Young Child Formula: A Position Paper by the ESPGHAN Committee on Nutrition

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ABSTRACT

Young child formulae (YCF) are milk-based drinks or plant protein–based formulae intended to partially satisfy the nutritional requirements of young children ages 1 to 3 years. Although widely available on the market, their composition is, however, not strictly regulated and health effects have not been systematically studied. Therefore, the European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) Committee on Nutrition (CoN) performed a systematic review of the literature to review the composition of YCF and consider their role in the diet of young children. The review revealed limited data but identified that YCF have a highly variable composition, which is in some cases inappropriate with very high protein and carbohydrate content and even high amounts of added sugars. Based on the evidence, ESPGHAN CoN suggests that the nutrient composition of YCF should be similar to that of follow-on formulae with regards to energy and nutrients that may be deficient in the diets of European young children such as iron, vitamin D, and polyunsaturated fatty acids (n-3 PUFAs), whereas the protein content should aim toward the lower end of the permitted range of follow-on formulae if animal protein is used. There are data to show that YCF increase intakes of vitamin D, iron, and n-3 PUFAs. However, these nutrients can also be provided via regular and/or fortified foods or supplements. Therefore, ESPGHAN CoN suggests that based on available evidence there is no necessity for the routine use of YCF in children from 1 to 3 years of life, but they can be used as part of a strategy to increase the intake of iron, vitamin D, and n-3 PUFA and decrease the intake of protein compared with unfortified cow's milk. Follow-on formulae can be used for the same purpose. Other strategies for optimizing nutritional intake include promotion of a healthy varied diet, use of fortified foods, and use of supplements.

Key Words: follow-on formula, growing up milk, toddler's milk, toddlers

(*JPGN* 2018;66: 177–185)

What Is Known

- There is no international legal definition or compositional criteria for young child formula.
- The composition of currently available young child formulas on the European market differs significantly.
- There is overall limited evidence on the health effects of young child formula on the children.

What Is New

- The article presents critical literature review on the role of young child formula for nutrition in European children.
- Based on available evidence European Society for Paediatric Gastroenterology, Hepatology and Nutrition Committee on Nutrition does not recommend routine use of young child formula in children from 1 to 3 years of life. They can, however, be used as part of a strategy to increase the intake of iron, vitamin D, and polyunsaturated fatty acid and decrease the intake of protein compared with unfortified cow's milk.

Toddler's milk, growing up milk, or formula for young children are synonyms referring to milk-based drinks or plant protein–based formulae intended to partially satisfy the nutritional

Received April 5, 2017; accepted October 24, 2017.

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J.B. has received honoraria for lectures and travel support from Nutricia and Nestlé. C.C. received research funding from ORDESA Laboratories, S.A. M.D. received lecture fees from Nestlé and Semper. M.F. received honoria for lectures (Nestlé Nutrition Institute) and editing book on growth (Danone). N.E. received speaker fees and research funding from manufacturers of infant milk formula (Nestle and Danone Baby Nutrition) for studies in preterm infants. A.L. received lecture fees from Nestlé and Mead Johnson Nutrition. The remaining authors report no conflicts of interest.

DOI: 10.1097/MPG.0000000000001821

requirements of young children aged 1 to 3 years (1). The European Food Safety Authority (EFSA) recommends the use of the term ''young child formula'' (YCF) because this age group (young child) is strictly defined as from 1 to 3 years. Furthermore, as YCF may not necessarily contain animal protein it is suggested to use term ''formula'' rather than ''milk.'' The term ''growing-up'' should not be used because it implies a specific impact on growth. In order to unify the terms, the European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) Committee on Nutrition (CoN) also recommends the use of the term YCF.

YCF have been available in Europe for more than 2 decades and their use is increasing (2); however, product information is mainly provided by manufacturers while scientific reviews on their necessity or effects are limited. Furthermore, there is no international legal definition or compositional criteria for these products and their availability and regulation differs between European countries (2).

Based on the EFSA report published in 2013, there are hundreds of YCFs present on the EU market, with the highest number in France (n = 34), Spain (n = 32), and Italy (n = 24), and the lowest in Scandinavian countries, Sweden (n = 2), and Denmark (n = 0) (1).

Regarding regulation within the EU, YCF were classified as foods intended for particular nutritional uses (so-called ''dietetic foods'') in 17 EU countries (Bulgaria, Cyprus, Czech Republic, Croatia, Finland, France, Germany, Hungary, Ireland, Italy, Lithuania, Netherlands, Poland, Portugal, Romania, Slovenia, and Sweden) and Norway (1). This legislation, however, was repealed in 2013 with effect from 20th of July 2016. Since that date the Foods intended for Specific Groups Regulation is applicable and the concept of ''dietetic foods'' ceased to exist (1). All YCF placed on the market as ''dietetic foods'' are now classified as normal foods, fortified with certain nutrients, and targeting a specific subgroup of the population (young children). This classification was already in use in 10 EU countries (Austria, Belgium, Estonia, Greece, Latvia, Luxembourg, Malta, Slovakia, Spain, United Kingdom) (1).

Recommendations from relevant pediatric and/or nutritional societies throughout Europe also differ. The German Federal Institute for Risk Assessment (BfR) report from 2014 concludes that after the age of 1 year, in general, there is no nutritional necessity for specific foods, meaning that young children should adapt to a diverse diet including fresh ingredients consumed within the family (3). The same report recognizes that YCF can increase the supply of some micronutrients in this specific population, nevertheless they are not better for these purposes than other fortified foods, or the early, adequate introduction of meat/fish in the diet of young children or use of supplements. The German Society of Paediatrics and Adolescent Medicine (DGKJ) recently adopted updated guidance stating that YCF are not necessary but may contribute to improving nutrient supply of the omega-3 polyunsaturated fatty acids (n-3 PUFA), iron, vitamin D, and iodine (4). It further recommends specific compositional requirements for YCF.

The medical community in France, specifically pediatricians, supports the consumption of YCF for the period from 12 to 36 months in an amount of 500 mL per day (5). A Belgian consensus statement on growing-up milks for children 12 to 36 months concludes that it is possible to meet nutritional requirements without YCF; however, present diets offered to toddlers often do not meet nutrient requirements and, therefore, supplemented foods could be helpful and YCF is one option (6). The EFSA report from 2013 concludes that there is no unique role of YCF in the provision of critical nutrients for young children in Europe and therefore they cannot be considered as a necessity compared with other foods that may be included in the normal diet of young children (7).

An additional problem is the lack of compositional guidelines for YCF. Recently, an International Expert Group Coordinated by the Nutrition Association of Thailand and the Early Nutrition Academy provided recommendations for composition of YCF (8). Similarly, other groups of authors have published their recommendations on the composition of YCF (9).

The aim of this ESPGHAN CoN position paper is to critically review the available evidence on the role of YCF for nutrition in children, to consider existing recommendations for their content and to propose recommendations for European children.

Nutritional Intake in European Toddlers: Current Situation

Although recommendations for adequate nutritional intakes in young children are available, data on actual intake in toddlers are limited (10–15). A recent systematic review examined macro- and micronutrient intakes in the pediatric population (8). This review of 5 studies from 3 European countries (Ireland, France, and Norway) (10–14) identified that alpha-linolenic acid, iron, and vitamin D intakes in particular were often insufficient. Similarly, EFSA mentions that dietary intakes in children from 1 to 3 years of age of vitamin D, iron, n-3 PUFA, and iodine are below requirements, and that particular attention should be paid to ensure an appropriate supply (7).

These deficiencies could be addressed by several approaches, including dietary counseling, supplements and fortified foods, and specific formula including follow-on formula and YCF (7). It should be mentioned that although recommended intakes for these nutrients were not met, no nutritional cases of rickets were detected within otherwise healthy European children (16).

METHODS

The databases Medline (via PubMed) and Cochrane were searched for keywords for publications up to January 2017. The following key terms were used (words in the title or abstract of the manuscript): (''toddler'' OR ''growing-up'' OR ''growing up'' OR ''young child'' OR ''young-child'') AND (''milk'' OR ''formula'' OR ''diet''). The searches were limited to human studies. An age filter to restrict the search to children (0–18 years) was applied. All types of articles, including original papers, reviews, recommendations, and guidelines were considered. Furthermore, the reference list from all relevant articles was also searched.

The search was limited to English language manuscripts and only published data were considered. The reference lists of identified studies and key review articles, including previously published reviews, were searched.

Outcomes were determined that may identify any possible beneficial effect of YCF, and to review available data on the composition of YCF.

Recommendations were formulated and discussed in a total of 3 face-to-face meetings which were held in Paris, Newcastle, and Prague. Between meetings CoN members interacted by iterative e-mails. All disagreements were resolved by discussion until a full consensus was reached for every statement.

Composition

The composition of currently available YCF on the market differs significantly. The majority (96%) are based on cow's milk, and others include goat's milk and soy protein (1). Table 1 provides the composition of 244 YCF, which are available on the EU market based on EFSA and Asociación de Investigación de la Industria Agroalimentaria reports; and the composition of 234 YCF based on cow's milk; together with the composition of cow's milk and proposed composition of follow-on formula (1,17–19).

TABLE 1. Composition of young child formulae present on the European market, compared to the composition of cow's milk and recommended composition of follow-on formula

Nutrient	Units for first 4 columns	YCF, median (min-max)	YCF, cow's milk based, median (P5-P95)	Full fat cow's milk, mean	EFSA recommendation for follow-on formula min-max or min	EFSA report on the total daily requirements for children 1–3 years/day
Energy	kcal/100 g	67 (50 – 81)	67 (50–81)	69	60–70	
Protein	g/100 kcal	2.6 (2–6.7)	2.6 (2.1–3.6)	4.8	1.6–2.5	10–13 g/day
Casein	g/100 kcal	1.7 (0.1–2.4)	NR	NR		
Whey protein	g/100 kcal	0.7 (0.4–1.2)	NR	NR		
Carbohydrates	g/100 kcal	12.6 (7.3–15.4)	12.6 (11.1–14.3)	6.8	9–14	45%–50% E
Total sugars		9.9 (3.1–13.7)	NR	NR	<20% of total carbohydrates	<10% of carbohydrates
Lactose	g/100 kcal	9 (0.1–13.5)	NR	NR	>4.5	
Sucrose	g/100 kcal	2.1 (0.6–10.4)	NR	NR	NR	
Glucose	g/100 kcal	0.5 (0–1.8)	NR	NR	0	
Maltose	g/100 kcal	0.2 (0.1–5)	NR	NR	NR	
Maltodextrin	g/100 kcal	4.1 (1.4–11.2)	NR	NR	NR	
Fiber	g/100 kcal	0.8 (0–2.4)	NR	NR	NR	10 g
Fat	g/100 kcal	4.3 (3–5.7)	4.3 (3.5–4.8)	6.1	4.4–6	35%–40%E
Saturated Fat	g/100 kcal	1.4 (0.2–4.3)	1.4 (0.4–2.1)	NR		
Monounsaturated	g/100 kcal	1.9 (0.7–3)	NR	NR		
Polyunsaturated	g/100 kcal	0.9 (0.4–3.4)	NR	NR		
Linoleic acid n-6	g/100 kcal	0.8 (0.1–2.4)	0.75 (0.5–1.04)	0.07	0.5–1.2	4%E
Arachidonic acid (ARA)	g/100 kcal	0 (0–0.2)	4.1 (1.1–14.3)	0		
Alpha-linolenic acid n-3	mg/100 kcal	103 (0–589.2)	103 (57.6–169.0)	0	50–100	0.5%E
Eicosapentaenoic acid (EPA)	mg/100 kcal	19 (11.8–81.8)	NR	NR		DHA 100 (<24 mo)
Docosahexaenoic acid (DHA)	mg/100 kcal	6.4 (0.4–42.6)	6.4 (2.2–22.3)	NR	20–50	DHA + EPA 250 (>24 mo)
Trans fatty acids		NR	NR	NR	<3% Total fatty acid	
Minerals						
Sodium	mg/100 kcal	40.4 (15.9–85.7)	40.3 (27.6–57.1)	64.3	25	170–370 mg
Potassium	mg/100 kcal	126.8 (85.9–322.9)	127.0 (101.0–199.0)	215.1	80	800 mg
Chloride	mg/100 kcal	75 (14.1–166.2)	75.0 (61.2–114.0)	146.5	60	270–570 mg
Calcium	mg/100 kcal	126.9 (77.1–270.8)	127.0 (94.4–220.0)	176.7	50	600 mg
Phosphorus	mg/100 kcal	77.6 (46.4–185.7)	77.3 (58.4–134.0)	138.3	25	450 mg
Magnesium	mg/100 kcal	10.4 (6.6–49)	10.4 (8.1–20.0)	16.8	5	85 mg
Trace elements						
Iron	mg/100 kcal	1.8 (1–2.9)	1.8 (1.3–2.4)	<0.1	0.6	8 mg
Zinc	mg/100 kcal	1.1 (0.1–3)	1.2 (0.7–2.0)	0.6	0.5	4 mg
Copper	mg/100 kcal	0.1 (0–0.1)	61.5 (35.0–118.0)	0	0.06	0.4 mg
Manganese	mg/100 kcal	0 (0–1)	0.01 (0.006–0.1)	0	1	0.5 mg
Fluoride	mg/100 kcal	0 (0–0.1)	NR	NR	NN	0.6 mg
Selenium	μg/100 kcal	2.4 (1–6.7)	1.6 (1.4–5.5)	1.9	3	20 μg
Iodine	μg/100 kcal	20 (0–54)	20.2 (12.2–34.8)	23	15	90 μg
Chromium	μg/100 kcal	1.4 (1.4–1.5)	NR	NR	NN	—
Molybdenum	μg/100 kcal	4.2 (4.1–4.4)	NR	NR	0.4	15 μg
Vitamins						
Vitamin A	μg/100 kcal	101.6 (9.6–176.3)	102.0 (77.8–141.0)	57.5	70	400 μg
Vitamin D	μg/100 kcal	2.1 (0.9–6)	2.1 (1.4–3.3)	0.1	2	10 μg
Vitamin E	mg/100 kcal	1.6 (0–7)	1.6 (0.9–3.1)	0.1	0.6	6 mg
Vitamin K	μg/100 kcal	7.5 (0–16.3)	7.5 (4.5–11.8)	0	1	12 μg
Vitamin B_1 (thiamin)	mg/100 kcal	0.1 (0–1.2)	0.12 (0.07–0.27)	0	0.04	0.5 mg
Vitamin B_2 (riboflavin)	mg/100 kcal	0.2 (0–1.2)	0.20 (0.14–0.35)	0.3	0.06	0.8 mg
Vitamin B_3 (niacin)	mg/100 kcal	0.9 (0–4.1)	0.90 (0.57–3.1)	1.0	0.4	9 mg
Vitamin B_5 (pantothenic acid)	mg/100 kcal	0.7 (0–6.8)	0.71 (0.42–1.3)	0.6	0.4	4 mg
Vitamin B_6 (pyridoxine)	mg/100 kcal	0.1 (0–0.7)	0.1 (0.06–0.3)	0	0.02	0.7 mg
Vitamin B_7 (biotin)	μg/100 kcal	3.1 (0–7.5)	3.1 (2.2–6.6)	4.3	1	20 μg
Vitamin B_9 (folic acid)	μg/100 kcal	22.4 (0–42.2)	22.4 (7.3–38.6)	9.1	15	100 μg
Vitamin B_{12} (cobalamin)	mg/100 kcal	0.3 (0–0.9)	0.27 (0.18–0.59)	0.7	0.1	0.9 mg
Vitamin C	mg/100 kcal	15.4 (2.2–34.8)	15.9 (8.7–23.4)	1.9	4	20 mg

Recommended nutritional intakes for toddlers (EFSA and Asociación de Investigación de la Industria Agroalimentaria [AINIA] report) are also provided (1,7,17–19).

E =energy; EFSA = European Food Safety Authority; NN = not necessary; NR = not reported; YCF = young child formula.

YCF was designed as an alternative to cow's milk or breast milk and aimed to further improve nutritional status in toddlers by adding nutrients, which are generally low (or lacking) in the diet. However, compared to infant and follow-on formula for which the composition is defined by regulatory agencies, the composition of YCF is not defined (1,20). It is difficult to make compositional recommendations for these products for several reasons; children gradually increase their intake and diversity of regular foods after the age of 6 months and the timing and duration of transition from complementary feeding to regular "family" food differs. During this period breast milk and/or formula milk consumption also decreases. Second, although recommendations for adequate nutritional intakes for young children are available, data on actual intake in toddlers, as presented above, are limited to only a few reports (10–14). Therefore, the scientific basis on which to define the composition of YCF, in terms of the "nutrient gaps" that need to be addressed, is extremely limited and depends on the group or population of infants.

Our systematic search found 2 articles which proposed the composition of YCF; one of these was a detailed and comprehensive review prepared by the International Expert Group coordinated by the Nutrition Association of Thailand and Early Nutrition Academy (8). A second, much shorter, international report was produced by a panel composed of several nutritional experts which was hosted and funded by a formula manufacturer and has several limitations; it is more general, some proposed limits are significantly different to follow-on formula and breast milk, and overall the methods are not clearly presented (9).

When discussing the composition of YCF some aspects of young children nutrition should be taken into account; first there is an overconsumption of energy dense foods and increasing obesity rates in European populations, and there is some evidence for an association between early high protein intake and a higher risk of obesity later in life (21,22). Second, there is generally a lower than recommended intake of n-3 PUFA, iron, and vitamin D (10–14). Therefore, it would be of interest to determine whether YCF intake could correct (and to what extent) some of these deficits as compared to cow's milk or follow-on formula. Regarding energy intake, if we assume a similar intake of YCF to cow's milk (4–6), then the overall energy content of the YCF should not exceed the energy content of whole fat cow's milk (68 kcal/100 mL) and follow-on formula (60–70 kcal/100 mL) (9,23). YCF currently available on the European market have energy contents from 50 to 81 kcal/100 mL (median 67 kcal/100 mL) (1). This means that a child who receives 300 mL of different YCF could receive between 150 and 240 kcal. Furthermore, unlike in resource-poor countries, in European populations there is generally a higher likelihood of energy excess than undernutrition (15); thus, energy content should not exceed the energy content of full fat cow's milk or follow-on formula. The ideal energy content for YCF designed for European infants may, however, be too low for resource-poor countries with a higher incidence of undernutrition.

A second nutrient, which may be overconsumed in European children is protein. There is limited evidence that excessive intake of protein during infancy increases the later risk for obesity (21). Furthermore, intake of protein in some European toddlers is much higher than recommended (6,15,24). Taking that into account, the amount of protein in YCF should be reduced to the amount in infant formula similar to breast milk. Previous reports stated that YCF should contain a minimum 1.6 g of animal protein/100 kcal (8). The amount of protein in YCF available on European market varies significantly (up to 6.7 g/100 kcal; although it is not mentioned whether the protein source is animal or plant), and the median is 2.6 g/100 kcal, although the majority of YCF have a lower protein content than regular cow's milk (4.8 g/100 kcal) (1). In general, children receiving YCF have a lower intake of protein compared to children taking cow's milk (10), yet, if cow's milk were replaced with YCF, protein intake would not decrease <15% of total energy intake (6). As previously mentioned, it is also of concern that even the median (2.6 g/100 kcal) was higher than the upper level recommended by EFSA for follow-on formula (2.5 g/100 kcal). All of these points suggest the need to lower the protein content of YCF toward the lower limit permitted in follow-on formula (1.6 g/100 kcal for products based on intact animal protein) (19).

Overall the amount of carbohydrate in YCF is similar to that in follow-on formula, and much higher than in cow's milk. The problem is, however, the amount of added sucrose which is high in some YCF (up to 10.4 g/100 kcal). There are data showing that YCF available on Asian markets with added carbohydrates (glucose or corn syrup solids, maltodextrins, sucrose, lactose, and fructose were the most common additives) increase glucose and insulin response significantly more than regular cow's milk (25). There is no need to add sugars other than lactose in amounts naturally present in milk (8,26). Preferably, no free sugars should be added to products for children up to 2 years of age and their amount should be limited to <5% of total energy intake in children older than 2 years (26).

A possible beneficial effect of YCF is the provision of nutrients that are often lacking in the diet of European children; alpha-linolenic acid, vitamin D, and iron. These deficits are largely due to the very low content (vitamin D, iron, alpha-linolenic acid) of these nutrients in nonsupplemented cow's milk (7).

The median content of alpha-linolenic acid in YCF is 103 mg/100 kcal, which is in the range recommended for follow-on formula. Approximately 4% of all YCF, however, have low levels of alpha-linolenic acid (7). Similarly, the median content of iron and vitamin D in YCF is within the recommended range for follow-on formula. Interestingly, none of the YCF have iron levels below the lower limit recommended for follow-on formulae and only 1.3% have a vitamin D content below this level (7). In contrast, nonsupplemented cow's milk is poor source of iron and vitamin D.

In summary, the biggest concern is the significant differences in the composition of available YCF. Specifically, some YCF available on the European market have a high protein content, added sweeteners, taste modifiers, different amounts of vitamins, and iron, and are without long-chain polyunsaturated fatty acids (LCPUFAs) (6).

Based on currently available data and taking into account the composition of breast milk there is no evidence which would support a significantly different composition of YCF compared to follow-on formulae used for infants after 6 months of age in European populations. This is mainly supported by the data revealing that European toddlers frequently have inadequate intakes of iron, vitamin D, and n-3 PUFA which are all added to follow-on formula in adequate amounts to prevent deficiency (17). Based on the EFSA statement, formulae consumed during the first year of life can also be used in young children (1). Indeed, this was the basis for the EFSA Panel's on Dietetic Products, Nutrition and Allergies (NDA) decision not to propose specific compositional criteria for formulae consumed after 1 year of age (17). In order to assure good quality of all products, currently the CODEX ALIMENTARIUS is in the process of developing a regulation for the composition of YCF, to which ESPGHAN is actively contributing (27).

After reviewing the literature, albeit limited, the ESPGHAN CoN found no reason why follow-on formulae could not be used beyond infancy, nor any rationale for the composition of YCF being different from that of follow-on formulae, although the protein content should be toward the lower permitted level in follow-on formulae. If YCF is considered as a substitute for cows' milk, a simpler composition may, however, be proposed; essentially fortified milk with only a few key nutrients specified, such as iron, vitamin D, and n-3 PUFA. This approach would presumably have the theoretical advantage of reducing the production costs of YCF.

Furthermore, regulation is needed not only to propose which nutrients should be added, but also to prevent and limit addition of unwanted components (eg, free sugars, flavorings).

Health Effects

There is limited evidence on the effect of YCF on health outcomes in toddlers. Systematic reviews of the literature identified 6 randomized controlled trials (RCTs) published in 8 scientific articles, which evaluated either the effect of YCF compared to cows' milk (28–32) or red meat (29–31), high versus low glycemic index formula (33), YCF supplemented with symbiotic (34) or prebiotics, and LCPUFAs (35) versus nonsupplemented YCF and 9 cross-sectional studies (Table 2).

TABLE 2. Available evidence

Author, y	Country	Subjects, age	Type of the study	Active and comparison	Objective	Results	Industry sponsored
Akkermans (2017) (32)	Germany, The Netherlands, United Kingdom	318 (1–3 y)	RCT	YCF vs nonfortified cow's milk	Ferritin and vitamin D levels	Iron and vitamin D deficiency was lower in YCF group; significant increase in serum ferritin and vitamin D levels in YCF group	Supported by Danone Nutricia Research
Chatchatee (2014) (35)	Malaysia	767 (14–24 mo)	RCT	YCF with scGOS/lcFOS/ LCPUFAs vs YCF	Infection rate	Decreased risk of developing at least 1 infection	3 authors are employees of Nutricia Research
Houghton (2011) (30)	New Zealand	225 (12–20 mo)	RCT	Red meat vs micronutrient-fortified cow milk vs vitamin D–fortified cow milk (both milks had vitamin D)	The effect of vitamin D–fortified milk on serum 25(OH)D and PTH	Increase in vitamin D in fortified milks, PTH was same	No; Heinz Wattie's New Zealand Ltd provided the micronutrient-fortified milk. Fonterra New Zealand Ltd provided the vitamin D-fortified milk.
Hower (2013) (28)	Germany	92 (2–6 y)	RCT	Vitamin D–fortified YCF vs non–semiskimmed regular milk	Vitamin D status	Daily consumption of fortified growing up milk contributed to the prevention of an otherwise frequently observed decrease in serum vitamin D concentration during winter Frequency of infection was similar	The study was funded by HiPP GmbH and Co.
Misra (2015) (33)	Malaysia	88 Toddlers	RCT	High vs low GI formula	Sleep pattern	NS	This research was funded by Fonterra Co-operative Group Limited
Morgan (2010) (31)	New Zealand	225 (12–20 mo)	RCT	Red meat vs fortified cow milk vs nonfortified cow milk	The effect on zinc status	No increase in serum zinc in all groups	No; Heinz Wattie's New Zealand Ltd provided the fortified milk; Fonterra New Zealand provided the non-fortified milk; Canpac International Ltd donated the cans and spoons; and Fisher and Paykel Appliances Ltd donated a freezer.
Szymlek-Gay (2009) (29)	New Zealand	225 (1–3 y)	RCT	Red meat, iron-fortified toddlers milk, regular cow milk	Iron status	Consumption of iron-fortified toddlers' milk can increase iron stores in healthy non-anemic toddlers, whereas increased intakes of red meat can prevent their decline.	No; Heinz Wattie's New Zealand Ltd provided the iron-fortified milk; Fonterra New Zealand provided the nonfortified milk; Canpac International Ltd donated the cans and spoons; and Fisher and Paykel Appliances Ltd donated a freezer.
Xuan (2013) (34)	Vietnam	368 (18–36 mo)	Cluster RCT	YCF supplemented with synbiotics (*Lactobacillus paracasei* NCC2461 and *Bifidobacterium longum* NCC3001; inulin and FOS) and vitamins (A, C, and E), minerals (zinc and selenium), and DHA vs regular YCF	IgA, growth, nutritional status (anemia, zinc, and vitamin A deficiencies), infection rate	Increase in IgA, NS for all other outcomes	The study was supported by a Nestlé research fund.
Bocquet (2015) (36)	France	1188 (15 days–3 y)	Cross-sectional	—	Nutrient intake	YCF intake increased between 2005 and 2013 survey	

Author, y	Country	Subjects, age	Type of the study	Active and comparison	Objective	Results	Industry sponsored
Brand-Miller (2013) (25)	Malaysia and Indonesia	58 Products	Cross-sectional	—	The percentage of declared carbohydrates contributed by added carbohydrates	Added carbohydrate content (excluding fiber) ranged from 0 to 21.5 g/serving Milk powders without added carbohydrates had similar GI values to standard liquid whole cow's milk Children's milk powders containing higher levels of added carbohydrates elicit higher glucose and insulin responses than liquid or powdered whole cow's milk	
Cairncross (2016) (37)	New Zealand	1329 (2–5 y)	Cross-sectional	—	Predictors of vitamin D deficiency	Children who drank YCF had 0 risk of vitamin D deficiency	
Ghisolfi (2012) (10)	France	118 (1–2 y)	Cross-sectional	Identified 2 groups: cow's milk (>250 mL/day) vs YCF (>250 mL/day)	Difference in protein, energy, nutrient status between cows and YCF consumption	Consumption of >250 mL cow's milk/day entails the risk of insufficiency in α-linolenic acid, Fe, vitamin C, and vitamin D Use of >250 mL YCF /day significantly reduces the risk of insufficiencies in the mentioned nutrients. Cow's milk intake increases the risk for high protein intake comparing to YCF	
Grimes (2015) (38)	USA	2740 (0–24 mo)	Cross-sectional	—	Dietary sources	YCF not separated; milks in general contributed as a main macronutrients source	
Pereira (2016) (39)	Cambodia, Nepal, Senegal, Cambodia	Not mentioned	Cross-sectional	—	Characteristics of labels of follow-on formula and YCF compared with infant formula	20%–85% had similar slogans/ mascots/symbols	
Scott (2016) (40)	Australia	832 (1 y)	Cross-sectional	—	Contribution of breast milk and infant formula to the nutritional intake of toddlers	4% Received YCF (53% still received infant formula) Iron intake was below recommendation in half of breastfed and quarter of formula fed toddlers	
Vieux (2016) (41)	United Kingdom	1147 (12–18 mo)	Computer modeling study using cross-sectional data	—	Dietary changes needed to ensure nutritional adequacy	Increasing YCF and supplement consumption was the shortest way to cover nutrient requirements	
Walton (2013) (13)	Ireland	85 (12–24 y)	Cross-sectional	Identified 2 groups: at least 300 g and consuming YCF (>100 g/ day) together with cow's milk or cow's milk only	Nutritional adequacy of 2 groups	Consumption of YCF reduced the risk of inadequacies of iron and vitamin D	
Yu (2016) (42)	China	914 (12–35 mo)	Cross-sectional	—	Feeding patterns in infants and toddlers	App 50% received YCF	
Eussen (2015) (43)	United Kingdom	1275 (12–18 mo)	Simulation study	Data extracted from the DNSIYC registry; 2 scenarios where cow's milk was theoretically replaced with matching volume of YCF (scenario 1) or 300 mL of YCF (Scenario 1)	Theoretical nutritional impact of replacing the cow's milk with YCF	Before simulation 95.2% of toddlers received inadequate amount of vitamin D and 53.8% of iron; after simulation inadequacy decreased to 4.9% and 0% for vitamin D and 2.7% and 1.1% for iron	

GI = glycemic index; RCT = randomized controlled trial; YCF = young child formulae.

A New Zealand study that tested risk factors for low vitamin D concentrations found that one of the poor prognostic factors was not drinking YCF (37). An RCT also performed in New Zealand showed that intake of YCF supplemented with vitamin D and whole milk supplemented with vitamin D significantly decreases the proportion of children with vitamin D deficiency compared to children who were supplemented with meat (30). There was no difference in the vitamin D levels between the milk groups (30).

The KiMi trial, a German double blind RCT, compared vitamin D-fortified YCF (2.85 μg/100 mL) with semi-skimmed cow's milk without added vitamin D (28). Daily consumption of fortified YCF contributed to the prevention of an otherwise frequently observed decrease in serum 25-hydroxy vitamin D concentration during winter. Furthermore, a recently published multicenter European RCT found that supplementation with YCF significantly increases vitamin D serum levels and decreases the risk of vitamin D deficiency compared to cow's milk (32).

An RCT which determined the efficacy of an increased intake of red meat, or the consumption of iron-fortified YCF compared to regular cow's milk on iron status found that YCF significantly increased ferritin levels in toddlers (29). Levels remained the same in the red meat group and decreased in the regular cow's milk group. There was no effect on the change in the prevalence of suboptimal iron status in healthy nonanemic 12- to 24-month-old children, although the fortified milk group was not powered sufficiently to detect this (29). Very recently, a multicenter European RCT (32) showed that those children randomized to cow's milk had a significant increase in iron deficiency (from 11.9% at baseline to 29.6% at the end of intervention) in contrast to those randomized to YCF in whom the incidence was unchanged (14.3% to 13.9%). However, due to the very small number of children with iron deficiency anemia (4% in cow's milk and 0% in YCF), this study was underpowered to differences in this outcome.

For YCF with synbiotics (34) and prebiotics in combination to LCPUFA (35) data are too limited to draw conclusions.

A cross-sectional Irish study found that children older than 12 months of age already eat a variety of foods and cow's milk was not the main source of nutrients (13). This study included children with an average daily total milk intake of at least 300 g per day who were stratified into 2 groups: those consuming >100 g YCF/day together with cow's milk or consuming cow's milk only. Although average total daily energy intakes were similar in both consumers and nonconsumers of YCF, intakes of protein, saturated fat, and vitamin B_{12} were lower and intakes of carbohydrate, dietary fiber, iron, zinc, vitamins C and D were higher in consumers of YCF. For children consuming cow's milk only, 59% had inadequate intakes of iron and 98% of vitamin D; these proportions were much lower in consumers of YCF (none and 69%, respectively) meaning that consumption of YCF reduced the risk of inadequate intake of iron and vitamin D, 2 nutrients frequently lacking in the diets of young children (13). Similarly, a computer modeling study using cross-sectional data from the UK found that use of YCF with a decrease in cow's milk consumption may be the most effective way to achieve adequate nutritional intake (41).

Very recently, a systematic review and meta-analysis evaluated the role of fortified milk on growth and other biochemical markers (44). This review did not limit its search to YCF but included all fortified milks (including regular fortified cow's milk) and included an age limit of children in some studies that was <1 year old. Altogether 15 RCTs were included. Fortification varied from iron, zinc, vitamins, essential fatty acids, to pre- and/or probiotics, and outcomes were weight and height gain and iron status. This systematic review concluded that fortified milk compared to control milk had minimal effects on weight gain (mean difference = 0.17 kg; 95% confidence interval 0.02–0.31 kg); however, most of included studies are from developing countries. The risk of anemia was reduced in fortified milk groups (odds ratio = 0.32; 95% confidence interval 0.15–0.66) compared with control groups. There were, however, no significant effects on height gain, changes in body composition, or hemoglobin concentration.

To conclude, reports from Europe do not suggest significant deficits in the nutritional intake of children except for iron, vitamin D, and n-3 PUFAs. Although EFSA concluded that YCF are one way to increase intake of these nutrients they are not the only solution (1) and there are other efficient alternatives such as fortified cow's milk, fortified cereals and cereal-based foods, supplements, or the early introduction of meat and sea fish into complementary feeding with continued regular consumption of these foods (1,7).

Limited available evidence shows that the use of YCF can increase vitamin D intake, but YCF are not superior to supplemented regular cow's milk. Their intake can also increase ferritin levels and reduce iron deficiency, but the clinical relevance of this effect is not clear. No clinical studies were identified regarding the effect of YCF on the status of other nutrients.

Disadvantages of Young Child Formulae

There are no published adverse effects associated with YCF. In addition to the already mentioned lack of recommendations and consequent high variability in YCF composition there are, however, other possible disadvantages, which include a continued preference for liquids in the diet (this may affect control of satiety), a reduced interest in other (''regular'') food with increased interest for YCF, and the potential for suggesting to parents and caregivers that manufactured foods for young children are a safer or healthier choice for meeting nutritional requirements (2,6).

Lastly, intake of YCF may result in a significant additional financial burden on the family compared to normal family foods including cow's milk (6). A comparison of the relative costs of different strategies (eg, healthy varied diet, enriched foods, follow-on formula, supplements, YCF) for meeting nutrient requirements for young children has, however, not yet been performed.

Marketing and Labeling

One third of the global spend on milk formula for infants and young children is attributed to YCF, making it the largest single milk type in this category (39). Evidence shows that advertisements for YCF are perceived by parents as promoting formula in general so they are considered collectively as formula—infant formula, follow-on formula, and YCF (39). This is mainly attributed to the use of brand advertising, meaning that all 3 types of formula appear similar to consumers. Because of this, the advertising of YCF may contribute to public perceptions around the use of, and potential benefits from, milk formula (compared to breast-feeding) in general. Since 2016, WHO regards YCF as breast milk substitutes (45), with the consequence that these products should be subject to the WHO International Code of Marketing of Breast-milk Substitutes (46). Regardless of advertising, ESPGHAN CoN considers that it is still important that parents understand the difference between milk formulae used in infancy compared to YCF, because milk contributes less to the nutrient intake of a toddler than a younger infant.

Conclusions and Recommendations

1. Breast-feeding should be recommended as part of a healthy diet after the first year of life if mutually desired by mother and child.

2. In order to unify terms ESPGHAN CoN endorses the term YCF proposed by EFSA in 2013 for all formula specifically designed for children from 1 to 3 years of age.
3. Based on available evidence there is no necessity for the routine use of YCF in children from 1 to 3 years of life, but they can be used as part of a strategy to increase the intake of iron, vitamin D, and n-3 PUFA and decrease the intake of protein compared to unfortified cow's milk. Follow-on formulae can be used for the same purpose.
4. Other strategies for optimizing nutritional intake include promotion of a healthy varied diet, use of fortified foods, and use of supplements.
5. There is a need for regulation of YCF to avoid inappropriate composition.
6. Based on the limited data there is no evidence to recommend a composition of YCF that differs from that of follow on formula for energy, iron, vitamin D, n-3 PUFAs, whereas the protein content should aim toward the lower end of the permitted range if animal protein is used.
7. Marketing of YCF should be clearly separated from infant and follow-on formula and the use of similar branding (whether images or text) on these different product categories should be discouraged.
8. Future studies are needed to further investigate the role of YCF in the diet of young children.

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