

# Complementary Feeding: A Position Paper by the European Society for Paediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN) Committee on Nutrition

\*Mary Fewtrell, †Jiri Bronsky, ‡Cristina Campoy, §Magnus Domellöf, ||Nicholas Embleton, ¶Nataša Fidler Mis, #Iva Hojsak, \*\*Jessie M. Hulst, ††Flavia Indrio, ‡‡§§Alexandre Lapillonne, and ||||¶¶Christian Molgaard

## ABSTRACT

This position paper considers different aspects of complementary feeding (CF), focussing on healthy term infants in Europe. After reviewing current knowledge and practices, we have formulated these recommendations:

**Timing:** Exclusive or full breast-feeding should be promoted for at least 4 months (17 weeks, beginning of the 5th month of life) and exclusive or predominant breast-feeding for approximately 6 months (26 weeks, beginning of the 7th month) is a desirable goal. Complementary foods (solids and liquids other than breast milk or infant formula) should not be introduced before 4 months but should not be delayed beyond 6 months. **Content:** Infants should be offered foods with a variety of flavours and textures including bitter tasting green vegetables. Continued breast-feeding is recommended alongside CF. Whole cows' milk should not be used as the main drink before 12 months of age. Allergenic foods may be introduced when CF is commenced any time after 4 months. Infants at high risk of peanut allergy (those with severe eczema, egg allergy, or both) should have peanut introduced between 4 and 11 months, following evaluation by an appropriately trained specialist. Gluten may be introduced between 4 and 12 months, but consumption of large quantities should be avoided during the first weeks after gluten introduction and later during infancy. All infants should receive iron-rich CF including meat products and/or iron-fortified foods. No sugar or salt should be added to CF and fruit juices or sugar-sweetened beverages should be avoided. Vegan diets should only be used under appropriate medical or dietetic supervision and parents should understand the serious consequences of failing to follow advice regarding supplementation of the diet. **Method:** Parents should be encouraged to respond to their infant's hunger and satiety cues and to avoid feeding to comfort or as a reward.

**Key Words:** breast-feeding, complementary feeding, formula feeding, health outcomes, infant

(*JPGN* 2017;64: 119–132)

Received October 19, 2016; accepted October 24, 2016.

From the \*Childhood Nutrition Research Centre, UCL Great Ormond Street Institute of Child Health, London, UK, the †Department of Paediatrics, University Hospital Motol, Prague, Czech Republic, the ‡Department of Paediatrics, University of Granada, Granada, Spain, the §Department of Clinical Sciences, Pediatrics, Umeå University, Umeå, Sweden, the ||Newcastle Neonatal Service, Newcastle Hospitals NHS Trust and Newcastle University, Newcastle upon Tyne, UK, the ¶Department of Gastroenterology, Hepatology and Nutrition, University Children's Hospital, University Medical Centre Ljubljana, Ljubljana, Slovenia, the #University Children's Hospital Zagreb, Zagreb, Croatia, the \*\*Erasmus MC, Sophia Children's Hospital, Rotterdam, The Netherlands, the ††Ospedale Pediatrico Giovanni XXIII, University of Bari, Bari, Italy, the ‡‡Paris Descartes University, APHP Necker-Enfants Malades Hospital, Paris, France, the §§CNRC, Baylor College of Medicine, Houston, TX, the ||||Department of Nutrition, Exercise and Sports, University of

## What Is Known

- Complementary foods are necessary for both nutritional and developmental reasons, and are an important stage in the transition from milk feeding to family foods.
- The complementary feeding period is one of rapid growth and development when infants are susceptible to nutrient deficiencies and excesses, and during which there are marked changes in the diet with exposures to new foods, tastes, and feeding experiences.
- The relatively limited scientific evidence base is reflected in considerable variation in complementary feeding recommendations and practices between and within countries.

## What Is New

- The position paper published by this Committee in 2008 has been updated to include new evidence, including data from randomized controlled trials on the introduction of gluten and allergenic foods.
- The article considers the timing and content of complementary feeding, the method of feeding, and specific dietary practices, and makes recommendations, focussing on healthy term infants in Europe.

Copenhagen, København, and the ¶¶Pediatric Nutrition Unit, Copenhagen University Hospital, Rigshospitalet, Denmark.

Address correspondence and reprint requests to Mary Fewtrell, MD, Childhood Nutrition Research Centre, UCL Great Ormond Street Institute of Child Health, 30 Guilford St, London WC1N 1EH, UK (e-mail: m.fewtrell@ucl.ac.uk).

Supplemental digital content is available for this article. Direct URL citations appear in the printed text, and links to the digital files are provided in the HTML text of this article on the journal's Web site ([www.jpjn.org](http://www.jpjn.org)).

The authors report no conflicts of interest.

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DOI: 10.1097/MPG.0000000000001454

Complementary feeding (CF), as defined by the World Health Organization (WHO) in 2002, is “the process starting when breast milk alone is no longer sufficient to meet the nutritional requirements of infants” so that “other foods and liquids are needed, along with breast milk” (1). Complementary foods (CF) are necessary for both nutritional and developmental reasons, and are an important stage in the transition from milk feeding to family foods. The CF period is one of rapid growth and development when infants are susceptible to nutrient deficiencies and excesses, and during which there are marked changes in the diet with exposures to new foods, tastes, and feeding experiences. Yet, in contrast to the large literature on breast and formula feeding, less attention has been paid to the CF period, especially to the type of foods given, or whether this period of significant dietary change influences later health, development, or behaviour. The more limited scientific evidence base is reflected in considerable variation in CF recommendations and practices between and within countries. Nevertheless, in recent years new evidence has been published, including data from randomized controlled trials (RCTs). The purpose of this article is to update the position paper published by this Committee in 2008 (2). We review current recommendations and practice; summarize evidence for nutritional aspects and short- and long-term health effects of the timing and composition of CF; provide advice to health care providers; and identify areas for future research. This article focuses on CF in the context of the whole diet during the first year of life in healthy term-born infants living in Europe, generally in affluent populations; but recognizes that within this population there are groups and families at risk of poor nutrition and differing risk for health and disease outcomes. The article has 4 sections, considering different aspects of CF: timing, with respect to developmental readiness, nutritional adequacy, and health effects; content, with respect to nutritional requirements and health effects; method of feeding; and specific dietary practices.

## METHODS

A systematic literature search was conducted up to March 11, 2016. For each outcome of interest relating to CF searches were conducted in PubMed, the Cochrane Library plus the reference lists of selected articles for relevant publications in English, including original papers, systematic reviews, and meta-analyses. Where possible systematic reviews, meta-analyses, and guideline documents produced by expert scientific groups or societies were used, including European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) Position Papers and Guidelines. Information on current feeding practices and recommendations was also identified from official publications of individual countries and by word of mouth. Search terms for the literature searches included firstly those related to infant feeding and CF, using medical subject heading terms (“breast-feeding,” “infant nutritional physiological phenomena,” “weaning,” “infant formula”) and other keywords. These were combined, as appropriate, with medical subject heading terms and keywords relating to the outcome or topic of interest (eg, infection, allergy, obesity, iron status/anaemia, cognitive outcome, food preferences, cardiovascular outcomes). The studies identified are heterogeneous in terms of sample size and design, and the quality of the data varies for different outcomes. These aspects have been considered in the relevant sections. A systematic review and meta-analysis on the timing of introduction of allergenic foods to the infant diet published in September 2016 was included because this summarizes trials and studies published before the cut-off for our literature review; the article also includes data from 3 trials published after the cut-off date currently only in abstract form.

## DEFINITIONS

Exclusive breast-feeding (EBF) as defined by the WHO means that the infant receives only breast milk and no other liquids or solids except for drops or syrups consisting of vitamins, mineral supplements, or medicines (3). Anything other than breast milk is defined as a complementary food; thus, infants who receive infant formula are considered to have started CF, even if this is from birth. The inclusion of infant formulas as CF is intended to emphasize and encourage breast-feeding. As in our previous position paper, and in agreement with a more recent European Food Safety Authority (EFSA) opinion (4), the Committee, however, regards this as unhelpful and even confusing because infants living in Europe are often fed infant formulas from the first weeks of life either alongside breast-feeding or as the sole diet. Although our preference is to use the term “CF” to include all solid and liquid foods other than breast milk or infant formula, it is recognized that studies reviewed in the article use different definitions, with many focussing on the duration of EBF rather than the introduction of solid foods. Throughout this position paper, 4 months equates to 17 weeks or the beginning of the 5th month and 6 months equates to 26 weeks or the beginning of the 7th month.

## BACKGROUND AND CURRENT RECOMMENDATIONS

### Timing of Introduction of Complementary Foods

The WHO recommends EBF for 6 months, followed by the introduction of CF alongside breast-feeding (3). This recommendation was based on a consideration of the optimal duration of EBF and, since infant formula is defined by WHO as a CF, it did not consider the optimal age for introduction of solid foods in formula-fed infants.

A systematic review of the optimal duration of EBF (5) commissioned by the WHO in 2000 compared mother and infant outcomes with EBF for 6 months versus EBF for 3 to 4 months followed by partial breast-feeding alongside CF. Of the 16 eligible studies, 7 were from low-income countries and 9 were from high-income countries. Only 2 were RCTs comparing different EBF recommendations, both conducted in a low-income setting (6,7). In the most recent update of the systematic review and meta-analysis (8), 23 eligible studies were identified with 11 from low- and 12 from high-income countries; no new RCTs were included. The review concluded that there were no deficits in growth, nor effects on allergy with 6 months EBF, but that it was not possible to rule out that EBF without iron supplementation through 6 months may compromise hematologic status in vulnerable infants. There were some benefits to mothers in low-income settings from 6 months EBF in terms of delayed return of menses (in Honduras, Bangladesh, and Senegal), and faster postpartum weight loss (in Honduras). The most relevant finding for infants in higher-income countries was, however, a reduced risk of 1 or more episodes of gastrointestinal infection with EBF for 6 months compared with EBF for 3 months with partial breast-feeding thereafter (adjusted odds ratio [OR] 0.61; 95% confidence interval [CI] 0.41–0.93); this came from observational analysis of data from a trial of a breast-feeding promotion intervention in Belarus (9).

Following the WHO systematic review and expert consultation, in 2001 the World Health Assembly revised its recommendation to EBF for 6 months and partial breast-feeding thereafter. The recommendations from the expert consultation emphasized that it applied to populations rather than individuals and that mothers who were unable or unwilling to follow this recommendation should also be supported to optimize their infant’s nutrition (4).

Many countries subsequently adopted this recommendation for the duration of EBF, sometimes with qualifications. For example, in Sweden and the Netherlands it is suggested that breast-fed infants can receive “trial foods” or “small tastes” between 4 and 6 months, but that these foods should not replace milk (10,11). Other countries continued to recommend the introduction of CF between 4 and 6 months (3). The WHO reviewers highlighted the need for larger randomized trials to test different recommendations on the timing of CF. To date, only 3 RCTs have been published (12–14), reflecting the practical and to some extent ethical difficulties of conducting such research particularly once a recommendation has been made. Only 1 randomized trial has investigated the effect of introducing solid foods at 3 to 4 versus 6 months in 147 predominantly formula-fed infants (15), and this study reported no effect of the intervention on growth, body composition, and energy or nutrient intake up to 12 months of age.

## Recommendations on Other Aspects of Complementary Feeding

Evidence for the optimal timing for the introduction of specific individual foods is generally lacking, and recommendations thus vary between countries, reflecting cultural factors and food availability. Most countries recommend that whole cow’s milk should not be introduced as a drink before the age of 12 months. Most authorities highlight the importance of providing good sources of iron during CF, although specific recommendations vary according to the population and risk of iron deficiency. Recognizing that infants consume foods and diets rather than individual nutrients, some European countries have translated nutrient intake recommendations for infants and young children into food-based dietary guidelines to help provide caregivers with an indication of suitable age-appropriate foods to meet dietary needs (16,17).

### CURRENT PRACTICE

Robust data on current CF practices for European countries are limited but most published figures suggest that a minority of mothers EBF for 6 months. For example, Schiess et al (18) reported data on the timing of introduction of CF in infants born between 2002 and 2004 in 5 EU countries (Belgium, Germany, Italy, Poland, Spain). CFs were introduced earlier in formula-fed infants (median 19 weeks, interquartile range 17–21) than breast-fed infants (median 21 weeks, interquartile range 19–24), with significant differences between countries. Approximately 37% of formula-fed infants and 17% of breast-fed infants received CF earlier than that at 4 months, with >75% versus >50% receiving CF at 5 months and 96% versus 87% receiving CF at 6 completed months for formula-fed and breast-fed infants, respectively. More recent data from the UK Infant Feeding Study (19) indicated that 17% of infants born in 2010 were EBF at 3 months, 12% at 4 months and only 1% at 6 months. In the Czech Republic 17% of mothers were EBF at 6 months (20), with figures from Sweden in 2013 of 40% EBF at 4 months and 9% at 6 months (21), and 2015 figures from the Netherlands of 47% EBF at 3 months and 39% at 6 months (22). It is likely that cultural and economic factors are responsible for variations in practice between and within countries.

In contrast to the situation in infants from low-income countries, the majority of European infants are unlikely to experience deficiencies of macronutrients during the CF period. Indeed, data on nutritional intakes of infants from a number of European countries (16) suggested that dietary intakes of energy, protein, sodium chloride, and potassium of infants and young children are generally higher than recommended. The same review, however,

concluded that intakes of n-3 polyunsaturated fatty acids (PUFAs), vitamin D, and iodine are critical in some infants and young children, and that some subgroups in this population may be at the risk of inadequacy. The potential consequences of this are discussed in subsequent sections.

## TIMING OF INTRODUCTION OF COMPLEMENTARY FEEDING

### Physiological and Neurological Maturation

The physiological maturation of renal and gastrointestinal function necessary for an infant to metabolize nonmilk foods and the neurodevelopmental changes necessary for safe and effective progression to a mixed diet have been reviewed in several reports (3,23). The available data suggest that both renal function and gastrointestinal function are sufficiently mature to metabolize nutrients from CF by the age of 4 months and that, to a large degree, gastrointestinal maturation is driven by the foods ingested.

With respect to neurodevelopment it is likely that there is a range at which infants attain the necessary motor skills to cope safely with solid foods. The skills required for an infant to safely accept and swallow pureed CF from a spoon typically appear during the 4- to 6-month period (3), whereas those required to handle lumpy (semisolid) foods or to self-feed, as currently advocated in the “baby-led” approach popular in some countries (see below), will appear later in the first year. From 9 months, most infants are capable of feeding themselves, drinking from a cup using both hands, and eating family foods with some adaptations (cut into bite-sized pieces and eaten from a spoon, or as finger foods). There is some evidence to suggest that there may be a critical window for introducing lumpy solid foods, and that failure to introduce such foods by approximately 9 to 10 months of age is associated with an increased risk of feeding difficulties and reduced consumption of important food groups such as fruits and vegetables later on (24,25). It is therefore important for both developmental and nutritional reasons to give age-appropriate foods of the correct consistency and by a method appropriate for the infant’s age and development.

### Nutritional Adequacy of Exclusive Breast-Feeding

Recommended nutrient intakes for infants during the first 6 months are based on the estimated nutrient intake of healthy term breast-fed infants who are growing normally. A WHO-commissioned review (26) and a more recent EFSA opinion paper (3) concluded that EBF by well-nourished mothers for 6 months can meet the needs of most healthy infants for energy, protein, and for most vitamins and minerals (apart from vitamin K in the first weeks and vitamin D; both of which can be addressed by supplementation (27,28)). The EFSA Panel also noted that the age at which EBF provides insufficient energy, however, cannot be defined by the available data and that the introduction of CF needs to be decided individually. Most available data on the nutritional adequacy of EBF for 6 months comes from mothers and infants who follow this practice; this group is a minority in all populations and caution must be exercised in generalizing findings because these mothers and infants may not be representative of the rest of the population. In an observational study using stable isotopes to measure milk intake and energy content noninvasively, Nielsen et al (29) reported that milk intake increased significantly between 17 and 26 weeks in infants who were EBF, whereas breast milk energy content did not change. All infants in the present study grew normally according to WHO growth charts and there were no obvious signs of “strain” in the breast-feeding process, demonstrating apparent physiological

adaptation with continued EBF. These were, however, a highly selected group of mothers—90% with a university degree—and it is uncertain whether their data can be considered representative of the rest of the population. Two RCTs have reported growth in infants randomized to different duration of EBF. In the Enquiring About Tolerance [EAT] study (13) 1303 British infants who were EBF for at least 3 months were randomized to introduce 6 allergenic CF alongside continued breast-feeding or to follow current UK advice to EBF for 6 months. The median (25th, 75th centile) age at introduction of CF was 16 (15, 17) weeks in the intervention group and 24 (21, 26) in the control group. The intervention group had a higher body mass index (BMI) at 12 months (BMI standard deviation [SD] score 0.40 [SD 0.91] versus 0.29 [0.92] in the control group,  $P=0.05$ ), but no significant difference in anthropometric measurements at the age of 3 years. A small ( $n=100$ ) RCT conducted in a high-income setting in which Icelandic mothers were randomized to 4 versus 6 months EBF, also reported that there was no difference in growth up to 6 months of age (12) or to preschool age (30) between groups.

As recently reviewed by the ESPGHAN CoN (31), infants and young children are at particular risk of iron deficiency because their rapid growth leads to high iron requirements. Two RCTs (7,32) and 2 observational studies (33–35) summarized in Supplemental Digital Content 1, Table 1, <http://links.lww.com/MPG/A836>) have investigated the effect of age at introduction of CF on iron stores and/or risk of iron deficiency and anaemia. Collectively, these data suggest there may be some beneficial effect on iron stores of introducing CF alongside breast-feeding from 4 months, even in populations at low risk for iron deficiency. The situation is, however, complicated because iron stores are dependent on a number of factors and may be optimized by methods other than the earlier introduction of CF, including delayed umbilical cord clamping (as recommended by this committee (31)) and iron supplementation in at-risk infants such as those born preterm or with a low birth weight. Regardless of timing, it is important that the first CF given to infants who are EBF should provide a good source of iron.

Because the composition and health effects of breast milk differ from those of infant formula, on a theoretical basis it may seem sensible to give different recommendations on CF to breast-fed versus formula-fed infants. Despite these theoretical considerations, devising and implementing separate recommendations for the introduction of solid foods for breast-fed infants and formula-fed infants may, however, present practical problems and cause confusion among caregivers.

## Timing of Introduction of Complementary Feeding and Health Outcomes

### Infection

Although numerous studies have investigated associations between breast-feeding and risk of infection, fewer have specifically addressed the effect of EBF duration or the introduction of solid foods, and all but one are observational. The findings are difficult to compare due to differences in definitions and categorization of breast-feeding/EBF, classification and definitions of infection, and methods of ascertainment for both exposure and outcome variables. Nevertheless, collectively the observational studies (9,13,36–42) summarized in Supplemental Digital Content 2, Table 2, <http://links.lww.com/MPG/A837>) suggest that more prolonged EBF may protect against infection and hospitalization for infection in infants in high-income settings with access to clean water supplies and safe CF. Importantly for practice, in the UK Millennium Birth Cohort Study (43), it was shown that it was the introduction of infant formula, not solid foods, that predicted an

increased likelihood of hospital admission. The monthly risk of hospitalization was not significantly higher in those who had received solids compared with those not on solids (for diarrhoea, adjusted OR 1.39, 95% CI 0.75–2.59; for lower respiratory tract infection, adjusted OR 1.14, 95% CI 0.76–1.70), and the risk did not vary significantly according to the age of starting solids. Most recently, the EAT RCT, in which the median duration of EBF was 16 weeks in the intervention group and 24 weeks in the control group, found that parent-reported upper respiratory tract infection in the 4- to 6-month period was significantly higher in the intervention group but there was no significant difference for parent-reported lower respiratory tract infection, bronchiolitis, or other infections, nor in parent-reported diarrhoea between groups (mean [SE] days affected between 4 and 6 months 0.62 [0.06] for the intervention group vs 0.66 [0.08] for controls,  $P=0.7$ ). Interestingly, infants in the intervention group consumed most of their CF as solid foods; use of infant formula was low with only 10.5% consuming >300 mL/day by 6 months (13,44). Thus these findings are consistent with the results from the Millennium Birth Cohort Study in suggesting that the introduction of solids alongside breast-feeding may not result in an increase in infection risk, with the exception of upper respiratory tract infection.

### Allergy

Paradoxically, many higher-income countries have observed rising rates of food allergy, despite advice to restrict and delay exposure to potentially allergenic foods, including cows' milk, egg, fish, gluten, peanut, and seeds. Moreover, countries in which peanuts are commonly used as weaning foods, such as Israel (45) have a low incidence of peanut allergy. These observations have prompted further research on the hypothesis that the development of immune tolerance to an antigen may require repeated exposure, perhaps during a critical early window, and perhaps modulated by other dietary factors including breast-feeding. Systematic reviews have concluded that there is evidence of an increased risk of allergy if solids are introduced before 3 to 4 months, but there is no evidence that delaying the introduction of allergenic foods beyond 4 months reduces the risk of allergy, either for infants in the general population or for those with a family history of atopy (46). Observational data also suggest an increased risk with delayed introduction of certain allergens (47). It is, however, impossible in these studies to exclude reverse causality as an explanation for the observed associations.

Data from a number of randomized trials investigating relations between the timing of introduction of allergenic food and later allergy are now available. A recent systematic review and meta-analysis (48) concluded that there was moderate-certainty evidence from 5 trials (1915 participants) that early egg introduction at 4 to 6 months was associated with reduced egg allergy risk (risk ratio [RR] 0.56 [95% CI 0.36–0.87],  $P=0.009$ ), with similar findings in studies undertaken in populations at normal-risk, high-risk, and very high-risk of allergy. Two of the trials reported that infants first exposed to egg in raw pasteurized form may experience severe allergic reactions due to prior sensitization, but this was not reported in trials using cooked or heated egg.

The meta-analysis also concluded that there was moderate-certainty evidence from 2 trials (1550 participants; 1 normal-risk [13 (EAT)], 1 high-risk (49) [learning early about peanut allergy (LEAP)]) that early peanut introduction at 4 to 11 months was associated with reduced peanut allergy risk (RR 0.29 [95% CI 0.11–0.74],  $P=0.009$ ). Follow-up of children from the LEAP trial at age 6 years, after a 12-month period of peanut avoidance, found no increase in the prevalence of peanut allergy in the intervention group (50). Based on this trial, interim advice from 10 International

Paediatric Allergy Associations recommended that infants at high risk of peanut allergy as defined in the LEAP study should be exposed early to peanut (51) following evaluation by an appropriately trained specialist. With regard to timing of introduction of peanut, although infants in the LEAP trial were recruited between 4 and 11 months, a post hoc analysis indicated that the percentage of subjects with positive skin prick test results progressively increased as the age at enrolment increased (52); thus, the introduction of peanut closer to the age of 4 to 6 months resulted in introduction to more nonsensitized infants with a reduced risk of reacting to peanut.

The third conclusion of the meta-analysis was that there was low- to very-low certainty evidence that early fish introduction was associated with reduced allergic sensitization and rhinitis. No associations were identified between the age at introduction of allergenic foods and other allergic or autoimmune diseases. The authors concluded that the systematic review findings should not automatically lead to new recommendations to feed egg and peanut to all infants, and there are a number of issues to consider in practice, including acceptability to parents and logistical aspects of screening high-risk infants. The findings are, however, consistent with advice that there is no need to delay the introduction of allergenic foods after 4 months. Importantly, the EAT study showed that the early introduction (from 3 to 4 months) of 6 allergenic foods in normal-risk infants was safe and had no apparent detrimental effect on breast-feeding; >96% of infants in both intervention and control groups were still breast-feeding at 6 months and >50% at 12 months (44).

### Celiac Disease

Celiac disease (CD) is a disorder in which consumption of gluten in a genetically susceptible individual results in an autoimmune reaction affecting the gut and other organs. It affects approximately 1% to 3% of the general population in most parts of the world, except for populations such as in Southeast Asia in which the human leukocyte antigen risk alleles (human leukocyte antigen-DQ2 and/or DQ8) are rare. There has been considerable discussion on whether infant feeding practices—notably the age at introduction of gluten and breast-feeding—can prevent the occurrence of CD. In 2008, based on the available evidence obtained exclusively from observational studies, the ESPGHAN CoN concluded that it is prudent to avoid both early (<4 months of age) and late ( $\geq 7$  months of age) gluten introduction and to introduce gluten while the infant is still being breast-fed, because this may reduce not only the risk of CD, but also type 1 diabetes mellitus and wheat allergy (2). Two recent RCTs, however, examined the effect of the age of gluten introduction on the risk of developing CD autoimmunity or CD during childhood in children at genetic risk for CD. Evidence from these RCTs showed that the age of gluten introduction into the infant's diet affected the incidence of each during the first 2 years, but not the cumulative incidence and prevalence of CD during childhood, thus indicating that primary prevention of CD through varying the timing of introduction of gluten is not possible at the present time (53,54). A systematic review that evaluated evidence from prospective observational studies published up to February 2015 also concluded that breast-feeding, any or at the time of gluten introduction, had no preventive effect on the development of CD autoimmunity or CD during childhood (55).

Updated recommendations on gluten introduction in infants and the risk of developing CD during childhood have been recently published by ESPGHAN (56) concluding that neither any breast-feeding nor breast-feeding during gluten introduction has been shown to reduce the risk of CD; gluten may be introduced into the infant's diet anytime between 4 and 12 months of age; and based on observational data pointing to the association between the amount of gluten intake and risk of CD, consumption of large

quantities of gluten should be avoided during the first weeks after gluten introduction and during infancy. The optimal amounts of gluten to be introduced at weaning have, however, not been established. Although the risk of inducing CD through a gluten-containing diet exclusively applies to persons carrying at least one of the CD risk alleles, since genetic risk alleles are generally not known in an infant at the time of solid food introduction, the recommendations apply to all infants.

### Type 1 Diabetes Mellitus

A recent systematic review (57) on the possible relation between infant feeding practices and the later development of type 1 diabetes identified 9 publications. Breast-feeding at the time of gluten introduction, as compared to gluten introduction after weaning, did not reduce the risk of developing type 1 diabetes autoimmunity or type 1 diabetes. In children at high risk of developing type 1 diabetes, gluten introduction at <3 months compared with gluten introduction at >3 months of age was associated with increased risk of type 1 diabetes autoimmunity, but beyond 3 months the age of gluten introduction had no effect on the risk of developing type 1 diabetes. The evidence came mainly from observational studies, highlighting the need for more robust data from RCTs.

### Growth and Body Composition

RCTs comparing infant growth in subjects randomized to 4 versus 6 months EBF in Honduras (58) and Iceland (12) reported no short-term effect, consistent with the findings from a randomized trial of introduction of solid foods at 4 versus 6 months of age in formula-fed infants (15). Data on the effects of age at introduction of CF and growth or obesity outcomes beyond 12 months of age come almost exclusively from observational studies. The interpretation of these data is complicated by the fact that infant feeding practices may themselves be influenced by infant growth and energy intake, because infant weight, weight gain, and energy intake have been found to predict earlier age at introduction of solid foods (59). A recent systematic review (60) identified 26 eligible studies and concluded that the majority, including the only RCT and 5 high-quality studies with robust adjustment for confounders, showed no association between age at introduction of solids and later anthropometry or risk of obesity. Evidence from 2 large, good-quality studies, however, suggested increased later obesity risk associated with early introduction of solids (<4 months) and a third good-quality study confirmed this association in formula-fed but not breast-fed infants. None of the 4 good-quality studies provided evidence for any clinically relevant protective effect of delaying solid introduction from 4 to 6 to >6 months of age. Consistent with this, follow-up data collected up to preschool age from Icelandic infants randomized to 4 compared with 6 months of EBF also reported no significant difference in anthropometric measures or in the risk of overweight and obesity between groups (30), whereas data from the EAT RCT showed higher BMI in the intervention group at 12 months (BMI SD score 0.40 [SD 0.91] vs 0.29 [0.92]) in the control group,  $P = 0.05$ , but no significant difference in anthropometric measurements at the age of 3 years (13).

### Neurodevelopment

The critical period during which the dietary supply of specific nutrients may influence the maturation of cortical function and specifically whether this window extends into the CF period, is unknown. Follow-up of Icelandic infants randomized to 4 versus 6

months of EBF reported no significant difference in developmental outcomes on routine preschool screening tests or parent-report measures (Parent’s Evaluation of Developmental Status questionnaire questionnaire at 18 months and Parent’s Evaluation of Developmental Status questionnaire plus Brigance Screens-II at 30–35 months) between groups (61). Similarly, in an observational analysis, children from the large PROBIT study who were EBF for 3 to 4 versus 6 months did not differ in their IQ measured at the age of 6 years (62).

## CONTENT OF THE COMPLEMENTARY FEEDING DIET AND EFFECT ON HEALTH OUTCOMES

### Nutrient Requirements During Complementary Feeding

Nutrient requirements for infants between 6 and 12 months of age are based on data from a combination of sources including the observed nutrient intakes of infants who are apparently healthy and growing normally, and a factorial approach (16). Requirements from CF are calculated as the difference between the nutrients provided by breast milk and the estimated total requirement. This approach may, however, be problematic because most infants, especially in higher-income populations, do not receive breast milk during the second 6 months of life. The nutrients provided by infant formulas and follow-on formulas differ from those provided by breast milk during this period—notably for protein and iron—and therefore the theoretical amount that needs to be provided by CF will vary. Thus the infant’s main source of milk is an important determinant of the amount of nutrients that are required from CF.

Fat intake is an important determinant of energy supply, and energy requirements remain high throughout the first year of life. A low-fat CF diet will typically result in a diet with a low energy density, which may mean that the total amount of food needed to meet energy requirements is so large that the infant is unable to eat enough (63,64). Conversely, a high-fat diet (with fat content >50%) may lead to reduced dietary diversity. An EFSA panel recommended that fat should constitute 40% of energy intake from 6 to 12 months, including 4% of energy from linoleic acid, 0.5% from alpha-linolenic acid, and 100 mg/day from docosahexaenoic acid (DHA) (16).

By 6 months of age, the infant’s endogenous iron stores will have been used up and the need for exogenous iron increases rapidly as the physiological requirement per kg body weight becomes greater than later in life. Based on theoretical calculations, the ESPGHAN CoN recently suggested the dietary iron requirement to be 0.9 to 1.3 mg · kg<sup>-1</sup> · day<sup>-1</sup> from 6 to 12 months (31) consistent with recommendations from other authorities for infants ages 6 to 12 months which range from 6 to 11 mg/day (16). The relatively high estimated dietary requirements may not be achievable in practice without using fortified foods, iron-supplemented formulas, or iron supplements. The requirement may, however, be lower if bioavailable sources of iron such as red meat are used. Dietary iron is available in haem and nonhaem forms. Haem iron is found in the haemoglobin and myoglobin of animal foods, notably red meat, liver, and organ meats. Absorption of iron from haem sources is approximately 25% and is not affected by dietary factors such as ascorbic acid, although the haem iron itself may enhance absorption of iron from nonhaem sources. Sources of nonhaem iron include pulses (eg, dried beans, peas, lentils, chickpeas), nuts, green leafy vegetables, dried fruit, and foods fortified with iron such as certain breads and cereal-based products. Facilitators of absorption include human milk, meat proteins, ascorbic and citric acids, and fermented vegetable products, whereas inhibitors include cocoa, polyphenols, phytates, tannins, dietary fibre, calcium, and cows’ milk (65).

TABLE 1. Nutrients that may become deficient in different vegetarian and vegan diets

Nutrient	Type of diet			
	Vegetarian			
	Lacto-ovo	Lacto	Ovo	Vegan
Iron	X	x	x	x
Zinc	X	x	x	x
Calcium			x	x
B12			x	x
B2				x
Vitamin D	X	x	x	x
Vitamin A				x
n-3 fats (DHA)	X	x	x	x
Protein	X	x	x	x

DHA = docosahexaenoic acid.

Studies investigating the effects of different CF practices and sources of iron on iron status are summarized in Supplemental Digital Content 1, Table 1, <http://links.lww.com/MPG/A836> (66–69). As summarized in the CoN position paper on iron requirements of infants and toddlers (31), there is some evidence that CF with a high meat content increase haemoglobin concentration. One RCT reported that a high meat intake had a similar effect on iron status to iron-fortified cereals, even though the daily iron intake from cereals was 5 times greater (67). Pilot data from the same study, however, suggested possible effects of the intervention on the microbiota raising the hypothesis that providing large amounts of iron in a form which is not easily absorbed could have adverse consequences. Observational studies also suggest that infants who consume large volumes of cows’ milk have a greater risk of iron deficiency and iron deficiency anaemia, which is likely to reflect both the low iron content and bioavailability of iron from cows’ milk and the displacement of other iron-rich foods (70,71).

## Growth and Body Composition

### Macronutrient Intake

Overconsumption of energy-dense CF may induce excessive weight gain in infancy, which has in turn been associated with a 2- to 3-fold higher risk of obesity in school age and childhood (72,73). A literature review considering the quantity and quality of fat intake between 6 and 24 months concluded that the amount of fat does not show associations with later health outcomes, and that relatively high-fat diets do not seem to be harmful. It also highlighted the need for further research on the effects of fat quality on health outcomes (74).

A systematic review of protein intake from 0 to 18 years of age and its relation to health conducted for the fifth Nordic Nutrition Recommendations (75) with literature reviewed up to December 2011, concluded that there was convincing (grade 1) evidence that higher protein intake in infancy and early childhood was associated with increased growth and higher BMI in childhood, particularly when the energy percentage from protein (PE%) at 12 months of age was between 15% and 20%. A mean intake of 15 PE% was proposed as the upper limit at 12 months on the basis that there is no risk of an inadequate protein intake at this level, and that this is also comparable to the protein content of an average diet among children in the Nordic countries during the first few years. Since this review, data from a 6-year follow-up of the European Childhood Obesity project reported that children randomized to infant formula and

follow-on formula with a lower protein content during the first year of life had lower BMI and a reduced risk of obesity than children randomized to higher protein formulas (with a protein content higher than that found in most current formulas); the greatest effect was seen in those with the highest BMI percentiles suggesting a potential interaction with either genetic or metabolic factors (76). Data from the observational Gemini twin cohort also show a positive association between PE% at mean 21 months and mean weight and BMI gain between 21 months and 5 years (77).

An important issue, with practical implications, is whether all protein sources have similar effects on growth and adiposity. The Nordic review concluded that there was limited-suggestive evidence (grade 3) that the intake of animal protein, especially from dairy, has a stronger positive association with growth than does vegetable protein, and the association found between higher intake of milk and increased levels of serum Insulin-like growth factor 1 (IGF-1) was considered to strengthen this finding (75). This has relevance for the protein content of infant formulas and follow-on formulas which are frequently used during the CF period in high-income countries. Given increasing evidence that the protein intake of infants in high-income countries generally exceeds recommendations, and that this may be causally related to an increased risk of obesity, the recent EFSA scientific opinion on the composition of infant formulas and follow-on formulas (78) recommended that the minimum level of protein in cows' milk-based infant formulas and follow-on formulas should remain at 1.8 g/100 kcal, but that the upper limit for protein content of follow-on formulas should be reduced from 3.0 to 2.5 g/100 kcal. The minimum permitted protein level for infant formulas still provides more protein than breast milk beyond 3 to 4 months of age and studies are now being performed evaluating whether the protein content of infant formulas for use beyond approximately 3 months of age can be safely reduced further using high-quality sources. Although further studies and longer follow-up is required, the findings from 2 trials (79,80) suggest that use of lower protein formulas with high-quality sources of protein alongside CF may be beneficial in terms of weight gain and subsequent obesity risk.

A recent article reporting data from the large prospective UK Avon Longitudinal Study of Parents And Children (ALSPAC) cohort investigated both the macronutrient intake and the type of milk fed at 8 months in relation to subsequent growth at 14 time points up to 10 years of age (81). After adjustment for potential confounding factors (maternal education, smoking, and parity), children with an intake of cows' milk >600 mL/day at 8 months were significantly heavier from 8 months to 10 years than those who received predominantly breast milk. Those who received >600 mL/day of infant formula at 8 months were also heavier and taller than those who received breast milk up to 37 months of age but not beyond this. At 8 months, infants receiving high volumes of cows' milk had significantly higher mean energy, protein, and fat intakes than breast-fed infants. Nonmilk energy intake was lower in the cows' milk and formula groups but this did not compensate for the additional energy consumed from the milk. Differences in macronutrient intakes had largely disappeared by 18 months of age. Interestingly, differences in later growth between cows' milk and breast-fed infants remained after adjusting for protein and energy intakes measured at each follow-up, suggesting that early intakes may have programmed the later outcomes, perhaps via stimulatory effects of cows' milk protein on IGF-1.

### **Dietary Patterns and Later Growth or Body Composition**

An approach increasingly adopted in recent years has been to derive measures describing dietary patterns rather than the intake of

individual nutrients or foods. For example, principal component analysis (PCA) can be used to identify dietary patterns that reflect foods that tend to be consumed together. Another approach is the use of dietary indices, which consider dietary variety, nutrient adequacy, or, most commonly, adherence to dietary guidelines to provide a summary measure reflecting diet quality. Using food frequency questionnaire data obtained at 6 and 12 months in 6065 infants from the British ALSPAC cohort, Golley et al (82) derived a Complementary Feeding Utility Index (CFUI) based on 14 components of the diet considered to reflect adherence to national and international guidance on optimal infant feeding. The CFUI score was shown to discriminate across food intake, nutrient intake, and socioeconomic patterns, and was associated with dietary patterns classified using PCA at the age of 3 years. There was a weak association between a higher (more favourable) CFUI score and lower waist circumference measured at the age of 7 years, but no association with BMI (83).

Using a similar approach, Robinson et al (84) used PCA to derive an "infant guideline" pattern of dietary intake in 1740 infants from the Southampton Women's Survey, which reflected high adherence to advice on CF, including a high intake of fruit and vegetables and use of home-prepared foods. At 4-year follow-up (n = 536), those in the top quartile for "infant guideline" pattern in infancy had significantly higher lean mass than those in the lowest quartile, after adjusting for confounding factors, which included current height and the duration of breast-feeding.

Meyerkort et al (85) assessed associations between dietary quality at the age of 1 year and later BMI in 2562 children from the Western Australian (Rayne) birth cohort. Dietary quality was assessed by the EAT diet score, which included 7 components: whole grain, vegetables, fruits, meat ratio, dairy, snack foods, and sweetened beverages; a higher score represented greater consumption of desirable foods and lower consumption of foods that are not recommended. There were no consistent associations between EAT score and BMI at 3, 5, 8, 10, 14, or 17 years.

## **Neurodevelopment**

### **Iron Intake**

In the recent ESPGHAN CoN position paper it was concluded that evidence from intervention trials testing iron supplementation of follow-on formulas show conflicting results on cognitive outcomes (31). Two studies have reported on the effects of meat intake during CF on later development. Meat is a good source of iron and zinc, but also arachidonic acid, which is important in brain development. In a prospective observational study using 7-day weighed food diaries to collect data at 4, 8, 12, and 16 months, Morgan et al (86) found positive associations between meat intake between both 4 and 12 and 4 and 16 months and Bayley psychomotor development scores at 22 months. In contrast, Krebs (67) reported data from a randomized trial comparing pureed beef and iron-fortified cereals given as the first complementary food to 5 to 7 months breast-fed American infants, and observed no significant difference in Bayley mental or motor development scores at 12 months.

### **Long-Chain Polyunsaturated Fatty Acids Intake**

Long-chain polyunsaturated fatty acids (LCPUFA), notably docosahexaenoic acid (DHA), play an important role in brain development. It is known that DHA status tends to decline during the complementary period when the intake of breast milk or LCPUFA-supplemented formula decreases. One study showed that breast-feeding, fatty acid dehydrogenase genotype and fish intake

are important determinants of blood DHA status in late infancy, with each 10-g increment in fish intake being associated with a 0.3 FA% increase in DHA status (87). Four studies have investigated the effect of supplying additional LCPUFA or precursor fatty acids in CF, demonstrating effects on red cell or plasma fatty acid status (88–91), although only 1 study incorporated a clinical outcome; breast-fed infants randomized to receive 1 jar per day of weaning foods containing DHA-enriched egg yolk had a greater increase in visual acuity resolution by 12 months than those fed control baby food. Two additional trials investigated the role of LCPUFA supplementation of infant formulae during the CF period, with infants randomized to LCPUFA-supplemented versus unsupplemented formulae when they stopped breast-feeding at either 6 weeks (92) of age or 4 to 6 months (93) of age. Those who received the supplemented formula had significantly better visual acuity up to 1 year of age than did those weaned to unsupplemented formula.

Collectively, these studies suggest that the intake of oily fish, DHA, or precursor fatty acids during the CF period may influence DHA status, with some evidence for effects of DHA-enriched egg yolk or supplemented follow-on formula on short-term visual function. This is important given the conclusions of the EFSA Panel (16) that intakes of n-3 PUFAs are critical in some infants and young children in Europe, and that some subgroups in this population may be at risk of inadequacy.

### Dietary Patterns

Using the CFUI (described previously), Golley et al (83) reported that, after adjusting for confounding factors, a 0.1 increase in the CFUI score was associated with a 1 to 2 point higher total, verbal, and performance IQ at the age of 8 years in 4429 children from the ALSPAC cohort. Further analyses adjusting for maternal IQ in a subgroup of 1776 children showed that a 0.1 increase in CFUI was associated with a 1.27 point increase in full scale IQ (95% CI 0.41–2.13) and a 1.55 (0.67–2.43) point increase in verbal IQ.

Using data from the same cohort, with dietary patterns classified using PCA, Smithers et al (94) also reported associations with IQ at the age of 8 years. Specifically, the “discretionary” pattern (biscuits, chocolate, sweets, soda, and crisps) was associated with 1 to 2 point lower IQ, whereas a “breast-feeding” pattern at 6 months and a “homemade contemporary” pattern at 15 and 24 months were associated with 1 to 2 point higher IQ.

Gale et al (95), using data from 241 children from the Southampton Women’s study reported that the “Infant guideline” pattern, indicating high adherence to recommendations for infant feeding as described previously, was associated with higher full-scale and verbal IQ at the age of 4 years, even after adjusting for maternal IQ.

Nyaradi et al (96) assessed associations between dietary quality at the age of 1 year and cognitive outcomes at age 10 years in 1455 children from the Western Australian (Rayne) birth cohort. Higher dietary quality scores at age 1 year were associated with higher measures of verbal and nonverbal IQ, with specific positive associations for fruit intake and negative associations with intake of sugar-sweetened beverages. In further analyses (97), a higher dietary quality score at the age of 1 year was also associated with higher scores for school achievement (maths, reading, writing, and spelling) at the ages of 10 and 12 years. These associations persisted after adjusting for confounders, although maternal IQ was not available.

### Cardiovascular Disease

Although there is increasing evidence for an adverse effect of rapid infant growth on later cardiovascular outcomes, less is known

about whether diet during the CF period may influence these outcomes. Follow-up of children from the PROBIT trial at 6.5 years reported no difference in blood pressure between those EBF for 3 to 4 versus 6 months (61). The specific role of LCPUFA intake during the CF period on later blood pressure was evaluated by a study in which 9-month-old infants were randomized to a fish oil supplement for 3 months or no supplement (98). Those receiving fish oil had significantly lower systolic blood pressure at 12 months of age (by 6.3 mmHg [95% CI 0.9–11.7]) but also higher plasma cholesterol (by 0.51 mmol/L [0.07–0.95]) and low-density lipoprotein-cholesterol (by 0.52 mmol/L [0.02–1.01]). Golley et al (83) reported a negative association between the CFUI in the ALSPAC cohort and diastolic blood pressure at 8 years of age, but no statistically significant association with plasma cholesterol.

### Dental Caries

Sugar intake is the major dietary risk factor for the formation of dental caries. Sucrose is the most cariogenic sugar because it can form glucans that enable bacterial adhesion to teeth and limit diffusion of acid and buffers in the plaque (99). Nutrition education and counselling aimed at reducing caries in children is directed at teaching parents the importance of reducing high-frequency exposure to apparent and hidden sugars (see below). Advice generally includes avoiding consumption of juice or other sugar-containing drinks in bottles or training cups, discouraging the habit of a child sleeping with a bottle, limiting cariogenic foods to mealtimes, and establishing good dental hygiene starting when the first tooth erupts.

## METHOD OF FEEDING

### Development of Taste and Food Preferences

A considerable amount of learning about food and eating occurs during the transition from an exclusive milk diet to the diet consumed in early childhood. Infants have innate, evolutionary-driven preferences for sweet and salty tastes, which would have been advantageous in situations in which energy and mineral-dense foods were scarce but which are likely to be a disadvantage in current obesogenic environments. They also have an innate dislike of bitter taste, which may indicate potentially toxic foods (100). There is, however, evidence that these predispositions can be modified by early experience, and parents thus play an important role in establishing good dietary habits.

A recent systematic review (101) including observational studies and RCTs investigated the effect of exposure to specific tastes in utero or during early infancy via breast milk or formula on later taste acceptance. Overall, there was evidence for programming of the acceptance of bitter and specific tastes. The review did not focus specifically on exposures during the CF period, although studies were identified that assessed exposure to sweet, salty, sour, and specific tastes with apparently similar numbers reporting either no change or increased intake following prior exposure to the different tastes. Beauchamp and Moran (102) examined the preference for sweet solutions versus water in approximately 200 infants. At birth, all of the infants preferred sweet solutions to water, but by 6 months of age, the preference for sweetened water was linked to the infants’ dietary experience. Infants who were routinely fed sweetened water or honey by their mothers (25%) maintained their preference for sweetened water, whereas this preference was no longer apparent in infants who were not exposed. There was no apparent effect of breast- or formula-feeding on sugar preferences at 6 months. Stein et al (103) found that early dietary experience was related to salt acceptance, with only those infants



previously exposed to starchy table foods ( $n = 26$ ; defined as cereals or processed grain products not labelled as infant foods) preferring salty solutions at 6 months of age ( $P = 0.007$ ). Infants eating starchy table foods at 6 months were more likely to lick salt from the surface of foods at preschool age ( $P = 0.007$ ) and tended to be more likely to eat plain salt ( $P = 0.08$ ). Preference for sweet taste at follow-up was not related to early feeding experience and early exposure to home-prepared fruit was not associated with salt-directed or sweet-directed behaviours.

Thus it appears that parents and caregivers can modify the innate preferences of their infant, but these preferences (good or bad) will only be reinforced if the infant continues to be exposed to the food. Preferences for healthy foods can be developed, for example, repeated early exposure to the taste of some vegetables enhances liking for those vegetables with effects persisting up to 6 years later (104,105). Infants exposed to an intervention with greater variety of vegetables during CF also consumed a greater variety at 6-year follow-up (105). This emphasizes the importance of optimizing dietary variety and including healthy foods during CF. Importantly, an infant may need to receive a new flavour 8 to 10 times before accepting it, and parents should therefore be encouraged to persist in offering infants a new food as long as they continue to accept it, even if the infant's facial expression may suggest it is disliked (104). The addition of salt and sugar to CF should be discouraged.

## Method of Feeding

Parents play a major role during the CF process, making decisions on the timing and content of the diet, and also the way in which the infant is fed, setting rules and expectations, and providing a role model. In addition to the timing and content of the CF diet, it is likely that the way in which foods are given to the infant, and the interaction between parent and infant during CF may influence outcomes such as food and dietary preferences and appetite regulation.

In recent years, infants in higher-income settings have generally been spoon-fed with their first CF in the form of purees, with subsequent introduction of semisolid and finger foods. Alongside recommendations to delay the introduction of solid foods until 6 months, there has, however, been an increasing tendency to avoid the initial "puree" stage altogether and progress straight to finger foods (106). In the "baby-led weaning" method, the infant feeds himself hand-held foods instead of being spoon-fed by an adult, sharing family foods and mealtimes. This approach may provide the infant with greater control over his intake and encourage more responsive parenting. It has been suggested that this may result in better eating patterns and reduce the risk of overweight and obesity. Given the self-selected nature of parents and infants who currently follow this practice, and the limited observational data available, it is, however, not possible to draw conclusions. Furthermore, data are lacking on whether infants who are fed CF using this approach obtain sufficient nutrients, including energy and iron, or eat a more diverse range of foods (106). These issues ideally need to be tested in an RCT. Recently, a modified version of baby-led weaning, called Baby Led Introduction to SolidS has been developed, which specifically highlights the importance of introducing iron and energy-rich CF and avoiding foods likely to constitute a choking hazard (107). A small observational pilot study suggested that this approach was feasible and had some benefits in increasing the range of iron-rich foods consumed by the infants.

## Parenting Style

It is increasingly recognized that parenting style, defined as the way parents interact with a child in terms of attitudes and

behaviours across different aspects of parenting, including feeding can influence the infant's feeding behaviour. Blissett (108) reviewed the literature examining relations between parenting styles, feeding behaviours, and the fruit and vegetable consumption of preschool children. An authoritative feeding style (typified by emotional warmth and responsiveness but high expectations for children's dietary adequacy and behaviour) accompanied by practices such as modelling consumption of fruit and vegetables, making these foods available within the home, moderately restricting unhealthy alternative snack foods, and encouraging children to try fruit and vegetables, is associated with better consumption in the childhood years. Most published studies are, however, observational and involved toddlers rather than infants; intervention studies are ideally needed to determine whether changing parental feeding style and practices during CF can favourably influence offspring food choice and feeding behaviour.

A recent systematic review of RCTs that aim to reduce the risk, either directly or indirectly, of overweight and obesity in infancy and early childhood (109) concluded that the most promising obesity prevention interventions for children younger than 2 years of age are those that focus on diet and responsive feeding, including education for carers on recognizing infant hunger and satiety cues and nonfood management of infant behaviour.

## SPECIFIC DIETARY PRACTICES AND FOODS

### Home-Made Versus Commercial Complementary Foods

Complementary foods can be home-prepared or commercially produced. In practice, the relative merits will depend on the quality of home-prepared foods that are offered. Well-prepared home-made foods may offer the opportunity for a greater variety of culturally appropriate flavours and textures, with greater energy density (110,111). There is, however, also the potential for home-made foods to be unsuitable, for example, with the addition of sugar or salt. Food preparation and cooking methods may also alter nutrient content. Two studies have highlighted a lack of vegetable variety in commercially prepared foods (112,113), with a predominance of sweet vegetables such as carrot and sweet potato rather than bitter tasting vegetables. In the German DONALD cohort, using 3-day weighed diaries in infancy and at 3 to 4 and 6 to 7 years, a higher percentage intake of commercial CF was also associated with decreased vegetable intake in infancy and, in boys, with decreased fruit and vegetable intake at preschool and school age (114). These findings suggest the need to emphasize to parents the importance of offering a variety of vegetables, including bitter tasting ones, as a component of the diet.

Although beyond the scope of this article, safety is an important issue during CF, and carers should receive advice on the safe preparation, feeding and storage of complementary foods to avoid contamination and the proliferation of pathogens, which are major underlying causes of childhood diarrhoea (1), and choking from large food items.

### Vegetarian and Vegan Diets

Particular care is required to ensure an adequate nutrient intake during CF when vegetarian or vegan diets are used, and the nutrients that may be insufficient increases as the diet becomes more restricted as shown in Table 1. Vegan diets have generally been discouraged during CF. Although theoretically a vegan diet can meet nutrient requirements when mother and infant follow medical and dietary advice regarding supplementation, the risks of failing to follow advice are severe, including irreversible cognitive

damage from vitamin B<sub>12</sub> deficiency, and death. If a parent chooses to wean an infant onto a vegan diet this should be done under regular medical and expert dietetic supervision and mothers should receive and follow nutritional advice (115). Mothers who are consuming a vegan diet need to ensure an adequate nutrient supply, especially of vitamins B<sub>12</sub>, B<sub>2</sub>, A, and D, during pregnancy and lactation either from fortified foods or supplements. Careful attention is required to provide the infant with sufficient vitamin B<sub>12</sub> (0.4 µg/day from birth, 0.5 µg/day from 6 months) and vitamin D, and iron, zinc, folate, n-3 fatty acids (especially DHA), protein, and calcium, and to ensure adequate energy density of the diet. Tofu, bean products, and soy products can be used as protein sources. Infants who are not receiving breast milk should receive a soy-based infant formula.

## Specific Foods to Avoid

Salt and sugar should not be added to complementary foods, and the intake of free sugars (sugars added to foods and beverages by the manufacturer, cook, or consumer, and sugars naturally present in syrups and fruit juices) should be minimized. Sugar-sweetened beverages should be avoided.

Honey should not be introduced before 12 months of age unless the heat-resistant spores of *Clostridium botulinum* have been inactivated by adequate high-pressure and high-temperature treatment, as used in industry (116) since the consumption of honey has been repeatedly associated with infant botulism.

Fennel, which is sometimes used in the form of a tea or infusion as a treatment for infant colic and digestive symptoms, contains estragole, which is a naturally occurring genotoxic carcinogen. Although occasional exposure to fennel products in adults is unlikely to be of concern, an expert panel of the European Medicines Agency concluded that fennel oil and fennel tea preparations are not recommended in children younger than 4 years of age due to the lack of adequate safety data (117).

To reduce exposure to inorganic arsenic, which is considered a first-level carcinogen, this Committee previously recommended that rice drinks should not be used for infants and young children (118).

## CONCLUSIONS

Having reviewed the available evidence the ESPGHAN CoN concludes:

### Regarding the Timing of Complementary Feeding

- Gastrointestinal and renal functions are sufficiently mature by approximately 4 months (17 weeks, beginning of the 5th month) to enable term infants to process CF, and by 4 to 6 months (26 weeks, beginning of the 7th month) they will have attained the necessary motor skills to cope safely with complementary foods. It is important for developmental and nutritional reasons to give age-appropriate foods of the correct consistency and by a method appropriate for the infant's age and development.
- EBF by a healthy mother can meet the nutrient requirements of healthy-term infants for most nutrients for approximately 6 months, although the lack of evidence from RCTs means that it is not certain whether this applies to all mothers and infants. Some infants may require additional energy or iron before 6 months. Delayed clamping of the umbilical cord will improve infant iron stores and reduce the likelihood of additional iron being required before 6 months.

- More prolonged EBF may be associated with a reduced risk of gastrointestinal and respiratory infections, and hospitalization for infections, including for infants living in high-income countries.
- There may be an increased risk of allergy if solids are introduced before 3 to 4 months. There is, however, no evidence that delaying the introduction of allergenic foods beyond 4 months reduces the risk of allergy, either for infants in the general population or for those with a family history of atopy.
- Infants at high risk of peanut allergy (those with severe eczema, egg allergy, or both as defined in the LEAP study) should have peanut introduced between 4 and 11 months; following evaluation by an appropriately trained professional.
- The timing of the introduction of complementary foods at 4 or 6 months has not been shown to influence growth or adiposity during infancy or early childhood, although introduction before 4 months may be associated with increased later adiposity.

### Regarding the Content of the Diet During Complementary Feeding

- Gluten may be introduced into the infant's diet when CF is started, anytime between 4 and 12 months of age. Based on observational data consumption of large quantities of gluten should be avoided during the first weeks after gluten introduction and during infancy. The optimal amounts of gluten to be introduced at weaning have, however, not been established.
- Neither any breast-feeding nor breast-feeding during gluten introduction has been shown to reduce the risk of CD.
- Neither gluten introduction after 3 months of age or breast-feeding at the time of introduction of gluten influence the risk of type 1 diabetes.
- A high protein intake during CF may increase the risk of subsequent overweight or obesity, especially in predisposed individuals, and the mean protein:energy% should not be >15%. Large volumes of cows' milk are associated with high intakes of energy, protein, and fat and with low iron intake.
- Iron requirements are high during the CF period and there is a need for iron-rich foods, particularly for breast-fed infants.
- Data are insufficient to make specific recommendations for choices or composition of CF based on cognitive or cardiovascular outcomes.
- It is not possible to alter infants' innate preferences for sugar and salty tastes, and dislike of bitter tastes, but parents may be able to modify subsequent preferences by offering complementary foods without added sugars and salt, and by the timely introduction of a variety of flavours, including bitter green vegetables.
- Vegan diets with appropriate supplements can support normal growth and development. Regular medical and dietetic supervision should be given and followed to ensure nutritional adequacy of the diet. The consequences of failing to do this can be severe and include irreversible cognitive impairment and death.

### Regarding Feeding Methods

- There is currently insufficient evidence to draw conclusions about the most appropriate method of feeding in terms of spoon-feeding compared with self-feeding. Parents should, however, be

encouraged to adopt a responsive style of parenting and understand how to recognize their infant's hunger and satiety cues. Feeding to comfort or as a reward should be discouraged.

## Recommendations

Based on these conclusions and considering current practice, the ESPGHAN CoN makes the following recommendations regarding CF. These recommendations are made for infants living in Europe, typically in relatively affluent populations with access to clean water and good healthcare. It is, however, important to ensure that advice reaches high-risk groups such as socioeconomically disadvantaged families and immigrant families, and to adapt advice for individual infants taking into account their circumstances and environment. It is also important to recognize that contact with parents to provide advice on CF also provides the opportunity to emphasize broader aspects of a healthy lifestyle for the infant, including play opportunities that promote physical activity.

### Definition

- To avoid confusion, the term "CF" (complementary foods) should include all solid and liquid foods other than breast milk or infant formula.

### Timing

- Exclusive or full breast-feeding should be promoted for at least 4 months (17 weeks, beginning of the 5th month of life) and exclusive or predominant breast-feeding for approximately 6 months is considered a desirable goal.
- Complementary foods (ie, solid foods and liquids other than breast milk or infant formula) should not be introduced before 4 months but should not be delayed beyond 6 months.

### Content

- Recommendations on specific types of complementary foods should take into consideration traditions and feeding patterns in the population. Infants should be offered a varied diet including foods with different flavours and textures including bitter-tasting green vegetables.
- Although there are theoretical reasons why different complementary foods may have particular benefits for breast-fed or formula-fed infants, attempts to devise and implement separate recommendations for breast-fed and formula-fed infants are likely to be confusing and is therefore not recommended.
- Continued breast-feeding is recommended along with the introduction of CF.
- Cows' milk is a poor iron source and provides excess protein, fat, and energy when used in large amounts. It should not be used as the main drink before 12 months of age, although small volumes may be added to complementary foods.
- Allergenic foods may be introduced when CF is commenced any time after 4 months (17 weeks).
- Infants at high risk of peanut allergy (those with severe eczema, egg allergy, or both as defined in the LEAP study) should have

peanut introduced (eg, as smooth peanut butter) between 4 and 11 months, following evaluation by an appropriately trained professional.

- Gluten may be introduced between 4 and 12 months of age. Consumption of large quantities of gluten should be avoided during the first weeks after gluten introduction and also during infancy.
- All infants should receive iron-rich complementary foods including meat products and/or iron-fortified foods. The strategy used will depend on the population, cultural factors, and available foods but can include iron-fortified foods or infant formulas, foods naturally rich in iron such as meat, or iron supplements.
- No sugar or salt should be added to complementary foods and fruit juices or sugar-sweetened beverages should be avoided.
- Vegan diets should only be used under appropriate medical or dietetic supervision to ensure that the infant receives a sufficient supply of vitamin B<sub>12</sub>, vitamin D, iron, zinc, folate, n-3 LCPUFA, protein, and calcium, and that the diet is sufficiently nutrient and energy dense. Parents should understand the serious consequences of failing to follow advice regarding supplementation of the diet.

### Method

- Foods should be of an appropriate texture and consistency for the infant's developmental stage, ensuring timely progression to finger-foods and self-feeding. Prolonged use of pureed foods should be discouraged and infants should be eating lumpy foods by 8 to 10 months at the latest. By 12 months, infants should drink mainly from a cup or training cup rather than a bottle.
- Parents should be encouraged to respond to their infant's hunger and satiety cues and to avoid feeding to comfort or as a reward.

## RESEARCH GAPS AND SUGGESTED AREAS FOR RESEARCH (FOR HIGH-INCOME SETTINGS)

- Introduction of complementary foods in formula-fed infants
- Iron requirements during CF in relation to functional outcomes, including the effect of the type/source of supplementation
- Effect of different protein sources on growth and body composition (milk vs nonmilk)
- Defining the amount of gluten to be introduced with CF and during infancy
- Defining the dose and timing of food allergens to introduce tolerance
- Effect of the method of introducing CF (traditional versus more baby-led) on nutrient intake, choking and health outcomes, especially appetite regulation and growth/obesity outcomes
- Effect of different parenting styles and responsive feeding during introduction of CF on later appetite, food intakes, and obesity outcomes

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