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### **1,000 Days – Meaza Getachew**

Age-appropriate marketing of complementary foods: Given the official mission of EFSA is food safety, which should include consumer protection, it is imperative that all labelling of complementary foods takes into consideration WHO's recommendation of exclusive breastfeeding for a child's first 6 months. While EFSA has stated that this draft scientific opinion should not be interpreted as providing public health recommendations, parents commonly understand indicated ages on product labels as official recommendations to use the product from this age on, thus EFSA's overall conclusion that "The considerations made above may serve as a basis for risk managers to determine an age that can be used for labelling purposes" (line 265) would seriously undermine WHO exclusive breastfeeding recommendations since in the context of this opinion, that could be as early as the 4th month - see line 154 on developmental readiness.

Assessing impact of complementary feeding without regard to exclusive breastfeeding: The introduction of complementary feeding in this recommendation is infants of 4 to 6 months of age, and the EFSA panel states that the assessment "was performed irrespective of whether infants were initially exclusively breast-fed or formula-fed" (line 84). This is problematic given WHO has clarified that exclusively breastfed infants must be the standard, thus when assessing short/long-term health outcomes on infants exclusively breastfed infants must be the control group for the 4-6 month old age group.

### **1.5. Interpretation of the Terms of Reference**

Comment: The authors assert that consideration of the optimal duration of breastfeeding is outside the scope of this mandate. However, a recommendation regarding introduction of complementary foods before six months will by definition result in shorter durations of exclusive breastfeeding.

The central issue is here “appropriate age,” and this term has not been defined by the authors. As noted by the authors (line 209: “also, the fact that, based on the available evidence CFs could be introduced at an early age does not mean that this is necessary or desirable”), the “appropriate age” is not the same as the earliest possible age. Defining the “appropriate age” for the introduction of complementary feeding is directly connected to the optimal duration of exclusive breastfeeding, which is the standard for infant feeding. Three pieces of evidence to consider:

1. The WHO Euro publication (2019) shows the positive health effects (in this case, obesity prevention) of longer exclusive breastfeeding: <https://www.karger.com/Article/FullText/500425>.
2. The SACN report (2018) states very clearly that the optimal duration of exclusive breastfeeding of six months is well established. Earlier introduction of complementary feeding will shorten the duration of exclusive breastfeeding and of any breastfeeding. This has negative effects for both mother and child (Victora et al, Lancet 387, 2016).

The authors themselves state that “considerations of the optimal duration, the health benefits or otherwise of breastfeeding itself are outside the scope of the mandate.” Here it should rely on the SACN report on feeding in the first year of life (see line 665), because the optimal duration of exclusive breastfeeding cannot be ignored when defining an “appropriate age for the introduction of complementary feeding.”

3. Dr. Dewey’s older recommendation (2002) should also be considered: exclusive breastfeeding for six months confers several benefits on the infant and the mother. On a population basis, there is no adverse effect of exclusive breastfeeding for six months on infant growth. Given that growth is generally not improved by complementary feeding before six months even under optimal conditions (i.e., nutritious, microbiologically safe foods) and that complementary foods introduced before six months tend to displace breast milk, Dewey et al. concluded that the potential health benefits of waiting until six months to introduce other foods outweigh any potential risks.

### **3.3. Neuromuscular coordination and neurodevelopment**

There is no foundation for the statement that the appropriate age for the introduction of CF begins at “3-4 months of age” (line 1825). Instead, Naylor and Morrow conclude that “oral motor function is developmentally ready for the introduction of semisolid and solid foods and thereby the discontinuation of exclusive breastfeeding between six and nine months of age.” (Naylor and Morrow 2001)

The data given above are about the time period between four and six months, not three months. The Commission clearly states that no empirical data have been found for this estimation. For developmental determinants, they arrive at the conclusion: “From the available data, this time span extends from between about 3-4 months to around 6 months of age for most term infants.” However, as physicians, we disagree. For example, they focus on the infant’s ability to “accept spoon-fed foods”

(1729) and “opening the mouth in response to a spoon approaching” (1782). In line 1809, they acknowledge that “The skills necessary to consume small amounts of pureed foods will differ from those required to consume more textured, lumpy or finger foods.” Reflexive opening of the mouth to a spoon is not sufficient to demonstrate developmental readiness which also requires the maturation of the immune and gastrointestinal systems. We must also be aware of the increasingly widespread marketing of food pouches for infants to suck on, but it can be squeezed into their mouth too, so no spoon feeding!

The EFSA-Panel states, in line 209: “the fact that, based on the available evidence, CFs could be introduced at an early age does not mean that this is necessary or desirable.” So while early introduction of complementary feeding seems technically possible, it is neither indispensable nor desirable.

It may be possible for some infants to ingest spoon-fed foods before six months; however, the fact that this is possible does not make it beneficial, safe, or without risk. As an analogy, it is possible for girls to become pregnant at menarche; however, it does not logically follow that it is beneficial, safe, or without risk for 12-year-olds to give birth.

### **Overall conclusions**

About labeling, the WHO states: “Messages, including package labels, should not include any image, text or other representation that might suggest use for infants under the age of 6 months (including references to milestones and stages)” (WHA69.7 Guidance on ending the inappropriate promotion of foods for infants and young children 2016). The indicated ages on the labels are commonly understood by parents as more or less official recommendations to use the product from this age on and are used by the industry as such.

The unfortunate result of the EFSA opinion is that it will be possible for producers of complementary food to label their products for a very early age. While in line 5259, the Panel states, “This opinion should not be interpreted as providing public health recommendations for the introduction of CFs,” it also states “The considerations made above may serve as a basis for risk managers to determine an age that can be used for labelling purposes.” The panel explicitly looked for “effects associated with the introduction of CFs before 6 months of age.” In the context of this opinion, based on the section on developmental readiness, that could be “from the 4th month.”

The official mission of EFSA is food safety, which includes consumer protection. For consumer protection, it is essential that the labelling of complementary foods takes into consideration the optimal duration for exclusive breastfeeding of six months. An official recommendation of the European Union should support the WHO-Guidance 69.7 from 2016 and recommend labeling complementary foods “from the 7th month” or “after the end of 6 months”

### **Literature:**

Ballard, O., and A. L. Morrow. "Human Milk Composition: Nutrients and Bioactive Factors." *Pediatr Clin North Am* 60, no. 1 (Feb 2013): 49-74.

Dewey K. *Guiding Principles for Complementary Feeding of the Breastfed Child*. WHO 2001.

Naylor A, Morrow A, (edit) (2001). *Developmental Readiness of Normal Full Term Infants to Progress from Exclusive Breastfeeding to the Introduction of Complementary Foods*. Linkages Project [http://pdf.usaid.gov/pdf\\_docs/PNACS461.pdf](http://pdf.usaid.gov/pdf_docs/PNACS461.pdf)

Rito AI, Buoncristiano M, Spinelli A, et.al.: Association between Characteristics at Birth and and Obesity in 22 Countries: The WHO European Childhood Obesity Surveillance Initiative COSI 2015/17. Obesity Facts 2019: 226-243. The WHO Euro publication comes quite in time as it shows the health effects (obesity prevention) of a longer exclusive breastfeeding <https://www.karger.com/Article/FullText/500425>.

Scientific Advisory Committee on Nutrition UK (SACN) (2018). Feeding in the first year of life - report <https://www.gov.uk/government/publications/feeding-in-the-first-year-of-life-sacn-report>

Smith H, Becker G (2016). Early additional food and fluids for healthy breastfed fullterm infants. Cochrane Database of Systematic Reviews 2016, Issue 8. Art. No.: CD006462 <http://bmjopen.bmj.com/content/bmjopen/6/1/e009163.full.pdf>

Victora CG, Barros AJD, França GVA, et al (2016). Breastfeeding in the 21st century: epidemiology, mechanisms, and lifelong effect. Lancet 387: 475–90

WHO (2016) Maternal, infant and young child nutrition. Guidance on ending the inappropriate promotion of foods for infants and young children. WHA 69.7 [http://apps.who.int/gb/ebwha/pdf\\_files/WHA69/A69\\_7Add1-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_7Add1-en.pdf)

## **Baby Milk Action – Patti Rundall**

### **1.6. General considerations on the outcomes assessed**

This comment endorses comments by WHO, the First Steps Nutrition Trust, Adriano Cattaneo and Gill Rapley. We strongly agree with FSNT that the draft opinion is based on wrong questions, some questionable data review and conclusions and insufficient disclosure of conflict of interest. Rather than repeat their detailed comments, we will briefly explain some of the historical context as we see it, the global impact the opinion may have and why it is imperative that its flaws are acknowledged and addressed.

Baby Milk Action and our IBFAN partners have worked to improve the advice provided to EU policy makers since the early 1990s before EFSA was established. Our aim has been to ensure that policy setting is kept as free as possible from commercial influence, to de-link scientific advice from political efforts to expand the EU market and to encourage the EU, as a major exporter, to consider the global impact of its policies. In 2000, following our questions to the Commission about the lack of transparency and hidden conflicts of interest of members of the Scientific Committee for Food (SCF), the SCF was closed down and EFSA was formed. Over the years EFSA opinions and the EU's Precautionary Principle, have played an important role in improving safeguards related to baby foods both within the EU and globally and we have appreciated EFSA's role in improving Codex standards. However, the issue of Conflicts of Interest (COI) has remained a problem that has never been fully resolved. This was evident in EFSA's 'Scientific Opinion on the appropriate age for introduction of complementary feeding of infants' in 2009, that concluded that "the introduction of complementary food into the diet of healthy term infants in the EU between the age of 4 and 6 months is safe and does not pose a risk for adverse health effects (both in the short-term, including infections and retarded and excessive weight gain, and possible long-term effects such as allergy and obesity)" EFSA ignored Panel Members COI, over-emphasised Coeliac Disease and failed to consider developmental readiness or the impact on public health recommendations on 6 months exclusive breastfeeding. <http://archive.babymilkaction.org/press/press23dec09.html>

### **20. Conclusions**

We reiterate WHO's comment regarding World Health Assembly 'global public health recommendations. The expert consultation that made the recommendation on 6 months exclusive breastfeeding clarified that it applies to populations, acknowledging that individual infants may need to receive complementary foods before or after this exact age. The conclusion of the EFSA panel that the "data do not allow the determination of a precise age at which complementary foods should be introduced to all infants" is consistent with this recommendation. However, it does not follow that the labelling of complementary foods should indicate introduction as early as 3 months simply because some individual infants may need to be introduced to complementary foods earlier than 6 months. The point of having public health recommendations is to provide general protection to the overall population while acknowledging individual variation. Labelling of commercial products should be consistent with evidence-based public health recommendations and not seek to exploit exceptional cases.

\*WHO. Infant and young child nutrition. World Health Assembly Resolution 54.2. 18 May 2001. [https://www.who.int/nutrition/topics/WHA54.2\\_itycn\\_en.pdf?ua=1](https://www.who.int/nutrition/topics/WHA54.2_itycn_en.pdf?ua=1).

\*\* WHO. The Optimal Duration of Exclusive Breastfeeding: Report of an Expert Consultation. Geneva, Switzerland, 28–30 March 2001.  
[https://apps.who.int/iris/bitstream/handle/10665/67219/WHO\\_NHD\\_01.09.pdf?sequence=1](https://apps.who.int/iris/bitstream/handle/10665/67219/WHO_NHD_01.09.pdf?sequence=1).

### **Other comments**

The publication of the Panel’s findings should include the interests declared by the authors regarding receipt of individual support from the food industry – both direct (e.g. consultancies, honoraria, or travel support) and indirect (e.g. research grants). In addition, the source of funding for the work of the Panel is not clear. Given the commercial implications of the recommendations being made, this clarity is critical.

## **Adriano Cattaneo, Italy**

### **1.3. Definitions**

Lines 722-724. "CF in this opinion comprises, therefore, all liquid, semisolid and solid foods other than breast-milk and formula, water and vitamins which are fed to infants. CFs can be beverages, spoon-fed foods, or finger-foods". This definition covers virtually any food and beverage an infant can be given. As such, it contrasts, in my opinion, with the obvious aim of the document: to provide evidence for labelling of "processed cerealbased foods and baby foods for infants and young children" (lines 596-597), i.e. industrial products (as nobody ever proposed to label eggs, peanuts, fish etc. available in shops and markets). In addition to the fact that I would call these industrial products ultra-processed (instead of simply processed), for the well-known implications that ultra-processing has, the definition implies deviating the attention of the reader from the real target (ultraprocessed industrial baby foods) and complicating unnecessarily the document (it imposes a literature search on all foods). Finally, the definition may hide a non-written objective: to provide "prescribers of CFs" (mainly paediatricians) with evidence for anticipating their introduction, as largely occurring after the dissemination of previous EFSA and ESPGHAN reviews.

### **1.5. Interpretation of the Terms of Reference**

In this section, and in fact throughout the document, the age of introduction of CFs and the duration of breastfeeding (or of formula feeding or, as it's often the case, of mixed breast and formula feeding) are treated as two separate entities. They are not; the earlier CFs are introduced, the shorter is the duration of exclusive breastfeeding and the total amount of breastmilk given to an infant. If, as shown by a large body of research worldwide, the benefits of breastmilk are proportional to its duration (total amount), shortening it unnecessarily may cause harms. It is probably true that if an infant is given his or her first CFs when he or she is developmentally ready, probably there will be no harm (and this is true if developmental readiness occurs at 4 or 5 months, but also at 7 or 8). But the problem is that by labelling industrial products "from 4 months" will tend to anticipate CFs before developmental readiness, both by direct effect of marketing and by indirect effect through prescribers.

## **2.0 Data and Methodologies**

More than 20 complex pages on data and methodologies are hard to digest even for a (retired) epidemiologist as I am. It probably took the 21 members of the panel many months (a couple of years?) of hard work to go through the thousands of available papers to select and analyse the hundreds of selected ones. How can someone repeat the search and the analysis in the few weeks of the public consultation? One has to blindly rely on the work done by the panel; but, having spotted some badly or inappropriately reported results (e.g. on neuromuscular coordination and neurodevelopment, or on infections associated with the early introduction of CFs), I am led to suspect that I could find other problems, should I have the time (and the resources) to fact check every reported result from the huge amount of studies revised. It would have been easier to carry out a check if the scope was restricted to the real target, i.e. industrial cereal-based and baby foods.

### **3.3 Neuromuscular coordination and neurodevelopment**

Here, and in other sections of chapter 3, I noticed a tendency to emphasize the lower side of the range. The range for sitting without support, for example, an essential developmental milestone for readiness to CFs, is rightly reported between 3.8 to 9.2 months; but the members of the panel seem to privilege the lower side of the range, omitting the fact that at 6 months many infants would not be ready for CFs on this parameter. This is probably a consequence of the decision to restrict the question of positive and negative outcomes to CFs before 6 months. What if the literature showed that those infants who introduce CFs at 7 or 8 months, because that's the age at which they can sit without support, would have better outcomes?

### **3.4. Developmental readiness of the term infant to receive CFs: conclusions**

Lines 1825-26. Consequent to the preference for the lower side of the range, the panel "concludes from the available developmental data that most term infants are ready to be introduced to CFs between about 3-4 months of age and around 6 months of age", thus leaving out all the infants who reach developmental readiness over 6 months. The panel seems to contradict in its conclusions the ones provided by Naylor and Morrow in their review of 2001, despite citing it often in section 3. The panel should perhaps explain the divergence, given the fact that many studies were used in both reviews (EFSA and Naylor and Morrow).

### **19. Integration of results**

Lines 4956-57. "The Panel wishes to clarify that, in this opinion, introduction of CFs was defined as 'early' or 'delayed' when it occurred before or after 6 months of age, respectively". Yet, in the data and methodologies section one reads that studies in which CFs were introduced only after 6 months were excluded. The rationale for this exclusion, while studies in which infants were introduced to CFs before and after 6 months were included, is unclear. As a consequence of this decision, the number of comparisons in Table 7 in which late introduction means over 6 months is low.

### **20. Conclusions**

Lines 5259-60. It is true that "this opinion should not be interpreted as providing public health recommendations for the introduction of CFs", but it will inevitably, contributing to the low rate of exclusive breastfeeding recorded in European countries (see Lancet series on breastfeeding, 2016). Line 5277 "Most infants do not need CFs for nutritional reasons up to around 6 months of age" is a fair statement, but labelling ultra-processed industrial CFs "from 4 months" will inevitably shorten the duration of exclusive breastfeeding. Even worse, should they be labelled "from 3-4 months".

Lines 5320-24 "The available data do not allow the determination of a precise age at which CFs should be introduced to all infants living in Europe. The appropriate age depends on the individual's characteristics and development ... In most infants, this age is between about 3-4 months and around 6 months". In my opinion, this is a dangerous conclusive statement. Why does the Panel state that the

appropriate age is between 3-4 and 6 months, if "the available data do not allow the determination of a precise age" and this "depends on the individual's characteristics and development"?

### **Other comments**

I was unable to find in the document and through a rapid search in the EFSA website the declarations of potential conflicts of interests of the members of the panel. Yet I know, through familiarity with some of the literature on infant and young child feeding, that some of the members of the panel declared potential conflicts of interests in other circumstances. Readers should be informed within the document about potential conflicts of interests.

## **First Steps Nutrition – Helen Crawley**

### **1.3. Definitions**

In lines 735-736 it is stated that: The Panel considers that the appropriate age of introduction of CFs (which is the subject of this mandate) should not be regarded as synonymous with the optimal duration of exclusive breast feeding. The age of appropriate introduction of foods other than breastmilk to an infant has to include the considerable body of evidence that shows that breastfeeding, and its exclusivity, is a key factor in reducing morbidity. To look at these separately in a review that uses the title 'appropriate age for introduction' is nonsensical. It is well known and acknowledged in the review (on lines 725-7) that as complementary foods are introduced that the amount of breastmilk consumed will reduce, therefore it is unrealistic to view the introduction of complementary foods separately to evidence about the optimal duration of breastfeeding. We believe that this review answers the wrong question and has a misleading title.

#### **1.4.2. Nutritional adequacy of exclusive breast-feeding: overall conclusions**

837-840 say that: The Panel concludes that exclusive breast-feeding is nutritionally adequate up to 6 months for the majority of healthy infants born at term from healthy well-nourished mothers. However, some infants at risk of iron depletion may need CFs, especially foods that are a source of iron, before 6 months of age in addition to breastfeeding. The first sentence acknowledges that most infants do not nutritionally require complementary foods until about 6 months of age, which begs the question why would you then introduce them earlier just because 'you can'? We do not believe adequate data is presented in this review to make the generalised statement relating to iron deficiency here, which is included without any reference. We review this in more detail in comments on section 15.

### **1.5. Interpretation of the Terms of Reference**

In the terms of reference, and throughout the document, the age of introduction of complementary foods and the duration of breastfeeding (or of formula feeding or, as is often the case, of mixed breast and formula feeding) are treated as two separate entities. They are not; the earlier complementary foods are introduced, the shorter the duration of exclusive breastfeeding and the total amount of breastmilk given to an infant. If, as shown by a large body of research worldwide, the benefits of breastmilk are proportional to its duration, then shortening it unnecessarily may cause harms. It is probably true that if an infant is given his or her first complementary foods when he or she is developmentally ready, there will be no harm (and this is true if developmental readiness occurs at 4 or 5 months, but also at 7 or 8 months). Labelling ultra-processed complementary foods from 4 months will promote the use of these foods before developmental readiness, both by the direct effect of marketing and by the indirect effect of health workers recommending products at an earlier age. The Panel did not appear to debate and consider this

### **2.0. Data and Methodologies**

There are more than 20 complex pages on data and methodologies and it would have taken the 21 members of the panel and the support staff at EFSA a considerable amount of hard work to go through the thousands of available papers, to decide on the many exclusion criteria cited and the suitability of papers to review. It is impossible for reviewers of this EFSA opinion to repeat the search and analysis in the few weeks the consultation is open. It would have been easier to consider the studies reviewed,

and conclusions, if the scope was restricted to the question which should have been at the heart of this review, which is the impact of adding commercial ultra-processed cerealbased and baby foods to the diets of infants and whether there is any rationale for encouraging the intake of solid food before 6 months of age. As it has not been possible to review all the sections of this report we have focused on a few sections to illustrate that, in our opinion, the evidence review does not appear in places to have been accurate. We think this may raise doubts about the results from other sections, and the overall conclusions of the review. We would also like to comment on the lack of information provided about conflicts of interest in studies reported.

### **3.0. Assessment of the developmental readiness of the term infant to receive CFs**

this and other sections of chapter 3, the lower end of the development range is continuously emphasized. The range for an infant sitting without support, for example, an essential developmental milestone for readiness to complementary foods, is reported between 3.8 to 9.2 months; but the members of the panel seem to privilege the lower side of the range, omitting the fact that at 6 months many infants would not be ready for complementary foods based on this parameter. This is probably a consequence of the decision to restrict the review to analysis of outcomes of complementary feeding before 6 months of age. Infants introduced to complementary foods at 7 or 8 months, because that's the age at which they can sit without support, could have better outcomes than those given foods earlier, but this evidence is ignored in this review. In chapter 3, lines 1715 to 1719; it is suggested that greater neurological control of the tongue movements start at 2-4 months of age, but then say the Panel was unable to retrieve empirical data for this estimation. In lines 1729- 1731 it is suggested that an infant has to be able to 'move the upper lip down to wipe food from a spoon when being spoon fed', but does not challenge whether spoon feeding (and what is being fed) is the best estimate of readiness for solids. In the discussion on the evidence relating to the swallowing reflex it is suggested that this develops alongside jaw stability, which develops alongside head and trunk stability and control. Very limited evidence is presented in lines 1748-1766 relating to head stability when lying or sitting aided, and this generally suggests that head control is not achieved well in infants under 5 months of age. The one study from Japan which reported that the majority of infants could maintain the head (based on 'pulling on the arms') at 3.25 months was based on reported data from the 4m health check, and it is not clear how the measurement was made, or its significance. As is reported, infants in this study were on average 6.66m before they could sit unaided, a measure of trunk and head stability.

Other data reported in lines 1767- 1779 suggest lower ages at which infants are able to sit unaided. However, the majority of these studies reported that most infants were greater than 5m of age when they could sit unaided, and babies who were born small for gestational age were 6-7m of age. The data on lower birthweight infants from the study by Yokoyama et al, 2011 is not reported in the review, but was 6.65m. In our opinion this section therefore fails to provide evidence for the ability of most infants to sit up unaided before about 6m of age. In lines 1780-1800 the ability of infants to reach out was examined, but limited evidence is provided. For example, no evidence is given on how reaching movements are structured, with evidence suggesting that straighter reaching movements are not achieved until about 6m of age (van Hofsten, 1991) and that reaching movements are linked to trunk stability and that control of both is needed, and this occurs at about 6m of age (Hopkins and Rönquist, 2001). In lines 1825-26 the panel "concludes from the available developmental data that most term infants are ready to be introduced to CFs between about 3-4 months of age and around 6 months of age", thus leaving out all the infants who reach developmental readiness after 6 months of age. The panel seems to contradict in its conclusions those of Naylor and Morrow in their 2001 review (Naylor

and Morrow, 2001), despite citing it often in section 3. There is no explanation of the divergence, given the fact that many studies were used in both reviews.

Throughout this section the authors repeatedly acknowledge that there is biological variability when infants develop the necessary motor skills for the introduction of solids, ranging from 3-4 months to around 6 months of age, but this is not supported by the data presented. It appears as if it was agreed in advance that the 3-4 months to 6 months age range would be suggested throughout the document, regardless of evidence presented. We suggest this whole section needs further critical review. Hopkins B and Rönnqvist L (2011) Facilitating postural control: effects on the reaching behaviour of 6m olds. *Developmental Psychobiology*, 40, 168-182. Von Hofsten (1991) Structure of early reaching movements a longitudinal study. *J Motor Behavior*, 23, 282-290

### **5.3. BMI: summary of the evidence**

Lines 2189-2191: For BMI or attained BMI, the evidence derived from the two RCTs (Jonsdottir et al., 2014; Perkin et al., 2016) did not show an effect of the timing of introduction of CFs at 3-4 months of age compared with the introduction at 6 months on these endpoints assessed up to 3 years of age. The study by Jonsdottir et al (2014) looked only at exclusively breastfed infants and the impact of the introduction of complementary foods at 4 months or at 6 months, but this is not highlighted. It is a relatively small study, father's weight was not included as an explanatory variable and there was a significant difference between the groups in terms of mode of delivery with significantly more babies in the group exclusively breastfed for 6 months being born by caesarean delivery. Whilst this study did at least intend to report on weight as an outcome, the study by Perkin et al (2016) aimed to look at the impact of the introduction of specific allergenic foods on allergy development, and weight outcomes were not stated outcome measures. Again, all babies were exclusively breastfed and it appears that the reviewers may have trawled through the supplementary papers to this study to find data related to weight as none are reported in the paper. Supplementary papers are not referenced. It is unlikely the study was powered to consider secondary outcome measures. It is odd that if such a data fishing exercise was undertaken such a firm conclusion is reached, and that the conclusion does not mention that these studies are only relevant to breastfed infants.

### **6.1. Obesity and overweight: final body of evidence**

In lines 2324-2327 it is concluded: The main line of evidence consists of six prospective cohort studies and no RCT (Reilly et al., 2005; Brophy et al., 2009; Neutzling et al., 2009; Huh et al., 2011; Layte et al., 2014; Zheng et al., 2015). For these studies, which mainly investigated introduction of CFs at <3-4 months of age, the result of the meta-analysis did not show a statistically significant association between the age of introduction of CFs and the chance of developing obesity up to 11 years of age. There are a number of studies that have looked at the age of introduction of complementary foods and overweight, and it is not clear how these six prospective studies were chosen. Data is included from China and Brazil as well as the USA and UK, so they were not chosen due to geographical relevance. However, a number of other studies (6) in this subject area that have been included in a meta-analysis of prospective studies (Wang et al, 2016) were not included. The meta-analysis by Wang et al (2016) concluded that introducing complementary foods before 4 months of age compared to at 4 to 6 months was associated with an increased risk of being overweight. This study had clear inclusion criteria and used a relatively consistent cut-off age to define an early (<4 months or  $\leq 3$  months) versus late ( $\geq 6$  months) introduction to complementary foods. In their conclusion the EFSA Panel give no age range for the timing of introduction of complementary foods in terms of risk of obesity development,

and as highlighted earlier the summary at the end of the section (lines 2459 – 2463) the terms early and later introduction are extremely confused: 'The ages of introduction of CFs ranged between <1 month and <4 months for early introduction and >2 months and ≥6 months for later introduction'. The suggestion here that early introduction of complementary foods is not associated with obesity even in very young infants is concerning. Wang J, Yuangue W, Cuoping X, Chao T et al (2016) Introduction of complementary feeding before 4 months of age increases the risk of childhood overweight or obesity: a meta-analysis of prospective cohort studies. *Nutrition Research*, 36, 759-770.

### **12.1. Infections: final body of evidence**

The evidence presented in this section appears contradictory because introduction of complementary foods before 6 months of age displaces breastmilk and leads to a shorter duration of exclusive breastfeeding and is therefore associated with an increased risk of a range of infections. For example, from one of the cited studies by Quigley et al (2007): 'each additional month of EBF reduced the risk of hospitalisation for diarrhoea and LRTI'. Milk feeding practices in the reviewed studies are not considered adequately, and the influence these may have on the findings and their generalisability is not discussed. The selection of studies also appears to be questionable. The evidence reviewed includes 3 RCTs and 7 prospective studies. However, 2 of the RCTs were conducted in Honduras and we question the appropriateness of the poorly defined exclusion criteria used to justify their inclusion: 'human studies were not considered pertinent if they: investigated the outcome 'infections' in low and lower-middle income countries in settings with poor hygiene conditions.' In the EFSA summary conclusion on infections in lines 246-250 it is stated that: 'For infections, there is no evidence that in countries with hygiene conditions that are similar to those in high-income countries the introduction of complementary foods <6 months of age compared with thereafter is associated with an increased risk of 1) gastro-intestinal infections (low level of confidence in the evidence) lower respiratory tract infections (moderate level of confidence in the evidence) or 3) infections in general (moderate level of confidence in the evidence). The evidence for upper respiratory tract infections is conflicting and insufficient to draw conclusions. Cohen et al (1994), authors of one of the 2 RCTs the panel included, state in their paper that subjects came from poor neighbourhoods in which environmental sanitation was poor (only 60% of the households had indoor piped water)'.

### **12.3. Gastro-intestinal infections: summary of the evidence**

Only one of the four studies cited was explicitly designed to look at infection as an outcome of early introduction of solid foods (Forsyth et al 1993). Including studies in which morbidity data was not collected as a pre-specified outcome, as is the case for all three RCTs cited, is questionable. We particularly disagree with the appropriateness of including the 'Randomized Trial of Introduction of Allergenic Foods in Breast-Fed Infants' by Perkin et al (2016), in which vomiting and diarrhoea subsequent to introduction to specific allergenic foods were reported as 'undesirable events' in a supplementary appendix (not the main paper). The justification to consider the diarrhoea ('no effect of the timing of CF') but not the vomiting ('earlier introduction of complementary foods related to a higher incidence of vomiting') is also not clear. It would also be appropriate to highlight that the data on morbidity that was collected in all 3 studies was retrospectively reported by parents, weakening its validity. Line 4150, relating to the reviewed RCTs, is misleading 'all of which compared the introduction of CFs at 3-4 months with 6 months of age' and we would like to highlight that Cohen et al (1994) and Dewey et al (1999) compared non-infection outcomes of infants exclusively breastfed to 6 months with those given complementary foods at 4 months, while the Perkins et al (2016) trial (the relevance of

which we question above) compared noninfection outcomes of infants exclusively breastfed to 6 months with those given complementary foods at 3 months. Whilst the results of the prospective cohort by Noppornlertwong and Tantibhaedhyangkul (2016) do not inform the panel's conclusions, an incorrect summary of some results is presented: reporting GI infections between 5 and 15 months of age, not 4 and 18 months of age (line 4167). Four further studies are cited as supportive evidence; three prospective cohorts and a cross sectional study. The design of two of the cohort studies (Morgan et al 2004 and Wright et al 2004) is inappropriate to support a conclusion comparing 'introduction of complementary foods at <6 months with thereafter'. The findings of the third prospective cohort (Lopez-Alacron et al 1997) and the cross-sectional analysis by Quigley et al (2009) are both misrepresented, as outlined below. The findings of the prospective cohort by Morgan et al (2004) do not support the panel's conclusions as they compare the morbidity of infants given complementary foods at <3 months with those given foods at >3 months. The prospective cohort by Wright et al (2004) is also irrelevant to the conclusion as it compares prevalence of parent reported diarrhoea by age at introduction of complementary foods at <3 months with 3-4 months and >4 months. Nonetheless it is interesting to see the higher odds of diarrhoea among those introduced at <3 months compared to thereafter (prevalence by age group: 31% at <3 months, 19% at 3-4 months and 14% at >4 months) (nb. it should be noted that lines 4195-4198 incorrectly summarise these findings stating the comparison was between introduction at <4 months with thereafter, when it was with <3 months and thereafter). If this data were relevant, the appropriateness of dwelling on the lack of significant difference in the proportions of children with diarrhoea who were brought to a doctor could be questioned as the sample size was small and this result may have been due to a lack of power. On lines 4191-4192 from the prospective cohort by Lopez-Alarcon et al (1997) it is reported that authors: 'did not find an association between the timing of introduction of CFs and the odds of diarrhoea between birth and 6 months of age'. However, this is misleading, as the study actually reported: 'Incidence, prevalence, and duration of individual episodes of diarrhea were lower in breast-fed infants. Incidence ( $r=-0.17$ ,  $P < 0.02$ ) and prevalence ( $r=-0.19$ ,  $P < 0.008$ ) were negatively associated with duration of full breast-feeding. Introduction of solid food was not associated with further episodes of diarrhea', and the text clarifies that logistic regression was carried out to examine the coincidence of an episode of diarrhea occurring immediately after solid food was introduced. In lines 4185-4188 it is stated that the cross-sectional analysis by Quigley et al (2009) reported the monthly risk of diarrhoea between birth and 8 months depending on whether complementary food had been introduced or not. This is incorrect as the outcome they reported on was hospitalisation for diarrhoea (or lower respiratory tract infection). The presented evidence does not appear to be sufficient to support the conclusion presented, and it is inappropriate to say there is: 'no evidence that the introduction of complementary foods <6 months of age increases gastro-intestinal infections.

#### **12.4. Upper respiratory tract infections: summary of the evidence**

Four studies are used as the 'main line of evidence'; the 3 RCTs already cited (Perkin et al 2016; Dewey et al 1999; Cohen et al 1994) and the prospective cohort cited above (Forsyth et al 1993). These studies do not all report on upper respiratory tract infections or define these in the same way and this should have been reflected in the conclusions. The inclusion of studies in which morbidity data was not collected as a pre-specified outcome is questionable, as is the case for all three RCTs cited. However, given that they are included, a number of issues can be highlighted: data on upper respiratory tract infections is not included in the paper by Perkin et al (2016) and any supplementary papers in which this may have been included are not referenced; and the paper by Dewey et al (1999) reports on 'nasal discharge', not upper respiratory tract infections.

The study by Forsyth et al (1993) was explicitly designed to look at infection as an outcome of early introduction of solid food, but it does not allow conclusions to be drawn in relation to the question of timing of introduction of complementary foods at < 6 months compared to thereafter as it compares infants given complementary foods at <8 weeks, 8-12 weeks and >12 weeks. Nevertheless, this study is reported as showing significant differences in the prevalence (not incidence as reported, line 4215) of respiratory illness (defined as persistent cough, wheeze and coryza) among children 14-26 weeks of old, by age at introduction of complementary foods: highest in the <8 weeks, lowest in the >12 weeks. i.e. the one relevant study shows early introduction of complementary foods is associated with higher prevalence of respiratory infection in infants 14-26 weeks old. To conclude, we believe that the summary on lines 4226-4231 is inappropriate (and inaccurate) and here and elsewhere in the report the available evidence for this outcome should simply be given as 'insufficient' to reach any conclusion. Again, it would be more appropriate to consider this question in light of the evidence that prolonged duration of exclusive breastfeeding is protective against respiratory infections. In their evidence review SACN in the UK reported that 'the early introduction of solids at three to four months is associated with greater risk of gastrointestinal, respiratory and ear infections than is continuing to breastfeed exclusively.' (SACN, 2018)

### **12.5. Lower respiratory tract infections: summary of the evidence**

The RCT by Perkin et al (2016) is used for the 'main line of evidence' and the 2 prospective cohorts cited above (Wright et al 2004 and Morgan et al 2004) and the cross-sectional study by Quigley et al (2009) as 'supportive evidence'. These studies do not all report on lower respiratory tract infections or define these in the same way and this should have been reflected in the conclusions. The appropriateness of including studies in which morbidity data was not collected as a pre-specified outcome should be questioned, as is the case for Perkin et al (2016), and this data is not reported in this paper but in unreferenced supplementary tables. The findings of the prospective cohort study by Morgan et al (2004) do not support the conclusions as they compare the morbidity of infants given complementary foods at <3 months with those given at >3 months and the only mention of lower respiratory tract infections in the paper is as follows: 'There was no effect of the age of weaning on the proportions of term infants developing atopy, lower respiratory tract infections, or gastroenteritis'. There was no data presented. The prospective cohort by Wright et al (2004) is also irrelevant to the conclusion as it compares prevalence of parent reported chest infections by age at introduction of complementary foods at <3 months with 3-4 months and >4 months. In lines 4247-4250 it is stated that the cross-sectional analysis by Quigley et al (2009) reported the monthly risk of lower respiratory tract infections between birth and 8 months depending on whether complementary foods had been introduced or not. This is incorrect as the outcome they reported on was hospitalisation for lower respiratory tract infection (or diarrhoea). It therefore appears to be misleading and inappropriate to report (lines 246249) there is 'no evidence that the introduction of complementary foods <6 months of age compared with thereafter is associated with an increased risk of lower respiratory tract infections' and for EFSA to classify its level of confidence in the evidence as 'moderate'. Again, the lack of review of the importance of exclusive breastfeeding on the reduction in infections means that evidence has not been included which would show a relationship between early introduction of complementary foods with lower respiratory tract infection. SACN (2018) concluded that: The introduction of solid foods or infant formula before 6 months of age is associated with greater risk of gastrointestinal, and lower and upper respiratory infections than continuing to breastfeed exclusively. Quigley et al (2007) reported that 27% of all lower respiratory tract infections could be prevented with each month of exclusive breastfeeding

## **12.6. Infections in general: summary of the evidence**

Firstly, this endpoint is not clearly defined, and the two studies included measured more specific outcomes which could have been included in the other sections; e.g. Stordal et al (2017): ‘When we analyzed all infections regardless of hospitalization, introduction of complementary foods <4 months was associated with an increased risk for gastrointestinal infections, upper respiratory tract infections, and frequent infections but not for lower respiratory tract infection’. It is not clear why this data was excluded from review of evidence relating to gastrointestinal and upper respiratory tract infections. Stordal et al (2017) concluded that: ‘Breast-fed children who received complementary foods at 4 to 6 months of age had similar risk for infection as those receiving complementary foods after 6 months’. The fact that their findings related to breastfed children, and this is only one of two studies included for this outcome, is not adequately reflected in the overall conclusion (lines 249-250). It would also have been relevant to highlight that the authors stated that the introduction of complementary food before 4 months was found to be risky: ‘Age at introduction of complementary foods was a significant predictor for hospitalization for infections among infants who were breastfed for a minimum of 6 months ... This association was driven by a higher risk for hospitalization in those with introduction of complementary foods at <4 months of age’. The overall conclusion was ‘In this large birth cohort, we found a small but significant trend for lower risk for hospitalizations for infections for each month of delaying complementary foods in breastfed infants’. The summary referring to Stordal et al (2017) on lines 4287-4290 appears incorrect and misleading. The second study cited by Heinig et al (1993) is stated as being in exclusively breastfed infants (line 4261), whereas the authors reported: ‘We examined if the timing of introduction of solid foods was related to growth, intake, morbidity, activity or motor development among infants either breast fed or formula fed until  $\geq 12$  months of age’. It appears both misleading and risk of lower respiratory tract infections between birth and 8 months depending on whether complementary foods had been introduced or not. This is incorrect as the outcome they reported on was hospitalisation for lower respiratory tract infection (or diarrhoea). It therefore appears to be misleading and inappropriate to report (lines 2462-249) there is ‘no evidence that the introduction of complementary foods <6 months of age compared with thereafter is associated with an increased risk of lower respiratory tract infections’ and for EFSA to classify its level of confidence in the evidence as ‘moderate’. Again, the lack of review of the importance of exclusive breastfeeding on the reduction in infections means that evidence has not been included which would show a relationship between early introduction of complementary foods with lower respiratory tract infection. SACN (2018) concluded that: The introduction of solid foods or infant formula before 6 months of age is associated with greater risk of gastrointestinal, and lower and upper respiratory infections than continuing to breastfeed exclusively. Quigley et al (2007) reported that 27% of all lower respiratory tract infections could be prevented with each month of exclusive breastfeeding

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Again, it should be highlighted that it would be more appropriate to consider the question of infection risk in infancy in light of the evidence that prolonged duration of exclusive breastfeeding is protective against a range of infections. In their evidence review SACN in the UK reported that 'The introduction of solid foods or infant formula before 6 months of age is associated with greater risk of gastrointestinal, and lower and upper respiratory infections than continuing to breastfeed exclusively.' (SACN, 2018) The EFSA review did not consider ear infections and it is not clear why. Lastly, it would be relevant to share where papers have a conflict of interest. This is the case in the studies by Perkins et al (2016), Heinig et al (1993) and Cohen et al (1994).

### **15.3. Iron status: summary of the evidence**

We have divided our comments across sections 15.3 and 15.4 as not enough characters were available here. Three RCTs are cited to provide the evidence to support the conclusion that Lines 4558-4568 'there is high confidence in the evidence that the introduction of complementary foods at 4 months of age compared with 6 months of age reduces the risk of iron depletion in exclusively breastfed infants at 6 months of age' This sentence is misleading as it appears to make a generalisation for all infants 'Exclusively breast-fed infants that may benefit from an early introduction of CFs that are a source of iron are infants born to mothers with a low iron status, infants with early umbilical cord clamping (<1 minute after birth), infants born pre-term, infants born small-for-gestational age, and infants with a high growth velocity'. This sentence listing the groups that 'may benefit from early introduction of CF' lacks the requisite evidence base from the cited RCTs. Even if this were supportable with the presented evidence, it seems irrelevant to the consultation question which pertains to the labelling of commercial foods available to the general public among which such infants will be a small proportion. We suggest that 3 RCTs cannot provide 'high confidence' for a broad recommendation, and this is especially the case given the questionable relevance of any of these trials to the current European setting. The two by Dewey et al were conducted in a low-income country and studied a majority of low birthweight infants. In the exclusion criteria for this opinion in line 976 it states that studies are excluded 'if they investigated growth or iron status in populations with high prevalence of undernutrition'. Honduras had a stunting rate of 23% in 2012 and this would have been higher when the studies were undertaken, therefore it is not clear why these studies were considered appropriate

for this review. In addition, the trial by Jonsdottir et al (2012) was conducted before delayed cord clamping became common practice. We also have concerns about how the data from these studies is presented. Selected results from these trials are given in a misleading manner by failing to highlight that differences between groups (exclusively breastfed for 6 months compared to introduction of complementary foods at 4 months alongside breastfeeding) were not statistically significant: Dewey et al (1998), lines 4484-4486; Dewey et al (2004), lines 4479-4480, and Jonsdottir et al (2012), lines 4488-4489 and 4490-4492. None of the 3 trials presented conclusions or recommendations in line with the panel's overall conclusion. Dewey et al (1998) highlighted that although infants given complementary foods from 4 months consumed far more iron than the exclusively breastfed group, this did not fully eliminate the risk of developing anaemia by 6 months of age. They actually recommended that iron drops are given to low birth weight breastfed infants, exclusively breastfed infants over 3000g do not need any additional iron before 6 months and that more research is needed on whether iron drops or complementary foods are more effective at preventing iron deficiency before 6 months in breastfed infants born weighing 2500-3000g. The study by Dewey et al (2004) examined iron drops and complementary foods, and the panel failed to point out that the results presented (lines 4479-4480) were from a sub-group analysis (as well as lacking statistical significance). In infants who did receive iron drops at 4-6 months, haemoglobin, haematocrit and transferrin saturation levels were actually higher in the exclusively breastfed group than in the group receiving complementary foods from 4 months. Over the entire 6 month study period, the cumulative probability of remaining non-anemic at 6 months without the use of iron drops was virtually identical in the two intervention groups. The authors recommended maintenance of exclusive breast-feeding to 6 months for low birth weight infants while providing supplemental iron drops.

#### **5.4. Iron status: conclusions and grading of the confidence in the evidence**

In the paper by Jonsdottir et al (2012), the authors conclude that 'No difference was seen between groups in iron deficiency anemia, iron deficiency, or iron depletion'. In addition, none of the trials reported functional outcomes. Infants usually have serum ferritin values near the cut-off reflective of depletion, though a value near the cut-off does not necessarily imply functional iron deficiency. Because of the criteria used for the review, data that might have contradicted the evidence presented was not considered. For example, a more recent study looking at iron deficiency among infants in Colombia exclusively breastfed for 4-5 months versus 6 months showed no difference in iron status at 6 months (Olaya et al, 2017). Lastly, it would be relevant to share where papers have a conflict of interest. This is the case in the Jonsdottir et al (2012) trial which was funded by Mead Johnson. We are concerned that the statements made in this review about iron status are potentially misleading and that the Panel's scrutiny of the relevance of the data presented may have been inadequate. If no relevant RCT were available to consider this outcome, then that should have been made clear.

## 20. Conclusions

In the conclusion in lines 5259-60 it is stated that 'this opinion should not be interpreted as providing public health recommendations for the introduction of complementary foods. However, it will inevitably be used in this way. We believe that this opinion will contribute to maintaining low rates of exclusive breastfeeding recorded in European countries (see Lancet series on breastfeeding, 2016) and the inappropriate provision of solid foods at even earlier ages than present. The constant recommendation of the 3-4m time period for introducing complementary foods has to be brought into question.2. In line 5277 it states 'Most infants do not need complementary foods for nutritional reasons up to around 6 months of age. Allowing the labelling of ultra-processed commercial complementary foods 'from 4 months' or 'from 3-4 months' will inevitably shorten the duration of exclusive breastfeeding, and lead to well documented harmful impacts on the health of infants and mothers. 3. In lines 5320-24 it states that 'The available data do not allow the determination of a precise age at which complementary foods should be introduced to all infants living in Europe. The appropriate age depends on the individual's characteristics and development ... In most infants, this age is between about 3-4 months and around 6 months. How can the Panel state that the appropriate age is between 3-4 and 6 months, if 'the available data do not allow the determination of a precise age' and this 'depends on the individual's characteristics and development?'

Additional Article, published by Baby Milk Action: The EFSA consultation on the appropriate age for introduction of complementary feeding into an infant's diet, May 2019. The wrong question criteria, some questionable data review and conclusions and insufficient disclosure of conflict of interest.

<http://www.babymilkaction.org/wp-content/uploads/2019/05/FSNT-EFSA-2.pdf>

## **1. Optimal duration of exclusive breastfeeding and “appropriate age for introduction of complementary feeding”**

In line 10, the Panel states that there was a request from the European Commission to EFSA to give an updated opinion on “the appropriate age for introduction of complementary feeding of infants.”

Exclusive breastfeeding is the accepted standard for infant feeding. The well established optimal duration of exclusive breastfeeding is 6 months. Thus from a public health point of view, the appropriate age for introduction of complementary feeding is the beginning of the 7th month. Any earlier introduction of complementary feeding will shorten the duration of exclusive breastfeeding to the detriment of the health and wellbeing not only of the child but also of the mother (SACN 2018, Smith 2016, Victora et al 2016).

In line 75 to 78, the EFSA-Panel describes the purpose of this opinion as to “assess the scientific evidence in relation to whether there are 1) any developmental determinants for the introduction of CFs, 2) any adverse effects associated with the introduction of CFs before 6 months of age, and 3) any benefits associated with the introduction of CFs before 6 months of age.”

In line 82-84, it states that “This opinion is not an evaluation of the optimal duration of exclusive breastfeeding, as this assessment was performed irrespective of whether infants were initially exclusively breast-fed oder formula-fed.”

This assessment-procedure astonishes. It seems to assume that breastfeeding or formula feeding does not make a difference. When studying any short- and longterm health outcomes, for both the mother and the child, exclusively breastfed children have to be the control group in the age group under 6 months.

The question that needs to be asked is, if children that are partially or wholly formula fed need complementary foods before 6 months of age. Apparently, this does not seem to be the case, as the results for the outcomes studied as summarized in lines 211 to 253 suggest. Thus 6 months is the appropriate age for the introduction of complementary feeding for all infants, whether they are breastfed or not.

## **2. Developmental determinants**

In this report, developmental determinants are considered as “limiting factors” for the earliest possible introduction of complementary feeding (Line 1700: “The Panel notes that renal function is not a limiting factor.”) The Panel also notes (line 209): “the fact that, based on the available evidence, CFs could be introduced at an early age does not mean that this is necessary or desirable.” This gives credit to the request of the European Commission, which did not ask for the earliest possible time point for complementary feeding but for the appropriate time. In line 1729 and following, the infants ability to “efficiently accept spoon-food” is named as another developmental determinant. A broader view of the necessary oral motor functions includes, for example, the development of fine motor coordination. Naylor and Morrow state that “this development of proximal musculature occurs at or after six months”. They conclude that “oral motor function is developmentally ready for the introduction of semisolid and solid foods and thereby the discontinuation of exclusive breastfeeding between six and nine months of age.” (Naylor and Morrow 2001)

Of course there always is an age range for the attainment of developmental milestones, so advice has to be tailored to the individual child.

### **3. “Public health recommendation”?**

In line 81, the panel states: “This opinion does not provide public health recommendations for the introduction of CFs.” and in line 265: “The considerations made above may serve as a basis for risk managers to determine an age that can be used for labelling purposes.”

The indicated ages on labels of complementary foods are commonly understood by parents as more or less official recommendations to use the product from this age on. Thus it begs the question whether or not the opinion provides public health recommendations for the introduction of CFs.

There is clear guidance by WHO: Messages, including package labels, should not “include any image, text or other representation that might suggest use for infants under the age of 6 months (including references to milestones and stages)” (WHO 2016). The EFSA opinion does not provide any evidence to suggest that a deviance from this guidance would benefit public health.

#### **Literature**

- Naylor A, Morrow A, (edit) (2001). Developmental Readiness of Normal Full Term Infants to Progress from Exclusive Breastfeeding to the Introduction of Complementary Foods. Linkages Project [http://pdf.usaid.gov/pdf\\_docs/PNACS461.pdf](http://pdf.usaid.gov/pdf_docs/PNACS461.pdf)
- Scientific Advisory Committee on Nutrition UK (SACN) (2018). Feeding in the first year of life - report <https://www.gov.uk/government/publications/feeding-in-the-first-year-of-life-sacn-report>
- Smith H, Becker G (2016). Early additional food and fluids for healthy breastfed fullterm infants. Cochrane Database of Systematic Reviews 2016, Issue 8. Art. No.: CD006462 <http://bmjopen.bmj.com/content/bmjopen/6/1/e009163.full.pdf>
- Victora CG, Barros AJD, França GVA, et al (2016). Breastfeeding in the 21st century: epidemiology, mechanisms, and lifelong effect. *Lancet* 387: 475–90
- WHO (2016) Maternal, infant and young child nutrition. Guidance on ending the inappropriate promotion of foods for infants and young children. WHA 69.7 [http://apps.who.int/gb/ebwha/pdf\\_files/WHA69/A69\\_7Add1-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_7Add1-en.pdf)

#### **1.4.1.2. Minerals, vitamins and fatty acids**

It should be emphasised that iron depletion is a risk factor for iron deficiency anaemia which is associated with deleterious effects (e.g. delayed attention, poor recognition memory, long-lasting poor cognitive and behavioural performance) comment with quotes from EFSA and Kersting: EFSA: „It has been shown that infants have the ability to up-regulate iron absorption when iron stores decrease (Domellöf et al., 2002a; Hicks et al., 2006). This ability of each individual to adapt iron absorption to iron status is likely to make infants more resistant to iron deficiency than the factorial approach would predict. (European Food Safety Authority (EFSA). Scientific Opinion on nutrient requirements and dietary intakes of infants and young children in the European Union. EFSA-Journal 2013;111 (10), p. 3408)

Kersting: „The assessment of the iron status and in particular the meaningful definition of Iron deficiency for infants are difficult, if not impossible, to achieve, as the EFSA currently sums up. It is true that serum ferritin is regarded as a specific biomarker of the total iron storage in the body and low ferritin levels signal iron storage depletion. In infancy with its high growth-related iron demand, it is difficult, however, to establish limit values for an iron deficiency with functional consequences. It is possible that the thresholds generally used so far, overestimate the prevalence of iron deficiency as well as iron deficiency anaemia in infants.“

Translated from: Kersting, M, Sonderwertung der PINGU-Studie zum Thema: Eisenversorgung, Stillen und Beikost bei Säuglingen bei Ernährung gemäß den Handlungsempfehlungen des Netzwerks Junge Familie“, 2015

#### **1.4.1.3. Growth of exclusively breast-fed infants**

Comment: Cohen et. al, Dewey et. al conducted their studies in Honduras. These studies play an important role in this report (i.e.iron depletion, infections) Honduras is a lower-income country with a high number of stunted children (34,5% in 2001) and malnourished pregnant women. (Global Nutrition Report, Honduras, 2018). So, taking into account your exclusion criteria these studies should be excluded.

#### **2.1.1.2. Exclusion**

„- investigated growth or iron status in populations with high prevalence of undernutrition, wasting and/or stunting, in populations under clinical care, or with diseases/disorders/medication use known to affect nutritional status (e.g. malaria and iron status)“ Line 980 „investigated the outcome ‘infections’ in low and lower-middle income countries in settings with poor hygiene conditions (see Section 12.2 for reasons). These countries were identified according to the World Bank criteria, comparing the year in which the studies were conducted with the historical data of the World Bank per country.“

Comment: As mentioned above: Cohen et. al, Dewey et. al conducted their studies in Honduras. These studies play an important role in this report (i.e.iron depletion, infections) Honduras is a lower-income country with a high number of stunted children (34,5% in 2001) and malnourished pregnant women. (Global Nutrition Report, Honduras, 2018). In 1996, the Ministry of Health of Honduras conducted a

national micronutrient survey that included anthropometric measurements to determine the nutrition status of children 12-71 months old. Among the 1744 children who participated, 38% of them were stunted, including 14% who were severely stunted; 24% were underweight, of which 4% were severely underweight; and 1% were wasted, of which 0.1% were severely wasted. (<http://www.bvsde.ops-oms.org/texcom/nutricion/0646.pdf>) So, taking into account your exclusion criteria these studies (and a lot more of studies from the list of references should have been excluded.

### **3.1. Gastro-intestinal function**

Line 1683 The human gut is anatomically and functionally mature at birth in the healthy term infant, although the secretion and activity of gastric and pancreatic enzymes are not developed to adult levels (Naylor and Morrow, 2001). These functions mature at very different rates and the ingested foods appear to play a part in triggering the maturation of gastric and pancreatic enzymes.

The Panel notes that gastro-intestinal function is not a limiting factor with respect to the timing of introduction of CFs once the infant has the necessary neuromotor skills and the infant has developed an interest in nonmilk foods and feeding.

Comment: This conclusion is not at all convincing, regarding the fact that Naylor and Morrow, who serve as reference draw a quite different conclusion (cited below)

Quote : „In general, the human gut is anatomically and functionally mature at birth in the full-term infant. However, subtle immaturities in luminal digestion, mucosal absorption and protective function exists at birth that may predispose the infant during the first six months of life to age-related gastrointestinal and systemic

diseases. Since access to gastrointestinal tissue during the third trimester and during infancy is problematic, a complete understanding of immaturities is lacking. However, it is suggested that exclusive breastfeeding provides both passive and active support of the infant’s gut function during the first six months of life as an extra-uterine extension of maternal influence.“

### **3.3 Neuromuscular coordination and neurodevelopment**

Another aspect to consider is that, in order to efficiently accept spoon-fed foods, the infant has to be able to move the upper lip down to wipe the food from the spoon with the lips (instead of suckling it off the spoon) (Stevenson and Allaire, 1991; Ayano et al.,

Comment: spoon-feeding is a widely used method to feed the new-born infant with breastmilk, if breastfeeding is temporally not possible. So, the ability to take food from the spoon can’t be regarded as a sign of maturity for CF. Line 1812 „Panel considers that some of the skills considered relevant for the consumption of pureed CFs as well as infant interest in these foods appear at about 3-4 months, but with a wide range up to around 6 months.“ comment: This summary is not convincing. The age data provided in this section rather indicate an average age of 4.5 to 6 months and older and not an age of 3 - 4 months.

#### **4.3.1. WAZ and attained weight**

Line 1888 For WAZ or attained weight, the evidence derived from the five RCTs (Cohen et al., 1995a; Mehta et al., 1998; Dewey et al., 1999; Jonsdottir et al., 2014; Perkin et al., 2016) did not show an effect of the of introduction of CFs at 3-4 months of age compared with introduction at 6 months on these endpoints assessed up to the age of 3 years (Appendix A.1 and A.3). This is true for the pooled estimate as well as for the results of the individual studies. Heterogeneity was not important (I<sup>2</sup>=0% for both WAZ and attained weight).

Comment. A closer look into the above mentioned studies reveal that Cohen, Dewey, and Jonsdottir examined the outcome of exclusively breastfed 4 months old children v. 6 months old children. Children who were exclusively breastfed for only 3 - 4 months were excluded from the studies. Perkin et al (Introduction of Allergenic Foods in Breast-Fed Infants) were not very successful with their intend to introduce (allergenic) foods before 4 months. In the Early Introduction Group (the median age of the participants at enrollment was 3.4 months) the median age of first consumption was: Dairy: 17.3 weeks, 7 egg: 19,6 weeks, fish: 19,6 weeks, sesame: 19,6 w., peanut: 19,6 w., wheat: 20,6 w. From these given data one can conclude that many of the children were older than 4 months when starting CF . It has to be emphasized that only 31.9% of the total number of participants enrolled in the early-introduction group adhered to the protocol. Introduction of CF at 3 - 4 months does not reflect the content of at least 3 of the cited studies.

#### **6.3 Obesity: summary of the evidence**

Line 2230 The Panel notes from the six prospective cohort studies (Tiers 1 and 2) that, in the main line of evidence, there is no evidence for an association between the timing of introduction of CFs and the chance of developing obesity up to 11 years of age.

Comment: This conclusion is not consistent with the publication cited below: „Conclusion: The present work confirms the beneficial effect of breastfeeding against obesity, which was highly increased if children had never been breastfed or had been breastfed for a shorter period. Nevertheless, adoption of exclusive breastfeeding is below global recommendations and far from the target endorsed by the WHO Member States at the World Health Assembly Global Targets for Nutrition of increasing the prevalence of exclusive breastfeeding in the first 6 months up to at least 50% by 2025.“ (Association between Characteristics at Birth, Breastfeeding and Obesity in 22 Countries: The WHO European Childhood Obesity Surveillance Initiative – COSI 2015/2017) This publication should be considered, as well.

#### **8.8 Atopic diseases: conclusions**

comment: SACN/COT 2011 is listed as reference but not SACN and COT „Assessing the health benefits and risks of the introduction of peanut and hen’s egg into the infant diet before six months of age in the UK“, 2017 which concludes:

„The benefit-risk assessment indicated that there were insufficient data to support the existence of a “window of opportunity” for the introduction of peanut before six months of age. Evidence that the introduction of hen’ s egg before six months might be beneficial was limited and derived from RCTs

where participants were not representative of the general population. The benefit-risk assessment indicated that there were insufficient data to demonstrate that the introduction of peanut or hen's egg into the infant diet between four and six months of age reduced the risk of developing food allergy to any greater extent than introduction from around six months."

### **9.3. Coeliac disease: summary of the evidence**

line 3874 The Panel notes that, from the RCT and the meta-analysis of four prospective cohort studies (Tiers 1 and 2) in the main line of evidence, there is no evidence for an association between various timings of introduction of gluten or gluten-containing foods and the hazard of developing coeliac disease up to 12 years of age. There are also no differential effects of gluten introduction <4 months of age and between 4-6 months of age, or gluten introduction <6 months of age while still breast-feeding.

comment: In children of high risk for CD, earlier introduction of gluten (4 vs. 6 mo or 6 vs 12 mo) is associated with earlier development of CD autoimmunity (defined as positive serology) and CD" (Szajewska et al., 2016). This conclusion should have been considered as well.

### **12.6. Infections in general: summary of the evidence**

Line 4258 The Panel notes that there is no evidence for an association between the timing of introduction of CFs and hospitalisation for infections in the study (Tier 1) in main line of evidence from a large cohort.

Comment: This study for example does not make a difference between exclusively and partially breastfed infants, which is a major problem of the complete report. Kramer et al., 2012, state as follows: „Infants who are exclusively breastfed for six months experience less morbidity from gastrointestinal infection than those who are partially breastfed as of three or four months, and no deficits have been demonstrated in growth among infants from either developing or developed countries who are exclusively breastfed for six months or longer“

### **15.3 Iron status: summary of the evidence**

Line 4473 Three RCTs (Dewey et al., 1998; Dewey et al., 2004; Jonsdottir et al., 2012) were available that investigated the effect of introduction of CFs at 4 months compared with exclusive breast-feeding up to 6 months of age on iron depletion.

Comment: Dewey et. al conducted their studies in Honduras. As mentioned above, Honduras is a lower-income developing country with a substantial number of stunted children (34,5% in 2001) and malnourished pregnant women. It is questionable to apply the results of these studies to European countries. Jonsdottir:

As it is mentioned in line 2377 „The RCT (Jonsdottir et al., 2014) that was available was relatively small in sample size“ „ However, this study was most likely underpowered for the outcome and its non-statistically significant findings were therefore not further used by the Panel for drawing conclusions“

This should apply to Jonsdottir, 2012 as well – same study collective.

The conclusion the panel has drawn is not convincing, at least not for European children

## 20 Conclusion

Line 5320 „The available data do not allow the determination of a precise age at which CFs should be introduced to all infants living in Europe. The appropriate age depends on the individual’s characteristics and development, even more so if the infant was born preterm. In most infants, this age is between about 3-4 months and

around 6 months. For pre-term infants, this refers to post-term age.“ Line 5259

„This opinion should not be interpreted as providing public health recommendations for the introduction of CFs.“

Line 5325: The considerations made above may serve as a basis for risk managers to determine an age that can be used for labelling purposes.

Comment: Though this report is not meant to serve as a public health recommendation, it will still be considered as a recommendation from many sides. It will also enable the food industry to label its products as being suitable for 3 months old babies. This contradicts all recommendations worldwide, which mainly recommend exclusive breastfeeding for the first 6 months of life, but at least for 4 months of life. Introducing CF early means a decrease in nursing frequency and duration, quote: „When complementary foods were introduced at 4 months, nursing frequency and duration decreased spontaneously. Even in the group that was advised to maintain nursing frequency, mothers reported that infants demanded less frequent feedings. Consequently their breastfeeding frequency generally declined by 21 weeks.“ (Cohen, 1994). The report with its statements undermines all efforts to promote breast-feeding for a longer period of time, as it is postulated in the Global Nutrition Targets 2025: „Increase the rate of exclusive breastfeeding in the first 6 months up to at least 50%. – Exclusive breastfeeding is part of optimal breastfeeding practices, which also include initiation within one hour of life and continued breastfeeding for up to 2 years of age or beyond.“

### Final comment:

What is an appropriate age for introducing complementary feeding? In all times the answer to this question has been influenced by many factors like the public opinion, medical advice, economical reasons and so on. History has shown, that it is possible to feed a child with solid foods from very early infancy on. In the 1950th it was propagated by some pediatricians to start complementary feeding from the age of 2 weeks or earlier. And up to the 1980th it was officially recommended to start complementary feeding, when the infant was 6 weeks old. All these recommendations were justified with being results of „scientific research“. Infants had to accept any feeding style, willing or not. Their maturity definitely did not matter. Usually they were and are able to survive, no matter at what time CF is introduced, at least in developed countries. So, it is quite clear that a child has to and will accept any kind of feeding style, if one only demands it strongly enough. - Is that appropriate? No, definitely not! „Appropriate“ means first of all, to include the childrens perspective. An appropriate age has been reached, when a child signals its readiness for CF: It can sit with just a little help, it has a good handmouth-eye coordination, it likes to imitate the persons around him, which for example could be reaching out for a piece of bread and putting it into his mouth. We have seen in the past that recommendations, which relied on scientific research only, were biased and also changed, frequently. This report, which is not meant to be a recommendation, should have included more aspects than only physical development, especially as the drawn conclusions are not comprehensible in many cases. Taking into account the child's perspective, an appropriate time for the introduction of CF, has

definitely not been reached, when it is 3 to 4 months old. A broader view would have shown that the appropriate age for the introduction of CF is usually around six months. After a thorough review of a great deal of the studies from the list of references, it has to be stated that the conclusions drawn by the panel are not at all convincing!

## **Helen Keller International – Jennifer Nielsen**

Helen Keller International is a global non-governmental organization dedicated to combating the causes and consequences of malnutrition, blindness and poor health.

Our programs are evidence-based, and we strive to generate and utilize the most up-to-date research on optimal nutrition practices and policies. The evidence is incontrovertible that exclusive breastfeeding for six months is superior nutritionally and in terms of bioactive content to all other feeding options (World Health Organization, 2013). Human breastmilk has a dynamic composition and contains many hundreds to thousands of distinct molecules, growth factors and prebiotics that protect against infection and inflammation and play a profound role in infant survival and health (Ballard & Morrow, 2013). The Lancet Commission on Maternal and Child Undernutrition estimated that failure to adhere to World Health Organization (WHO) breastfeeding recommendations, which include putting an infant to the breast within one hour of birth, exclusive breastfeeding for six months and continued breastfeeding for an additional 18 months or longer, contributes to 11.6 percent of all child deaths. This translates to hundreds of thousands of lost lives. Exclusive breastfeeding is also the best option for infants of mothers who are HIV positive (World Health Organization & United Nations Children’s Fund, 2016).

A soon to be published review of the recommendations on exclusive breastfeeding reaffirms the longstanding conclusions that complementary foods should be introduced at around six months of age (Pérez-Escamilla, Buccini, Segura-Pérez, & Piwoz, In Press). It also concludes that the risk of iron-deficiency in the first six months of life can be successfully mitigated in term infants by delayed

umbilical-cord clamping and by medicinal iron drops beginning at 2-3 months of age for low birthweight infants. These data reflect decades of research and scientific consensus. We therefore find the draft opinion of the EFSA Panel on the “Appropriate age for introduction of complementary feeding into an infant’s diet” that this can be as early as three months of age to be misguided, inaccurate and dangerous. It is especially so in countries and localities with a high burden of malnutrition, where the conditions your opinion assumes, namely that breastmilk substitutes are “prepared following good hygiene practices,” are often not assured. We dispute the conclusion that “There is no evidence for adverse effects of introduction of CFs in infants (term/pre-term) at the ages investigated by the studies (ranging from <1 to <6 months of age)”. A systematic review has shown that exclusive breastfeeding for six months compared to three to four months reduces gastrointestinal infections among infants in both developed and developing countries (Kramer & Kakuma, 2012; Quigley, Kelly, & Sacker, 2007). There are benefits to the mother as well of lactational amenorrhea (Labbok et al., 1997) and accelerated weight loss (Dewey, Heinig, & Nommsen, 1993).

Our own research across multiple countries shows clearly that complementary food products manufactured in Europe are exported to low-income countries. We conducted a cross-sectional study of the labeling of commercially produced complementary foods sold by enterprises in Cambodia, Senegal and Tanzania (Sweet et al., 2016). We found 33, 74 and 46 percent of these products, respectively, were produced and labeled in Europe (JB Consultancy, 2015). In these three countries stunting rates among children under five range from 17 to 34 percent, while infant mortality rates range from 26 to 43 (United Nations Children’s Fund, 2017). In these settings, suggesting an early age for the introduction of food - and thus early cessation of exclusive breastfeeding - is not only contrary to global, evidence-based guidance, it can be life-threatening. The draft opinion would therefore seem to violate the mandate of the European Food Safety Authority as well as its core values of scientific excellence and independence. A number of well-designed studies suggest that exclusive breastfeeding

is protective against later obesity, a public health problem of mounting significance (Swinburn et al., 2019). A recently published analysis of data from 22 European countries found the odds of being obese were higher among children never breastfed or breastfed for less than six months compared for children breastfed for at least six months (Rito et al., 2019). A metaanalysis conducted by researchers in the UK that pooled data from 10 studies found a significant 15 percent reduced odds of overweight among breastfed compared to non-breastfed infants (Weng, Redsell, Swift, Yang, & Glazebrook, 2012)

### **1.3. Definitions**

The definition already sets the start to a very biased selection and interpretation of the data. In line 722 -724 the definition says: CF in this opinion comprises, therefore, all liquid, semisolid and solid foods other than breast-milk and formula, water and vitamins which are fed to infants. CFs can be beverages, spoon-fed foods, or finger-foods. This is highly problematic when in the terms of reference the Directive 2006/125/EC on processed cereal based foods and baby foods for infants and young children is especially mentioned! Complementary food should cover the period where there is a diversification from a liquid diet to semisolid and solid food to achieve participation in family food. The panel seems to ignore that infants modulate their caloric intake and that every calorie intake from CF before the age of 6 months and later during the continued BF period reduces the intake of breastmilk and the duration of breastfeeding!

Line 735 -37: "The Panel considers that the appropriate age of introduction of CFs (which is the subject of this mandate) should not be regarded as synonymous with the optimal duration of exclusive breastfeeding." This sentence written to calm objections makes no sense as the introduction of CF means that exclusive BF is stopped! From a scientific viewpoint the health effects of breastfeeding are dose-dependent so every food introduced before six months has a negative health impact on the breastfed child and no positive impact on a non breastfed child!

#### **1.4.1.2. Minerals, vitamins and fatty acids**

"However, the Panel considers that the iron status of the infants is a determinant for the need to introduce CFs." This conclusion omits the different bioavailability of iron from breastmilk compared to other sources of iron. It also ignores that research has shown that late clamping of the cord gives larger iron stores to the infants compared to the immediate or nearly immediate clamping practiced in most countries but these practices are about to change.

#### **2.1.0. Data**

When searching for data there was no criteria to check if the research comes from an independent public funded source, or if the funding source may have created bias or a conflict of interest! There was no investigation in the researchers of the selected studies to exclude studies where researchers have a conflict of interest! This is not really surprising as the expert panels declarations of interests, that I received after asking for them, as I could not find them, were for some incomplete and for others, even that relations with manufacturers of CF were declared, did not lead to their exclusion!

### **3.4. Developmental readiness of the term infant to receive CFs: conclusions**

The conclusions omit that the neuromuscular development consists of different endpoints and for receiving CF all these endpoints should be met, just opening the mouth is not enough nor sitting in the lap of a care-giver (which means some support) nor reaching for food or swallowing a small quantity! The conclusion should reflect the variation when most endpoints are met and not introduce the 3 months when only one endpoint is met in some very precocious infants.

### **6.5. Obesity and overweight: conclusions and grading of the confidence in the evidence**

For a non epidemiologist all the sorting and analyses of the studies can be hardly followed through but the following text in line 2461-63: "The age s of introduction of CFs ranged between <1 month and <4 months for early introduction and >2 months and ≥6 months for later introduction." Categorizing 2 and 3 months as early introduction in some studies and as late introduction in others shows for me a total confusion! The new publication of WHO Cosi showed a relationship!

## **20. Conclusions**

How can introduction of complementary food be called delayed after 6 months when during the discussion of the development milestones it became clear that development happens at different pace for different children and some will only achieve the milestones at 9 months. This should mean that all those age ranges should be part of normal diversity. But the terms of reference were only interested in earlier introduction! Analyzing if late introduction after 6 or 7 months would have adverse effects or not was excluded adding to the bias of the analysis. Including any texture is opening the conclusions to a too early age even that there is no benefit in exchanging IF with cereals in a bottle and surely harm done on a population basis if exclusive breastfeeding is undermined or stopped as this will negatively affect the long term health of women and children as proven in numerous studies (Those studies were not part of the assessment, were only some health effects were included in this assessment!)

### **Other comments**

I hope that the risk managers who will now have to decide on the labelling of industrially produced complementary foods will seriously reflect on the message that labelling sends to care givers and not undermine the WHO recommendation on introduction of CF nor undermine the actual Codex standard but hopefully align with the international community.

### **1.3 Definitions**

Pages 15-16: The value of breastmilk and breastfeeding is well known and has been proven extensively, with exclusivity a key factor in reducing morbidity. The addition of any other foods to the diet destroys that exclusivity. In addition, there is good evidence that breastfeeding infants are able to regulate their intake, which means it is likely that the introduction of complementary foods (CFs) will not only interfere with the digestive and protective effects of (exclusive) breastfeeding but will also trigger a reduction in the amount of breastmilk the infant takes. Lines 725-7 (page 15) acknowledge this, stating that the ‘gradual reduction of frequency and volume of breast-milk or formula ... starts with the first introduction of CFs’. It is therefore unrealistic and misleading to suggest (page 16, lines 735-7) that the introduction of CFs can (or should) be viewed separately from the optimal duration of exclusive breastfeeding

#### **1.4.2 Nutritional adequacy of exclusive breastfeeding: overall conclusions**

Page 18, lines 837-8: The introduction of solid foods to an infant who is too immature to be able to feed himself with them (i.e. to pick them up, with or without a spoon, and transport them to his mouth) is not seen in any other mammal group. It can therefore be considered an intervention in the life of human infants, who, it can be reasonably assumed, would otherwise progress to solid foods through mimicry of their parents and self-feeding. Any divergence from the biological norm should be justified through proven benefit, not merely the absence of evidence of harm (which is, in any case, not the same as evidence of no harm). Adherence to the current recommendation of around 6 months for the majority of infants would ensure the protection of the majority without precluding the earlier introduction of CFs for individual infants for whom they are deemed necessary.

##### **2.1.1.1. Inclusion**

Page 20, lines 918-20: While infants in either an exclusively breastfed or an exclusively formula-fed group may be considered to be alike in terms of milk-feeding, those in a ‘mixed feeding’ group are likely to be very disparate, with some receiving a large proportion of their milk as breastmilk and others very little. Without more information, any comparison of mixed-fed infants with either fully breastfed or fully formula-fed infants is likely to be invalid and unreliable.

##### **2.1.1.2. Exclusion**

Page 21, lines 961-5: It is unfortunate that studies comparing the introduction of CFs at the same age in breastfed versus formula-fed infants were not considered, since it is quite possible that different recommendations may be appropriate for breastfed vs. formulafed infants. This may relate, for example, to the need for iron-rich foods or the introduction of new flavours, or to foods that require chewing.

##### **2.1.2.1. Inclusion**

Page 24, lines 1053-7: It is unfortunate that the ability to take food to the mouth is not seen as relevant to the introduction of CFs. Most infants achieve this at around 6 months, which is the age at which, the Panel agrees, CFs begin to become necessary nutritionally. Why should this key motor skill not be considered a useful indicator of readiness? It is equally unfortunate that two of the milestones considered relevant, namely the disappearance of the extrusion reflex and the ability to transport food to the back of the mouth, necessitate the insertion of food into the mouth in order to assess them.

### **3.0. Assessment of the developmental readiness of the term infant to receive CFs**

Page 42, lines 1676-7: The concept of the infant as a recipient of CFs, rather than as an active consumer of them, is prevalent throughout the document. This image is at odds with the self-feeding that infants become capable of as they near 6 months. Statements and discussion that centre around the infant's readiness to 'receive' CFs tend to support the idea that introducing them at younger ages is appropriate, thereby colouring the debate.

Page 42, lines 1680-1: 'The infant's emerging interest in non-milk foods and feeding' is mentioned as a relevant milestone in several places within this section of the document. I cannot find a definitive description of this interest anywhere in the text yet it appears to be given equal weight with motor development, for which more concrete, observable signs are described. Identification of 'interest' – never mind 'emerging interest' – by either a parent or a professional would seem to be very subjective, and as such can hardly be considered a reliable indicator of anything. Indeed, parents are commonly advised not to confuse an infant's general interest in his parents' activities (including eating) with a readiness for CFs, not least because the infant has yet to connect what he sees them doing with his own feelings of hunger. The relevance of this supposed indicator to a discussion of readiness for CFs is therefore questionable. (But see also my comments in relation to Section 3.3).

### **3.3. Neuromuscular coordination and neurodevelopment**

Page 43, lines 1717-9: On what has been, admittedly, a rather rapid reading of the draft opinion (owing to time constraints) it appears that the estimation of 3-4 months for the initiation of voluntary oral control is the basis for the proposed lower end of the recommended age for the introduction of CFs. This is in spite of the fact that, as the Panel acknowledges, there is a lack of data to support this. Even if there were better evidence, initiation of a behaviour does not equate to competence or mastery of the underlying skill. It would be inappropriate to make a recommendation for all infants on the basis of a skill that some may have begun to develop at a particular age. Page 43, lines 1729-31: There is a clear emphasis here on the skills required to accept semi-solid foods from a spoon. The work of Stevenson and Allaire (1991) is used as a reference and yet these authors comment in the same paper that the case for semi-solids is not proven but is instead based on child-rearing beliefs and customs. It would seem more pertinent to consider the acquisition of biting, munching and chewing skills, which enable the consumption of a range of textures (and which rarely appear before around 6 months). In any case, as any parent knows, it is perfectly possible to bypass an infant's lip-clearing (in) ability by wiping the spoon upwards against his or her top lip and gum, thereby enabling semi-solid foods to be given to very young infants.

Page 44, lines 1767-79: The ability to sit alone is acknowledged by the Panel as a key indicator of well-developed head and trunk control, which is considered necessary for the safe feeding of CFs. The range of ages at which infants achieve this is noted to be very wide, with an average, as reported in the

studies quoted, of between 5.4 and 6.9 months for AGA infants. This suggests that the majority of infants do not have the required ability at 3-4 months.

Page 44, lines 1780-5: I suggest that reaching for the spoon 'when hungry' is not an indicator of a relevant skill. It is not clear that infants necessarily associate a spoon with resolving hunger, especially if they have not yet been offered CFs. Equally unreliable is opening the mouth in response to the touch of a spoon on the lips, primarily because – as suggested by the age range over which this behaviour is reported (0.5 to 9 months) – infants commonly open their mouths in response to touch (for example of a nipple or teat), so may well do the same for a spoon irrespective of any readiness for CFs. A similarly large age range is reported for the ability to move food to the back of the mouth using the tongue, which would seem to indicate merely that it is possible to give very young infants food which they will then swallow, not that it is safe to do so.

Pages 44-5, lines 1785-96: It seems illogical to report on the age at which infants 'reach out for food', which is open to a liberal interpretation of what may be very vague actions, while not considering the development of the ability to pick food up and transport it to the mouth, which is easier to define accurately and likely to be at least as relevant. Although not overtly stated, it appears that reaching for the spoon or food and/or opening the mouth are proposed as evidence of the infant's 'emerging interest in food', as referred to elsewhere in the document. To assume this is highly unsatisfactory, for the reasons stated.

### **3.4. Developmental readiness of the term infant to receive CFs: conclusion**

Page 45, lines 1808-14: If 'the skills necessary to consume small amounts of pureed foods ... differ from those required to consume more textured, lumpy or finger foods' (which are usually present by around 6 months), maybe the question should be 'Are pureed foods needed at all for the majority of infants?'

Page 45, lines 1820-4: It is difficult to see how the lower age of 3-4 months has been deduced from the presented evidence, especially that concerning neuromuscular coordination and neurodevelopment – aspects which, the Panel argues, are to be considered of greater importance than either gastrointestinal or renal function. Most of the evidence would seem to point to an age nearer 6 months.

Page 45, lines 1825-6: The conclusion that 'most term infants are ready to be introduced to CFs between about 3-4 months of age and around 6 months of age' is alarming. This wording could be taken to mean that any age within that range is appropriate for any infant, rather than that each individual infant will achieve readiness at a specific point within that range. Clinical experience suggests that, when an age range is stated, it is commonly misinterpreted in this way, making it likely that such a statement could lead to huge numbers of infants receiving CFs before they either need or are ready to manage them. In addition, past experience has shown that there is a tendency for parents and professionals to lean towards the lower end of a recommended age range. Indeed, the change to 'around 6 months' has resulted in fewer infants being introduced to CFs prior to 4 months. Were the recommendation to refer once more to 4 months – or worse, 3 months – this trend would almost certainly be reversed.

Where there is a 'large biological variability', such that a precise age cannot be determined, the risks of opting for a wide recommended age range should be weighed against the potentially safer alternative of leaning towards the higher end of the range, especially given the accepted absence of nutritional need at the lower end. It is also worth noting that 'between about 3-4 months of age and around 6 months of age' is a very vague statement. It contains two qualifiers ('about' and 'around') and two potential interpretations of the age range (3-6 months and 4-6 months). Additionally, the

mention of two lower ages tends to reinforce that part of the wider range. At worst, it could be interpreted as ‘around 3 months’, thereby apparently condoning the introduction of CFs before 12 weeks of age.

### **8.7.3. Timing of introduction of egg**

Page 86, lines 3635-7: The Panel’s stated conclusion in relation to the effect of the age of introduction of CFs on egg allergy is at odds with quality of the evidence and the confidence level (rightly) assigned, and with the Panel’s decision that the evidence is not robust enough to justify a recommendation for the early introduction of egg to all infants.

## **12.2. Infections: endpoint and study selection**

Page 99, lines 4134-7: I suggest that it is not ‘implausible’ that infections occurring several months later might be related to the timing of the introduction of CFs if the length of time over which there has been a reduction in the intake of breastmilk is taken into account. It may be that, as the infant’s intake of breastmilk reaches a critical level (as yet undefined), the risk of infection is suddenly increased. Thus, infants who start CFs earlier may be at greater risk of infection at a younger and more vulnerable age (over one year) than those who start later. Put another way, the duration of the protective effect of (any) breastfeeding may be reduced by the early introduction of CF.

Page 99, lines 4138-41: It is very revealing that studies conducted in low and lowermiddle income countries were excluded for the outcome relating to infections, owing to the difficulties of disentangling the effects on infections of poor food hygiene, suboptimal nutritional status and/or the nutritional inadequacy of CFs in these countries from the timing of introduction of CFs. The introduction of CFs is inevitably and inextricably tangled up with the risk of exposure to infection, and areas of poverty, where risks of poor food hygiene etc. abound, exist in even the most affluent (European) countries. Even if this were not so, the fact that the remit of the Panel is restricted to European countries does not ensure that the effects of their opinion will not be felt throughout the world. This is why recommendations and labelling matter so much, and why CFs should not be condoned or encouraged for any infants for whom they are not necessary nutritionally.

## **12.4. Upper respiratory tract infections: summary of the evidence**

Page 101, lines 4230-1: Two studies (Forsyth et al, 1993, and Perkin et al, 2016) found an increased risk of URTI at 3-6 and 5-6 months of age, respectively. It is not clear why this should be dismissed merely because it is transitory, not least because URTIs commonly lead to unnecessary antibiotic usage.

## **15.3 Iron status: summary of the evidence**

Page 108, 4492-4: On a point of accuracy: it is more correct to state that premature clamping of the umbilical cord decreases iron stores than that delaying clamping increases them. It is important to start from a position of what is biologically normal.

Page 108, lines 4502-4: This statement does not appear to reflect the evidence accurately. The following points are relevant:

1. The combination of the three RCTs for the purposes of meta-analysis is questionable, since it allows the predominance of SGA infants in the two studies by Dewey et al to affect the data from the study by Jonsdottir et al. In all, well over half the infants in the combined analysis were SGA. Taking the three studies separately, it is clear that the greatest risk for iron depletion (and therefore the greatest benefit attributable to the early introduction of CFs) was found within the SGA cohorts.

2. The risk of iron depletion in exclusively breastfed infants whose umbilical cord was not clamped prematurely has not been established.

3. Jonsdottir et al (2012) reported that 'Whereas infants in CF group had higher iron stores at 6 months compared with those in EBF group, both had adequate stores as measured by SF levels' (my emphasis). In addition, 'no significant differences were seen between groups in iron deficiency with or without anemia'. This seems at odds with the data from this study presented by the Panel.

4. In the 1998 study by Dewey et al no exclusively breastfed infant with a birth weight over 3000g had a low ferritin value at 6 months.

5. Dewey et al (2004) found that iron levels were higher in exclusively breastfed infants receiving iron supplements than in those receiving CFs. They hypothesized that CFs might interfere with iron utilization and considered supplements a preferable option for infants in need of additional iron.

The statement in the Conclusion (Section 20, Page 130, lines 5277-82) is noted to be much less stark than this one, suggesting as it does that the early (i.e. before 6 months) introduction of iron-rich CFs may be indicated in babies whose iron levels are compromised, as a way of reducing the risk of iron depletion.

### **16.3.1 Timing of introduction of CFs in general**

Page 112, lines 4633-5: The less desirable eating behaviours listed have the potential to influence the development of lifelong conditions such as obesity and feeding/eating disorders. Given that CFs are unlikely to be needed nutritionally until 6 months, this represents a strong argument for avoiding them below this age.

Page 113, lines 4679-82: The introduction of CFs before 3 months has been found to increase the proportion of daily energy intake obtained from ultra-processed foods. This does not mean that delaying the introduction of CFs until 3-4 months will avoid this. On the other hand, it does imply that recommending an age at which the infant no longer needs finely pureed foods (i.e. nearer 6 months) may make it less likely that parents will rely on commercial (processed) products.

## **19. Integration of results**

Page 123, lines 5017-24: This wording suggests that iron depletion is a risk for all exclusively breastfed infants, whereas the evidence suggests that only some infants are at risk and that these are identifiable. As discussed elsewhere in my comments, it is not clear that, for these infants, the early introduction of CFs is a better option than iron supplementation.

Page 125, lines 5055-8: In my view it is not sufficient to offer, as part-justification for a potential lowering of the recommended age for the introduction of CFs, evidence that the early introduction of specific CFs does not appear to cause harm. This is firstly because a lack of evidence of increased risk

is not the same as evidence of no increased risk, and secondly because any intervention beyond the biological norm should be implemented only if it has been proven to be positively beneficial.

Page 125, lines 5062-6: I am in agreement with this paragraph; it is the strength of the evidence considered sufficient to justify the early introduction of CFs that concerns me.

## **20. Conclusions**

Page 130, lines 5294-6: It is reassuring to read this statement. However, as discussed elsewhere in my comments, the evidence offered for neuromotor developmental readiness to consume CFs (rather than merely to 'receive' them) is not convincing.

Page 130, lines 5261-2: As I have explained, for breastfed infants the age of introduction of CFs is synonymous with to the duration of exclusive breastfeeding.

Page 130, lines 5271-3: As I have argued, I do not consider that the rationale, based on developmental skills, for a lower limit of 3-4 months has been established.

Page 130, lines 5274-6: This point is crucial, especially if the assessment of neurodevelopmental readiness is questionable.

Page 130, lines 5294-6: Another crucial point.

Pages 130-1, lines 5315-8: The evidence regarding infections has been distilled to a minimum here, implying that the risks are similar for any infection, and for any age of introduction of CFs between 0 and 6 months. This is at odds with the wider discussion in Section 12. Issues of family income and hygiene are crucial and cannot be divorced from any discussion of infection. Recommendations that can really only be considered applicable to families with high standards of hygiene (as it appears those in this opinion are) should not be used as the basis for the labelling of products that will be – or may become – available more widely.

Page 131, lines 5325-6: Labels are very influential. For the reasons stated above it is difficult to conclude that any commercial baby food should be labelled as anything other than suitable 'from around 6 months'.

## **Other comments**

Lines 604-6 (page 13) state that the Panel's opinion is sought because of an EC requirement for a statement as to the appropriate age from which 'processed cereal-based food and baby food' may be used. This has prompted a review and update of the Panel's previous scientific opinion regarding the recommended age for the introduction of any type of complementary food (CF), including that prepared at home. Unfortunately, the possibility that commercially produced foods may be appropriate at a different age from home-prepared foods is not discussed. Indeed, studies comparing the use of commercial baby food with that of homecooked food have been deliberately excluded (line 975, page 22) and it is unclear which type(s) of food was used in the various studies that have been included. This point is important for several reasons: First, there are risks inherent in commercial food production that have the potential to affect many more infants than would be true of home preparation. Second, any suggestion that commercial foods may be safer than, or preferable to, home-prepared food would have huge implications for parents' choices, for their finances, and for the development of food preferences related to family foods. The draft opinion identifies groups of infants

who may benefit from the introduction of CFs as early as 3-4 months but does not present convincing evidence that such foods are either desirable or safe for the majority of infants of that age. It is unfortunate that so many of the studies referred to by the Panel have considered the introduction of CFs at 3-4 months and not, say, at 5 months. An infant of 6 months is double the age of a 3-month-old, representing a huge difference in all aspects of development. To suggest that the introduction of CFs may be appropriate at an age so far below the age at which they are needed nutritionally feels unsafe. Lines 607-9 (page 13) remind the reader that 'the product, if its use is recommended from 4 months, may indicate that it is suitable from that age unless independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care, advise otherwise'. A safer approach would be one in which the use of a particular product is not recommended earlier than 6 months unless independent persons ... advise otherwise.

I recognise what a huge piece of work has been undertaken by the Panel. However, this means that it is not possible for an individual to read all the papers reviewed and one must instead rely on the interpretations of them by the Panel. The lack of any declaration within the document of possible conflicts of interest amongst the members of the Panel makes it difficult to do this with confidence, not least because I am aware of at least one such conflict and have found several instances of what I consider to be misinterpretation of some of the studies with which I am familiar.

## **Unicef - Staff**

UNICEF is concerned about the draft opinion of the EFSA Panel on Nutrition, Novel Foods and Food Allergens regarding the “Appropriate age for introduction of complementary feeding into an infant’s diet”, and in particular its conclusions regarding the labelling of complementary foods and the impact these might have on infant and young child health.

Breastfeeding is recognized as a vital component in ensuring the child’s right to the highest attainable standard of health under Article 24 of the Convention on the Rights of the Child, and the 2002 WHO expert consultation on the optimum duration of breastfeeding clearly points out that the potential health benefits of waiting until 6 months to introduce complementary foods outweigh any potential risks<sup>1</sup>. Two more recent Cochrane reviews found no evidence to disagree with current global recommendations; both reviews confirmed and added strength to the evidence showing that exclusive breastfeeding for six months, compared to exclusive breastfeeding for a shorter duration, confers health benefits and no apparent harms<sup>2</sup>.

Since the Panel decided that “Considerations of the optimal duration, the health benefits or otherwise of breast-feeding itself are outside the scope of this mandate”, it seems contentious and irresponsible that the Panel then concludes that it may be appropriate to introduce complementary foods as early as 3 months of age and that this “may serve as a basis for risk managers to determine an age that can be used for labelling purposes”. The two issues cannot be separated. Product labels are often a vehicle for public health messaging and promotion, but can also undermine the health and well-being of consumers if inappropriate or misleading. A WHO-commissioned review of marketing for commercially-available complementary foods, and the impact that this has on carer attitudes and infant and young children feeding practices, identified that marketing strategies are based on the understanding of, and playing to, mothers’ concerns about the nutritional and health needs of infants and young children. The review found that marketing can mislead and confuse caregivers about nutritional and health-related qualities of CACFs and about the appropriate age of introduction. Marketing was found to influence knowledge, attitudes, preferences and behaviours of caregivers and resulted in increased use of products and negative impacts on breastfeeding exclusivity, duration of breastfeeding or early introduction of solid foods<sup>3</sup>. Parents and caregivers often understand the suggested age of introduction on the label of baby foods as an official recommendation, and any suggestion that a food should be fed before the age of six months would undermine the World Health Assembly’s global public health recommendation of exclusive breastfeeding for six months<sup>4</sup>, undermining the child’s right to the highest attainable standard of health. Marketing of commercial

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<sup>1</sup> The optimal duration of exclusive breastfeeding. Report of an expert consultation. Geneva: World Health Organization; 2002 (<http://apps.who.int/iris/handle/10665/67219>).

<sup>2</sup> Smith HA, Becker GE. Early additional food and fluids for healthy breastfed full-term infants. *Cochrane Database Syst Rev.* 2016(8); Kramer MS, Kakuma R. Optimal duration of exclusive breastfeeding. *Cochrane Database Syst Rev.* 2012;(8): CD006462. doi:10.1002/14651858.CD006462.pub4.

<sup>3</sup> Smith JP, Sargent GM, Mehta K, James J, Berry N, Koh C et al. A rapid evidence assessment. Does marketing of commercially available complementary foods affect infant and young child feeding? Canberra: Australian National University; 2015

<sup>4</sup> WHO. Infant and young child nutrition. World Health Assembly Resolution 54.2. 18 May 2001. [https://www.who.int/nutrition/topics/WHA54.2\\_ycn\\_en.pdf?ua=1](https://www.who.int/nutrition/topics/WHA54.2_ycn_en.pdf?ua=1)

complementary foods can affect optimal feeding practices and there is evidence of a reduction in the duration of breastfeeding<sup>5</sup>.

Recognising this, WHO has issued clarifying guidance which states that, irrespective of the format (online information, sponsorship or packaging labels), there should always be a statement about the importance of continued breastfeeding for up to 2 years or beyond and messages should not make any suggestions that they are suitable for infants under 6 months (i.e. through “suitable from” labels). The Sixty-ninth World Health Assembly called upon Member States, manufacturers and distributors, health-care professionals, the media and civil society to implement the WHO guidance<sup>6</sup>.

The focus of the opinion on the exceptions (some exclusively breast-fed infants at risk of iron depletion) who may potentially benefit from earlier introduction of CFs that are a source of iron in justifying a change in the age for introduction of complementary food is inappropriate in a public health document where the emphasis should be on recommendations for the majority of infants, with a mention of concerns for any minority group. Such a document should reflect the fact that it is generally accepted that the nutrient needs of full-term, normal-birth-weight infants can typically be met with human milk alone for the first six months, if the mother is well nourished<sup>7 8 9 10</sup>

In undermining recommended breastfeeding practices, this opinion also overlooks the importance of breastfeeding for maternal health, being protective against breast and ovarian carcinoma, and reducing the risk of type 2 diabetes<sup>11</sup>. The link between exclusive breastfeeding and lactational amenorrhea, which helps to reduce/prevent anemia should also be considered so that the opinion does not also undermine the health rights of mothers.

UNICEF disagrees that there is no evidence that the timing of introduction of CFs is associated with a higher chance of developing overweight and obesity. On the contrary, there is extensive work demonstrating the beneficial role of breastfeeding for later weight status<sup>12</sup>. Indeed, more and more

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<sup>5</sup> Tzioumis E, Kay M, Wright M, Adair L. Health effects of commercially available complementary foods: a systematic review. Chapel Hill: Gillings School of Global Public Health, University of North Carolina; 2015

<sup>6</sup> Resolution WHA69.9. Ending inappropriate promotion of foods for infants and young children. Sixty-ninth World Health Assembly agenda item 12.1. Geneva: World Health Organization; 2016 ([http://apps.who.int/gb/ebwha/pdf\\_files/WHA69/A69\\_R9-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_R9-en.pdf)).

<sup>7</sup> EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA). Scientific opinion on the appropriate age for introduction of complementary feeding of infants. EFSA Journal 2009;7(12):1423.

<sup>8</sup> Fewtrell M, Bronsky J, Campoy C, Domellöf M, Embleton N, Fidler Mis N et al. Complementary feeding: a position paper by the European Society for Paediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN) Committee on Nutrition. J Pediatr Gastroenterol Nutr. 2017;64(1):119–32.

<sup>9</sup> Complementary feeding of young children in developing countries: a review of current scientific knowledge. Geneva: World Health Organization; 1998 ([http://www.who.int/nutrition/publications/infantfeeding/WHO\\_NUT\\_98.1/en/](http://www.who.int/nutrition/publications/infantfeeding/WHO_NUT_98.1/en/)).

<sup>10</sup> Smith HA, Becker GE. Early additional food and fluids for healthy breastfed full-term infants. Cochrane Database Syst Rev. 2016(8): Kramer MS, Kakuma R. Optimal duration of exclusive breastfeeding. Cochrane Database Syst Rev. 2012;(8): CD006462. doi:10.1002/14651858.CD006462.pub4.

<sup>11</sup> Chowdhury et al. Breastfeeding and maternal health outcomes: a systematic review and meta-analysis, Acta Pædiatrica 2015 104, pp. 96–113

<sup>12</sup> Horta BL, Victoria CG. Long-term effects of breastfeeding. A systematic review. Geneva: World Health Organization; 2013 ([http://apps.who.int/iris/bitstream/handle/10665/79198/9789241505307\\_eng.pdf?sequence=1](http://apps.who.int/iris/bitstream/handle/10665/79198/9789241505307_eng.pdf?sequence=1)); Lefebvre CM, John RM. The effect of breastfeeding on childhood overweight and obesity: a systematic review of the literature. J Am Assoc Nurse Pract. 2014;26(7):386–401.

evidence to this effect is emerging from the European region<sup>13</sup>. While, due to the nature of studies available, the evidence on the impact of introducing foods before 6 months (versus at 6 months) is not as clear, there is consensus that risks are greater when foods are introduced before 4 months<sup>14</sup>, particularly in non-breastfed infants<sup>15 16, 17</sup>

In concluding that there is no evidence that in high-income countries with good hygiene conditions the early introduction of complementary foods is associated with an increased risk of gastro-intestinal or respiratory tract infections, the authors have ignored the recent and comprehensive report from the United Kingdom SACN which did find an association with higher risk of both types of infection when introducing solids at 3–4 months rather than continuing exclusive breastfeeding<sup>18</sup>. This approach also ignores the fact that within high-income countries or regions not all groups enjoy the same levels of wealth and standard of living, and there may not always be access to the levels of hygiene conditions referred to, with significant implications on health outcomes if the panel's recommendation on labelling is followed. Similarly, products targeted at populations living in high-income countries often find their way across borders into territories that lack the financial and hygiene conditions that the authors (mistakenly) claim reduce the risk of the early introduction of complementary foods.

As an organization dedicated to the realization of the rights of every child, UNICEF seeks to ensure that, in every action (including the drafting of an opinion from the EFSA Panel), the best interests of the child are regarded as a primary consideration. We do not consider this to have been the case in the drafting of this opinion.

While the Panel finds that complementary foods are not nutritionally needed before 6 months of age for most infants, it does not provide any evidence of advantages to introducing them before this age. Thus, it seems contentious to make recommendations for labelling complementary foods to be introduced as early as 3 months of age when there is no clear benefit in doing so. As indicated by the literature, early introduction of complementary foods undermines recommended breastfeeding practices and hence the health of infants, even in high-income countries. The Panel needs to seriously reflect on the consequences of making such recommendation and its potential impact on every child's right to attain the highest standard of health.

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<sup>13</sup> Rito AI, et al. Association between Characteristics at Birth, Breastfeeding and Obesity in 22 Countries:

<sup>14</sup> . Daniels L, Mallan KM, Fildes A, Wilson J. The timing of solid introduction in an "obesogenic" environment: a narrative review of the evidence and methodological issues. *Aust N Z J Public Health* 2015;39(4):366–73.

<sup>15</sup> Huh SY, Rifas-Shiman SL, Taveras EM, Oken E, Gillman ME. Timing of solid food introduction and risk of obesity in preschool-aged children. *Pediatrics* 2011;127(3):e544–51.

<sup>16</sup> Moss BG, Yeaton WH. Early childhood healthy and obese weight status: potentially protective benefits of breastfeeding and delaying solid foods. *Matern Child Health J.* 2014;18

<sup>17</sup> English LK, et al. Timing of introduction of complementary foods and beverages and growth, size, and body composition: a systematic review. *American Journal of Clinical Nutrition*, 2019:109(1);935S–955S. <https://doi.org/10.1093/ajcn/nqy267>.

<sup>18</sup> Feeding in the first year of life: draft SACN report [website]. London: Public Health England; 2017 (<https://www.gov.uk/government/consultations/feeding-in-the-first-year-of-life-draft-sacn-report>)

## **1.6. General considerations on the outcomes assessed**

The draft opinion of the EFSA Panel on Nutrition, Novel Foods and Food Allergens regarding the “Appropriate age for introduction of complementary feeding into an infant’s diet” is problematic in several regards – detailed below – and has potentially harmful consequences for the nutrition and lifelong health of children. We urge EFSA to reconsider its final conclusions with regard to the labelling of complementary foods for the reasons below. The draft opinion claims that it is not providing public health recommendations on the introduction of complementary foods and is not evaluating the optimal duration of exclusive breastfeeding. However, this distinction is illogical, as the issues cannot be separated. A conclusion that it is appropriate to introduce complementary foods as early as 3 months of age clearly implies the end of exclusive breastfeeding and thereby is in direct conflict with the evidence and understanding that the optimal duration of exclusive breastfeeding for the overall health and well-being of infants, is 6 months. In nearly all European countries, a majority of 6-month old infants are still breastfeeding,\* so introduction of complementary foods in the region is implicitly related to the continuation of exclusive breastfeeding. \* Rito AI, et al. Association between Characteristics at Birth, Breastfeeding and Obesity in 22 Countries: The WHO European Childhood Obesity Surveillance Initiative – COSI 2015/2017. *Obes Facts* 2019;12;226–243. <https://www.karger.com/Article/PDF/500425>.

### **2.1.1.2 Exclusion**

It is problematic that the literature reviews conducted by the Panel are limited to high-income countries. While it is important to ensure that the evidence examined is appropriate to the settings where the recommendations will be applied, the Panel must recognize that not all populations in Europe have similar socioeconomic status and living conditions. Inequities within high-income countries lead to significant subpopulations that do not always have the safe and hygienic conditions associated with the upper-income groups. As such, it is important to consider what the effects of recommendations will be on all population groups.

## **6.5. Obesity and overweight: conclusions and grading of the confidence in the evidence**

The development of childhood obesity is a significant concern, especially in high-income countries. The EFSA Panel concluded that “there is no evidence for an association between the timing of introduction of complementary foods and the chance of developing obesity up to 11 years of age.” However, a recent systematic review by the US Departments of Agriculture and Health and Human Services came to the conclusion that “introduction of complementary foods and beverages before age 4 months may be associated with higher odds of overweight/obesity.”\* There is therefore at least some evidence of harm from early introduction of complementary foods. A recommendation by EFSA to legitimise labelling of complementary foods from 3 months of age in the context of a burgeoning global epidemic of childhood obesity and type 2 diabetes in the face of this evidence would be reckless.

\*English LK, et al. Timing of introduction of complementary foods and beverages and growth, size, and body composition: a systematic review. *American Journal of Clinical Nutrition*, 2019;109(1);935S–955S. <https://doi.org/10.1093/ajcn/nqy267>.

### **12.7. Infections: conclusions and grading of the confidence in the evidence**

A key rationale for the WHO recommendation for exclusive breastfeeding for 6 months was based on the increased risk of infectious diseases for those introduced to complementary foods earlier. The EFSA Panel concluded that there is no evidence that the introduction of complementary foods before 6 months of age increases gastrointestinal infections. This stands in direct contrast to the conclusion of a previous Cochrane review that concluded “infants who continue exclusive breastfeeding for six months or more appear to have a significantly reduced risk of gastrointestinal infection.”\* The EFSA Panel did not consider a large group randomized trial in Belarus that is quite relevant to this issue.\*\* This trial found a 40% reduction in the odds of gastrointestinal infection in the arm with longer exclusive breastfeeding. Similarly, a U.S.-based study found the odds of diarrhoea to be 65% higher in infants introduced to complementary foods before 3 months compared to later,\*\*\* but the panel ignored these results simply because the significance dropped barely below 95% when only severe cases were considered. Clearly, it is not true that there is “no evidence” of increased gastrointestinal infections with early introduction of complementary foods in high income settings.

There is an abundance of data from middle-income settings documenting this increased risk.

\* Kramer MS, Kakuma R. Optimal duration of exclusive breastfeeding. *Cochrane Database of Systematic Reviews* 2012; Issue 8. Art. No.: CD003517.DOI: 10.1002/14651858.CD003517.pub2. <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD003517.pub2/epdf/full>.

\*\* Kramer MS, et al., Promotion of Breastfeeding Intervention Trial (PROBIT): A Randomized Trial in the Republic of Belarus. *JAMA*. 2001;285(4):413-420. doi:10.1001/jama.285.4.413. <https://jamanetwork.com/journals/jama/fullarticle/193490>.

\*\*\* Wright CM, Parkinson KN and Drewett RF, 2004. Why are babies weaned early? Data from a prospective population-based cohort study. *Archives of Disease in Childhood* 2004;89; 813-816. <https://adc.bmj.com/content/archdischild/suppl/2004/08/25/89.9.813.DC1/899813.pdf>

### **15.4. Iron status: conclusions and grading of the confidence in the evidence**

The EFSA Panel concludes that earlier introduction of complementary foods can reduce the risk of iron depletion if those complementary foods provide a good source of iron. However, the Panel provides no evidence or discussion of whether this is the most effective or best strategy for preventing iron depletion. Delayed umbilical cord clamping is a recommended intervention to prevent iron deficiency anaemia.\* The failure of the health system to implement this evidence-based practice should not become an excuse for introducing policies that undermine exclusive breastfeeding. In addition, it is recommended that preterm/low birthweight infants be given iron supplements in the first six months of life to prevent iron deficiency.\*\* The Panel recognized that supplementation with vitamin D is the recommended strategy and thus did not examine vitamin D deficiency as a relevant endpoint. The same logic should be applied to iron. Justifying early introduction of complementary foods as an alternative to recommended medical practices is inappropriate. \* World Health Organization. *Guideline: Delayed Umbilical Cord Clamping for Improved Maternal and Infant Health and Nutrition Outcomes*. Geneva; 2014. [https://apps.who.int/iris/bitstream/handle/10665/148793/9789241508209\\_eng.pdf?sequence=1](https://apps.who.int/iris/bitstream/handle/10665/148793/9789241508209_eng.pdf?sequence=1).

\*\* World Health Organization Secretariat on behalf of the participants to the Consultation. *Conclusions and recommendations of the WHO Consultation on prevention and control of iron deficiency in infants and young children in malaria endemic areas*. *Food and Nutrition Bulletin* 2007;28(4);S621-S627.

## 20. Conclusions

The World Health Assembly promotes exclusive breastfeeding for 6 months “as a global public health recommendation.”\* The expert consultation that made this recommendation\*\* clarified that it applies to populations, acknowledging that individual infants may need to receive complementary foods before or after this exact age. The conclusion of the EFSA panel that the “data do not allow the determination of a precise age at which complementary foods should be introduced to all infants” is consistent with this recommendation. However, it does not follow that the labelling of complementary foods should indicate introduction as early as 3 months simply because some individual infants may need to be introduced to complementary foods earlier than 6 months. The point of having public health recommendations is to provide general protection to the overall population while acknowledging individual variation. Labelling of commercial products should be consistent with evidence-based public health recommendations and not seek to exploit exceptional cases. The EFSA panel seems to conclude that introduction of complementary foods between about 3-4 and around 6 months is “appropriate” primarily because infants have the developmental skills to consume complementary foods and show an interest in foods at these ages. Following this logic, we should also conclude that sugar-sweetened beverages are “appropriate” for toddlers simply because they are able to drink them and show an interest in them. The \*ability\* to consume foods should not be equated with the \*appropriateness\* of consuming them. The Panel finds that complementary foods are not nutritionally needed before 6 months of age for most infants and fails to document any advantages to introducing them before this age. Thus, it is hard to understand why the panel would make recommendations for labelling complementary foods to be introduced as early as 3 months of age when there is no demonstrated benefit in doing so. Such a labelling change would likely expand the commercial sales of packaged complementary foods, posing increased costs to families with no health advantages. The EFSA Panel may be of the opinion that the benefits of delaying introduction of complementary foods to 6 months are not substantial in industrialized countries where safe and hygienic foods are readily accessible. However, as they rightly point out “the fact that complementary foods could be introduced at an early age does not mean that this is necessary or desirable.” There is no demonstrated benefit to early introduction and at least some evidence of harms resulting from early introduction, even in high-income countries. Opening the door to labelling complementary feeding products for introduction earlier than 6 months is a dangerous strategy that threatens the health of many young infants.

\* WHO. Infant and young child nutrition. World Health Assembly Resolution 54.2. 18 May 2001. [https://www.who.int/nutrition/topics/WHA54.2\\_iycn\\_en.pdf?ua=1](https://www.who.int/nutrition/topics/WHA54.2_iycn_en.pdf?ua=1).

\*\* WHO. The Optimal Duration of Exclusive Breastfeeding: Report of an Expert Consultation. Geneva, Switzerland, 28–30 March 2001. [https://apps.who.int/iris/bitstream/handle/10665/67219/WHO\\_NHD\\_01.09pdf?sequence=1](https://apps.who.int/iris/bitstream/handle/10665/67219/WHO_NHD_01.09pdf?sequence=1).

### Other comments

The publication of the Panel’s findings should include the interests declared by the authors regarding receipt of individual support from the food industry – both direct (e.g. consultancies, honoraria, or travel support) and indirect (e.g. research grants). In addition, the source of funding for the work of the Panel is not clear. Given the commercial implications of the recommendations being made, this clarity is critical.