Original Article

Composition requirements of follow-up formula for 6–12-month-old infants: recommendations of a Chinese expert group

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Background and Objectives: The Chinese national standard of formula for 6–12-month-old infants (GB 10767-2010) requires review and revision because it does not correspond to current scientific knowledge and data. The aim of this paper was to summarize the formula composition recommended for 6–12-month-old infants by a Chinese expert group. **Methods and Study Design:** Formula composition recommendations for 6–12-month-old infants were devised by a Chinese expert group based on a detailed systematic review, which included nutrient intake, nutrient content of Chinese women's breast milk, and the latest adequate intake and tolerable upper intake levels, also referencing the Codex Alimentarius recommendations and those of other countries and considering the practice in products on the market. **Results:** Compared with current standards, it was recommended that most compositional requirements be modified, including decreasing the maximum energy density from 85 to 75 kcal/100 mL, decreasing the protein content in milk-based formula from 2.9–5.0 g/100 kcal to 1.8 – 3.5 g/100 kcal, increasing the minimum content of lipids from 2.9 g/100 kcal to 3.5 g/100 kcal, providing the maximum amount of vitamins and minerals (including vitamin E, vitamin K, thiamin, riboflavin, vitamin B_6, vitamin B_{12}, niacin, folic acid, pantothenic acid, vitamin C, biotin, magnesium, calcium, phosphorus, and iodine), and changing the content of optional components such as taurine, docosahexaenoic acid, and arachidonic acid. **Conclusions:** These nutrient standard modifications based on recent evidence are expected to enhance feeding practices and further guarantee the health of 6–12-month-old infants in China.

Key Words: formula, 6–12-month-old infant, Chinese national standard, nutrition, composition

INTRODUCTION

Breast milk is the best source of various nutrients for infants. Based on a systematic review published in 2001 and further updated in 2009, the World Health Organization (WHO) has issued a global public health recommendation that infants be exclusively breastfed for the first 6 months of life to achieve optimal growth, development, and health.[1] WHO also advocates partial breastfeeding during the second half of infancy, up to 2 years of age or beyond, along with the provision of safe and nutritionally adequate complementary foods.[2]

The Chinese government strongly advocates breastfeeding but acknowledges that formulas are an option for infants and young children when breast milk is insufficient or unavailable. However, the Chinese government does not promote formulas as the main food source for infants. The period of 6–12 months old is when infants start transitioning from exclusive breastfeeding to a combination of breastfeeding and complementary nutrition, where breast milk or follow-up formula (FUF) remains an essential source of nutrients for them.[3]

The Codex Committee on Nutrition and Food for Special Dietary Uses (CCNFSDU) has made great progress in revising its standard for FUF (Codex Stan156-1987).[4] Similarly, the European Commission has issued a new regulation on infant formulae and follow-on formulae[(EU) 2016/127],[5] replacing Commission Directive 2006/141/EC. Other countries are currently revising their national FUFstandards.[6,7]

At the CCNFSDU meeting, representatives of various countries and organizations discussed the nutritional necessity of FUF as complementary nutrition introduced after 6 months of age. The committee concluded that FUF

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Manuscript received 22 July 2018. Initial review completed 14 August 2018. Revision accepted 03 January 2019.
doi: 10.6133/apjcn.201906_28(2).0017

is already on the market, requiring a regulatory framework to ensure product safety and quality; that is, a standard was necessary. China supported this conclusion of the CCNFSDU.

The current standard in China is the National Food Safety Standard – Formula for Older Infants and Young Children (GB 10767-010),issued in 2010 and referring to the previous Codex standard and an earlier edition of the Chinese Dietary Reference Intake(Chinese DRI) from 2000.[8] The Chinese Nutrition Society revised the Chinese DRI in 2013,[9] and additional data on the nutrient content of breast milk and the nutritional status of infants and children in the Chinese population has also been published. Therefore, the current standard requires revision to further ensure the nutrition and health of Chinese infants.

In 2016, the National Health and Family Planning Commission of China announced the revision of the aforementioned standard,[10] and the China National Center for Food Safety Risk Assessment established a working group and an expert group to undertake the tasks of reviewing and revising this standard. The current standard for older infants and young children is divided into two separate parts, namely, one for 6–12-month-old infants and the other for young children 12–36-months old.

The aim of this paper is to present proposals for the composition of formula for 6–12-month-old infants. These proposals were developed by the work group following a general review of the information available in China on breast milk content and dietary nutrient intakes and comparison with the recommended nutrient intake (RNI) and then submitted to the expert group for discussion and approval.

METHODS

Literature search and selection

A system analysis framework was established for search and selection of the literature on each nutrient. The literature search on components of Chinese women's breast milk, infant nutrient intake, China's latest RNI and adequate intake (AI), and current nutrient levels in the standards or regulations of various countries were conducted using both English and Chinese databases. Information on energy and each nutrient, including proteins, lipids and fatty acids, carbohydrates, lactose, vitamins, and minerals, for 6–12-month-old infants were extracted from the relevant sources.

Information analysis

Information on each nutrient was collected and tabulated according to the following template:

1. Minimum and maximum amount allowed by the current national standard (GB 10767-2010);
2. Concentration of each nutrient in breast milk;
3. RNI or AI and upper intake level (UL) values of each nutrient for 6–12-month-old infants, based on the 2013 Chinese DRI;
4. Actual intake of each nutrient for 6–12-month-old infants;
5. Prevalence of deficient or excessive intake of individual nutrients in 6–12-month-old infants in China;
6. Minimum and maximum amount of each nutrient allowed by the standards or regulations of international organizations and other countries, including the Codex Alimentarius Commission, the United States, the EU, Australia, and New Zealand, with the focus on current standards and up-to-date data for older infants;
7. Actual content and distribution of each nutrient in products found on the Chinese market.

Based on analysis of these data, the working group comprehensively evaluated the rationale for the amount of each nutrient in the current standard and provided suggestions for its revision. These were then discussed and confirmed by the expert group.

RESULTS

The Chinese Feeding Guidelines for 7–24-month-old infants and young children recommend that infants more than 6 months should still be breastfed while gradually being introduced to a variety of foods. Infants and young children who are not or only insufficiently breastfed should be given formula as a supplement.[3] Therefore, formula represents an indispensable food in the diet of 6–12-month-old infants, and its nutrient content should be similar to that of human breast milk.

Because formula is a substitute for human milk in 0–6-month-old infants, the working group suggested that minimum and maximum levels of nutrients in formula for 6–12-month-old infants should be defined similarly to those of infant formula, but also considering the different AI and UL values in the Chinese DRI (2013)[9] and studies on actual nutrient intake and the health consequences and physiological changes caused by nutrient deficiency or excess. Because no maximum limit is indicated for certain micronutrients in the current standard, the working group also suggested setting a maximum limit for each nutrient contained in it. This recommendation was aimed at further guaranteeing safe formula use in older infants. A general maximum limit of 3–5 times the minimum level was established, based on current products in the Chinese market or limits in other countries.

Cow's milk, goat's milk, and isolated soy protein (ISP) represent safe, suitable protein sources for use in formula. However, ISP is low in sulphur-containing amino acids and contains trypsin inhibitors, lectins, and 1%–2% of inositol hexaphosphate (phytic acid), which decrease the bioavailability of protein, iron, zinc, and phosphorus,[11,12] whose content must therefore be increased in formula derived from ISP.

The following sections describe the main changes for certain nutrients compared with the current standard and indicates the reasons for their revision.

Energy density

Studies have indicated that the energy density in formula was much higher than in human milk. This could increase total energy intake and lead to greater weight gain,[13,14] something which is undesirable in healthy children during their first 2 years because it is associated with increased risk of subsequent obesity and related diseases.[15,16]

The energy density specified in GB 10767-2010 is 60–85 kcal/100 mL.[8] Studies have indicated that the average energy density in breast milk from mature Chinese women is 65 kcal/100 mL.[17] The energy density in commercial formula products for older infants in the Chinese market is in the 63–84 kcal/100 mL range, most ranging from 63 to 70 kcal/100 mL.

To protect the health of older infants, the energy density of FUF for 6–12-month-old infants should be reduced. Taking detection error into account, the newly proposed standard energy density in formula for 6–12-month-old infants is 60–75 kcal/100 mL.

Protein content

Protein is an essential component of the human body, with various physiological functions including immune function, growth and development, nerve transmission, and nutrient transport. Adequate protein intake during the first year of life can ensure healthy growth and development, but excessive intake is discouraged.

Studies have indicated that the protein content in breast milk from mature Chinese women is in the 1.4–1.6 g/100 kcal range.[18–20] The minimum and maximum protein levels in GB 10767-2010 are 2.9 and 5.0 g/100 kcal, respectively, which is much higher than that of human milk. Many studies have demonstrated that artificially fed infants had a higher growth rate than those in the breastfed control group. However, multicenter studies have revealed that higher protein intake in excess of metabolic requirements during the first year of life leads to excessive weight gain, thus increasing the risk of obesity and other associated diseases in adulthood.[21-23]

To avoid the increased risk of subsequent obesity, many countries have begun decreasing the protein content in formula. For example, the protein level allowed for older infants in the Codex standard has been revised from 3.0–5.0 g/100 kcal to 1.8–3.0 g/100 kcal,[4] whereas EU regulations have reduced the protein level for older infants from 1.8–3.5 g/100 kcal to 1.6–2.5 g/100 kcal.[5]

In the Chinese DRI (2013), the protein AI for older infants is 20 g/d.[9] Studies of dietary intake have reported that the protein intake of 6–12-month-old infants in various parts of China have median values of 18.3–24.9 g/d, with intake among urban infants slightly higher than the AI.[24-27]

To protect the health of older infants, the expert group recommended that the protein level in formula for 6–12-month-old infants should be reduced. Given that the protein quality of formula is inferior to that of human milk and also considering the current protein intake of Chinese infants, especially those in rural areas, the expert group proposed a protein level of 1.8–3.5 g/100 kcal in milk-based formula for 6–12-month-old infants. The group stated that such protein intake is suitable for supporting growth in healthy infants, provided they also receive adequate complementary feeding.

Due to the low bioavailability of ISP, the minimum level of protein in soybean-based FUF should be about 1.25 times higher than in milk-based FUF.[11,12] Therefore, the recommended protein level for soybean-based FUF is 2.2–3.5 g/100 kcal.

Protein quality

The current Chinese standard (GB 10767-2010) contains no requirements on protein quality. The expert group recommended that protein quality be improved, given that the recommended protein content in the standard has been reduced. Whey protein is easy for infants to digest and absorb, and it contains many active ingredients. Therefore, it was proposed that whey protein represent 40% of total protein in milk-based formula for 6–12-month-old infants, similar to the percentage in human milk.

Table 1. Recommended content of essential and semiessential amino acids

Amino acid	mg/g N	mg/100 kcal
Cystine †	131	38
Histidine	141	41
Isoleucine	319	92
Leucine	586	169
Lysine	395	114
Methionine †	85	24
Phenylalanine ‡	282	81
Threonine	268	77
Tryptophan	114	33
Tyrosine ‡	259	75
Valine	315	90

†For calculation purposes, the concentration of methionine and cysteine can also be added when their ratio is less than 2:1.
‡For calculation purposes, the concentrations of tyrosine and phenylalanine may be combined.

Essential and semi-essential amino acids may also be added to improve the protein quality of formula. Because no representative data on amino acids in Chinese women's breast milk exists, the experts suggested using the CCNFSDU recommendations.[4] When adding such amino acids to the product, their content should be similar to reference protein and not less than the levels defined in Table 1. The safety and quality of added amino acids should also be ensured.

Lipids

Lipids are key nutrients for development of the brain, nerve tissue, and the retina in infants. A study showed that mothers with a higher fat content in their breast milk tended to have children who were less fat, as indicated by lower BMI and skin fold adiposity.[28]

The average lipid content in mature Chinese women's breast milk is 3.1–3.6 g/100mL, representing approximately 43%–49% of total energy.[18,29-31] The Chinese DRI (2013) recommends that lipid energy should account for 40% of total energy intake in older infants.[9]

In GB10767-2010, lipid content is set at 2.9–5.9 g/100 kcal.[2] Studies on dietary intake have reported that the median lipid energy values in older infants from various parts of China is 22.1%–31.7% of total energy,[26,27,32] which is lower than that recommended by the Chinese DRI (2013).

To improve fat intake in older Chinese infants, it was recommended that the minimum fat level in formula for 6–12-month-old infants be increased. Considering the decreased protein content in the new standard, the newly proposed lipid content was set as 3.5–6.0 g/100 kcal, thus ensuring that lipids provide 32%–54% of energy in these products, which more closely approximates the lipid energy ratio inhuman milk.

Essential fatty acid

In GB10767-2010, the linoleic acid content of FUF is set at 0.29 g/100 kcal–NS (NS: not specified).[8] Studies have indicated that the average linoleic acid level in mature human breast milk is 0.56 g/100 mL (7.7% of total energy).[9] The Chinese DRI (2013) recommends that energy from linoleic acid should account for 6.0% of total energy in older infants.[9] Revision of the minimum amount of linoleic acid is not required.

One study revealed that excessive intake of linoleic acid may induce untoward metabolic effects with regard to lipoprotein metabolism, immune function, eicosanoid balance, and oxidative stress.[33] Therefore, it was necessary to set a maximum level for linoleic acid in the new standard. In the new Codex standard for 6–12-month-old infants, the maximum level of linoleic acid is 1.4 g/100 kcal.[4] Following discussion, the expert group proposed a similar maximum level, namely, 0.3–1.4 g/100 kcal, which ensures that linoleic acid provides 2.6%–12.6% of the total energy in FUF, to support the growth of healthy older infants who receive adequate complementary feeding.

No requirements are given for α-linolenic acid (18:3n-3) in the current standard (GB10767-2010).8 Studies have revealed that α-linolenic acid content in mature human breast milk represents 1.89% of total lipids (0.99% of total energy).[9] The Chinese DRI (2013) recommends that energy from α-linolenic acid should represent 0.66% of total energy in older infants. To meet this recommended amount, the expert group proposed a minimum α-linolenic acid level of 50 μg/100 kcal. Additionally, the ratio of linoleic acid:α-linolenic acid should be 5:1–15:1, whereby α-linolenic acid would provide 0.45%–2.5% of energy in FUF.

Carbohydrates

The current standard (GB10767-2010) contains no requirements for carbohydrates.[8] The calculated carbohydrate content for FUF is 9–14 g/100 kcal, taking into account the newly proposed content of energy, protein and fat.

Lactose is the main carbohydrate in human milk, with small amounts of glucose, galactose, and oligosaccharide also present.[3] Lactose not only provides energy but can also alter the intestinal microbe balance. Studies have indicated that lactose content in human breast milk is about 66.1 g/L and the proportion of lactose in total carbohydrates is over 90%.[18]

The expert group recommended that lactose content should account for more than 90% of the total carbohydrates in milk-based formula for 6–12-month-old infants. Only pre-gelatinized starch may be added to the product, whereas adding sucrose and fructose is not permitted.

Vitamins

Vitamin A

Vitamin A aids several vital functions, including vision, maintenance of epithelial surfaces, immune ability, growth, development, and reproduction. A vitamin A deficiency leads to neonatal growth retardation and negatively affects functions such as vision, immunity, and reproduction, whereas excessive vitamin A intake can have adverse effects such as dry skin, hair loss, and decreasing appetite.[9]

The vitamin A amount specified in GB 10767-2010 is 75–225 μg RE/100 kcal. In the Chinese DRI (2013),[9] the AI for vitamin A in older infants is 350 μg RE/d, and the UL is 600 μg RE/d. However, the estimated vitamin A intake would exceed the UL if the maximum of 225 μg RE/100 kcal in the standard were used. Considering this, the expert group recommended lowering the maximum amount of vitamin A. The 95th percentile of vitamin A value in current commercial formula of Chinese market is 176 μg/100 kcal, the proposed maximum level of vitamin A is 180 μg RE/100 kcal, similar to that of the new Codex standard.[4]

Vitamin D

Vitamin D plays a key role in calcium and phosphate metabolism and bone health. Research has indicated that the serum 1,25-(OH)2-vitamin D3 deficiency rate in 6–12-month-old infants throughout China is 10.64%–36.3%.[34–38]

The vitamin D amount specified in GB 10767-2010 is 1.05–3.14 μg/100 kcal, which is marginally lower compared with that in the Chinese DRI (2013).[9] The expert group therefore proposed that the vitamin D content in formula for 6–12-month-old infants should be increased, with the minimum level at 2.0 μg/100 kcal and the maximum at 5.0 μg/100 kcal.

Vitamin E

The major biological function of vitamin E is its antioxidant activity, which contributes to preventing the propagation of free radicals in various lipid structures within the organism.

The vitamin E amount specified in GB 10767-2010 is 0.63-NSmg α-TE/100 kcal. In human breast milk, the average vitamin E content is 2.5–2.9 mg α-TE/L (0.38–0.45 mg α-TE/100 kcal).39–41 The Chinese DRI (2013) suggests 4 mg α-TE/d as the AI value of vitamin E for 6–12-month-old infants. The median vitamin E intake in such infants in China is 3.95 mg α-TE/d.[26] Therefore, no sufficient evidence exists to prompt revision of the minimum level of vitamin E in FUF.

To avoid excess vitamin E intake in infants, it was proposed that the maximum level be set at 5.0 mg α-TE/100 kcal, similar to the levels recommended by both Codex and EU regulations.

Choline

Choline has a number of essential functions. It is a precursor of phospholipids and platelet-activating factor and involved in lipid metabolism and transport.

In GB 10767-2010, choline is an optional ingredient whose amount is specified as 7.1–50.2 mg/100 kcal. However, considering the vital role of choline, the expert group proposed that choline be treated as an essential nutrient.

The average choline content inhuman breast milk is 160 mg/L, and the Chinese DRI (2013)[9] specifies the choline AI for 6–12-month-old infants as 150 mg/d. Because the current minimum level of choline in the standard is too low to meet the recommended amount for older infants, the newly proposed minimum amount of choline is 20 mg/100kcal and the maximum is 100 mg/100kcal.

Minerals and Trace Elements

Iron

Iron has many functions in the body, such as in oxygen-transporting hemoglobin and myoglobin or in the enzymes of numerous metabolic pathways in the liver, brain, and endocrine organs. Iron deficiency and iron deficiency anaemia can have a serious effect on the health and later development of infants and children, including alteration of immune status, delayed behavioral and mental development.[42-44]

The amount of iron specified in GB 10767-2010 is 1.05–2.09 mg/100 kcal. According to research, no sufficient evidence exists to revise the iron levels in milk-based FUF.

Considering the lower bioavailability of iron in soybean-based formula, it was proposed that the minimum iron level in such FUF be increased to 1.5 times that of milk-based formula.[29] The recommended content of iron in soybean-based FUF is therefore 1.5–2.0 mg/100 kcal.

Zinc

Zinc is involved in many aspects of cell metabolism and plays a role in immune function, protein synthesis, wound healing, DNA synthesis, and cell division.[9]

The zinc level specified in GB 10767-2010 is 0.4–1.3 mg/100 kcal. Studies have indicated that zinc content in Chinese women's breast milk is 1.56–2.78 mg/L (0.24–0.43 mg/100 kcal).[45-54] As the bioavailability of zinc in formula is lower than in human milk, its content should be increased. Some clinical studies have reported a high zinc deficiency rate in older Chinese infants.[55-57] According to the Chinese DRI (2013),[9] the AI of zinc for older infants is 3.5 mg/d. Therefore, the newly proposed minimum zinc level is 0.50 mg/100 kcal and the maximum 1.50 mg/100 kcal.

For soybean-based FUF, the minimum level should similarly be 1.5 times that of milk-based FUF, namely, 0.75–1.50 mg/100 kcal.

Calcium

Calcium is an integral structural component of the skeleton and is necessary for bone rigidity, strength, and elasticity. Calcium deficiency in children leads to inadequate growth and bone deformity, whereas excessive calcium intake can result in hypercalcemia, calcification of blood vessels and soft tissue, and kidney stones.

The minimum calcium level specified in GB 10767-2010 is 71 mg/100 kcal, with no maximum limit defined. In the Chinese DRI (2013),[9] the calcium AI for older infants is 250 mg/d and the UL is 1500 mg/d.

Because a deficiency of serum calcium is associated with insufficient vitamin D intake, the increased vitamin D level in the standard renders it unnecessary to revise the minimum calcium level. To prevent the adverse effects of excessive calcium intake, the newly proposed maximum level of calcium in formula for 6–12-month-old infants is 180 mg/100 kcal.

Optional Ingredients

Docosahexaenoic acid (DHA; 22:6n-3) and arachidonicacid (ARA;20:4 n-6)

DHA and ARA are treated as optional ingredients in the current standard (GB 10767-2010). The amount of DHA permitted is NS–0.5% of total fat; if DHA is added, ARA should also be added in the same amount.

The Chinese DRI (2013)9 specifies an AI for DHA of 100 mg/d in older infants. Studies have indicated that the average DHA amount in Chinese women's breast milk is 0.33% of total fat (17.6 mg/100 kcal).[9] To meet the health requirements of infants, the expert group suggested setting a minimum level for DHA.

Using this AI value and considering the products available in the Chinese market, the experts proposed that the minimum DHA level be set at 15 mg/kcal, thus meeting 75% required amount of older infants. The proposed maximum level is 40 mg/kcal, calculated on the basis of the current standard.

To maintain balance between DHA and AA, the expert group proposed, with reference to the Codex standard,[4] that when adding DHA to formula for 6–12-month-old infants, ARA should be added in at least the same amount. The content of eicosapentaenoic acid (20:5 n-3), which can occur by adding long chain fatty acids, should not exceed the content of DHA.

Taurine

Taurine can promote brain development in infants and also improve nerve conduction and visual function.[58-60]

The taurine content specified in GB10767-2010 is NS–13 mg/100 kcal. To ensure its beneficial properties, it was proposed that a minimum level of taurine in formula for 6–12-month-old infants be defined. In Food Standards Australia New Zealand (FSANZ), the minimum taurine level is 0.8 mg/100KJ (3.5 mg/100 kcal).[7] Although little data on taurine content in Chinese women's breast milk exists, the expert group proposed that the FSANZ value be adopted as the minimum taurine level in the Chinese standard.

Taurine content in products based on goat's milk protein can be as high as 16.7 mg/100 kcal without adding, therefore, it was suggested that this serve as the maximum taurine level in formula for 6–12-month-old infants. The proposed taurine content in the new standard is thus 3.5–16.7 mg/100 kcal.

DISCUSSION

The minimum and maximum levels of all nutrients in the current and proposed standards of formula for 6–12-month-old infants are listed in Table 2. The Chinese government strongly advocates partial breastfeeding during the second half of infancy, up to 2 years of age or beyond, along with the provision of safe and nutritionally adequate complementary foods. When breast milk is insufficient or unavailable, formulas are an option for infants and young children. Comparing to food such as milk, specific formula which contains lower protein, lower minerals and also modified some other nutrients which following the data of breast milk and considering other scientific evidences, can better meet the nutrients requirement of 6–12-month-old infants.

This paper has summarised the available recent scientific data on the nutritional composition requirements of follow-up formula for 6–12-month-old infants, the trend of the modification is following the newest development

Table 2. Proposed composition of formula for 6–12-month-old infants

Component	GB 10767-2010		Proposal	
	Minimum	Maximum	Minimum	Maximum
Energy kcal/100 mL	60	85	60	75
Proteins†				
Milk-based protein, g/100 kcal	2.9	5.0	1.8	3.5
Soybean-based protein, g/100 kcal	—	—	2.2	3.5
Lipids ‡				
Total lipids, g/100 kcal	2.9	5.9	3.5	6.0
linoleic acid, g/100 kcal	—	—	0.3	1.4
α-linolenic acid, mg/100 kcal	—	—	50	N.S.
Ratio linoleic/α-linolenic acids	—	—	5:1	15:1
Carbohydrates §				
Total carbohydrates, g/100 kcal	—	—	9.0	14.0
Vitamins				
Vitamin A¶, μgRE/kcal	75	225	75	180
Vitamin D††, μg/kcal	1.05	3.14	2.0	5.0
Vitamin E‡‡, mgα-TE/kcal	0.63§	N.S.	0.6§§	5.0§§
Vitamin K, μg/kcal	4	N.S.	4.0	27.0
Thiamin, μg/kcal	46	N.S.	60	300
Riboflavin, μg/kcal	46	N.S.	80	500
Vitamin B-6, μg/kcal	46	N.S.	46	175
Vitamin B-12, μg/kcal	0.17	N.S.	0.17	1.50
Niacin§§, μg/kcal	460	N.S.	460	1500
Folic acid, μg/kcal	4	N.S.	10	50
Pantothenic acid, μg/kcal	293	N.S.	400	2000
Vitamin C, mg/kcal	7.5	N.S.	10	70
Biotin, μg/kcal	1.7	N.S.	1.7	10.0
Choline, mg/kcal	7.1	50.2	20	100
Minerals and trace elements				
Sodium, mg/kcal	N.S.	84	N.S.	84
Potassium, mg/kcal	75	289	75	225
Copper, μg/kcal	29	146	35	120
Magnesium, mg/kcal	5.9	N.S.	5.0	15.0
Iron				
Iron (milk-based protein), mg/kcal	1.05	2.09	1.0	2.0
Iron (soybean-based protein), mg/kcal	—	—	1.5	2.0
Zinc				
Zinc (milk-based protein), mg/kcal	0.4	1.3	0.50	1.50
Zinc (soybean-based protein), mg/kcal	—	—	0.75	1.50
Manganese, μg/kcal	1.05	100.4	1.0	100.0
Calcium, mg/kcal	71	N.S.	71	180
Phosphorus				
Phosphorus (milk-based protein), mg/kcal	34.7	N.S.	35	110
Phosphorus (soybean-based protein), mg/kcal	—	—	42	110
Ratio calcium/phosphorus	1.2:1	2:1	1.2:1	2:1
Iodine, μg/kcal	5.9	N.S.	15	59
Chloride, mg/kcal	N.S.	218	N.S.	218
Selenium, μg/kcal	2.05	7.95	2.0	8.0
Optional Components				
Inositol, mg/kcal	4.2	39.7	4	40
Taurine, mg/kcal	N.S.	13	3.5	16.7
L-Carnitine, mg/kcal	1.3	N.S.	1.3	6.3
Docosahexaenoic acid (22:6 n-3), % of fat	0.2	0.5	—	—
Docosahexaenoic acid (22:6 n-3)¶¶, mg/kcal	—	—	15	40
Arachidonic acid (20:4 n-6), % of fat	N.S.	1	—	—
Arachidonic acid (20:4 n-6)¶¶, mg/kcal	—	—	N.S.	80

N.S.: Not specified.
†The protein content in infant formula is calculated as nitrogen (N) × 6.25. Whey protein in milk-based infant formula should not be less than 40% of total protein. If essential and semiessential amino acids are added to FUF, their content should not be less than recommended in Table 1; ‡Lauric and myristic acids are fat constituents, but combined should not exceed 20% of total fatty acids. The content of trans-fatty acids should not exceed 3% of total fatty acids. Trans-fatty acids are endogenous components of milk fat, and acceptance of up to 3% of trans-fatty acids is intended to enable milk fat to be used in infant formula. The erucic acid content should not exceed 1% of total fatty acids; §Lactose should account for at least 90% of total carbohydrates in milk-based products. When calculating the percentage of lactose in total carbohydrates, added oligosaccharides and polysaccharides should not be considered; ¶RE = retinol equivalent; 1 μg of RE = 1 μg of all-trans-retinol. Retinol content should be provided using preformed retinol, and any carotenoid content should not be included in the calculation of vitamin A activity; ††Calciferol; 1 mg of vitamin D = 40 IU of vitamin D; ‡‡1 mg of dα-tocopherol = 1 mg of α-TE (α-tocopherol equivalent); 1 mg of dlα-tocopherol = 0.74 mg of α-TE (α-tocopherol equivalent); §§Niacin refers to preformed niacin; ¶¶If DHA (22:6 n-3) is added to FUF for older infants, ARA (20:4 n-6) should be added in at least the same concentration. The content of eicosapentaenoic acid (20:5 n-3) should not exceed the amount of DHA.

of international standards, and most data is coming from China studies, in order to better meet the need of Chinese babies.

As the compositional standards proposed in this paper are based on current understanding of the available evidence, future scientific data may render it necessary to update them. Modifications of the formula standard or addition of other ingredients should be evaluated with regard to safety and possible benefits, on the basis of scientific data that preferably include clinical trials.

AUTHOR DISCLOSURES

The authors declare no conflict of interest.

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