



European Food Safety Authority

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

Fields marked with * are mandatory.

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

*Select the chapters you want to comment

- Abstract - [not for comment](#)
- Summary - [not for comment](#)
- 1. Introduction
- 2. Data and Methodologies
- 3. Assessment of the developmental readiness of the term infant to receive CFs
- 4. Assessment of the data on weight, length and head circumference in term infants or mixed population
- 5. Assessment of the data on BMI and related endpoints in term infants or mixed populations
- 6. Assessment of the data on obesity and overweight in term infants or mixed populations
- 7. Assessment of the data on body composition in term infants or mixed populations
- 8. Assessment of the data on atopic diseases in term infants or mixed populations
- 9. Assessment of the data on coeliac disease in term infants or mixed populations
- 10. Assessment of the data on type 1 diabetes mellitus in term infants or mixed populations
- 11. Assessment of the data on risk factors for cardiovascular diseases in term infants or mixed populations
- 12. Assessment of the data on infections in term infants or mixed populations
- 13. Assessment of the data on sleep-related endpoints in term infants or mixed populations
- 14. Assessment of the data on infant and child development in term infants or mixed populations
- 15. Assessment of the data on indicators of nutrient status in term infants or mixed populations
- 16. Assessment of the data on food preferences and eating behaviours in term infants or mixed populations
- 17. Assessment of the data on other health outcomes
- 18. Assessment of the data on the timing of introduction of CFs in pre-term infants
- 19. Integration of results
- 20. Conclusions
- References - [not for comment](#)
- Glossary and abbreviations - [not for comment](#)
- Appendix A – Data analysis and synthesis in forest-plots
- Appendix B – Publications considered in the assessment
- Appendix C – Specific items considered in the appraisal of studies
- Appendix D – Search strings of the literature searches undertaken by EFSA
- Annex A – Outcome of the data extraction from the included prospective and retrospective studies
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Annex B – Result of the assessment of the risk of bias per question and outcome for randomised controlled trials and prospective observational studies

- Annex C – List of papers excluded at full text screening (step 2) of the searches
- Annex D – Funnel plots for the assessment of publication bias
- Annex E – Sensitivity analyses on the use of different between-study variance estimators in the random effects meta-analyses
- Other comments

1. Introduction

- 1.1. Background and Terms of Reference as provided by the requestor - [not for comment](#)
- 1.2. Previous assessments
- 1.3. Definitions
- 1.4. Need for complementary foods for infants
- 1.5. Interpretation of the Terms of Reference
- 1.6. General considerations on the outcomes assessed

1.3. Definitions

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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 cereal-based 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 (ultra-processed 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

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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. Data and Methodologies

- 2.0. Data and Methodologies

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

2.0. Data and Methodologies

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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. Assessment of the developmental readiness of the term infant to receive CFs

- 3.0. Assessment of the developmental readiness of the term infant to receive CFs
- 3.1. Gastro-intestinal function
- 3.2. Renal function
- 3.3. Neuromuscular coordination and neurodevelopment
- 3.4. Developmental readiness of the term infant to receive CFs: conclusions

3.3. Neuromuscular coordination and neurodevelopment

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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

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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

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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

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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

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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.

[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

2 Annex B - Result of the assessment of the risk of bias

3 Annex C - List of papers excluded at full text screening

4 Annex D - Funnel plots for the assessment of the publication bias

5 Annex E - Sensitivity analysis

6 Privacy statement EFSA Public Consultation

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