

Composition of Follow-Up Formula for Young Children Aged 12–36 Months: Recommendations of an International Expert Group Coordinated by the Nutrition Association of Thailand and the Early Nutrition Academy

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Key Words

Young child feeding · Food standards · Follow-up formula · Nutritional requirements

Abstract

Background: There are no internationally agreed recommendations on compositional requirements of follow-up formula for young children (FUF-YC) aged 1–3 years. **Aim:** The aim of the study is to propose international composi-

tional recommendations for FUF-YC. **Methods:** Compositional recommendations for FUF-YC were devised by expert consensus based on a detailed literature review of nutrient intakes and unmet needs in children aged 12–36 months. **Results and Conclusions:** Problematic nutrients with often inadequate intakes are the vitamins A, D, B12, C and folate, calcium, iron, iodine and zinc. If used, FUF-YC should be fed along with an age-appropriate mixed diet, usually contributing 1–2 cups (200–400 ml) of FUF-YC daily (approximately 15% of total energy intake). Protein from cow's milk-based

formula should provide 1.6–2.7 g/100 kcal. Fat content should be 4.4–6.0 g/100 kcal. Carbohydrate should contribute 9–14 g/100 kcal with >50% from lactose. If other sugars are added, they should not exceed 10% of total carbohydrates. Calcium should provide 200 mg/100 kcal. Other micronutrient contents/100 kcal should reach 15% of the World Health Organization/Food and Agriculture Organization recommended nutrient intake values. A guidance upper level that was 3–5 times of the minimum level was established. Countries may adapt compositional requirements, considering recommended nutrient intakes, habitual diets, nutritional status and existence of micronutrient programs to ensure adequacy while preventing excessive intakes.

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Introduction

The aim of this position paper is to provide recommendations on the composition of follow-up formula for young children (FUF-YC) aged 1–3 years. These recommendations were developed by an international expert group based on a review of available information on dietary nutrient intakes and their comparison with reference nutrient intakes (RNIs) to identify problematic nutrients for which reference intakes often are not achieved in this age group.

During the first 3 years of life, children have high requirements of both macro and micronutrients to support their fast growth and development of organs, including the brain. The World Health Organization (WHO) recommends, as a global public health recommendation, that infants be exclusively breastfed for the first 6 months of life to achieve optimal growth, development and health, based on a systematic review that was published in 2001 and updated in 2009 [1]. WHO advises the continuation of partial breastfeeding during the second half of infancy and for up to 2 years of age or beyond, along with the provision of nutritionally adequate and safe complementary foods [2]. Locally produced foods should be used whenever feasible. The age of 12–36 months is a period of transition from breastfeeding combined with complementary feeding to consuming a variety of regular family foods, with a greater risk of inadequate nutrient supply as compared to the age of full breastfeeding or older ages. Young children around the world, particularly those in developing countries as well as those in disadvantaged groups in all countries, are prone to developing nutrient deficiencies and growth faltering due to

inadequate amounts and/or poor quality of complementary feeding and family foods, often aggravated by high infection rates.

In the early 1990s, various agencies, particularly the UN agencies and national governments, aimed at harmonizing their efforts in improving child nutrition. Victora et al. [3] used data from the Demographic and Health Survey from 54 low to middle income countries to examine the patterns of growth faltering in various geographical regions of the world. In both Africa and Southeast Asia, faltering in weight and height was observed from approximately 6 months of age onwards and continued through 24 months. Declines in height or length were more drastic than in weight, and the degree of faltering in these 2 regions was worse than in other regions of the world.

Improvements regarding the prevalence of all forms of undernutrition (i.e. stunting, wasting and underweight) have been reached [4]. Although the global target of reducing stunting in young children may not be fully met by 2025, a significant reduction has been reached in various countries. Meanwhile, the rapid rise in prevalence of childhood overweight and obesity worldwide has resulted in a dual burden of malnutrition in several countries dealing with high rates of both under and overnutrition. Micronutrient deficiencies of public health importance, such as vitamin A, iron and iodine deficiencies, remain a major challenge. While iron deficiency (ID) was the main cause of anemia in Europe, it contributed to a smaller percentage of anemia in Asia and Africa. While 63% of young child anemia in Europe was corrected by iron supplementation, only 34% was corrected in Africa and even less (18%) in Southeast Asia [4]. Hence, iron interventions alone will not completely eradicate anemia in these 2 regions where the problem of anemia has been more severe relative to other regions of the world. Other than the 3 micronutrient deficiencies mentioned above, deficiencies in zinc, folate, vitamin B12 and, recently, vitamin D have emerged as potential public health concerns.

When children do not achieve adequate nutrient intake from eating normal foods, fortified foods and nutrient supplements including formula products should be considered to complement locally available foods for satisfying nutritional requirements [5].

Formula products for children aged 1–3 years have been marketed and used in many countries for about 2 decades [6]. Information on nutrient contents in 244 FUF-YC marketed in the European Union has been published [7]. In 1987, the Codex Alimentarius Commission adopted a standard for follow-up formula (FUF) for in-

fants from the 6th month and for young children [8], which is currently under review [9]. However, there are no internationally agreed definitions and compositional requirements for FUF-YC. Such products have been called 'growing up milks', 'growing up formulas' or 'toddlers' milk'. We propose not using the term 'growing up' in the name of products or the product category because no specific effect on growth has been shown. Also, we favor not using the term 'milk' because such formulas are not necessarily based on animal milk but may also be based on plant protein sources. Therefore, the term 'follow-up formula for young children' (FUF-YC) is preferred.

In 2013, the European Food Safety Authority (EFSA) concluded that FUF-YC is one of several means to increase intakes of critical nutrients in young children wherever inadequate intakes are common, along with the possible contribution from other sources, such as fortified cow's milk, fortified cereals and cereal-based foods, supplements or the regular consumption of meat and fish [10]. This expert group supports the conclusion that FUF-YC does not have a unique role in providing critical nutrients to young children, and it therefore cannot be considered an irreplaceable necessity to satisfy the nutritional requirements of young children. However, this expert group agrees that FUF-YC with an appropriate composition under appropriate conditions of use can provide a major and valuable contribution toward improving the supply of critical nutrients, overall nutritional status and hence help to support child health. In this context, we provide, here, the recommendations for the appropriate composition of FUF-YC.

Recommendations on the composition of fortified foods are based on data on nutrient intakes and on nutritional needs of the target population. In 2013, EFSA published an evaluation of the nutrient requirements and the dietary intakes of infants and young children in the European Union, to inform their review of infant formula and FUF for ages of 0–36 months. Although the EFSA review identifies key nutrients which are either inadequate or excessive throughout Europe, there are only limited data on nutrient intakes outside of Europe [10]. Subsequently, EFSA released a scientific opinion on the compositional requirements of infant formula and of FUF for infants aged 6–12 months [11]. A recommendation with a global perspective on the compositional requirements of FUF for use in infancy (6–12 months) was published by an international expert group coordinated by the Early Nutrition Academy (ENA), which also recommended that the compositional requirements of formula products

for young children aged 12–36 months should be further considered [12].

Therefore, the Nutrition Association of Thailand (NAT) under the Patronage of Her Royal Highness Princess Maha Chakri Sirindhorn, in collaboration with the ENA and the Federation of International Societies on Pediatric Gastroenterology, Hepatology and Nutrition (FISPGHAN), agreed to coordinate the development of recommendations on the composition of FUF-YC with a global perspective, based on a review on nutritional requirements and dietary intakes for young children worldwide.

Methods

NAT and ENA coordinated the review and issued a call for qualified experts, which was circulated throughout the FISPGHAN and its member societies in Asia-Pacific, Europe, North America and South America. Proposals for experts from Africa, Asia, Asia-Pacific, Europe, North America and South America were submitted to NAT. Experts were then selected from the nominations based on having documented expertise, skills and experience to be able to contribute the required knowledge for the task and its objectives. The participating experts (cf. list of authors) were asked to review and evaluate the results about the detailed literature reviews performed by NAT and to attend an Expert Meeting on the 'Compositional considerations of formula products for young children aged 12–36 months' held in Bangkok on 30 April and 1 May, 2014.

A working group of the NAT (N.C., P.W. and S.C.) performed a review of global data on nutrient intakes of young children aged 12–36 months and on dietary intake. A systematic search of peer-reviewed English language articles in PubMed from 2004 onwards was conducted during February 2014 using the keywords: 'nutrient or dietary or diet' and 'intake' and 'infant or toddler or preschool'. The strategy was followed to perform a systematic literature search for a period of 10 years (2004–2014) and to hand search key references of previously published papers cited in detected publications. The electronic literature search identified 5,020 publications of potential relevance. From 5,020 articles, the working group selected those performed as either national surveys or cross-sectional community-based surveys, that included children aged 12–36 months. Gray literature sources consisting of government reports of national surveys were also included. The nutrient intake data were collected using food records, 24-hour food recalls and/or food frequency questionnaires, and then converted into nutrient intakes using computerized softwares. After the screening of titles, abstracts and full texts, 23 publications from 19 countries were included in the review.

The expert group reviewed the dietary intake reference values for young children aged 12–36 months and decided that the WHO/FAO reports on protein, energy and most vitamin and mineral RNI values [13–16] were the most appropriate references for assessing the adequacy of dietary intakes for the current project. An exception was made for vitamin D which was based on the average

given by the US Institute of Medicine of the National Academies (IOM; 15 µg/day) and by the WHO/FAO RNI (5 µg/day) values.

Taking into consideration the data on nutritional status and dietary intakes, the expert group identified those nutrients that are most often limited in the diets of children aged 12–36 months. Recommendations for the composition of FUF-YC were based on the assumption that these products should provide approximately 15% of a child's energy requirement. Minimum values for micronutrients were established for those nutrients that were identified as problematic.

Nutrient Intakes and Status of Young Children Aged 12–36 Months

Data on nutrient intakes and biochemical status in young children aged 12–36 months from 19 countries were reviewed by the expert group [17–41]. They are obtained from both national surveys and cross-sectional community-based surveys in Asia (Bangladesh, India, Indonesia, Malaysia, People's Republic of China, Philippines, Thailand and Vietnam), Australia, New Zealand, Europe (France, Ireland and Norway), Africa (Cameroon and South Africa), North America (Canada, Mexico and USA) and South America (Brazil). Reports that included the amount of nutrient intakes in the population of interest were found in 17 countries (mentioned above except Cameroon and South Africa). Nutrients in those reports include carbohydrate, fat, protein, calcium, iron, zinc, vitamins A, B1, B2, B12, C, D, E and folate. Data on energy intake were available from all 17 countries. However, data were not always available for all nutrients or for the specific 12–36 month age group in all surveys. For example, a report from China showed energy intakes of children aged 12–36 months, while another from Norway reported energy intakes of infants and children aged 0–24 months. Table 1 lists daily energy and nutrient intakes of young children aged 12–36 months by countries.

According to the available data, young children in Bangladesh, China, India and Philippines had a reported mean energy intake of <800 kcal/day, which is lower than the FAO/WHO/UNU energy intake recommendation of 950–1,125 kcal/day for boys and 850–1,050 kcal/day for girls aged 1–3 years, respectively. Young children in most countries had protein intakes clearly exceeding the recommended intakes, except for Bangladesh where protein intakes were just close to recommendations. In contrast, average daily micronutrient intakes were often much lower than the WHO/FAO RNIs. Among the national surveys in children aged 12–36 months, micronutrient intakes and assessment of adequacy were reported using

different criteria. Hence, the magnitude of inadequacy cannot be directly compared across surveys. Further details are provided for those nutrients which could be considered problematic as a result of a large discrepancy between reported intakes and the WHO/FAO RNIs, high prevalence of inadequate intakes or biochemical insufficiency.

Vitamin A

Vitamin A intakes of young children in Brazil, Mexico, the Philippines and some subgroups of the population in Indonesia were much lower than the WHO/FAO RNIs.

Vitamin A inadequacy was reported in 6.8% of young children aged 16–24 months in Australia using estimated average requirement (EAR; 210 µg retinol equivalent (RE)) as the reference [27], in 81.5% of those in India according to intake below 50% of RNI (400 µg RE) [19] and in 50% of children aged 1–9 years in South Africa concerning the intake less than two-thirds of the RNI (300 µg RE for 1–3 years, 400 µg RE for 4–8 years and 600 µg RE for 9–13 years) [40]. In addition, 44 and 60% of children aged 0.5–1.9 and 2–4.9 years, respectively, in Vietnam, had vitamin A intake below the local dietary requirement (400 µg/day) [25]. Similarly, >50% of Thai children (in all studied age groups, 0.5–12.9 years) had low vitamin A intake [24]. In Mexico, vitamin A inadequacy, based on an EAR of 210 µg RE, was found in 37.6, 30.5 and 26.7% of children aged 1, 2 and 3 years, respectively [36]. Using serum retinol concentration for the assessment of vitamin A status, 1.5, 9 and 15.2% of children in Indonesia [20], New Zealand [29] and Philippines [23], respectively, were found to have insufficient vitamin A (serum or plasma retinol <0.7 µmol/l or <20 µg/dl).

Vitamin B1

Vitamin B1 intakes of young children aged 12–24 months in Brazil [38] and the Philippines [23] were lower than the WHO/FAO RNIs while those of children from Australia, Canada, France, Ireland, Vietnam and the USA were adequate. Since the problem was limited to only 2 countries, it was not deemed to be of global concern.

Vitamin D

Using serum 25-hydroxyvitamin D concentration to define status, vitamin D deficiency (serum 25-hydroxyvitamin D <27.5 nmol/l or <50 nmol/l) was found in 10% of children aged 6–23 months in New Zealand [42], and in 34.9 and 42.8% of children aged 2–4.9 years in urban and rural areas of Indonesia, respectively [20]. Nutrient intake data from Brazil found that 92–94% of children

Table 1. (continued)

Nutrient	WHO reference values	Asia				Europe				North America			Brazil [38, 39]						
		Bangladesh [17]	India [18, 19]	Indonesia [20]	Malaysia [21]	China [22]	Philippines [23]	Thailand [24]	Vietnam [25]	Australia [26, 27]	New Zealand [28, 29]	France [30]		Ireland [31]	Norway [32-34]	Canada [35]	Mexico [36]	USA [37]	
Vitamin A, µg	400	-	468 (9-36 mo)	471±19 (urban; 6-23 mo)	844.4±25.9 (urban)	-	269.1 (1y)	582±11.3 (urban)	477±26 (6-23 mo)	464±10 (16-24 mo)	-	392±121 ^c (476±35 ^d)	759 ^d (969 ^d)	-	530±12	310.7	684±10.6 (12-23 mo)	320 (12-24 mo)	1,006.1; 678.3 (2-3 y, public school; private school)
Vitamin B1, mg	0.5	-	0.5 (rural)	463±12 (rural; 6-23 mo)	883.1±29 (rural)	-	0.41 (1y)	0.6±0 (6-23 mo)	0.89±0.02 (16-24 mo)	0.89±0.02 (16-24 mo)	-	0.76±0.03 ^c (0.89±0.04 ^d)	1	1.21±0.02	-	1.1±0.01 (12-23 mo)	0.4 (12-24 mo)	1.6; 1.3 (2-3 y, public school; private school)	
Vitamin B2, mg	0.5	-	0.3 (rural)	273±10 (rural; 24-59 mo)	-	-	0.68 (1y)	0.8±0 (24-59 mo)	1.7±0.04 (16-24 mo)	1.7±0.04 (16-24 mo)	-	1.48±0.07 ^c (1.44±0.05 ^d)	1.9 ^e (1.7 ^d)	1.82±0.03	-	1.8±0.02 (12-23 mo)	0.95 (12-24 mo)	1.8; 1.6 (2-3 y, public school; private school)	
Vitamin B12, µg	0.9	-	-	-	-	-	-	-	-	-	-	3.24±0.51 ^c (2.58±0.23 ^d)	5.4 ^e (3.6 ^d)	3.4±0.1 (2 y)	3.1	4.4±0.06 (12-23 mo)	-	6±0.1 (24-47 mo)	
Folate, µg	150	-	55.5±40.4	42±2 (urban; 6-23 mo)	89±2.6 (urban)	-	25.8 (1y)	52.2±2.7 (urban)	37±2 (6-23 mo)	371.6 (boys 24-36 mo)	-	-	174 ^c (169 ^d)	87 (2 y)	283±6	125.1	352±4.8 (12-23 mo)	-	543±7.2 (24-47 mo)
Vitamin C, mg	30	-	36 (9-36 mo)	34±1 (rural; 6-23 mo)	94.1±3 (rural)	-	21.6 (2y)	41.4±2.7 (rural)	41±2 (24-59 mo)	85±3 (16-24 mo)	59 (boys 12-24 mo)	52±3.7 ^c (82±4.1 ^d)	58 ^c (118 ^d)	135±3	47.9	73±1.5 (12-23 mo)	24 (12-24 mo)	258.9; 475.2 (2-3 y, public school; private school)	

Table 1. (continued)

Nutrient	WHO reference values	Asia					Europe			North America		Brazil [38, 39]						
		Bangladesh [17]	India [18, 19]	Indonesia [20]	Malaysia [21]	China [22]	Philippines [23]	Thailand [24]	Vietnam [25]	Australia [26, 27]	New Zealand [28, 29]		France [30]	Ireland [31]	Norway [32-34]	Canada [35]	Mexico [36]	USA [37]
Calcium, mg	500	-	339 (9-36 mo)	506±29 (urban; 6-23 mo) 330±13 (rural); 429±32 (urban; 24-59 mo) 255±13 (rural); 24-59 mo)	694.5±19.8 (urban) 714.2±23.6 (rural)	-	430 (1y) 350 (2y) 300 (3y)	593±8.6 (urban) 541±8.7 (rural) (6-36 mo)	-	775±14 (16-24 mo) 829.8 (boys 12-24 mo) 780.2 (girls 12-24 mo)	687 (boys 12-24 mo)	800±36 ^c 755±19 ^d	996 ^c 902 ^d	732.5±306.4 (2 y)	1,051±18	769.8	892±8.5 (12-23 mo) 821.6; 762.2 (2-3 y; public school; private school)	559 (12-24 mo)
Iron, mg	5.8	-	5 (9-36 mo)	7.0±0.5 (urban; 6-23 mo) 4.7±0.3 (rural); 6-23 mo) 6.8±0.4 (urban; 24-59 mo) 4.9±0.3 (rural); 24-59 mo)	11.8±0.3 (urban) 13±0.3 (rural)	-	4.6 (1y) 5.1 (2y) 5.5 (3y)	8.4±0.2 (urban) 7.3±0.2 (rural) (6-36 mo)	4.8±0.2 (6-23 mo) 6.3±0.2 (24-59 mo)	5.8±0.23 (16-24 mo) 8.3 (boys 12-24 mo) 24-36 mo) 7.8 (girls 12-24 mo)	4.4 (boys 12-24 mo) 4.8 (girls 12-24 mo)	5.19±0.25^c 9.37±0.31^d	5.9 ^c 10.4 ^d	7±2.7 (2 y)	9.7±0.2	6.2	10.3±0.13 (12-23 mo) 13.5; 12.9 (2-3 y; public school; private school)	2.8 (12-24 mo) 12.9±0.17 (2-3 y; public school; private school)
Zinc, mg	4.1	-	-	-	-	-	-	4.5±0.1 (urban) 4.1±0.1 (rural) (6-36 mo)	-	5.2±0.12 (16-24 mo) 8 (boys 24-36 mo) 7.6 (girls 24-36 mo)	-	4.58±0.28 ^c 6.35±0.42 ^d	5.1 ^c 7.3 ^d	-	7.4±0.1	4.9	7.2±0.07 (12-23 mo) 9.8; 9.3 (2-3 y; public school; private school)	4.7 (12-24 mo)

The bold cells indicate nutrient intakes which are lower than the WHO reference values; italic numbers express median. mo = months; y = years.

* The conversion factor for energy unit is: 1 kJ = 0.239 kcal.

^a Data from national surveys using a dietary record. ^b Children aged 24-35 months. ^c Children aged 12-24 months consuming cow's milk. ^d Children aged 12-24 months consuming growing-up milk.

aged 2–3 years had inadequate intakes of vitamin D (EAR of 10 µg) [39]. In a survey from France, all children consuming milk and milk-based products had dietary vitamin D intake below RNI (10 µg/day) while 75% of those consuming growing-up milk had dietary vitamin D intake below RNI [30]. In Ireland, a vitamin D intake below EAR (10 µg/day) was reported in 98% of children consuming milk and milk-based products and in 69% of those consuming growing-up milk [31]. It must be recognized that not many foods contain vitamin D, and the food composition database may be incomplete.

Recent surveys in young children from 4 countries in Southeast Asia also showed that vitamin D insufficiency may be a problem in tropical countries [20, 24], in addition to countries that are at higher latitudes such as North America [43, 44] and Europe [10].

Vitamin B12

Vitamin B12 deficiency has been reported in those subgroups of the populations with low intake of foods from animal sources due to unavailability or cultural or religious beliefs [45]. Prevalence of vitamin B12 deficiency was approximately 6–9% in Mexican children aged 1–3 years from the National Health and Nutrition Survey in 2006 [46]. According to a cross-sectional survey in 1997, no Norwegian children aged 2 years had cobalamin intake below RNI (Norwegian RNI of 0.8 µg or WHO RNI of 0.9 µg) [34].

Folate

Approximately, 40% of Indian children aged 1–3 years had an inadequate folate intake (<50% of RNI which is 80 µg/day). Similarly, 50% of children aged 1–9 years in South Africa had a folate intake less than two-thirds of the RNI (150 µg/day) [40]. In Mexico, food records revealed that 43–58% of children aged 1–3 years had insufficient folate intake [36]. Another study from Mexico showed, by biochemical assessment, that only 0.7–8% of children aged 1–3 years had folate insufficiency [46]. In Norway, folate intake below the recommended level (80 µg/day) was found in 35% of children aged 2 years although only 5.8% of them had low serum folate levels (<10 nmol/l) [34].

Vitamin C

Several reports from Asian countries showed low or inadequate vitamin C intake among young children. Vitamin C intakes in children aged 12–24 months in Brazil [38], in those aged <5 years in the Philippines [23] and in some subgroups of the population in Indonesia [20] were much lower than the WHO/FAO RNIs. In India, 76.9%

of children had vitamin C intake of <50% that of RNI (40 mg/day) [19]. Similarly, 68–74% of children aged 1–3 years, in the Philippines had a vitamin C intake of <80% of the recommended level (recommended energy and nutrient intake (RENI) of 30 mg/day) [23]. Likewise, 71% of Vietnamese children, during their first 2 years, had lower than recommended vitamin C intake (30 mg/day) [25]. In Thailand, over 50% of children aged 0.5–12.9 years had low vitamin C intake [24]. A similar picture was also observed in other geographical regions. In South Africa, 50% of children aged 1–9 years had a vitamin C intake of less than two-thirds of RNI (15 mg/day) [40]. Vitamin C insufficiency was reported in 8–12% of Mexican children aged 1–3 years [36]. In France, 11% of children consuming growing-up milk formula and 49% of those consuming milk and milk-based products but not receiving growing-up formula or FUF had vitamin C intake below RNI (60 mg/day) [30]. Lastly, 13.8% of children aged 16–24 months in Australia had a vitamin C intake below EAR (25 mg/day) [27].

Calcium

In the non-milk-drinking populations, low calcium intake is common. Calcium intakes were lower than RNIs of FAO/WHO for young children in India, Indonesia and Philippines. In the Philippines, 60–80% of children aged 1–3 years had calcium intakes below 80% of RENI (500 mg/day) [23]. In Indonesia, 67 and 78% of boys and girls aged 18–36 months had calcium intake below RNI (500 mg/day), respectively. In contrast, in Australia, only 8.3% of children had calcium intake below EAR (360 mg/day) [27].

Iodine

Low iodine intake (less than EAR of 65 µg/day), based on the 24-hour dietary recall, was reported in 7% of children aged 2–3 years in Australia [26]. In New Zealand, the estimation of mean daily exposure to iodine for a toddler group aged 1–3 years (47–57 µg) was below the RNI of 90 µg [47]. The 4th Thailand Health Examination Survey during 2008–2009 showed that median urinary iodine concentration of children aged 1–3 years was >100 µg/l, which indicated adequate intakes.

Iron

Reports from several countries in Asia showed that iron intake among young children aged 1–3 years were generally low. Low iron intakes were reported among young children in Brazil, France, India, New Zealand, Philippines and Vietnam. In Philippines, iron intake of

<80% the RENI (8 mg/day) was reported in 69–76% of children aged 1–3 years [23]. In Indonesia, 71 and 79% of boys and girls, respectively, aged 2–4.9 years, had an iron intake below RNI (8–10 mg/day) [20]. Over 80% of Vietnamese children aged 6 months to 3 years had low iron intake [25]. In India, 48.9% of children aged 1–3 years had an iron intake of <50% that of the RNI (9 mg/day) [19]. In contrast, only 8.4 and 2.4% of children in the urban and rural areas of Malaysia, respectively, had iron intake below RNI (6 mg/day) [21]. Almost 60% of children aged 12–24 months, consuming cow's milk, in France [30] and Ireland [31], had iron intake below RNI or EAR, respectively. Approximately, 23% of Australian children aged 16–24 months had iron intake below EAR (4 mg/day) [27]. ID (serum ferritin <12 µg/l) and ID anemia were reported in 6.3 and 3.1%, respectively, of children aged 12–24 months in New Zealand. The prevalence of ID and ID anemia were also much more severe in developing countries, for example, 74.3 and 30.8% in children aged 12–24 months in Brazil.

Zinc

Due to limited zinc values in most food composition databases, direct assessment of zinc intake is infrequently available. Among 8 countries who reported their dietary zinc intakes, only children in Thailand had low zinc intakes [24]. Low zinc intake was reported in 56% of French children consuming milk and milk-based products and 33% of those consuming growing-up milk [30]. In Cameroon, 8 and 9% of non-breastfeeding children aged 12–59 months had low zinc intake according to the International Zinc Nutrition Consultative Group EAR of 2 mg/day and the IOM EAR of 2.5 mg/day, respectively [41]. Plasma zinc concentration showed that 82.6% of these children had zinc deficiency (adjusted plasma zinc <65 µg/dl).

Using national food availability and dietary requirement, it was estimated that 17% of the world's population had inadequate zinc intake, with Asia and Africa being the most affected regions [48].

Docosahexaenoic Acid

Compared to the adequate intake of docosahexaenoic acid (DHA) for young children of 100 mg/day as defined by EFSA [10], reported intakes were low. A recent national survey from Australia published in 2013 [49] reported very low DHA intakes in Australian children aged 2–3 years at median value of 3.9 (IQR 0.6–24) mg/day. In the subgroup of children who ate fish, the energy adjusted intakes of DHA were 16-fold higher (median 50, IQR 25–

109 mg/1,000 kcal/day). The median DHA intake value was much lower than the mean intake of 31.2 ± 77.2 mg/day, suggesting a skewed data distribution. Likewise, data from the National Health and Nutrition Examination Survey in 1999–2000 for the US population reported the mean intake of DHA around 20 mg/day in children <6 years of age [50]. The recent FAO report in 2010 [15] set the Adequate Intake (AI) of DHA for infants aged 6–24 months at 10–12 mg/kg/day, based on the supply with human milk, under the assumption that human milk provides half of the daily energy needs after 6 months. The values for children aged 2–4 years were the AI of 100–150 mg/day. There is a paucity of DHA intake data from developing countries. A small survey in China reported the mean (\pm SD) DHA intake of toddlers who were 1–3 years, in Yunnan, at 34 ± 148 mg/day [22], similar to the mean (5th–95th percentile) of 40 (10–80) mg/day for the breastfed toddlers who were 2–3 years from Bangladesh [51]. For those non-breastfed Bangladeshi children, the reported intake in this age group was much lower at 20 (0–30) mg/day. The mean DHA intake of Gambian toddlers was 10 mg/day [52].

In summary, from the limited data available, DHA intake of toddlers who were not breastfed and did not eat fish, in both developed and developing countries, were clearly lower than the AI set by different authorities.

Problematic Nutrients

In summary, the expert group considered the following nutrients to be often limited in the diets of young children, namely vitamins A, D, B12, C and folate and calcium, iodine, iron, zinc and DHA.

The results of this review are in agreement with those of several reviews that have assessed those micronutrients which are limited in the diets of young children across various regions.

In the EFSA review of dietary intakes of young children in Europe, average intakes of alpha-linolenic acid (ALA), DHA, iron, vitamin D and iodine, in some European countries, were low compared to recommended intakes [10]. Dietary intakes of protein, salt and potassium are generally high in young children across Europe. Intakes of dietary fiber in young children are low, although not at levels that were considered to be a concern to the EFSA.

Young children, particularly those in developing countries or disadvantaged groups, are prone to nutrient deficiencies due to inadequate and poor quality

complementary feeding as well as due to infection. In developing countries, the usual problem nutrients are iron and zinc. In children who consume plant-based diets predominantly, the bioavailability of iron and zinc is also lowered. Other nutrients which may be insufficient include the B vitamins (B1, B2, niacin, B6, B12 and folate), vitamins A, C and E and calcium and iodine [53]. Recent reports both by the WHO [5] and the EFSA [10] highlight the need to improve dietary iron supply to older infants and young children and, in some situations, also iodine supply. Neither of the report found issues with reaching protein requirements, but concerns about high intakes were raised.

Proposed Compositional Requirements of FUF-YC Aged 12–36 Months

This expert group considered that the use of adequately composed FUF-YC is one of several options that can contribute to improving nutrient supply to young children up to the age of 3 years, and thus reduce the prevalence of micronutrient deficiencies. The group based its recommendation on the concept that FUF-YC is not the exclusive source of nutrients but will be fed along with appropriate meals and at times also along with partial breastfeeding. FUF-YC should preferably be consumed as a drink from a cup, not by bottle feeding, to promote desirable eating habits. The recommended number of daily servings is 1–2 cups (200–400 ml) providing an average consumption of 300 ml/day or approximately 15% of total energy intake in young children.

The proposed minimum and maximum values of nutrient contents in the formula products are derived from scientific evidence on nutritional requirement and safety in young children. This expert group recognizes the variation of nutrient requirements, dietary intakes and the nutritional status of population groups in different geographical areas. Also, micronutrient supplementation programs vary among different countries and should be considered in setting values for prevention of excessive nutrient intakes. Therefore, the desirable levels of nutrients in FUF-YC may differ to some extent among countries. However, nutrient contents per 100 kcal for FUF-YC that are generally considered adequate are presented in table 2.

Energy Density

After preparing the FUF-YC according to the manufacturer instruction, it shall contain not <45 kcal (190 kJ) and not >70 kcal (295 kJ) of energy per 100 ml. The min-

Table 2. Proposed compositional requirements of FUF-YC aged 12–36 months

Component	Minimum	Maximum	GUL
Energy, kcal/100 ml	45	70	
Proteins, g/100 kcal			
Cow's milk protein	1.6	2.7	
Soy protein isolate	2	2.7	
Lipids			
Total fat, g/100 kcal	4.4	6	
LA, mg/100 kcal	500	NS	
ALA, mg/100 kcal	50	NS	
Trans-fatty acids, % of fat	NS	2	
DHA ¹ , % of fat	0.3	NS	
Carbohydrates, g/100 kcal			
Total carbohydrates	9	14	
Vitamins			
Vitamin A ² , µg RE/100 kcal	60		180
Vitamin D, µg/100 kcal	1.5		4.5
Vitamin B12, µg/100 kcal	0.15		0.75
Folic acid, µg/100 kcal	20		100
Vitamin C, mg/100 kcal	4.5		22.5
Minerals and trace elements			
Iron ³ (formula based on cow's milk protein), mg/100 kcal	1		3
Iron (formula based on soy protein isolates), mg/100 kcal	NS		NS
Calcium, mg/100 kcal	200		NS
Sodium, mg/100 kcal	25		75
Iodine, µg/100 kcal	12		36
Zinc, mg/100 kcal	0.6		1.8

NS = Not specified.

¹ The addition of DHA is optional.

² 1 µg RE = 1 µg all-trans retinol = 3.33 IU vitamin A. Retinol contents shall be provided by preformed retinol, while any contents of carotenoids should not be included in the calculation and declaration of vitamin A activity.

³ The bioavailability is approximately 10%.

imum energy density is similar to fat-reduced cow's milk (1.6 g of fat/100 ml) which is about 45 kcal/100 ml. This energy density is appropriate in populations with a generally sufficient energy supply and a significant risk of excessive weight gain and development of obesity. The maximum value is close to the energy content of breast milk, which is about 65 kcal/100 ml, and which is also the energy content that should be approached in populations of young children with a high prevalence of early childhood growth faltering.

Protein

The safe level of protein intake for children who are 1–3 years as established by the WHO/FAO is about 11–13 g/day, which is close to the recommendations of the IOM, the EFSA, and the National Health and Medical Re-

search Council of Australia. Excess protein intakes during infancy and early childhood may enhance weight gain and later risk of obesity [54–56]. High protein intakes that exceed the metabolic requirements can induce higher levels of insulin and insulin-like growth factor-1 (IGF-1), and it can also alter the concentrations of IGF-binding proteins. A high protein supply also increases renal molar solute load and water loss which can increase risk of dehydration when fluid intake is insufficient. A double-blind, randomized clinical trial conducted by the European Childhood Obesity Trial Study Group found that feeding infant formula and FUF with a lower protein content during the first year of life induces a marked health benefit in reducing BMI and obesity risk at school age, as compared to conventional formula with high protein contents [55]. A systematic literature review assessing the health effects of protein intake in infancy and childhood in a Nordic setting revealed that a protein intake between 15 and 20% of energy intake in early childhood is associated with an increased risk of overweight later in life [56].

The EFSA proposed that the minimum protein content in infant formula and FUF should be 1.8 g/100 kcal for cow's and goat's milk-based formula. This proposal is based on previous studies regarding the adequacy of infant formula containing about 1.8 g protein/100 kcal, but did not take into account the lower protein requirements according to the growing-up age at which FUF is consumed, as compared to early infancy. Given that the review generally identified high protein intakes in young children, and the safe level of intake for protein established by the WHO/FAO/UNU for infants aged 12 months (1.14 g/kg/day) is approximately 6% of their energy requirement, the expert group proposes that the minimum protein content in the formula products for children aged 12–36 months should be 1.6 g/100 kcal, which is around 6% of energy. The maximum level should be 2.7 g/100 kcal, which is around 10% of energy.

Plant proteins generally have lower amino acid scores and are less digestible than animal proteins. Therefore, when protein sources of FUF-YC are plant proteins, such as soy protein isolate, the minimum protein content has been set at 1.25 times the minimum of cow's milk-based formula, equivalent to 2 g/100 kcal, while the maximum value is set at the same level, that is, 2.7 g/100 kcal [12].

For protein sources other than cow's milk and soy protein isolate, the approximate minimum and maximum values should be determined based on scientific evidence, preferably from randomized controlled clinical trials.

The expert group did not provide values for hydrolyzed protein because there is no evidence to support the use of hydrolyzed protein for allergy prevention in early childhood.

Fat

The recommended total fat content is 4.4–6.0 g/100 kcal, which is equivalent to about 40–55% of energy, similar to that in breast milk. FUF-YC should contain essential fatty acids (EFA), that is, linoleic acid (LA, 18:2, n-6) and alpha-linolenic acid (ALA, 18:3, n-3), since dietary EFA intakes are often lower than the recommended level in young children [10]. The minimum values for LA and ALA are 500 and 50 mg/100 kcal, respectively, which is similar to those proposed for formulas used in infancy by the EFSA [11]. The addition of DHA as an optional ingredient should be permitted, since there are indications of potential benefits of a supply of preformed DHA and intakes are often low in young children [10]. If added, the proposed minimum content of DHA is 15 mg/100 kcal, equivalent to 0.3% of total fat, based on the proportion of DHA in human milk which is 0.2–0.5% (weight percentage) of total fatty acids [11]. Since the FUF-YC is supposed to provide only 15% of the nutritional requirement (around 200 kcal/day), the toddlers in this age group can and should be encouraged to receive DHA from other food sources. Moreover, they are able to synthesize DHA from its precursor ALA more effectively than those of the younger age or those born preterm. For the same reason, the DHA:AA ratio is not defined since the variation in the DHA and AA intake is dependent on other food sources rather than the FUF-YC alone. The content of trans-fatty acids should be <2% that of the total fatty acids, given the potential adverse effects of trans-fatty acids [57, 58].

Carbohydrates

The minimum and maximum values of carbohydrates in the formula products are calculated based on residual energy after the subtraction of minimum and maximum energy from protein and fat contents. The proposed minimum carbohydrate content is 9 g/100 kcal (36% of energy) while the maximum value is 14 g/100 kcal (56% of energy).

The main source of carbohydrates should be lactose, which should provide not <50% of total carbohydrates, equivalent to 4.5 g/100 kcal. For formula with protein from plant source, lactose is not required.

The expert group agreed that there is no need to add sugars other than lactose for nutritional reasons. If addition of sugar is deemed necessary to achieve palatability,

the content of sugars other than lactose should not exceed 10% of total carbohydrates or approximately 5% of total energy content, which is similar to the WHO guideline on added sugar intake for the general population [59].

Other carbohydrates may be added provided that the maximum carbohydrate content is not exceeded. Oligosaccharides, glucose polymers, maltodextrin and pre-cooked or gelatinized starches can be added to provide energy. Non-digestible carbohydrates and fibers that are proven to be suitable for age and safe may be added.

Micronutrients

Recent national or community-based nutritional surveys of young children found insufficient intakes of many micronutrients in the subgroups of population, both at the country and global level. Problematic vitamins include vitamins A, D, B12, C and folate. The problematic minerals and trace elements include calcium, iodine, iron and zinc. Therefore, the expert group considered it important that minimum contents of these vitamins and minerals should be established for FUF-YC.

The expert group proposes that, except for calcium, the minimum values for 100 kcal are 15% of the RNI established by the WHO/FAO. The upper values are not based on hard evidence, but on a precautionary principle approach, and thus should be considered as guidance upper levels (GULs). The expert group proposes that a GUL should be set at 3–5 times that established as the minimum level. For those nutrients with high upper tolerable intake levels (ULs) set by the WHO, such as vitamins C and B group, the maximum levels should be 75%, and for those nutrients with low UL, such as iron and others, the maximum levels should be 45% of RNI values. In any case, the maximum nutrient levels should not exceed UL for this age group. Other micronutrients may be added in a certain proportion of RNIs based on evidences of insufficient diet and safety.

Calcium

Milk and dairy products are good sources of bioavailable calcium in young children. Based on the rationale that drinking an average 300 ml/day of the formula products with the same energy density as whole cow's milk will provide at least a similar amount of calcium as the latter, the proposed minimum value for calcium content is 200 mg/100 kcal. This value is equivalent to about 40% of the recommended intake established by the WHO/FAO (500 mg/day). The maximum value is not established.

Non-Nutrient Components

Other non-nutrient components such as probiotics and prebiotics may be added based on documented benefits, efficacy and safety. To promote appropriate feeding habits and behavior, artificial flavors should preferably not be added.

Other Aspects

While the proposed compositional requirements of FUF-YC are based on current scientific information, progress in scientific understanding and food technology may require modification of these conclusions over time. While this expert group considers the use of nutrient fortified products such as FUF-YC beneficial for improving nutritional status, this should not replace the active promotion of appropriate dietary and eating habits of young children including the protection, promotion and support of breastfeeding and appropriate complementary foods.

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U.S. has had scientific and educational collaborations with Nestlé Nutrition, Mead Johnson Nutrition and Dumex. P.O.A. received an honorarium for chairing a scientific session from Wyeth Nutrition. S.C. has had scientific and educational collaborations with Nestlé Nutrition and Mead Johnson Nutrition. N.C. has had scientific and educational collaborations with Nestlé Nutrition, Mead Johnson Nutrition and Dumex. S.C. has had scientific and educational collaborations with Biocodex, Danone, Nestlé Nutrition and Pfizer Nutrition. P.S.W.D.'s research group (The Children's Nutrition Research Centre) has received support from Nestlé Nutrition, Bayer, Nutricia, Pfizer Nutrition, Aspen, Danone Nutrition, Abbott Nutrition and the Infant Nutrition Council. J.B.G. received research grants and speaker fees from various formula companies. He is actively supporting breastfeeding and is a member of the National Breastfeeding Council and the National Nutrition Council in the Netherlands. E.R.N. received a publica-

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