing it with family foods. Thus, despite being bigger, an 11-month-old child should be drinking less breast milk than a 6-month-old child. We also know that when children are sick the amount of food they consume decreases because of loss of appetite and sometimes decreased ability to eat. If the mother is ill, the quantity of her breast milk can decrease, the nutrient profile of the milk can change, and the frequency of breast-feeding can decline. With all of these factors in mind, we decided it was best to look at estimates of the average intake of infants 9 to 11 months old, since they consume less than infants 6 to 8 months old, and then use the low end of the standard deviation to best control for the aforementioned issues.

We used the WHO publication *Complementary Feeding of Young Children in Developing Countries* (WHO, 1998). In this publication, WHO reviewed numerous studies of breast milk consumption as well as nutrient content, the end result being a table with average consumptions for different age groups, as well as an estimate of nutrient content for mature breast milk (> 21 days) of women in developing countries. These tables, numbers 7 and 22 in the WHO document, are provided at the end of this appendix in their entirety. We based our calculations on the assumed average intake of children 9 to 11 months of age, 660 g of breast milk per day with a standard deviation of 153 g. We took the lower end of the estimate, 444 g per day, for our calculations. This amount has the estimated nutrient profile provided in the table

⁴³ It was decided to create the nutrient profile around the target group with the highest nutrient needs per kilocalorie. Because infants 6 to 11 months old have a limited stomach capacity, it is necessary to meet their recommended levels with a small amount (50 g in this case) of food. See Chapter 2 for further explanation.

below. This estimate was used to create the ideal nutrient profile for the FBF, if it was the only source of food outside of breast milk. We also needed an estimated breast milk intake for children older than 12 months. We used the same procedure, looking at the estimate for the age group and taking the lower end of the standard deviation. These numbers are shown below.

Breast milk content used in calculations

Nutrient	Amount per 444 g (for 6–11 mo)	Amount per 362 g (for 12–36 mo)
Macronutrients		
Energy (kcal)	280.28	235.3
Protein (g)	4.5	3.8
Fat (g)	16.8	14.1
Minerals (mg)		
Calcium	124.3	101.4
Chromium	0.022	0.018
Copper	0.111	0.0905
Iodine	0.049	0.040
Iron	0.13	0.11
Magnesium	15.5	12.7
Manganese	0.0027	0.0022
Phosphorus	62.2	50.7
Potassium	233.1	190.1
Selenium	0.009	0.007
Sodium	66.6	54.3
Zinc	0.0005	0.0004
Vitamins (mg)		
Vitamin A	0.222	0.181
Vitamin B ₁ (thiamin)	0.093	0.076
Vitamin B ₂ (riboflavin)	0.155	0.127
Vitamin B ₃ (niacin)	0.666	0.543
Vitamin B ₅ (pantothenic acid)	0.799	0.652
Vitamin B ₆ (pyridoxine)	0.0413	0.034
Vitamin B ₇ (biotin)	0.0018	0.0014
Vitamin B ₉ (folic acid)	0.0226	0.018
Vitamin B ₁₂ (cobalamin)	0.00043	0.00035
Vitamin C	17.76	14.48
Vitamin D	0.00024	0.0002
Vitamin E	1.02	0.833
Vitamin K	0.0009	0.0008

In assuming 444 g of breast milk intake, we recognized this was a conservative estimate but felt it would provide a better nutrient profile for the FBFs. Doing this placed a greater dependence on the micronutrients added to the FBFs. This process was carried out early in the work performed by the FAQR, as it was the basis of

building our FBF nutrient profile. Following our decision, a research study was carried out estimating the quantity of breast milk consumed by infants using stable isotope methodology (da Costa et al., 2010). The study found that WHO had higher estimates of intake in the first 8 months of life, but starting at 9 months the findings of the two reports were equivalent. This means that our use of the low end of the standard deviation was appropriate for our needs. Our goal was to use a realistic but low estimate in order to try to correct for the worst case scenario when breast milk is low in supply due to the mother's health status or the infant's inability to consume an adequate amount of breast milk is impeded due to health status.

From page 47 of WHO document.

Complementary feeding of young children in developing countries

Table 7. Intakes of breast milk and energy from breast milk in developing countries, by age group

	Age Group (months)				
	0-2	3-5	6-8	9-11	12-23
PARTIALLY BREAST-FED (PBF)					
ALL STUDIES (16) ^a					
No. of subjects ^b :	381	437	533	342	377
Breast-milk intake (g/d):	617±168 (8) ^c	663±155 (9)	660±153 (14)	616±172 (13)	549±187 (9)
Breast-milk energy intake (kcal _{th} /d)	376±110 (8)	412±104 (9)	403±99 (14)	379±111 (13)	346±128 (9)
SUBSET ^d (8)					
No. of subjects:	0	91	212	91	182
Breast-milk intake (g/d):	----	750±142 (1)	740±149 (6)	663±187 (5)	526±214 (5)
Breast-milk energy intake (kcal _{th} /d)	----	500±97 (1)	459±93 (6)	420±120 (5)	329±150 (5)
Breast-milk energy intake (kcal _{th} /kg/d):	----	76±14 (1)	67±16 (6)	56±14(5)	39±18 (5)
Body weight (kg):	----	6.7 (1)	7.0 (6)	7.6 (5)	8.6 (5)
EXCLUSIVELY BREAST-FED (EBF):					
ALL STUDIES (5)					
No. of subjects:	172	259	70	----	----
Breast-milk intake (g/d):	714±131 (3)	784±128 (5)	776±141 (2)	----	----
Breast-milk energy intake (kcal _{th} /d):	437±79 (3)	474±80 (5)	483±87 (2)	----	----
SUBSET (4)					
No. of subjects:	140	229	50	----	----
Breast-milk intake (g/d):	690±124 (2)	795±131 (4)	813±126 (1)	----	----
Breast-milk energy intake (kcal _{th} /d):	442±78 (2)	488±79 (4)	553±88 (1)	----	----
Breast-milk energy intake (kcal _{th} /kg/d):	104±21 (2)	78±12 (4)	73±12 (1)	----	----
Body weight (kg):	4.4 (2)	6.3 (4)	7.6 (1)	----	----
ALL STUDIES (PBF +EBF):					
ALL STUDIES (21)					
No. of subjects:	553	696	603	342	377
Breast-milk intake (g/d):	644±159 (11)	706±146 (14)	674±151 (16)	616±172 (13)	549±187 (9)
Breast-milk energy intake (kcal _{th} /d):	393±103 (11)	434±96 (14)	413±98 (16)	379±111 (13)	346±128 (9)
SUBSET (12)					
No. of subjects:	140	320	262	91	182
Breast-milk intake (g/d):	690±124 (2)	786±134 (5)	750±146 (7)	663±187 (5)	526±214 (5)
Breast-milk energy intake (kcal _{th} /d):	442±78 (2)	490±83 (5)	472±92 (7)	420±120 (5)	329±150 (5)
Breast-milk energy intake (kcal _{th} /kg/d):	104±21 (2)	78±13 (5)	68±16 (7)	56±14 (5)	39±18 (5)
Body weight (kg):	4.4 (2)	6.4 (5)	7.1 (7)	7.6 (5)	8.6 (5)

a Number of studies

b Number of subjects pooled over studies

c Numbers represent arithmetic Mean±SD from various studies, and numbers in parentheses indicate number of studies for each age group.

d Subset indicates data from the subset of studies which provided body weight and/or information on energy intake as kcal_{th}/kg.

From page 84 of the WHO document.

Table 22. Estimated nutrient concentrations (mean±SD) in mature human milk^a

Nutrient	Amount
Lactose (g/L)	72±2.5
Protein (g/L)	10.5±2.0
Fat (g/L)	39.0±4.0
<i><u>Vitamins</u></i>	
Biotin (µg/L)	4±1
Folate (µg/L)	85±37
Niacin (mg/L)	1.50±0.20
Pantothenic Acid (mg/L)	1.80±0.20
Riboflavin (mg/L)	0.35±0.025
Thiamin (mg/L)	0.21±0.03
Vitamin B ₆ (µg/L)	93±8
Vitamin B ₁₂ (µg/L)	0.97
Vitamin C (mg/L)	40±10
Vitamin A (µg RE/L) ^b	500 ^b
Vitamin D (µg/L)	0.55±0.10
Vitamin E (mg/L)	2.3±1.0
Vitamin K (µg/L)	2.1±0.1
<i><u>Minerals</u></i>	
Calcium (mg/L)	280±26
Chloride (mg/L)	420±60
Chromium (µg/L)	50±5
Copper (mg/L)	0.25±0.03
Fluoride (µg/L)	16±5
Iodine (µg/L)	110±40
Iron (mg/L)	0.30±0.10
Magnesium (mg/L)	35±2
Manganese (µg/L)	6±2
Phosphorus (mg/L)	140±22
Potassium (mg/L)	525±35
Selenium (µg/L)	20±5
Sodium (mg/L)	180±40
Zinc (mg/L) ^c	1.2±0.2

^aInstitute of Medicine 1991, unless otherwise indicated. Mature signifies ≥ 21 days postpartum.

^bUnderwood, 1994. Value for well-nourished women is 670 µg/L.

^cKrebs et al. (1995) have reported zinc concentration in breast milk of 0.93±0.58 and 0.77±0.51 mg/L at 6-8 and 9 months of lactation, respectively. We have used Krebs' values for computing the amount of zinc from breast milk.

Appendix 7: Implementing Partner Survey Respondents (by country/agency)

The Food Aid Quality Review would like to acknowledge all those organizations who participated in the Implementing Partner Survey (FAQR, 2010).

Implementing partner survey—interviews conducted

	Country	Implementing partner
01	Afghanistan	World Vision
02	Afghanistan	WFP
03	Algeria	WFP
04	Bangladesh	CARE
05	Bangladesh	Save the Children - U.S.
06	Burkina Faso	Catholic Relief Services
07	Burkina Faso	Africare
08	Burundi	Catholic Relief Services
09	Burundi	WFP
10	Central African Republic	WFP
11	Cameroon	WFP
12	Chad	Africare
13	Chad	WFP
14	Colombia	WFP
15	Côte d'Ivoire	WFP
16	Democratic Republic of the Congo	ADRA
17	Democratic Republic of the Congo	Food for the Hungry International
18	Democratic Republic of the Congo	Mercy Corps
19	Democratic Republic of the Congo	WFP
20	Ecuador	WFP
21	Ethiopia	CARE
22	Ethiopia	Catholic Relief Services
23	Ethiopia	Food for the Hungry International
24	Ethiopia	REST
25	Ethiopia	Save the Children - France
26	Ethiopia	Save the Children - UK
27	Ethiopia	WFP
28	Georgia	WFP
29	Ghana	OICI
30	Guatemala	Catholic Relief Services
31	Guatemala	Save the Children - France
32	Guatemala	Mercy Corps

33	Guatemala	SHARE
34	Guinea	OICI
35	Haiti	Catholic Relief Services
36	Haiti	ACDI/VOCA
37	Honduras	Save the Children - France
38	India	Catholic Relief Services
39	Kenya	WFP
40	Madagascar	Catholic Relief Services
41	Madagascar	WFP
42	Malawi	Catholic Relief Services
43	Mali	Catholic Relief Services
44	Mali	Africare
45	Mauritania	Counterpart International
46	Nepal	WFP
47	Niger	Africare
48	Niger	Catholic Relief Services
49	Niger	Counterpart International
50	Pakistan	WFP
51	Philippines	WFP
52	Rwanda	ACDI/VOCA
53	Rwanda	WFP
54	Senegal	Counterpart International
55	Sierra Leone	CARE
56	Somalia	WFP
57	Sri Lanka	WFP
58	Sudan	WFP
59	Tanzania	WFP
60	Uganda	ACDI/VOCA
61	Uganda	Mercy Corps
62	West Bank/Gaza (OPT)	WFP
63	Yemen	WFP
64	Zimbabwe	WFP

Appendix 8: Implementing Partner Survey (adapted from the online version) (FAQR 2010)

The FAQR Implementing Partner survey was set up and administered as a computer-assisted telephone interview (CATI). The Food Aid Quality Review conducted this survey among 64 USAID/Food for Peace Title II implementing partners in 40 different countries. A summary of the findings from this survey can be found in Chapter 3.

1. Region:
2. Country:
3. Agency:

Section I: Food Commodities Used in Your Programs

1. Below is a list of enriched, fortified, and/or blended food commodities used in many Title II programs. Please let me know (by responding yes or no) if your agency currently uses any of these commodities in its programming. I will now read the list:

- Corn Soy Blend
- Wheat Soy Blend
- Fortified Vegetable Oil
- Soy Fortified Corn Meal
- Soy Fortified Bulgur
- Soy Fortified Grits
- Enriched Wheat Flour
- Enriched Corn Meal
- Other Soy-fortified Foods
- Other 1 (specify) _____
- Other 2 (specify) _____

(This question was a branching question in the original CATI survey. For each food selected, we asked questions 3 through 7.)

2. If you did not select Corn Soy Blend, please explain why:

Food Commodity:

3. What instructions (if any) are given to program participants on how to use this commodity?

	Yes	No
Instructions on how to prepare it	<input type="radio"/>	<input type="radio"/>
Instructions to prepare it with another food	<input type="radio"/>	<input type="radio"/>
Instructions on what amount to serve	<input type="radio"/>	<input type="radio"/>
Instructions on how frequently to serve	<input type="radio"/>	<input type="radio"/>
Instructions on who in the household should consume it	<input type="radio"/>	<input type="radio"/>
Instructions on how to store it	<input type="radio"/>	<input type="radio"/>

If instructed to prepare this commodity with another food, what food?

4. Below are some statements about how program participants may feel about this commodity. Please indicate your agreement with each statement, from the point of view of the participant.

	Agree strongly	Agree somewhat	Neither agree nor disagree	Disagree somewhat	Disagree strongly
Product tastes good	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Product is easy to prepare	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Product is easy to use	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Product is liked by all household members	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Product is easy for program participants to transport	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Product is easy to store safely	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

5. Do you have any further comments about the program participants' attitudes toward this commodity?
6. In selecting this commodity, what were the key nutrients your agency intended to provide through the commodity? (check all that apply)
- Calories
 - Proteins
 - Fats
 - Micronutrients (please specify) _____
 - Other (please specify) _____

7. General Comments:

Section II: The Use of Food Commodities According to Technical Sector

8. The following questions refer to **current** Technical Sectors in which your agency operates. Please indicate which Technical Sectors your agency currently operates in by checking "yes" or "no." Then, please respond to the three questions that follow (checking the box only if you answer yes):

	Did your agency take any nutrition considerations into account when designing the ration for this Technical Sector?		Do you use any fortified, enriched, or blended food commodities in this Technical Sector?	Do you monitor & report on any specific nutrition outcomes in this Technical Sector?
	Yes	No		
Agriculture/Natural Resource Management	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>
Education	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>
Emergency Preparedness/Disaster Mitigation	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>
Health and Nutrition	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>
Non-Agriculture Income Generation	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>
Vulnerable Group Feeding/Social Safety Net	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>
Water and Sanitation	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other: _____				

(This question was a branching question in the original CATI survey. For each Technical Sector selected, we asked question 9.)

Technical Sector:

9. What are the Target Groups served within this Technical Sector? For each Target Group that you select, is there any other criterion for them being targeted? If so, please select from the nutritional status and infection drop-down menus. (select all that apply)

Target Group 5
[- Select One -]
*see list #4

Nutritional Status
[- Select One -] *see
list #5

Infection
[- Select One -] *see
list #6

Infection
[- Select One -]
*see list #6

(The original CATI survey had more than one Target Group option.)

List #4

Children 0-5 months
Children 6-59 months (U5)
Children 6-35 months (U3)
Children 6-23 months (U2)
School-age Children
Orphans and Vulnerable Children
Household of PM2A child
Pregnant or Lactating Women
Adult Workers/Trainees
Refugees/IDPs
Disaster Victims
Elderly/Disabled
Caretakers
Other Adult

List #5

Underweight
Moderately Wasted
Severely Wasted
Not Applicable

List #6

HIV+
HIV Exposed
TB Infected
Malaria Infected
Other Infected
Not Applicable

(This was a branching question in the original CATI survey. For each Target Group selected we asked questions 10-26.)

10. Is the ration take-home or on-site? Take-home On-site Don't know
11. Is the ration intended for the household or an individual? Household Individual Don't know
12. If intended for the the household, what household size do you base this ration on? _____
13. Please list all foods that make up this ration, filling in **all currently used foods**, not just fortified/blended foods:

Commodity

Food 1: [- Select One -] *see list #7

Measurement

grams _____
kilograms _____
ml _____
liters _____

Frequency

per day wk mo

(The original CATI survey included options to select more than one food.)

List #7

Corn Soy Blend

Wheat Soy Blend
 Fortified Vegetable Oil
 Soy Fortified Corn Meal
 Soy Fortified Bulgur
 Soy Fortified Grits
 Enriched Wheat Flour
 Enriched Corn Meal
 Other Soy-fortified Foods
 Other (specify)

14. Do you have information about how this ration is **actually** used by the program participants?

- Yes No

15. If yes, what is the source of this information? (check all that apply)

- Formal assessments (such as questionnaires or a survey)
 Informal assessments (such as conversations with program participants)
 Direct observation in markets or on home visits
 General knowledge of the context
 Other (please specify) _____

16. If yes, what do you observe about how the ration is being used?

17. Are any of the commodities in this ration intended for a specific individual within the household?

- Yes No Don't know

If yes, which commodity? _____

If yes, for whom? _____

18. If this ration is intended for specific individuals, is it still shared within the household?

- Never or Rarely
 Sometimes
 Often or Always
 Don't know
 Not applicable; ration is intended to be shared

19. If the ration is ever shared, among whom is it shared?

- Among the children only
 Among everyone in the household
 Don't know
 Other (please specify) _____

20. Are any of the commodities in this ration ever sold or traded?

- Never or Rarely
- Sometimes
- Often or Always
- Don't know

If so, which commodities? _____

21. Are any of the commodities in this ration every given away or fed to animals?

- Yes
- No
- Don't Know

If so, which commodities? _____

22. For this Target Group, what are the specific nutrition objectives of providing the ration? (check all that apply)

- Maintaining adequate growth (height, weight gain)
- Treating moderate malnutrition
- Treating severe malnutrition
- (For PLWHA): Delay progression of the disease
- (For PLWHA): Improve the outcomes of ART
- (For PLWHA): Improve adherence to ART regimen
- (For PLWHA): Improve/maintain nutrition status
- (For Emergencies) Ensuring micronutrient adequacy of a general ration
- No specific nutrition objective; food is part of a general ration
- No specific nutrition objective; food is used as incentive or pay
- Treating specific micronutrient deficiencies
(please list which ones) _____
- Preventing specific micronutrient deficiencies (please list which ones) _____

23. Do you monitor the nutritional outcomes in this Target Group?

- Yes
- No

If yes, what indicator(s) do you measure? (check all that apply)

- height/age (stunting)
- weight/age (underweight)
- weight/height (wasting)
- weight gain (growth)

If yes, what indicator(s) do you measure? (check all that apply)

- height gain (growth)
- body mass index (BMI)
- middle-upper arm circumference (MUAC)
- Anemia (hemoglobin count)
- Other (please specify) _____

24. Do you have evidence of whether or not this program has had a nutritional impact on this Target Group?

- Yes No

If yes, what is the source of that evidence?

- Midterm evaluation
- Final evaluation
- Special studies (explain) _____
- Indicator (specify) _____

25. If you could select any commodity to use for this Target Group, which commodity would you select and why?

26. General Comments:

Section III: New Commodities

27. In addition to the food commodities used in Title II, I have a list of fortified, blended and/or enriched food commodities that are NOT currently available under Title II. I would like to know if your agency is currently using any of these commodities in its programming. Please indicate your response by saying yes or no. I will now read you the list:

- Lipid-Based Nutrient Supplements (like QBMIX (R); PlummyDoz(R))
- Ready-to-Use Therapeutic Foods (like Plumpy'nut (R))
- Micronutrient supplement pills or syrups
- Powders/Fortificants (like Sprinkles (R))
- High Energy Biscuits
- F-75
- F-100
- Other (please specify) _____

WFP has developed two types of Corn Soy Blend for different nutrition program uses: one for children under 24 months, and one, less nutrient dense, for older children, pregnant and lactating women, and other vulnerable groups. Please answer the following set of questions regarding this development:

28. In general, would it be useful to have different formulations of Corn Soy Blend, similar to WFP's model, available under Title II?
- Yes No

Please explain your answer: _____

29. Overall, would you prefer to have various Corn Soy Blend formulations available for different program participant needs, or simply to adjust for different needs by adjusting the ration quantity of a single Corn Soy Blend formulation?
- different formulations for different needs
 one formulation; quantity can be adjusted for different needs
 prefer not to use CSB

Please explain your answer: _____

30. Do you have any other recommendations about the food commodities available under Title II and how they are used in nutrition programs?
31. General Comments:

Section IV: Logistics

For every food commodity that you selected in Section I, I would like to ask you a few questions about logistics.

Food Commodity:

32. Have you encountered any problems with quality or availability of this commodity?
- Yes No

If yes, please indicate the frequency with which the following problems have occurred with this commodity **in the past year**:

<u>Problems:</u>	Rarely/Never	Sometimes	Often
Commodity arrives damaged (wet, moldy, off-color, infested, etc.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Packaging is damaged (torn, smashed, etc.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
There are delays or breaks in pipeline	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Commodity is not available	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Commodity spoils quickly	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Commodity is reported to cause illness when consumed	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other 1 (specify)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If you have had problems in the past year, how did you deal with the problem(s)?

- | | |
|---|------------------------------|
| Commodity arrives damaged (wet, moldy, off-color, infested, etc.) | [- Select One -] |
| Packaging is damaged (torn, smashed, etc.) | [- Select One -] |
| There are delays or breaks in pipeline | [- Select One -] |
| Commodity is not available | [- Select One -] |
| Commodity spoils quickly | [- Select One -] |
| Commodity is reported to cause illness when consumed | [- Select One -] |
| Other 1 | [- Select One -] *see list 8 |

List #8

- Cut ration size
- Did not distribute
- Obtained replacement from donor
- Obtained substitute from donor
- Procured substitute from a different donor
- Procured substitute from the market
- Borrowed from another program in-country
- Repackaged commodity
- Other

33. Comments:

34. The last time a commodity arrived damaged or unusable, did you report it?
 Yes No Not Applicable

35. If yes, to whom did you report the problem?
 The Supplier
 The Transporter/Transportation Company
 Your agency HQ (please specify where) _____
 USAID, Food for Peace or another office (please specify) _____
 Other (please specify) _____

36. The last time a commodity arrived damaged or unusable, was the problem resolved satisfactorily in your view?
 Yes No Not Applicable

Please explain your answer? _____

37. How long did it take to fully resolve the problem?
 _____ Days
 _____ Weeks
 _____ Months
 _____ Years

Problem is still unresolved

38. Do you have any general recommendations about the quality, content, or timeliness of delivery of Title II food commodities?

39. In your programming, do you have experience with **local or regional procurement** of fortified, enriched and/or blended food commodities?

Yes

No

40. If yes, which foods? (check all that apply)

Corn Soy Blend

Wheat Soy Blend

Fortified Vegetable Oil

Soy Fortified Corn Meal

Soy Fortified Bulgur

Soy Fortified Grits

Enriched Wheat Flour

Enriched Corn Meal

Other Soy-fortified Foods

Other 1 (specify) _____

41. What are the reasons for procuring locally or regionally as opposed to procuring through Title II?

42. In your experience of local or regional procurement, compared to your procurement through Title II, how satisfied are you? (Please mark the appropriate column)

	Very Satisfied	Somewhat Satisfied	Somewhat Dissatisfied	Not Satisfied
Quality of Product	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Quality of packaging	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Availability	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Timeliness of delivery	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cost	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Acceptability to program participants	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

43. Do you have any other comments about local or regional procurement?

44. General Comments:

THIS CONCLUDES OUR SURVEY

Appendix 9: New Commodity Proposal for Use in the Title II Food for Peace Program

Information on proposed commodity should be provided that clearly addresses the following points:

- Origin of all ingredients. Note that P.L.480 legislation requires that all commodities be produced in the United States. Off-shore packaging purchases are also subject to special provisions of the U.S. Federal Acquisition Regulations.
- Complete specifications for processing the commodity by the industry. Composition of the commodity. The percentage contribution of each ingredient making up the product. Note that P.L.480 commodities cannot be sole-sourced. All commodities are purchased by the U.S. Department of Agriculture (USDA) through full and open competition.
- Estimated cost of the commodity to the U.S. Government per metric ton (MT). Also indicate estimated commodity cost per metric ton delivered to a U.S. port, either in the Gulf or on the Mississippi River, if applicable.
- Macronutrient and micronutrient information per 100 g of dry commodity (uncooked) to include information on protein, energy (calories), fat, carbohydrates, ash content, and when appropriate, vitamin A, vitamin C, thiamin, niacin, riboflavin, vitamin B₁₂, vitamin B₆, folic acid, iron, iodine, calcium, phosphorus, zinc, and other micronutrients.
- Consumer preparation instructions including requirements for potable water, fuel, and cooking time.
- Any special packaging and/or shipping requirements, such as U.S. source loading at the vendor's plant or containerization requirements, which would impact the total cost of commodity and limit shipping competition. All products must be available for shipment under both break bulk and containerization modalities in accordance with standard Title II procurement and shipping terms. Product packaging must also be designed to include USAID's Brand Identity Trademark and other Title II markings. Please provide one packaging sample that meets the above packaging and markings requirements.
- Expected shelf life under normal storage conditions and adverse conditions that might be expected in developing countries (e.g., high humidity and temperature). Also include any history/documentation of successful storage performance.

- Report on prior use of commodity, if any, both in United States and abroad describing population using commodity, nutritional impact, nutrient stability, organoleptic trials, consumer acceptance, adverse allergic reactions to, etc.
- Report on current production capability in the United States.
- If the manufacturing process or products' formulation are proprietary, indicate whether or not you are willing to waive this restriction in the event approval is granted for programming and purchase of the product.

The proposal submission (typed in 14-pitch New Times Roman Type, in Microsoft-Word format, and not more than eight pages, single-sided, double-spaced pages) should be submitted to:

U.S. Agency for International Development

Bureau for Democracy, Conflict, and
Humanitarian Assistance
Office of Food For Peace
Director, Program Operations Division
Ronald Reagan Building
Room 7.6-80
1300 Pennsylvania Avenue, N.W.
Washington, DC 20523-7600

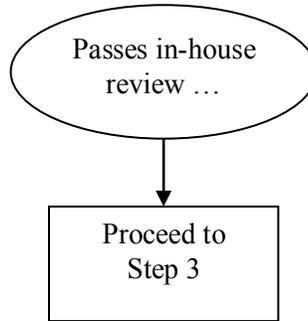
PLEASE DO NOT SEND PRODUCT SAMPLE UNTIL REQUESTED TO DO SO.

STEP 1

Initial inquiry made to USAID's Office of Food For Peace (FFP). FFP provides response within five (5) calendar days enclosing a copy of the New Commodity Proposal information packet describing process and proposal submission format. For informational purposes only, FFP also sends a copy of the response cover letter to technical panel members comprising representatives from the U.S. Department of Agriculture (USDA), USAID's nutrition advisor in FFP's Policy/Tech Division and Global Health (GH) Bureau, the Food and Nutrition Technical Assistance (FANTA) project, and the World Food Programme (WFP) Headquarters' Office in Washington, D.C.

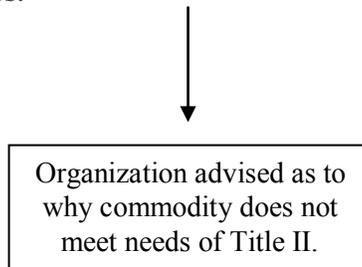
STEP 2

Within five calendar days of receipt, FFP disseminates copies of a complete commodity proposal to technical panel members, either via electronic format (e-mail), if available, or via hard copy format. Technical panel members shall review/comment within 30 calendar days from the date of mailing. As part of their response, technical panel members are requested to provide written comments and recommendations for either a "Pass/Fail" determination. FFP also sends a notice to the requesting entity conveying final, technical panel recommendations.



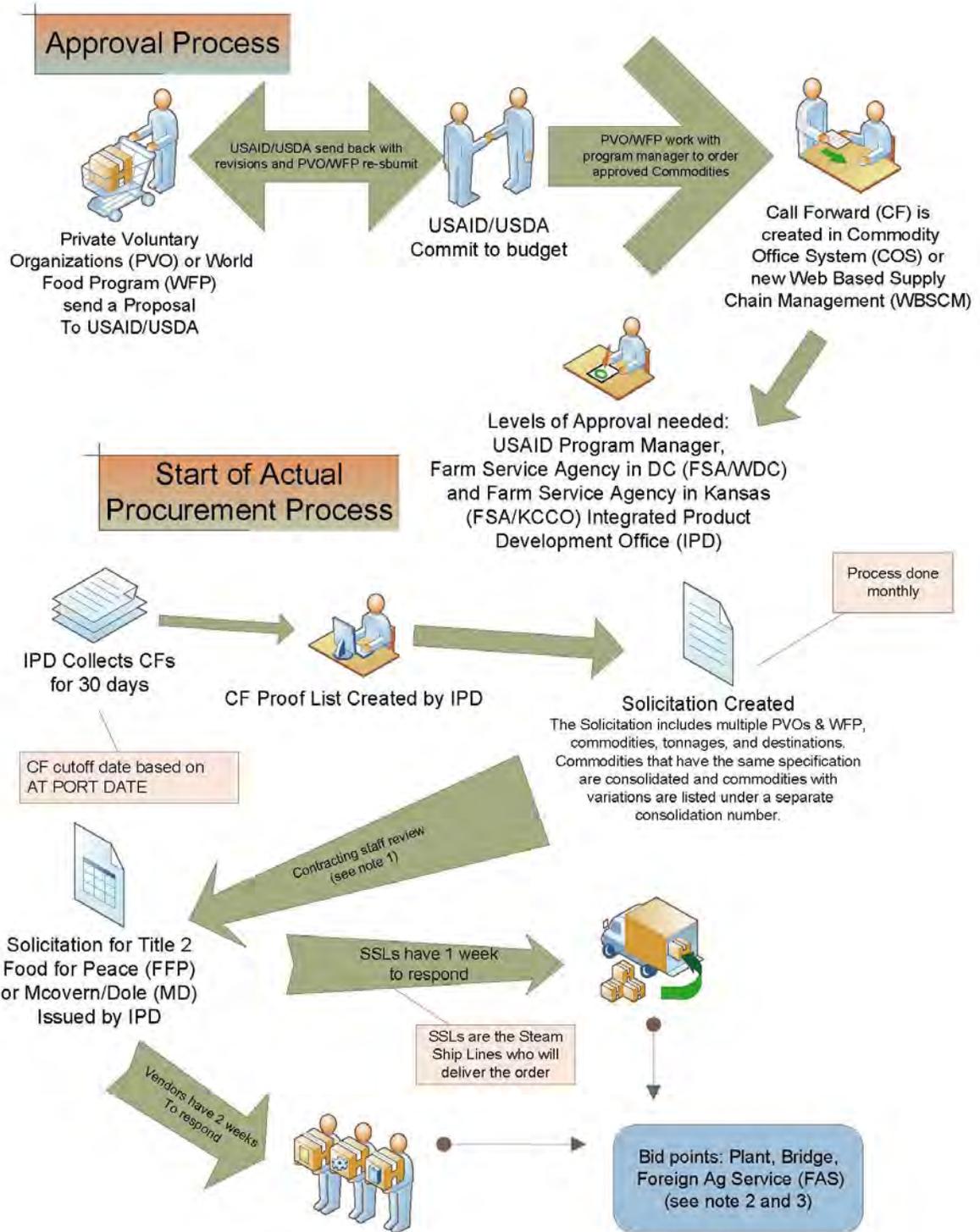
STEP 3 If the technical panel determines that the commodity is acceptable for future procurement consideration under the Title II program, and USDA simultaneously determines that base ingredients meet eligibility criteria, as defined in the New Commodity Proposal Checklist, FFP promptly sends a letter to USDA advising the technical panel's acceptance and FFP notifies requesting entity of proposal acceptance. This notice serves as a "heads up" for further USDA standard procurement specification developments for procurement announcements or USDA's Notices To The Trade, the website, FEDBIZOPS.GOV, or FBO.GOV notices, to be used for future commodity procurement upon request from Title II cooperating partners.

STEP 4 If the technical panel determines that the commodity does not meet the eligibility criteria listed in the New Commodity Proposal Checklist, within five calendar days, FFP conveys a written notice to the requesting entity and technical panel members.

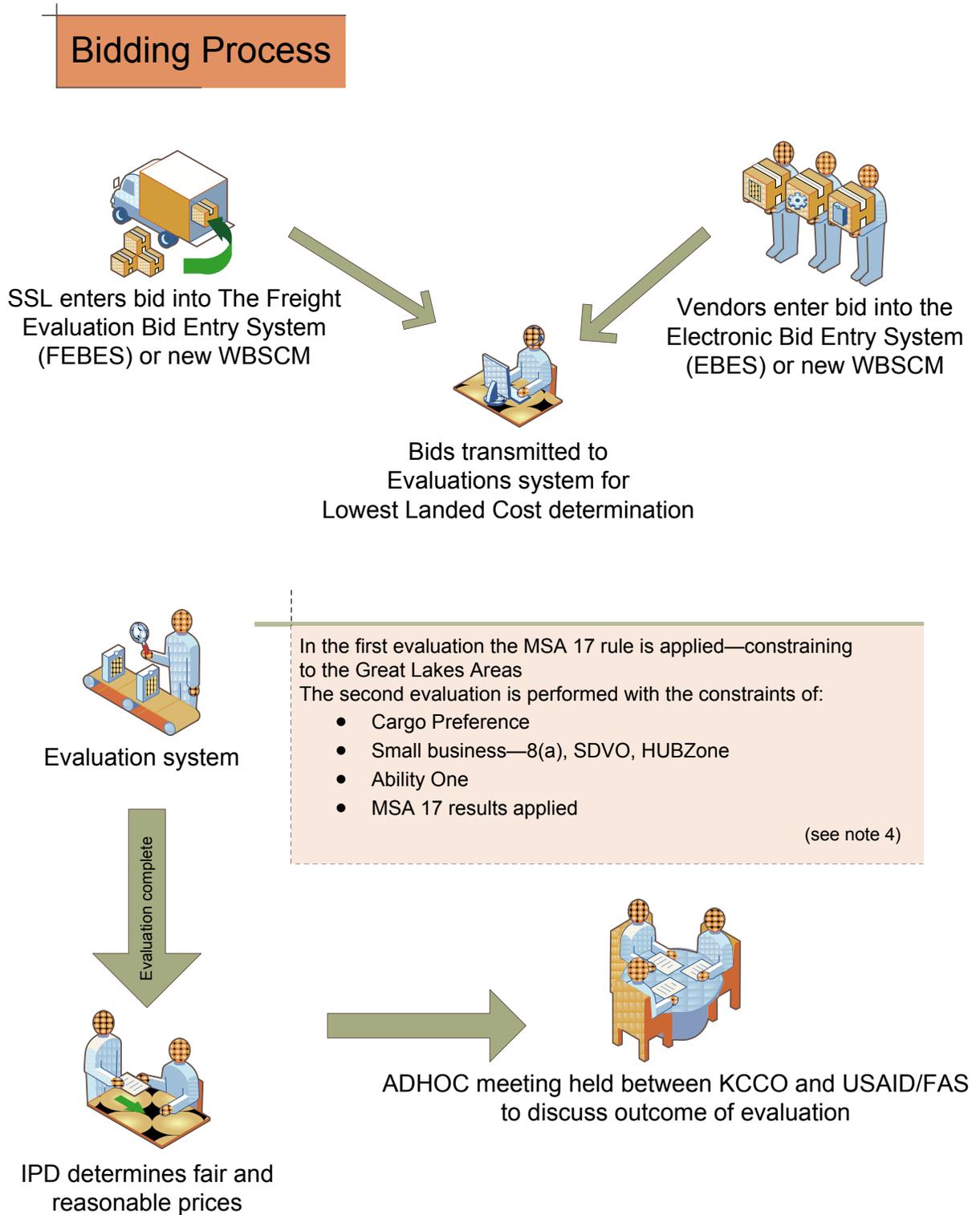


Appendix 10: Procurement Flow Charts

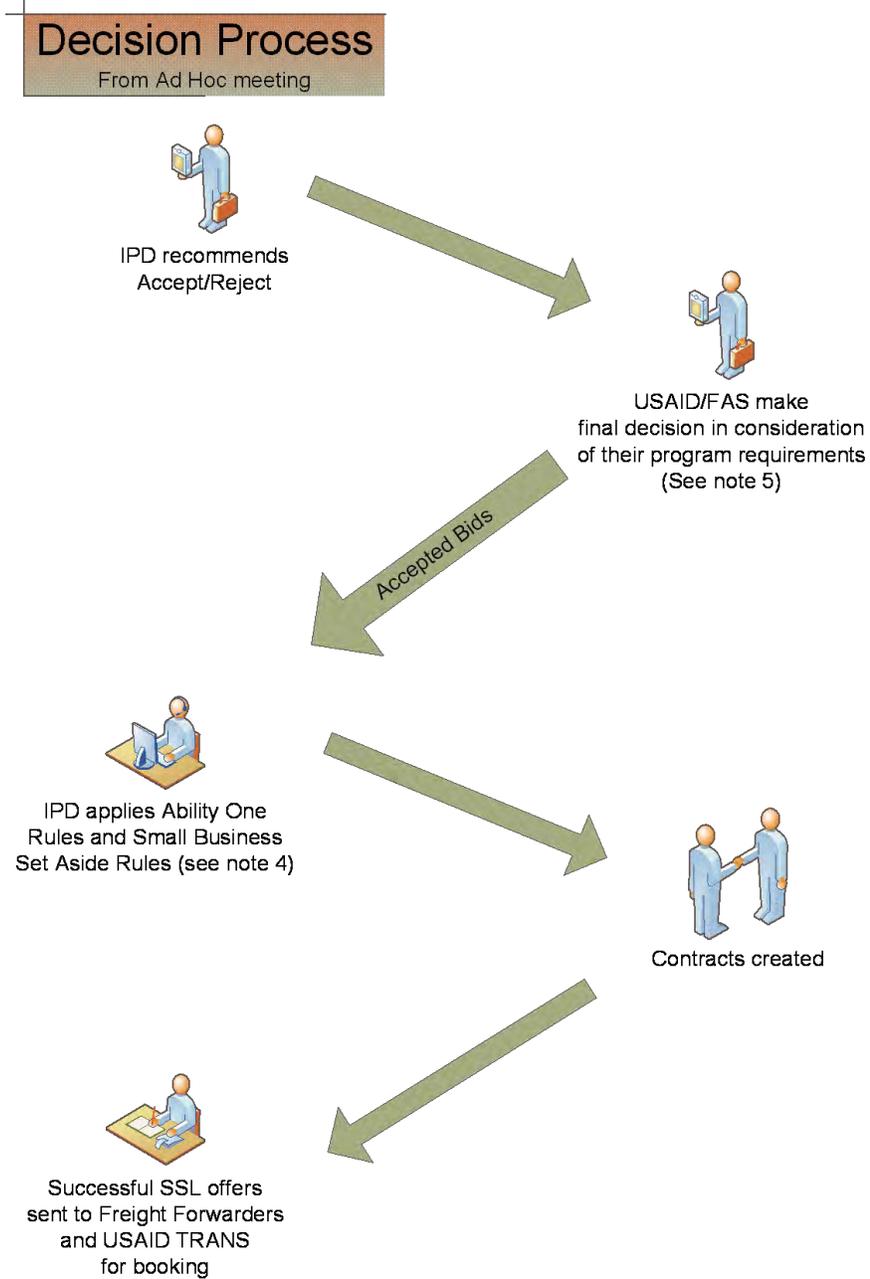
1. Approval Process (Part 1); Start of Actual Procurement Process (Part 2)



2. Bidding Process (Part 3)

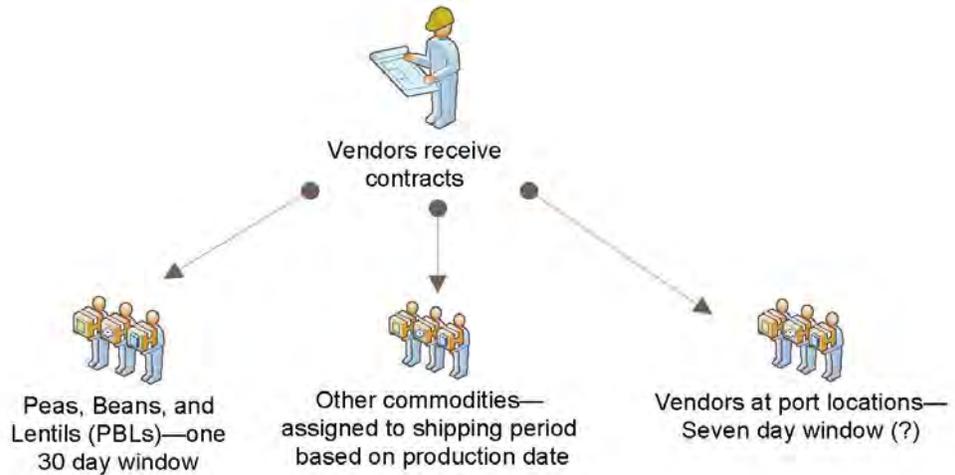


3. Decision Process (Part 4)



1. Commodity Delivery Process (Part 5)

Commodity Delivery Process



Estimated Time of Arrival for SSL based on last delivery date in commodity contract



PROCUREMENT FLOW CHART –EXPLANATORY NOTES

1. Contracting staff review Call Forward Proof List:

- If it meets specifications as listed in Commodity Requirements Document (CRD)
- If there is industry capacity to insure quantities can be met
- If there are any nonconforming specifications
- Review terms and conditions of contract

Following this, ports are to submit their capacities and final solicitations are created.

2. See the KC 362 for list of all approved bid points. The form KC-362 is a list of U.S. ports of export and “U.S. intermodal points,” which are plant locations and bridges identified by city and state.

3. Steam ship line (SSL) bids are received by

- USAID’s Transportation Department Freight forwarders (AID TRANS)
- Integrated Product Development Office (IPD)

Clarifications are made and *only* USAID can approve the clarification and *only* IPD can correct this in the system (Freight Evaluations Bid Entry System/Web Based Supply Chain Management [FEBES/WBSCM]). All bids that meet the terms and conditions of the solicitation are then included in the evaluation process.

4. IPD uses accepted bids and then applies the following rules:

- Ability One (also known as JWOD for Javits-Wagner-O'Day) is a mandatory source of procurement from nonprofit agencies that employ disabled individuals for 20% of program agencies’ needs for vegetable oil.
- 2. 8 (a) refers to service-disabled- and veteran-owned set-asides to assure they have an opportunity to be competitive.
- 3. Small business set-aside to assure they have competitive access to contracts.
- 4. Historically Underutilized Business Zone (HUBZone) is a preference program to promote job growth, capital investment, and economic development to historically underutilized business zones, referred to as HUBZones, by providing contracting assistance to small businesses located in these economically distressed communities.

5. If the government is unsuccessful in procuring all quantities advertised, the program agency, in consultation with the USDA Kansas City Commodities Office (KCCO), determines how to procure the needed quantities.

Appendix II: Impact of Macro- and Micronutrients on HIV Progression (Untreated)

Year	Authors	Country	Type of study	N	Intervention	Duration	Outcomes
2003	Jiamton et al.	Thailand	Randomized, placebo-controlled.	481 HIV+ men and women with CD4 cell counts in the range 50×10^6 to $550 \times 10^6/L$ (242 intervention, 239 placebo).	High-dose multiple micronutrient supplementation (vitamin A 3000 μg , beta-carotene 6 mg, vitamin D ₃ 20 μg , vitamin E 80 mg, vitamin K 180 μg , vitamin C 400 mg, vitamin B ₁ 24 mg, vitamin B ₂ 15 mg, vitamin B ₆ 40 mg, vitamin B ₁₂ 30 μg , folacin 100 μg , panthothenic acid 40 mg, iron 10 mg, magnesium 200 mg, manganese 8 mg, zinc 30 mg, iodine 300 μg , copper 3 mg, selenium 400 μg , chromium 150 μg , and cysteine 66 mg). Trial participants were examined clinically every 12 wk and tested for CD4 cell count every 24 wk. A subset was tested for HIV plasma viral load at 48 wk.	12 mo	79 (16%) trial participants were lost to follow-up and 23 (5%) died. The death rate was lower in the micronutrients arm with mortality hazard ratios of 0.53 (95% CI, 0.22–1.25; $p = 0.1$) overall and 0.37 (95% CI, 0.13–1.06; $p = 0.052$) and 0.26 (95% CI, 0.07–0.97; $p = 0.03$) among those with CD4 cell counts $< 200 \times 10^6/L$ and $< 100 \times 10^6/L$, respectively. No impact on CD4 cell count or plasma viral load.
1999	Fawzi et al.	Tanzania	Randomized, double-blind, placebo-controlled.	648 children admitted to hospital with pneumonia.	Baseline, 4 mo, and 8 mo after hospital discharge: placebo or 400 000 IU (or half that for infants) of vitamin A , in addition to standard treatment for pneumonia. Children who were severely malnourished or had clinical signs of vitamin A deficiency were excluded.	~24 mo	Vitamin A supplements resulted in a 49% reduction in mortality (RR, 0.51; 95% CI, 0.29–0.90; $p = 0.02$). Vitamin A supplements reduced all-cause mortality by 63% among HIV-infected children (RR, 0.37; 95% CI, 0.14–0.95; $p = 0.04$) and by 42% among uninfected children (RR, 0.58; 95% CI, 0.28–1.19; $p = 0.14$). Vitamin A supplements were also associated with a 68% reduction in AIDS-related deaths ($p = 0.05$) and a 92% reduction in diarrhea-related deaths ($p = 0.01$).

Year	Authors	Country	Type of study	N	Intervention	Duration	Outcomes
2004	Fawzi et al.	Tanzania	Double-blind, placebo-controlled.	1078 pregnant HIV+ women.	Daily supplements of vitamin A (preformed vitamin A and beta-carotene). Multivitamins (vitamins B, C, and E).	~71 mo	Of 271 women who received multivitamins, 67 had progression to stage 4 disease or died vs. 83 of 267 women who received placebo (24.7% vs. 31.1%; RR, 0.71; 95% CI, 0.51–0.98; $p = 0.04$). Multivitamin use was also associated with reductions in the relative risk of death related to AIDS (0.73; 95% CI, 0.51–1.04; $p = 0.09$), progression to WHO stage 4 (0.50; 95% CI, 0.28–0.90; $p = 0.02$), or progression to stage 3 or higher (0.72; 95% CI, 0.58–0.90; $p = 0.003$). Multivitamins also resulted in significantly higher CD4 and CD8 cell counts and significantly lower viral loads. The effects of receiving vitamin A alone were smaller than, and for the most part not significantly different from, those produced by placebo. Adding vitamin A reduced benefit with regard to some of the endpoints examined.
1995	Coutsoudis et al.	South Africa	Randomized, placebo-controlled.	118 offspring of HIV+ women.	Supplements were given with 50,000 IU vitamin A at 1 and 3 mo of age, 100,000 IU at 6 and 9 mo, and 200,000 IU at 12 and 15 mo. Morbidity in the previous month was then recalled at each follow-up visit.	806 child-months	Among all children, the supplemented group had lower overall morbidity than the placebo group (OR = 0.69; 95% CI, 0.48–0.99). Among 85 children of known HIV status (28 infected, 57 uninfected), morbidity associated with diarrhea was significantly reduced in the supplemented infected children (OR = 0.51; 95% CI, 0.27–0.99), whereas no effect of supplementation on diarrheal morbidity was noted among the uninfected children.

Year	Authors	Country	Type of study	N	Intervention	Duration	Outcomes
1999	Kelly et al.	Zambia	Randomized, placebo-controlled.	106 HIV+ patients with persistent diarrhea.	Patients were randomized to receive oral albendazole plus micronutrient supplement (vitamin A 10,500 IU, vitamin C 300 mg, vitamin E 300 mg, selenium 150 µg, and zinc 200 mg) or albendazole plus placebo.	3 mo	<p>Serum vitamin A and E concentrations before treatment were powerful predictors of early mortality, but supplementation did not reduce time with diarrhea or mortality during the 1st month, even after taking into account initial vitamin A and E concentrations, CD4 cell count, or clinical markers of illness severity.</p> <p>Serum concentrations of vitamins A and E did not increase significantly in supplemented patients compared with those given placebo, and there were no changes in CD4 cell count or hematological parameters. No adverse events were detected except those attributable to underlying disease.</p> <p>Although micronutrient deficiency is predictive of early death in patients with diarrhea-wasting syndrome, short-term oral supplementation does not overcome nor influence morbidity or mortality.</p>
1999	Humphrey et al.	Tanzania	Randomized, placebo-controlled.	40 HIV+ women of reproductive age.	Single oral dose of 9900 µmol (300,000 IU) vitamin A or placebo.	8 wk follow-up	<p>No differences were found between treatment groups in the frequency of signs or symptoms of acute vitamin A toxicity, nor were differences evident in any lymphocyte subset or activation marker at any time during follow-up.</p> <p>Mean and median viral load concentration at each time point and change in viral load from baseline to each follow-up point did not differ between treatment groups. No difference was measured between treatment groups in the proportion of women who responded to PHA or Candida.</p>

Year	Authors	Country	Type of study	N	Intervention	Duration	Outcomes
2002	Baeten et al.	Kenya	Randomized, double-blind, placebo-controlled.	400 HIV-1-infected women	Daily oral vitamin A (10,000 IU retinyl palmitate)	6 wk	<p>No statistically significant difference in the prevalence of HIV-1 DNA (18% vs. 21%, $p = 0.4$) or the quantity of HIV-1 RNA (3.12 vs. 3.00 \log_{10} copies/swab, $p = 1.0$) in vaginal secretions of women receiving vitamin A vs. placebo.</p> <p>No significant effect of supplementation on plasma HIV-1 load or CD4 or CD8 cell counts was observed, and no effect was seen among women who were vitamin A deficient at baseline.</p>
1998	Semba et al.	U.S.	Randomized, double-blind, placebo-controlled.	120 HIV+ intravenous drug users	<p>Single high-dose vitamin A supplementation, 60-mg retinol equivalent (200,000 IU)</p> <p>Plasma vitamin A level, CD4 lymphocyte count, and HIV load measured at baseline and 2 and 4 wk after treatment.</p>	4 wk	Vitamin A supplementation had no significant impact on HIV load or CD4 lymphocyte count at 2 and 4 wk after treatment.
1998	Allard et al.	Canada	Randomized, double-blind, placebo-controlled.	49 HIV+ patients	Supplements of both DL-alpha-tocopherol acetate (800 IU daily) and vitamin C (1000 mg daily), or matched placebo	3 mo	<p>The vitamin group ($n = 26$) had an increase in plasma concentrations of alpha-tocopherol ($p < 0.0005$) and vitamin C ($p < 0.005$) and a reduction in lipid peroxidation measured by breath pentane ($p < 0.025$), plasma lipid peroxides ($p < 0.01$), and malondialdehyde ($p < 0.0005$) vs. controls ($n = 23$).</p> <p>There was also a trend toward a reduction in viral load (mean \pm SD changes over 3 mo, -0.45 ± 0.39 vs. $+0.50 \pm 0.40 \log_{10}$ copies/mL; $p = 0.1$; 95% CI, -0.21 to -2.14). The number of infections reported was 9 in the vitamin group and 7 in the placebo group.</p>

Year	Authors	Country	Type of study	N	Intervention	Duration	Outcomes
2004	Olsen et al.	Kenya	Randomized, double-blind, placebo-controlled.	181 adults.	Supplement of 60 mg of elemental iron twice weekly.	4 mo	No effect on viral load.
2004	McClelland et al.	Kenya	Randomized, double-blind, placebo-controlled.	400 HIV-1 seropositive women.	Multivitamin plus selenium supplementation (20 mg vitamin B ₁ , 20 mg vitamin B ₂ , 25 mg vitamin B ₆ , 100 mg niacin, 50 mg vitamin B ₁₂ , 500 mg vitamin C, 30 mg vitamin E, 0.8 mg folic acid, and 200 mg selenium vs. placebo.	6 wk	<p>The odds of detection of vaginal HIV-1-infected cells were 2.5-fold higher ($p = 0.001$) and the quantity of HIV-1 RNA in vaginal secretions was 0.37 log₁₀ copies/swab higher ($p = 0.004$) among women who received micronutrients vs. placebo, even after adjustment for potential confounders including baseline HIV-1 shedding and CD4 count.</p> <p>The increase in vaginal HIV-1 shedding was greatest among women who had normal baseline selenium levels. Micronutrient supplementation resulted in higher CD4 (+23 cells/μL, $p = 0.03$) and CD8 (+74 cells/μL, $p = 0.005$) counts compared with placebo but did not alter the plasma viral load. Micronutrients resulted in higher levels of genital HIV-1 shedding compared with placebo.</p>
2010	Mda et al.	South Africa	Randomized, double-blind.	118 HIV+ children (4–24 mo) who were hospitalized with diarrhea or pneumonia.	Daily dose of a multimicronutrient supplement (300 mg retinol, 0.6 mg thiamin, 0.6 mg riboflavin, 8 mg niacin, 0.6 mg pyridoxine, 1 mg cobalamin, 70 mg folic acid, 25 mg ascorbic acid, 5 mg 1,25-dihydrocholecalciferol, 7 mg d,l atocopherol, 700 mg copper, 8 mg iron, 30 mg selenium, and 8 mg zinc) vs. placebo until discharge from hospital.	18 mo	<p>Duration of hospitalization was shorter ($p < 0.05$) among children who were receiving supplement (7.3 ± 3.9 days) (mean \pm SD) vs. placebo (9.0 ± 4.9 days), independently of admission diagnosis.</p> <p>In children admitted with diarrhea, the duration of hospitalization was 1.6 days (19%) shorter among children receiving supplement than among those receiving placebo, and hospitalization for pneumonia was 1.9 days (20%) shorter among children receiving supplement.</p>

Year	Authors	Country	Type of study	N	Intervention	Duration	Outcomes
2010	Mburu et al.	Kenya	Randomized, placebo-controlled.	180 HIV+ adults	<p>Food composed of 500 g unfortified, unsweetened maize (90%)–soy (10%) blend per day per family.</p> <p>Multimicronutrient capsules were taken daily. The micronutrients in the capsule were (15mg) zinc as zinc glutamate and vitamin A palmitate (800 mg RE), beta-carotene (30 mg), cholecalciferol (200 mg), dl-α-tocopheryl acetate (6.71 mg RRR-α-tocopherol equivalents), vitamin C (70 mg), thiamin (1.4 mg), riboflavin (1.4 mg), niacin (18 mg), pyridoxine hydrochloride (1.9 mg), cyanocobalamin (2.6 mg), folic acid (400 mg), iron (30 mg), copper (2 mg), selenium (65 mg), and iodine (150 mg).</p>	?	<p>There were no differences between men and women either in plasma zinc or in the responses to the supplements, and their data were combined.</p> <p>Plasma zinc lower in those with inflammation. Repeated-measures analysis of variance (ANOVA) showed inflammation blocked increases in plasma zinc, and there was a 10% increase in plasma zinc concentration in response to multimicronutrient supplementation ($p = 0.023$) in cases where there was no inflammation.</p> <p>Subgroup analysis showed mean changes in plasma zinc of 0.95 and 0.83 mmol/L ($p = 0.031$) in response to the multimicronutrient and food treatments, respectively, in those without inflammation at both time points. Inflammation blocks increase in plasma zinc after multimicronutrient supplement, and it is important to identify those without inflammation to determine the effectiveness of a zinc supplementation program.</p>

Year	Authors	Country	Type of study	N	Intervention	Duration	Outcomes
2010	Aghdassi et al.	Canada	Randomized, double-blind, placebo-controlled.	52 HIV+ subjects with elevated glucose, lipids, or body fat redistribution and insulin resistance.	400 µg/day chromium-nicotinate or placebo.	16 wk	<p>Chromium was tolerated without side effects and resulted in significant decreases in HOMA-IR (median [IQR]: pretreatment 4.09 [3.02–8.79], posttreatment 3.66 [2.40–5.46]; $p = 0.004$), insulin (median [IQR]: pretreatment 102 [85–226] pmol/L, posttreatment 99 [59–131] pmol/L; $p = 0.003$), triglycerides, total body fat mass (mean \pm SE: pretreatment 17.3 ± 1.7 kg, posttreatment 16.3 ± 1.7 kg; $p = 0.002$), and trunk fat mass (mean \pm SE: pretreatment $23.8 \pm 1.9\%$, posttreatment $22.7 \pm 2.0\%$, $p = 0.008$).</p> <p>Blood glucose; C-peptide; total, HDL, and LDL cholesterol; and hemoglobin A1c remained unchanged. Biochemical parameters did not change in the placebo group except for LDL cholesterol, which increased significantly. Body weight and medication profile remained stable throughout the study in both groups. Chromium improved insulin resistance, metabolic abnormalities, and body composition in HIV+ patients.</p>
2009	Kupka et al.	Tanzania	Randomized, placebo-controlled.	915 pregnant women.	<p>Daily oral dose of 200 mg of selenium (selenomethionine) tablet or placebo from enrollment to 6 mo postpartum.</p> <p>Hemoglobin concentration measured at baseline (12–27 wk of gestation) and at 6 wk and 6 mo postpartum. Morbidity data collected during monthly visits to the clinic.</p>	6 mo postpartum	<p>Selenium supplements had no effect on hemoglobin concentrations during follow-up (mean difference, 0.05 g/dL; 95% CI, –0.07 to 0.16 g/dL) but reduced diarrheal morbidity risk by 40% (relative risk, 0.60; 95% CI, 0.42 to 0.84).</p>

Year	Authors	Country	Type of study	N	Intervention	Duration	Outcomes
2009	Arpadi et al.	U.S.	Randomized, placebo-controlled.	56 HIV+ children and adolescents aged 6–16 yr.	Vitamin D (100,000 IU bimonthly) and calcium (1 g/day; $n = 29$) or double placebo ($n = 27$).	12 mo	<p>No group differences were seen in the change in CD4 count or CD4% or viral load.</p> <p>The overall mean monthly serum 25-hydroxyvitamin D concentrations were higher in the group that received vitamin D and calcium than in the placebo group, as was the monthly serum 25-hydroxyvitamin D area under the curve.</p> <p>After completing 12 mo of study, 2 (6.7%) participants in the group that received vitamin D and calcium had a trough serum 25-hydroxyvitamin D concentration < 20 ng/mL, compared with 14 (50%) in the placebo group. Twelve (44.4%) in the vitamin D/calcium group had trough serum 25-hydroxyvitamin D concentration ≥ 30 ng/mL, compared with 3 (11.1%) in the placebo group.</p>
2008	Kelly et al.	Zambia	Cluster-randomized double-blind, placebo-controlled.	500 individuals aged >18 yr.	Daily tablet containing 15 micronutrients : beta-carotene 4.8 mg, ascorbic acid (vitamin C) 70 mg, cholecalciferol (vitamin D ₃) 5 µg, tocopherol (vitamin E) 10 mg, thiamin (vitamin B ₁) 1.4 mg, riboflavin (vitamin B ₂) 1.4 mg, niacin 18 mg, vitamin B ₆ 1.9 mg, cyanocobalamin (vitamin B ₁₂) 2.6 µg, folic acid 400 µg, iron 30 mg, zinc 15 mg, copper 2 mg, selenium 65 µg, and iodine 150 µg) at just above the recommended nutrient intake or placebo.	3.3 yr (midpoint crossover)	<p>The primary endpoint, incidence of diarrhea (1.4 episodes/yr/person), did not differ with treatment allocation.</p> <p>However, severe episodes of diarrhea were reduced in the supplementation group (OR = 0.50; 95% CI, 0.26–0.92; $p = 0.017$). Mortality was reduced among HIV+ participants from 12 with placebo to 4 with supplementation ($p = 0.029$ by log-rank test), but this was not due to changes in CD4 count or nutritional status.</p>
2007a	Semba et al.	Malawi	Randomized, placebo-controlled.	1402 HIV+ and HIV– adults with pulmonary tuberculosis.	Daily micronutrient supplementation (specific micronutrients not accessible) vs. placebo.	24 mo	<p>During follow-up, 328 HIV+ and 17 HIV– participants died.</p> <p>The proportion of HIV+ participants who died in the micronutrient and placebo groups was 38.7% and 40.4%, respectively ($p = 0.49$). Micronutrient supplementation did not reduce mortality (hazard ratio, 0.93; 95% CI, 0.75–1.15) among HIV+ adults.</p>

Year	Authors	Country	Type of study	N	Intervention	Duration	Outcomes
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2007b	Semba et al.	U.S.	Double-blind, randomized, placebo-controlled.	458 hepatitis C-positive female injection drug users.	Daily micronutrients with 18 mg of iron (iron group) vs. micronutrients without iron (control group) for 12 mo.	12 mo	<p>There were no significant differences in the proportion of women with anemia, the proportion of women with ferritin < 30 ng/mL, log₁₀ plasma HCV RNA, or log₁₀ plasma HIV RNA between treatment groups at enrollment.</p> <p>The proportions with anemia in the iron and control groups, respectively, were 20.7% vs. 31.3% ($p = 0.026$) at 6 mo and 26.2% vs. 30.4% ($p = 0.5$) at 12 mo; the proportions with ferritin < 30 ng/mL were 29.2% vs. 55.5% ($p < 0.0001$) at 6 mo and 26.2% vs. 46.9% ($p = 0.0018$) at 12 mo.</p> <p>In iron and control groups, mean log₁₀ plasma HCV RNA (IU/mL) was 5.2 vs. 5.2 ($p = 0.86$) at 6 mo and 5.4 vs. 5.3 ($p = 0.6$) at 12 mo. Among HIV+ subjects, mean log₁₀ plasma RNA (copies/mL) in iron and placebo groups, respectively, was 3.8 vs. 3.7 ($p = 0.75$) at 6 mo and 3.7 vs. 4.1 ($p = 0.19$) at 12 mo.</p>
2010	Swaminathan et al.	India	Prospective interventional study.	361 ART-naïve patients.	Patients at 1 center received nutritional counseling and standard care, whereas patients at 2 centers additionally received a macronutrient supplement providing 400 kcal and 15 g of protein daily.	18 mo	<p>Significant increases in body weight, BMI, MUAC, fat-free mass, and body cell mass were observed in the supplement group but not in the control group at 6 mo.</p> <p>Gains were greater in patients with CD4 cell counts < 200 cells/μL. No changes were observed in lipid levels, whereas the CD4 cell count decreased in the control group. However, after adjustment for baseline differences, these changes were not statistically significantly different between the groups.</p>

Year	Authors	Country	Type of study	N	Intervention	Duration	Outcomes
2005	Ndekha et al.	Malawi	Cohort.	93 HIV+ children > 1 yr old discharged from the nutrition unit.	Three dietary regimens: RUTF , RUTF supplement, or blended maize–soy flour. RUTF and maize–soy flour provided 730 kJ/kg/day, while the RUTF supplement provided a fixed amount of energy, 2100 kJ/day. Children were followed every 2 wk.	(?) Children in study until 100% weight-for-height, relapsed, or died	52/93 (56%) of all children reached 100% weight-for-height. Children receiving RUTF gained weight more rapidly and were more likely to reach 100% weight-for-height than the other 2 dietary groups ($p < 0.05$).
1999	Schwenk et al.	Germany	Randomized, nonblinded control.	55 HIV+ patients with 15% weight loss since infection or 13% during previous month.	Nutritional counseling to increase dietary intake by 600 kcal/day; in group A ($n = 24$) by normal food , and in group B ($n = 26$) by a range of fortified drink supplements with a calorific value of 0.6 to 1.5 kcal/mL.	8 wk	Fat-free mass increased from baseline to week 8 ($p < 0.05$), with no difference between groups A and B ($p = 0.97$). Body cell mass and weight gain were not significant and equal between groups. Assessed at weeks 2 and 4, group B patients consumed 11 ± 6 kcal/kg as supplements, and their total energy intake was 6 kcal/kg higher than in group A ($p < 0.01$). Total energy intake was not different between groups at weeks 6 and 8.
1999	Shabert et al.	U.S.	Randomized, placebo-controlled.	26 HIV+ patients with < 5% weight loss since infection or >3% during previous month.	40 g/day of L-glutamine and antioxidants vs. placebo.	12 wk	Significant increase in body weight (2.2 vs. 0.3 kg, $p = 0.04$) and body cell mass (1.8 vs. 0.4 kg, $p = 0.007$) in experimental group compared with control group; CD4 lymphocyte counts remained stable throughout the study (140 ± 115 and 206 ± 164 cells/mm ³ for experimental and control groups, respectively).

Year	Authors	Country	Type of study	N	Intervention	Duration	Outcomes
2000	Berneis et al.	Switzerland	Randomized, placebo-controlled.	15 HIV+ patients with BMI < 21 kg m ² or CD4 T cells < 500/μL in stable clinical condition.	Either oral nutritional supplements providing 2510 kJ with complete macro- and micronutrients (26 g whey protein, 88 g carbohydrates, 17 g fat as corn oil, trace elements, and vitamins) plus dietary counseling (<i>n</i> = 8) or identical monitoring but no supplements or specific nutritional advice (controls, <i>n</i> = 7).	12 wk	<p>Leucine oxidation (protein catabolism) decreased in the group receiving nutritional intervention from 0.33 ± 0.02 to 0.26 ± 0.02 μmol/kg/min after 12 wk (<i>p</i> < 0.05; <i>p</i> < 0.05 vs. control group) but remained unchanged in the control group.</p> <p>Whole body leucine flux showed a tendency to decrease in the intervention group from 1.92 ± 0.19 to 1.73 ± 0.14 μmol/kg/min (<i>p</i> = 0.07) and remained unchanged in the control group (2.21 ± 0.16 and 2.27 ± 0.14 μmol/kg/min, respectively).</p> <p>Lean body mass determined by bioelectrical impedance analysis increased in the nutritional intervention group from 84 ± 2% to 86 ± 2% (<i>p</i> < 0.05), and fat mass decreased from 17 ± 2% to 14 ± 2% (<i>p</i> < 0.05) of total body weight, whereas neither mass changed in the control group.</p> <p>Nutritional intervention had no significant effect on CD4 lymphocyte count; plasma TNFR 55, TNFR 75, and ILR 2 concentrations; and quality of life.</p>
2000	Clark et al.	U.S.	Randomized, double-blind, placebo-controlled.	68 HIV+ patients with documented weight loss of at least 5% in the previous 3 mo.	Experimental group: 200 kcal/day of amino acid mixture containing 14 g arginine, 14 g glutamine, and 3 g β-hydroxy-β-methylbutyrate. Control group: 200 kcal/day of maltodextrin.	8 wk	<p>Significant gain in body weight (3.0 vs. 0.4 kg, <i>p</i> = 0.009) and lean body mass (2.55 ± 0.75 vs. -0.70 ± 0.69 kg, <i>p</i> = 0.003) in experimental group compared with control group.</p> <p>No significant improvement in CD4 lymphocyte count or HIV viral load in either group.</p>

Year	Authors	Country	Type of study	N	Intervention	Duration	Outcomes
2003	de Luis et al.	Not reported	Randomized, placebo-controlled.	70 HIV+ patients 20–60 yr of age with 15% weight loss during previous 6 mo.	Experimental group: Ensure oral formula , 3329 kJ/day (54% carbohydrate, 32% protein, 14% fat) and nutrition counseling. Control group: nutrition counseling alone (no intake target specified).	12 wk	<p>At baseline, patients (OKG, $n = 22$; placebo, $n = 24$) had similar CD4 counts (338 ± 172 and 310 ± 136 cells/mL), viral load (3.6 ± 1.3 and 3.5 ± 1.3 \log_{10} copies/mL), BMI (20.0 ± 2.4 and 20.6 ± 3.0 kg/m^2), weight loss (9.0 ± 3.12 and 9.4 ± 3.0 kg), and food intake (2509 ± 962 and 2610 ± 808 kcal/day).</p> <p>Both groups increased their BMI ($p = 0.02$ vs. baseline) and triceps skinfold thickness ($p < 0.01$ vs. baseline).</p> <p>They showed a similar positive correlation between handgrip strength and fat-free mass. Frequency of gastrointestinal symptoms increased in the OKG group (86% vs. 54% in the placebo group, $p = 0.025$). CD4 lymphocyte count and HIV viral load unchanged in both groups. No other differences were observed between groups.</p>
2010	Villamor et al.	Tanzania	Randomized, placebo-controlled.	594 HIV+ breast-feeding women.	Randomized to receive MVI, Multivitamins; VA/BC, vitamin A and β -carotene; MVI +VA/BC, multivitamins plus vitamin A and β -carotene; placebo.	2 yr	<p>VA/BC supplementation in lactating women increased viral load in breast milk. Effect persisted for > 6 mo; BC levels but not retinol levels were associated with increased viral load.</p>
2004	Karsegard et al.	Switzerland	Double-blind, prospective, randomized, placebo-controlled.	46 HIV+ patients >18 yr of age, 5%–15% weight loss since infection, CD4 count 1150 cells/ mm^3 , body fat mass 15%.	Experimental group: 10 g/day l-ornithine alpha-ketoglutarate (OKG) . Control group: isonitrogenous placebo (milk proteins).	12 wk	<p>Significant increase in BMI ($p = 0.02$ vs. baseline) and triceps skinfold thickness ($p = 0.01$ vs. baseline) in both groups; no significant difference between groups.</p> <p>Muscle area, fat-free mass, and body fat mass did not significantly change during the course of study in either group.</p> <p>CD4 lymphocyte count and HIV viral load were unchanged in both groups. Higher incidence of gastrointestinal disturbance with OKG.</p>

Note: BMI, Body Mass Index; HCV, hepatitis C virus; HDL, high-density lipoprotein; HOMA-IR, Homeostasis Model of Assessment - Insulin Resistance; LDL, low-density lipoprotein; MUAC, mid-upper-arm circumference; PHA, phytohemagglutinin; RUTF, Ready-to-Use Therapeutic Food; WHO, World Health Organization.

Appendix 12: Impact of Macro- and Micronutrients on Response to ART Therapy

Year published	Authors	Country	Type of study	N	Intervention	Duration	Outcomes
MICRONUTRIENTS							
2001	Batterham et al.	Australia	Nonrandomized trial without placebo control, prospective dose comparison.	66 enrolled, 48 completed study (32 receiving HAART, 3 receiving dual therapy, 13 not receiving any HIV medications).	An antioxidant regimen (5450 IU vitamin A as beta-carotene, 250 mg vitamin C, 100 IU vitamin E, 100 µg selenium, 50 mg coenzyme Q10) or a high-dose antioxidant regimen (21,800 IU vitamin A as beta-carotene, 1000 mg vitamin C, 400 IU vitamin E, 200 µg selenium, 200 mg coenzyme Q10).	12 wk	The changes over treatment time were significant for selenium, glutathione, glutathione peroxidase, and lipid peroxides ($p < 0.03$). Changes in allantoin, uric acid, and viral load were not significant ($p > 0.05$). The main effects for group and the interaction effects were not significant for any of the parameters measured ($p \geq 0.05$). No significant differences between those receiving low-dose and those receiving high-dose regimens.
2002	Burbano et al.	U.S.	Randomized, placebo-controlled.	186 HIV+ injection drug users (85 receiving HAART, 39 receiving dual or monodrug therapy, 52 not receiving any HIV medications).	Daily selenium (200 µg) for 2 yr.	2 yr	Significantly fewer participants in the intervention group than in the placebo group had a decrease in CD4 cell count of > 50 cells/µL during the study. Intervention significantly reduced hospital admissions because of opportunistic infections and other HIV-related conditions. The placebo group had a 2.4 times greater risk of hospitalization ($p = 0.01$).
2002	Jaruga et al.	Denmark	Randomized, placebo-controlled.	30 HIV+ adults receiving HAART.	Daily vitamin A (5000 IU), vitamin C (50 mg), and vitamin E (100 IU).	6 mo	Intervention significantly increased concentrations of catalase and superoxide dismutase and significantly lowered thiobarbituric acid-reactive substances; the CD4 cell count increased in the intervention group from baseline, whereas the mean CD4 count in the placebo group decreased, but the difference was not statistically significant.

Year published	Authors	Country	Type of study	N	Intervention	Duration	Outcomes
MICRONUTRIENTS							
2002	Spada et al.	Brazil	Randomized, placebo-controlled.	29 HIV+ adults with CD4 count < 500 cells/ μ L. 26 initiated HAART and 3 dual combination therapy.	Daily vitamin E (800 mg alpha- tocopherol).	6 mo	Intervention had no significant effect on CD4 cell count, CD4:CD8 cell ratio, or plasma viral load as compared with placebo; intervention significantly increased lymphocyte viability compared with placebo.
2003	Jensen-Fangel et al.	Denmark	Randomized crossover trial without placebo control.	15 HIV+ adults receiving HAART, all with chronic nelfinavir-associated diarrhea.	Twice-daily calcium carbonate (1350 mg). A subset of 6 patients were additionally treated with twice-daily calcium gluconate (2950 mg) and an extra 300 mg calcium carbonate.	2 wk	Intervention had no significant effect on clinical measurements of diarrhea..
2003	McComsey et al.	U.S.	Nonrandomized, open-label pilot study without placebo control.	10 HIV+ adults receiving HAART for >12 mo.	Daily vitamin C (1000 mg) and vitamin E (800 IU) and twice-daily N-acetyl cysteine (600 mg).	24 wk	Intervention significantly increased fasting glucose and insulin resistance and decreased waist-to-hip ratio compared with placebo; intervention had no significant effect on peripheral fat, lipotrophy, CD4 cell count, or plasma viral load.

Year published	Authors	Country	Type of study	N	Intervention	Duration	Outcomes
MICRONUTRIENTS							
2003	Shor-Posner et al.	U.S.	Randomized, double-blind, placebo-controlled.	63 HIV+ drug users.	200 mg/day of selenium or placebo.	2 yr	<p>The majority of the study participants reported elevated levels of both State (68%) and Trait (70%) anxiety.</p> <p>Approximately 25% reported overall mood distress (POMS > 60) and moderate depression (BDI > 20). Psychological burden was not influenced by current drug use, ART treatment, or viral load. At the 12-mo evaluation, participants who received selenium reported increased vigor ($p = 0.004$) and had less anxiety (State, $p = 0.05$ and Trait, $p = 0.02$), compared with the placebo-treated individuals.</p> <p>No selenium-related effect on depression or distress was observed. The risk of State anxiety was almost 4 times higher and the risk of Trait anxiety was nearly 9 times higher in the placebo-treated group than in the selenium-treated group after controlling for ART, CD4 cell decline (> 50 cells), and years of education.</p>

Year published	Authors	Country	Type of study	N	Intervention	Duration	Outcomes
MICRONUTRIENTS							
2004	Gerber et al.	U.S.	Open, prospective trial.	14 HIV+ individuals with dyslipidemia.	ER-niacin at maximum doses of 2000 mg/day.	14 wk	<p>Significant reductions in serum levels of triglycerides ($p = 0.02$), total cholesterol ($p = 0.005$), and non-HDL cholesterol ($p = 0.04$) were seen after ER-niacin therapy.</p> <p>7 of 11 subjects were glucose intolerant after ER-niacin therapy; for 3 of these subjects, this was a new finding.</p> <p>b-Cell sensitivity to basal glucose levels increased significantly without concomitant increase in overall glucose disposition indices.</p> <p>The values for the homeostasis model of insulin resistance index increased significantly ($p = 0.005$).</p>
2006	Kaiser et al.	U.S.	Prospective, randomized, double-blinded, placebo-controlled.	40 HIV+ adults receiving HAART.	Micronutrient supplementation: 1200 mg <i>N</i> -acetyl cysteine, 1000 mg acetyl L-carnitine, 400 mg alpha-lipoic acid, 20,000 IU beta-carotene, 8000 IU vitamin A, 1800 mg vitamin C, 60 mg thiamin, 60 mg riboflavin, 60 mg pantothenic acid, 60 mg niacinamide, 60 mg inositol, 260 mg vitamin B ₆ , 2.5 mg vitamin B ₁₂ , 400 IU vitamin D, 800 IU vitamin E, 800 µg folic acid, 800 mg calcium, 400 mg magnesium, 200 µg selenium, 150 µg iodine, 30 mg zinc, 2 mg copper, 2 mg vitamin B, 99 mg vitamin K, 18 mg iron, 10 mg manganese, 50 µg biotin, 100 µg chromium, 300 µg molybdenum, 60 mg choline, 300 mg bioflavonoid complex, 100 mg L-glutamine, and 150 mg betaine HCl twice daily.	12 wk	Intervention significantly increased absolute CD4 cell count ($p = 0.03$) and mean change in CD4 cell count from baseline ($p = 0.01$) and had no significant effects on fasting glucose, insulin, lipids, or plasma viral load.

Year published	Authors	Country	Type of study	N	Intervention	Duration	Outcomes
MICRONUTRIENTS							
2007	Hurwitz et al.	U.S.	Double-blind, randomized, placebo-controlled .	450 HIV-1-seropositive men and women.	High selenium yeast supplementation (200 µg/day).	9 mo	<p>The intention-to-treat analyses indicated that the mean change in serum selenium concentration increased significantly in the selenium-treated group and not the placebo-treated group (delta = 32.2 ± 24.5 vs 0.5 ± 8.8 µg/L, <i>p</i> < 0.001), and greater levels predicted decreased HIV-1 viral load (<i>p</i> < 0.02), which predicted increased CD4 count (<i>p</i> < 0.04). Follow-up analyses evaluating treatment effectiveness indicated that the nonresponding selenium-treated subjects whose serum selenium change was ≤ 26.1 µg/L displayed poor treatment adherence (56.8% ± 29.8%), HIV-1 viral load elevation (delta = +0.29 ± 1.1 log₁₀ units), and decreased CD4 count (delta = -25.8 ± 147.4 cells/µL).</p> <p>Selenium-treated subjects whose serum selenium increase was > 26.1 µg/L evidenced excellent treatment adherence (86.2% ± 13.0%), no change in HIV-1 viral load (delta = -0.04 ± 0.7 log₁₀ units), and an increase in CD4 count (delta = +27.9 ± 150.2 cells/µL).</p>

Year published	Authors	Country	Type of study	N	Intervention	Duration	Outcomes
MACRONUTRIENTS							
2008	Cantrell et al.	Zambia	Pilot program.	636 food-insecure, HIV+ adults.	Food-insecure patients (and households) received monthly rations of 37.2 kg high-energy protein supplement, 1.9 L oil, 37.2 kg maize, and 3.7 kg beans. Adult daily requirements (WHO) : The composition of the household ration provided 68% of daily energy needs based on 2310kcal, 98% of daily protein needs based on 53g of protein, and 105% of daily fat based on 40g of fat	6 mo with option to continue another 6 mo if criteria met	Food supplementation was associated with better adherence to therapy. 258 of 366 (70%) patients in the food group achieved medication possession ratio of > 95% vs. 79 of 166 (48%) among controls (RR, 1.5; 95% CI, 1.2–1.8). This finding was unchanged after adjustment for sex, age, baseline CD4 count, baseline WHO stage, and baseline hemoglobin. No significant effect of food supplementation on weight gain or CD4 count.
2009a	Ndekha et al.	Malawi	Nonrandomized, longitudinal cohort.	336 wasted adults with AIDS.	To test the hypothesis that individuals on ART for 3 mo with a greater BMI as a result of supplementary feeding with ready-to-use fortified spread would maintain a higher BMI 9 mo after the feeding ended. Ready-to-use fortified spread , an energy-dense lipid paste; or corn-soy blended flour .	12 mo	9 mo after stopping food supplements, both groups had similar BMI, fat-free body mass, hospitalization rate, and mortality. Lower BMI, lower CD4 count, and older age at baseline were associated with a higher risk of death (odds ratio for BMI = 0.63; 95% CI, 0.47–0.79). Adherence to the ART regimen and quality of life were similar in both cohorts.
2009b	Ndekha et al.	Malawi	Randomized, investigator-blinded, controlled.	491 adults with BMI <18.5.	Ready-to-use fortified spread (n = 245) or CSB (n = 246).	3.5 mo	After 14 wk, patients receiving fortified spread had greater increases in BMI and fat-free body mass than those receiving CSB. Increase in BMI: 2.2 ± 1.9 (SD) vs. 1.7 ± 1.6; difference, 0.5; 95% CI, 0.2–0.8. Increase in fat-free body mass: 2.9 ± 3.2 vs. 2.2 ± 3.0 kg; difference, 0.7 kg; 95% CI, 0.2–1.2 kg. The mortality rate was 27% for those receiving fortified spread and 26% for those receiving CSB. No significant differences in CD4 count, HIV viral load, assessment of quality of life, or adherence to ART were noted between the 2 groups.

Note: ART, antiretroviral therapy; BDI, Beck Depression Inventory; BMI, Body Mass Index; CSB, Corn–Soy Blend; HAART, Highly Active Antiretroviral Treatment; HCV, hepatitis C virus; HDC, hepatitis delta virus; HOMA-IR, Homeostasis Model of Assessment - Insulin Resistance; LDL, low-density lipoprotein; MUAC, mid-upper-arm circumference; POMS, profile of mood states; RUTF, Ready-to-Use Therapeutic Food; WHO, World Health Organization.

Appendix 13: Comparison of Published Trials of FBFs and LNSs

Author	Year	Title	Results	Country	Clinic or community	SAM, MAM, preventive	Quantities (kcal): Including sharing, protective ration, information on package	Study population	Outcomes measured	Duration of feeding	Duration to follow-up	Instructions given
Briend et al.	1999	Ready-to-use therapeutic food for treatment of marasmus	RUTF avoids problems of quality control and bacterial contamination. RUTF might be useful in contaminated environments or where residential management is not possible, such as during a war or disaster. It might also be useful for treatment at home or in centers without a kitchen.	Chad	Clinic	SAM	RUTF: 40 x 2 kcal/kg/feed. F100: 20 x 2 kcal/kg/feed; 6 feedings daily.	>12 mo, SAM, edema. Included when they had been gaining weight rapidly for at least 3 days (<i>n</i> = 20).	N/A	N/A	N/A	Mothers were told to offer food repeatedly over 1 h, not to force-feed, and to give water if child was thirsty.

Author	Year	Title	Results	Country	Clinic or community	SAM, MAM, preventive	Quantities (kcal): Including sharing, protective ration, information on package	Study population	Outcomes measured	Duration of feeding	Duration to follow-up	Instructions given
Diop et al.	2003	Comparison of the efficacy of a solid ready-to-use food and a liquid, milk-based diet for the rehabilitation of severely malnourished children: a randomized trial	<p>RUF was significantly more effective than was F100 in the most wasted children.</p> <p>The mean daily energy intake in the RUF group was 808 ± 280 kJ/kg body wt/day, and that in the F100 group was 573 ± 201 kJ/kg body wt/day. The average weight gains in the RUF and F100 groups were 15.6 and 10.1 g/kg body wt/day, respectively ($p < 0.001$). The difference in weight gain was greater in the most wasted children ($p < 0.05$). The average duration of rehabilitation was 17.3 days in the F100 group and 13.4 days in the RUF group ($p < 0.001$).</p>	Senegal	Clinic	SAM	<p>F100 group: F100: 275 ± 111 kJ/kg/day or 65.73 ± 26.53 kcal/kg/day. Local foods: 298 ± 128 kJ/kg/day or 71.22 ± 30.59 kcal/kg/day.</p> <p>RUF group: RUTF: 557 ± 219 kJ/kg/day or 133.13 ± 52.34 kcal/kg/day. Local foods: 251 ± 106 kJ/kg/day or 59.99 ± 25.33 kcal/kg/day.</p>	Children 6–36 mo with WHZ < -2.0 , during recovery phase ($n = 70$).	Weight gain, daily.	Average duration of rehabilitation was 17.3 days in F100 group and 13.4 days in RUTF group.	Recruitment and follow-up were conducted between March and September 2001.	Children in the F100 group were fed directly from the cup or with a spoon if it was more convenient for the mother. Children in the RUTF group were usually fed directly from the packet and more rarely with a spoon. In both groups, local meals were served from a cup with a spoon.

Author	Year	Title	Results	Country	Clinic or community	SAM, MAM, preventive	Quantities (kcal): Including sharing, protective ration, information on package	Study population	Outcomes measured	Duration of feeding	Duration to follow-up	Instructions given
Lopriore et al.	2004	Spread fortified with vitamins and minerals induces catch-up growth and eradicates severe anemia in stunted refugee children aged 3–6 y	Linear growth of children fed fortified spread was 30% faster at 3 mo than in unfortified spread and control groups, after which HAZ increased only slightly in the fortified spread group and remained unchanged in the other groups. Increase in hemoglobin concentrations in the fortified spread group at 6 mo was twice that in the unfortified spread and control groups, and anemia was reduced by nearly 90%.	Algeria (refugee camp)	Clinic	Stunting (HAZ < -2)	Fortified and unfortified spread: 318.75 kcal/day.	3–6 yr, stunted (HAZ < -2), most were severely stunted (<i>n</i> = 374).	Weight, height, knee–heel length, hematologic indexes, parasitic infection, and morbidity assessed at 0, 3, and 6 mo.	6 mo	Collected 2.5 yr after study	Mothers were asked to bring their children to these feeding centers, where supplements were consumed on site under the direct supervision of study personnel.
Maleta et al.	2004	Supplementary feeding of underweight, stunted Malawian children with a ready-to-use food	There was higher intake of energy, fat, iron, and zinc in the RTUF group than in the maize and soy flour group. Both supplements resulted in modest weight gain, but the effect lasted longer after RTUF supplementation. Height gain was not affected in either group.	Malawi	Community	MAM	Both supplements provided 500 kcal.	Underweight, stunted children 42–60 mo (<i>n</i> = 61).	Height gain, weight gain, dietary intake measured at 4-wk intervals.	12 wk	12 wk	Caregivers were requested to serve the study children separately using plates that had been provided.

Author	Year	Title	Results	Country	Clinic or community	SAM, MAM, preventive	Quantities (kcal): Including sharing, protective ration, information on package	Study population	Outcomes measured	Duration of feeding	Duration to follow-up	Instructions given
Manary et al.	2004	Home based therapy for severe malnutrition with ready-to-use food	Children receiving RTUF were more likely to reach WHZ > 0 than those receiving RTUF supplement or maize- <i>soy</i> flour. The average weight gain was 5.2 g/kg/day in the RTUF group compared with 3.1 g/kg/day for the maize- <i>soy</i> and RTUF supplement groups. Use of RTUF led to a higher recovery rate and more rapid weight and height gains than RTUF supplement or maize- <i>soy</i> flour.	Malawi	Community	GAM	<ol style="list-style-type: none"> 1. RTUF 733 kJ/kg/day or 175 kcal/kg/day. 2. Fortified RTUF 2090 kJ/day. 3. Maize-<i>soy</i> flour for entire nuclear family (child received a quantity sufficient for full catch-up growth). 	Children > 12 mo discharged from Queen Elizabeth Central Hospital in Blantyre, Malawi (n = 282).	Recovery, catch-up growth; children measured at clinic every 14 days.	16 wk or until graduating (WHZ > 0), relapsed (recurrence of edema or infection), or died.	6 mo	Carers in the RTUF and RTUF supplement groups were instructed to feed the entire prescribed quantity of RTUF over the course of a day, and encouraged to achieve this by feeding small amounts at frequent intervals. Carers receiving maize- <i>soy</i> were instructed to feed their children 7 times a day and advised to save portions of porridge and cooked dough for feedings between family meals. A malnourished child on average needed to consume 1500 g/day of cooked maize- <i>soy</i> to receive 733 kJ/kg/day.

Author	Year	Title	Results	Country	Clinic or community	SAM, MAM, preventive	Quantities (kcal): Including sharing, protective ration, information on package	Study population	Outcomes measured	Duration of feeding	Duration to follow-up	Instructions given
Sandige et al.	2004	Home-based treatment of malnourished Malawian children with locally produced or imported ready-to-use food	Home-based therapy with RTUF was successful in effecting complete catch-up growth. 80% of those receiving locally produced RTUF and 75% of those receiving imported RTUF reached WHZ > -0.5. The difference between recovery rates was 5%. The rate of weight gain was 0.4 g/kg/day greater among children receiving locally produced RTUF.	Malawi	Clinic	SAM	Both local and imported RTUF 175 kcal/kg/day.	1–5 yr, discharged from hospital upon return of appetite or resolution of complications (<i>n</i> = 260).	Recovery, height (every 4 wk), weight (every 2 wk), MUAC (every 4 wk).	16 wk (or until reaching WHZ > -0.05)	6 mo	N/A
Ciliberto et al.	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	Children who received home-based therapy with RUTF were more likely to achieve WHZ > -2 than were those who received standard therapy and were less likely to relapse or die. Children who received home-based therapy with RUTF had greater rates of weight gain and a lower prevalence of fever, cough, and diarrhea than those who received standard therapy.	Malawi	Community	MAM	Home-based therapy with locally produced RUTF: 175 kcal/kg/day (1 jar of RUTF). Standard therapy: F100 given to inpatient children. 50 kg maize–soy blend upon discharge from hospital for consumption 7 times/day.	10–60 mo, WHZ < -2, mild edema, or both and a good appetite; recruited from NRU (<i>n</i> = 1178).	Recovery, weight, length, and MUAC every 2 wk.	8 wk (or until reaching WHZ > 0)	6 mo	N/A

Author	Year	Title	Results	Country	Clinic or community	SAM, MAM, preventive	Quantities (kcal): Including sharing, protective ration, information on package	Study population	Outcomes measured	Duration of feeding	Duration to follow-up	Instructions given
Patel et al.	2005	Supplemental feeding with ready-to-use therapeutic food in Malawian children at risk of malnutrition	Children receiving RUTF were more likely to recover (58% vs. 22%, difference 36%; 95% CI, 20–52) and had greater rates of weight gain (3.1 g/kg/day vs 1.4 g/kg/day; difference 1.7; 95% CI, 0.8–2.6) than children receiving CSB.	Malawi	Community	Preventive	RUTF: Mother given 7 kg/mo (5700 kJ/day, 1362.33 kcal/day) CSB: Given 50 kg/mo (28,300 kJ/day, 6763.86 kcal/day). Significant sharing of CSB expected.	10–60 mo, 85% > weight-for-height median > 80% without edema; recruited from NRU (<i>n</i> = 93).	Recovery (weight-for-height median > 90%), rate of weight gain; weight, length, and MUAC measured every 2 wk.	8 wk (or until weight-for-height median > 90%).	6 mo	Mothers were asked to feed their children 7 times/day.
Ndekha et al.	2005	Home-based therapy with ready-to-use therapeutic food is of benefit to malnourished, HIV-infected Malawian children	56% of all children reached 100% weight-for-height. Regression modeling found that the children receiving RUTF gained weight more rapidly and were more likely to reach 100% weight-for-height than the other 2 groups (RUTF supplement and CSB).	Malawi	Community	SAM	RUTF: 175 kcal/kg/day. RUTF supplement: ~ 500 kcal/kg/day. CSB: 175 kcal/kg/day. CSB was not fortified, but multimineral/vitamin supplement was provided. CSB was given in a quantity sufficient to feed the entire family.	HIV+ children with SAM 12–60 mo old recently discharged from hospital (<i>n</i> = 372).	Primary: reaching 100% weight-for-height median. Secondary: rate of weight gain, rate of statural growth, rate of growth in MUAC, prevalence of infectious symptoms, anthropometric indices after reaching 100% weight-for-height	Until weight-for-height median > 100%.	Assessment every 2 wk, follow-up 6 mo after discharge.	Mothers of children receiving RUTF were encouraged to feed the child all of the RUTF; mothers of children receiving RUTF supplement were asked to feed the child habitual family foods in addition to the supplement; mothers of children receiving CSB were encouraged to feed the child 7 times/day.

Author	Year	Title	Results	Country	Clinic or community	SAM, MAM, preventive	Quantities (kcal): Including sharing, protective ration, information on package	Study population	Outcomes measured	Duration of feeding	Duration to follow-up	Instructions given
Chaiken et al.	2006	The promise of a community-based approach to managing severe malnutrition: a case study from Ethiopia	87.8% of children graduated; 8.8% were referred to medical facility because of unsuccessful treatment or underlying medical complications; 2.3% defaulted; less than 1% died. Recovery rates were comparable with international standards, and coverage far exceeded that of traditional center-based care.	Ethiopia	Community	SAM	200 kcal/kg of RUTF plus supplementary ration of flour, oil, and soap. Flour was intended to supplement the household food supply to discourage sharing of RUTF.	Weight-for-height median < 70%, MUAC < 11 cm or bilateral edema; children with 70% < weight-for-height median < 80% were enrolled in SFP (<i>n</i> = ??).	Recovery (weight-for-height median > 80% at 2 successive weighings), weight, height, MUAC.	Until weight-for-height median > 80% for 2 successive weighings.	Enrolled into SFP after graduation, discharged from SFP when weight-for-height median > 85%.	Instructions on how to use the RUTF were given.

Author	Year	Title	Results	Country	Clinic or community	SAM, MAM, preventive	Quantities (kcal): Including sharing, protective ration, information on package	Study population	Outcomes measured	Duration of feeding	Duration to follow-up	Instructions given
Kuusipalo et al.	2006	Growth and change in blood haemoglobin concentration among underweight Malawian infants receiving fortified spreads for 12 weeks: a preliminary trial	Average weight and length gains were higher among infants receiving 25–75 g fortified spread daily than among those receiving 0–5 g; mean hemoglobin concentration remained unchanged among unsupplemented controls but increased by 10–17 g/L among infants receiving any fortified spread. Mean difference in 12-wk gain between infants in the 50 g milk-based fortified spread group and the unsupplemented group was 290 g (95% CI, –130 to 700 g), 0.9 cm (95% CI, –0.3 to 2.2 cm), and 17 g/L (95% CI, 0 to 34 g/L) for weight, length, and blood hemoglobin concentration, respectively. Results were comparable between soy- and milk-based fortified spread groups.	Malawi	Community	Underweight (WAZ < –2)	3 dosing regimens of milk- and soy-based fortified spread (25, 50, and 75 g/day); 1 group of infants receiving 5 g/day milk-based fortified spread; 1 unsupplemented group; energy content varied from 96 kcal (5 g milk-based fortified spread) to 397 kcal (75 g milk-based fortified spread).	617 mo, WAZ < –2; not eligible if weight < 5.5 kg, WHZ < –3, severe medical condition requiring hospitalization, or adverse reaction to fortified spread (n = 125).	Weight, length, blood hemoglobin concentration.	12 wk	N/A	N/A

Author	Year	Title	Results	Country	Clinic or community	SAM, MAM, preventive	Quantities (kcal): Including sharing, protective ration, information on package	Study population	Outcomes measured	Duration of feeding	Duration to follow-up	Instructions given
Adu-Afarwuah et al.	2007	Randomized comparison of 3 types of micronutrient supplements for home fortification of complementary foods in Ghana: effects on growth and motor development	All 3 supplements had positive effects on motor milestone acquisition by 12 mo compared with no intervention, but only Nutributter affected growth. At 12 mo, after control for initial size, the Nutributter group had a significantly higher WAZ (-0.49 ± 0.54) and LAZ (-0.20 ± 0.54) than did the crushable Nutritabs (WAZ, -0.67 ± 0.54 ; LAZ, -0.39 ± 0.54) and the Nutritabs and Sprinkles groups combined (WAZ, -0.65 ± 0.54 ; LAZ, -0.38 ± 0.54). The difference from the nonintervention group was not significant (WAZ, -0.74 ± 1.1 ; LAZ: -0.40 ± 1.0). A lower percentage of the nonintervention group (25%) than of the intervention groups (Sprinkles 39%, Nutritabs 36%, Nutributter 49%) could walk independently by 12 mo.	Ghana	Community	Preventive, SAM and MAM	Sprinkles: no calories. Nutritabs: no calories. Nutributter: 108 kcal/day.	Children 6–12 mo, receiving any breast milk ($n = 313$).	Growth, morbidity, and observed motor milestone acquisition at 12 mo.	6 mo (stops when infant is 12 mo).	N/A	Mothers were instructed to administer the daily dose in a single meal, 7 days/wk. To ensure that children consumed the entire dose, mothers were told to mix the supplement with 1–2 tablespoons (15–30 mL) of the child's food.

Author	Year	Title	Results	Country	Clinic or community	SAM, MAM, preventive	Quantities (kcal): Including sharing, protective ration, information on package	Study population	Outcomes measured	Duration of feeding	Duration to follow-up	Instructions given
Galpin et al.	2007	Breast milk intake is not reduced more by the introduction of energy dense complementary food than by typical infant porridge	Complementary feeding of infants with fortified spread has the same effect on their breast milk intake as complementary feeding with traditional CSB porridge, since the difference between the groups in effect on breast milk consumption was not significant.	Malawi	Community	Preventive	3 complementary feeding regimens: 25 g/day fortified spread (535 kJ/day or 127.87 kcal/day), 50 g/day fortified spread (1070 kJ/day or 255.74 kcal/day), and 72 g/day CSB (1190 kJ/day or 284.42 kcal/day).	6-mo-old infant and mother pairs. Exclusion factors: children with WHZ < -2.0, presence of edema (<i>n</i> = 44 mother-child pairs).	Difference in breast milk intake after 1 mo of complementary feeding as measured by the dose-to-mother deuterium oxide dilution technique.	1 mo	N/A	Mothers were asked not to disrupt the child's habitual breast-feeding pattern with the complementary foods.
Lin et al.	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 6–18 months	Children who received fortified spread gained 110 g more (95% CI, 10–220) from 6 to 12 mo of age than children receiving fish powder. Weight gain did not differ between the two groups from 12 to 18 mo of age, nor did statural growth from 6 to 12 mo or from 12 to 18 mo. Neither fortified spread nor fish powder was associated with significantly improved zinc status.	Malawi	Community	Preventive	Both diets provided 200 kcal/day and increased to 300 kcal/day when infant reached 9 mo.	All children 5.5–6.5 mo residing in the villages without evidence of edema or severe chronic illnesses (<i>n</i> = 240).	Primary: Rates of weight and length gain from 6 to 12 mo and from 12 to 18 mo. Secondary: Incidence of fever, cough, and diarrhea from 6 to 12 mo and from 12 to 18 mo in the 2 groups; changes in zinc and selenium plasma concentrations from 6 to 12 mo of age.	12 mo	Monthly	Fish powder group: Mothers shown how to mix the porridge. They demonstrated understanding by preparing porridge and feeding their child under the study nurse's observation. Fortified spread group: Mothers shown how to mix the spread. They demonstrated understanding by mixing the spread and feeding their child under the study nurse's observation.

Author	Year	Title	Results	Country	Clinic or community	SAM, MAM, preventive	Quantities (kcal): Including sharing, protective ration, information on package	Study population	Outcomes measured	Duration of feeding	Duration to follow-up	Instructions given
Linneman et al.	2007	A large-scale operational study of home-based therapy with ready-to-use therapeutic food in childhood malnutrition in Malawi	89% of children with SAM and 85% of those with MAM recovered. Therapy failed in 34 (4%) of the children with MAM, with 20 (2%) deaths, and in 61 (3%) of the children with SAM, with 29 (1%) deaths.	Malawi	Clinic	GAM	RUTF: 175 kcal/kg/day.	Children 6–60 mo with MAM (weight-for-height median: 70-85%) or SAM (weight-for-height median < 70%) based on WHO reference ($n = 2131$ SAM, $n = 806$ MAM)	Recovery.	8 wk or until WHZ > 0	Reassessment every 2 wk	Caretakers were instructed by staff as to the proper administration of food.
Adu-Afarwuah et al.	2008	Home fortification of complementary foods with micronutrient supplements is well accepted and has positive effects on infant iron status in Ghana	At 12 mo, all 3 intervention groups had significantly higher ferritin and lower plasma transferrin receptor concentrations than did nonintervention groups. Mean hemoglobin was significantly higher in infants receiving Nutritabs, but not in those receiving Sprinkles, than in those receiving no intervention. The prevalence of iron deficiency anemia was 31% in the nonintervention group compared with 10% in the intervention groups combined.	Ghana	Community	Preventive	Sprinkles: 1 sachet/day, no calories. Nutritabs: 1 tablet/day, no calories. Nutributter: 108 kcal/day.	Children > 5 mo and receiving breast milk. Excluded: those who were asthmatic or allergic to peanuts or whose parents were planning to leave the study during the next 7 mo (Sprinkles $n = 105$, Nutritabs $n = 105$, Nutributter $n = 103$, nonintervention $n = 96$).	Naked weight, recumbent length, and head circumference measured at 6, 9, and 12 mo. At 12 mo, assessment of 4 gross motor milestones (standing with assistance, walking with assistance, standing independently, and walking independently). Plasma iron assessment: hemoglobin, plasma ferritin, plasma transferrin receptor, C-reactive protein.	6 mo (stops when infant is 12 mo)	Every week	Mothers were instructed to administer the daily dose in a single meal, 7 days/wk. To ensure that children consumed the entire dose, mothers were told to mix the supplement with 1–2 tablespoons (15–30 g) of the child's food.

Author	Year	Title	Results	Country	Clinic or community	SAM, MAM, preventive	Quantities (kcal): Including sharing, protective ration, information on package	Study population	Outcomes measured	Duration of feeding	Duration to follow-up	Instructions given
Flax et al.	2008	Feeding patterns of underweight children in rural Malawi given supplementary fortified spread at home	Fortified spread supplementation is feasible for community-based nutrition interventions in Malawi. Introduction of fortified spread reduced the number of plain porridge meals but did not decrease the total number of meals or breast-feeds per day and did not change the daily mean time caregivers spent on feeding. Children accepted the fortified spread well, but more fortified spread was wasted when it was offered mixed with porridge than when given alone.	Malawi	Community	Underweight (WAZ < -2; -3 < WHZ < 0)	Fortified spread: 250 kcal/day.	Children 6–17 mo old (WAZ < -2.0; -3.0 < WHZ < 0) (<i>n</i> = 16).	Number and duration of feeding periods before and after fortified spread supplementation; teaspoons of fortified spread offered and eaten per episode each week.	12 wk	10 12-h observations were carried out on 2 consecutive days during weeks 1, 4, 8, and 12 of fortified spread use.	Caregivers were informed that they should feed the study child 7 teaspoons (~50 g) of fortified spread/day and that fortified spread was specifically for the study child.

Author	Year	Title	Results	Country	Clinic or community	SAM, MAM, preventive	Quantities (kcal): Including sharing, protective ration, information on package	Study population	Outcomes measured	Duration of feeding	Duration to follow-up	Instructions given
Phuka et al.	2008	Complementary feeding with fortified spread and incidence of severe stunting in 6- to 18-month-old rural Malawians	1-yr-long complementary feeding with fortified spread does not have a significantly larger effect than CSB on mean weight gain in all infants. But it is likely to boost linear growth and thus decrease the incidence of severe stunting. The 12-mo incidence of severe stunting was 13.3% for CSB, 0.0% for FS50, and 3.5% for FS25 ($p = .01$).	Malawi	Community	Preventive (exclusion criterion was $WLZ < -2.0$)	<p>CSB (71 g daily): 282 kcal/day.</p> <p>FS25 (25 g fortified spread daily): 127 kcal/day.</p> <p>FS50 (50 g fortified spread daily): 256 kcal/day.</p> <p>Note: Micronutrient contents of 25 g and 50 g supplements were similar</p>	Children 5.50 to 6.99 mo with $WLZ > -2.0$ ($n = 182$).	Primary: weight gain. Secondary: length gain; mean change in WAZ, LAZ, WLZ; incidence of severe or moderate to severe underweight, stunting or wasting; change in head circumference or MUAC; change in blood hemoglobin and serum ferritin concentrations.	12 mo	Data collected at weeks 17, 34, and 52	Caretakers were provided spoons and were advised to offer their infants porridge daily containing 12 spoonfuls of CSB, 8 spoonfuls of FS50, or 4 spoonfuls of FS25, divided into 2 or 3 daily doses. Mothers were encouraged to continue breast-feeding on demand and to feed their infants only as much of the food supplement as the infant wanted to consume at a time.

Author	Year	Title	Results	Country	Clinic or community	SAM, MAM, preventive	Quantities (kcal): Including sharing, protective ration, information on package	Study population	Outcomes measured	Duration of feeding	Duration to follow-up	Instructions given
Chaparro and Dewey	2010	Use of lipid-based nutrient supplements (LNS) to improve the nutrient adequacy of general food distribution rations for vulnerable sub-groups in emergency settings	Typical general food distribution rations provided in emergency settings—based on cereals, pulse, an FBF, oil, salt and sugar—do not meet the nutritional needs of infants and young children and pregnant or lactating women. Adding RUTF to the general food distribution ration compensates for their nutritional inadequacies. However, addition of RUTF to the general food distribution, even after eliminating the FBF, increases the cost by 34–52%.	N/A	N/A (theoretical)	General food distribution for emergencies	N/A	N/A	N/A	N/A	N/A	N/A
Defourny et al.	2009	A large-scale distribution of milk-based fortified spreads: evidence for a new approach in regions with high burden of acute malnutrition	Throughout the period of RUF distribution, the incidence of SAM (MUAC < 110 mm) remained at extremely low levels. Comparison of year-over-year admissions to the therapeutic feeding programs showed that the 2007 blanket distribution had essentially the same flattening effect on the seasonal rise of admissions as the 2006 individualized treatment of almost 60,000 moderately wasted children.	Niger	Community	Preventive	250 kcal (3 tablespoons/day).	Children with height between 60 and 85 cm. Since precise age is often unknown in this context, height was used as a proxy of age in order to target children 6-36 months (n = 60,000).	MUAC.	Monthly distribution of 4 pots of Plumpy'doz (325 g/pot) to each child from May to October 2007.	Monthly follow-up when the mothers came to pick up the rations from May to October 2007.	Mothers were instructed that the RUF (Plumpy'doz) was to be used as a supplement in addition to the foods the young children were typically receiving and not a replacement for breast-feeding. Families were told that the RUF was not appropriate for infants < 6 mo.

Author	Year	Title	Results	Country	Clinic or community	SAM, MAM, preventive	Quantities (kcal): Including sharing, protective ration, information on package	Study population	Outcomes measured	Duration of feeding	Duration to follow-up	Instructions given
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Huybregts et al.	2009	Prenatal food supplementation fortified with multiple micronutrients increases birth length: A randomized controlled trial in rural Burkina Faso	The group receiving fortified food supplement had a significantly greater birth length (+4.6 mm). Fortified food supplementation resulted in a modestly greater but not statistically significant birth weight (+31 g; $p = 0.197$). Women with early pregnancy anemia who received fortified food supplement gave birth to longer newborns than those who received multimicronutrient supplementation.	Burkina Faso	Community	Preventive	Fortified food supplement: 372 kcal/day. Multimicronutrient: No calories, just micronutrient supplement.	All pregnant women in the catchment area of 2 rural health centers in Burkina Faso ($n = 1175$).	Primary: birth weight, birth length, and Rohrer's ponderal index. Secondary: % of LBW infants, % of SGA infants, % of LGA infants, thoracic circumference, head circumference, and MUAC at birth.	Throughout pregnancy (~9 mo)	Daily monitoring	N/A
Matlisky et al.	2009	Supplementary feeding with fortified spreads results in higher recovery rates than with a corn/soy blend in moderately wasted children	Children receiving fortified spread were more likely to recover than those receiving CSB (80% in both fortified spread groups vs. 72% in the CSB group). The rate of weight gain in the first 2 wk was greater among children receiving fortified spread than among children receiving CSB. There was no significant difference between the 2 fortified spread groups. Rates of length gain did not differ among the 3 groups.	Malawi	Community	MAM	Milk/peanut fortified spread, soy/peanut fortified spread, CSB: 314 kJ/kg/day or 75.05 kcal/kg/day.	Children 6–60 mo with WHZ < -2 but WHZ \geq -3 ($n = 1302$).	Recovery (WHZ > -2), rates of weight gain, stature, MUAC, and incidence of adverse outcomes.	8 wk	Biweekly	Caretakers were instructed on how much of the supplementary food to feed the enrolled child daily and to increase the feeding frequency by giving 2 additional meals during the day. Emphasis was placed on not sharing the supplementary food with other members of the household.

Author	Year	Title	Results	Country	Clinic or community	SAM, MAM, preventive	Quantities (kcal): Including sharing, protective ration, information on package	Study population	Outcomes measured	Duration of feeding	Duration to follow-up	Instructions given
Ndekha et al.	2009b	Supplementary feeding with either ready-to-use fortified spread or corn-soy blend in wasted adults starting antiretroviral therapy in Malawi: randomised, investigator blinded, controlled trial	After 14 wk, patients receiving fortified spread had a greater increase in BMI (2.2 vs 1.7) and fat-free body mass (0.5 kg vs. 0.7 kg) than those receiving CSB. No significant differences in mortality rate, CD4 count, HIV viral load, assessment of quality of life, or adherence.	Malawi	Clinical	MAM	Fortified spread: 1360.9 kcal/day. CSB: 1360.9 kcal/day.	HIV+ adults who were starting ART with BMI < 18.5 (total n = 491, fortified spread n = 245, CSB n = 246).	Primary: changes in BMI and fat-free body mass after 3.5 mo. Secondary: survival, CD4 count, HIV viral load, quality of life, and adherence to ART.	14 wk	Weeks 2, 6, 10, and 14	Participants were advised to consider the food supplements as part of their medical treatment and told that the food should not be shared with others.
Phuka	2009	Efficacy of complementary food supplementation with Lipid-Based Nutrient Supplements (LNS) on growth of Malawian children (Summary of the Phuka 2008, Phuka 2009b, Phuka 2009c studies)	Short-term supplementation with fortified spread or CSB improved weight gain similarly, but neither of them had a short-term effect on length. Long-term provision of fortified spread resulted in greater length gain and weight gain and decreased incidence of stunting compared with provision of isoenergetic CSB. Provision of multiple micronutrients through fortified LNS and CSB supplements had similar effects on child development.	Malawi	Community	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Author	Year	Title	Results	Country	Clinic or community	SAM, MAM, preventive	Quantities (kcal): Including sharing, protective ration, information on package	Study population	Outcomes measured	Duration of feeding	Duration to follow-up	Instructions given
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Phuka et al.	2009b	Supplementary feeding with fortified spread among moderately underweight 6-18-month-old rural Malawian children	<p>There were no statistically significant differences between the outcomes in the two intervention groups</p> <p>Mean WAZ increased by 0.22z (95% CI, 0.07–0.37) and 0.28z (95% CI, 0.18–0.40) in the CSB and FS50 groups, respectively.</p> <p>The increase in WLZ was 0.39z (95% CI, 0.20–0.57) and 0.52z (95% CI, 0.38–0.65) in the CSB and FS50 groups, respectively.</p> <p>The rates of recovery from underweight and wasting were 20% and 93%, respectively, in the CSB group and 16% and 75% in the FS50 group. Few individuals recovered from stunting.</p>	Malawi	Community	Moderately underweight (WAZ < -2)	<p>FS50: 256 kcal/day. CSB: 282 kcal/day</p> <p>Note: fortified spread was packed into a 50-g daily dose.</p>	Children 6–15 mo with WAZ < -2.0 (n = 176).	<p>Primary: weight gain.</p> <p>Secondary: WAZ, LAZ, WLZ, recovery, MUAC, hemoglobin.</p>	12 wk	Measurement at weeks 6 and 12	<p>The guardians were provided with spoons and advised to offer their children daily either a packet of fortified spread or porridge containing 12 spoonfuls of FBF. All mothers were encouraged to continue breast-feeding on demand and to feed their children only as much of the food supplement as the child wanted to consume at a time.</p>
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Author	Year	Title	Results	Country	Clinic or community	SAM, MAM, preventive	Quantities (kcal): Including sharing, protective ration, information on package	Study population	Outcomes measured	Duration of feeding	Duration to follow-up	Instructions given
Phuka et al.	2009a	Postintervention growth of Malawian children who received 12-mo dietary complementation with a lipid-based nutrient supplement or maize-soy flour (2-yr follow-up study of the intervention in Phuka 2008)	12-mo-long complementary feeding with 50 g/day fortified spread is likely to have a positive and sustained impact on the incidence of severe stunting in rural Malawi. The cumulative 36-mo incidence of severe stunting was 19.6% in the CSB group, 3.6% in the FS50 group, and 10.3% in the FS25 group ($p = 0.03$). Mean WAZ changes were -1.09 , -0.76 , and -1.22 ($p = 0.04$); differences in changes in mean HAZ and WHZ were not statistically significant. Differences in length developed during the intervention at age 10–18 mo, whereas weight differences continued to increase after the intervention.	Malawi	Community	N/A	Follow-up study of intervention in Phuka 2008, no dietary intervention.	Same population as Phuka 2008 ($n = 149$ due to deaths and loss to follow-up at 36 mo).	Primary: incidence of moderate-to-severe stunting (LAZ/HAZ < -2) and changes in mean anthropometric indices.	N/A	At months 4, 8, 12, 18, and 36	N/A
Skau et al.	2009	Outcome of evaluation study of the Targeted Supplementary Food (TSF) program in Ethiopia	The mean change in WHZ was statistically significantly greater in the intervention children than in the control children (0.56 vs. 0.25). However, weight gain did not differ significantly between the control and intervention groups.	Ethiopia	Community	MAM	CSB: 1101 kcal/day. Oil: 277 kcal/day. TSF total: 1378 kcal/day.	Children 6–59 mo with MUAC of 11.0–11.9 cm ($n = 1411$).	WHZ, change in weight, change in MUAC.	6 mo	1, 2, 3, and 6 mo after enrollment	N/A

Author	Year	Title	Results	Country	Clinic or community	SAM, MAM, preventive	Quantities (kcal): Including sharing, protective ration, information on package	Study population	Outcomes measured	Duration of feeding	Duration to follow-up	Instructions given
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Isanaka et al.	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: a cluster randomized trial	The WHZ difference between the intervention and nonintervention groups was 0.12z (95% CI, 0.02–0.21) after 8 mo of follow-up. The absolute rates of wasting and severe wasting, respectively, were 0.17 and 0.03 events per child-year, compared with 0.26 and 0.07 events per child-year in the nonintervention group.	Niger	Community	Preventive	RUTF (Plumpy'nut): 500 kcal/day.	Children 6–60 mo with weight-for-height median \geq 80%. (Intervention $n = 1671$, control $n = 1862$.)	WHZ, wasting (WHZ < -2).	3 mo	Monthly for 8 mo.	N/A
Nackers et al.	2010	Effectiveness of ready-to-use therapeutic food compared with a corn/soy-blend-based premix for the treatment of childhood moderate acute malnutrition in Niger	Children in the RUTF group had a higher recovery rate than those in the CSB group (79.1% vs. 64.4%, $p < 0.0001$). More transfers to inpatient therapeutic feeding were observed for the CSB group than for the RUTF group (19.1% vs. 9.3%, $p = 0.003$). The length of stay was 2 wk shorter in the RUTF group ($p < 0.001$).	Niger	Community	MAM	RUTF (Plumpy'nut): 1000 kcal/day. CSB: 1231 kcal/day.	Children with height between 65 and 110 cm with weight-for-height median between 70% and 80% of NCHS (RUTF $n = 215$, CSB $n = 236$)	Recovery (weight-for-height median $\geq 85\%$ for 2 consecutive weeks).	16 wk	Weekly assessments; children who recovered were followed up for 6 mo after their discharge.	N/A

Author	Year	Title	Results	Country	Clinic or community	SAM, MAM, preventive	Quantities (kcal): Including sharing, protective ration, information on package	Study population	Outcomes measured	Duration of feeding	Duration to follow-up	Instructions given
Thakwalakwa et al.	2010	A lipid-based nutrient supplement but not corn–soy blend modestly increases weight gain among 6- to 18-month-old moderately underweight children in rural Malawi	Primary outcome measured was weight change, taken during follow-up period. The mean weight increase was 620 g in the LNS group, 510 g in the CSB group, and 470 g in the control group. WAZ changes were +0.02 in the LNS group, –0.31 in the CSB group, and –0.32 in the control group ($p = 0.03$).	Malawi	Community	MAM	43 g (921 kJ) LNS or 71 g (1189 kJ) CSB daily.	Underweight 6- to 18-mo-old children.	Weight change, WAZ	12 wk		Food was delivered to homes, spoons were provided, and guardians were instructed to give either 3 spoonfuls LNS or 3 spoonfuls CSB porridge (made from 5 spoonfuls CSB) twice daily. Mothers were encouraged to give the supplement in addition to breast-feeding.
Lagrone et al.	2010	Locally produced ready-to-use supplementary food is an effective treatment of moderate acute malnutrition in an operational setting	Of the 2417 children enrolled, 80% recovered, 4% defaulted, 0.4% died, 12% remained moderately wasted, and 3% developed SAM. Weight, length, and MUAC gains were 2.6 g/kg/day, 0.2 mm/day, and 0.1 mm/day, respectively. Cost per child treated was \$5.39.	Malawi	Clinic	MAM	RUSF: 65 kcal/kg/day.	Children 6–59 mo with MAM ($-3 < \text{WHZ} < -2$) ($n = 2417$).	Primary: recovery ($\text{WHZ} > -2$). Secondary: rates of weight gain and MUAC.	8 wk or until $\text{WHZ} > -2$	Re-assessment every 2 wk	N/A

Note: ART, antiretroviral therapy; BMI, Body Mass Index; CSB, Corn–Soy Blend; FBF, Fortified Blended Food; HAZ, height-for-age z-score; LAZ, length-for-age z-score; LBW, low birthweight; LGA, large for gestational age; MAM, Moderate Acute Malnutrition; MUAC, mid-upper-arm circumference; NCHS, National Center for Health Statistics; NRU, Nutrition Rehabilitation Unit; RTUF, RUF, Ready-to-Use Food; RUTF, Ready-to-Use Therapeutic Food; SAM, Severe Acute Malnutrition; SFP, supplementary feeding program; SGA, small for gestational age; WAZ, weight-for-age z-score; WHZ, weight-for-height z-score; WLZ, weight-for-length z-score.

Appendix I4: Contrasting Two Forms of Dairy-Source Protein: Whey Protein Concentrate and Dried Skimmed Milk Powder (DSMP)

Stunting is widespread in developing countries and is associated with increased morbidity and impaired development. Worldwide, one third of children under 5 years of age in developing countries are stunted (Hoppe et al., 2006); however, in many countries stunting rates reach 60% or 70%. Evidence that animal-based protein is key to linear growth is abundant in the literature (Allen, 1994; Allen et al., 1992; Leonard et al., 2000; Marquis et al., 1997). Leonard et al. (2000) found that linear growth were rates positively correlated with intakes of animal protein, and Marquis et al. (1997) found a positive association between animal-product foods and linear growth, even in children with low intakes of complementary foods.

Adding cow's milk as the animal-source food to the diet of stunted children has been shown in several observational and intervention studies in developing countries to be an effective and relatively inexpensive way of improving linear growth. Improved linear growth leads to a reduction in morbidity and mortality and improves development. There are many factors hypothesized and proven as to why cow's milk has such an effect, such as a high protein content (3.5 g/100 g), excellent source of micronutrients, and a good source of bioactive factors that may have growth-promoting abilities (Hoppe et al., 2006).

With greater evidence mounting for the importance of dairy for infant and child growth, it has been proposed that dairy be included in the fortified blended foods (FBF) distributed through Title II programming and other U.S. programs. There are several options to include dairy: Whey Protein Isolate (WPI), Whey Protein Concentrate at 34% and 80% concentration (WPC34, WPC80), various other forms of whey, and dried skimmed milk powder (DSMP). WFP has been developing and is now testing a new FBF targeted at children under 2 years of age that includes DSMP as part of its protein source.

As part of the process in the FAQR, we were asked to develop a new CSB⁴⁴ for USDA. Experts on the author team and expert panel debated as to what source of dairy protein would best serve the target populations and other necessities of USDA. It was determined that WPC80 would best fill this role. This decision was based on discussions with industry experts in nutrition, processing, and dairy as well as a literature review. We show here the results of our research and why WPC80 was chosen. As WPC80 and DSMP are the two main options for use as the dairy source of protein in FBFs, this document will compare and contrast the two.

However, it should be clear that this recommendation was made on the basis of the information available to us during the process of this review, and the criteria upon which we based our recommendation can and most likely will change as further research is conducted. As part of the ongoing process to assure FBFs are providing the best possible nutrition for target populations, the sources of protein should also be revisited.

⁴⁴ As a reference for other possible FBFs.

WPC80 versus DSMP—Protein Quality

Several indices are used to assess dietary protein. Table 1 compares WPC80 and DSMP with reference to five different indices of protein quality: the Protein Digestibility Corrected Amino Acid Score⁴⁵ (PDCAAS), the essential amino acid score, the amount of sulfur-containing amino acids, the amount of branched-chain amino acids (BCAAs), and the quantity of protein in grams per 100 g of the product. Currently, the PDCAAS is the accepted measure of protein quality; however, further refinement of this index will most likely occur in the future. The PDCAAS is the essential amino acid score with an added digestibility component. The essential amino acid score measures essential⁴⁶ amino acids present in the protein source and compares the values with a reference protein (usually egg whites). The protein is rated based upon the most limiting essential amino acid. Values greater than 1.0 for both the essential amino acid score and the PCDAAS indicate that the protein contains essential amino acids in excess of the human requirements. Proteins having values higher than 1.0 are generally just reported as having a value of 1.0, since the level above 1.0 is irrelevant, because this is a perfect score (FAO/WHO, 1991). However, in this report, numbers greater than 1.0 are reported for comparison.

TABLE 1
Protein quality index

Measurement	WPC80	DSMP
PDCAAS	1.14–1.61	1.24
Essential amino acids	46.32	44.22
Sulfur-containing amino acids	5.41	3.27
BCAAs	21.69	21.46
Protein in g/100 g of product	79.89	33.5

Note: BCAAs, branched-chain amino acids; DSMP, dried skimmed milk powder; PDCAAS, Protein Digestibility Corrected Amino Acid Score; WPC80, Whey Protein Concentrate 80%.

Whey proteins are more easily digested than other milk proteins, such as casein (Hoppe et al., 2008). Whey protein concentrate, which, unlike casein, does not contain DSMP, capitalizes on this fact. Whey proteins are also higher in the amino acids arginine and lysine. Arginine and lysine are among the amino acids thought to stimulate the body's production of growth hormone. The amino acid composition of whey protein is also very similar to that of skeletal muscle, providing almost all of the amino acids in near proportion to the ratios in muscle (Bergstrom et al., 1974). It is assumed that this

⁴⁵ PDCAAS = AAS × TD, where AAS is the amino acid score and TD is true digestibility (true digestibility of the test protein measured in a rat assay). There are several limitations that must be considered when using PDCAAS: the validity of using the protein requirement of children in a reference amino acid pattern and the validity of using true digestibility and the truncation of values above 100%. The reference scoring pattern is based on the amino acid requirements of children older than 1 year. The basic data were obtained from children who were recovering from malnutrition, which can question the relevance of these amino acid requirements for healthy children (Sarwar, 1997). However, in our case of working with FBFs planned for moderately malnourished children and women, it serves better for our purpose.

⁴⁶ There are nine essential amino acids. They must be consumed, as they cannot be produced by our bodies, and thus are essential in the diet.

compatibility would position whey as an effective anabolic supplement, or a supplement that helps build muscle (Ha and Zemel, 2003). For this reason, whey protein is the protein supplement of choice for professional body-builders.

Insulin in the circulation contributes to the uptake of amino acids, thus contributing to anabolism.⁴⁷ When insulin levels are low, intracellular protein catabolism, or degradation, increases. Although the percentage of amino acids that stimulate the secretion of insulin is the same in casein and whey proteins, the higher proportion of BCAAs in whey proteins results in a synergistic effect with insulin on protein metabolism (Garlick and Reeds, 1993). Moreover, the number of amino acids that stimulate secretion of glucagon, the opposing hormone to insulin, is substantially lower in whey proteins than in casein. Therefore the catabolic effect of glucagon is less after a whey protein meal (Hoppe et al., 2008).

Soy flour has approximately the same protein content as DSMP and WPC80. Thus, replacing part of the soy flour with one of the two dairy-source proteins will result in approximately the same protein energy percentage (PE%), but the protein quality will increase as a result of the higher PDCAAS of milk products (Hoppe et al., 2008). Table 2 shows the change in PDCAAS with the addition of WPC80 or DSMP in a CSB. When the soy content is reduced in CSB to make room for 5% WPC80 or 10% DSMP, the PDCAAS increases. However, because of the higher quality and quantity of protein in WPC80, a smaller amount of WPC80 can increase the PDCAAS more than a greater amount of DSMP. When corn content is replaced, the PDCAAS increases are higher due to the lower-quality protein found in corn compared with soy.

TABLE 2
CSB PDCAAS with WPC80 or DSMP

Fortificant	Reduced corn content	Reduced soy content	CSB without dairy
5% WPC80	.82	.80	.69
10% DSMP	.76	.74	.69

Note: BCAAs, branched-chain amino acids; CSB, Corn–Soy Blend; DSMP, dried skimmed milk powder; PDCAAS, Protein Digestibility Corrected Amino Acid Score; WPC80, Whey Protein Concentrate 80%.

The proteins specific to whey protein each have features that contribute to better nutrition and health. Beta-lactoglobulin, the most abundant protein in whey, binds fat-soluble vitamins, making them more available to the body. Alpha-lactalbumin is the second most abundant whey protein component and is the primary protein found in human breast milk. Lactoferrin, another component of whey protein, inhibits the growth of bad bacteria and fungi by its ability to bind iron. It also promotes the growth of beneficial bacteria such as Bifidus in the infant gut. Lactoferrin may also help reduce inflammation, an important benefit for individuals with illness (Gould, 2010).

⁴⁷ Anabolic functions in the body build and catabolic functions break down components such as bone or muscle.

Benefits for Growth with WPC80

Whey protein contains the highest concentration of BCAAs available from any food source. BCAAs are important in growth, as they must be present in the muscle cells to promote protein synthesis (Walzem et al., 2002). Circulating BCAAs are unique among amino acids because they can be metabolized for energy by the muscles rather than by the liver, as is the case with all other amino acids. This helps to increase carbohydrate availability and counteract muscle protein breakdown (Hoppe et al., 2008). Whey protein stimulates osteoblasts, the cells that build bones, and inhibit osteoclasts, the cells that break down bones (Takada et al., 1997).

Whey is known to stimulate the production of insulin-like growth factor (IGF) (USDEC, 2003). The IGF family of growth factors consists of three ligands, or molecules, that bind to receptors. These ligands are insulin, IGF-I, and IGF-II. IGF-I facilitates bone growth by increasing the uptake of amino acids, which are then integrated into new proteins in bone tissue (Cameron, 2002). This connection can explain part of the growth-stimulating effects of dairy, specifically whey (Hoppe et al., 2008). Insulin levels are decreased during starvation and malnutrition, and thus intake of BCAA might be more important to decrease body protein breakdown during these times (Garlick and Reeds, 1993). IGF-I and IGF-II have been shown to play roles in the promotion of cell production and reduction of cell death. Analysis of a cohort study found a positive association between intake of dairy products and IGF-I levels (Rogers et al., 2006)

A study found that weight gain from 0 to 2 years was positively associated with IGF-I levels measured at the age of 5 years. In other words, infants who showed catch-up growth from 0 to 2 years had higher IGF-I values in analyses controlling for their current height (Ong et al., 2002). Consequently, providing children from the age of 6 months and above with whey, which stimulates the production of IGF-1, may support catch-up and healthy growth.

Immune System Benefits with WPC80

Whey contains a relatively high proportion of sulfur-containing amino acids, especially cysteine. The high cysteine content of whey may spare protein from breakdown when the immune system is being challenged, as in bouts of diarrhea or upper respiratory infection. When the immune system is challenged, it produces acute phase proteins. Acute phase proteins are exceedingly rich in cysteine, and as a result, sulfur-containing amino acids are in greater demand during times of stress on the body. Cysteine is also the main source of the sulfhydryl group of glutathione peroxidase. Glutathione peroxidase is depleted in individuals with serious illness, such as PLHIV and children suffering from kwashiorkor. Secondary to these findings, it has been hypothesized that whey protein might increase glutathione levels and thus reduce the progression of HIV (Hoppe et al., 2008).

Pregnancy and WPC80

As mentioned above, the IGF axis, or group of growth-promoting hormones, is positively affected by the consumption of whey protein. The IGF axis is also key in regulating placental development (Forbes and Westwood, 2008). The IGF axis is also essential in regulating normal fetal and postnatal growth, and issues within the axis frequently result in short stature and compromise adult height and thus health (Savage et al., 2010). It can be postulated that providing whey protein to pregnant mothers will improve the health of their fetuses via improved placental and fetal development.

Lactose

Lactose is a type of sugar found in dairy products. Lactose intolerance results from insufficient lactase, the enzyme that digests the lactose sugar, in the gut. Lactose intolerance is common in many populations; it is estimated to be present in 75% of the world's population (Wardlaw et al., 2004). Lactose maldigestion is also frequent among individuals who are ill, such as people living with HIV and AIDS and children suffering from kwashiorkor. (Miller et al., 1991) observed that lactose malabsorption was a common finding in HIV-infected children. One can have a temporary lactose intolerance following a bout of intestinal disease, as the production of lactase is sensitive to disruptions in intestinal health.

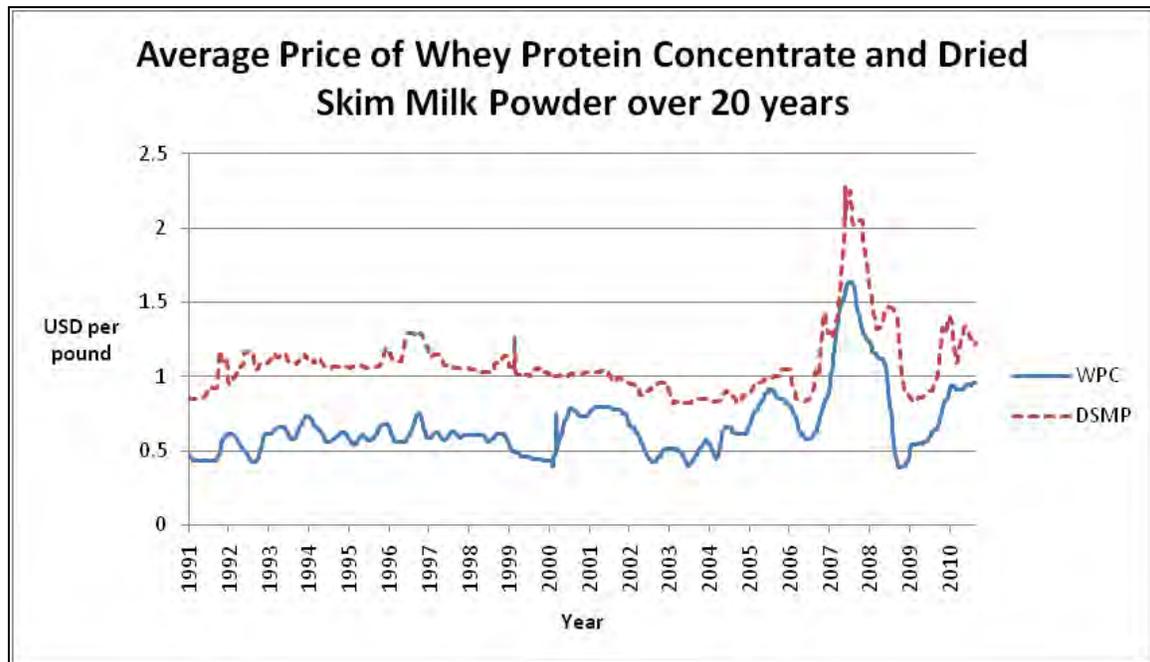
Lactose intolerance has been a common point of discussion in the creation of therapeutic foods, back to when the therapeutic milks F-75 and F-100 were first formulated. However, it has been shown through observational research that the lactose intolerance most likely experienced by many patients consuming F-100, for example, does not seem to impede recovery. However, the incidence of lactase insufficiency is high, which can cause problems when milk and milk products are consumed (Hoppe et al., 2006). Minimizing lactose content in foods designed for individuals experiencing illness would be practical. DSMP has a lactose content of about 50%, whereas WPC80 contains only 4% to 8% lactose (USDEC, 2003).

HIV/AIDS with WPC80

There is much research yet to be done in the area of nutrition and HIV (see Chapter 3 for more information). However, we do know that PLHIV have decreased ability to synthesize proteins and poor ability to mobilize body protein into amino acids for circulation. Because ART, and especially the group of AIDS retroviral drugs that are protease inhibitors, cause lipodystrophy and metabolic syndrome (Grinspoon and Carr, 2005; Estrada et al., 2006; Haugaard et al., 2004), an increased intake of BCAAs may be especially beneficial for patients on these drugs, as BCAAs may serve to counteract these side effects (Hoppe et al., 2008).

Financial Considerations with WPC80

There are financial reasons that whey protein is an excellent choice for use in FBFs. The supply of whey is constant, as it is a by-product of cheese production, whereas the availability of DSMP can be more volatile with the market. Because of the increased demand for cheese in the U.S. market, whey production has an estimated growth rate of 4% annually (Affertsholt, 2010).



The graph shows the average price of both WPC and DSMP over the past 20 years. WPC is consistently cheaper (Gould, 2010). Moreover, because it is a concentrate, less WPC needs to be added to improve the PDCAAS of an FBF, leading to a less expensive input.

Future Research

There is ongoing research in the area of dairy-based protein and the role it can play in assisting in treatment of malnutrition as well as various disease states, such as HIV. A list of a few of the ongoing and completed trials can be found at <http://dairyglobalnutrition.org/IndepRes/>. As stated at the beginning of this Appendix, the current recommendation is to incorporate WPC80 into FBFs, but progress in research on the relation between protein source and linear growth, as well as recovery from MAM, will lead to better formulations of what is needed by target populations.

Appendix 15: Fortificant Compounds Used in Fortified Foods

This appendix provides a review of the fortificant compounds that are currently used in food fortification programs around the world today. It is divided into two sections, the first on vitamins and the second on minerals.

VITAMINS

This section covers the following vitamins and their compounds in food fortification programs: **A, B₁, B₂, B₃, B₅, B₆, B₉ (folic acid), B₁₂, D, and K**. Each vitamin and its compounds and types listed have been reviewed covering the forms, compounds and types, stability, and bioavailability characteristics.

1. Vitamin A

Forms: Vitamin A in its form as retinol is an oil-based, unstable compound (Allen et al., 2006). The compound exists in seven different isomer forms, each with different biological activity levels. The all-trans isomer has the highest biological activity at 3,333,000 IU/g (Bauernfeind and Lachance, 1991). To improve its stability, commercially available vitamin A is produced in an ester form using palmitic or acetic acid known as retinyl (vitamin A) palmitate or retinyl (vitamin A) acetate. These compounds are commercially available in liquid or dry forms and are protected with antioxidants to prolong their shelf life.

In addition, the precursor of vitamin A known as beta-carotene is commercially available. Beta-carotene is available in a range of intense colors in the orange to yellow section of the visible spectrum. In some food applications, such as oils, oil-based foods, and margarines, the beta-carotene is used as a food colorant with the added side benefit as a fortificant.

Forms of vitamin A and their applications in food fortification

Form	Application
Oil vitamin A acetate	Fat-based foods, oils, margarines, and dairy products
Oil vitamin A palmitate	Fat-based foods, oils, margarines, and dairy products
Oil vitamin A acetate or palmitate with vitamin D ₃	Fat-based foods, oils, margarines, and dairy products

Cereals contain no natural vitamin A and very low levels of beta-carotene, a vitamin A precursor. They are, however, potential vehicles for vitamin A fortification in deficient populations. Flour and maize meal are not usually fortified with vitamin A in developed countries, where margarine and milk are often fortified and vitamin A deficiency is not a problem. The U.S. Title II (Food for Peace) Food Program provides vegetable oil, wheat flour, and maize meal fortified with vitamin A.

Vitamin A has been added to precooked maize flour in Venezuela since 1993. At the fortification level of 2.7 mg/kg and an intake of 80 g flour/day, it supplies about 40% of the recommended intake of the vitamin (Chavez, 1997). South Africa adds it to flour (1.6 mg/kg) and maize meal (1.9 mg/kg). Nigeria started requiring the addition of vitamin A to flour at a very high level of 9 mg/kg in 2002. In the Philippines, wheat flour was fortified with 4.5 mg/kg so that the level in the bread was 2.2 µg/g. This supplied about 33% of the Filipino RDA for the vitamin for school children and increased their liver stores of retinol significantly by the end of a 30-week efficacy trial (Solon et al., 2000).

Several forms of vitamin A are available for food fortification. These include retinyl acetate, retinyl palmitate, and provitamin A (beta-carotene). Beta-carotene has an intense orange color that makes it unsuitable as a fortificant for many foods, but it is used to give an orange-yellow color to margarines and beverages. The retinyl esters are available in an oil-soluble form (for fortification of oils and fats), spray-dried (for flours and powdered milk), and as water-dispersible beadlets (for fortification of sugar and other water-soluble foods). A special coated, protected form of retinyl palmitate, often generically referred to as *SD250*, is the recommended form of vitamin A for flour fortification because it is considered to be the most stable in this application. This product contains encapsulates and antioxidants that differ between manufacturers, making it impractical to specify its exact composition. Alternatively, the USDA specifies that the product used in PL480 (Food for Peace) commodities retain at least 80% of its activity under defined storage conditions. The stability of vitamin A in these commodities was found to be surprisingly good, with over 95% retained after 9 months (SUSTAIN, 1999b). There were additional losses during milling and baking, so that about 80% of the vitamin A added is actually consumed. Lower retentions, even down to 50%, can occur for non-bread baked products and maize meal.

It would be feasible to add vitamin A to any kind of flour or maize meal, including the high-extraction or whole wheat (atta) flours prevalent in some countries. The primary constraint is the cost (see Table 3.13). Inclusion of vitamin A can double or triple the cost of a cereal fortification program. Vegetable oil may be a better carrier because the form of vitamin A that can be used in oil is cheaper and the stability is somewhat better. However, in many countries, wheat flour or maize meal may be the only processed food consumed widely enough to deliver vitamin A to at-risk populations through food fortification.

2. Folic Acid

Folic acid has been included in cereal fortification programs for only the past 10 years but has proven so successful that now it is considered a leading reason to fortify cereal staples, even in developed countries with few overt micronutrient deficiency problems. The initial reason to include folic acid was to prevent the neural tube birth defects of spina bifida and anencephaly. These can occur if the mother has insufficient stores of folic acid during the first few weeks of pregnancy. Folic acid supplements taken prior to pregnancy will help prevent this, but many women are not aware that they are in early pregnancy when folic acid is needed or they simply fail to take supplements.

It is nearly impossible to get adequate intakes of folates from natural sources through dietary means, since the natural folates have only 60% of the vitamin activity of synthetic folic acid. The level of folates in cereals is low, even in whole grain products. The surest way to get folic acid to the whole population is to add it to a food staple, with wheat flour and maize meal being the preferred vehicles, particularly if it can be included in an existing or planned fortification program. A standard recommendation in the prevention of neural tube defects is to have women consume 0.4 mg/day folate equivalents. This is only achievable with mass fortification of a cereal staple such as flour.

Folic acid fortification of flour has proven to be highly effective. Studies have shown a threefold increase in serum folate after cereals were fortified in North America with 1.5 ppm folic acid (Lawrence et al., 1999) and a 19% decrease in neural tube defects (Honein et al., 2001). Canadian studies showed similar results in reducing serum folate insufficiency (Ray et al. 2002b) and a 50% reduction in neural tube defects (Persad et al., 2002; Ray et al., 2002a). Folic acid has been shown to be effective in the prevention of 50% to 70% of cases of neural tube defects. Additional benefits include the correction of folic acid deficiency anemia, decreased homocysteine levels, and possibly a reduced risk of other birth defects, stroke, heart disease, and cancer.⁴⁸

There is growing evidence that folic acid fortification will reduce the incidence of elevated homocysteine levels (Jacques et al., 1999), considered a major factor in cardiovascular disease and stroke. With the benefits of folic acid fortification now firmly established, many countries are now adding it to flour. An expert panel convened by the Micronutrient Initiative recommended a 2.4 ppm folic acid addition level to all flours.

There has been concern that high folic acid levels could mask neurologic problems in people with low intakes of vitamin B₁₂. This has led to reluctance to fortify with folic acid in some countries, but there have been no reports of folic acid fortification masking anemia in vitamin B₁₂ deficiency. This is more of a worry in developed countries, where people may get multiple sources of folic acid from supplements and other fortified foods. It may be possible, then, for some people to exceed the upper safety limit of folic acid of 1.0 mg/day, which is based on this vitamin B₁₂ interaction. An obvious solution to this is to add vitamin B₁₂ along with folic acid.

Folic acid has a light yellow color, which does not carry over to the flour or cereal food because it is added at such low levels, typically from 1.5 to 2.4 ppm. There is some loss of the vitamin on exposure to light and during cooking and baking, but not as much as originally supposed. Yeast-leavened breads will actually have a higher level of folic acid than that which is contributed by the fortified flour, since yeast has a significant level of folate activity. The biggest loss of folic acid will occur in cookies and pasta, but this is probably no more than 20%. Folic acid is difficult to analyze, so levels reported in fortified flour and baked products can have considerable assay error.

⁴⁸ Conclusions of 2004 Cuernavaca workshop (see Section 1).

3. Riboflavin (Vitamin B₂)

Cereals are not very good sources of riboflavin, so people dependent on wheat, rice, or white refined maize are likely to be deficient in this vitamin. This can result in a variety of skin and mucous membrane problems, which although not life-threatening can be very unpleasant. Riboflavin deficiency, along with deficiencies of some of the other B vitamins, has been implicated in elevated serum homocysteine levels (Jacques et al., 2001).

There can be a large loss of the vitamin when the food is exposed to sunlight or UV light. Its bright yellow color, although desirable in some cereal foods such as pasta and yellow cornmeal, may cause problems in products where whiteness is preferred, such as rice and white cornmeal. Riboflavin has been part of most cereal fortification programs. Its cost is higher than that of folic acid and thiamin, but not excessive. There is good reason to include riboflavin in most cereal fortification programs.

4. Thiamin (Vitamin B₁)

Thiamin has been included in cereal fortification programs since their inception in the 1940s. The levels in wheat and maize are not particularly low, even in the refined products, but the level of the vitamin that makes it through to the final food product that is actually consumed is much reduced due to its poor stability, particularly under alkaline (high pH) conditions. The thiamin level in white rice is quite low, causing more of a problem with thiamin deficiency (beriberi) in rice-eating populations. There is also concern about thiamin deficiency causing Wernicke–Korsakoff syndrome in alcoholics (Yellowlees, 1986). Australia and New Zealand started fortifying bread flour with thiamin for this reason, leading to a significant reduction in the prevalence of Wernicke–Korsakoff in these countries (Harper et al., 1998).

Thiamin can be added as either thiamin mononitrate or thiamin hydrochloride. The mononitrate form is preferred because it is considered more stable. Both are white powders and add no color to the flour. There are no known functional problems in adding thiamin to flour, and the cost of thiamin fortification is not very high.

5. Vitamin B₁₂

Cereals contain no vitamin B₁₂. It is present only in animal products. Deficiencies occur mainly in the elderly. The main justification for adding vitamin B₁₂ is so that high levels of folic acid can be added without the risk of masking B₁₂ deficiencies (Ray et al., 2000), but it is also implicated, along with some other B vitamins, in reducing serum homocysteine levels (Bower and Wald, 1995). Currently only one country, Israel, has included vitamin B₁₂ in its cereal fortification program, but there have been increasing calls that it be included (Quinlivan et al., 2002).

Vitamin B₁₂ (cyanocobalamin) is a complex molecule and difficult to produce. Its cost is very high, but the fortification cost is reasonable since it is needed in such small amounts.

It is a dark red compound, typically sold in a 1% dilution to make it easier to handle. It is relatively stable, but its stability in baking has not been tested. It is one of the most difficult vitamins to analyze in foods, with a microbiological procedure being the preferred method. There have been no reports of its addition adversely affecting the color or baking properties of wheat flour.

6. Pyridoxine (Vitamin B₆)

There is some suggestion that pyridoxine, along with folic acid and vitamin B₁₂, can help lower homocysteine levels and thereby reduce the incidence of heart disease and stroke (Jacques et al., 2001; Duell and Malinow, 1997; Kelly et al., 2003). Whole grains are good sources of this vitamin, but refined wheat flour and maize meal are not. However, because it is found in a variety of foods, overt vitamin B₆ deficiency is uncommon.

Pyridoxine hydrochloride is a white powder and is not known to cause any problems when added to cereals. Its cost of fortification is similar to that of riboflavin. There is some loss of pyridoxine on exposure to UV light. Currently, only South Africa includes vitamin B₆ in its cereal fortification program.

7. Niacin (Vitamin B₃)

Niacin is low in refined flours, and much of the niacin in whole maize, although the content is fairly high, is unavailable because it is in a bound form. The bound niacin is released and made available in the nixtamalization process of making tortillas, but other types of maize staples will be low in available niacin. This helped cause a high incidence of pellagra in the southeastern United States in the early 1900s, where maize was the main food staple, resulting in thousands of deaths each year. It was for this reason that niacin was included in the original cereal fortification program, which proved very successful in preventing pellagra. There is good reason to fortify maize with niacin in countries with maize-eating populations, particularly those that do not use a nixtamalization process, such as countries in sub-Saharan Africa and South America. However, it is relatively expensive and could be added at a lower rate to wheat flour, or even excluded from flour fortification programs in wheat-consuming populations.

One reason for not fortifying wheat flour with niacin is that wheat flour contains tryptophan, an amino acid in proteins that acts as a niacin precursor (60 mg tryptophan = 1 mg niacin = 1 Niacin Equivalent [NE]). The RDA for niacin is now given in NE units. When tryptophan content is considered, even refined wheat flour becomes a fairly good source of niacin, but maize meal is still inadequate.

Niacin comes in two chemical forms: niacinamide and nicotinic acid. The latter is normally referred to as niacin so as not to be confused with nicotine, a totally different compound. Niacinamide is slightly more expensive but it has the advantage over nicotinic acid of not acting as a vasodilator, which results in a flushing and skin reddening reaction in those handling the fortification premix. Both are white powders and

have no detrimental effects on taste or flour functionality. Niacin is very stable and has no problem with cooking or baking losses.

8. Vitamin C

Ascorbic acid or vitamin C provides a number of important nutritional benefits (Bendich and Langseth, 1995), but the one considered most desirable for cereal products is its ability to enhance the absorption of both native and added iron by severalfold. Ascorbic acid is routinely added to bread flour around the world at levels from 15 to 100 ppm to improve its bread-baking properties. Enzymes in the flour quickly convert ascorbic acid to dehydroascorbic acid, which acts as an oxidative improving agent during fermentation, giving a larger loaf volume and a lighter crumb. Unfortunately, further oxidation during and after baking destroys any remaining vitamin C activity. Non-baked foods prepared from maize meal retain more added vitamin C than does bread. About half of the ascorbic acid added to CSB, which is mainly maize meal, was retained when it was prepared as a paste (ugali or pap), commonly used in Africa (Ranum and Chome, 1998). The ascorbic acid added to CSB is lightly coated with ethyl cellulose (4%), but this has little benefit in preventing loss during cooking. Greater cooking stability is possible with more heavily coated products.

The cost of adding the levels of ascorbic acid necessary to improve iron absorption may be prohibitive. It could be cheaper to use iron in the form of NaFeEDTA. This is an area that has received more research and development in recent years. NaFeEDTA has been shown to be effective in various feeding studies in Africa. A full discussion NaFeEDTA is given in the Minerals section of this appendix.

9. Vitamin D

Milk, including dry and evaporated milk, is the preferred vehicle to fortify with vitamin D. Addition of vitamin D was included as optional in the early cereal fortification programs in the U.S., but it was never practiced and has since been removed. No country currently adds vitamin D to cereal staples, but it has been proposed for Mongolia. Vitamin D is often added to complementary foods targeted to children, such as CSB, and to margarine.

Vitamin D is a fat-soluble compound. Either vitamin D₂ (also called cholecalciferol or ergocalciferol) or vitamin D₃ (cholecalciferol or 7-dehydrocholesterol) can be added to foods, and both forms have similar biological activity, but the D₃ form is preferred for cereals. One International Unit (IU) of vitamin D is equivalent to 0.025 µg of the vitamin. Both forms are very sensitive to oxygen, moist air, and minerals. Dry stabilized vitamin D is available and contains an antioxidant (usually tocopherol) that protects potency for much longer, even in the presence of minerals. The form commonly used in cereals contains 100,000 IU or 2.5 mg of vitamin D₃ per gram.

MINERALS

The essential minerals can be classified as follows, depending on their concentration in

the body and dietary requirements. Differences in the quantity needed have a major impact on cost and other aspects of mineral fortification.

- Major elements: calcium, phosphorus, sodium, potassium, chloride, and magnesium.
- Elements needed in small amounts: iron and zinc.
- Trace elements needed in tiny amounts: include iodine, copper, and selenium.

For more comprehensive sources on mineral fortification, consult *The Mineral Fortification of Foods* (Hurrell, 1999) and *Guidelines on Food Fortification with Micronutrients* (Allen et al., 2003).

10. Iron

Iron has the greatest complexity and produces more problems with fortification than any other micronutrient. Creating an effective iron fortification program for cereals can be very challenging. Iron is included in nearly all the cereal fortification programs in the world to date. Despite lingering questions on its effectiveness, it would not be wise to exclude it from cereal fortification programs in countries with high levels of iron-deficiency anemia.

In 2004, the Cuernavaca Workshop concluded that wheat flour fortification with iron compounds with an adequate Relative Biological Value can make a significant contribution to reducing the prevalence of iron deficiency. The goal of iron fortification of cereal flours and soy–cereal blends should be to prevent iron deficiency rather than simply to restore flour to its original nutritional content. Iron compounds should be selected to maximize the bioavailable iron delivered to the population at the lowest cost, without adversely affecting the organoleptic and storage properties of fortified food products.

Because of the importance and difficulty of iron fortification, there are already a number of good publications on this topic, which can be consulted for additional information. A major concern is which iron source to use. Guidelines that can be consulted on iron in cereal fortification programs have been prepared by SUSTAIN (2001a), WHO (Allen et al., 2003), and PAHO (PAHO, 2002)

In 2008, a workshop was held in Stone Mountain, Georgia, USA, to review existing data on the five most important micronutrients and their deficiencies that are deemed to have the most significant impact on public health. The recommendations of the workshop were reviewed by WHO which then published the following document in 2009: *Recommendations on Wheat and Maize Flour Fortification. Meeting Report: Interim Consensus Statement* (WHO, 2009). The key recommendations of the Stone Mountain workshop and the WHO Interim Consensus Statement for iron are given in the table below.

Recommendations on iron fortification of wheat and maize flour based on different consumption levels

Flour extraction	Iron compound	< 75 g/day	75–149 g/day	150–300 g/day	> 300 g/day
Low	NaFeEDTA	40 ppm	40 ppm	20 ppm	15 ppm
	Ferrous sulfate	60 ppm	60 ppm	30 ppm	20 ppm
	Ferrous fumarate	60 ppm	60 ppm	30 ppm	20 ppm
	Electrolytic iron	NR	NR	60 ppm	40 ppm
High	NaFeEDTA	40 ppm	40 ppm	20 ppm	15 ppm

Notes: Added levels listed in the table refer to added iron content (not compound content).

NR, not recommended.

The main criteria in choosing an iron source are bioavailability, effect on product quality, color and cost.

Bioavailability, or the degree to which the body can utilize or absorb a particular mineral source, is a particularly important factor with iron, since it varies greatly with different iron sources. Ferrous sulfate and ferrous fumarate are considered to have good bioavailability, whereas that of elemental (reduced) iron powders is believed to be lower. There are many factors in the meal, the diet, and the way the food is processed that will affect the ability of people to absorb different forms of iron. There is ongoing research on the bioavailability of the different forms of iron from different products made from wheat flour and maize that will hopefully provide answers about which type of iron is best to use.

Organoleptic changes. Ferrous sulfate is a pro-oxidant that can accelerate rancidity development in unsaturated lipids. Because flour contains small amounts of fats, the addition of ferrous sulfate can reduce its acceptable shelf life. This is not normally a problem with flour that is used within a month after milling, such as flour for commercial bakeries (bakery flour), but it can cause unacceptable flavor developments in household flour after months of storage. Reduced elemental iron is considered safe in any type of flour, even those requiring extended storage periods and flours of higher extractions and therefore higher levels of fat.

Iron fortificants that can be added to flour without causing adverse sensory changes in one situation do not necessarily work with the same food product in another situation. One example is ferrous sulfate, which is added as a fortificant to wheat in Chile but could not be used for this purpose in Central America. This may have been due to differences in climate, type and extraction of the wheat flour, or the quality of the ferrous sulfate purchased from different suppliers.

The extent to which fat oxidation has occurred in cereal flours can be determined by measuring hexanal (2,4-dimethyl-2-pentene) levels with gas chromatography. This can be used to make a rapid estimate (within hours) of the propensity of a flour to go rancid by comparing a fortified with an unfortified flour (Bovell-Benjamin et al., 1999). Others have preferred to use more long-term storage of cereal products in cans at 37°C for 4

months, followed by measurement of pentane in the headspace (Hurrell et al., 1989). Both chemical detection methods agree well with taste panel evaluations of rancidity. Trained sensory evaluation panels should determine if there are changes in texture, flavor, color, or aroma in the fortified food compared with an unfortified control food as a result of processing or storage (including simulated shelf life conditions) and during food preparation (Bovell-Benjamin et al., 2000). The amount of detectable rancidity correlates closely with pentane and hexanal production, which can increase 10-fold.

Color. A potential problem with iron fortification is development of unwanted colors. These include a green or bluish color when free iron interacts with cereals and a gray color when it interacts with chocolate or cocoa. Dried ferrous sulfate is a light tan powder and adds no color to flour, but it can react with other compounds and ingredients (e.g., bananas) to cause noticeable color changes in dough. Ferrous sulfate added to maize meal can cause undesirable blue or green colors in cooked products made from maize meal. Encapsulated forms of ferrous sulfate are recommended for maize. Large-particle-size ferrous sulfate can cause black spots on breadcrust. Hydrated ferrous sulfate is blue-green in color and will cause color problems in the fortified flour and bread. For this reason, hydrated ferrous sulfate should never be used in flour fortification.

Ferrous fumarate is dark red in color and can be noticed in white flour or white maize meal if used at high levels. It is not as soluble or reactive in dough as is ferrous sulfate. Elemental iron powders are black in color. They add no color to maize meal or wheat flour but have a slight darkening effect, which is considered acceptable. They produce no known color reactions in dough.

The color of fortified flour and baked products can be assessed by both visual and instrumental methods. The latter are very sensitive to small changes that are not visually noticeable. The potential of an iron fortificant to cause color changes can sometimes be assessed by the “blue banana test,” in which the iron fortificant is added to a hot cereal porridge mixed with puréed bananas. Soluble iron compounds such as ferrous sulfate will rapidly turn the porridge a deep blue.

Sources of Iron

Encapsulated Iron Salt

There are coated forms of ferrous sulfate and ferrous fumarate available. The encapsulates used include hydrogenated vegetable oils, mono- and diglycerides, maltodextrins, and ethyl cellulose. The best products have a fat coating that protects them from chemically reacting with unsaturated fats in the flour or meal but that will melt on baking and/or be degraded by lipases in the gut so that the ferrous salt is available for absorption. These products may have a large particle size, causing them to be removed from the flour during final (rebolt) sifting. The products are fairly expensive, costing 4 to 8 times more than the uncoated product on an equal iron basis. However, preliminary studies have shown them to be well absorbed, even with high-extraction flour, and costs may drop if their use becomes more prevalent.

NaFeEDTA Sodium Iron Ethylene diamine tetraacetic acid

A proposed solution to the problem of phytic acid inhibiting the bioavailability of added iron (discussed in Section 3) is to use NaFeEDTA (INACG, 1993; Lynch 1993). The iron in this compound is chelated with ethylenediaminetetraacetate (EDTA), a commonly used food additive. This prevents the iron from being bound to phytic acid, making it more easily absorbed by the body. In the human gut, the iron is released from the EDTA, allowing it to be absorbed.

There have been several studies that show the benefits of using NaFeEDTA in school feeding programs and in maize meal (consumed as maize porridge) in Africa. In addition the atta flour fortification project that was started in Pakistan (supported by GAIN) was the first wheat flour fortification project that stipulated the use of NaFeEDTA.

There is little advantage in adding NaFeEDTA to low-extraction white flour used in a yeast-leavened bread-making process, since the final level of phytic acid is very low. However, there is good justification for using it in high-extraction wheat flours, such as atta used in South Asian countries to make unleavened chapattis. In the case of maize flours, maize meals, and cereal–soy blends such as WSB and CSB, NaFeEDTA does have significant advantages over other forms of iron with respect to bioavailability. The main drawbacks with NaFeEDTA are its much higher cost compared with the other iron sources and its tendency to cause color changes in some foods; however, unlike other soluble iron compounds, it does not promote lipid oxidation in stored cereals. It is fairly soluble, which causes it to be leached out into the cooking water from pasta and noodles, making it of questionable utility in those products.

There is a WHO guideline that recommends a maximum intake of Ethylene diamine tetraacetic acid EDTA of 2.5 mg per kilogram of body weight. The 2004 workshop in Cuernavaca, Mexico, proposed the following recommendation for low-extraction flours: “Sodium iron EDTA (NaFeEDTA) is the preferred iron fortificant for low extraction flours where there is no fermentation process in food preparation” (FFI 2004). The 2008 Stone Mountain Workshop proposed that “Sodium Iron EDTA (NaFeEDTA) is the preferred iron fortificant for high extraction flours” (FFI 2008).

Elemental Iron Powders

These powders, called reduced iron or ferrum reductum, are the most common iron sources used in cereal fortification because they have the least detrimental effect on product quality and shelf life and the lowest cost. Five types are commercially available, as shown in the following table. They differ in their method of manufacture and physical properties, which in turn affect their bioavailability. The current thinking is that only electrolytic iron should be used. Studies have shown that electrolytic iron has about half the bioavailability of ferrous sulfate, so it should be used at twice the level to achieve the same effect, a strategy that was first adopted by WHO/EMRO for flour fortification in the Middle East. Other forms of elemental iron powders, i.e., of all the elemental iron powders that are available i.e. electrolytic, carbonyl reduced and hydrogen reduced forms, and other forms which have a large particle size (> 44 microns) should not be used. The rationale is that the larger particle sizes will be heavier than cereal flours and

more likely to separate out from the flour or be removed by food safety magnets during processing and packaging.

Types of elemental iron powder used in fortification

Type	Use in fortification	Cost	Bioavailability ⁴⁹
Hydrogen reduced	Common	Low	Poor to medium
Carbon monoxide reduced	Seldom	Low	Poor
Atomized	Common	Low	Uncertain
Electrolytically reduced	Occasional	High	Good
Carbonyl reduced	Never	Very high	Uncertain

Magnets and Metal Detectors

All of the elemental iron powders are attracted to a magnet, whereas the iron salts are not. Many mills and bakeries use magnets to remove tramp iron from the flour in order to prevent equipment damage and maintain food safety. There is sometimes a concern that the magnets will remove elemental iron powders that have been added in a fortification program. Ferrous sulfate, ferrous fumarate, and NaFeEDTA will not be attracted to a magnet, so there is no problem in having a magnet in the line when these two iron salts are used.

There are three types of magnets in common use: iron, ceramic, and rare earth. Only the rare earth magnet, the strongest and most expensive, can pull reduced iron out of flour. The iron magnet type is the cheapest and the weakest. Ceramic types fall between these two other types of magnets and are the most common in mills, but the rare earth types are generally used in new equipment. When a magnet is used with flour that has been fortified with reduced iron, the problem is not that the magnet will remove the iron from the flour but that the magnet will become clogged with iron, causing it to lose its effectiveness in removing tramp iron. This problem can be solved by a self-cleaning magnet or by directing the flour at the magnet surface so that it continually cleans it of reduced iron.

There is no evidence of separation of any of the enrichment components added to flour on a continuous basis at the flour mill, during transport and storage, at the bakery, or in the final bread. Studies on flour passing by a magnet showed no difference in iron content before and after the magnet (Fortmann et al., 1974). There was also no evidence of flour streaking, which might be expected if large clumps of reduced iron were falling off the magnet. Alternatively, to ensure uniformity and minimize separation, sieves can be used in conjunction with magnets. Reduced iron has a very small particle size (< 325 mesh) and will easily go through the finest reboil or final sifter (100 mesh), which will remove all tramp iron or any ferrous or nonferrous metals of a large enough size to be dangerous. A mill can then use magnets at the start of the milling process before the iron is added and rely on the final screen to remove any tramp metal.

⁴⁹ Studies were conducted by SUSTAIN (www.sustaintech.org) to better assess the bioavailability of these products.

Food manufacturers often use metal detectors to ensure that no large clumps of iron are in the final food product. These detectors may respond slightly to elemental iron powder added to the flour, but they can be calibrated so that they ignore the added iron and still detect larger iron particles that would be noticeable or possibly harmful to the consumer.

Phytic Acid/Iron Ratio

It has been asserted that the molar ratio of phytic acid to iron should be at least 1:1 and optimally less than 0.5:1 in order to get good iron absorption (Hurrell, 2002). Achieving this low a molar ratio is difficult. It requires both reducing phytic acid content and increasing iron content. The former is achieved through milling and baking and the latter through fortification.

Milling refinement lowers the amount of phytic acid in flour by 60% to 90%, depending on the extraction rate. The final level of phytic acid is closely related to ash content: the lower the ash, the lower the phytic acid. The relationship between ash and phytic acid content found by Ranum (2000) in atta flours from Bangladesh gave a correlation coefficient of 0.997, allowing the phytic acid to be estimated from ash. The natural iron content also varies with ash content ($r = 0.0985$). The combination of flour ash and added iron necessary to achieve a phytic acid/iron ratio below 1.0 can then be calculated based on these relationships. Highly refined flour with 0.45% ash and a high iron addition level of 76 ppm is shown to be required to reach this ratio. Such conditions are rarely found in actual practice.

Fortunately, yeast fermentation during bread baking also reduces the phytic acid content, allowing higher ash flours to be used with lower levels of added iron and still have a phytic acid/iron ratio below 1.0. Yeast fermentation during bread baking lowered the phytic acid content from added bran by 60% after 2 hours and by up to 85% after longer periods of fermentation (Navert et al., 1985). The lower the pH during fermentation, the more phytic acid is removed (Fretzdorff and Brummer, 1992).

The following table shows possible combinations of flour ash and added iron for different levels of fermentation. This illustrates that fermentation is required for added iron to be well absorbed from wheat-based foods. If there is no fermentation, as with noodles and pasta, addition of NaFeEDTA may be advisable, since it is not affected by phytic acid. However, with highly fermented bread, any of the standard types of iron can be used.

Iron addition levels (in ppm) needed to get a phytic acid (PA)/iron molar ratio below 1.0

Flour ash	Flour natural	Fermentation
-----------	---------------	--------------

(%)	iron content (ppm)		Low 50% PA reduction	Moderate 75% PA reduction	High 90% PA reduction
0.45	8	76	34	13	0
0.55	11	129	59	24	3
0.75	17	235	109	46	8
1.25	30	500	234	102	23

Note: Values in bold type are possible iron addition levels.

Soaking and germination of the grain stocks prior to milling further reduces the level through the action of phytase, which is naturally present in cereals. One potential method is to add the phytase enzyme (from *Aspergillus niger*) during baking, but the dough must be allowed to sit for some time prior to baking for the enzyme to have any effect. There have been some reports of breeding wheat with lower phytic acid contents, but this approach would take a long time to accomplish.

Safety of Iron Fortification

One of the recurring concerns with iron fortification is its safety, particularly for individuals with iron overload diseases. Iron absorption is carefully controlled according to the body's iron status. The more iron that is needed, the more will be absorbed, up to the limit of how much absorbable iron is in the diet. The greater the iron stores the body has, the less it absorbs. But this control is faulty in a few individuals with inherited conditions that lead to excessive iron storage, the main ones being hemochromatosis and thalassemia major. Hemochromatosis is found in people of northern European ancestry, while thalassemia is found in people of Mediterranean, Central African, and Asian ancestry. These conditions are rare and affect mainly adult males.

The Cuernavaca and Stone Mountain workshops concluded on the basis of current evidence that the increase in the rate of iron accumulation by individuals with such iron overloading disorders from consuming fortified flour would be small over time and pose little additional risk for them.

If a person consumed a 2000-kcal daily diet consisting solely of foods made from flour fortified with iron at the highest level recommended for the more absorbable iron salts (45 ppm), the greatest amount of iron the person could receive would be 24 mg. This level is well under the Safe Upper Level (UL) of 45 mg/day recommended by the Food and Nutrition Board of the IOM.

11. Zinc

Although zinc deficiencies are not as obvious and measurable as iron-deficiency anemia, they often accompany iron deficiencies. Zinc and iron have similar dietary requirements and levels in cereals, and the absorption of both of them is inhibited by phytic acid, so any dietary deficiency in iron usually means there will be a deficiency of zinc as well. Based on estimates of zinc intake and bioavailability from FAO's food balance data, it is estimated that about 20% of the world is at risk for zinc deficiency. See Brown et al.

(2004) for a comprehensive discussion of zinc deficiency and its control. Zinc only started to be included in cereal fortification programs in the 1990s after recognition of this situation and the serious problem with its deficiency, particularly in children, where it can result in stunting and increased risk of disease. It is now being added to wheat flour in Mexico, South Africa, Central Asia, and Indonesia and to maize meal in South Africa and Mexico. The levels added are typically 20 to 30 ppm zinc, or restoration levels.

Zinc Sources

Unlike the iron sources used in cereal enrichment, all of the zinc sources are white in color, so inherent color is not a problem. There is a potential problem with some of the more soluble sources causing color changes in certain food ingredients, such as chocolate. All zinc salts have undesirable flavors. For example, zinc oxide has a bitter taste and zinc sulfate is very astringent. It does not appear that these inherent flavors carry over to the fortified foods at the levels used in fortification. As with ferrous sulfate, there are both dried and hydrated forms of zinc sulfate. The hydrated form is reported to cause problems with caking, giving a preference to the dried form.

Perhaps the most important difference in the zinc sources is in their solubility, which affects both bioavailability and food quality. Zinc oxide is insoluble in water but soluble in dilute acid. This implies that it will be inert in dry foods but should be available for absorption following exposure to stomach acid. Zinc acetate, zinc gluconate, and zinc sulfate are soluble in water, and the chloride is very soluble.

Zinc oxide is the most commonly used zinc source in the fortification of cereal-based foods, followed by zinc sulfate and, to a very limited extent, zinc gluconate. Zinc sulfate is specified for use in CSB and WSB produced for the U.S. FFP Program. It is also used in similar weaning or complementary foods made throughout the world. Zinc acetate and zinc gluconate find use only in dietary supplements and some weaning foods. There is a wide range in the cost. The least expensive source is zinc oxide, which costs approximately one third as much as zinc sulfate, the next cheapest source.

Bioavailability of Zinc Sources

The absorption of zinc from foods is similar to that of iron. Approximately 15% of a zinc fortificant will be absorbed on average. This percentage will be lower for absorption from high-phytate foods such as whole maize (closer to 5% to 10%), and higher for absorption from refined or low-phytate cereals (10% to 40%) (Sandstrom, 1997, 1989). One study on rats (Ranhotra et al., 1977) showed little difference in absorption of zinc from bread fortified with zinc from different sources. Absorption of zinc from zinc carbonate was poor, but absorption of zinc from zinc oxide was nearly as good as absorption from the more soluble forms. Absorption of zinc from the oxide is as good as absorption from zinc sulfate when zinc oxide is used to fortify tortillas in Mexico (Diaz et al., 2001) or low- or high-phytate wheat-based meals in the United States (Lopez de Romana et al., 2002), presumably because it is soluble in gastric acid. Zinc absorption from the oxide may be poor in individuals with low stomach acid secretion. In healthy, well-nourished adults in the United States, zinc absorption from the sulfate or oxide added to a low-phytate bread meal was about 14%, compared with around 6% when either fortificant was added to a

higher-phytate wheat porridge meal (Lopez de Romana et al., 2003). Studies in Turkey (Saldamli et al., 1996) reported that bread fortified with zinc acetate had acceptable quality and was effective in preventing zinc deficiency in children.

Effect on Product Quality

A number of studies have shown zinc fortification to have few detrimental effects on flour, bread, and noodle quality, even at levels several times higher than those normally used (Kilic et al., 1998; Ranhotra et al., 1977; Lopez de Romana et al., 2002).

12. Selenium

Selenium functions as a component of enzymes involved in antioxidant protection and thyroid hormone metabolism. Selenium deficiency (Keshan and Urov diseases) is rare and is found mainly in areas where the soil is very low in selenium. Asian wheat tends to have lower selenium content than wheat from North America, where soil selenium levels are higher. The greatest interest in selenium fortification of flour is in Asia and countries in the former Soviet Union because of the low soil selenium content in that region as well as the belief that selenium helps provide protection against radiation damage, such as occurred after the Chernobyl nuclear disaster.

Salt has been fortified with sodium selenite (15 mg/kg) since 1983 in regions of endemic selenium deficiency in China. Sodium selenate is the most common form used in food fortification. It has been added to infant formula and sports drinks. Sodium selenate is colorless and is less soluble in water and more stable than the selenite, especially in the presence of copper or iron. High-selenium forms of inactive yeast are available that could be used to fortify baked products.

When tested in milk-based infant formulas, more selenium was absorbed from the selenite than from the selenate (97% vs. 73%) but more was excreted in the urine (36% vs. 10%), so the net retention of selenium from both sources was similar (Van Dael et al., 2002). Most cooking procedures cause relatively little loss of selenium from foods.

No country currently fortifies flour or any cereal staple with selenium, but there has been some interest in doing so, particularly in Russia. The very small amounts (0.1 to 0.2 ppm) of selenium that would be required to provide a major portion of the RDA would not be expected to have a detrimental effect on the color, baking properties, or consumer acceptance of wheat flour. The cost of adding selenium is very low.

13. Calcium

Wheat and maize are very poor sources of calcium. Most of the calcium provided by cereal foods comes from the calcium-containing ingredients that are added to bread and biscuits as functional ingredients, such as calcium propionate, calcium phosphates, and whey. These ingredients are not normally added to bread in developing countries, however. Dried, nixtamalized maize flour, called masa flour, used to make tortillas is a common product in Mexico and Central America. This product has high calcium content

due to the addition of calcium carbonate in the nixtamalization process, so there is no need for additional calcium. Self-rising flour also contains high levels of calcium due to the addition of the chemical leavening ingredients. All other cereal products are very low in calcium.

Calcium has a long history of being added to flour and bread, originally as ground bone meal but now as calcium salts. During the Second World War the UK Government decreed that the milling industry should produce flour milled to an 85% extraction to conserve wheat supplies. The Medical Research Council recommended that calcium carbonate be added to this flour to counteract the effect of phytic acid. In 1942 the UK Government ordered the addition of calcium carbonate at the rate of 156 mg per 100 g of flour, which was increased to 235 to 390 mg per 100 g of flour in 1946. Many other Commonwealth countries, including India, Pakistan, Kenya, Uganda, and Nigeria, adopted the UK flour fortification regulations that included calcium on a voluntary basis. While a number of other countries permit the addition of calcium to flour, no country requires it. However, because of the positive marketing and cost advantages, some millers find it advantageous to fortify some of their flour brands with calcium without being required to.

The main calcium sources used in cereal fortification are calcium sulfate (gypsum) and calcium carbonate (limestone). Both are white and bland in flavor. Calcium sulfate is produced from mined gypsum by a precipitation process and is available as either the dihydrate, with 23% calcium, or the anhydrous form, which has a higher calcium content (27%) but generally a higher price as well. Calcium carbonate used in cereal fortification is normally made by grinding limestone mined from very pure deposits. There is a considerable variation in the particle sizes available, from very fine to coarse. Manufacturers can recommend which of their products is best for flour fortification. All of the calcium sources are added directly and not in a premix (with other micronutrients) and can produce packaging and flow problems if the product is overly fine or damp.

There are many other calcium salts (such as calcium phosphates, calcium lactate, and calcium citrate) that are used to fortify different types of foods, but they are much more expensive and offer no real additional benefits over the sulfate and carbonate in cereal fortification. They may differ somewhat in bioavailability, but that is not considered as critical an issue with calcium as it is with iron. Tricalcium phosphate is currently used to fortify complementary blended foods (CSB and WSB), since it provides both phosphorus and calcium and is believed to help prevent infestation of the food on storage. While the body needs a balanced intake of both calcium and phosphorus, cereals already contain a high level of phosphorus; however, it is considered necessary to add more to CSB and WSB where these FBFs are being used as complementary foods for children under 2 years old.

Calcium fortification has no effect on the color or taste of flour or bread, even at the high levels used. Calcium carbonate has a slight pH raising and buffering action on flour. Added calcium is generally believed to be beneficial for yeast-leavened bread baking.

Calcium fortification will greatly increase the flour's ash content, making ash levels unusable as a way of measuring flour quality or extraction.

14. Iodine

Iodine fortification is usually reserved for salt; there are no countries that currently require iodine to be added to flour. However, there can be situations where salt iodization is not adequate and additional measures are needed to prevent the occurrence of iodine-deficiency disorders. If flour or maize meal is being fortified in these countries, iodine can be included for hardly any additional cost.

Iodates function as oxidative bread improvers and have been added to flour and bread dough for that reason, typically at levels up to 15 ppm, which is 10 times the amount that would be added for nutritional reasons. An addition of 10 ppm calcium iodate would add 412 µg of iodine per 100 g of bread or 110% of the RDA for iodine per slice serving size. Bread is normally made with flour containing 2% salt. The amount of salt has been reduced in recent years because of concerns about high sodium levels, but it normally stays above 1.5%. If the salt is iodized to U.S. standards of 77 mg/kg, the use of flour containing 2% salt will add 96 µg of iodine per 100 g of bread, which will provide 25% of the RDA per serving, assuming no loss during baking. That would make bread an important source of iodine. However, if noniodized salt is used in baking, as may often be the case, this source of iodine is lost.

Iodized bread has been used in some countries. This can be achieved either by adding special iodized bakers' salt, as done in the Netherlands, or deliberately adding iodine to bread, the preferred source being calcium iodate. The level of iodine fortification suggested is 0.2 to 0.4 ppm iodine, which would put it in line with the levels of other micronutrients added. This level of fortification would be insufficient to either cause safety problems or have much of an oxidative improving effect, and would add very little cost to the premix.

Appendix I6: Stability of Micronutrients in Premix

Losses of Added Micronutrients

Some of the added micronutrients are lost during the milling process due to a combination of exposures to heat, oxygen, and light. In addition, moisture can contribute to the acceleration of the degradation process. Some of the very light or small-particle-size materials with large surface-to-volume ratios may be physically removed with the dust during pneumatic suction, whereas larger particles may be removed during sieving. The tables below give estimates of how much of each nutrient is retained during typical milling practices. Higher losses might be expected in mill products with larger particle size, such as semolina, farina (fine semolina), and soy–cereal products. These milling and production losses should be factored in when calculating how much of each nutrient to add to meet a minimum standard.

Mineral Losses in Processing of Fortified Foods

Minerals are considered to be stable when added to fortified cereals and blended foods. Minerals do not degrade when exposed to heat, light, and moisture. In the case of porridges, in which the water added during cooking is absorbed by the cereal, no minerals are lost to the cooking water. In the case of cooked porridges the mineral losses during processing have been estimated at 5% to 10%. This estimation of cooking losses has been done to take into account a limited variation in the addition rate of added minerals during the fortification process.

However, in the case of fortified rice and boiled pasta products made from fortified wheat semolina and flour, where the excess water is drained from the cooked food before eating, there will be losses.

Micronutrient Retention Tables

The following tables have been prepared as a summary of the sources of data on the losses.

Retention of minerals from CSB, WSB, and fortified cereals

Mineral	Retention during storage and distribution	Cooked food	Retention	Source of data
Iron	> 95%	Porridge	90%–95%	Cereal Chemistry
		Bread	90%–95%	Cereal Chemistry
		Pasta	> 80%	Cereal Chemistry
		Fortified rice	> 85%	Cereal Chemistry
Zinc, calcium, phosphorus, magnesium, copper, manganese	> 95%	Pasta	> 80%	Cereal Chemistry

Retention of vitamins from CSB, WSB, and fortified cereals

Vitamin	Retention during storage and distribution	Source of data	Retention during cooking as gruel or porridge	Source of data
A	86% CSB, 64% WSB	SUSTAIN report 1998 IFT	46% CSB and WSB	SUSTAIN report 1998 IFT
C	87% WSB, > 97% CSB	SUSTAIN report 1998 IFT	30% CSB and WSB	SUSTAIN report 1998 IFT
D	Considered to be same as A		Considered to be same as A	
K	Considered to be same as A		Considered to be same as A	
B ₁	Cereal flours 90%–100%	Cereal Chemistry 1965–79	Cereal flours 75%–80%	Cereal Chemistry 1965–79
B ₂	Cereal flours 90%–95%	As above	Cereal flours 70%–75%	As above
B ₃	Cereal flours > 95%	As above	Cereal flours 85%–90%	As above
B ₆	Cereal flours > 95%	As above	Cereal flours 85%–95%	As above
Folate	Cereal flours > 95%	As above	Cereal flours 70%–80%	As above
B ₁₂	Cereal flours 85%–90%	See below	Cereal flours 60%–75%	See below

Notes:

See Table 8 in http://www.mostproject.org/Updates_Feb05/Stability.pdf.

Vitamin retention data for baked products and boiled pasta were excluded because the main use of blended foods is in porridges

There are very limited published data on the stability of vitamin D and K in cooked products. In the case of vitamins D and K, there are no data, but the literature states that vitamins D and K are light sensitive, so an equivalence with vitamin A has been used.

B group vitamin losses were dependent on cooking time: the longer the cooking time, the greater the losses. Since CSB and WSB have shorter cooking times than uncooked cereals, the higher retention ranges (lower losses) were used.

Vitamin B₁₂ data are based on Table 8 above for processed cereals.

Retention of vitamins from vegetable oil

Vitamin	Retention during storage and distribution	Source	Retention in gruel excluding frying	Source
A	90%–95%	University of Guelph and Micronutrient Initiative report	80%–85%	University of Guelph And Micronutrient Initiative report
D	90%–95%	See note	80%–85%	See note
E	90%–95%	See note	85%–90%	See note
K	90%–95%	See note	80%–85%	See note

Notes:

In the Web page http://www.mostproject.org/Updates_Feb05/Stability.pdf from Fortification Basics, the overages used for vitamin A and D in Table 8 equate to storage and processing losses combined.

There are no data for vitamin K, but the literature states that vitamin K is light sensitive, so an equivalence with vitamin A has been used.

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