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Global Alliance for Improved Nutrition

Nutritional Guidelines for Complementary Foods and Complementary Food Supplements Supported by GAIN

Version 1

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INVESTING IN PARTNERSHIPS TO STOP MALNUTRITION

Nutritional guidelines for complementary foods and supplements supported by GAIN

OVERVIEW

GAIN is supporting companies and agencies in the development, production and marketing of fortified complementary foods (FCF), complementary food supplements (CFS), and multiple micronutrient powders (MNP) to improve nutritional status of older infants and young children in several developing countries. GAIN is providing this support to test the feasibility of the private sector being able to reach low-income groups, whether these low-income groups will purchase such products and whether this can be sustainable without external funding. GAIN's intent is to support products likely to have an impact on nutrient status and growth of young children 6-24 months of age. A particular focus is placed on supporting products that address anemia. This is because the prevalence of anemia in children is highest in this age group, exceeding 75 percent in Uganda, Ghana and most other countries in Sub-Saharan Africa, Bangladesh and India[1]. Iron deficiency is believed to be a primary driving factor in about half the cases of anemia[2]. Focus is also placed on products that support linear growth, because malnutrition results in a growth deficit of about 4 cm in children in this age group, which accounts for 50 to 75 percent of total growth deficits seen in young children in developing countries[3].

The Sub-group on Formulations of the Ten Year Strategy to Reduce Vitamin and Mineral Deficiencies Maternal, Infant, and Young Child Nutrition Working Group reviewed the literature on recommendations for fortified complementary foods and complementary food supplements that have been used successfully to impact nutrient status and growth[4]. Additionally a joint WHO, UNICEF, WFP and UNHCR Consultation on the Dietary Management of Moderate Malnutrition in Under-5 Children that was held in October 2008[5] to determine what diets should be recommended to feed moderately malnourished children. One objective of the consultation was to identify areas of consensus on the nutrient needs and dietary management of moderate malnutrition in children that could be translated into evidence-based global guidelines. The dietary recommendations and complementary food supplements discussed are also relevant for young children (6-24 months) at risk for becoming moderately malnourished[6], which includes children living where the local diet is lacking or inadequate in essential nutrients in developing countries.

Based on conclusions from the review and October 2008 Consultation, the nutritional guidelines in this document establish characteristics and nutrient levels for products that GAIN will support. The types of products included are: (1) fortified blended foods (FBF) which are used in addition to good-quality traditional local foods and instead of poor-quality porridges, (2) complementary food supplements (CFS) which are fortified food-based products to be added to other foods (as "point of use" or "home" fortificants) or eaten alone to improve intakes of macronutrients, micronutrients and essential fats, and (3) micronutrient powders (MNP) which are home fortificants containing only vitamins and minerals that are used to fortify the complementary food consumed by

the child. These guidelines are not meant to guide ready to use supplementary or therapeutic foods[7] for treating moderately or severely malnourished children.

1 PRODUCT CHARACTERISTICS

All products should be semi-solid or solid in order to assist transition from a liquid diet to a regular diet and should not be able to be fed from a bottle, which might interfere with breastfeeding. Products should ideally be precooked or instant in order to improve ease of preparation for the end-users (and reducing caregivers' time for preparation and fuel needed). It is also desirable that the manufacturing processes used assist in lowering the levels of phytate, fiber and other anti-nutrient factors. The marketing of all products should comply with International Code of Marketing of Breast-milk Substitutes and subsequent World Health Assembly Resolutions.

1.1 Number of servings and energy/macronutrients content per serving

In order to support breastfeeding, ensure dietary diversity and inclusion of good-quality local foods in a child's diet and to avoid excess energy consumption (or reduced appetite for breast milk), products supported by GAIN for complementary feeding should be energy- and nutrient-dense and consumed in small amounts.

The amount of energy provided by the product on a daily basis should be less than amounts needed by a breastfed child from complementary foods. In developing countries, a breastfed child 6-8 and 9-11 months of age needs only 200 and 300 kcal, respectively, in addition to breast milk from all complementary foods, and a breastfed child aged 12-23 months needs 550 kcal in addition to breast milk[8] (**Table 1**). Consumption of one serving of a product should allow children to eat other local complementary foods, such as porridge, to conform to local dietary customs (for example, congee or *zhou* in China, or *uji* in Kenya, or *suji* in India) and other nutrient-dense foods such as fruits, vegetables and animal source foods.

Energy intake among young children is often limited because of gastric capacity and the types of foods young children are usually fed, which are too high in volume and low in energy density. If foods replace breast milk (which has about 50% of energy from fat and is high in many micronutrients such as vitamin A), then the total energy and nutrient intake might be reduced. For children 6-23 months of age, large volumes of food can displace breast milk from the child's diet, and can also interfere with consumption of local foods, thereby decreasing diet diversity.

Table 1. Energy needed from complementary foods for breastfed and non-breastfed older infants and young children in developing countries and estimated gastric capacity.

Age of child (mo.)	*Recommended daily feeding frequency (meals/snacks)*		*Energy needs from complementary foods*		*Gastric capacity[9] (ml)* [i]	
	Breastfed	Not breastfed	Breastfed[ii] (kcal/day)	Not breastfed (kcal/day)	Average child ml/meal	Growth retarded child ml/meal
6-8	2-3	4-5	200	600	249	192
9-11	3-4	4-5	300	700	285	228
12-23	3-4	4-5	550	900	345	273

Source: PAHO/WHO (2003). Guiding principles for complementary feeding of the breastfed child. http://www.who.int/child_adolescent_health/documents/a85622/en/index.html

One serving of either FBF or CFS should provide 100 to 150 kcal per day and directions on packages should state one serving per day is recommended for children 6-23 months of age.

Because children have small stomachs and can only eat limited amounts of food, ***the energy density of FBF such as porridges should be at least 0.8 kcal/g of product[10] as served, and a*** higher energy density is preferable. It will likely not be possible to achieve an energy density of 4 kcal/g dry weight unless fat is included in the formulation. The nutritional advantages of the type of fat added and its stability when added to a fortified porridge may make production difficult.

Table 2 shows that in some countries, up to 40 percent of children 12-15 months of age are not breastfed. They especially need the calories and nutrients for growth and development. Because non-breastfed children need between 600-900 kcal per day (6-8 mo.: 600 calories, 9-11 months: 700 kcal, 12-23 mo.: 900 kcal), one serving of either FBF or CBS with 100-150 kcal per day would provide 17% to 25% of the daily energy requirements for the youngest 6-8 month old children. Children who are infected with HIV/AIDS or raised by caregivers with HIV/AIDS can benefit especially from GAIN-supported products, because they are often at increased risk for micronutrient deficiencies and poor diets due to poverty, inattention by sick caregivers, or lack of appetite and need extra energy.

[i] Assumes body weight of 8.3 kg, 9.5 kg, and 11.5 kg for well nourished children and 6.4 kg, 7.6 kg and 9.1 kg for growth retarded children in the three age groups respectively (6-8, 9-11, 12-23 mo.) and gastric capacity of 30 g/kg body weight
[ii] Assuming average breast milk intake

Because many complementary foods are based on plant proteins, their protein quality may not be sufficient. The Protein Digestibility Corrected Amino Acid Score (PDCAAS) is a method of evaluating the protein quality based on the amino acid requirements. PDCAAS has been adopted by FAO/WHO (2007) as the preferred method for the measurement of the protein value in human nutrition. The method is based on comparison of the concentration of the first limiting essential amino acid in the test protein after taking digestibility into account with the concentration of that amino acid in a reference (scoring). The amino acid requirement of the preschool-age child is used as the reference. A minimum PDCAAS score of 70 percent is required. While protein is needed for growth, high protein levels increase renal solute load and may interfere with appetite[5].

GAIN-supported FBF and CFS should have a PDCAAS of at least 70 percent and between 10%-15% of energy from protein.[4-5]

Complementary foods in developing countries are often low in fat and essential fatty acids, which are required for growth and development. Because breast milk provides a large amount of fat, non-breastfed children in developing countries often have even higher risk of inadequate fat intake. Fortified CFS may need to contain higher proportions of these nutrients than normally present in the child's diet to make up for lack of fat in other foods consumed[4]. The amount of fat in the total diet is recommended to be at least 35 percent of energy, and 35-45 percent is considered to be advantageous for most CFS if the density of micronutrients is adequate[5]. The use of full-fat milk, full-fat soy flour, peanuts or soybean oil in a product can help increase energy density and essential fatty acid content, but including these ingredients might reduce the shelf life of the product if the fat becomes rancid. Lipid-based Nutrient Supplements (LNS) generally have higher total fat content than fortified blended foods, and thus improve fat and essential fatty acid content in the total diet. The iLiNS (International Lipid-Based Nutrient Supplements) group is testing an LNS with a higher percentage of energy from fat (80%) and a lower sugar content, compared to a previously used LNS called Nutributter ® (58.3% energy from fat) in order to enhance fat intake and reduce sweetness of the product. This is to discourage overconsumption, given that only one serving per day is recommended for children at risk for malnutrition.

Recommendation: Fat should comprise at least 20% of energy for FBF and at least 30% of energy for CFS, while considering the product taste and composition*. The reason for the difference between FBF and CFS is that it is easier to have a higher percentage energy from fat in CFS than in FCFs because of the nature of the raw ingredients and their proportions.*

In order not to encourage excessive consumption of the product, and to be in-line with the recommended % dietary energy coming from added sugar, the percent sugar should be preferably lower than 10 percent [4-5]. However, organoleptic issues might warrant a higher percentage of energy from sugar, particularly for FBF.

Table 2. **Percent of children breastfed at 12-15.9 months of age.**

	Percent of children 12-15.9 months of age still breastfed	
Country/state	Rate (%)	Source
Ethiopia (2005)	94	DHS
Ghana (2003)	88	DHS
Kenya (2003)	57	DHS
Nigeria (2003)	80	DHS
South Africa (1998)	61	DHS
Uganda (2006)	91	DHS
Bangladesh (1998-9)	87	DHS
India (2005-6)	88	NFHS
Indonesia (2002-3)	77	DHS
Cambodia (2005)	90	DHS
China (2006) Poor areas	66	Mother Baby Package Survey, MOH, UNICEF

1.1.1 Food components

Milk

Animal-source foods such as milk are important for complementary feeding because they provide high quality protein, bioavailable micronutrients, and have low levels of anti-nutrients and fiber[5]. Compared to FBF, lipid-based nutrient supplements usually have more milk solids and fat and their volume can be smaller for the same amount of calories. This may allow more gastric capacity for additional foods. High cost is a potential barrier to usage of milk in complementary foods.

The addition of milk products to complementary foods has been suggested to be beneficial for growth[4]. It appears that intake of cow's milk stimulates IGF-I secretion, which has a direct effect on linear growth[11,12]. Milk also contains high levels of nutrients, such as calcium, phosphorus and magnesium, and proteins that may have growth-promoting abilities[13]. Most products that have shown an impact on growth in children less than 2 years of

age have contained milk solids (generally 5-10 percent for FBFs and up to 25 percent in an LNS). The amount of milk solids added has ranged from 3.5 to 12.5 g (where reported) [4]. The UN World Food Program (WFP) has recently revised their standards and now recommends use of 8 percent milk solids in Corn Soy Blend (50 g recommended per day provides 4 g of milk solids) [6].

The formulations of LNS being studied by iLiNS include 40 g, 20 g, and 10 g of products, and those containing milk solids have 10 g, 5 g, and 2.5 g of milk, respectively. The impact of milk is being tested at the amounts of 5 g and 10 g.

Recommendation: GAIN-supported products should preferably contain at least 5 g milk solids non-fat (MSNF) per 25 g serving

Essential Fatty Acids

Diets of young children in developing countries are often limited in essential fatty acids. Intakes of both alpha-linolenic acid (an omega-3 fatty acid) and linoleic acid (an omega-6 fatty acid) can be low, or there may be an inappropriately high ratio of linoleic to alpha-linolenic acid. Consumption of foods with high alpha-linolenic acid content should be encouraged in particular[4]. Because emerging evidence suggests that low intake of essential fatty acids is associated with growth retardation, enhanced essential fatty acid content of complementary foods is likely to be beneficial[14,15]. Thus, oils containing both linoleic and alpha linolenic acid such as soybean or canola oil are preferable to oils such as corn, peanut, or palm oil which contain little omega-3 fatty acids (i.e. alpha-linolenic acid). Full-fat soy flour or fatty fish are also good sources of alpha-linolenic acid.

The Codex standard for processed cereal-based foods for infants and young children (CODEX STAN 074-1981, REV. 1-2006) recommends that if lipids exceed 3.3g fat /100 kcal, the level of linoleic acid should not be less than 300 mg per 100 kcal and not exceed 1200 mg per 100 g of product [10]. The October 2008 consultation on moderate malnutrition[5] recommended a ratio of linoleic to alpha-linolenic acid ranging from 5:1 to 15:1 for formulated complementary foods but others[16] have suggested that 5:1 to 10:1 may be better, especially where fat intakes are low. Both Nutributter ® and a full-fat fortified soy product used in China have over 1000 mg of linoleic acid in only 10-20 g of food. The ratios of linoleic to alpha-linolenic acid are 4.4:1 in Nutributter® and 9.8:1 in the product used in China[4]. The amounts of alpha-linolenic acid in the two products are 290 mg and 131 mg, respectively[4]. The 20 g and 40 g products being tested by the iLiNS studies contain between 290 mg and 580 mg of alpha-linolenic acid. The US recommendation of 700 mg per day of alpha-linolenic acid for children 1-3 years of age is based on average intakes in the US[17], and estimated intakes from the WHO/FAO interim regulations [18] are 400-600 mg per day for children12-23 mo. of age[19].

Recommendation: FBF and CFS preferably should contain at least 130 mg of* alpha-*linolenic acid*[iii] *and higher amounts are preferable. The essential fatty acid ratio of linoleic to alpha-linolenic acid preferably should be between 5:1 and 10:1*[16]*.

Fiber and anti-nutrients

The importance of reducing anti-nutritional factors and fiber in complementary foods was emphasized at the October 2008 Consultation[5]. Anti-nutrients (such as phytates, tannins, and saponins) can inhibit bioavailability of nutrients and anti-nutrients (such as alpha amylase inhibitors, trypsin inhibitor, and haemagglutenins) can interfere with digestion [20]. Whole grains (often used in traditional complementary foods) contain high levels of dietary fiber and anti-nutrients. Milling reduces fiber and anti-nutrients in whole grains. For this reason, white rice, wheat flour with 85% extraction rate and maize flour with a 60% extraction rate are preferable to unmilled grains for complementary foods[13]. If wheat, maize, sorghum and millet are used, only refined flours with reduced fiber, tannin and phytate content and longer shelf life are recommended[13].

De-hulling coloured legumes or certain sorghums and millet will remove the polyphenols and phytate. De-hulling reduces tannins in chickpeas and reduces fiber in some legumes. Removing phytate in soy completely and beans is difficult because it is located in the cotyledon and not the hull.

Dietary fiber increases bulk and satiety and reduces nutrient digestibility and energy density and should be limited in diets of moderately malnourished children. In the countries where GAIN's projects for older infants and young children (IYCN) are taking place, moderate malnutrition is high, affecting over 50 percent of children 12-23 months of age in India and Bangladesh, 40 percent in Kenya and 35% in Ghana.

Recommendation: GAIN-supported products should use milled grains to keep fiber and other anti-nutrients at a minimum

Aflatoxin

Peanuts provide a good source of protein and fat. When producing food products using peanuts and other crops that are vulnerable to mold that produce aflatoxin, safety must be assured. Finished food products should contain less than 5 ppb of aflatoxin, based on WFP standards for corn soy blend for young children[4].

Recommendation: GAIN-funded products should have no or minimum levels of aflatoxin

[iii] based on what was contained in Ying Yang Bao

The amounts of nutrients and food components recommended above might need to be different from proposed, depending on organoleptic properties and shelf life considerations.

Boxes 1-3 summarize these ***suggested*** guidelines.

Box 1. Suggested characteristics for GAIN-supported Fortified Blended Foods for children 6-23 mo. of age.

- **Recommended number of servings**: One serving per day
- **Kcal/kilojoules (kJ) per serving**: up to 100-150 kcal / 418-628 kJ
- **Kcal/g of product as served:** At least 0.8 kcal/g (3.3 kJ/g) but higher energy density preferable.
- **Serving Volume (prepared product or ready to eat):** < 175 ml
    - **Viscosity:** Not possible to be fed in a bottle
    - **Consistency of product or when eaten:** semi-solid (not liquid)
- **Protein:** 10 -15 percent of energy as protein
    - **PDCAAS** $\geq$ 70 percent
- **Fat:** at least 20 percent of energy as fat and more preferable
    - **Essential fatty acids:** Ratio linoleic to alpha-linolenic acid 5 to 10:1
    - **alpha-linolenic acid content**: Contain at least 130 mg, more preferable
    - **No hydrogenated fats with trans-fatty acids**
- **Added sugar**: Preferably less than 10 percent of energy
- **Milk:** Should contain at least 5 g of milk solids non-fat (MSNF); sources of MSNF include dried skim milk, whey, full-fat milk, and semi-skimmed milk solids
- **Aflatoxins:** Maximum <5 ppb
- **Anti-nutrients**: If feasible, low extraction flours should be used to reduce phytate levels, and dehulled legumes should be used to lower fiber and polyphenols if colored varieties are used.
- **Micronutrients: See Table 4**
- Instant, pre-cooked or ready-to-eat.
- Labeling and marketing must comply with International Code of Marketing of Breast-Milk Substitutes and subsequent World Health Assembly Resolutions.

Box 2. Suggested characteristics for GAIN-supported Complementary Food Supplements for children 6-23 mo. of age

- **Recommended number of servings**: One serving per day
- **Kcal/kilojoules (kJ) per serving**: up to 100-150 kcal / 418-628 kJ
- **Kcal/g of product as served:** At least 4.0 kcal/g (3.3 kJ/g) but higher energy density preferable.
- **Serving Volume (prepared product or ready to eat):** < 40 ml or < 40 g
    - **Viscosity:** Not possible to be fed in a bottle
    - **Consistency of product or when eaten:** semi-solid (not liquid)
- **Protein:** 10 -15 percent of energy as protein
    - **PDCAAS** ≥ 70 percent
- **Fat:** at least 30 percent of energy as fat and more preferable
    - **Essential fatty acids:** Ratio linoleic to alpha-linolenic acid 5 to 10:1
    - **alpha-linolenic acid content**: Contain at least 130 mg, more preferable
    - **No hydrogenated fats with trans-fatty acids**
- **Added sugar**: Preferably less than 10 percent of energy
- **Milk:** Should contain at least 5 g of milk solids non-fat (MSNF); sources of MSNF include dried skim milk, whey, full-fat milk, and semi-skimmed milk solids
- **Aflatoxins:** Maximum <5 ppb
- **Anti-nutrients**: If feasible, low extraction flours should be used to reduce phytate levels, and dehulled legumes should be used to lower fiber and polyphenols if colored varieties are used.
- **Micronutrients: See Table 4**
- Instant, pre-cooked or ready-to-eat.
- Labeling and marketing must comply with International Code of Marketing of Breast-Milk Substitutes and subsequent World Health Assembly Resolutions.

Box 3. Suggested characteristics for GAIN-supported Multi Micronutrient Powder Supplements for children 6-23 mo. of age

- **Recommended number of servings:** One serving per day
- **Consistency product or when eaten:** should be a powder that can be mixed with food (should not be used in a liquid);
- **Micronutrients: See Table 5**
- Labeling and marketing must comply with International Code of Marketing of Breast milk Substitutes and subsequent World Health Assembly Resolutions

1.1.2 Nutrient levels

Type of iron fortificant and other nutrients important to reducing anemia

The choice of iron compound is as important as is the amount added. WHO 2006 recommends ferrous sulfate, encapsulated ferrous sulfate, ferrous fumarate and electrolytic iron at 2 times the level of iron as ferrous sulphate for wheat and maize flour fortification. A recent study reported that ferrous sulfate, ferrous fumarate and ferric pyrophosphate (10mg Fe/d) had the same positive influence on iron status in a one year complementary food feeding study[21]. The use of sodium iron EDTA (NaFeEDTA) is especially beneficial for reducing iron deficiency anemia, because it is highly bioavailable and helps improve absorption of iron from other foods in the diet. Because of a low recommended average daily intake of EDTA, one can mix a small amount of NaFeEDTA with other ferrous compounds (e.g. ferrous sulfate, ferrous fumarate) to deliver the desired amount of iron. A modeling exercise has estimated that 2 mg of iron from NaFeEDTA would not exceed the upper level for EDTA in 6-8 month old children, even in populations with a high prevalence of underweight[22]. For this reason, we recommend that on a per serving basis GAIN-supported products contain 2 mg of iron as NaFeEDTA and additional amounts of another type of iron to reach the desired percentage of the WHO/FAO Recommended Nutrient Intake.

A main objective of GAIN-supported products is to reduce anemia. In order to do this effectively, several nutrients including riboflavin, $B_{6,}$ $B_{12,}$ folic acid, vitamin A and copper might be needed in addition to iron to enhance hemoglobin synthesis, iron transport or absorption. The addition of vitamin C also helps improve absorption of non-heme iron.

Need for nutrient levels above the RNI

WHO/FAO has established levels of Reference Nutrient Intakes (RNIs) and Upper Levels (ULs), which are based on needs of healthy children[23] [24]. The October 2008 Consultation on moderate malnutrition reported that "the nutritional requirements of moderately malnourished children probably fall somewhere between the nutritional requirements for healthy children and those of children with severe acute malnutrition during the catch up growth phase." Because there is evidence that some children who consume fortified complementary foods are still moderately malnourished or at-risk for becoming so in low-income countries, nutrient standards based on the RNIs might be too low. A study of malnourished children 3-6 years of age that showed positive impacts on linear growth used between 1.5-3 times the RNI[25]. Furthermore, 100 g (approx. 500 kcal) of ready to use therapeutic food (RUTF) called Plumpy'nut® that is used to treat severe acute malnutrition, contains many nutrients that are over 2 times the RNI. However, national regulations and Codex regulations may not permit levels greater than the RNIs[4].

Type 1 and 2 nutrients

Professor Michael Golden describes [26], Type 1 nutrients as those whose deficiencies are associated with clinical symptoms, and they include vitamins, calcium, iron, iodine and selenium. For poor children in developing countries, requirements for Type 1 nutrients might be higher than the RNIs because of additional nutrient needs due to exposure to environmental stress (e.g., pollution, smoke) and infections[4,26].

Type 2 nutrients are those needed for growth of lean tissues, and include sulfur (mostly from protein), magnesium, phosphorus, potassium, and zinc[26]. Except for zinc and sometimes magnesium, the other Type 2 nutrients have often not been included as fortificants in complementary foods or supplements[20]. This might be a reason why impacts on growth have been limited with complementary foods or supplements used in the past.

Inclusion of Type 2 nutrients in formulated products

There are some examples of Type 2 nutrients being included in product formulations. A type of MNP called Sprinkles® that contains 14 nutrients including zinc has been developed and is used widely. The UNICEF/WHO/WFP recommendations for MNPs (developed initially for emergencies and now used in all their programs) add selenium to this formulation (15 nutrients) [29, 30]. Additional nutrients such as Vitamin K, biotin, and pantothenic acid might also be helpful[20]. The addition of more Type 2 nutrients would be preferable but it might not be feasible for some nutrients.

Nutrient levels for formulated complementary foods and supplements

Because children will be receiving other foods in addition to formulated complementary foods and complementary food supplements, in contrast to emergency situations where the consumption of other foods may not be assured (and 100% of nutrients are provided), these GAIN nutritional guidelines for complementary foods and supplements recommend that products contain at least 50% of the RNIs. While GAIN acknowledges that these levels might be too low to promote adequate growth or reduce anemia effectively, until guidance is available from WHO on suggested nutrient levels for fortified complementary foods and supplements for moderately malnourished children, GAIN will be cautious and conservative in its recommended fortification levels for nutrients.

Table 3 gives the distribution of recommended levels of 22 proposed micronutrients in GAIN-supported FBFs and CFS products. This includes 18 nutrients for MNPs and 4 additional nutrients (calcium, phosphorus, magnesium and manganese[27]) for FBFs. ***These levels include both naturally occurring and nutrients from premixes.*** The amounts suggested, however, may need to be different than proposed, depending on

organoleptic properties of some nutrients (such as magnesium or calcium) in the finished product. Adding choline is not proposed because there is no RNI and it is expensive to add as a fortificant, and sodium and potassium are not proposed because there is no RNI.

This table compares the GAIN proposed levels to the RNIs, the upper levels and levels in F100, a product used for treating severely malnourished children. Compared to F100, the recommended levels in GAIN-supported products are relatively low. GAIN's proposed levels are also below the UL even if three to four servings per day are consumed by mistake. Because even higher levels than what GAIN is recommending might be needed to promote growth, GAIN's proposed levels are unlikely to be excessive even if consumed more than once daily. For example, GAIN recommends 2.5 mg of Vitamin E per serving, but F100 has 22 mg per 1000 kcal, and the upper level is 200 mg; GAIN recommends 250 mg of calcium, F100 has 1008 mg, and the UL is 2500 mg.

Even though Sprinkles® that contain nearly 100% of the RNI for 14 nutrients have been tested in efficacy trials and have been found to be safe in non-malaria endemic areas, because of concerns with iron intake in malaria endemic areas, levels of iron in GAIN-supported foods and supplements should not contain more than 50% of the RNI for children 1-3 years of age where malaria is endemic. In countries where products with higher levels of nutrients are already in use (e.g. Bangladesh), GAIN will support the use of the same formulation that UNICEF and others are buying to avoid running lines for different products (increasing the production volumes of a single product will bring down costs). It is important to get as many countries using the same formulation as possible in order to create a commodity market for MNPs (regional and international).

Summary recommendation: One serving of a product should contain at least 50% and up to 100% of the WHO RNIs for 19 nutrients, up to 80% for niacin, up to 93% for folic acid, and no more than 50% for vitamin A for children 1-3 years of age up. National standards take precedence over these recommendations and all decisions on fortification levels should be based on joint situation assessments and the need of individual countries.

If the product has naturally occurring nutrients, fortification might not be needed (depending on losses in processing or preparation) and the levels might naturally exceed 50% of the RNI (for example for vitamin $B_{12,}$ or magnesium[iv]). Additionally, levels may exceed 50% of the RNI when nutrients are added to account for loss in storage or for addition of other nutrients such as ascorbic acid for its anti-oxidant and iron absorption enhancing characteristics.

Recommendation: Because children in developing countries experience many deficiencies, and the October 2008 Consultation on moderate malnutrition emphasized the importance of an appropriate balance of nutrients to enhance growth, GAIN-supported MNP should optimally contain up to 18 nutrients (15 used in the UNICEF/WHO/WFP guidelines for emergencies plus vitamin K, pantothenic acid, and biotin), except where local government regulations do not permit this. If feasible, additional

[iv] Magnesium upper limit only applies to "supplemental magnesium" not food magnesium. See section 1.4 for analyses of GAIN-supported products

nutrients likely to be missing in the diet (e.g. calcium, phosphorus, magnesium, and manganese) should also be included if feasible in FBFs and CFS, bringing the total number of added nutrients up to 22.

In line with GAIN's intent to support the best product possible (given constraints of organoleptic qualities, stability, regulations and cost), limitations due to national standards will be viewed as an entry point for programming on policy and advocacy.

In order to allow the best chance for success in reducing anemia through GAIN-supported products, it is recommended that these products contain the types and amounts of micronutrients recommended in these guidelines for iron, zinc, copper and vitamins A, C, B_2, B_6, B_{12} and folic acid. These micronutrients are present in inadequate amounts in typical diets in developing countries. For the other micronutrients there can be some flexibility on which micronutrients are included and the amounts in order to satisfy organoleptic, cost or other needs that will be critical to the products' acceptability or sustainability.

Table 4 shows the recommended levels of the 18 nutrients recommended by GAIN for MNP comparing these levels to UNICEF/WHO/WFP guidelines for emergencies and levels previously used in Sprinkles®.

Table 5 lists the types of nutrient compounds that should be used.

Table 3. **Recommended levels of nutrients for GAIN-supported FBFs and CFS products compared to RNIS, ULs and F100**

	RNIs1-3 yrs	*UL 1-3 yrs**	*UL (infants 7-11 months)*	*F-100 per 1000 kcal*	*2 servings per day at 100% RNIs 1-3 yrs, per serving*	*GAIN Suggested amount per serving*	*% of RNIs*
Vitamin A (µg)	400	600	600	1500	800	200	50% of RNI (keeps < UL 7-11 mo if 2 servings consumed)
Vitamin D (µg)	5	50	25	30	10	2.5–5.0 (100–200 IU)	50% -100% of RNI
Vitamin E (mg)	5	200	N/A	22	10	2.5–5.0 (mg α-TE)	50% - 100% of RNI
Vitamin C (mg)	30	400	N/A	100	60	≥15 (to improve absorbability of iron)	≥50% of RNI
Thiamin (vitamin B1) (mg)	0.5		N/A	0.7	1	0.25–0.5	50%-100% of RNI
Riboflavin (vitamin B2) (mg)	0.5		N/A	2	1	0.25–0.5	50% -100% of RNI
Niacin (vitamin B3) (mg)	6	10	N/A	10	12	3.0–4.8	50% - 80% of RNI to keep below UL if 2 servings consumed
Vitamin B6 (mg)	0.5	30	N/A	0.7	1	0.25–0.5	50% -100% of RNI
Vitamin B12 (µg)	0.9	None	N/A	1	1.8	0.45–0.90	50%-100% of RNI
Folic acid (µg)	150	300	N/A	350	300	75–140	50%-93% of RNI to keep below UL if 2 servings consumed
Iron (mg)	11.6	40	40	24	23.2	2.0 mg NaFeEDTA +3.8–9.6 other types	50% -100% of RNI
Zinc (mg)	8.3	23-28 b	N/A	22.1	16.6	4.2–8.3	50%-100% of RNI
Copper (mg)	0.56 d (.34 IOM)	1	N/A	2.7	1.12	0.28–0.34	50%-61% of RNI to keep below UL if 2 servings consumed
Selenium (µg)	17	90	60	55	34	8.5–17.0	50% -100% of RNI
Calcium (mg)	500	2500	N/A	1008	1000	250–500	50%-100% of RNI
Iodine (µg)	90	200	N/A	18	180	45–90	50% -100% of RNI
Vitamin K (µg)	15		N/A	40	30	7.5–15.0	50% -100% of RNI
Biotin (µg)	8		N/A	10	16	4–8	50%-100% of RNI
Choline (mg)	200 *	1000	N/A	Na	400		helpful but costly to add and no RNI
Pantothenic acid (mg)	2		N/A	3	4	1–2	50% -100% of RNI
Magnesium (mg)	60	65 b	N/A	175	120	30	50% of RNI to keep below UL and depending on taste
Manganese (mg)	1.2c	2c	N/A	.7	2.4	0.6	50% of RNI to keep below UL and F100 if 2 servings consumed)
Phosphorus (mg)	460 c	3000 c	N/A	762	920	230–460	50%-100% of RNI depending on taste
Potassium (mg)	N/A	N/A	2400	N/A			
Sodium (mg)	N/A	N/A	454	N/A			
Reference	a RNIs (WHO/FAO 2004) and ULs reported from WHO/FAO, 2006 (23,27) , except zinc/magnesium b WHO/FAO, 2004 (23) and manganese and phosphorus c IOM 2002/2005 (17); d: Copper RNI/UL from FAO/IAEA/WHO: Trace elements in human nutrition and health. WHO. Geneva. 1996 (24) * *Adequate intakes.						

Table 4. **Suggested recommended amount of nutrients per serving of Micronutrient Powders**

	WHO/FAO RNIs 1-3 yrs.	*Sprinkles formulation* [28]	*UNICEF/WHO/ WFP MNP* [29 30]	*GAIN Guidelines*	*Percent of RNI*
Vitamin A (µg)	400	300 (acetate)	400	200	50% of RNI (keeps < UL 7-11 mo if 2 servings consumed)
Vitamin D (µg)	5	5 (D3)	5	2.5–5.0 (100–200 IU)	50% -100% of RNI
Vitamin E (mg)	5	6 (acetate)	5	2.5–5.0 (mg α-TE)	50% -100% of RNI
Vitamin C (mg)	30	30 (ascorbic acid)	30	≥15 (to improve absorbability of iron)	≥50% of RNI
Thiamin (vitamin B1) (mg)	0.5	0.5 (mononitrate)	0.5	0.25–0.5	50%-100% of RNI
Riboflavin (vitamin B2) (mg)	0.5	0.5 (riboflavin)	0.5	0.25–0.5	50% -100% of RNI
Niacin (vitamin B3) (mg)	6	6 (niacinamide)	6	3.0–4.8	50% - 80% of RNI to keep below UL if 2 servings consumed
Vitamin B6 (mg)	0.5	0.5 (pyridoxine hydrochloride)	0.5	0.25–0.5	50% -100% of RNI
Vitamin B12 (µg)	0.9	0.9 (cyanocobalamin)	0.9	0.45–0.90	50%-100% of RNI
Folic acid (µg)	150	160 (folic acid)	150	75–140	50%-93% of RNI to keep below UL if 2 servings consumed
Iron (mg)	11.6	12.5 (encapsulated ferrous fumarate)	10 (encapsulated fumarate or other soluble iron)	2.0 mg NaFeEDTA + 3.8–9.6 other types	50% -100% of RNI
Zinc (mg)	8.3	5 (gluconate)	4.1 (zinc gluconate)	4.2–8.3	50%-100% of RNI
Copper (mg)	.56	0.3 (sulfate)	0.56 (copper gluconate)	0.28–0.34	50%-61% of RNI to keep below UL if 2 servings consumed
Selenium (µg)	17		17	8.5–17.0	50% -100% of RNI
Iodine (µg)	90	90 (potassium iodide)	90	45–90	50% -100% of RNI
Vitamin K (µg)	15			7.5–15.0	50% -100% of RNI
Biotin (µg)	8			4–8	50%-100% of RNI
Pantothenic acid (mg)	2			1–2	50%-100% of RNI

Table 5. Suggested chemical forms of nutrients included in products

Vitamin A	Retinyl acetate or retinyl palmitate or beta-carotene
Vitamin D	ergocalciferol (D2) or cholecalciferol (D3)
Vitamin E	Acetates of D or DL-alpha-tocopherol
Vitamin C	L-ascorbic acid
Thiamin (vitamin B1)	Thiamin mononitrate (preferred for dry products) or Thiamin hydrochloride
Riboflavin (vitamin B2)	Riboflavin
Niacin (vitamin B3)	Niacinamide
Vitamin B6	Pyridoxine hydrochloride
Vitamin B12	Cyanocobalamin (diluted form (0.1% or 1%) with 100% active particles, spray dried form
Folic acid	Pteroyl monoglutamic acid
Iron	NaFeEDTA (subject to guidance on upper limits but can be combined with ferrous sulfate), ferrous sulfate, ferrous fumarate, encapsulated ferrous sulfate, encapsulated ferrous fumarate ** and micronized ferric pyrophosphate *** could also be used but costs need to be considered. All compounds should be added together with ascorbic acid (AA) at 2:1 AA:Fe molar ratio and packaging which prevents ascorbic acid losses during storage.++
Zinc	Zinc sulfate, zinc gluconate**, zinc oxide**** +
Copper	Copper sulfate or Copper gluconate +
Selenium	Sodium selenate, Sodium selenite
Calcium	Several forms available some with higher contents of Ca, such as Ca phosphate and Ca carbonate; Soluble organic Ca salts such as Ca Citrate [5] Calcium salts containing well absorbed anions (such as chloride) should be avoided as they may induce acidosis[5]
Magnesium	Soluble organic magnesium salts such as Mg Citrate[5] Magnesium salts containing well absorbed anions (such as chloride) should be avoided as they may induce acidosis[5]
Iodine	Potassium iodide
Based on WHO/FAO Food fortification guidelines[27] ; **Sprinkles Global Health Initiative [28]; *** ; Dary and Hainsworth, 2008[31] ;**** [32] Rosado (2003); + in cases where there are interactions due to storage, stabilized forms of minerals should be considered subject to cost constraints,.++ Hurrell, personal communication	

1.2 Quality standards

All GAIN-supported products must follow a standard set of quality parameters. They will be specifically formulated with the objective of maintaining consistent nutritional quality, minimizing factors that could have a negative effect on nutritional acceptability and ensuring product safety and consumer acceptability. They will be formulated in such a manner as to be easily managed and enforced in those manufacturing operations where skills levels are relatively low. For this reason, elaborate quality systems requiring extensive documentation will not be utilised directly but rather used as a theoretical basis for more simple procedures. The quality parameters and systems will therefore be derived partly from Codex standards for the products concerned, partly from other global standards such as ISO 22000 and partly from the personal technical knowledge and expertise of the task team. Companies are responsible for monitoring these standards, and GAIN will independently assess products obtained from the field for safety and quality.

1.3 Implications of costs for optimizing nutritional guidelines

While these nutritional guidelines are written to support optimal nutrition for young children, in order for products to be able to be purchased by poor families or by governments for distribution to poor children, their costs need to be kept as low as feasible. The costs of inputs (e.g., premix, packaging) will affect product costs, thus influencing whether they will be effectively utilized by families. However, if products offer little advantage over local porridges or other complementary foods, except for the fortificants they contain, then use of a lower cost MNP might be preferable to a higher cost FBF or CFS that has little added nutritional benefit over the local complementary food (i.e. no addition of essential fatty acids, milk or high quality protein). However, higher cost products that are optimal nutritionally might not have the intended results (improvements in iron status or growth), if families cannot afford to use them frequently enough.

Because instant or pre-cooked products require little or no cooking, they can save caregivers' time and fuel. Families might see these as important advantages and might be willing to shift funds to purchase these higher quality but more expensive products. Thus finding the appropriate balance between the optimum product nutritionally and one that provides some additional benefits in addition to fortification and is affordable and feasible to produce is the challenge. Additionally, it is important to ensure clean water is used in preparing products, and this must be emphasized in labeling and social marketing.

Factors that affect costs include which micronutrients are selected for the premix, and the quantities and forms of each nutrient. Vitamins A and C are expensive nutrients, but others such

as biotin and B vitamins, add little to overall premix costs. Some micronutrients have costs that fluctuate depending on the market (e.g. copper). Milk solids nonfat (MSNF) costs also fluctuate and can add substantially to the total cost, but yield an important benefit for the product in enhancing child growth and organoleptic properties of the product (making it more creamy). The addition of full-fat soy flour or soy bean oil, adds beneficial essential fatty acids, but these may need to be imported, which can add to costs. There is a need for low-cost sources of essential fatty acids that could be added to a premix (such as fatty acids made from algae). Because children's diets in developing countries are too low in fat, the guidelines recommend at least 20% and 30% of energy from fat for FBF and CFS, respectively, but this may mean additional packaging or shorter shelf life, adding costs to products.

GAIN has thus proposed nutritional guidelines for GAIN-supported projects for infants and young children, and works with manufacturers to modify products to keep costs low and nutritional quality as high as feasible. GAIN works with the premix facility (GPF) to find low cost sources of micronutrients, and provides technical support to companies to help them formulate products that can meet nutritional goals at minimal costs.

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