



European Food Safety Authority

Public Consultation on the draft scientific opinion on appropriate age for introduction of complementary feeding into an infant's diet

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Public consultation on a draft opinion on appropriate age for introduction of complementary feeding into an infant's diet

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1. Introduction

- 1.1. Background and Terms of Reference as provided by the requestor - [not for comment](#)
- 1.2. Previous assessments
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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. Data and Methodologies

- 2.0. Data and Methodologies
- 2.1. Data
- 2.2. Methodologies
- 2.3. Protocol amendments

2.1. Data

- 2.1.0. Data
- 2.1.1. Eligibility criteria for the systematic literature search

- 2.1.2. Eligibility criteria for the extensive literature search (developmental readiness)
- 2.1.3. Considerations on the included data

2.1.1. Eligibility criteria for the systematic literature search

- 2.1.1.1 Inclusion
- 2.1.1.2. Exclusion

2.1.1.2. Exclusion

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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 sub-populations 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. Assessment of the data on obesity and overweight in term infants or mixed populations

- 6.1. Obesity and overweight: final body of evidence
- 6.2. Obesity and overweight: endpoint and study selection
- 6.3. Obesity: summary of the evidence
- 6.4. Overweight: summary of the evidence
- 6.5. Obesity and overweight: conclusions and grading of the confidence in the evidence

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

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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. Assessment of the data on infections in term infants or mixed populations

- 12.1. Infections: final body of evidence

- 12.2. Infections: endpoint and study selection
- 12.3. Gastro-intestinal infections: summary of the evidence
- 12.4. Upper respiratory tract infections: summary of the evidence
- 12.5. Lower respiratory tract infections: summary of the evidence
- 12.6. Infections in general: summary of the evidence
- 12.7. Infections: conclusions and grading of the confidence in the evidence

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

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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. Assessment of the data on indicators of nutrient status in term infants or mixed populations

- 15.1. Nutrient status: final body of evidence
- 15.2. Nutrient status: endpoint and study selection
- 15.3. Iron status: summary of the evidence
- 15.4. Iron status: conclusions and grading of the confidence in the evidence

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

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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.

** 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

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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.

** 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.

Other comments

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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.

Upload file(s) if necessary

* Do you need to upload file(s)?

- YES
 NO

Background Documents

[00 Draft Opinion Age of introduction of Complementary Feeding no appendix A](#)

[01 Appendix A - Age of introduction of Complementary Feeding](#)

[1 Annex A - Outcome of the data extraction from the included studies](#)

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[6 Privacy statement EFSA Public Consultation](#)

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