# Proposed Nutrient Composition for Fortified Complementary Foods[1]

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ABSTRACT A proposed nutrient composition for fortified processed complementary foods (FPCF) is developed based on the other papers in this publication, which consider a number of factors such as age range, daily ration size, recommended nutrient requirements, contribution of human milk to these requirements, macronutrient interactions, compound bioavailability, methods of production and overage. The proposed fortification levels are based on a daily ration size of 40 g for infants aged 6–12 mo and 60 g for children aged 12–23 mo. A desired protein–energy ratio of 6–10% is used to estimate energy from protein. The desired percentage of energy from lipid is estimated at 24% for infants aged 6–11 mo and 28% for children aged 12–23 mo, with the remaining energy to be supplied from carbohydrate. An FPCF should provide a quantity of iron sufficient to meet the Recommended Dietary Allowance in the form of dried ferrous sulfate of small particle size. Ascorbic acid, 70–140 mg for infants aged 6–11 mo and 50–100 mg for children aged 12–23 mo, will enhance iron absorption. Because of the lower bioavailability of zinc in cereal-based diets in developing countries, 4–5 mg of zinc in the form of zinc oxide is recommended. Proposed fortification levels are also provided for copper, calcium, vitamin D, magnesium, phosphorus, vitamin A, the B vitamins and iodine. To prevent micronutrient losses, it is recommended that the FPCF be precooked. The knowledge base to develop an FPCF is quite limited, and much additional research is needed before an optimal formulation can be recommended. J. Nutr. 133: 3011S–3020S, 2003.

KEY WORDS: • *fortification* • *complementary foods* • *infants* • *nutrient requirements*

Adequate nutrition during the 1st 2 y of life is critical to ensure optimal physical and mental development of infants and young children. Programmatic and policy initiatives to promote the behaviors necessary to achieve exclusive breastfeeding for 6 mo are essential to ensure adequate nutrition during the first half of infancy. Thereafter, access to nutrient-dense foods during the complementary feeding period along with appropriate feeding practices and continued breast-feeding is needed to ensure optimal growth and development.

Strategies to improve the availability of and accessibility to low cost fortified complementary foods can play an important role in behavioral changes necessary to improve the nutritional status of infants and young children. However, the nutritional quality of complementary foods used in publicly funded programs is not always optimal (1,2). In Latin America, large amounts of money are spent on publicly funded young child feeding programs, and it is incumbent upon public health professionals to ensure that these programs deliver the highest quality food at the lowest possible cost. Also, with nearly 50% of the population in Africa and Asia and nearly 80% in Latin America and the Caribbean living in urban areas (3) and purchasing most of their food, the availability of low cost high quality and easy to prepare complementary foods in the commercial market could potentially address inadequacies in the macro- and micronutrient content of typical complementary food diets (4).

The objective of this summary paper is to provide information on how to improve the nutritional formulations of fortified complementary foods. This objective is in keeping with the recently ratified WHO Global Strategy on Infant and Young Child Feeding, which notes that industrially processed complementary foods are an option for mothers who can afford them and have the knowledge and facilities to safely prepare and feed them (5). It is also in keeping with evidence that fortification of complementary foods is one possible strategy for addressing the pressing problem of iron deficiency anemia in this age group (6).

## *Approach taken*

A framework for developing a recommended level of fortification for complementary foods is not currently available. This paper is the first attempt to provide such a framework and to propose a nutrient composition. This composition will need to be revised when the various nutrient requirements for the target population currently in use are harmonized and data are available to take the more rigorous approach outlined in the recent publication, *Dietary Reference Intakes: Applications in Dietary Planning* (7).

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[1] Presented as part of the technical consultation “Nutrient Composition for Fortified Complementary Foods” held at the Pan American Health Organization, Washington, D.C., October 4–5, 2001. This conference was sponsored by the Pan American Health Organization and the World Health Organization. Guest editors for the supplement publication were Chessa K. Lutter, Pan American Health Organization, Washington, D.C.; Kathryn G. Dewey, University of California, Davis; and Jorge L. Rosado, School of Natural Sciences, University of Queretaro, Mexico.

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0022-3166/03 $3.00

The proposed fortification levels in this supplement were developed after considering a number of factors: age range; daily ration size; recommended nutrient requirements; contribution of human milk to these requirements and the proportion of total requirements that should be provided through a fortified food; micronutrient interactions; bioavailability of the compounds used and inhibiting and enhancing properties of macronutrients; methods of production and use, such as whether the product is instant or requires cooking, packaging, expected losses during storage, and cost; and overage needed to compensate for losses because of cooking (if required), packaging, and storage

### *Age range*

A fundamental question in developing a proposed nutrient formulation is whether one formulation or age-specific formulations should be recommended. As described by Dewey (8), between age 6 and 24 mo the intake of complementary foods ranges 10-fold, from <25 to >250 g of dry food per day. Intake depends on age, which in turn is related to body size and energy requirements, and to human milk intake. Therefore, a major challenge is to ensure that the nutrient needs of both infants (6–11 mo) and young children (≥12–23 mo) are met. In general, infants consume the lowest amounts of complementary food. Depending on the nutrient in question their specific nutrient needs may be as great as or greater than those of children aged 12–23 mo because of their rapid rate of growth and development. Ensuring nutrient adequacy for infants, because of their lower consumption, requires a higher nutrient density. However, a formulation that ensures an optimal nutrient density for infants could result in excessive intakes of some nutrients by children aged 12–23 mo because of their greater consumption. For example, a food developed for children aged 12–23 mo is likely to be inadequate to meet the calcium, iron and zinc requirements of infants aged 6–8 mo. At the same time, a food developed for infants aged 6–8 mo results in intakes of calcium, iron, and zinc that are too high for older children. In this paper, nutrient recommendations are provided for three age groups: 6–11, 12–23 and 6–23 mo.

### *Daily ration size*

The proposed daily ration (grams of dry product) is the starting point in developing a nutrient composition of a fortified processed complementary food, because it determines the volume of food to which the proposed amounts of micronutrients are added. The development of a proposed daily ration should be based on empirical data on the age-specific amount of fortified complementary food consumed in grams and kilocalories and the proportion of the total daily diet that this amount would comprise. This level of precision could be obtained by either 24-h recall or weighed intake data. Ideally, such empirical data would be obtained in different settings and several months after the introduction of the food. This would ensure that the novelty of the food is not a factor in the measurement and that the measurement reflects intake in the context of the usual diet and breast-feeding patterns.

Despite the many programs that use fortified complementary foods, data are scarce on the actual amount consumed. Only three studies were identified that collected information on energy consumption from fortified complementary foods. In all three, the food was provided free of charge to study or program participants. Data were collected in Peru 11 mo after the fortified complementary food was introduced and in the context of the evaluation of a social development program so that the intake of the food was analyzed in the context of the typical diet (9). In contrast, data were collected in Mexico as part of an acceptability trial (10) and in Ghana as part of an efficacy study (11).

In Peru, children aged 12–23 mo consumed 67.3 ± 34.4 g of the daily ration of 90 g of the complementary food. This amount corresponded to 302 ± 153 kcal out of a total of 597 ± 275 kcal (T. López Preciado, personal communication, 2001), providing 51% of their energy consumption from complementary foods. However, only 69 out of the 110 children who received the fortified complementary food actually consumed any on the day before the interview and were included in the above estimate. When all 110 children are included in the denominator, daily intake of the fortified food averages 42.2 g. Neither breast-feeding status nor the amount of human milk consumed were considered in the estimate of the contribution of energy provided by the fortified complementary food.

Data from an efficacy study in Ghana showed that infants aged 6–8 mo consumed 150 kcal/d (30 g of dry product) from the fortified complementary food provided, corresponding to 71% of their energy intake from complementary foods (11). Infants aged 9–11 mo consumed 173 kcal/d (35 g of dry product), corresponding to 54% of their energy intake from complementary foods. Data from a 2-wk acceptability trail in Mexico showed that infants aged 6–11 mo consumed 45.1 ± 17 g and children aged 12–23 mo consumed 52.0 ± 16.9 g of the complementary food provided (J. Rivera, personal communication, 2001). Information is not available from the Mexican study on total consumption and the proportion of total energy that the intakes represent.

In light of the data presented above, it seems reasonable to estimate a daily ration of 40 g for infants aged 6–11 mo and 60 g for young children aged 12–23 mo. If only one formulation was to be developed, a daily ration size of 50 g would seem reasonable. However, more data on consumption are needed to improve the basis for these estimates.

### *Recommended nutrient intakes*

Selecting the appropriate daily requirement for micronutrients for infants and young children aged 6–24 mo is challenging because several different sources of information exist, each of which uses different methodologies (**Table 1**). In the United States, the Dietary Reference Intakes (DRI)[3] recently published by the Institute of Medicine (13–17) provide recommendations for most micronutrients for infants and young children. The DRI are sets of recommendations that include the following: Estimated Average Requirements (EAR), Recommended Dietary Allowances (RDA), Adequate Intakes (AI) and Tolerable Upper Intake Levels (UL). EAR reflect the average daily nutrient intake level estimated to meet the requirement of half the healthy individuals in a particular life stage or gender group. They are used as the basis for setting the RDA, which is the average daily nutrient intake level sufficient to meet the nutrient requirement of nearly all (97–98%) healthy individuals in a particular life stage and gender group. RDA are set at 2 SD above the EAR. An AI is a recommended average daily nutrient intake level based on observed or experimentally determined approximations or estimates of nutrient intake by a group (or groups) of apparently healthy people

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[3] Abbreviations used: AI, Adequate Intake; DRI, Dietary Reference Intake; DRV, Dietary Reference Value; EAR, Estimated Average Requirement; RDA, Recommended Dietary Allowance; RE, retinol equivalent; UL, Tolerable Upper Intake Level.

**TABLE 1**

*Comparison of nutrient requirements of infants aged 6–8, 9–11 and 12–23 mo, WHO 1998, Dietary Reference Intakes, and FAO/WHO 2002*[1]

| | 6–8 mo | | | 9–11 mo | | | 12–23 mo | | |
|---|---|---|---|---|---|---|---|---|---|
| | WHO (12) | IOM (13–17) DRI | FAO/WHO (21) | WHO (12) | IOM (13–17) DRI | FAO/WHO (21) | WHO (12) | IOM (13–17) DRI | FAO/WHO (21) |
| Protein, *g* | 9.1 | 9.9 | NA | 9.6 | 9.9 | NA | 10.9 | 13.0 | NA |
| Vitamin A, *μg RE* | 350 | 500 | 400 | 350 | 500 | 400 | 400 | 300 | 400 |
| Folate, *μg* | 32 | 80 | 80 | 32 | 80 | 80 | 50 | 150 | 160 |
| Niacin, *mg*[2] | 4[2] | 4 | 1.5 | 5 | 4[2] | 4 | 8 | 6 | 6 |
| Pantothenic acid, *mg* | 1.7[3] | 1.8[2] | 1.8 | 1.7[3] | 1.8[2] | 1.8 | 1.7[3] | 2.0[2] | 2.0 |
| Riboflavin, *mg* | 0.4 | 0.4[2] | 0.4[2] | 0.4 | 0.4[2] | 0.4 | 0.6 | 0.5 | 0.5 |
| Thiamin, *mg* | 0.2 | 0.3[2] | 0.3 | 0.3 | 0.3[2] | 0.3 | 0.5 | 0.5 | 0.5 |
| Vitamin B-6, *mg* | 0.3[3] | 0.3[2] | 0.3 | 0.4 | 0.3[2] | 0.3 | 0.7 | 0.5 | 0.5 |
| Vitamin B-12, *μg* | 0.4 | 0.5[2] | 0.5 | 0.4 | 0.5[2] | 0.5 | 0.5 | 0.9 | 0.9 |
| Vitamin C, *mg* | 25 | 50[2] | 30 | 25 | 50[2] | 30 | 30 | 15 | 30 |
| Vitamin D, *μg* | 7 | 5[2] | 5 | 7 | 5[2] | 5 | 7 | 5[2] | 5 |
| Vitamin K, *μg* | 10[3] | 2.5[2] | 10 | 10 | 10[3] | 2.5[2] | 10[3] | 30[2] | 15 |
| Calcium, *mg* | 525 | 270 | 400 | 525 | 270[2] | 400 | 350 | 500[2] | 500 |
| Chloride, *mg* | 500 | NA | NA | 500 | NA | NA | 800 | NA | NA |
| Copper, *mg* | 0.3 | 0.2[2] | NA | 0.3 | 0.2[2] | NA | 0.4 | 0.3 | NA |
| Fluoride, *μg* | 0.05[3] | 0.5[2] | NA | 0.05[3] | 0.5[2] | NA | 0.05[3] | 0.7[2] | NA |
| Iodine, *μg* | 21 | 130[2] | NA | 21 | 130[2] | 90 | 12 | 90 | 90 |
| Iron, *mg* | 11[4] | 11[4] | 9.3[4] | 11[1] | 11 | 9.3 | 6 | 7 | 5.8 |
| Magnesium, *mg* | 75 | 75[2] | 54 | 80 | 75[2] | 54 | 85 | 80 | 60 |
| Manganese, *mg* | 0.02[3] | 0.6[2] | NA | 0.2[3] | 0.6[2] | NA | 0.02[3] | 1.2[2] | NA |
| Phosphorus, *mg* | 400 | 275 | NA | 80 | 75[2] | 54 | 270 | 460 | NA |
| Potassium, *mg* | 700 | NA | NA | 400 | 275[2] | NA | 800 | NA | NA |
| Selenium, *μg* | 10 | 20[2] | 10 | 10 | 20[2] | 10 | 15 | 20 | 17 |
| Sodium, *mg* | 350 | NA | NA | 320 | NA | NA | 500 | NA | NA |
| Zinc, *mg* | 2.8[5] | 3 | 4.1[6] | 2.8[5] | 3 | 4.1[6] | 3 | 0.7 | 1.1 |

[1] Source: Dewey and Brown (20). DRI, Dietary Reference Intakes; IOM, Institute of Medicine; NA = not yet available.

[2] Based on Adequate Intake estimates.

[3] Based on "Safe Nutrient Intake" from British Dietary Reference Values.

[4] Assuming medium bioavailability (10%).

[5] Based on Annex III of World Health Organization (12).

[6] Assuming moderate bioavailability (30%).

that are assumed to be adequate; AI are used when an RDA cannot be determined. A UL is the highest average daily nutrient intake level likely to pose no risk of adverse health effects to almost all individuals in the general population.

Because of the paucity of data on nutrient requirements for infants and young children, all recommendations for infants aged 7–12 mo, except for iron and zinc, and some of the recommendations for young children aged 1–3 y are based on AI. Because AI are derived from studies examining the diets of healthy children from developed countries, many of whom consume fortified infant foods, they potentially overestimate the actual requirement. For children aged 1–3 y, most of the recommendations are based on RDA that have been extrapolated from other age groups. These two different methods for estimating the DRI have led to inconsistencies in the recommendations for some nutrients across the two age groups.

The recommendation for vitamin A illustrates this problem. An AI of 500 μg retinol equivalents (RE) is set for infants and a RDA of 300 μg RE is set for the age group 1–3 y (16). There is no biological basis for setting the requirement for vitamin A higher in the first year of life than in the second. Rather, the reference intakes reflect the different methodologies and sources of data used in their development. As a further complication, the UL is set at 600 μg RE, which is only 100 μg RE above the AI for the younger age group. Given that the contribution of vitamin A from human milk is highly variable and that some children will be receiving no human milk, the desired content of vitamin A in a fortified complementary food is challenging to determine.

Another source of dietary requirements frequently used for infants and young children is the Recommended Nutrient Intakes from the Dietary Reference Values (DRV) from the United Kingdom Department of Health (19). These were used as the basis for complementary feeding guidelines by WHO (12) and Dewey and Brown (20) for most nutrients. Recommended Nutrient Intakes are based on the estimated average requirements plus 2 SD and the factorial method is generally used to derive them.

More recently, WHO and the FAO issued a preliminary report on recommended intakes (21). As noted by Lutter and Rivera (4), harmonization of these various recommended intakes is urgently needed to ensure a standardized approach to infant and young child feeding issues.

Published estimates of the energy requirement for infants and young children have been decreasing over the past several decades, reflecting new scientific techniques that permit the evaluation of requirements based on energy expenditure and deposition rather than observed intakes. The most recent data are based on longitudinal measures of total energy expenditure and energy deposition from 76 healthy children at 3, 6, 9, 12, 18 and 24 mo of age living in Houston, Texas (22). Energy requirements of these children differed by age, breast-feeding status, and sex. Once adjustments were made for weight, the requirements differed only by breast-feeding status, with the

## TABLE 2

*Energy requirements from complementary foods by age group, based on longitudinal studies of U.S. children*[1]

| Age group | Total energy requirements | Milk energy intake | Energy required from complementary foods |
|---|---|---|---|
| mo | *kcal* | | |
| 6–8 | 615 | 413 | 202 |
| 9–11 | 686 | 379 | 307 |
| 12–23 | 894 | 346 | 548 |

[1] Source: Dewey and Brown (20).

energy requirements for breast-fed infants aged 6–24 mo ~4–5% less than those for nonbreast-fed infants. These new estimates are about 5–18% less than those published in 1998 by WHO when expressed as a function of age and about 5–13% less when expressed as a function of body weight (20). They are about 20% less than the 1985 FAO/WHO/UNU recommendations (23).

The new energy requirements are 615, 686 and 894 kcal/d for ages 6–8, 9–11 and 12–24 mo, respectively (**Table 2**). Average human milk energy intakes in developing countries are 413 kcal for infants aged 6–8 mo, 379 kcal for infants aged 9–11 mo and 346 kcal for young children aged 12–23 mo (12). Therefore, the energy requirements from complementary food are 202, 307 and 548 kcal for ages 6–8, 9–11 and 12–23 mo, respectively. As suggested by Dewey and Brown (20), these can be rounded off to 200 kcal for infants aged 6–8 mo, 300 kcal for infants aged 9–11 mo and 550 for young children aged 12–23 mo.

Using these revised energy requirements and assuming an energy density of 440 kcal/100 g of dry product, the recommended daily ration sizes would provide 87, 57 and 48% of the energy needs from complementary foods for infants and young children aged 6–8, 9–11, and 12–23 mo, respectively. This assumes a daily ration of 40 g for infants aged 6–11 mo and 60 g for young children aged 12–23 mo and that all children consume an average amount of human milk for their age group. The inverse relationship between the proportion of energy requirements that would be met and age makes intuitive sense because the child should gradually consume a greater proportion of complementary foods from the family diet.

### *Contribution of human milk and proportion of total requirements to be provided through a fortified complementary food*

Breast-feeding status and the nutrients contributed by human milk are key factors in the determination of a desired micronutrient density in a fortified complementary food. This is best illustrated by looking at the proportion of micronutrients needed from complementary foods (assuming average human milk intake), as outlined by WHO (12) and Dewey and Brown (20) and briefly summarized by Lutter and Rivera (4). Breast-feeding status is not important for nutrients for which human milk makes a small contribution toward total requirement, such as iron and zinc (12). For these nutrients, nearly the entire requirement must be met through complementary foods. However, for thiamin, riboflavin, vitamin B-6, vitamin B-12, vitamin A, iodine and selenium the contribution through human milk is variable and can be influenced by maternal nutritional status. Among nonbreast-fed children or children of mothers deficient in these nutrients, a significantly greater proportion of the requirement needs to be met through complementary foods.

### *Micronutrient interactions*

Although micronutrient interactions among some of the minerals are possible, none is likely to be important at the concentrations suggested here. Fortification with mineral salts has the potential risk of reducing the bioavailability of other minerals in the food by either changing their intestinal solubility or by competing for uptake at absorption sites, as noted by Abrams and Atkinson (24). Data on the potential for such mineral–mineral interactions have resulted primarily from studies of single mineral dietary supplements rather than minerals used as fortificants in foods.

Concern has primarily centered on the effect of calcium and phosphorus fortification on iron and zinc absorption, zinc fortification on copper absorption and iron fortification on zinc absorption. However, several studies showed that neither iron absorption nor its status is affected when infants are fed calcium- and phosphorus-fortified formulas (25) or when children are fed a calcium-fortified breakfast cereal (26). Data are not available to support recommendations on optimal dietary calcium-zinc ratios (24). Negative effects of typical zinc intakes on copper absorption have not been demonstrated (27), but the addition of conservative amounts of copper to zinc in fortified foods may need to be considered. Fortification of foods with iron does not have a negative effect on zinc absorption (28). The only exception to this finding is when the iron:zinc molar ratio is 25:1, a ratio that is highly unlikely to occur in fortified foods.

### *Bioavailability of compounds used*

The compounds used in fortification have important implications for bioavailability (29). Recent attention has focused on iron compounds and the concern that those commonly used in staple food fortification may have limited bioavailability and, hence, biological impact (30). For each of the minerals addressed in this supplement, recommendations are given for the most bioavailable compounds.

Plant foods high in protein (e.g., legumes) are often mixed with cereals in fortified complementary foods as noted by Hurrell (31). Both contain a large amount of phytic acid, a powerful inhibitor of trace element and mineral absorption. The influence of phytic acid on calcium, copper and magnesium absorption is of less concern than its effect on iron and zinc absorption. Although methods for phytic acid degradation and removal are available, none has been tested in large-scale production. Ascorbic acid is usually added in quantities that exceed the RDA to facilitate iron absorption in mixtures with high levels of phytate. However, such products must be precooked to avoid the loss of ascorbic acid through heat exposure. Also, to prevent loss of ascorbic acid during storage, high quality packaging is needed, which adds to the cost of the product.

### *Methods of production*

To prevent micronutrient losses because of cooking, the fortified complementary foods used in social programs in Ecuador, Mexico and Peru are precooked so that only water or other liquid needs to be added before consumption. Precooking requires extrusion during processing of the raw ingredients. In Peru cottage industries using older simple extruders produced the fortified complementary food used in social programs. In contrast, in Ecuador a state-of-the-art extruder and a new processing plant was built to respond to the government's competitive bidding process to produce the fortified complementary food. In both countries, food safety was ensured by following standard hazard analysis and critical control point guidelines (32).

Precooked products have other advantages in addition to avoidance of the loss of heat-sensitive micronutrients. They can be prepared instantly and, therefore, are highly convenient. Foods that need to be cooked may be more likely to be prepared once each day and stored for subsequent feedings, increasing the risk of bacterial contamination. However, if contaminated water or liquid is added to the precooked food, the risk of gastrointestinal illnesses increases. Use of precooked products in social programs and in conditions of poverty in Ecuador, Mexico and Peru has not resulted in increased prevalence of diarrhea, showing this to be a feasible option.

The packaging materials used are important vis-à-vis the stability of certain micronutrients, shelf life and product quality perceived by the consumer. They also have important implications for cost. One difficulty with previous attempts to market fortified complementary foods to low income populations is that the foods were marketed as a low income food and perceived to be of inferior quality. Packaging that breaks, leaks and cannot be easily resealed contrasts poorly with the attractive, durable packaging of fortified complementary foods produced by multinational corporations available in cities throughout Latin America and the Caribbean (although the latter are too costly for all but the most affluent consumers).

### *Nutrient composition*

The section below and **Table 3** summarize the levels of fortification proposed in the papers in this publication. Each author has taken a slightly different approach to estimating a level, but all have used an age-appropriate nutrient requirement and the estimated daily ration size, described earlier, as a starting point.

### *Iron and ascorbic acid*

Liver iron stores at birth are major determinants of iron status and risk of anemia during the 1st 6 mo of life. Risk of

**TABLE 3**

*Summary of the recommended nutrient composition of fortified complementary foods per daily ration and 100 g*[1]

| | Per daily ration | | | Per 100 g | | |
|---|---|---|---|---|---|---|
| | 6–11 mo (40 g) | 12–23 mo (60 g) | 6–23 mo (50 g) | 6–11 mo | 12–23 mo | 6–23 mo |
| Energy and nutrients | | | | | | |
| Energy, *kcal* | 176 | 264 | 220 | 440 | 440 | 440 |
| Protein, *g* | 3–4.5 | 4–6.5 | 3–5.5 | 7.5–11.3 | 6.7–10.8 | 6–11 |
| Fat,[2] *g* | 4.8 | 8.2 | 6.3 | 11.7 | 13.7 | 12.7 |
| Vitamins | | | | | | |
| Vitamin A, *µg RE* | 200 | 300 | 250 | 500 | 500 | 500 |
| Biotin, *µg* | 0.58–0.67 | 1.74 | 1.45 | 1.45–1.68 | 2.90 | 2.90 |
| Choline, *mg* | 32.4–40.4 | 54.0 | 45.9 | 81.0–101.0 | 90.0 | 91.8 |
| Folic acid, *µg* | 17.4–21.8 | 49.8 | 41.5 | 43.6–54.5 | 83.0 | 83.0 |
| Niacin, *mg* | 1.8–2.7 | 1.9 | 3.3 | 4.6–6.8 | 3.2 | 6.1 |
| Panthothenic acid, *mg* | 0.28–0.31 | 0.38 | 0.35 | 0.70–0.78 | 0.63 | 0.70 |
| Riboflavin, *mg* | 0.11–0.15 | 0.15 | 0.18 | 0.28–0.38 | 0.25 | 0.36 |
| Thiamin, *mg* | 0.11–0.15 | 0.18 | 0.18 | 0.28–0.38 | 0.30 | 0.36 |
| Vitamin B-6, *mg* | 0.14–0.20 | 0.21 | 0.22 | 0.35–0.50 | 0.35 | 0.44 |
| Vitamin B-12, *µg* | 0.14–0.15 | 0.32 | 0.26 | 0.35–0.38 | 0.53 | 0.52 |
| Vitamin C, *mg* | 70–140 | 50–100 | 70–140 | 175–350 | 83–167 | 140–280 |
| Vitamin D, *µg* | 1–2 | 1–2 | 1–2 | 2.5–5 | 1.7–3.3 | 2–4 |
| Vitamin E,[3] *mg* | 5 | 5 | 5 | 12.5 | 8.3 | 10 |
| Minerals | | | | | | |
| Calcium, *mg* | 100–200 | 100–200 | 100–200 | 250–500 | 170–330 | 200–400 |
| Chloride,[4] *mg* | | | | | | |
| Copper, *µg* | 200–400 | 200–400 | 200–400 | 500–1000 | 333–667 | 400–800 |
| Iodine, *µg* | 90 | 90 | 90 | 225 | 150 | 180 |
| Iron, *mg* | 11 | 7 | 7–11 | 27.5 | 11.7 | 14 |
| Magnesium, *mg* | 40–60 | 40–60 | 40–60 | 100–150 | 67–100 | 80–120 |
| Manganese,[5] *mg* | 0.6 | 0.6 | 0.6 | 1.5 | 1 | 1.2 |
| Phosphorus, *mg* | 75–100 | 75–100 | 75–100 | 188–250 | 125–167 | 150–200 |
| Potassium,[4] *mg* | | | | | | |
| Selenium,[5] *µg* | 10 | 10 | 10 | 25 | 17 | 20 |
| Sodium,[4] *mg* | | | | | | |
| Zinc, *mg* | 4–5 | 4–5 | 4–5 | 10–12.5 | 6.7 | 8.3 |

[1] Levels indicate the total content of food (native amount in the macro ingredients plus any fortificant).

[2] Based on 24% of energy as fat for infants ages 6–11 mo, 28% of energy as fat for children ages 12–23 mo, and 26% of energy as fat for infants ages 6–23 mo.

[3] Based on the Adequate Intake for ages 7–12 mo (15).

[4] Insufficient information to establish a recommended level.

[5] Based on FAO/WHO (21).

iron deficiency during this period is generally low for term infants of normal birth weight. For infants of low birth weight, the risk is much greater and medicinal iron drops are recommended starting at age 2–3 mo (6). Although the iron in human milk is highly bioavailable, the concentration is low, and human milk provides only a very small proportion of iron requirements. After age 6 mo nearly all iron must come from complementary foods. It has been estimated that complementary foods need to provide 97% of iron requirements for infants aged 9–11 mo (33).

Complementary food diets are generally low in absorbable iron, as described by Lutter and Rivera (4). This is due to the low iron content of the diet and the poor bioavailability of the iron that is present. Most cereal-based complementary foods are not good sources of iron because of their high phytate content, as described by Hurrell (31). Also, such diets provide little if any foods from animal sources, which contain heme iron (the most bioavailable source of iron) and enhance the absorption of iron from nonanimal sources.

A fortified complementary food should provide a quantity of iron sufficient to ensure that the food at least meets the RDA of 11 mg for infants aged 7–12 mo and 7 mg for toddlers, as described by Lynch and Stoltzfus (34). The compound used should also have a bioavailability of at least 10%. To enhance absorption, ascorbic acid should be added in quantities of 70–140 mg/d for infants aged 6–11 mo and 50–100 mg/d for young children aged 12–23 mo. These amounts exceed the requirement for ascorbic acid but pose no risk of toxicity. Dried ferrous sulfate of small particle size is the recommended iron compound because the absorption-enhancing effects of ascorbic acid have been established for this compound only (34).

### *Zinc and copper*

The daily ration of a fortified complementary food should contain 4–5 mg of zinc as described by Rosado (27). This exceeds the RDA of 3 mg and is justified because of the lower bioavailability of zinc in cereal-based diets typical in developing countries. Zinc oxide is the compound most commonly used because it is well absorbed, produces no organoleptic changes and is significantly less expensive than the other zinc compounds. Copper is not currently added to most complementary foods, but 200–400 μg may be added as copper gluconate. The recommended intake of copper is 220 μg for infants aged 7–12 mo (based on an AI) and 340 μg for children aged 1–3 y (based on an RDA).

### *Calcium, vitamin D, magnesium and phosphorus*

In the United States the calcium AI for infants aged 7–12 mo and young children aged 1–3 y are 270 and 500 mg/d, respectively (13). These differ from the United Kingdom DRV, which are 525 and 350 mg/d for infants and young children aged 7–12 mo and 12–23 mo, respectively (33). The estimated calcium retention from human milk is 50% and for solid food is 20–25%, as described by Abrams and Atkinson (24). Infants aged 7–12 mo obtain an estimated 130 mg calcium from human milk, leaving another 140 mg to be supplied by complementary foods. Children aged 12–23 mo obtain an estimated 100 mg calcium from human milk; another 250 mg/d from food would ensure calcium retention of 100 mg/d. An intake of calcium of 350 mg/d is consistent with United Kingdom recommendations although lower than United States recommendations at 7–12 mo (24).

Based on the analysis above, Abrams and Atkinson (24) propose the level of calcium fortification to be 100–200 mg per daily ration. This amount is safe and could be incorporated into food with no undesirable organoleptic changes. For infants and young children neither breast-fed nor receiving another source of milk, this level of fortification is not likely to meet their entire requirement but would effectively help prevent calcium deficiency. The calcium compound used does not appear to be critical with respect to bioavailability.

In the United States the AI for magnesium for infants aged 7–12 mo is 75 mg/d (13). For young children aged 1–3 y, an RDA of 80 mg is set by extrapolating from the data for older children. Although magnesium does not appear to be limiting in the diets in Latin America, the fortification of foods with calcium in the absence of magnesium is controversial (24). The addition of 40–60 mg of magnesium per daily ration is very unlikely to have side effects. In the United States the AI for phosphorus for infants aged 7–12 mo is 275 mg/d. The factorial method was used to set an RDA of 460 mg/d for children aged 1–3 y. The diets of infants and young children do not appear to be limiting in phosphorus and routine fortification of complementary foods is not likely to be necessary (24). However, if fortification were to be undertaken, 75–100 mg per daily ration would be reasonable.

Human milk contains little vitamin D. Dietary sources of this vitamin are particularly important for populations with dark skin and those that receive little sunlight exposure. Vitamin D–fortified products may not be available or may not be consumed by children aged 6–24 mo (24). The AI for infants aged 7–12 mo and children aged 1–3 y is 5 μg/d (13). Fortification at 1–2 μg per daily ration is proposed and would be safe.

### *Vitamin A*

The United Kingdom DRV for vitamin A are 350 μg RE and 400 μg RE for children aged 6–11 and 12–24 mo, respectively (19). The Recommended Daily Intake set by FAO/WHO is 400 μg RE for both age groups (21). The AI, set in the United States, is 500 μg RE for infants aged 6–12 mo and the RDA is 300 μg RE for children aged 1–3 y (16). The UL has been set at 600 μg RE. Human milk is an important source of vitamin A and can meet a large proportion of the needs of infants and young children if their mothers are well nourished, as described by Mora (35). Nonbreast-fed children who do not receive vitamin A (retinol) from animal source foods may not receive sufficient provitamin A carotenoids from plant sources, which have lower bioavailability than does preformed retinol. Satisfying the needs of nonbreast-fed children through a fortified food while ensuring that breast-fed children do not receive too much vitamin A is a challenge because of the relatively low UL (600 μg RE).

Mora (35) estimates that a fortified complementary food that provided 500 μg RE/100 g of dry product would meet 50% of the needs of weaned infants aged 6–11 mo and all the needs of breast-fed infants, assuming an intake of 40 g/d of the food. The same level of fortification would provide 75% of the needs of weaned children and all the needs of breast-fed children aged 12–23 mo, assuming an intake of 60 g/d of the food. Vitamin A provided through high dose vitamin A supplementation programs is not considered in the fortification levels recommended above. This is because at present the coverage of semiannual doses necessary to keep vitamin A stores adequate and prevent subclinical deficiency is not widely achieved. Also, a negligible risk of toxicity in the presence of both vitamin A supplementation and the proposed levels of fortification is likely.

### B vitamins

Because of a lack of quantitative data on which to set precise recommendations, the recommended intakes of B vitamins for infants aged 7–12 mo are based on AI. For children aged 1–3 y, recommended intakes are based on RDA extrapolated from older age groups, except for pantothenic acid, biotin and choline, which are based on AI. The United States recommendations are similar to the United Kingdom recommendations except for a lower United Kingdom recommendation for folate. UL have only been established for niacin, folic acid and choline.

The proposed fortification levels are calculated by subtracting the amount of B vitamins provided by human milk from the requirement (AI or RDA), as described in detail by Allen (36). The proposed amounts per 50 g of food for children aged 6–24 mo are 0.18 mg of thiamin, 0.18 mg of riboflavin, 3.03 mg of niacin, 0.22 mg of vitamin B-6, 41.47 $\mu$g of folic acid, 0.26 $\mu$g of vitamin B-12, 0.35 mg of pantothenic acid, 1.45 $\mu$g of biotin and 45.91 mg of choline. Allen also provides amounts per 40 g of food for infants aged 6–12 mo and per 60 g food for children aged 12–24 mo. Estimates of overage for cooking losses, if the product is not precooked, are also provided.

### Iodine

The International Council for the Control of Iodine Deficiency Disorders and WHO recommend a daily intake of 90 $\mu$g of iodine for infants and young children. This recommendation is similar to that of the U.S. Institute of Medicine (16). Despite worldwide efforts to fortify salt with iodine, pockets of deficiency continue to exist; however, at the same time excess iodine intake has been documented in a number of countries in Latin America, as described by Dunn (37). Iodine is not routinely added to fortified complementary foods. Dunn has proposed the addition of 90 $\mu$g per daily ration to ensure adequate intake of infants and young children.

### Macronutrients

As noted by Hurrell (31), the vegetable protein sources used in a food affect trace element and mineral bioavailability. Uauy and Castillo (38) noted that the composition of dietary fat may be an important determinant of growth, infant development and long-term health. The fat content of infant and toddler complementary food diets is often low because of the dependence on cereal sources (4). Although total nitrogen appears to be adequate when assessed as total protein, the extent to which utilization is impaired because of limiting amino acids has not been carefully assessed. These observations point to the importance of both the macronutrient composition of a fortified complementary food and the source of these macronutrients for infant and young child development.

Uauy and Castillo (38) recommend that between ages 6 and 36 mo, fat intake be gradually reduced from 40 to 60% to 30–35% of energy. Dewey and Brown (20) provide calculations for the percentage of lipid required from complementary foods when either 30 or 45% of energy is from lipid and the level of human milk intake is low, medium or high (**Table 4**). These calculations show that for infants aged 6–11 mo, the percentage of energy from lipid that should be provided in complementary foods ranges from 0 to 24% (for 30% energy as lipid) or from 0 to 43% (for 45% energy as lipid). For children aged 12–23 mo, the percentage of energy from lipid that should be provided in complementary foods ranges from 0 to 28% (for 30% energy as lipid) or from 34 to 44% (for 45% energy as lipid). Because human milk is a rich source of lipid, for both age groups the range is a function of the amount of human milk (low versus high) ingested. The percentage of energy as lipid in complementary foods needed to ensure a minimum total intake of 30% energy as lipid for an infant who receives a low amount of human milk is 19, 24 and 28% at ages 6–8, 9–11 and 12–23 mo, respectively (Table 4).

## TABLE 4

*Percentage of energy from complementary foods that should be provided as lipid to prepare diets with 30% or 45% of total energy as lipid, by age group and level of human milk intake*[1]

| Percentage of total dietary energy as lipid | Level of human milk energy intake | Age group<br>6–8 mo | <br>9–11 mo | <br>12–23 mo |
|---|---|---|---|---|
| | | | % | |
| 30 | Low | 19 | 24 | 28 |
| | Medium | 0 | 5 | 17 |
| | High | 0 | 0 | 0 |
| 45 | Low | 42 | 43 | 44 |
| | Medium | 34 | 38 | 42 |
| | High | 0 | 7 | 34 |

[1] Source: Dewey and Brown (20).

To meet essential fatty acid requirements, the total diet should provide infants with at least 3–4.5% of total energy from linoleic acid (38). At the same time, intake of linolenic and the other (n-6) fatty acids should be limited to around 10% of energy and intake of total PUFA should be limited to around 15% energy. The ratio of (n-6) to (n-3) fatty acids should range from 5:1 to 10:1, which is similar to that found in human milk. *Trans* fatty acids should be as low as possible. Hydrogenated fish oils should be avoided.

The requirements for maintenance of body protein equilibrium as well as the optimum pattern of individual essential amino acids change little between ages 6 and 24 mo (39). The calculations of the dietary requirement for whole protein suggest that a minimum protein–energy ratio of 6% in complementary foods is desirable. The amount of protein from complementary foods needed to supply the RDA for the first limiting amino acid is similar to that needed to supply the RDA for protein. The amounts of individual amino acids that need to be provided by complementary foods were derived by subtracting the amounts of amino acids provided by human milk (assuming an intake in the 25th centile). The amounts of selected protein sources that could provide the additional amino acid needs from complementary foods show that the requirements for the sulfur containing amino acids (methionine and cysteine) could be met, for example, by providing 0.18–0.48 g of bovine milk protein or soy protein per kilogram body weight per day. Between 0.65 and 0.79 g of cereal protein per kilogram body weight per day could provide the needed amount of lysine.

A methodological approach for determining the ideal proportion of macronutrients in a fortified complementary food has not previously been proposed. The Codex Alimentarius Guidelines for Formulated Supplementary Foods for Older Infants and Young Children (18) propose an energy density of at least 400 kcal/100 g of dry food, an amino acid score of not <70% of that of casein, and a fat content between 20 and 40% of energy, corresponding to 10–25 g of fats or oils per 100 g of

**TABLE 5**

*Calculation of macronutrient content of a fortified processed complementary food (FPCF)*

| | 6–11 mo | 12–23 mo | 6–23 mo |
|---|---|---|---|
| Ration size, *g/d* | 40 | 60 | 50 |
| Energy density of FPCF, *kcal/d* | 176 | 264 | 220 |
| If desired protein:energy ratio is 6–10%, energy intake from protein, *kcal/d* | 11–18 | 16–26 | 13–22 |
| Desired energy from lipid, % | 24 | 28 | 26 |
| Energy intake from lipid in FPCF, *kcal/d* | 43 | 74 | 57 |
| Remaining energy from carbohydrate, *kcal/d* | 115–122 | 164–174 | 141–150 |
| Energy from carbohydrate in FPCF, % | 65–69 | 62–66 | 64–79 |

dry food, with the level of linoleic acid not < 300 mg/100 kcal or 1.4 g/100 g of dry product.

No guidance is given on recommended sources of protein, lipid or carbohydrate

The approach taken here for the recommended macronutrient composition uses as a starting point the recommended total protein intake of the target population, from which the protein provided by human milk is subtracted. The energy value of the recommended protein intake from complementary foods is then calculated. Next the lipid content is calculated to ensure that the food contains at least 24% of energy as lipid for infants aged 6–11 mo and 28% of energy as lipid for children aged 12–23 mo. This will ensure that total lipid intake is at least 30% for children consuming a low amount of human milk. The energy not provided by either protein or lipid is then used as the basis for calculating the carbohydrate content. **Table 5** illustrates this calculation, which yields a macronutrient composition (as percentage of energy) of 6–10% protein, 24–28% lipid and 62–70% carbohydrate. The protein and lipid proportions can be higher, if desired, which would correspondingly lower the proportion of carbohydrate.

Several recent abstracts showed an association between milk consumption and growth (40,41) suggesting that milk may have a special role in child growth. The biological basis for this effect is not known, but calcium is associated with changes in body composition in favor of higher fat-free mass. One hypothesis for this phenomenon is that branched-chain amino acids, which are abundant in dairy foods, promote growth of lean body mass. These amino acids enhance the recycling of glucose and favor muscle protein synthesis (42). This suggests that milk should be included in a fortified complementary food as a calcium and fat source, but information on the optimal quantity to include is not yet available. Data are also not available to guide a recommendation for the optimal mix of legumes and cereals or the appropriate ratio of simple to complex carbohydrates. However, it seems prudent to restrict sugar content to ≤10% of energy, as is the case for the fortified processed complementary food produced in Ecuador.

## *Discussion*

This paper is the first attempt to propose a composition for both micro- and macronutrients in a fortified processed complementary food. It is somewhat crude in light of the rigorous approach recently outlined by the Institute of Medicine (7), however, data are not available to apply this approach. Data are also limited on a number of the factors considered herein, such as the appropriate daily ration size, contribution of human milk to meeting requirements and bioavailability of certain compounds. Harmonization of the nutrient requirements for infants and young children is also needed to ensure a more standardized approach. Because of these limitations, the recommendations should be considered preliminary and reviewed periodically as more data become available.

Where data permitted, recommendations were made for specific micronutrient compounds to be used. Use of the recommended compound is critical to ensure adequate bioavailability of the nutrient in question. Unfortunately data are not sufficiently robust to provide a basis for recommendations on the proportions of macronutrients that should be provided by specific foods, such as dry milk or specific cereals or legumes. Given the differences in cost of specific ingredients, with milk among the most expensive, such data are critical to ensure that the most nutritionally adequate food is obtained at the least cost. Linear programming methods will be useful to calculate the lowest cost ingredients to meet the nutrient composition suggested here (43). However, the lowest cost ingredients may not be the most palatable, and acceptability trials would be necessary to ensure that the food will be served by mothers and consumed by infants. To prevent micronutrient losses due to cooking, it is recommended that fortified processed complementary foods be precooked and require only the addition of a clean source of water or other liquid before serving, although this may not be possible in emergency situations such as refugee camps where hygienic conditions are particularly poor.

The recommendations herein are similar to the Codex Alimentarius guidelines for formulated supplementary foods for older infants and young children (18) in many respects, although there are some key differences. The calculated energy density of 440 kcal/100 g of dry food is similar to the recommendation in the guidelines of an energy density of at least 400 kcal/100 g of dry food. The desired proportion of energy from lipid of 24% for infants aged 6–11 mo and 28% for children aged 12–23 mo proposed in this paper is within the 20–40% range recommended in the guidelines. One key difference is the estimated daily ration size, which is 100 g in the guidelines and which we estimate from empirical data to be 40 and 60 g for infants aged 6–11 and 12–24 mo, respectively. This difference may reflect the narrow age range, 6–24 mo, for which we are targeting the food. With respect to micronutrients, the guidelines recommend that if micronutrients are added, two-thirds of the daily requirement should be included per 100 g. The micronutrient levels we recommend depend on the specific nutrient and use the daily ration size described above. For example, for iron the recommended level of fortification is 100% of the RDA because of the low iron content of human milk. For the B vitamins, the contribution from human milk is subtracted from the RDA to arrive at a recommended level of fortification.

One motivating factor for developing a recommended nutrient composition was providing a scientific basis for the review of the formulations of fortified processed complementary foods currently used in social programs in Latin America and for the development of new formulations because of the wide variation in nutrient composition of the foods currently being used (1). The percentage of energy as lipid suggested here is similar to that in the recently formulated fortified complementary foods in social programs in Ecuador and Peru, which have 21 and 30% of energy as lipid, respectively (44). Both foods contain at least 15% of energy as dry milk, which in addition to providing lipid and protein of high quality is a good source of calcium. The fortified complementary food in Mexico is milk based, containing 80 g of powdered whole milk per 100 g of dry ingredient. The fortified complementary foods formulated in the 1960s and 1970s range from a low of 4% energy as lipid in Bienestarina (Colombia) to 17% energy as lipid for Corn Soy Blend (World Food Program). Incaparina, which is sold in Guatemala, provides 13% of energy as lipid. These foods tend to be higher in protein, reflecting the concern about protein being limiting in the diet at the time they were formulated. Although less expensive to produce, these foods may not provide an optimal amount of lipid.

The knowledge base for developing fortified processed complementary foods is still quite limited, and much additional research is needed before an optimal formulation can be recommended. It is sobering to realize that far more is known about formulating optimal foods for domestic livestock than about complementary feeding of young children. Several key research needs are as follows:

- Evaluation of the bioavailability of key nutrients, particularly iron, zinc and calcium, in various formulations of fortified processed complementary foods. Lynch and Stoltzfus (34) mention several critical issues with respect to iron, including *1*) the absorption of ferrous fumarate and different forms of elemental iron from such foods and the influence of ascorbic acid and gastric acidity and *2*) the efficacy of novel methods to improve bioavailability, such as removal of phytate or addition of lactic acid.
- For certain nutrients, determination of the appropriate amounts to be included in a fortified complementary food. As indicated in Table 3, information is insufficient regarding the desirable amounts of potassium, sodium and chloride, and uncertainty exists about the recommended amounts of several other nutrients, particularly magnesium and phosphorus. This is partially due to the lack of consistent recommended nutrient intakes for this age range but also reflects a lack of data on typical intakes of these nutrients from complementary foods in various populations.
- Evaluation of the optimal fat intake for the age range 6–24 mo and the appropriate amounts of total fat and of specific fatty acids to be provided by a processed complementary food in various populations. There is still considerable debate about the desirable level of dietary fat at this age as well as great interest in the potential health benefits of ensuring an appropriate balance of (n-3) and (n-6) fatty acids, as explained by Uauy and Castillo (38).
- Determination of the stability of nutrient content and shelf life of fortified processed complementary foods packaged in different ways. The long-term goal is to identify packaging that preserves nutrient content and prevents oxidation for as long as possible at the lowest cost.
- Investigation of the effects of adding probiotics or prebiotics to processed complementary foods on child immune function and health outcomes. Mounting evidence shows that probiotic bacteria such as lactobacilli can protect against gastrointestinal diseases (45). In developing countries, the addition of probiotics or prebiotics to complementary foods could be an effective way of reducing the incidence and severity of infection.
- Evaluation of the need for including animal source foods such as milk powder in processed complementary foods. Further documentation is needed of the apparent growth-enhancing effect of dairy products and of the mechanism for this effect. If the constituent of milk that is responsible for this effect can be identified (branched-chain amino acids are one possibility), efficacy trials to evaluate the effect of adding this constituent to complementary foods would be the next logical step.
- Investigation of food processing methods that can reduce the risk of microbial contamination in the food after preparation in the home, such as fermentation. In Ghana, coliform counts of a maize-legume porridge prepared in the morning and sampled in the evening were reduced by 50% when the food included maize that had been fermented and dried before being incorporated into the processed complementary food before cooking, compared with the processed food that included unfermented maize (46).
- Efficacy and effectiveness of programs to promote the use of fortified processed complementary foods, including longer-term outcomes such as child immune function and behavioral development. It has become clear that child growth is a relatively crude outcome that may not adequately reflect the overall health benefits of improved nutritional status. For example, some of the long-chain PUFA could have a beneficial effect on mental development without any effect on child growth. Inexpensive methods for assessing functional outcomes in studies with relatively large sample sizes are needed to make this type of research more feasible.

The development of a recommended nutrient composition for a fortified processed complementary food is only one of many factors that could lead to improved infant and young child nutrition. Such foods need to reach the intended target population, either through public programs or through purchase in the commercial sector. Identifying the highest quality, lowest cost food that is acceptable to mothers and young children will be a key factor in determining the coverage that can be reached. Feeding behaviors, including breast-feeding, responsive feeding, safe preparation and storage of complementary foods, food consistency and meal frequency, are also critical to ensuring good nutrition during this vulnerable period of development (47).

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