



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

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- References - [not for comment](#)
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- Appendix A – Data analysis and synthesis in forest-plots
- Appendix B – Publications considered in the assessment
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- 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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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. Need for complementary foods for infants

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

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

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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. 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

2.1.1.1. Inclusion

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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

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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. formula-fed 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. Eligibility criteria for the extensive literature search (developmental readiness)

- 2.1.2.1. Inclusion
- 2.1.2.2. Exclusion

2.1.2.1. Inclusion

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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. 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

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

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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

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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: conclusions

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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 gastro-intestinal 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. Assessment of the data on atopic diseases in term infants or mixed populations

- 8.1. Atopic diseases: final body of evidence
- 8.2. Atopic diseases: endpoint and study selection
- 8.3. Outcome cluster of atopic diseases: summary of the evidence
- 8.4. Asthma-like symptoms: summary of the evidence
- 8.5. Eczema: summary of the evidence
- 8.6. Allergic rhinitis: summary of the evidence
- 8.7. Symptomatic food allergy: summary of the evidence
- 8.8. Atopic diseases: conclusions

8.7. Symptomatic food allergy: summary of the evidence

- 8.7.1. Timing of introduction of CFs in general
- 8.7.2. Timing of introduction of CFs in general and symptomatic food allergy: conclusions and grading of the confidence in the evidence
- 8.7.3. Timing of introduction of egg
- 8.7.4. Timing of introduction of egg and symptomatic food allergy: conclusions and grading of the confidence in the evidence
- 8.7.5. Timing of introduction of cereals
- 8.7.6. Timing of introduction of cereals and symptomatic food allergy: conclusions and grading of the confidence in the evidence
- 8.7.7. Timing of introduction of fish
- 8.7.8. Timing of introduction of peanuts
- 8.7.9. Timing of introduction of peanuts and symptomatic food allergy: conclusions

8.7.3. Timing of introduction of egg

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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. 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

12.2. Infections: endpoint and study selection

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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 lower-middle 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

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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. 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

15.3. Iron status: summary of the evidence

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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 hypothesised that CFs might interfere with iron utilisation 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. Assessment of the data on food preferences and eating behaviours in term infants or mixed populations

- 16.1. Food preferences and eating behaviours: final body of evidence
- 16.2. Food preferences and eating behaviours: endpoint and study selection
- 16.3. Food preferences and eating behaviours: summary of evidence
- 16.4. Food preferences and eating behaviours: conclusions

16.3. Food preferences and eating behaviours: summary of evidence

- 16.3.1. Timing of introduction of CFs in general
- 16.3.2. Timing of introduction of fruits and vegetables

16.3.1. Timing of introduction of CFs in general

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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

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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

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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

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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 home-cooked 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.

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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