CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 6 **CX/NFSDU 14/36/7**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

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REVIEW OF THE STANDARD FOR FOLLOW-UP FORMULA (CODEX STAN 156-1987) (at Step 4)

(Prepared by an EWG led by New Zealand with the assistance of France and Indonesia)[1]

1. BACKGROUND

1.1 Previous consideration by CCNFSDU

1. At the 35th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU), the Committee agreed to continue the review of the follow-up formula standard (CODEX STAN 156-1987) and continue with an electronic working group (eWG) working in English, with the Terms of Reference (ToR) outlined below:

Terms of Reference

1. Continue to review the nutritional requirements of the older infants and young children taking into account recent scientific developments and global data;
2. Compare the requirements identified under the ToR (1) above with current compositional requirements of the existing infant formula and follow-up formula standards, taking in to account dietary intakes and the role of the follow-up formula products as covered by the existing standard in the diet of the older infants and young children;
3. Develop a discussion document outlining the findings of the eWG.

1.2 Conduct of the Electronic Working Group (eWG)

2. The eWG considered two Consultation Papers circulated in March and July respectively. As per the ToR, the first Consultation Paper presented data to review the nutritional requirements of older infants and young children taking into account recent scientific developments and global data; and requested eWG members provide any additional data on nutrient requirements, dietary intakes, and nutritional status for infants and young children. Twenty-three submissions were received from the first round of consultation (19 Member Countries, one Member Organisation, and three Codex Observers).

3. The second Consultation Paper collated the responses from the eWG to refine the review of nutrient requirements, and proposed nutrient intake levels which could be considered adequate for the majority of older infants and young children. In addition, a summary of the global data received from the eWG on nutrient intakes and nutritional status was prepared to highlight those nutrients which were commonly inadequate in the diets of older infants and young children. Using the evidence that had been collated through the eWG the Chair's proposed an option to assess the adequacy of the current Codex infant and

[1] Members of the EWG: Argentina, Australia, Brazil, Canada, Chile, Columbia, Costa Rica, European Union, Ghana, India, Iran, Japan, Malaysia, Mexico, Nicaragua, Norway, Philippines, Russia, Sweden, Switzerland, Thailand, Tunisia, Uruguay, the United States of America, Calorie Control Council, Federation of European Specialty Food Ingredients Industries, European Network of Childbirth Associations, Helen Keller International, International Association of Consumer Food Organisations, International Baby Food Action Network, International Dairy Federation, International Special Dietary Foods Industries, National Health Federation

follow-up formula standards in comparison to nutrient requirements for this age group, taking into account dietary intakes and role of follow-up formula (ToR 2). Thirty submissions were received in response the second consultation paper (21 Member Countries, one Member Organisation, and 8 Codex Observers).

4. The Chairs of the eWG have used feedback from the March and July eWG consultations to prepare this Agenda Paper. All participating members are acknowledged above.

2. EXECUTIVE SUMMARY

5. Over the last two years eWGs have gathered a considerable amount of data to inform the review of the Standard for Follow-up Formula (CODEX STAN 156-1987). This has included reviewing the nutritional requirements, nutritional intakes, and the role of product in the diets of older infants (6-12 months) and young children (12-36 months) globally.

6. This year the eWG has reviewed the nutritional requirements of older infants and young children. It has been identified that significant scientific advances in defining the nutritional requirements of this age group have occurred since the development of the original standard. Notable advances include the revised estimates of reference body weights of older infants and young children which have resulted in lower estimates for protein requirements. In addition to this there has been increased recognition of the importance of the quality of fat in the diets of this age group. Through evaluating global data on nutrient requirements it has come to light that there is increased evidence to support higher vitamin D requirements.

7. At the time of the revision of the Codex infant formula standard many of the advances in nutrient requirements were addressed. Although the compositional requirements of the infant formula standard are generally appropriate for older infants, minimum levels of iron in the infant formula standard would not address the increased requirements for iron during this period of life.

8. Assessment of global dietary intake and nutritional status data highlighted several nutrients of global concern for where there is evidence to suggest that older infants and young children may have difficulty in achieving adequate intakes. Globally, iron and the quality of dietary fat in the diet were consistently found to be inadequate in sub-groups of the population. Other nutrients which were most frequently found to be limited in the diets of older infants and young children included alpha-linolenic acid (ALA), docosahexanoic acid (DHA), vitamins A and D, calcium, iron, zinc and iodine; however these differ regionally.

9. The eWG was also tasked with undertaking a comparison of the current compositional requirements of existing Codex infant and follow-up formula standards against the nutrient requirements of older infants and young children. The current follow-up formula standard is inadequate in its provision of essential fatty acids, iron, iodine, selenium, and B vitamins compared to recommendations. Alignment with the infant formula standard would partially address this, but would not provide a greater contribution to iron intakes.

10. As follow-up formula for young children is often used as a replacement for cows' milk, the nutritional contribution of cows' milk to the diet was also compared to the Codex infant formula and follow-up formula standards. Cows' milk provides significant contributions to the dietary requirements of calcium, riboflavin and B12 of young children. The Codex follow-up formula standard minimum specifications provide less of these nutrients, but the lack of a maximum enables formulation of products that are nutritionally equivalent to cows' milk. The compositional requirements within the infant formula standard do not permit calcium to be added to formula in amounts that are equivalent to cows' milk.

11. There is majority support from eWG members to retain a Codex standard for follow-up formula, with most proposing that the current age range (6-36 months) continue to be regulated. Most members of the eWG recognised a point of difference in the role of follow-up formula in the diet of infants and young children at 12 months of age. This reflected the way product is consumed, and the variability of use between different age groups and countries.

12. In recognition of the variation in the role that follow-up formula for young children plays in the diet there is a need for the Committee to consider a regulatory approach which provides flexibility in its composition to contribute nutrients at risk, as well as supporting the specific needs of different countries.

Whilst most eWG members agree that follow-up formula is not nutritionally necessary in the diets of older infants and young children, the majority agreed that nutritional necessity should not be a defining feature when deciding whether or not to review or develop a Codex Standard.

3. NUTRIENT REQUIREMENTS AND DIETARY INTAKES OF OLDER INFANTS AND YOUNG CHILDREN GLOBALLY

3.1 Review of nutritional requirements of older infants and young children

13. In accordance with the first ToR for the eWG, the nutrient requirements for older infants and young children have been extensively reviewed, taking into account recent scientific developments and global data. The purpose of reviewing the nutrient requirements is to determine the level of intake for nutrients that are considered adequate for the majority of infants and young children and to identify where scientific advances have occurred since the development of the original standard.

14. Recent and relevant WHO and FAO reports were accessed and the derivations of daily intake reference values (DIRVs) were assessed for both age groups. The eWG assessed DIRVs that had also been derived by recognised authoritative scientific bodies (RASBs) and identified where differences existed between these and the WHO/FAO. The eWG proceeded to review the scientific basis for the establishment of DIRVs which was assessed alongside global data on nutrient intake and status to identify which DIRV or DIRVs were considered adequate for the majority of older infants and young children. A summary of the key findings are presented in the agenda paper and further details of the methods used and assessment of nutrient requirements are presented in the appendix.

15. There was widespread support that the WHO/FAO was considered as the most internationally relevant source of nutrient requirement data and alternative nutrient requirements levels were only proposed by eWG members when a RASB had conducted a primary evaluation of nutrient requirements and either more recent scientific data had become available or alternative methods to derive DIRVs were considered more appropriate.

Scientific updates from WHO and FAO

16. The eWG considered WHO and FAO reports on reference body weights (WHO 2006), energy (FAO 2004), protein (WHO/FAO/UNU 2007) and fat (FAO 2010) requirements to be both the most recent and internationally relevant. Several important updates to these reports have occurred since the development of the original follow-up formula standard including revised estimates of reference body weights based on the growth of breast fed children which are lower than previously estimated. This has led to lower estimates of energy and protein requirements. Also of importance is the FAO/WHO update on the importance of quality of dietary fat in early life as a determinant of growth. The FAO/WHO deemed there to be convincing evidence to support linoleic acid (LA C18:2 n-6) and α-linolenic acid (ALA C18:3 n-3) as essential fatty acids and indispensible since they cannot be synthesized by humans; and that docosahexaenoic acid (DHA) plays a critical role in retinal and brain development in the 0-24 month age group (FAO 2010).

17. The WHO/FAO most recently reviewed vitamin and mineral requirements in 2004. Of the vitamins and mineral requirements established by the WHO/FAO and other RASBs there were very few differences in the values set for vitamin A, thiamine, riboflavin, niacin, and vitamin B6, therefore the eWG supported the use of the WHO/FAO (2004) DIRVs as adequate for the majority of older infants and young children.

18. The eWG have noted that nutrient requirements for older infants are often extrapolated from DIRVs for young infants (0-6 months) which are derived from nutrient intakes from breast milk. The only deviation from this is when nutrient requirements are based on the factorial method (iron, calcium, zinc); or when breast milk concentrations of the nutrient of interest vary markedly according to maternal status (vitamin A, C, D, iodine). Nutrient requirements for young children are often extrapolated from data that have been used to establish nutrient requirements for adults.

Recent reviews from authoritative scientific bodies

19. Since the publication of the WHO/FAO (2004) report on vitamin and mineral requirements more recent systematic reviews have been conducted for pantothenic acid, biotin and vitamin C. These reviews did not find any new evidence or scientific rationale to deviate from the earlier recommendations of the WHO/FAO. Subsequently the values derived by WHO/FAO in 2004 were also considered adequate for the majority of older infants and young children by the eWG.

20. Reviews of vitamin D requirements that have recently been conducted recommend elevating the DIRV for this age group. Recent evidence suggest that the physiological endpoint which the WHO/FAO value is based upon is too low as rickets have been observed at circulating 25-hydroxyvitamin D (25(OH)D) levels above 30 nmol/L. Consequently, many eWG members supported adopting an AI of at least 10 µg for both age groups noting that this intake level is only relevant in populations with minimal sun exposure.

Inconsistencies in WHO/FAO dietary reference values and nutritional status

21. As mentioned, the eWG reviewed the nutritional requirements alongside data on nutrient intakes and status. As a result of this, the nutrient requirement levels set for vitamin E and folate by WHO/FAO in 2004 for young children may overestimate requirements. Some countries have reported high proportions of the population with inadequate intakes yet adequate status as assessed by biochemical measures. For these nutrients, the exact nutrient requirements levels are difficult to establish and the eWG have identified a range of intakes that might be considered adequate for this age group.

22. In evaluating iron, it came to light that there were large discrepancies between iron requirements and iron status for this age group. The factorial method for calculating iron requirements has been used by both the WHO/FAO and IOM (2000) who established comparable estimates for the physiological iron requirements for older infants but quite different estimates for young children resulting in much lower values being set for the iron requirements compared to almost all RASBs. As estimates of inadequate intakes using the WHO/FAO DIRVs do not correspond well with estimates of iron depletion, the eWG considered that the WHO/FAO values might not be appropriate. If the adequacy of iron intakes is compared to iron status then this suggests that the higher iron requirements set by RASBs may be more appropriate, however requirements have only been set for diets containing moderately absorbed iron (between 14-18% absorption). For diets containing moderately absorbed iron, requirements would fall within range of 8-11 mg/day for older infants and 7-9 mg/day for young children.

3.2 Review of dietary intakes and nutritional status of older infants and young children

23. Dietary intake and nutritional status data submitted by the eWG members highlighted several common nutrients of global concern for which there is evidence to suggest that older infants and young children may have difficulty in achieving adequate intakes. A summary of the key findings are presented below and a detailed review of the dietary intakes and nutritional status for each of the key nutrients identified are presented in the appendix.

24. Nutrients which are frequently found to be limited in the diets of older and infants and young children globally include ALA and DHA, vitamins A and D, calcium, iron, zinc and iodine; however, these differ regionally and geographically. Iron is most consistently found to be inadequate in the diets of this age group; whereas protein intakes tend to be adequate and even excessive in some countries. The quality of dietary fat and availability of the omega-3 fatty acids (particularly ALA and DHA) has been reported as inadequate in many countries. It should be noted that global variation in intakes of vitamin A, D, calcium, zinc and iodine are a result of differing dietary patterns, environmental factors or national public health programmes.

25. There is limited data available for this age group, and although efforts were made to gather globally representative data, it was not possible to obtain nutrient intake and status data for all countries and regions for all nutrients.

Protein

26. Globally, several national and regionally representative surveys of dietary protein intakes of older infants and young children have been conducted. The results of these surveys have consistently identified that protein intakes in this age group are adequate for the majority of infants and young children, and may even be excessive. Mean intakes in young children have ranged from 20 g to 60 g per day – two to six times higher than the WHO/FAO/UNU safe intake level, although the WHO/FAO/UNU report states that there is no risk to individuals with excessive intakes considerably higher than the safe intake levels (WHO/FAO/UNU 2007). No upper limit has been set by the WHO/FAO for protein and the effects of a diet habitually high in protein are unclear. Although there is evidence to suggest that excessive protein intakes in early childhood may be associated with differences in growth and obesity risk later in life, there is no conclusive evidence that protein intakes of the magnitude observed in the dietary surveys have adverse health consequences in the short or long term. However, as noted in Section 3.1, estimations of protein requirements have decreased since the original standard development. In addition, the WHO stated that current follow-up formula products lead to higher protein intakes than those recommended by WHO and FAO for adequate growth and development (WHO 2013), for these reasons the review of the follow-up formula standard should consider decreasing minimum protein composition in line with the Codex infant formula standard.

27. It is acknowledged that some sub-groups of the population will be at risk of protein deficiency in resource limited settings, and that the dietary surveys have generally only measured protein quantity and do not provide insight as to the quality of protein in the diets of older infants and young children.

Fatty Acids

28. Recently there have been two reviews assessing the adequacy of fatty acid intakes in Europe (EFSA 2013) and in low income countries (Michaelsen 2011). In Europe the review indicated that mean intakes of both ALA and DHA were low and particular attention should be paid to ensuring an appropriate supply of these fatty acids. Intakes of linoleic acid (LA) appeared to be adequate in Europe. Data from low income countries indicate that there is limited availability of omega-3 rich foods in the food supply, and inadequate intakes of DHA were reported in some countries which had evaluated intakes (Yakes 2011, Prentice 2000, Schwartz 2010, Sioen 2007, Barbarich 2006). In light of the recent FAO/WHO report signalling the heightened importance fat quality in the diets of older infants and young children, and the limited availability of omega-3 fatty acids (particularly ALA and DHA) in the food supply, these fatty acids are considered of global concern for this age group.

Vitamins

29. The latest review of global vitamin A status was conducted by the WHO from 1995-2005 and included 156 countries with a GDP < US$ 15 000 (WHO 2009). It was estimated that a third of children under five years of age had subclinical vitamin A deficiency (serum retinol <0.7 µmol/L). The African and South-East Asian regions had the highest prevalence of subclinical deficiency (44.4% and 49.9%, respectively), whereas the Western Pacific and Americas had the lowest (12.96% and 15.6%, respectively) (WHO 2009). The dietary intake collated by the eWG also found wide variation in intakes globally with several countries reporting adequate intakes (Appendix). It is evident from the review that vitamin A is limited in the diets of older infants and young children within certain settings, particularly low income countries (WHO 2009).

30. As vitamin D can be synthesised endogenously through the exposure of skin to sunlight, vitamin D insufficiency is generally limited to populations or sub-groups of the population with limited sunlight exposure; and where no public health interventions (i.e. fortification and supplementation) have been implemented. Of the countries which have conducted nationally representative surveys, almost all reported significant levels of vitamin D insufficiency in older infants and young children (<50 nmol/L). Paradoxically, vitamin D insufficiency has also been observed in some lower latitude countries; over a quarter of children in Mexico (Flores 2013), Indonesia (Sandjaja 2013), Malaysia (Poh 2013), Thailand (Rojroongwasinkul 2013), Iran (Olang 2010) and Jordan (Abdul-Razzak 2011) were reported to be vitamin D insufficient (<50 nmol/L).

Minerals

31. Globally the prevalence of iron deficiency anaemia (Hb<110 g/L) is estimated to be 18.1% in children under five years, ranging from 12% in Europe to 20% in the African region (Black 2013). It has been observed that in almost all surveys investigating iron intakes in this age group, sub-groups of the population have inadequate iron intakes and iron depletion, the extent of which varies globally.

32. The identification of zinc as a public health problem can be assessed as the proportion of the population with zinc deficiency, inadequate intakes or the proportion of the population who are stunted (WHO/UNICEF/IAEA/IZiNCG 2007). Data on zinc intakes and zinc deficiency are limited and sometimes inconsistent. Despite zinc intakes appearing to be adequate in many countries, the prevalence of zinc deficiency is often greater than 20% for this age group, even in high income countries. Low and middle income countries have higher rates of stunting than high income countries (28% and 7.2%, respectively). Based on the WHO/UNICEF/IAEA/IZiNCG zinc indicators data on the prevalence of stunting and zinc deficiency, it would appear that zinc is a public health problem in many countries, particularly low and middle income countries.

33. Calcium intakes globally vary and generally reflect intakes of dairy products in this age group.

34. Iodine insufficiency continues to be prevalent in iodine deplete countries and/ or regions. There is limited data on iodine status of older infants and young children globally, however in countries where data is available, iodine insufficiency affects more than 20% of older infants and young children in Australia, Belgium, France, Germany, New Zealand, Nigeria, Spain and Switzerland (Appendix).

4. ROLE OF FOLLOW-UP FORMULA

35. The role of follow-up formula has been raised in relation to the second ToR, whereby the role of product should be taken into consideration when comparing the nutritional requirements of older infants and young children to current compositional requirements. When taking into consideration the role of product, the concept of nutritional necessity of the product should also be considered.

4.1 Data on follow-up formula consumption

36. In 2013, eWG participants were requested to gather data on the usage and perception of follow-up formula and so-called ‘growing-up milk’ type products in their country or region to understand the role of follow-up formula in the diet.

37. Results from the data provided by the 2013 eWG suggest that the role of follow-up formula in the diet often varies with age. In older infants aged 6-12 months, follow-up formula is used either as the only source of milk intake or as part of a mixed milk feeding scheme.

38. From one year on, caregivers are often opting to use cows' milk (either fresh or powdered) or they are choosing specially formulated milk powder or formula for young children. The use of formula products from one year is often as an alternative to cows' milk. At this age, children will often either transition to cows' milk, specially formulated milk, or move onto a 'growing-up milk' type product with very few children still receiving breast milk.

39. Generally in Europe, use of formula products decreases with age, and by 31 months of age most children are no longer drinking any type of fortified milk based product (Turberg-Romain 2008; Irish Submission; Alexy & Kersting, 2003; Fantino 2008; Siega-Riz 2010). However, data from Mexico, the Philippines and Hong Kong highlight that at 36 months formula products and fortified milks are still frequently used. In Hong Kong, usage of follow-up formula increases with age and peaks at 24 months with 94% of young children consuming it, by 48 months 80% of children are still consuming follow-up formula (FHS 2012).

4.2 eWG views on role

40. The majority of the submissions from the eWG to the 2014 September Consultation Paper were in agreement that the role in the diet of follow-up formula differs between older infants and young children. Most eWG members are of the view that as the diet of young children is more diverse than that of older infants, the role of follow-up formula is different, particularly in relation to the contribution to a child's total daily nutrient intake.

41. Follow-up formula often constitutes an important part of the liquid diet of the older infant. As the older infant transitions to a diet which includes appropriate complementary foods in increasing amounts with advancing age, they begin to rely less on breast milk or infant formula and more on complementary foods. During this time, follow-up formula is often still a dominant source of nutrition, especially at the beginning of the complementary feeding period. As such, it is important that follow-up formula provides a more complete compliment of essential nutrients which needs to be reflected in the compositional criteria.

42. As the older infant grows to a young child, the contribution that food makes to the diet increases and the role of follow-up formula changes due to a reduced contribution to the total energy intake. Many eWG members commented that follow-up formula for young children is often used as a substitute or alternative for cows' milk, this was considered particularly important in countries where availability of fluid milk was limited. In some countries follow-up formula and specially formulated milk products for young children are considered an important source of nutrients in the diet, and in at least one instance has been recommended in national feeding guidelines.

43. Consequently, many eWG members support an approach whereby follow-up formula for young children is a distinctly different product to follow-up formula for older infants as it does not need to fulfil the complete nutritional requirements of young children. Several eWG members suggested that the composition of follow-up formula for young children should provide the main nutrients in cows' milk, as well as those that are lacking in the diet. Whereas others suggested that follow-up formula for young children should provide those nutrients that are lacking in the diet and which may vary according to national nutritional status.

5. COMPARISON OF NUTRITIONAL REQUIREMENTS TO CURRENT ESSENTIAL COMPOSITIONAL STANDARDS FOR INFANT AND FOLLOW-ON FORMULA

44. Under the second ToR, the eWG was tasked with comparing the current compositional requirements for the existing Codex infant and follow-up formula standards against nutrient requirements taking into consideration dietary intakes and the role of follow-up formula products in the diet of older infants and young children. A comparison of the infant and follow-up formula standards to cows' milk per 100 kcal has also been included taking into consideration that follow-up formula for young children is often used as an alternative to cows' milk (Table 1).

45. In order to take into consideration dietary intakes and role of product and compare these to daily nutrient requirements, the Chairs have calculated the estimated daily contribution of nutrients provided by the current Codex infant and follow-up formula standards (Table 2). The comparison tables presented in this paper have been updated taking into consideration feedback from the eWG. Calculations are based on formulas containing the average energy density permitted in the respective standards, and have been updated to reflect the eWG conclusions on nutrient requirement levels that are considered to be adequate for the majority of older infants and young children. Daily contributions of nutrients have been calculated taking into consideration the WHO Guidelines for the non-breast fed child and studies reporting intakes of formula products in this age range. National guidelines for recommended daily intakes may differ to those used in this paper.

Average daily intakes

46. The 2005 WHO Guiding Principles for Feeding Non-breastfed Children 6-24 Months of Age, state that when commercial infant formula products are available, affordable, and can be safely used; the amounts of prepared formula that are needed by an infant (6-12 months) are between 280 and 550 mL per day (WHO 2005). Using this is as a guide, the average intake of formula for this age range would be ~415 mL/day for older infants. This corresponds well with the data that was received by the eWG in last year's working group, whereby in those studies which reported formula product consumption in this age group, on average ~500 mL was consumed. The nutritional contribution of 450 mL of infant formula, follow-up formula and cows' milk per day to the dietary requirements of older infants are presented in Table 2. As some eWG members stated that 450 mL intakes may be lower than recommended by their national guidelines; intakes have also been compared at 600 mL in some cases.

47. The Guiding Principles also state that that amount of milk required in the diet of non-breastfed children aged 6-24 months is ~200-400 mL/d if adequate amounts of other animal-source foods are consumed regularly, otherwise, the amount of milk needed is ~300-500 mL/d (acceptable milk sources include full-cream animal milk, UHT milk, reconstituted evaporated milk, fermented milk, yoghurt, and expressed breast milk). The nutritional contribution of 300 mL of infant formula, follow-up formula and cows' milk per day to the daily dietary requirements of young children are presented in Table 2. As some eWG members stated that 300 mL intakes may be lower than recommended by their national guidelines; intakes have also been compared at 500 mL which is the upper level recommended by national authorities and the WHO.

Adequacy of the Codex Infant Formula and Follow-on Formula Standards to the diets of older infants

48. As illustrated in Table 1, the Codex infant formula standard differs to that of the follow-up formula standard. The infant formula standard provides less protein per 100 kcal, specifications for fat quality (LA, ALA, and optional addition of DHA), specifies maximum (or guiding upper levels) for almost all nutrients, and additional essential nutrients. Notably, protein requirements in the follow-up formula standard are more than double the requirements that have been set for infant formula and an intake of 450 mL per day would provide an older infant with 95-175% of their protein requirements.

49. Of the nutrients of concern identified in Section 3.2, the infant formula standard would provide adequate nutrients for almost all nutrients, with the exception of iron. Minimum compositional specifications of the infant formula standard provide only 14% of iron requirements at intakes of 450 mL. Although the follow-up formula standard is able to provide a larger contribution of iron in the diets of older infants, it still provides less than that considered adequate for the majority of older infants and young children with the current compositional specifications at intakes of 450 mL/day. However if older infants consumed 600 mL per day, this would provide between 46-92% of iron requirements for this age group. Although vitamin D requirements cannot be met under the infant formula standard when consuming 450 mL per day, if older infants consume 600 mL of either infant formula or follow-up formula this would provide 100% of vitamin D requirements.

Adequacy of the Codex Infant Formula and Follow-up Formula Standards to the diets of young children

50. In assessing the current Codex infant and follow-up formula standards against the dietary requirements of young children; it is important to note that this product is no longer relied upon as a sole or dominant source of nutrition in the diet for this age group. As such, it is not necessary that product provides 100% of nutrient requirements, but should not provide an insignificant contribution to dietary intakes. The recently revised Guidelines for Formulated Complementary Foods for older infants and young children (GL- CAC/GL 8-1991) suggest that a daily intake of the food should provide 50% of the INL_{98}. Taking this into account, 50% of the requirements for the following nutrients would not be provided by 300 mL of infant formula: vitamin D, niacin, magnesium. However, the lack of a maximum limit in the follow-up formula standard and wider compositional range would enable 50% of requirements to be filled for all nutrients.

51. As there are no maximum limits for follow-up formula, the adequacy of the standard can only be assessed against the minimum composition levels. The minimum levels in the follow-up formula standard would provide less than 20% of requirements for the following nutrients assuming an intake of 300 mL per day: thiamine (17%), niacin (10%), vitamin B 6 (20%), folate (16%), iodine (12%), selenium (not specified).

52. As noted by WHO, and supported by Table 2, current formulations of follow-up formula *'lead to higher protein intake and lower intake of essential fatty acids, iron, zinc and B vitamins than those recommended by WHO for adequate growth and development of infants and young children'* (WHO 2013). Alignment of the follow-up formula standard with that of the infant formula standard would provide lower intakes of protein, and higher intakes of essential fatty acids, iodine, selenium, and some B vitamins (thiamine, riboflavin, folate). However, the infant formula standard would provide lower levels of iron than those required by young children.

53. Taking into consideration the role of product in the diet, it may not be considered necessary for follow-up formula to provide all essential nutrients for this age group.

Contribution of cows' milk to nutrient requirements

54. Cows' milk would be classified as containing high amounts of vitamin A, riboflavin, niacin, vitamin B12, folate, calcium, iodine, magnesium, selenium and zinc under the Codex Guidelines for use of Nutrition and Health Claims (CAC/GL 23-1997). Cows' milk is a major contributor to calcium, riboflavin, and vitamin B12 requirements for young children – providing over 70% of a young child's nutrient requirements in a 300 mL serve. The minimum requirements specified within the current follow-up formula standard provide significantly less calcium (39%), riboflavin (26%) and vitamin B12 (36%), but no upper limit is specified so a manufacture could still formulate products that are nutritionally equivalent to cows' milk with regards to these nutrients.

55. The infant formula standard minimum essential composition provides equivalent nutritional contributions of vitamin A as cows' milk. However, the range for formulation (min-max levels) does not permit the product to contain equivalent amounts of calcium or magnesium as found in cows' milk. The infant formula standard can accommodate products that are nutritionally equivalent to cows' milk in the riboflavin, niacin, folate, vitamin B12, iodine, selenium and zinc content (Table 1).

Table 1: Comparison of essential compositional requirements between the Codex Infant Formula and Follow-up Formula Standards and the composition of cows' milk (per 100 kcal)

Nutrients	IF Standard		FUF Standard		Cows' milk full fat
	Min	Max[a]	Min	Max	
Energy (kcal/100 mL)	60	70	60	85	69.0
Protein (g/100kcal)	1.8	3.0	3.0	5.5	4.8
Fat (g/100kcal)	4.4	6.0	3.0	6.0	6.1
LA (mg/100kcal)	300	1400[a]	300	-	70
ALA (mg/100kcal)	50	N.S.	-	-	0
DHA (mg/100kcal)	Optional		Optional		0
Carbohydrates (g/100kcal)	9.0	14.0	-	-	6.8
Vitamins					
Vitamin A (µg RE/100 kcal)	60	180	75	225	57.5
Vitamin D (µg /100 kcal)	1	2.5	1	3	0.1
Vitamin E (mg α-TE/100 kcal)	0.5	5[a]	0.7	N.S.	0.1
Vitamin K (µg/100 kcal)	4	27[a]	4	N.S.	0
Thiamine (µg/100 kcal)	60	300[a]	40	N.S.	0
Riboflavin (µg/100 kcal)	80	500[a]	60	N.S.	0.3
Niacin (µg/100 kcal)	300	1500[a]	250	N.S.	1000
Vitamin B_6 (µg/100 kcal)	35	175[a]	45	N.S.	0
Vitamin B_{12} (µg/100 kcal)	0.1	1.5[a]	0.15	N.S.	0.7
Pantothenic acid (µg/100 kcal)	400	2000[a]	300	N.S.	600
Folic acid (µg/100 kcal)	10	50[a]	4	N.S.	9.1
Vitamin C (mg/100 kcal)	10	70[a]	8	N.S	1.9
Biotin (µg/100 kcal)	1.5	10[a]	-	-	-
Minerals					
Iron (mg/100 kcal)	0.45	-	1	2	<0.1
Calcium (mg/100 kcal)	50	140[a]	90	N.S.	177
Phosphorous (mg/100 kcal)	25	100[a]	60	N.S.	138
Magnesium (mg/100 kcal)	5	15[a]	6	N.S.	17
Sodium (mg/100 kcal)	20	60	20	85	64
Chloride (mg/100 kcal)	50	160	55	N.S.	147
Potassium (mg/100 kcal)	60	180	80	N.S.	215
Manganese (mg/100 kcal)	1	100[a]	-	-	0
Iodine (µg/100 kcal)	10	60[a]	5	N.S.	23
Selenium (µg/100 kcal)	1	9[a]	-	-	1.9
Copper (µg/100 kcal)	35	120[a]	-	-	0
Zinc (mg/100 kcal)	0.5	1.5[a]	0.5	N.S.	0.6

Table 2: Contribution of nutritional requirements of the current Codex Infant and Follow-up Formula Standards and cows' milk to the diets of older infants and young children

	Older infants 6-12 months consuming 450 mL/day					Young Children 12-36 months consuming 300 mL/day					
Nutrients	**DIRV**	**IF Std**		**FUF Std**		**DIRV**	**IF Std**		**FUF Std**		**Cows' milk**
		Min	**Max**	**Min**	**Max**		**Min**	**Max**	**Min**	**Max**	
Vitamin A (µg RE/100 kcal)	400	44%	132%	61%	184%	400	29%	88%	41%	122%	30%
Vitamin D (µg /100 kcal)	[10]	30%	73%	33%	98%	[10]	20%	49%	22%	65%	2%
Vitamin E (mg α-TE/100 kcal)	2.7	54%	540%	85%	-	[3.5-5]	23%	230%	36%		5%
Vitamin K (µg/100 kcal)	[8.5]	138%	930%	150%		[12]	65%	440%	73%		-
Thiamine (µg/100 kcal)	300	59%	290%	44%		500	23%	117%	17%		-
Riboflavin (µg /100 kcal)	400	59%	365%	49%		500	31%	195%	26%		124%
Niacin (µg /100 kcal)	4000	22%	110%	21%		6000	10%	49%	10%		35%
Vitamin B_6 (µg/100 kcal)	300	34%	170%	49%		500	14%	68%	20%		-
Vitamin B_{12} (µg/100 kcal)	[0.5]	59%	880%	98%		0.9	22%	325%	36%		160%
Pantothenic acid (µg/100 kcal)	1800	65%	325%	54%		2000	40%	195%	32%		62%
Folate (µg DFE/100 kcal)	80	61%	304%	27%		[80-100]	36%	180%	16%		35%
Vitamin C (mg/100 kcal)	[20-30]	117%	820%	100%		[20-30]	78%	546%	70%		16%
Biotin (µg/100 kcal)	6	73%	488%	82%		8	37%	244%	41%		-
Iron (mg/100 kcal)	[8-11]	14%	NS	34%	69%	[7-9]	11%	NS	27%	54%	-
Calcium (mg/100 kcal)	400	37%	102%	73%		500	20%	55%	39%		73%
Magnesium (mg/100 kcal)	54	27%	81%	36%		60	16%	49%	22%		56%
Iodine (µg/100 kcal)	90	33%	195%	18%		90	22%	130%	12%		52%
Selenium (µg/100 kcal)	[15]	20%	176%	NS		[20]	10%	88%	NS		20%
Zinc (mg/100 kcal)	4.1	36%	107%	40%		4.1	24%	71%	27%		30%

Where a range has been reported the mid-point of the DIRV range was used.

DIRVs represent WHO/FAO (2004) values except when placed in square brackets. Values in square brackets represent those values that the eWG considered adequate for the majority of older infants and young children

6. NUTRITIONAL NECESSITY

6.1 WHO information concerning the use and marketing of follow-up formula

56. In July 2013, WHO issued a statement concerning the use and marketing of follow-up formula (WHO 2013). WHO recommends that infants be exclusively breastfed for the first six months of life to achieve optimal growth, development and health. Mothers should continue to breastfeed their child until they are two years of age or older, whilst providing them with safe and appropriate complementary foods from six months of age. The WHO position makes the statement that follow-up formula is unnecessary and it is not a suitable substitute for breast milk due to its nutritional composition.

57. At the 35th session of CCNFSDU, the representative of WHO informed the Committee that *'in principle WHO considers that there is no need of a Codex Standard for products which are not necessary in general. The Representative emphasised that even if the composition would be modified based on a thorough scientific review of the nutritional needs of older infants and young children, and thereby ensure better quality of the product, this would not validate its necessity. The Representative however noted that as the products were currently on the market, regulation of its composition and marketing was needed' (*para. 100, REP14/NFSDU).

58. The Committee agreed that breast milk was best for feeding to infants and young children and that the replacement product, which existed on the market and was traded internationally, must be safe and meet their nutritional needs if it had to be replaced *(*para. 101, REP14/NFSDU).

6.2 EFSA Scientific Opinion on nutrient requirements and dietary intakes of infants and young children in the European Union

59. The EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) concluded in its 2013 Scientific Opinion that; *No unique role of young-child formulae with respect to the provision of critical nutrients in the diet of infants and young children living in Europe can be identified, so that they cannot be considered as a necessity to satisfy the nutritional requirements of young children when compared with other foods that may be included in the normal diet of young children (such as breast milk, infant formulae, follow-on formulae and cow's milk)'.*

60. In EFSA's June 2014 Scientific Opinion on the essential composition of infant and follow-on formula, the Panel stated that *'they did not consider it necessary to propose specific compositional criteria for formula consumed after one year of age, as formulae consumed during the first year of life can continue to be used by young children'.* The Opinion acknowledges that formula for young children are marketed and sold in many Member States with varying composition as no compositional requirements for these products currently exists in EU legislation. No statement was made as to the necessity of regulation of follow-up formula for the 6-12 month age group but specific compositional requirements for follow-up formula were established by EFSA for older infants.

61. The European Commission are currently considering future regulatory options on whether specific rules should be adopted for young-child formulae.

6.3 eWG comments

62. There was almost total support from eWG members that follow-up formula is not considered nutritionally necessary in the diets of older infants and young children in accordance with the WHO statement. Some eWG members stated that follow-up formula was not necessary as optimal nutrition could be achieved through following food and nutrition guidelines; or that follow-up formula did not have a unique role in providing critical nutrients to satisfy nutritional requirements of young children. It was noted by several eWG members that although not nutritionally necessary, follow-up formula is currently, or could be, one of several means to help address critical nutrients in the diet.

63. Two Member Countries disagreed that follow-up formula is not nutritionally necessary as they were of the view that follow-up formula has a definite role in the diets of older infants and young children. One Codex Member reiterated that EFSA had not addressed the question of necessity for products targeted to older infants (6-12 months) but had proposed different minimum composition requirements for iron in infant formula and follow-up formula.

64. Although there was general agreement that follow-up formula is not nutritionally necessary, the majority of eWG members did not consider that nutritional necessity was a critical component of the development or review of a Codex Standard. Subsequently there was wide support for the continued review of follow-up formula regulation. Views of the eWG related to the future regulatory options for a Codex Standard for follow-up formula are presented in the following section.

7. EWG VIEWS ON FUTURE REGULATION

7.1 Views on the need to regulate FUF

65. Electronic working group members were asked to comment on, in their view, the consequences of removing the Codex Standard for follow-up formula at both the global and national level.

66. Despite the majority of eWG members agreeing that follow-up formula is not a nutritionally necessary product, many highlighted that the absence of the Codex standard would not affect the presence of follow-up formula on the global market. The consequences of no regulation could result in a proliferation of sub-standard product on the global market with misleading claims and very different nutritional, quality and labelling criteria. Members of the eWG strongly indicated that consumer protection for this age group was of the utmost importance, yet strategies on how to achieve this goal differed between those who favoured a regulatory or deregulatory approach.

67. Several eWG members commented that the continuation of a follow-up formula standard is aligned with the mandate of the Codex Alimentarius Commission which is: protecting the health of consumers and ensuring fair practices in the food trade; and promoting coordination of all food standards work undertaken by international governmental and non-governmental organisations (Codex Alimentarius 2014). Repealing the Codex follow-up formula standard would not only affect harmonisation of international regulations, but it was also seen as a risk to consumer protection as market forces would be more competitive and the impetus for reformulation under general purpose food regulation would not necessarily be health focussed. Instead the composition might not align with the nutritional needs of the target population and could be driven by economic factors. Consequently, the majority of eWG members recommended maintaining a follow-up formula standard to ensure that follow-up formula meets harmonised criteria for composition, safety, quality and labelling, and to maintain product safety and integrity. Regulation also allows provisions to be set for ingredients such as sugars and flavours.

68. The lack of an international regulatory framework was regarded by many eWG members to disadvantage countries with limited resources or technical expertise to develop their own domestic regulations. These countries would have no guidance to look to for oversight of follow-up formula safety and suitability.

69. Repealing the Codex follow-up formula standard was also viewed by some eWG members to have a negative impact on international trade in terms of possible differences amongst countries in relation to import and export parameters for follow-up formula causing possible trade barriers. Retaining a standard provides legal clarity and certainty for governments, as well as consumers, in relation to the regulation of follow-up formula.

70. Some Codex Observers considered that abolishing the standard could give national authorities greater clarity to take action against misleading claims and would assist with protecting infant and young child feeding through the promotion of breastfeeding. Concern was expressed by some eWG members that a standard could be viewed as legitimising a product which is not considered nutritionally necessary. Some eWG members who do not support continuation of a follow-up formula standard were of the view that continuation of a standard creates confusion as it suggests that follow-up formula is necessary and fulfils a role in the diet of older infants and young children. Concern was expressed that the existence of a Codex Standard for follow-up formula undermines the optimal duration of breastfeeding message, exploits parents and caregivers concerns about infant and young child feeding. , encourages promotion of follow-up formula, and by proxy undermines the WHO Code of Marketing of Breast Milk Substitutes (for example, through staging of different formula products).

71. However, others regarded the review of the standard as an opportunity to consider the definition and regulation of breast milk substitutes as well as considering the needs for regulating and customising labelling and consumer information on follow-up formula products as key factors relating to the practices of breastfeeding. Others commented that should the follow-up formula standard remain, this should not be seen as endorsement of, or legitimisation of, the need for follow-up formula in the diet of older infants and young children. The comment was made that the labelling, marketing and advertising of follow-up formula must be considered as part of the review so as to not mislead the consumer as to the role of follow-up formula (i.e not nutritionally necessary), in the diets of older infants and young children.

7.2 eWG views on mechanisms for future regulation

72. As already discussed, from the eWG submissions, there was a majority agreement to continue to regulate formula products for older infants and young children and several approaches on how this might be achieved were communicated. The majority of respondents favoured maintaining the current age range within the follow-up formula standard covering the 6-36 months. There was strong support to consider a distinction at 12 months to take into account differing nutritional requirements and role of products between the two age groups. Some eWG members noted that it may not be necessary to determine exactly how best to present the standard until the Codex provisions were formulated.

73. Many eWG members were of the view that there needs to be clear differentiation between infant formula and follow-up formula and any overlap in terms of regulation should be avoided.

74. Some eWG members shared the view that there is no need for a follow-up formula standard which includes provisions for older infants (6-12 months) as it was their view that the Codex infant formula standard is suitable for this age range. Others were of the view that if product for older infants was covered by the Codex infant formula standard, then there needs to be some flexibility within that standard to allow some compositional differences between infant formula for infants 0-6 months and follow-up formula for older infants 6-12 months, such as parameters for iron. The potential overlap between the Codex infant and follow-up formula standards has been previously communicated by the eWG.

75. Of those eWG members who favoured retaining the current 6-36 month age range for the follow-up formula standard, most supported differentiation at 12 months. Many were of the view that regulation of follow-up formula for young children 12-36 months should be more flexible (than follow-up formula for older infants), in recognition that follow-up formula is part of a more diversified diet after the age of 12 months. It was also suggested that flexibility in terms of compositional provisions will assist in accommodating the varying needs of different countries. This will allow for formulation of products for specific markets depending of the nutritional status of the target population in that market. Comment was also made that provisions for follow-up formula for young children should be less prescriptive (than follow-up formula for older infants), as there is no need for the full complement of nutrients that are in follow-up formula for older infants. One Member Country supportive of less prescriptive compositional criteria for follow-up formula for young children, stated that a prescriptive standard for follow-up formula for young children would imply nutritional necessity and this should be avoided.

76. One possible option would be to create two distinct product categories by splitting the current follow-up formula standard in to two parts. Alternatively, there could be recognition within the follow-up formula standard that from 12 months not all nutrients would be mandatory additions. Other options for how this differentiation might be recognised and regulated require further exploration and consideration.

7.3 General principles for Standard development and review

77. In analysing the submissions of the eWG, there were several common themes which could be used as guiding principles for the review of the follow-up formula standard. These are as follows:

- Consumer protection and safety should be the primary focus of the review. Consumers need assurance of the integrity of product, through safe and suitable composition and customised labelling with respect to safe preparation, storage and usage. This includes:
    - Ensuring integrity of product through consideration of appropriate ingredients.
    - Ensuring consumers are not misled; consideration must be given to the labelling aspects of the Standard, including claims.
- A regulatory approach that allows for flexibility to support the variable role of product for older infants and young children, and different market demands, while maintaining nutritional integrity.

8.0 SUMMARY

8.1 Findings of the eWG

78. In summary, the key findings of the eWG and areas where there is general agreement are as follows:

- Follow-up formula is not considered nutritionally necessary in the diets of older infants and young children.

- There is general agreement to retain a Codex standard for follow-up formula.
- The current age range of the current follow-up formula standard, 6 – 36 months should be retained.
- There should be a recognised point of differentiation at 12 months of age due to different nutritional requirements and the different role of follow-up formula in the diets of older infants compared to that of young children.

8.2 Evidence to date

79. The eWG has reviewed and presented a considerable amount of data and evidence to inform the review of the follow-up formula standard. These include:

- Nutritional requirements of older infants and young children (Appendix)
- Global dietary intake and nutritional status data (Appendix)
- Global data on the role of FUF in the diets of older infants and young children (CX/NFSDU 13/35/7)

80. These data form the basis of the findings of the eWG to date. The findings highlight several common nutrients of global concern for which there is evidence to suggest that older infants and young children may have difficulty in achieving adequate intakes. This will assist with informing the essential composition of follow-up formula.

81. The Committee will need to consider if there is a need for additional technical guidance and/or expert advice to enable progress on the product composition.

9.0 ISSUES FOR DISCUSSION

82. As already presented, the majority consensus of the eWG that a Codex standard for follow-up formula is retained, if the Committee supports this decision the following areas have been identified as requiring discussion and decision going forward in order for the review to progress.

9.1 Scope

83. A decision as to the scope of the standard needs to be made in order to progress this work. Principally a decision is required as to the age range that the standard is to cover. In considering the scope of the follow-up formula standard, the Committee needs to make a decision on whether they agree with the preferred approach of the eWG to retain the 6-36 month age range.

84. In addition to retaining the 6-36 month age range, there was strong support for recognition of a point of differentiation at 12 months of age. This distinction at 12 months takes in to account differing nutritional requirements and the different role of follow-up formula products in the diet of older infants compared to that of young children.

85. The Committee may decide on a preferred structure for the standard before progressing work finalising the compositional parameters. Alternatively, the Committee could consider defining the composition of follow-up formula for the two different age groups, 6-12 months and 12-36 months separately, before deciding on the final structure or framework of the follow-up formula standard.

9.2 Description

86. In describing or defining follow-up formula it is important that the Committee builds on the findings of the eWG in that follow-up formula: can provide key nutrients; is not the sole source of nutrition; is used differently in different countries in terms of amount consumed, age of consumer, and national complementary feeding patterns.

87. The Committee should therefore consider the appropriateness of the current Codex definition of follow-up formula:

> ***Follow-up formula*** *means a food intended for use as a liquid part of the weaning diet for the infant from the 6th month and for young children.*

9.3 Approach for determining composition

88. Through the eWG, members have identified some key concepts which could help frame discussions as to how product targeted to the 6 to 36 month age group can be appropriately formulated to accommodate both the differing nutritional requirements and role in the diet that the product for older infants plays, compared to that of young children.

89. Nutritional requirements for the 6-12 month age group are often based on those of younger infants, and infant formula (when used) is often a significant contributor to the diet of this age group. Some eWG members therefore consider it appropriate that the Codex infant formula standard should be considered the basis, or starting point, for reviewing the appropriate composition of follow-up formula for older infants recognising that the infant formula standard does not adequately cover all the nutrient needs of the older infant.

90. Recognising the variation of the role that follow-up formula for young children has in the diet there is a need for the Committee to consider a regulatory approach which provides flexibility in its composition to contribute nutrients which may be inadequate, as well as supporting the specific needs of different countries. In addition, some eWG members consider that the composition of follow-up formula for young children should also provide the main nutrients in cows' milk as this was the product most commonly replaced.

10. FUTURE WORK

91. If the Committee agrees to progress work on the review of the Standard for Follow-up Formula for the 6 to 36 month age range. The Chairs have proposed the following steps for consideration.

92. Provided the Committee can agree to the scope of the review and general approach for determining composition (including whether external technical advice is required), work can progress on establishing the compositional requirements of the standard. The Chairs would recommend beginning this work by defining the compositional requirements for the 6-12 month age group, and then to assess the adequacy of this for young children. Decision making on the structure of future standard(s) could be deferred until compositional parameters have been established

93. Key principles to underpin the labelling aspects of the standard have yet to be discussed by the Committee and would require further consideration by a working group. Some data has already been collated in previous eWGs and could inform this work.

Possible revised timeline for completion of work:

November 2015-November 2016	Working group to progress work defining compositional parameters of follow-up formula which will inform the framework for regulation
November 2016-November 2017	Working group to review labelling requirements of the standard and other areas of the standard which require updating
November 2017	Consideration of draft standard and advancement
July 2018	CAC adoption of draft standard

The progression of this work is likely to require ongoing electronic and physical working groups.

Appendix

Review of nutritional requirements of older infants and young children

1. Review of nutritional requirements for older infants and young children

The eWG initiated a review of nutrient requirements of older infants and young children, taking into account recent scientific developments and global data as per their first term of reference. The purpose of reviewing the nutrient requirements is to identify the level of nutrients that are considered adequate for the majority of infants and young children. A review of nutrient requirements is not intended to be used to derive NRVs for labelling purposes for older infants and young children; this will be addressed by the Committee at a later date as a separate piece of work.

To review the nutrient requirements of this age group, the eWG reviewed the daily intake reference values (DIRVs) established by WHO/FAO (2004) as a basis and to consider recently derived values established through independent reviews of the science by recognised authoritative scientific bodies (RASBs). The individual nutrient level 98[2] (INL_{98}) value is considered the best estimate to meet the needs of almost all in the population. There is limited data available to derive nutrient requirements for this age group and consequently many RASBs have only derived adequate intake (AI) values[3]. Both INL98 and AI values have been considered by the eWG.

The approach taken was in accordance with the *General Principles for Establishing Nutrient Reference Values for the General Population* (CAC/GL 2-195). As a starting point the Chairs considered those RASBs identified in the review of the "Proposed Draft additional or revised nutrient reference values for labelling purposes in the Codex guidelines on Nutrition Labelling". The steps undertaken to identify nutrient intakes are reproduced below.

Step 1: Select and accept appropriate RASBs in accordance with the agreed definition of RASB.

Step 2: Identify DIRVs established by accepted RASBs for the vitamins and minerals under consideration for older infants and young children

Step 3: Compare the DIRVs derived by RASBs and WHO/FAO and identify those DIRVs established by WHO/FAO which are considered potentially unsuitable

Step 4: Detail the methods and physiological endpoints used to derive DIRVs by the WHO/FAO and each RASB

Step 5: From consideration of the differences between suitable candidate DIRVs, recommend the most appropriate NRV-R

In order to compare the nutrient requirements derived by each scientific body the Chairs collated individual nutrient level (INL_{98}) or adequate intake (AI) values for each nutrient for older infants and young children. The median and range of DIRVs derived by scientific bodies was then calculated and compared to the WHO/FAO values. WHO/FAO values were considered suitable when the median of values of RASBs coincided with the WHO/FAO (2004) values. The following DIRVs derived by WHO/FAO were considered adequate for the majority of infants and young children:

- Older infants -thiamine, riboflavin, niacin, vitamin B6, biotin, folate
- Young children – thiamine, riboflavin, niacin, vitamin B12, iodine

The scientific derivation and physiological endpoints used by the WHO/FAO and each RASB to derive DIRVs were documented and assessed alongside global data on nutrient intake and status to identify which DIRV or DIRVs were considered adequate for the majority of older infants and young children.

[2] INL_{98} is the daily intake reference value that is estimated to meet the nutrient requirement of 98 percent of the apparently healthy individuals in a specific life stage and sex group. Different countries may use other terms for this concept, for example, Recommended Dietary Allowance (RDA), Recommended Daily Allowance (RDA), Reference Nutrient Intake (RNI), or Population Reference Intake (PRI).

[3] The recommended average daily intake level based on observed or experimentally determined approximations or estimates of nutrient intake by a group (or groups) of apparently healthy people that are assumed to be adequate used when an INL_{98} cannot be determined

The following nutrients were reviewed by the eWG and results are presented in this document alongside nutritional intake and status data.

Energy	Vitamin A	Vitamin E	Calcium
Protein	Folate	Vitamin K	Iron
Fat	Vitamin B12	Pantothenic acid	Zinc
Carbohydrates	Vitamin C	Biotin	Selenium
Fatty acids	Vitamin D		Iodine

1.2 Selection of suitable data sources

The eWG reviewed DIRVs derived by WHO/FAO in addition to those derived more recently through independent review by a RASB. To be considered as a RASB three criteria must be met: supported by one or more government(s) or competent national or regional authorities; provides independent and transparent authoritative scientific advice through primary evaluation of the evidence; is one whose advice on DIRVs is recognised through use in policy in one or more countries.

As not all RASBs have conducted a primary evaluation and subsequently not considered suitable this has been identified in the comparison tables.

The following RASBs have been considered by the eWG:

The European Food Safety Authority	European Union
The Institute of Medicine	USA and Canada
The National Health Medical Research Council/Ministry of Health	Australia and New Zealand
The National Institute of Health and Nutrition	Japan
The Nordic Council of Ministers	Denmark, Finland, Iceland, Norway and Sweden

Summary of WHO/FAO DIRVs compared to those summary of those derived by RASBs

	Infants (7-11 months)			Young children (12-36 months)		
		RASB			RASB	
Vitamins	**WHO**	**Median**	**Range**	**WHO**	**Median**	**Range**
Vitamin A(µg RE)	400	415	350 - 500	400	350	300 - 400
Vitamin C (mg)	30	35	20 - 50	30	30	15 - 40
Vitamin D (µg)	5	7.5	5 - 10	5	10	5 -15
Vitamin E (mg α-TE)	2.7	5	2.7 - 5	5	5	3.5 - 6
Vitamin K (µg)	10	4.75	2.5 - 10	15	25	12 - 30
Thiamin (mg)	0.3	0.3	0.3	0.5	0.5	0.5
Riboflavin (mg)	0.4	0.4	0.4	0.5	0.5	0.5 - 0.8
Niacin (mg)	4	4	3 - 5	6	6.0	6 - 9
Vitamin B6 (mg)	0.3	0.3	0.3 - 0.4	0.5	0.5	0.5 - 0.7
Folate (µg DFE)	80	80	65 - 80	150	100	100 - 150
Vitamin B12 (µg)	0.7	0.5	0.5 - 0.7	0.9	0.9	0.9
Pantothenic acid (mg)	1.8	2.6	1.8 - 5	2	3.3	2 - 4
Biotin (µg)	6	6	6 - 10	8	14.0	8 - 20
Minerals						
Calcium (mg)	400	265	260 - 400	500	600	400 - 700
Phosphorous (mg)	-	275	260 - 300	-	460	460 - 600
Potassium (mg)	-	700	700 - 800	-	850	800 - 3000
Sodium (mg)	-	370	170 - 600	-	650	200 - 1000
Chloride (mg)	-	570	570	-	1035	1500
Iron (mg)	9.3	9.5	4.75 - 11	5.8	8.0	4.25 - 9
Zinc (mg)	4.1	3	2.9 - 4.1	4.1	4.3	3 - 5
Iodine (µg)	90	120	90 - 160	90	90	50 - 90
Selenium (µg)	10	15	10 - 20	17	20	10 - 25
Copper (mg)	-	0.26	0.22 - 0.3	-	0.4	0.3 - 0.7
Magnesium (mg)	54	75	54 - 80	60	80	60 - 85
Manganese (mg)	-	0.55	0.02 - 0.6	-	1.4	0.5 - 2

2. Review of dietary intake reference values, nutrients intakes and status

The eWG reviewed the derivation of DIRVs established by the WHO/FAO and other RASBs where differences have been identified. The eWG deemed that the most pragmatic way to evaluate nutrient intakes was to review nutrients on a case by case basis to determine the most suitable DIRV. Nutrient requirements were reviewed alongside data on nutrient intakes and status where available.

Nutritional intake and status data were submitted from the eWG to provide a global overview for this age group. Although the eWG had good representation globally, limited data was available for all nutrients and several countries commented that they do not have nationally representative dietary intake data or nutrient adequacy data for young children aged 1-3 years. Please note the ability to make comparisons between countries and regions is limited by different reference points used in individual studies/surveys, such as different DIRVs, the use of different biochemical cut-offs as indicators of nutritional status, as well as variations in the age ranges surveyed. The information does however highlight common themes in terms of nutrients of concern for which there is some evidence suggesting older infants and young children may have difficulty in achieving adequate intakes.

As mentioned previously, nutrients which were not further considered by the eWG were those for which the there was no difference in the DIRV derived by the WHO/FAO (2004) and median of those of the nominated RASBs. There are several minerals (phosphorous, potassium, sodium, chloride, copper, manganese) which currently have compositional requirements in the Codex infant formula and follow-up formula standards but for which the WHO/FAO have not set any DIRVs. These have not been evaluated by the eWG at this stage.

2.1 Reference Body Weights

It is particularly important to consider internationally applicable reference body weights when reviewing energy and macronutrient requirements for this age group. The Chairs and eWG view the reference body weights derived from the WHO Multicentre Growth Reference Study Group (WHO 2006) for the 6-36 month age group as the most internationally relevant. This study was conducted between 1997 and 2003 and included approximately 8500 children from Brazil, Ghana, India, Norway, Oman and the USA. The survey was specifically designed to describe normal child growth from birth to five years under optimal environmental conditions. The growth standards are promoted by the WHO as relevant to all children, regardless of ethnicity, socioeconomic status or type of feeding (WHO 2006). In 2011, 125 countries had adopted the WHO Child growth standards (Onis 2012).

It is worth noting that the EFSA Scientific Opinion on nutrient requirements and dietary intakes of infants and young children in the EU also applied the WHO reference body weights to their calculations of energy and protein requirements (EFSA 2013). Median weight-for-age values are reported for each month for children 6 to <12 months and every six months for the 12 to <36 month age group (Table 1).

Table 1: WHO reference body weights for the 6 to 36 month age group

	Body weight (kg)				**Body weight (kg)**	
Age (months)	**Boys**	**Girls**		**Age (months)**	**Boys**	**Girls**
6	7.9	7.3		12	9.6	8.9
7	8.3	7.6		18	10.9	10.2
8	8.6	7.9		24	12.2	11.5
9	8.9	8.2		30	13.3	12.7
10	9.2	8.5		35	14.2	13.7
11	9.4	8.7		**12 to <36**	**12.0**	**11.4**
6 to <12	**8.7**	**8.0**				

Adapted from the WHO Child Growth Standards (2006)

2.2 Energy

Energy requirements for infants and young children were last reviewed in an FAO/WHO/UNU Expert consultation in 2001 and reported in the FAO Food and Nutrition Technical Report Series (FAO 2004). Energy requirements are based on total energy expenditure and optimal growth of healthy, well-nourished infant populations. The expert consultation examined an analysis of 13 studies with double labelled water performed on a total of 417 healthy, well-nourished, non-stunted infants from 0 to 12 months of age and the longitudinal

study of 76 health infants followed during the first two years of life. The longitudinal study of Butte and colleagues (2000) was used to establish equations to predict total energy expenditure (TEE).

Formula fed infants have been shown to have higher total energy expenditure than their breast fed counterparts during the first year of life, but no difference at 18 and 24 months of life (Butte 2000, FAO 2004). As this review is based on development of a formula product the requirements presented below are those for formula fed older infants, and all young children.

At the time that the FAO/WHO energy requirements document was published the results of the WHO Multicentre Growth Study were not available. The eWG have applied the FAO/WHO energy requirement estimates to the revised WHO reference body weights (Table 2). There was almost no difference in the original WHO/FAO/UNU daily energy requirements (6-12 months 2.9 MJ/day; 12-36 months 4.2 MJ/day) to those calculated by the eWG.

Table 2: FAO/WHO energy requirements for the 6 to 36 month age group applied to the more recent WHO reference body weights

	Body weight (kg)[1]		Energy kJ/kg bodyweight per day[2]		Energy requirement (MJ) per day	
Age (months)	**Boys**	**Girls**	**Boys**	**Girls**	**Boys**	**Girls**
6	7.9	7.3	350	355	2.8	2.6
7	8.3	7.6	340	340	2.8	2.6
8	8.6	7.9	340	340	2.9	2.7
9	8.9	8.2	340	340	3.0	2.8
10	9.2	8.5	340	340	3.1	2.9
11	9.4	8.7	340	340	3.2	3.0
6 to <12 months[3]			**2.9**			
12-24	10.9	10.2	345	335	3.8	3.4
24-36	13.3	12.7	350	335	4.7	4.3
12 to <36 months[4]					**4.0**	

[1]Median weight-for-age values from the WHO Growth Standards (WHO 2006)

[2]Energy requirements per kJ body weight from the WHO/FAO/UNU expert consultation (FAO 2004)

[3]Older infant energy requirements based on those of formula fed children

[4]Young children physical activity level assumed as 1.45 and 1.40 for boys and girls respectively

[3,4] Age grouped estimates are based on the median requirements

2.3 Protein

The WHO/FAO/UNU (2007) review of protein requirements calculated protein requirements based on the factorial method which take into consideration protein required for maintenance and growth. The calculations are based on maintenance of requirements of 0.66 g/kg bodyweight per day and a protein efficiency utilisation of 58%. The most recently published RASB report also used the same factorial method calculations (EFSA 2013).

The report of the WHO/FAO/UNU states that protein requirements for children should be calculated in two stages: first, the requirement per kg should be obtained, according to age range; second this should be multiplied either by the actual weight or by the median weight for age to obtain the total requirement. A summary of requirements for infants and children was produced in the report, but it was noted that more detailed values should be calculated for specific age and reference body weights. Additionally, the WHO/FAO/UNU report was based on the old WHO growth standards. The Chairs have recalculated the protein requirements based on safe intake levels (WHO/FAO/UNU 2007) and the WHO Multicenter Growth Study Growth Standards (WHO 2006). This approach was also adopted by EFSA in their review of protein requirements for older infants and young children (EFSA 2014[e]).

More recently derived estimates of protein requirements are lower than previous estimates (WHO/FAO/UNU 2007) primarily as a result of changes in the reference body weights that were previously used. Almost all recently derived values are based on the WHO/FAO/UNU report requirements per kg bodyweight.

Converting protein requirements on a per day basis to percentage of energy requirements recommended by WHO/FAO/UNU results in a contribution of 6% energy from protein for older infants, and 5% for young children. It is acknowledged that protein quality and methods to assess protein quality are of equal important to protein requirements and will need to be considered by the Committee at a later stage.

Intakes

Several nationally and regionally representative surveys of dietary protein intakes of older infants and young children have been conducted globally, a selection of which is presented in Table 4. The results of these surveys have consistently identified that protein intakes in this age group are adequate for the majority of infants and young children, and may even be excessive. Mean intakes have ranged from 20 g (Philippines FNRI) to 60 g (Australia DOHA 2008) – two to six times higher than the WHO/FAO/UNU safe intake level. In Uganda data were presented as percentiles and highlighted that even at the 5th percentile intakes were twice those recommended by WHO/FAO/UNU (19.2 g/day) (Harvey 2010). The WHO/FAO/UNU report states that there is no risk to individuals with excessive intakes considerably above the safe intake levels (WHO/FAO/UNU 2007). No upper limit has been set by the WHO/FAO for protein and the effects of a diet habitually high in protein intakes are unclear.

There are some studies which are suggestive that excessive protein intakes in early childhood may be associated with differences in growth and obesity risk later in life. There is no conclusive evidence that protein intakes of the magnitude observed in the surveys identified in Table 4 have adverse health consequences in the short or long term.

Table 3: Protein requirements calculated from WHO/FAO/UNU protein requirements per kg bodyweight applied to WHO weight-for-age growth standards (WHO 2006)

	Body weight (kg)		**Maintenance requirement**	**Growth Requirement**	**Protein requirement**	**INL_{98} (g/day)**	
Age (months)	**Boys**	**Girls**	**g protein/kg bodyweight per day**			**Boys**	**Girls**
6	7.9	7.3	0.66	0.46	1.31	10.3	9.6
7	8.3	7.6	0.66	0.42	1.27	10.5	9.6
8	8.6	7.9	0.66	0.39	1.23	10.5	9.7
9	8.9	8.2	0.66	0.36	1.19	10.6	9.8
10	9.2	8.5	0.66	0.33	1.16	10.7	9.9
11	9.4	8.7	0.66	0.31	1.14	10.7	9.9
6 to <12 months							**10.2**
12	9.6	8.9	0.66	0.29	1.12	10.7	9.9
18	10.9	10.2	0.66	0.19	1.03	11.2	10.5
24	12.2	11.5	0.66	0.11	0.98	12.0	11.3
36	14.3	13.9	0.66	0.07	0.90	12.9	12.5
12 to <36 months							**11.3**

Protein requirements calculated from WHO/FAO/UNU (2007) and WHO weight-for-age growth standards

6 to <12 month and 12 to <36 months age grouped estimates are median values

Table 4: Global protein intakes presented as grams per day and contribution to percentage energy

Country	Age	N	Mean (SD)	% Energy
USA (Butte 2010)	6-11 months	505	19* (IQR 14, 27)	10% (0.1%)
	12-23 months	925	43* (IQR 35, 51)	15% (0.1%)
Canada (Health Canada 2009)	12-36 months	2117	-	15.2% (0.2%)
Argentina (Duran 2009)	6-23 months	-	40.75	15.9%
Mexico (Mundo-Rosas 2009)	1-4 years	3552	35 (IQR 26, 47)	13.1%
Australia (DOHA 2008)	24-48 months		60	16.9%
Ireland (IUNA 2012)	12 months		39.2 (10.3)	15.6% (2.5%)
	24 months		42.6 (11.7)	15.3% (2.5%)
	36 months		42.7 (9.9)	14.9% (2.4%)
Holland (Ocke 2008)	24-48 months	327	B: 44 (38, 50)	13% (11, 15%)
		313	G: 43 (38, 48)	13% (12, 15%)
France (Nutribébé SFAE 2013)	6 months 12-17 months 18-23 months 24-29 months	90 121 120 125	17.8 (3) 35.6 (14) 40.3 (15) 41.7 (14)	11% 16% 17% 17%
China (Barbarich 2006)	12-36 months	126	18 (8)	11% (3%)
India (ICMN 2012)	12-36 months	2895	21.3 (11.9)	14.7%
Indonesia (Sandja 2013)	6-24 months	2391	21 (1)	11%
Malaysia (Poh 2013)	6-12 months	68	U: 20.9 (1.5) R: 25.8 (3.6)	11.4% 13.2%
	12-48 months	538	U: 39.1 (0.8) R: 44.3 (1.0)	14.8% 14.9%
Philippines (FNRI 2008)	6-11 months 12-23 months 24-35 months		14.2 20.8 25.5	12.7% 13.3% 13.0%
Thailand (Rojroongwasinkul 2013)	6-36 months	216 473	U: 35 (0.4); R: 47 (0.5)	15.0% 15.9%
Vietnam (Nguyen 2013)	6-24 months	289	U: 50 (1) R: 37 (1)	19.0% 17.5%
Uganda (Harvey 2010)	24 – 59 months	468	32.1* (IQR 26, 39)	10% E

Notes: U: Urban; R: Rural; B: Boy; G: Girl

* Median values (interquartile range)

2.4 Percentage Energy from Macronutrients

In the most recent Joint FAO/WHO Expert Consultation on Fats and Fatty Acids in Human Nutrition (FAO 2010) it was reported that fats normally provide around half of the energy of human milk (and most infant and follow-up formulas). The FAO/WHO state that during the first six months of life, dietary total fat should contribute 40-60% of energy and that this should be reduced gradually between 6-24 months (depending on the physical activity of the child) to ~35% of energy (convincing level of evidence) (FAO 2010).

There is strong evidence underlying the DIRVs for fat and protein for this age group and the recommendations for the acceptable macronutrient distribution range (AMDR). However the WHO/FAO recommendations for carbohydrate intakes are not specific to this age range and have been set for the general population. Due to the high percentage of fat required in early childhood, use of the current WHO/FAO general population recommendation for carbohydrate results in energy intakes in excess of the requirements (contribution of macronutrients to percentage energy requirements: 141% in older infants, 115% in young children). The percentage energy from carbohydrate should make up the difference to ensure total percentage of energy equates to approximately 100%.

The calculated percentage of energy that would need to be supplied from protein, fat and carbohydrate to equate to approximately 100% are presented in Table 5. These values are aligned with those derived by the majority of RASBs and are based on the strong evidence supporting the WHO/FAO recommendations for protein and fat intakes for this age group.

Table 5.Summary of macronutrient requirements established by WHO/FAO presented as % energy and grams per day

	6-12 months		12-36 months	
FAO/WHO recommendations	% Energy	g/day[1]	% Energy	g/day
Protein (WHO/FAO/UNU 2007)	6%	10 g (8-11)	5%	11.4 g (10-13)
Fat (FAO 2010)	<40-60%	<31- 47 g	~35%	~38 g
Chair proposal				
Protein	6%	10 g	5%	11.4 g
Fat	~40%	31 g	~35%	~38 g
Carbohydrate	~45-55%	85 g	~50-60%	~130 g

[1] g/day based on average energy intake of 2900 kJ and 4000 kJ for older infants and young children respectively
[2]Chairs proposal is based on total percentage of energy from protein, fat and carbohydrate equalling approximately 100%
[3]Percentage energy from carbohydrate calculated to make up to approximately 100%

2.5 Fatty Acids

The Joint FAO/WHO Expert Consultation on Fats and Fatty Acids in Human Nutrition (2008) identified that there is increasing interest in the quality of dietary fat in early life as a major determinant of growth (FAO 2010). The report reinforced that convincing evidence exists to support linoleic acid (LA C18:2 n-6) and α-linolenic acid (ALA C18:3 n-3) as essential fatty acids and indispensible since they cannot be synthesized by humans. For the 6-12 month age group it was concluded that "there is convincing evidence that the AI for the essential fatty acids for optimal growth and development of this age group are 3-4.5% for LA and 0.4-0.6% energy for ALA."

Although it was deemed by the WHO/FAO that there was convincing evidence that docosahexaenoic acid (DHA) plays a critical role in retinal and brain development in the 0-24 month age group, the AI that was set for DHA was 10-12 mg/kg (approximately 100 mg/day) at a probable level of evidence (FAO 2010). The reports of EFSA and IOM are aligned with the WHO/FAO recommendations. Individual essential fatty acid requirements were not derived by the NIHN or NNR 2012. The NHMRC/MoH (2006) values are based on dietary intakes in Australia.

EFSA have reviewed the dietary intakes of essential fatty acids and long chain polyunsaturated fatty acids (LCPUFA) from available studies in Europe (EFSA 2013). Generally intakes of LA and ALA in older infants were found to be adequate for the majority of European infants (EFSA 2013). Older infants in Germany, France, the Netherlands and Finland reported intakes of LA of 3.4-6.8% E and mean intakes of ALA ranged from 0.46 - 0.86% E. Conversely, the majority of young children in European surveys obtained less than the adequate intake of ALA from the diet. It was concluded that data on intakes and status of LA were of no concern for European infants and young children, but that mean intakes of both ALA and DHA were reported to be low and particular attention should be paid to ensuring an appropriate supply of these nutrients.

Table 6: Essential fatty acid requirements established for older infants and young children

	Age range	WHO/FAO (2009)	EFSA (2010)	IOM (2005)	NHMRC (2006)
LA	6-24 mo	3-4.5% E (AI) [convincing[4]]	4% (AI)	12-36 mo: 7 g	12-36 mo: 5 g
ALA	6-24 mo	0.4-0.6% E [probable[5]]	0.5% E (AI)	7-12 mo: 0.5 g 12-36 mo: 0.7 g	12-36 mo: 0.5 g
DHA	6-24 mo:	10-12 mg/kg [probable[5]]	100 mg/day	NS	12-36 mo: 40 mg (DHA+EPA+DPA)

There is very limited data available on essential fatty acids globally. A recent review assessed the fat and fatty acid intakes in a range of low income countries utilising food balance data (Michaelsen 2011). This review indicated that the availability of fat and omega three fatty acids in the food supply in low income countries is low, often below the minimum recommended intake for infants, young children, pregnant and lactating women. For children under two years of age, the key sources of long chain polyunsaturated fat (LC-PUFA), particularly omega three fatty acids, are breast milk and fish. However LC-PUFA concentrations in breast milk are highly influenced by maternal intakes (FAO 2010). Based on this data it is likely that essential fatty acids

[4] Convincing: Evidence based on epidemiological studies showing consistent associations between exposure and disease, with little or no evidence to the contrary. The available evidence is based on a substantial number of studies including prospective observational studies and where relevant, randomized controlled trials of sufficient size, duration and quality showing consistent effects. The association should be biologically plausible (WHO 2003)

[5] Probable: Evidence based on epidemiological studies showing fairly consistent associations between exposure and disease, but where there are perceived shortcomings in the available evidence or some evidence to the contrary, which precludes a more definite judgement. Shortcomings in the evidence may be any of the following: insufficient duration of trials (or studies); insufficient trials (or studies) available; inadequate sample sizes; incomplete follow-up. Laboratory evidence is usually supportive. Again, the association should be biologically plausible (WHO 2003)

are inadequate in the diets of older infants and young children. Data received from the eWG indicate that several nutrient intake surveys also indicate low intakes of DHA in the diets of older infants and young children (Yakes 2011, Prentice 2000, Schwartz 2010, Sioen 2007, Barbarich 2006).

2.6 Vitamin A

The eWG considered that the DIRVs derived by WHO/FAO were adequate for the majority of older infants and young children globally. Vitamin A intake from breast milk varies according to maternal vitamin A status, ranging from 0.70 – 2.45 µmol/L across countries (WHO/FAO 2004). The WHO/FAO values are aligned with those derived by other scientific bodies and take into account the variability of breast milk concentrations globally.

The safe intake level derived by the WHO/FAO is based on an average breast milk intake of 650 ml/day and an average concentration of vitamin A in breast milk of 1.75 µmol/L, providing 325 µg per day. This was then rounded up to 400 µg per day due to the high risk of mortality from six months onwards in endemic vitamin A deficient areas. The recommended safe intake level for young children was extrapolated from the data on older infants (WHO/FAO 2004).

The latest review of global vitamin A status was conducted by the WHO from 1995-2005 and included 156 countries with a GDP < US$ 15 000 (WHO 2009). It was estimated that a third of children under five years of age had subclinical vitamin A deficiency (serum retinol <0.7 µmol/L). The African and South-East Asian regions had the highest prevalence of subclinical deficiency (44.4% and 49.9%, respectively), whereas the Western Pacific and Americas had the lowest (12.96% and 15.6%, respectively) (WHO 2009).

The data gathered by the eWG (Table 8) supports the findings of the assessment undertaken by WHO (WHO 2009), whereby vitamin A deficiency was largely limited to low and middle income countries, particularly within Asia. In the EFSA review of dietary intakes in Europe, dietary intake data was available for Belgium, Denmark, France, Finland, Germany, Greece, Holland, Iceland, Ireland, Italy, UK: all of which had intakes at or above the AI of 400 µg. The survey in Belgium also assessed prevalence of vitamin A deficiency and found less than 1% of infants and young children were deficient (<0.64 µmol/L) (EFSA 2013).

It is evident from the WHO/FAO review that vitamin A is a problem nutrient for infants and young children within certain regions, particularly low and middle income countries (WHO 2009) and that the current WHO/FAO DIRVs are adequate for the majority of older infants and young children.

Vitamin A requirements

Scientific body [year last citation]	**Daily intake reference values**	**Scientific justification for daily intake reference value**
WHO/FAO 2004 [2002]	400 µg RE (AI)	A recommended safe intake level of 400 µg retinol equivalents has been set for the 6-12 and 12-36 month age group based on average breast milk intakes.
IOM 2001 [2000]	*7-12 mo:*500 µg RAE (AI) *12-36 mo:*300 µg RAE (INL_{98})	Values for older infants are based on extrapolation of breast milk intake values from young infants plus average contribution from complementary foods. Value for young children is based on extrapolation of INL_{98} from adults adjusted for metabolic weight factors.
EFSA (2013)	*6 to <12 mo:* 350 µg RE (AI) *12 to<36 mo:* 400 µg RE (AI)	Not primary evaluation. Estimations were based on observed breast milk intakes and derived by the Scientific Committee on Food (SCF) in 1993 and are still considered adequate for the majority of older infants and young children.
NHMRC 2006 [2003]	*6-12 mo:* 430 µg RE (AI)	Adequate intake value is based the intake of vitamin A from breast milk (186 µg) plus the contribution from complementary foods (244 µg).
NIHN 2010 [2008]	*6-12 mo:* 400 µg RAE (AI) *12-36 mo:* 375 µg RAE (INL_{98})	Older infants' requirements extrapolated from breast milk intakes of young infants (0-6 months old). Requirements for young children were extrapolated from adult data based on maintenance of liver stores.
NNR 2012 [2011]	*12 to 36 mo:* 350 µg RE (INL_{98})	No direct studies on requirements available for this age group, thus adult requirements values were extrapolated taking into account metabolic weight and growth factors.
eWG proposal	400 µg RE (AI)	WHO/FAO values considered suitable

RE: Retinol equivalents; RAE: Retinol activity equivalents; highlighted row indicates DIRV proposed by the Chairs as adequate for the majority of older infants and young children

Table 8: Vitamin A intakes and status of older infants and young children

Country/region	Age range	N	Median	Prevalence	Cut-off
Canada (Health Canada 2009)	12-36 mo	2117	509 ug RAE	<3%	<210 µg
USA	7-12 mo 12-36 mo			<12.5% 1.5%	<500 µg <210 µg
Mexico	12-48 mo	3552	310.7 ug RE	33.6%	<210 µg
Australia (DOHA 2008)	24-36 mo		657.2 ug RE	<1%	<210 µg
Uganda (Harvey 2010)	24-59 mo	225	40-121 ug RE	52-99%	<286 µg
India (IIPS 2012)	12-36 mo	2895	61 ug	81.5%	<200 µg
Thailand (Rojroongwasinkul 2013)	6-36 mo		U: 582 ug RAE R: 552 ug RAE		
Vietnam (Nguyen 2013)	6-24 mo 24-59 mo	161 128 314 349	U: 477ug R: 301 ug U: 388 ug R: 241 ug	U: 44% R: 77% U: 60% R: 87%	< 400 µg
Malaysia (Poh 2013)	6-12 mo 12-48 mo	43 25 294 244	U: 859 ug R: 753 ug U: 844 ug R: 883 ug	U: 2.4% R: 4.3% U: 8.9% R: 2.1%	< 400 µg
Status					
Indonesia (Sandjaja 2013)	24-59 mo	959 1089	U: 1.7 µmol/L R: 1.5 µmol/L	U: <1% R: 1.5%	<0.7 µmol/L
Pakistan (Government of Pakistan 2011)	<59 mo			54%	<0.7 µmol/L

2.7 Vitamin B12

Scientific body [year last citation]	Daily intake reference values	Scientific justification for daily intake reference value
WHO/FAO 2004 [1999]	6-12 mo: 0.7 µg (AI) 12-36 mo: 0.9 µg (INL_{98})	6-12 mo: based on upper end of breast milk concentrations (0.8 µg/L x 0.75L) 12-36 mo: Extrapolated from adults
IOM 1998 [1998]	6-12 mo: 0.5 µg (AI) 12-36 mo: 0.9 µg (INL_{98})	6-12: extrapolated from requirements for young infants which are based on breast milk intakes (0.78 Lx 0.42 µg/L) and adjusted for body weight 12-36 mo: Extrapolated from adults
EFSA 2013	6-12 mo: 0.5 µg (AI) 12-36 mo: 0.9 µg (INL_{98})	6-12 mo: Not primary evaluation based on SCF 1993 12-36 mo: Not primary evaluation, based on IOM and WHO/FAO
NHMRC/MoH 2004 [2004]	6-12 mo: 0.5 µg (AI) 12-36 mo: 0.9 µg (INL_{98})	Not primary evaluation, based on IOM.
NIHN 2013 [2002]	6-12 mo: 0.6 µg (AI) 12-36 mo: 0.9 µg (INL_{98})	6-12 mo: Extrapolated from young infant requirements which are based on breast milk intake (0.78 L x 0.45 µg/L) and the EAR for adults using a body weight ratio 12-36 mo: Extrapolated from adults
NNR 2012 [1977]	>24 mo: 0.8 µg (INL_{98})	Based on 0.05 µg/kg body weight
eWG proposal	6-12 mo: 0.5 µg (AI) 12-36 mo: 0.9 µg (INL_{98})	6-12 months: based on breast milk concentrations of healthy mothers (not supplemented) 0.4 µg/L 12-36 months: WHO considered suitable

Vitamin B12 was highlighted as a nutrient for which the requirement level set my WHO/FAO for older infants required further consideration by the eWG. There is strong agreement between the WHO/FAO requirements for young children and all RASBs that 0.9 µg per day of vitamin B12 is adequate for the majority of young children.

All scientific bodies have based requirements for older infants on breast milk intakes for young infants and extrapolated based on body weight. Differences between the WHO/FAO requirements and those of the NIHN and IOM (only primary evaluations for this age group) highlight that differences are due to the concentration of vitamin B12 in breast milk. The WHO/FAO selected the upper end of the spectrum of breast milk

concentrations (0.8 µg/L) which is approximately double that used by the IOM, NIHN, and EFSA. As vitamin B12 concentrations in milk are known to reflect maternal status and can be affected by supplementation (Allen 2012); and the WHO/FAO state in their review that breast milk concentrations of 0.4 µg/L reflect normal status; it may be more appropriate to base adequate intake levels on this. The eWG considered that intakes of 0.5 µg/day of B12 are adequate for the majority of older infants.

2.8 Folate

Scientific body [year last citation]	Daily intake reference values	Scientific justification for daily intake reference value
WHO/FAO 2004 [1999]	6-12 mo: 80 µg DFE (AI) 12-36 mo: 150 µg DFE (INL_{98})	Based on IOM, not primary evaluation.
IOM 1998 [1998]	6-12 mo: 80 µg DFE (AI) 12-36 mo: 150 µg DFE (INL_{98})	6-12 mo: Based on folate intakes of young infants from breast milk (0.78 L x 85 µg/L), and extrapolated to older infants. 12-36 mo: Extrapolated from adults adjusting for body weight and allowance for growth, CV 10%. Adult requirements were based on metabolic studies to maintain or restore folate status, RBC status (>305 nmol/L), homocysteine (<16 µmol/L), and serum folate (>7 nmol/L).
EFSA 2014 [2014]	6-12 mo: 80 µg DFE (AI) 12-36 mo: 80 µg DFE (INL_{98})	6-12 mo: Based on folate intakes of young infants from breast milk (0.8 L x 80 µg/L), and extrapolated to older infants. 12-36 mo: Extrapolated from adults using isometric scaling and allowance for growth. Adult requirements were based on metabolic studies maintaining adequate folate status (serum folate status >10 nmol/L) in adults with unknown MTHFR genotypes.
NHMRC/MoH 2004 [2004]	6-12 mo: 80 µg DFE (AI) 12-36 mo: 150 µg DFE	Based on IOM, not primary evaluation.
NIHN 2013 [2002]	6-12 mo: 65 µg DFE (AI) 12-36 mo: 100 µg DFE (INL_{98})	6-12 mo: Based on folate intakes from breast milk of Japanese women (0.78 L day x 54 µg/L) for the 0-6 month age group and extrapolated to older infants. 12-36mo: Extrapolated from adults adjusting for body weight and allowance for growth, EAR multiplied by 1.2 to calculate INL98. Adult requirements were based on RBC folate (> 300nmol/L) and plasma total homocysteine (<14 umol/L).
NNR (2014) [1977]	>24 mo: 80 µg DFE (INL_{98})	Based on intakes of 5 µg folate per kg body weight. A diet supplying between 3.5-5.0 µg/kg maintained growth, haemopoiesis and clinical wellbeing in a study of 24 infants (Asfour 1977).
eWG proposal	6-12 mo: 80 µg DFE (AI) 12-36 mo: 80-100 µg DFE (INL_{98})	6-12 months: WHO/FAO values suitable 12-36 months: Intakes of 80-100 µg DFE considered adequate for the majority of young children based on most up to date systematic reviews (EFSA, NIHN, NNR)

1 µg Dietary folate equivalents (DFE) is equivalent to: 1 µg folate, 0.6 µg of folic acid

For the 6-12 month age group the primary evaluations for requirements have largely relied on the contribution from breast milk during the 0-6 month age group and extrapolating to older infants based on bodyweight. The NIHN requirements differ substantially to those derived by all other RASBs due to the concentration of folate in breast milk used in the calculation of requirements. A more recent analysis of breast milk in North American women found average concentrations of folate in breast milk of 80 µg/L (Houghton 2009); this was used by EFSA in the most recent systematic review published by any RASB (2014). Folate is considered a Group II nutrient in breast milk, meaning that maternal status does not affect the breast milk concentrations and concentrations in breast milk are maintained even if the mother is deficient (Allen 2012). Furthermore, the IOM evaluated evidence from five formula fed infant feeding studies which supported the use of the AI of 80 µg for older infants (IOM 1998). The lower estimated folate concentration in breast milk used by the NIHN is most

likely due to different analytical methods used to detect folate. As the IOM (1998) value is in agreement with the latest review of folate in breast milk, supported by five studies, and has been adopted by the WHO, NHMRC and EFSA it is considered that this is the most appropriate DIRV for the 6-12 month age group.

Of those countries which have provided data on folate intakes, the majority report dietary intakes above the AI of 80 µg DFE for the 6-12 month age range. The data available indicate that there is a very low prevalence of inadequacy using the WHO/FAO DIRVs for young children in Australia, Canada, Uganda and the United States (DOHA 2008, Health Canada 2009, Harvey 2010). Dietary surveys for young children report mean intakes of folate in Germany, Ireland and the Netherlands fall between the WHO/FAO EAR and INL_{98} (120 - 150 µg DFE).

Lower median intakes have been observed in Norway and India, yet low prevalence of folate insufficiency exists in Norway (IIPS 2007, Hay 2011). In Norway 35% of children 24 months of age had folate intakes less than 80 µg DFE and 75% less than 105 µg DFE, yet only 6% had insufficient folate status (serum folate <10 nmol/L) (Hay 2011). The WHO define folate deficiency as serum folate levels less than 6.8 nmol/L (WHO 2012), none of the children in the Norwegian study had serum folate less than 15 nmol/L which suggests that there is a discrepancy between cut-offs used to determine dietary and blood folate sufficiency..

The available evidence supports the continued use of the WHO/FAO (2004) requirements for older infants (80 µg DFE) as new evidence on breast milk concentrations supports the continued use of the WHO/FAO and IOM estimations of folate concentrations in breast milk (WHO/FAO 2004; IOM 1998). More recent systematic reviews have established DIRVs of 80-100 µg DFE per day (EFSA 2014, NNR 2012). This may be more appropriate for the young child age group.

Table 7: Folate intakes and status of older infants and young children

				Dietary intakes		**Biochemical status**	
Country/region	**Age range**	**N**	**Median**	**%**	**Cut-off**	**%**	**Cut-off**
USA (FDA 2014)	7-12 mo			<1%	<80 µg DFE (AI)	-	-
	12-36 mo			<1%	<120 µg DFE (EAR)	<1%	SF <4.5nmol/mL RBF <215 nmol /mL
Norway (Hay 2011)	24 mo	178	87 µg DFE IQR:74-104	35%	<80 µg DFE	5.8 %	SF <10 nmol/L

Table 8: Dietary folate intakes of older infants and young children

Country/region	**Age range**	**N**	**Median**	**Prevalence**	**Cut-off**
Canada (Health Canada 2009)	12-36 mo	2117	274 µg	2.9%	120 µg DFE
Australia (DOHA 2008)	24-36 mo		362.2 µg*	<1%	<120 µg DFE (ANR)
Uganda (Harvey 2010)	24-59 mo	225	133-168 µg	0-17%	<167 µg DFE
India (IIPS 2012)	24-36 mo	2895	55.5 µg	40.3%	<40 µg (half of the INL_{98})
Netherlands (Ocke 2008)	24-36 mo	640	M: 136 µg F: 117 µg	% less than AI - low	AI 85 µg
Germany (EFSA 2004)	<12 mo	443	M: 110 µg* F:104 µg *	-	-
	12 mo	468	M: 128 µg* F: 107 µg*	-	-
	24-36 mo	501	M: 138 µg* F: 133µg*	-	-
Ireland (IUNA 2012 intakes)	12 mo	126	159 µg*	-	-
	24 mo	124	180 µg*	-	-
	36 mo	126	188 µg*	-	-

2.9 Vitamin C

Scientific body [year last citation]	Daily intake reference values	Scientific justification for daily intake reference value
WHO/FAO 2004 [1998]	*7-12 mo:* 30 mg (AI) *12-36 mo:* 30 mg (AI)	Based on prevention of scurvy (8 mg/day) and arbitrarily set at 25 mg/day for young infants and increasing gradually as children get older
IOM 2000 [2000]	*7-12 mo:* 50 mg (AI) *12-36 mo:* 15 mg (INL_{98})	Older infants: Based on 27 mg/day intake of vitamin C from breast milk intake (0.6 L/day x 45 mg/L) plus intake from complementary food (22 mg/day). Young children: Extrapolated from adults adjusting for body weight.
EFSA 2013 [2013]	*7 to <12 mo:* 20 mg (AI) *12 to<36 mo:* 20mg (INL_{98})	Older infants: based on three times the known level required to prevent scurvy. Young children: Extrapolated from adults adjusting for body weight using isometric scaling.
NHMRC 2006 (2001)	*6-12 mo:* 30 mg (AI) *12-36 mo:* 35 mg (INL_{98})	Older infants: Extrapolated from young infants and adjusted for bodyweight. Young infants data based on breast milk intake (0.78 L/day x 30mg/L). Young children: Based on interpolating between infant and adult recommendations.
NIHN 2010 [2006]	*6-12 mo:* 40 mg (AI) *12-36 mo:* 40 mg (INL_{98})	Older infants: Extrapolated from young infants and adjusted for bodyweight. Young infants data based on breast milk intake (0.78 L/day x 50mg/L). Young children: Extrapolated from adults adjusting for body weights.
NNR 2012 [2011]	*>24 mo:* 30 mg (INL_{98})	Young children: Extrapolated from adults adjusting for body weights
eWG proposal	20-30 mg (INL_{98})	WHO/FAO and EFSA values considered adequate for the majority of older infants and young children

The concentration of vitamin C in breast milk varies according to maternal status and is not reflective of infants' needs (WHO/FAO 2004). Observed dietary median intakes will be highly influenced by the fortification status of a country (EFSA 2013). As such, the vitamin C content of breast milk is not considered a good indicator of requirements for older infants. Intakes above 8 mg/day are sufficient to prevent scorbutic signs in infants (WHO/FAO 2004). Taking this into account the DIRV established by the WHO/FAO in 2004 has been arbitrarily set at 25 mg for young infants and gradually increases with age.

EFSA have most recently reviewed the nutrient requirements for vitamin C for this age group and concluded that no new data has arisen since the Scientific Committee on Food's (SCF) recommendations in 1993. As such it was considered appropriate to continue to base requirements on three times the known level required to prevent scurvy. The levels derived for young children were derived by extrapolating data from adult requirements and adjusting for body weight using isometric scaling (EFSA 2013).

Dietary intake data from the US, Canada and Australia indicate that less than five percent of young children have inadequate intakes (Table 8). In the EU, EFSA reported that mean or median intakes were generally at or above the DIRV and overt deficiencies were not reported (EFSA 2013). In Ugandan children aged 24-59 months, the prevalence of inadequate intakes varied by region, but was less than 15% in all regions (Harvey 2010). In South-east Asia three studies are available, in the Philippines 30% of children (6-36 months) had inadequate intakes (FNRI 2008), in Malaysia average intakes were almost three times the WHO/FAO AI (Poh 213), while in Indonesia mean intakes for the 6-24 month age group were approximately 40 mg/day (Sandjaja 2013).

The values derived by EFSA and the WHO/FAO (2004) although arbitrarily derived appear the most reasonable and it is likely that requirements for this age group range between 20 to 30 mg per day. Vitamin C deficiency and inadequacy were rarely reported, however in Uganda, the Philippines and Indonesia there would likely be some proportion of the population with intakes less than 20-30 mg/day.

Table 8: Vitamin C intakes and status of older infants and young children

Country/region	Age range	N	Median	Prevalence	Cut-off
Canada (Health Canada 2009)	12-36 mo	2117	135 mg*	<3%	<13 mg
USA	7-12 mo 12-36 mo		-	6% 1.3%	<50 mg (AI) <13 mg
Mexico	12-48 mo	3552			
Australia (DOHA 2008)	24-36 mo		83.7 mg*	4%	<25 mg
Uganda (Harvey 2010)	24-59 mo	225			
India (IIPS 2012)	12-36 mo	2895	9 mg	76.9%	<20 mg
Thailand (Rojroongwasinkul 2013)	6-36 mo				
Vietnam (Nguyen 2013)	6-24 mo 24-59 mo	161 128 314 349			
Malaysia (Poh 2013)	6-12 mo 12-48 mo				
Status					
Indonesia (Sandjaja 2013)	24-59 mo				

2.10 Vitamin D

Scientific body [year last citation]	Daily intake reference values	Scientific justification for daily intake reference value
WHO/FAO 2004 [1998]	5 µg (INL_{98})	The INL_{98} value was set as 5 µg for both the 6-12 and 12 to 36 month age groups were based on IOM Food and Nutrition Board 1997 recommendations based on maintaining plasma 25(OH)D above 27 nmol/L.
IOM 2011 [2010]	*7-12 mo:* 10 µg (AI) *12-36 mo:* 15 µg (INL_{98})	The AI for older infants is based on maintaining serum 25(OH)D concentrations above 50 nmol/L which appears to adequately support normal bone accretion. The INL_{98} value for young children is based on maintenance of serum 25(OH)D above 50 nmol/L.
EFSA 2013	10 µg (AI)	Not primary evaluation. Based on the Scientific Committee on Food 1993 recommendation and considered adequate for the majority of infants and young children having minimal sun exposure.
NIHN 2010 [2008]	*6-12 mo:* 5 µg (AI) *12-36 mo:* 2.5 µg (AI)	Values for older infants are based on 25(OH)D with adequate sun exposure. The adequate intake for young children is based on median intakes in Japanese children.
NNR 2012 [2012]	*>24mo:* 10 µg (INL_{98})	The recommended intake was set at maintaining a serum 25(OH)D concentration of 50 nmol/L.
eWG proposal	10 µg (INL_{98})	10 µg considered adequate for the majority of older infants and young children with minimal exposure to sun. Based on IOM and NNR recommendations

The WHO/FAO in their recommendations note that it must be recognised that in most locations in the world the most physiologically relevant and efficient way of acquiring vitamin D is to synthesise it endogenously in the skin (WHO/FAO 2004). WHO/FAO recommends that in individuals not synthesising vitamin D it should be acquired through the diet. The WHO/FAO (2004) vitamin D requirements adopted the IOM 1997 DIRVs (which have now been updated) with the caveat that these are applicable in the absence of adequate exposure to sunlight. It is worth noting that when considering the body's ability to synthesise vitamin D through sunlight is dependent on amount of skin exposed and skin pigment. Recommendations of almost all of the RASBs reviewed included a statement on sunlight exposure.

In the IOM report there was deemed to be insufficient data to establish an INL_{98} for infants, this was also the case in the review conducted by the NNR. Consequently an AI value was established for the 7 to 12 month age group of 10 µg based on maintaining serum 25-hydroxyvitamin D (25(OH)D) concentrations above 50 nmol/L. In populations that are not calcium deficient it has been observed that rickets occurs at serum 25(OH)D

below 30 nmol/L. In addition to this, maximal calcium absorption and bone mineral content is associated with serum 25(OH)D levels of 50nmol/L (IOM 2011). The IOM recommended an EAR of 10 µg per day for older infants and INL98 of 15 µg for young children. The NNR recommended that 10 µg vitamin D per day was adequate for the majority of children aged two years and older, whereas EFSA considered 10 µg as adequate for the majority of older infants and young children having minimal sun exposure.

There is a paucity of data available on dietary intakes of vitamin D for this age group; however of the data available, very few countries have usual intakes of more than 10 µg per day. In North America more than 80% of young children in Canada and the US had inadequate intakes (<10 µg) (FDA 2014, Health Canada 2009), whereas in Malaysia a third of young children had intakes less than 5 µg per day (Poh 2013).

As vitamin D can also be synthesised endogenously, serum 25(OH) D levels are generally considered to be the best indicator of vitamin D status in a population. Of the nationally representative surveys that have been conducted in this age group, high prevalence of insufficiency has been observed across a range of countries. In the Americas, 24% of Mexican children (2-5 year) (Flores 2013), 21% of Argentinean children (6-23 months) (Durána 2011), and 8% of American children (1-3 years) had serum 25 (OH)D levels less than 50 nmol/L (FDA 2014). In South-East Asia vitamin D insufficiency was observed in 35-43% of Indonesian children (2-5 years) (Sandjaja 2013), 18-35% Malaysian children (4-7 years) (Poh 2013), and 25-31% of Thai children (3-6 years) (Rojroongwasinkul 2013). In the Middle East 33% of Iranian children (15 – 23 months) (Olang 2010) and 28% of Jordanian children (6-36 months) had serum 25 (OH)D levels less than 50 nmol/L (Abdul-Razzak 2011). In Europe, between 10 to 30% of infants and young children were vitamin D deficient (25 (OH) D levels < 50 nmol/L), even in populations with a high percentage of supplement users (EFSA 2013).

Paradoxically, a north-south gradient has been observed in Europe and the Americas, whereby high serum 25(OH)D levels have been found in countries at higher latitude (Lips 2010). For example, higher vitamin D status was reported in the American compared to Mexican children. This is likely a consequence of public health interventions in countries at higher latitude (i.e fortification and supplementation programmes). It is evident that vitamin D status is an issue in many countries, however without further information on regions which lack data it is not possible to establish if these issues are limited to certain regions or a global area of concern.

More recent systematic reviews of vitamin D requirements for this age group have recommended that in populations with minimal exposure to sunlight, at least 10 µg of vitamin D per day is adequate for the majority of older infants and young children.

2.11 Vitamin E

Scientific body [year last citation]	**Daily intake reference values**	**Scientific justification for daily intake reference value**
WHO/FAO 2004 [2002]	*6-12 mo:* 2.7 mg (AI) *12-36 mo:* 5 mg (AI)	Older infants requirement estimates were based on breast milk intake of 2.7 mg α-TE (0.85 L x 3.2 mg α-TE/L) Young child recommendations based on preventing oxidation of PUFAs
IOM 2000 [2000]	*7-12 mo:* 5 mg (AI) *12-36 mo:* 6 mg (INL_{98})	Older infants requirements based on breast milk intake of young infants (0.78 L x 4.9 mg/L) and extrapolated adjusting for metabolic body size and growth and adding a factor for variability. Young child requirements were extrapolated from data on adults adjusting for metabolic body weight and growth.
EFSA 2013	*6 to <12 mo:* 5 mg (AI) *12 to<36 mo:* 6 mg (AI)	Not primary evaluation. EFSA opinion deemed the IOM and NHMRC as adequate for the majority of older infants and the IOM value as adequate for young children.
NHMRC 2006 [2003]	*12 to < 36 mo:* 5 mg α-TE (AI)	Young children adequate intake value based on median intakes.
NIHN 2010 [2008]	*6-12 mo:* 3.5 mg α-TE (AI) *12-36 mo:* 3.5 mg α-TE (AI)	Older infants AI was extrapolated from adults by adjusting based on 0.75th power of the bodyweight ratio. Young child AI value based on median intake of Japanese children.
NNR 2012 [2013]	*>24 mo:* 5 mg α-TE (INL_{98})	The recommended intakes for children are based on a ratio of at least 0.6 α-TE/g total PUFA and a mean intake of PUFA corresponding to 5 E%.
eWG proposal	*6-12 mo:* 2.7 mg (AI) *12-36 mo:* 3.5 -5 mg α-TE (AI)	6-12 months: WHO/FAO considered suitable 12-36 months: unable to propose an appropriate DIRV therefore the range of values of RASBs has been selected

Vitamin E is the major lipid-soluble antioxidant in the cell antioxidant defence system and is exclusively obtained from the diet. Vitamin E deficiency associated with inadequate dietary intakes has not been observed in healthy populations. Vitamin E deficiency is very rare in humans, and clinical signs of deficiency have been limited to children and adults with prolonged fat malabsorption and genetic disorders or diseases which lead to an inability to utilise vitamin E adequately (WHO/FAO 2004).

There is limited data available to derive nutrient requirements for these age groups and recommended intakes are largely based on the vitamin E content in breast milk for older infants. Recommended intakes for young children are either based on median intakes in relevant population groups, or extrapolated from adult requirements. Adult requirements have been predominantly based on preventing oxidation of PUFAs.

The WHO/FAO (2004) report stated that there was insufficient data to establish an RNI as such only "best estimate of requirements" were established for all age groups. This is a similar concept to that of an AI derived by other scientific bodies.

The average concentration of vitamin E in breast milk used by the scientific bodies ranged from 3.2 mg α-TE/L (WHO/FAO 2004) to 4.9 mg α-TE/L (IOM 2000). In a recent study of vitamin E concentrations in breast milk concentrations around the world were reported to range between from 0.9 mg α-TE/L – 6.2 mg α-TE/L, and averaging 3.8 mg α-TE/L (Antonako 2011) – suggestive that the WHO/FAO breast milk estimates may be the most internationally relevant.

There is some concern that vitamin E requirements for young children (5 -6 mg α-TE) have been overestimated (Devaney 2004, Butte 2010). In a nationally representative study of US toddlers 63% of young children were found to have inadequate intakes of vitamin E from food and dietary supplements (median intake 3 mg α-TE), yet less than 2% had low serum tocopherol levels, (Devaney 2004, Butte 2010) and there is no record of vitamin E deficiency. Similarly a nationally representative survey of Australian toddlers found more than 50% of toddlers had vitamin E intakes considerably lower than the AI (4.3 mg α-TE) (DOHA 2008). In the EU, mean intakes of vitamin E were lower than the AI and ranged between 2.9 to 5.2 mg TE in British, Norwegian, Finnish, German and Italian young children. Yet as serum alpha tocopherol levels in Belgium and Norway were sufficient it was concluded that there was no concern over the risk of inadequate intakes (EFSA 2013).

The WHO/FAO note in their 2004 report that diets generally contain sufficient vitamin E intakes to satisfy needs. Current vitamin E DIRVs for young children appear to overestimate requirements and as such inadequate intakes of vitamin E do not appear to be a concern. However, the consequences of lowering vitamin E requirements on oxidation of PUFAs are unknown and therefore compositional requirements for a FUF standard may need to be set at a level higher than to prevent vitamin E deficiency.

2.12 Vitamin K

Scientific body [year last citation]	**Daily intake reference values**	**Scientific justification for daily intake reference value**
WHO/FAO 2004 [1998]	*6-12 mo:* 10 µg (AI) *12-36 mo:* 15.0 µg (AI)	Based on maintenance of haemostatic function, and no evidence of subclinical deficiency at intakes of 1 µg/kg body weight.
IOM 2000 [1999]	*6-12 mo:* 2.5 µg (AI) *12-36 mo:* 30 µg (AI)	6-12 mo: Extrapolation from younger infants and for young children. Average breast milk concentration of phylloquinone 2.5 µg/L 12-36 mo: Highest median intake for each age group
EFSA 2013	*6-12 mo:* 8.5 µg (AI) *12-36 mo:* 12 µg (AI)	Not primary evaluation. Based on SCF 1993 recommendation of 1 µg/kg body weight and applied to reference body weights
NHMRC 2006 [2003]	*6-12 mo:* 2.5 µg (AI) *12-36 mo:* 25 µg (AI)	6-12 mo: Based on IOM, not primary evaluation. 12-36 mo: median intakes of Australian children
NIHN 2010 [2006]	*6-12 mo:* 7 µg (AI) *12-36 mo:* 25 µg (INL_{98})	6-12 mo: amount of vitamin K from sources other than breast milk 12-36 mo: extrapolation from adults according to bodyweight. Adult values based on prevention of mild deficiency.
NNR 2012 [2012]	Insufficient evidence to set a recommendation but 1 µg/kg body weight considered adequate for the majority of individuals to maintain haemostatic function.	
eWG proposal	*6-12 mo:* 8.5 µg (AI) *12-36 mo:* 12 µg (AI)	Application of WHO recommendation 1 µg/kg body weight to revised WHO reference body weights (WHO 2006)

Vitamin K is an essential fat soluble micronutrient which is needed for synthesis for various proteins required for maintenance of normal coagulation. Although vitamin K can be synthesised by bacteria in the intestine, this is not sufficient to maintain normal levels of vitamin K.

The WHO/FAO recommend that for the 0-6 months age group must receive a vitamin K supplement at birth in order to prevent bleeding due to vitamin K deficiency as requirements cannot be met through breast milk alone which is highly considerably (0.85-9.2 µg/L) (WHO/FAO 2004). Taking this into consideration, it is not considered appropriate to base requirements on concentrations of breast milk and extrapolate to requirements for older infants. The WHO/FAO recommendations are based on the physiological outcome to maintain haemostatic function and prevent subclinical deficiency. This approach has been endorsed by the two most recent reviews of vitamin K requirements (EFSA, NNR). The NNR has conducted the most recent systematic review of vitamin K requirements and concluded that more recent evidence does not support deviation from earlier recommendations that 1 µg/kg body weight is adequate for the majority older infants and young children (NNR 2012).

Application of the 1 µg/kg body weight to the new WHO Growth Standards (2006) equates to a recommended intake of 8.5 and 12 µg for older infants and young children, respectively. This is considered as adequate for the majority of older infants and young children.

2.13 Pantothenic Acid

Scientific body [year last citation]	**Daily intake reference values**	**Scientific justification for daily intake reference value**
WHO/FAO 2004 [1997]	*6-12 mo:* 1.8 mg (AI) *12-36 mo:* 2.0 mg (AI)	6-12 mo: Based on intakes of young infants from breast milk (0.75 L x 2.2 mg/L), and extrapolated to older infants taking into consideration body size and allowance for growth. 12-36 mo: Unlcear if extrapolated from younger infants or adolescents, or taking both into consideration.
IOM 1998 [1996]	*6-12 mo:* 1.8 mg (AI) *12-36 mo:* 2.0 mg (AI)	6-12 mo: Value extrapolated from both young infants and the EAR for adults and averaged. Requirements for young infants based on intakes from breast milk (0.78 L x 2.2 mg/L). 12-36 mo: Extrapolated from adults adjusting for body weight with reference to growth needs. Only an AI has been developed for adults as the values are based on dietary intakes.
EFSA 2014 [2009]	*6-12 mo:* 3.0 mg (AI) *12-36 mo:* 4.0 mg (AI)	6-12 mo: Based on intakes of young infants from breast milk (0.8 L x 2.5 mg/L), and extrapolated to older infants using allometric scaling. 12-36 mo: Based on approximate midpoints of the observed median/mean intakes of this age group.
NHMRC 2006 [2004]	*6-12 mo:* 2.2 mg (AI) *12-36 mo:* 3.5 mg (AI)	6-12 mo: Based on intakes of young infants from breast milk (0.78 L x 2.2 mg/L), and extrapolated to older infants using metabolic body weight ratios. 12-36 mo: adequate intake is based on median intakes in Australian young children.
NIHN 2010 [2009]	*6-12 mo:* 5.0 mg (AI) *12-36 mo:* 3.0 mg (AI)	6-12 mo: Based on intakes of young infants from breast milk (0.78 L x 5.0 mg/L), and extrapolated to older infants using metabolic body weight ratios. 12-36 mo: adequate intake is based on median intakes in Japanese young children.
NNR 2012 [2011]	*Insufficient evidence to derive a recommendation*	
eWG proposal	*6-12 mo:* 1.8 mg *12-36 mo:* 2.0 mg	WHO considered suitable

According to the WHO/FAO the widespread occurrence of releasable pantothenic acid in food makes a dietary deficiency unlikely (WHO/FAO 2004). There is a lack of evidence upon which to base DIRVs in any population group and consequently all RASBs have based DIRVs dietary intake data in relevant population groups either from food or breast milk. Furthermore, there is a paucity of food composition data available upon which to estimate dietary intakes in a variety of populations.

As it appears that the likelihood of developing a deficiency of pantothenic acid is low, it would appear that the WHO/FAO values which were based on breast milk intakes would appear adequate for the majority of older infants and young children. The WHO/FAO (2004) and IOM (1998) have established the lowest DIRVs for both age groups. There appears no strong justification to deviate from the WHO/FAO (2004) DIRVs.

2.14 Biotin

Scientific body [year last citation]	Daily intake reference values	Scientific justification for daily intake reference value
WHO/FAO 2004 [1997]	*6-12 mo:* 6 µg (AI) *12-36 mo:* 8 µg (AI)	Requirements for older infants and young children are based on intakes of breast milk in young infants (0.75 L x 6 µg/L) and adjusted for body weight.
IOM 1998 [1997]	*6-12 mo:* 6 µg (AI) *12-36 mo:* 8 µg (AI)	Requirements for older infants and young children are based on intakes of breast milk in young infants (0.78 L x 6 µg/L) and adjusted for body weight.
EFSA 2014 [2014]	*6-12 mo:* 6 µg (AI) *12-36 mo:* 20 µg (AI)	6-12 mo: Extrapolated from young infant AI (breast milk intake) using allometric scaling in order to take into account the role of biotin in energy metabolism and rounded to the nearest unit. 12-36 mo: Based on observed median intakes in this age group. In consideration of the AI set for older infants a value at the lower end of the range of observed intakes was chosen.
NHMRC 2006 [2002]	*6-12 mo:* 6 µg (AI) *12-36 mo:* 8 µg (AI)	Not primary evaluation, based on IOM 1998 report for older infants and young children.
NIHN 2010 [2009]	*6-12 mo:* 10 µg (AI) *12-36 mo:* 20 µg (AI)	6-12 mo: Extrapolated from both AI values derived for young infants and adults and adjusted for body weight. The AI for young infants is based on milk intakes (0.78 L x 5 µg/L) 12-36 mo: Extrapolated from adult AI adjusting for body weight. The adult requirements are based on average daily biotin intake in Japanese adults (adult AI: 50 µg).
NNR 2012 [2012]	*Insufficient evidence to derive a recommendation*	
eWG proposal	*6-12 mo:* 6 µg (AI) *12-36 mo:* 8 µg (AI)	WHO considered suitable

Data available on biotin intakes and health consequences are very limited and cannot be used to derive DIRVs for biotin. The lack of evidence led the NNR not to derive DIRVs for any population group following review of the available evidence. Although dietary deficiency is rare, biotin deficiency has been observed in cases of parenteral nutrition with solutions lacking biotin (WHO/FAO 2004).

Almost all scientific bodies that have established AI values have based requirements for the 6-12 month age group on contribution from breast milk in young infants. The only AI for the 6-12 month age group that deviates from the WHO/FAO value is that derived by the NIHN which is extrapolated from both young infants and average dietary intakes from adults (NIHN 2013). As dietary intakes do not reflect dietary requirements, it would seem more relevant to base requirements for older infants on breast milk intakes.

Scientific bodies have established AI values for young children either based on extrapolation from young infants, or based on dietary intakes either in a relevant population group or from adult data and adjusted for body weight. As there appears to be an unlikelihood of developing a deficiency of biotin due to inadequate intakes, limited data on dietary intakes globally, and no data linking dietary inadequacy to functional health outcomes there is no strong basis to deviate from the DIRVs established by the WHO/FAO. The DIRV developed by the WHO/FAO appears adequate for the majority of older infants and young children.

2.15 Calcium

Scientific body [year last citation]	Daily intake reference values	Scientific justification for daily intake reference value
WHO/FAO 2004 [2000]	6-12 mo: 400 mg (AI) 12-36 mo: 500 mg (INL_{98})	6-12 mo: Factorial method: accretion 100 mg, losses 20 mg. Net absorption 0.5SD that of adults 12-36 mo: Factorial method: accretion120 mg; losses 100 mg. Net absorption 2 SD of adults
IOM 2011 [2010]	6-12 mo: 260 mg (AI) 12-36 mo: 700 mg (INL_{98})	6-12 mo: Based on calcium intake from breast milk (126 mg/day) and complementary foods (140 mg/day) and rounded up 12-36 mo: factorial method was based on accretion of 142 mg/d and 74 mg losses. Assumption that 30% calcium retention would meet the needs of 97.5 percent
EFSA 2013	6-12 mo: 400 mg (AI) 12-36 mo: 600 mg (AI)	Not primary evaluation, based on the evaluation by D-ACH which used a factorial approach; accretion 142 mg, losses 74 mg, absorption 45.6%
NHMRC 2006 [2005]	6-12 mo: 270 mg (AI) 12-36 mo: 500 mg (INL_{98})	6-12 mo: Based on IOM, not primary evaluation 12-36 mo: Based on WHO/FAO factorial approach, not primary evaluation
NIHN 2010 [2008]	6-12 mo: 250 mg (AI) 12-36 mo: 400 mg (INL_{98})	6-12 mo: Based on intakes from breast milk and complementary food 12-36 mo: Factorial method: accretion 95-99 mg; losses 43 mg, absorption 40%
NNR 2012 [2012]	12-36 mo: 600 mg (INL_{98})	Maintained recommendation from 2004 as no strong evidence to alter
eWG proposal	6-12 mo: 400 mg (AI) 12-36 mo: 500 mg (INL_{98})	WHO considered suitable

Calcium requirements for older infants have either been established based on the factorial method (WHO/FAO; EFSA) or intakes from breast milk and complementary foods (IOM, NHMRC, NIHN). These two approaches result in very different values with intakes based on the factorial method resulting in a recommendation of 400 mg, compared to 250-270 mg based on dietary intakes.

Dietary intakes are generally not considered to accurately reflect nutritional needs in young children. It is also observed that a very large difference exists when determining nutrients requirements based on dietary intakes for older infants and the factorial method for young children. Due to the importance of calcium in its structural role in bone development during this rapid period of growth, basing requirements on the factorial approach which takes into consideration accretion and requirements for normal growth appears be justified.

There does not appear to be a clear scientific justification to deviate from the WHO/FAO DIRV for either older infants or young children which have both used the factorial method and result in gradual increase in calcium requirements with age. Therefore the eWG propose to continue considering the WHO/FAO the nutrient intakes levels which are considered adequate for the majority of older infants and young children.

Calcium intakes vary markedly with intakes ranging from as low ~250 mg per day in Uganda and India to 1041 mg in Canadian children (Harvey 2010, IIPS 2007, Health Canada 2009). Less than 5% of the children had inadequate intakes (intakes less than 470-500 mg) in Australia, Canada, Ireland and the Netherlands (DOHA 2008, Health Canada 2009, IUNA 2012, Ocke 2008) compared to almost all Ugandan children (88-93% (Harvey 2010). Interestingly, in the USA when adequacy was compared across age ranges, less than 1% of older infants had intakes less than the AI (260 mg) but 12% had an inadequate intake at 12-36 months (EAR 500 mg). It is clear that inadequate calcium intakes affect young children in many countries (Argentina, India, Indonesia, Uganda), particularly those where milk products are not commonly consumed by young children.

Table 9: Calcium intakes

Calcium intakes					
Country	Age	N	Median intake	Prevalence	Cut-point used
USA (FDA 2014)	7-11 months		-	<1%	AI 260 mg
	12-36 months		-	11.7%	EAR 500 mg
Canada	12-36 months	2117	1041 mg	3%	AI 500 mg
Argentina	6-23 months		702 mg	28%	EAR 500 mg
Mexico (Mundo-Rosas 2009)	1-4 years 12-23 months 24-35 months		770 mg	36.4% 32.8% 30.7%	EAR 500 mg
Australia (	24-48 months		805 mg*	<1%	
Ireland (IUNA 2012)	12-36 months		12 mo: 840 mg* 24 mo:786 mg* 36 mo: 718 mg*	~5%	EAR 470 mg
Holland (Ocke 2008)	24-48 months		-	~5%	EAR 470 mg
France (NutriBébé SFAE 2013	6 months 12-17 months 18-23 months 24-29 months 30-35 months	90 121 120 125 81	619 mg 775 mg 781 mg 744 mg 737 mg		
Norway (Andersen 2004)	1-2 years		-	~50%	EAR 470 mg
India (IIPS 2007)	1-3 years		247 mg	74.1%	300 mg
Indonesia (Sandjaja 2013)	6 -24 mo	2391	526 mg	52-71%	INL_{98} 500 mg
Malaysia (Poh 2013)	6-12 months 1-3.9 years	25 244	554 mg 694 mg	17% 27.4%	INL_{98} 500 mg
Thailand (Rojroongwaskinkul 2013)	6-36 months		541-593 mg		
Uganda (Harvey 2010)	24 – 59 months	468	257-358 mg	88-93%	AI 459 mg

* mean

2.16 Iron

Scientific body [year last citation]	**% absorption**	**Daily intake reference values**	**Scientific justification for daily intake reference value**
WHO/FAO 2004 [1998]	10% (INL_{98})	6-12 mo: 9.3 mg 12 – 36 mo: 5.8 mg	Physiological requirements were derived using the factorial method based on mean body weights, the iron requirement for growth, median basal iron losses. The recommendation is based on requirements at the 95th percentile. These were translated to dietary requirements taking into account percentage absorption.
	15% (INL_{98})	6-12 mo: 6.2 mg 12 – 36 mo: 3.9 mg	
IOM 2000 [2000]	10% (INL_{98})	7-12 mo:11 mg	Physiological requirements at the 97.5th percentile derived using the factorial method based on body surface area, basal losses, and iron requirements for growth.
	18% (INL_{98})	12-36 mo:7 mg	
EFSA (2013)	NS	6 to <12 mo: 8 mg 12 to<36 mo:8 mg	The EFSA opinion supported the recommendations established by D-ACH (2013).
NHMRC 2004 [2003]	10% (INL_{98})	7-12 mo:11 mg	The IOM physiological requirements were used and applied to a bioavailability factor of 14% for the young child age group.
	14% (INL_{98})	12-36 mo: 9 mg	
NIHN 2010 [2008]	15% (INL_{98})	6-11 mo: 4.75 mg 12-35 mo: 4.25 mg	Physiological requirements for the EAR derived using the factorial method based on body weight, basal losses, and iron requirements for growth. The INL98 was calculated by multiplying the EAR by 1.4.
NNR 2012 [2013]	NS	>24 mo: 8 mg (INL_{98})	Not specified
eWG Proposal	Moderate absorption	6-12 mo: 8-11 mg 12-36mo: 7-9 mg	Range of values derived by RASBs (excluding WHO/FAO and NIHN)

Iron is an essential trace element that has several vital functions in the body, including oxygen transport, redox reactions, and as an integrated part of important enzyme systems in various tissues. Full-term infants have iron stores sufficient to cover their needs during the first 4–6 months of life. The concentration of iron in human milk is low but more bioavailable than that provided by foods.

Physiological iron requirements increase markedly after 4-6 months of age (WHO/FAO 2004). The 95th percentile of physiological iron requirements for older infants and young children was estimated to be 0.93 mg/day and 0.58 mg/day, respectively (WHO/FAO 2004). Taking into consideration dietary absorption of iron of 15% this equates to a DIRV of 5.8 mg and 3.9 mg per day for older infants and young children, respectively (WHO/FAO 2004). These requirements are very high, especially in relation to body size and energy intake.

The IOM also used the factorial method to determine physiological iron requirements for the 97.5th percentile of older infants and young children. The physiological iron requirements values for young children calculated by the IOM are higher than those calculated by the WHO/FAO. The major difference in the derivation of the values for young children is due to differences in the estimates of basal losses in spite of similar reference body weights for this age group. The IOM estimated basal losses are 1.7 times higher than that of the WHO/FAO despite using the same experimental data, similar reference body weights and adjusting for body surface area (WHO/FAO 0.19 mg/day vs IOM 0.32 mg/day) (see Table 7 below). It is unclear from the documentation as to how these differences have arisen.

It has been noted that the WHO/FAO (2004) iron requirements are the lowest derived by any RASB for the 12 to 36 month age group which conflicts with the lower bioavailability used by the WHO/FAO. For equivalent levels of bioavailability, the WHO/FAO nutrient requirement is half that of those established by the IOM, NHMRC, EFSA and NNR. This is likely a direct result of the lower value calculated for basal losses in the derivation of physiological estimates for the WHO/FAO (2004) values.

Table 10: Comparison of the physiological requirements underpinning the INL98 values from the WHO/FAO and IOM

	Body Weight	Basal Losses	Required intakes for growth	Median absolute requirements
6 – 12 mo				
WHO/FAO	9 kg	0.17 mg/day	0.55 mg/day	0.72 mg/day
IOM	8.7 kg	0.26 mg/day	0.43 mg/day	0.69 mg/day
12-36 mo				
WHO/FAO	13 kg	0.19 mg/day	0.27 mg/day	0.46 mg/day
IOM	~13 kg	0.32 mg/day	0.27 mg/day	0.61 mg/day

Comparing adequacy of iron intakes to iron status is suggestive that the higher iron requirements set by RASBs may be more appropriate. In the EU it has been observed that in almost all surveys investigating iron intakes, sub-groups of the population have inadequate iron intakes and iron depletion (EFSA 2013). In the US NHANES study both intake and status data are available for young children. In the US 1% of young children are reported to have inadequate iron status yet 18% have depleted iron stores (serum ferritin <12 ng/mL) and eight percent iron deficiency (ferritin model), (note that the US requirement levels are based on high percentage absorption). These results suggest that higher iron requirement levels appear to reflect prevalence of iron depletion fairly well.

Globally the prevalence of iron deficiency anaemia (Hb<110 g/L) is estimated to be 18.1% in children under five years, ranging from 20% in the African region to 12% in Europe (Black 2013).

Consideration of application of bioavailability factors established by the WHO/FAO (2004) to the physiological requirements derived by alternative scientific bodies are warranted, particularly as iron inadequacy and iron deficiency are such pertinent problems globally. Application of the IOM physiological requirements to the bioavailability factors used by the WHO/FAO (i.e 10% and 15%) would be an INL_{98} value of 12.6 mg and 8.4 mg, respectively. These values are aligned with the requirements set by other scientific bodies and may be considered a suitable starting point to assess the adequacy of iron intakes in young children in diets with lower (10%) absorption and moderate (15%) absorption. Excluding the values derived by WHO/FAO and NIHN, an average DIRV of the values derived by the remaining RASBs results in similar value: 9.5 mg and 8 mg for older infants and young children, respectively.

Table 11: Iron status data from various countries

Country/region	Age range	N	Indicator	Prevalence	Cut-off
Europe (EFSA 2013, Male 2001)	12 mo	488	ID IDA	7.2% 2.3%	Two or more abnormal values (MCV<70 fL, SF< 10 ug/L, TSAT <10%, TfR >4.4 mg/L) Hb <110 g/L plus two or more abnormal values of iron status indicators (see above)
Malaysia (Poh 2013)	4 – 12 yrs	2936	ID Anaemia	4.4% 6.6%	SF < 12ug/L (< 5 years) SF <15 ug/L (≥ 5 years) Hb <110 g/L (< 5 years) Hb <115 g/L (5-11.9 years) Hb <120 g/L (≥ 12 years)
Thailand (Rojroongwasinkul 2013)	6-36 mo	689	IDA	26 - 41.7%	Hb <110 g/L (< 5 years)
India (IIPS 2007)	6-59 mo		Anaemia	26% 40% 3%	Hb 100 - 109 g/L (mild) Hb 70 - 99 g/L (moderate) Hb < 70 g/L (severe)
Brazil (Szarfarc 2004)	6-12 mo	5146	Anaemia	51.7%	Hb <110 g/L
Philippines (FNRI 2008)	1 – 5 yrs	2279	Anaemia	20.9%	Hb <110 g/L
Argentina (Duran 2009)	6 – 23 mo		IDA	35.3%	
Mexico (ENSANUT 2012)	12-23 mo 24-35 mo 36-47 mo 48-59 mo	1773 1888 1954 1988	Anaemia	38.3% 25.6% 17.2% 13.7%	Hb <110 g/L
USA (FDA 2014)	1 – 3 yrs		Depleted ID IDA	17.7% 7.9% 1.8%	SF <12 ug/L Two or more: SF <12 ug/L, EPP >1.42 umol/L, TSAT <10%, Hb<110 g/L & 2 or more of the above indicators
Australia (Mackerras 2004)	1-4 years	1371	IDA	2%	Haematocrit <33%
Nigeria (IITA 2004)	< 5 yrs	3091	Depleted ID	8.1% 19.4%	SF < 20 ug/L SF < 10 ug/L
Uganda (Uganda Bureau of Statistics 2012)	6 – 8 mo 9 – 11 mo 12 – 17 mo 18 – 23 mo 24 – 35 mo	124 120 250 265 444	Severe anaemia	12.5% 6.7% 5.0% 7.4% 5.6%	Hb < 80 g/L
New Zealand (Soh 2004)	6– 12 mo	263	Depleted ID IDA	8.3% 4.2% 6.9%	SF ≤ 12 ug/L & not ID or IDA Two or more: MCV ≤73 fl, ZPP ≥70 umol/mol haem, SF ≤ 12 ug/L Hb <110 g/L, & two or more of the above indicators
	12-24 mo		Depleted ID IDA	23.3% 6.3% 3.1%	SF ≤ 12 ug/L & not ID or IDA Two or more: MCV ≤73 fl, ZPP ≥70 umol/mol haem, SF ≤ 12 ug/L Hb <110 g/L, & two or more of the above indicators
Global (WHO) statistics (Black 2013)	< 5 years		IDA	18.1%	Hb <110 g/L

MCV: mean cellular volume SF: serum ferritin concentration Hb: haemoglobin concentration
TSAT: transferrin saturation TfR: serum transferrin receptor SF: serum ferritin concentration
ZPP: zinc protoporphyrinn

2.17 Zinc

Scientific body [year last citation]	% absorption	Daily intake reference values	Scientific justification for daily intake reference value
WHO/FAO 2004 [1998]	15%	*6-12 mo:* 8.4 mg *12 – 36 mo:* 8.3 mg (INL_{98})	Factorial method using extrapolated data from adults to estimate endogenous zinc losses.
	30%	*6-12 mo:* 4.1 mg *12 – 36 mo:* 4.1 mg (INL_{98})	
IOM 2000 [1999]	*30%*	*6 to <12 mo:* 3 mg *12 to<36 mo:*3 mg (INL_{98})	Factorial method using extrapolated data from adults to estimate endogenous zinc losses. CV 10%. Physiological requirement 0.84 mg/day for older infants and 0.74 mg/day for young children.
EFSA 2014 [2014]	*30%*	*6 to <12 mo: 2.9* mg *12 to<36 mo: 4.3* mg (INL_{98})	Factorial method using extrapolated data from adults to estimate endogenous zinc losses taking into account losses via urine, integumental, faeces and requirements for growth. CV 10%. Physiological requirement 0.732 mg/day for older infants and 1.074 mg/day for young children.
NHMRC 2004 [2004]	*M: 24%* *F: 31%*	*6 to <12 mo:* 3 mg *12 to<36 mo:* 3 mg (INL_{98})	Factorial method using extrapolated data from adults to estimate endogenous zinc losses. CV 10%.
NIHN 2010 [2003]	*15%*	*6 to <12 mo:* 3 mg (AI) *12 to<36 mo:* 5 mg (INL_{98})	Older infants: Average of two methods. Factorial method using extrapolated data from adults to estimate endogenous zinc losses and mean intake from breast milk and complementary foods. Young child requirements based on a balance study in Japanese children and extrapolated to younger children.
NNR 2012 [2013]	*NS*	*>24 mo:* 6 mg (INL_{98})	Factorial method using extrapolated data from adults to estimate endogenous zinc losses. Basal losses 0.1 mg/kg BW and growth of 30 mg/kg weight gain.
IZiNCG* (International Zinc Nutrition Consultative Group)	*Moderate 26-34%*	*6 to <12 mo:* 4 mg *12 to<36 mo:* 3 mg (INL_{98})	Factorial method using extrapolated data from adults to estimate endogenous zinc losses. Physiological requirement 0.84 mg/day for older infants and 0.53 mg for young children.
	Low 18-25%	*6 to <12 mo:* 5 mg *12 to<36 mo:* 3 mg (INL_{98})	
eWG Proposal	*15%*	*6-12 mo:* 8.4 mg *12 – 36 mo:* 8.3 mg	WHO considered best estimate for diets with lower absorption of zinc.
	30%	*6 to <12 mo:* 4.1 mg *12 to<36 mo:* 4.1 mg	WHO considered best estimate for diets with moderate absorption of zinc.

*Not nominated as RASB but included for comparative purposes as some national surveys have used these cut-offs

Zinc deficiency is an important cause of morbidity in developing countries and is reported to account for 1.7% of deaths in children less than five years of age (Black 2013). During 2007, WHO/UNICEF/IAEA/IZiNCG held an interagency meeting on zinc status indicators to identify recommended dietary requirement levels and biochemical indicators. They state that a public health intervention is warranted if zinc deficiency is greater than 20% in a population, 25% of a population have inadequate intakes, or 20% of the population is stunted (de Benoist 2007).

All scientific bodies have established an INL_{98} value based on the factorial method using extrapolated data from adults to calculate endogenous zinc losses. RASB INL_{98} values range from 2.9 to 4.1 mg per day for older infants, and 3-6 mg in young children for diets with moderate zinc absorption. Similarly all scientific bodies have used a 30% percentage zinc absorption factor for diets with moderate levels of absorption. Variations in estimates are due to differences in the estimated physiological requirements and there is no clear scientific consensus as to which factors might be most appropriate for this age range.

This is further complicated by the discrepancy between estimates of dietary inadequacy and biochemical deficiency for many of the DIRVs. This is observed in the recent EFSA report on dietary intakes and status of

older infants and young children where dietary intake surveys report less than 5% of children with inadequate intakes, yet almost all national surveys measuring status have observed that between 21 and 56% of older infants and young children were zinc deficient (EFSA 2013). This has also been observed in low income countries, notably in the Cameroon where 8% of children had inadequate intakes (using IZiNCG cut-offs), yet 83% were zinc deficient and 30% were stunted (Engle-Stone 2014). The Ugandan National Survey is the only survey which reports use of the WHO/FAO low bioavailability DIRVs and reports the highest prevalence of inadequate intakes of approximately 80% (Harvey 2010). Smaller studies in Uganda have indicated that zinc deficiency affects approximately 54% of children aged 1-5 years.

Although the prevalence of stunting in LMI countries appears to be decreasing, Black et al reported that in 2011 the prevalence of stunting in children less than five years old in LMI countries was 28% when compared to WHO Child Growth Standards. This was a decrease from 32% in 2005. Low and middle income countries have higher rates of stunting than high income countries (28% and 7.2% respectively). Based on the WHO/UNICEF/IAEA/IZiNCG zinc indicators data on the prevalence of stunting and zinc deficiency, it would appear that zinc deficiency is a public health problem in many countries, particularly LMI countries.

Based on the very low estimates of inadequacy in populations when using the IOM or IZiNCG DIRVs with high prevalence of zinc deficiency, it appears as though the WHO/FAO DIRVs for diets with low zinc absorption (15%) may be better at estimating the extent of inadequate intakes of zinc for this age group.

The WHO/FAO values for diets with moderate absorption are very similar to those most recently derived by EFSA in a systematic review which may be considered adequate for the majority of older infants and young children until further evidence becomes available.

Table 12: Zinc status of older infants and young children

Country/region	Age range	N	Prevalence	Cut-off
Zinc status				
New Zealand (Morgan 2010)	12 – 20 months	225	38%	Serum zinc < 9.9 umol/L:
Nigeria (International Institute of Tropical Agriculture 2004)	< 5 years	2725	20%	Serum zinc < 12.2 umol/L
Cameroon (Engle-Stone 2014)	12-59 mo	817	83% 30%	Plasma zinc < 9.9 umol/L Stunting
Pakistan (Government of Pakistan 2011)	< 5 years	12,139	39.2%	Serum zinc < 9.2 umol/L
Mexico (Sharmah-Levy 2011)	< 5 years	NR	27.5 %	Serum zinc < 9.9 umol/L
France (Bougle 200)	<3 years	66	21%	Serum zinc < 12 umol/L
Belgium (Van Biervliet 2003)	0-14 years		25%	Serum zinc <10.4 umol/L
Sweden (Lind 2003)	6 months 12 month	300	22% 25%	Serum zinc <10.7 umol/L
Turkey (Sezer 2013)	6 -28 months	100	56%	Serum zinc <10.7 umol/L
Global (WHO) statistics (Black 2013)	Global Africa Americas Asia Europe Oceania	-	17.3% 23.9% 9.6% 19.4% 7.6% 5.7%	Proportion of the national population estimated to have an inadequate zinc intake on the basis of national food availability & dietary requirements

Table 13: Dietary zinc intakes of older infants and young children

Zinc intakes				
Country	Age	N	Prevalence	Cut-point used
USA (FDA 2014)	7-11 months		<1%	EAR 2.5 mg
	12-36 months		1.4%	EAR 2.5 mg
Canada (Health Canada 2009)	12-36 months		<3%	EAR 2.5 mg
Argentina (Duran 2009)	6-23 months		11.6%	EAR 2.5 mg
Australia (DOHA 2008)	24-48 months		<1%	EAR 2.5 mg
Ireland (IUNA 2012)	12-36 months		~5%	EAR 3.15 mg
Holland (Ocke 2008)	24-48 months		<5%	EAR 3.15 mg
Cameroon (Engle-Stone 2014)	12-59 months	882	8% 9%	EAR 2 mg/day (IZiNCG) EAR 2.5 mg (IOM)
Uganda (Harvey 2010)	24 – 59 months	468	74-82%	EAR 7.5 mg (5% absorption)

2.18 Selenium

Scientific body [year last citation]	**Daily intake reference values**	**Scientific justification for daily intake reference value**
WHO/FAO 2004 [1998]	6-12 months: 10 µg (INL_{98}) 12-36 months: 17 µg (INL_{98})	Based on extrapolation from adult data on a metabolic weight basis, and allowing a 25% increase to EAR values to allow for individual variation. Adult data is based on achieving 2/3 of plasma saturation GPx activity
IOM 2000 [1999]	7-12 months: 20 µg (AI) 12-36 months: 20 µg (INL_{98})	6-12 mo: Extrapolated from that of younger infants on a metabolic weight basis and similar to value derived from average intakes from breast milk and complementary food 12-36 mo: Extrapolated from adult data on a metabolic weight basis and rounded to the nearest 5 ug. Adult data based on maximal GPx activity.A CV of 10% used
EFSA 2014[a] (draft) [2014]	6-12 months: 15 µg (AI) 12-36 months: 15 µg (AI)	6-12 mo: Extrapolation from young infants (breast milk intake 0.8 L/day, selenium in breast milk 15 µg/L) using isometric scaling. 12-36 mo: Extrapolated from adults using isometric scaling. Adult data based on maximal SEPP1 concentrations
NHMRC 2004 [2005]	6-12 months: 15 µg (AI) 12-36 months: 25 µg (INL_{98})	6-12 mo: Extrapolated from younger infants based on metabolic weight, 12-36 mo: Extrapolated from adult data on a metabolic weight basis and rounded to the nearest 5 ug. Adult data based on maximal GPx activity. A CV of 10% used
NIHN 2010 [2010]	6-12 months: 15 µg (AI) 12-36 months: 10 µg (INL_{98})	6-12 mo: requirement extrapolated from 0-6 month age group (based on breast milk intake - concentration 17 µg/L). 12-36 mo: Extrapolated from adult data based on maximal GPx activity, adjusting for metabolic weight.
NNR 2012 [2013]	>24 months: 25 µg (INL_{98})	Based on saturation of plasma of SePP activity in adults adjusting for body weight
eWG proposal	6-12 months: 15 µg (AI) 12-36 months: 20 µg (INL_{98})	Median value of all DIRVs Median value of all DIRVs based on maximal saturation of selenoproteins (GPx or SEPP1).

Selenium is found in all tissues, mainly as selenomethionine and primarily functions as a co-factor in antioxidant activities. Responses to the first consultation paper highlighted that further consideration of selenium requirements was needed as the WHO/FAO DIRVs fell outside the range of those derived by other RASBs for the older infant age group. As indicated in the summary above the WHO/FAO requirements are based on achieving two-thirds of glutathione peroxidise activity (GPx) activity, whereas those derived by almost all other scientific bodies have been based on maximal saturation of GPx activity. The most recent systematic review by EFSA and the NNR has based their DIRV for children and adults on new data that has identified that saturation of plasma selenoprotein P (SePP1) may be a better indicator for selenium status and adjusted for body weight.

Calculating the median value of all RASB values which have been based either on maximal saturation of selenoproteins (GPx or SePP activity) results in requirements levels of 15 µg per day for older infants and 20 µg per day for young children. Calculation of a median value of all scientific bodies and the WHO/FAO also results in the same requirement levels. This may be the most pragmatic approach until further evidence becomes available.

2.19 Iodine

Scientific body [year last citation]	**Daily intake reference values**	**Scientific justification for daily intake reference value**
WHO/FAO 2004 [2001]	6-12 months: 90 µg (AI) 12-36 months: 90 µg (INL_{98})	Extrapolated from younger infants, positive iodine balance achieved at 15 µg/kg bodyweight per day in term infants. Daily iodine requirement decreases on a body weight basis. Young child recommendations based on requirement of 6 µg/kg bodyweight per day.
IOM 2000 [2000]	7-12 months: 130 µg (AI) 12-36 months: 90 µg (INL_{98})	AI for older infants is based on breast milk concentrations of 146 µg/L. 12-36 mo: Based on balance study of children aged 1.5-2.5 years. CV 20% and rounded.
EFSA 2014[e] [2014]	6-12 months: 70 µg (AI) 12-36 months: 90 µg (AI)	Calculated based on maintain urinary iodine concentration above 100 µg/L, 92% absorption efficiency and the average urinary volume in older infants and young children (0.637 L/day and 0.827 L/day, respectively).
NHMRC 2004 [2001]	6-12 months: 110 µg (AI) 12-36 months: 90 µg (INL_{98})	Extrapolated from younger infants breast milk intake (concentration 115µg/L) using a metabolic weight ratio. 12-36 mo: not primary evaluation, based on IOM 2001.
NIHN 2010 [2008]	6-12 months: 130 µg (AI) 12-36 months: 50 µg (INL_{98})	6-12 mo: requirement extrapolated from 0-6 month age group (based on breast milk intake - concentration 133 µg/L). 12-36 mo: Extrapolated from adult data on thyroid iodine accumulation and turnover adjusting for metabolic weight.
NNR 2012 [2012]	>24 months: 90 µg (INL_{98})	Based on data on goitre prevalence and urinary iodine excretion in European children and extrapolations from adults based on energy and growth requirements.
eWG proposal	6-12 months: 90 µg 12-36 months: 90 µg	WHO/FAO considered suitable

The iodine content of human milk varies markedly according to maternal intakes and as such the WHO /UNICEF/ICCIDD do not recommend basing dietary requirements for iodine on breast milk concentrations but on achieving iodine balance (WHO/UNICEF/ICCIDD 2008). This approach was also taken recently in the derivation of European DIRVs for iodine, in which EFSA calculated that approximately 70 µg and 90 µg were adequate for the majority of older infants and young children, respectively to achieve a urinary iodine concentration of at least 100 µg/L. An iodine concentration of at least 100 µg/L has been associated with the lowest prevalence of goitre in school aged children (EFSA 2014) and iodine concentrations below 50-60 µg/L have been associated with subclinical hypothyroidism (WHO/FAO 2004).

Median urinary iodine concentration reflects the iodine status of a population and is therefore the most commonly assessed indicator. Iodine sufficiency of a population is defined by WHO as a median urinary iodine concentration in children of 100 – 299 µg/L together with less than 20% of the population showing urinary iodine concentrations of < 50 µg/L (WHO/UNICEF/ICCIDD 2007).There is limited data on iodine status of older infants and young children globally, partly because the WHO recommend assessment of iodine status in school-aged children to assess the population iodine status. The most recent WHO assessment of global iodine status found that approximately 31.5% of school-aged children were iodine insufficient. Yet iodine intakes are more than adequate, and may even be excessive 34 countries (de Benoist 2008).

Limited data was provided by the eWG on iodine status in older infants and young children. Urinary iodine data in New Zealand and Australia (pre mandatory fortification), Belgium and Germany indicate that more than 20% of older infants and young children have moderate to severe iodine deficiency. Taking into account the WHO definition to assess population iodine sufficiency, iodine deplete areas will typically expose some sub-groups of infants and young children to inadequate iodine intakes.

There is general agreement amongst scientific bodies that 90 µg/day is adequate for the majority of young children on the basis of iodine balance studies, calculated intakes to maintain a urinary iodine concentration of more than 100 µg/L. Intakes of 90 µg/day are adequate for the majority of older infants according to the WHO/FAO (2004) and WHO/ICCIDD (2008), and intakes of at least 70 µg/day may be adequate according to the latest EFSA calculations (EFSA 2014). Based on the available data on iodine status in older infants and young children, iodine insufficiency continues to be prevalent in iodine deplete countries and/ or regions.

Table 14: Iodine status of older infants and young children

Country/region	Age range	N	Prevalence	Cut-off
New Zealand (Skeaff 2005) - Severe deficiency - Moderate deficiency - Iodine insufficiency	6 – 24 months	230	 11.7% 37.0% 67.4%	 MUIC < 20 µg/L MUIC < 50 µg/L MUIC < 100 µg/L
Australia (Skeaff 2012)	1-5 years	279	35%	MUIC < 100 µg/L
Nigeria (International Institute of Tropical Agriculture 2004) - Severe deficiency - Moderate deficiency - Mild iodine status - Optimal iodine status - Possible excess	< 5 years	3091	 4.2% 8.7% 14.6% 26% 29.8%	 MUIC < 20 µg/L MUIC 20-49 µg/L MUIC 50-99 µg/L MUIC 100-199 µg/L MUIC > 300 µg/L
Korea (Lee 2014)	2-7 years	611	3.9% 66.4%	MUIC < 100 µg/L MUIC > 300 µg/L
Switzerland (Andersson 2010)	6 months 12 months	279 228	55% 48%	MUIC < 100 µg/L
France (Pouessel 2008)	<12 months	95	20% 25%	MUIC < 100 µg/L MUIC > 400 µg/L
Belgium (Delange 2001)	6-36 months	111	21% 49%	MUIC < 50 µg/L MUIC < 100 µg/L
German (Thamm 2007)	0-24 months		24% 45%	MUIC < 50 µg/L L MUIC < 100 µg/L L
Spain (Ansótegui , 2012)	6-36 months	130	36.9%	MUIC < 100 µg/L L
WHO (de Benoist 2008) Global Africa Americas South-East Asia Europe Western Pacific	6-12 years School aged children		 31.5% 40.8% 10.6% 30.3% 52.4% 22.7%	MUIC < 100 µg/L

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