Infant Nutrition Council
Industry supporting both Breastfeeding & Infant Formula
AUSTRALIA & NEW ZEALAND

REVIEW OF THE STANDARD FOR FOLLOW-UP FORMULA

(CODEX STAN 156-1987)
(Chaired by New Zealand and co-chaired by Indonesia and France)

Second Consultation Paper Response

June 2015

SUMMARY

In relation to requirements for the older infant, in the majority of cases, INC supports alignment with the Early Nutrition Academy (ENA) Guideline for follow up formula. At times this aligns with CODEX STAN 72-1981 (Rev 2007) and at other times with CODEX STAN 156-1987.

INC recommends using the term “increasingly diversified diet” rather than “progressively diversified diet” because the term ‘increasingly’ more accurately reflects the increasing variability of solid food being introduced to the older infant. The use of progressively occurs in several places in the consultation and we have commented at each occurrence.

In relation to essential composition for older infants, one of the more important areas relates to protein levels. INC strongly supports a minimum of 1.65 g/100 kcal as per the ENA recommendations based on the WHO/FAO/UNU revised guidelines on protein requirements (2007) and lowered the estimates of protein requirements for the age group 6-12 months compared to the previous estimates, in addition to the lower protein content of human milk when compared to follow-up formula.

Concerning a maximum protein level, of the options proposed, INC strongly supports 3.5g/100kcal primarily on the basis that it facilitates trade, noting that in many countries currently the **minimum** limit for protein is 3.0g/100kcal and that the EFSA Panel acknowledged that there was no scientific data available that supported the establishment of precise cut off values for the maximum protein content in infant and follow on formulas (EFSA, Scientific opinion on the essential composition of infant and follow-on formulae. EFSA Journal 2014;12(7):3760). Given the significant decrease in protein proposed, INC supports an increase in the maximum level of fat, in alignment with CODEX 72-1981, to provide more flexibility to accommodate this change.

INC is also concerned regarding the following proposals made in relation to milk protein: proposed added comma in definition 2.2, and text proposed for footnote 5). INC advocates for approaches that better reflect that only proteins derived from the milk of cows’ and goats’ milks have undergone clinical evaluation to determine suitability for use in formulas for infants (as recognized in the EFSA 2014 report), while still allowing for use of proteins from milks of other animals providing their use has been appropriately evaluated.

A repeating concern with changing minimum and maximum levels of vitamins and minerals is that for technical manufacturing purposes, it is important to maintain a range of permitted

levels for the relevant substance for which compliance is feasible. INC has noted this in several places in its response.

INC supports the provision for adding optional ingredients for several reasons set out in the following response, but importantly INC believes optional ingredients need to provide a beneficial effect as demonstrated by generally accepted scientific evidence. In this regard, scientific evaluation conducted in other countries or related prescriptive regulation should be recognised to facilitate lead times in bringing innovative products to market and reduce regulatory burden. INC recognises that such ingredients can be, but do not need to be, present in breast milk. INC also suggests that any provisions relating to optional ingredients drawn from CODEX STAN 72-1981 (Rev.2007) may need to be amended to take account of their application to the older infant target population

In relation to the process for reviewing the essential composition of follow-up formula for young children (12-36 months) INC supports the proposal where not all nutrients or substances that have compositional requirements established for older infants need to be mandated for addition to follow-up formula for young children. Young children start having an increasingly diversified diet and consume a wider variety of food groups as their key source of nutrition. As a result, the composition of follow up formula for young children can safely be less prescriptive than the composition for follow up formula for older infants. This increased flexibility reflects the different roles that such products play in the diet of the developing older infant/young child.

Even so, INC supports the compositional requirements of follow up formula for older infants serving as a basis for the compositional requirements of follow up formula for younger children, but most importantly, with the necessary adjustments to further adapt it to the different nutritional requirements of the child as the child grows up and consumes an increasingly diversified family diet. As follow up formula for the young child is often used as a substitute for cows' milk for young children (Ghisolfi 2012, Alexy & Kersting, 2003), the beneficial nutrients that are part of cows' milk should be considered. Compositional requirements must be flexible enough to include both highly formulated products and those that are predominately based on cows' milk with addition of the key nutrients.

In relation to nutritional integrity of follow up formula for young children, INC considers that the balance of protein, carbohydrate and fat in the context of total energy, needs to be carefully considered with regard to the dietary intake of young children 12-36 months. We also believe that follow up formula for young children should seek nutritional equivalence to certain nutrients in products it might replace. In this respect, reference should be made to the particular nutritional properties of cows' milk that are important contributors to intake of such nutrients in the young child's diet, particularly levels of calcium, riboflavin (vitamin B2), vitamin B12, vitamins A, D, zinc, and the quality of dairy protein. As follow up formula for young children may be used to replace cow's milk it is important that mandatory minimums of key nutrients present in cow's milk are included in the revised standard.

Clinical assessment and scientific evaluation of aspects of infant formula for the more vulnerable 0-6 month group should adequately address the needs of the older infant and any clinical assessment of those same aspect should not be required to be repeated.

INC considers two other issues are worthy of consideration by the eWG and has included commentary on these issues after the responses provided to the questions raised in consultation paper. The first relates to observed inconsistencies in Codex standards and other regulations between values specified per 100kcal vs per 100kJ. We suggest that the conversion factor applied to convert per 100kcal requirements to per 100kJ requirements is specifically stated within the standard and that other strategies may also need to be considered to eliminate, or significantly reduce these inconsistencies.

The second issue is the need to take account of matters relating to trade, ingredient supply and technical issues that have the potential to impact on the implementation and/or technical viability of the revised standard. These matters need to be considered in parallel with scientific and nutritional considerations. There is concern that issues of this nature raised by INC in the first 2015 consultation did not get mentioned or taken into account in this second consultation. INC has therefore provided a list of the key trade and technical issues relevant to the review at the end of this submission and requests that these are covered in the New Zealand and Australian submissions to the electronic Working Group.

Finally, both in the discussion on the format of the revised standard and in relation to composition, the level of consensus being sought is more than 23/25 submitters supportive of a position. INC appreciates that Codex operates on consensus and that this can allow for some dissension. At this stage in development there remains the opportunity for further consideration within a reasonable time period and this is advantageous to the achievement of consensus. However, 23 out of 25 submitters in favour of a particular proposal would seem to represent a reasonable level of consensus.

In this context, INC considers that progressing is very important and as in many other fora, New Zealand and Australia are seen as deal brokers and stalemate breakers. We therefore encourage Australia and New Zealand, in the interests of progressing, to ‘go with the majority’ in the areas that INC has explicitly identified in responses to questions where we consider going with the majority could be accommodated.

DESCRIPTION OF FOLLOW-UP FORMULA (SECTION 2)

STRUCTURE	
Two approaches were proposed by eWG members for the structure of section 2. Description, please indicate your preferred approach:	
Should the structure of section 2. Description be;	
☐ Aligned with the Codex IF std **2. DESCRIPTION** **2.1 Product Definition** 2.1.1 Follow-up Formula means a food intended… 2.1.2 Follow-up Formula is a food processed by physical means… **2.2 Other Definition** 2.2.1 The term *infant* means… 2.2.2 The term *young child* means… Move current FUF definitions to other sections: *2.2 moved to 3.1 Essential composition* 2.2 Follow-up formula is a food prepared from the milk… *2.4 mover to 9.5.1 Information for Use* 2.4 Follow-up formula when in liquid form, is suitable for use….	☐ Modified **2. DESCRIPTION** **2.1 Product Definition** 2.1.1 Follow-up Formula means a food intended… 2.1.2 The term *infant* means… 2.1.3 The term *young child* means… **2.2 Product Description** 2.2.1 Follow-up formula is a food prepared from the milk… 2.2.2 Follow-up Formula is a food processed by physical means… 2.2.3 Follow-up formula when in liquid form, is suitable for use….
INC could support either form so long as the content and relevant definitions remain in place. Therefore, in the interests of progressing, INC believes Australia and New Zealand should go with the chair and the majority.	

DEFINITION 2.1.1
Current Codex Standard for Follow-up Formula text: ***Follow-up formula*** means a food intended for use as a liquid part of the weaning diet for the infant from the 6th month on and for young children.
Please comment on whether you support a broad definition for follow-up formula, or one definition which incorporates separate product categories. See the following examples; a) Follow-up formula means a food intended for use as ……. **OR** b) Follow-up formula means a food used by: - [older] infants from 6 months (followed by role and purpose in the diet)……. and, - young children (followed by role and purpose in the diet).
INC supports option b), that is, a definition which incorporates separate product categories. The use of the term 'older infant' is consistent with the Guidelines for Formulated Complementary Foods for Older Infants and Young Children (CAC/GL 8-1991, Rev. 2013).
The Chairs propose that *'from the 6th month'* be replaced with *'from 6 months'* within the definition for follow-up formula. If you do not support this approach, please provide comment and justification for your answers.
INC supports this proposal.

The Chairs propose that the term 'weaning diet' is not used in the definition of follow-up formula. If required, it should be replaced with 'complementary feeding'. If you do not support this approach, please provide comment and justification for your answers
INC supports this proposal (that complementary feeding be used instead of 'weaning diet'). The reason for this is that 'weaning' suggests the cessation of breastfeeding. The term 'complementary feeding' removes this connotation.
The Chairs propose inclusion of the terminology ***progressively diversified diet*** in the definition for follow-up formula. If you do not support this approach, please provide comment and justification for your answers
INC supports this proposal but recommends the term 'increasingly' replace 'progressively'. The term 'increasingly' more accurately reflects the increasing variability of solid food being introduced to the older infant.

DEFINITION 2.1.2 & 2.1.3
2.1.2 The term ***infant*** means a person of not more than 12 months of age 2.1.3 The term ***young child*** means persons from the age of more than 12 months up to the age of three years (36 months)
Based on eWG responses and to retain consistency with other relevant Codex texts, the Chairs propose retaining the current definition 2.1.2 and 2.1.3 in their current drafting. Please provide comment and justification for your answers if you do not support this approach.
INC supports this proposal, that is, to retain the current definition 2.1.2 for *infant* and 2.1.3 for *young child*.

OLDER INFANT
The Chairs propose *either* including a definition for 'older infant' (as defined in the Guidelines for Formulated Complementary Foods for Older Infants and Young Children (CAC/GL 8-1991, Rev. 2013) in the Follow-up Formula Standard, OR including a reference to/qualifier of 'older infant' within the definition 2.1.1 of follow-up formula. Please select your preferred approach.
INC supports the categorisation of 'older infant'. Whether this is included in a separate definition (consistent with the Guidelines for Formulated Complementary Foods for Older Infants and Young Children (CAC/GL 8-1991, Rev. 2013)) or as a reference or qualifier within the definition of 2.1.1 is less of an issue. In the interests of progressing, INC believes Australia and New Zealand should go with the majority so long as the term 'older infant' is referred to/defined/qualified.

DEFINITION 2.1.4
Current Codex Standard for Follow-up Formula text: *The term calorie means a kilocalorie (kcal). 1 kilojoule (kJ) is equivalent to 0.239 calories (kcal)*
Based on eWG responses, the Chairs propose deleting definition 2.1.4 related to the term calorie. Please provide comment and justification if you do not support this approach
INC supports this approach, that is deleting definition 2.1.4 related to the term *calorie*.

DEFINITION 2.2

Current Codex Standard for Follow-up Formula text:

Follow-up formula is a food prepared from the milk of cows or other animals and/or other constituents of animal and/or plant origin, which have been proved to be suitable for infants from the 6th month on and for young children.

Based on eWG responses to align terminology, the Chairs propose the following draft text as a starting point. The Chairs propose including a comma after the wording 'other animals' so that it is clear that it is the other ingredients that need to have been to be suitable (not the milk base).

> ***Follow-up formula*** *is a ~~food prepared from the milk of cows or other animals and/or other constituents of animal and/or plant origin,~~ [product based on milk of cows or other animals or a mixture thereof[,] and/or other ingredients] which have been proved to be suitable [and nutritionally adequate] for [the intended age range]. ~~infants from the 6th month on and for young children.~~*

Please provide comment on the above suggested wording as well as; should any additional wording from the equivalent statement from the Infant Formula Standard be incorporated into the definition for follow-up formula, should the concept of 'safety' be captured in the definition, should all ingredients/additives in follow-up formula be gluten free, and should the statement include wording around 'supporting growth and development'?

INC supports the proposed text except for the addition of the comma after "*product based on milk of cows or other animals or a mixture thereof*". Currently EFSA considers that only milk protein from cows' or goats' milk have been adequately evaluated for use in formula products for infants, the latter only accepted after a significant amount of research and submission from New Zealand. The addition of the comma at the point proposed means that protein from any other animal milk does not have to be proved nutritional suitable, only 'other ingredients'. INC considers this is inappropriate especially considering the lower protein levels proposed to be permitted. Similarly INC does not support the removal of text, "For ~~infant~~ formula based on other/non cows' milk protein, other minimum values may need to be applied," (from protein footnote 5).

INC does not support the inclusion of the term 'nutritionally suitable' since this would be part of the test of 'suitability' generally. No additional wording is necessary from CODEX STAN 72-1981 (Rev 2007). The concept of safety should be included before 'and suitable' since suitability is secondary to safety.

Some INC members do not support the requirement that all ingredients/additives in follow-up formula for older infants be gluten free. In the current environment, the definition of 'gluten free' is defined differently in a number of areas/countries and INC believes this point is worthy of further consideration.

The statement should not include wording around 'supporting growth and development'. The difficulty with adding such a statement is that there it would be very difficult to standardise the contribution that formula contributes to growth and development versus other complementary foods. As well, the definition of follow-up formula (see below) includes the requirement that the product "shall be nutritionally adequate to contribute to normal growth and development".

DEFINITION 2.3

Current Codex Standard for Follow-up Formula text:

Follow-up formula is a food processed by physical means only so as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution.

Based on eWG responses to align terminology, the Chairs propose amending this definition to align with the equivalent statement within point 2.1.1 of the Infant Formula Standard.

> ***[Follow-up formula*** *is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold]*

Please provide comment on the above suggested wording.

INC supports the wording but suggests that the phrase "in the country where the product is sold" be deleted. This is because, on further consideration, the definition also applies in the country of manufacture, whether sold in that country or not, and also throughout the distribution network which could involve movement around the globe.

DEFINITION 2.4

Current Codex Standard for Follow-up Formula text:

Follow-up formula, when in liquid form, is suitable for use either directly or diluted with water before feeding, as appropriate. In powdered form it requires water for preparation. The product shall be nutritionally adequate to contribute to normal growth and development when used in accordance with its directions for use

The Chairs propose that the information contained within definition 2.4 of the Follow-up Formula Standard be moved to Section 9.5 with consideration of the appropriate wording to be given at the time that that section 9.5 is reviewed. If you do not support this approach, please provide comment and justification for your answers.

INC supports the proposal.

INC notes that one eWG member suggested that a definition of 'Guidance Upper Level' (GUL) be included in the Follow-up Formula Standard. Given the proposed use of GULs in the essential composition for formulas for 6-12 month olds, INC believes this would be helpful as either a footnote (as in CODEX STAN 72-1981 (Rev 2007) in Section 3, Essential Composition) or in CODEX STAN 156-1987 in Section 2.

ESSENTIAL COMPOSITION

Macronutrients

Protein

No consensus was reached on the establishment of protein requirements. Please provide scientific rationale to support your preferred value:

Protein

Unit	**Minimum**	**Maximum**	**GUL**
g/100 kcal	[1.8] [1.7] [1.65]	[3.0] [2.5] [3.5]	-
g/100 kJ	[0.45][0.41][0.39]	[0.7] [0.6] [0.8]	-

Minimum

☐ Codex IF std 1.8 g/ 100 kcal 0.45 g/ 100 kJ	☐ 1.7 g/100 kcal 0.41 g/100 kJ	☒ 1.65 g/100 kcal 0.39 g/100 kJ

INC strongly supports a minimum of 1.65 g/100 kcal for the following reasons:

- In 2007, primarily as a result of changes in the reference body weights that were previously used, WHO/FAO/UNU revised guidelines on protein requirements and lowered the estimates of protein requirements for the age group 6-12 months compared to the previous estimates. EFSA adopted the same approach in its 2013 published "Scientific Opinion on nutrient requirements and dietary intakes of infants and young children in the European Union".
- There is no evidence of inadequate intakes in an Australian and New Zealand context (*Lioret S. et al.,* 2013*)*.
- Protein content in follow-up formula is much higher than in human milk. After the age of 6 months protein content of human milk is significantly decreased (0.7-0.8g/100ml or 1.08-1.2g/100kcal, Lönnerdal 2003).
- An expert group coordinated by the Early Nutrition Academy (ENA) reported that "High infant milk protein intakes during the first year of life that markedly exceed metabolic requirements were shown to lead to excessive weight gain which can increase the risk of later obesity and associated diseases." The ENA recommends setting the minimum content of cow's milk protein in follow-up formula at 1.65g/100kcal, based on a good protein quality /an adequate content of bioavailable essential amino acids.

INC supports a minimum level of protein of 1.65 g / 100 kcal. We note some respondents to the first 2015 consultation paper support a minimum level of 1.8 g / 100 kcal. INC would like to draw attention to two factors that may ameliorate some of their concerns. Firstly, please refer to our suggestion for Footnote 6 that states when the level of protein is less than 1.8g / 100 kcal, the formula should be clinically evaluated. The inclusion of a modified Footnote 6 may increase the comfort level of respondents with the suggested minimum protein level of 1.65 g / 100 kcal. As such this supports innovation, and safety is evaluated on the basis of clinical evidence and substantiation. The second factor is that minimum levels specified for all nutrients, including protein, are not achieved in practice. This is due to the fact that manufacturers need to target higher levels to account for variability in raw material composition and manufacturing variations. Consideration of these factors may increase the comfort level of respondents with the suggested minimum protein level of 1.65 g / 100 kcal.

References:

Koletzko B, Bhutta ZA, Cai W, et al. Compositional requirements of follow-up formula for use in infancy: recommendations of an international expert group coordinated by the early nutrition academy. Ann Nutr Metab 2013;62(1):44-54.

Lönnerdal B, Nutritional and physiologic significance of human milk proteins. Am J Clin Nutr 2003; 77: 1537-43.

Lioret S. et al. Tracking of dietary intakes in early childhood: the Melbourne InFANT Program. Eur J Clin Nutr. 2013; 67(3): 275-81.

Following the approach recently set in the Commission Directive 2013/46/EU and in CODEX STAN 72-1981 (Rev 2007), the suitability of a formula with a protein content below 2.25g/100kcal for formula manufactured from cow's milk protein hydrolysates should be required to be demonstrated.

Protein quality should be maintained while reducing protein quantity.

If supporting a value other than the Codex IF std please provide comment on how the energy, total fat, and carbohydrate content requirements should be amended to accommodate this.

Adoption of the approach proposed in the first consultation paper in 2015, to align the fat content of formulas for older infants with that specified in CODEX STAN 72-1981 (Rev 2007) is recommended. INC considers that this approach will provide sufficient flexibility to manage decreased protein content.

Maximum		
☐ Codex IF std 3.0 g/ 100 kcal 0.7 g/ 100 kJ	☐ EFSA/IEG 2.5 g/100 kcal 0.6 g/100 kJ	☒ 3.5 g/100 kcal 0.8 g/100 kJ

Of the three options proposed for maximum protein level for follow up formula for older infants, INC strongly advocates for the maximum limit of 3.5g/100kcal. This is needed to facilitate trade for the following reasons, noting that in many countries currently the **minimum** limit for protein is 3.0g/100kcal as per the current CODEX STAN 156-1987:

- Applying a maximum of 3.0g/100kcal, which aligns with the maximum in CODEX STAN 72-1981 (Rev 2007) for infant formula, or an even lower maximum, will result in the protein range for older infants in the revised CODEX STAN 156-1987 being mutually exclusive from the range which currently applies. This approach will necessitate all current follow up formula products for older infants to be reformulated in order to fully comply with the new protein maximum. Conversely, it does not allow for products to be reformulated to meet the new Codex protein requirements within the scope of existing national regulations that specify a minimum of 3.0g protein/100kcal.

  INC considers that reduction of the maximum protein from 5.5 to 3.5g/100kcal is a substantial shift and sends a very clear message to manufacturers that lower protein levels are sought. Products will be reformulated with a focus on achieving protein levels at the lower end of the permitted range as has happened with infant formula products since lower protein levels have been advocated.

- A key issue which needs to be taken into account in this context is that the timing of implementation of new requirements is not synchronised between different national jurisdictions around the world. Codex setting new requirements that are mutually exclusive from existing Codex requirements that form the basis of regulations applied by many national jurisdictions poses a significant risk of resultant trade barriers. For example, a change of this magnitude has the potential to become a significant trade issue caused by mutually exclusive requirements applying in the country of manufacture and the country of sale.

For this reason INC advocated, in response to the first consultation paper in 2015, for a maximum of 3.5g/100kcal to be applied. This approach would provide a small window for compliance with both the existing and proposed new requirements and will still be effective at delivering the move to lower protein levels sought.

We note also that a maximum limit of 3.5g protein/100kcal results in 14% of energy from protein assuming an intake of 500kcal/day;

- 14% of 500 kcal = 70 kcal coming from protein
  Protein gives 4 kcal per g --> 70 kcal protein = (70/4) 17.5 g protein
  17.5 g protein per 500 kcal = (17.5/5) **3.5 g protein/100 kcal.**

We refer also to the EFSA Panel acknowledgement that there is no scientific data available that supports the establishment of precise cut off values for the maximum protein content in infant and follow on formulas (EFSA, Scientific opinion on the essential composition of infant and follow-on formulae. EFSA Journal 2014; 12(7):3760). There is also no UL established for protein.

If supporting a value other than the Codex IF std please provide comment on how the energy, total fat, and carbohydrate content requirements should be amended to accommodate this.

Adoption of the approach proposed in the first consultation paper in 2015, to align with the fat content of formulas for older infants with that specified in the CODEX STAN 72-1981 (Rev 2007) is recommended. INC considers that this approach will provide sufficient flexibility to manage decreased protein content.

Protein Footnote 2

[2]For the purpose of this standard the calculation of the protein content of the final product ready for consumption should be based on N x 6.25, unless a scientific justification is provided for the use of a different conversion factor for a particular product. The protein levels set in this standard are based on a nitrogen conversion factor of 6.25. The value of 6.38 is generally established as a specific factor appropriate for conversion of nitrogen to protein in other milk products, and the value of 5.71 as a specific factor for conversion of nitrogen to protein in other soy products.

Or

[2]For the purpose of this standard the calculation of the protein content of the final product ready for consumption should be based on N x 6.25 **[or as specified in a relevant Codex commodity Standard or the Codex Recommended Methods of Analysis and Sampling]** The protein levels set in this standard are based on a nitrogen conversion factor of 6.25.

☒ Retain as footnote 2 in the Codex IF std	☐ Amend to reflect the use of other Codex texts

INC strongly supports retaining the footnote as contained in in CODEX STAN 72-1981 (Rev 2007). The reason for this is:

- There was lengthy and detailed discussion of this issue when the footnote was developed for in CODEX STAN 72-1981 (Rev 2007) and as was reflected in the ESPGHAN response to CCNSFDU's request for commentary on nutrient levels in infant formula (Koletzko B et al "Global standard for the composition of infant formula: recommendations of an ESPGHAN Coordinated International Expert Group" Journal of Pediatric Gastroenterology and Nutrition, 41:584–599 November 2005)
- Retention ensures consistency across the Codex texts for 6-12 months
- Avoids potential confusion arising from different conversion factors quoted in other texts or methods.

Footnote 3

Taking into account comments from the eWG, do you support the removal of the sentence related to ratios of amino acids?

[3] For an equal energy value the formula must contain an available quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast-milk as defined in Annex I); nevertheless for calculation purposes, the concentrations of tyrosine and phenylalanine may be added together. [~~The concentrations of methionine and cysteine may be added together if the ratio is less than 2:1; in the case that the ratio is between 2:1 and 3:1 the suitability of the formula has to be demonstrated by clinical testing.~~]

☐ Yes	☒ No

INC is strongly opposed to deleting the first phrase of the last sentence in Footnote 3 concerning the acceptability of adding together the concentrations of methionine and cysteine. If it is not possible to sum methionine and cysteine for calculation purposes, this would exclude the use of unmodified cows' or goats' milk protein (the latter of which was the protein source used for clinical evaluation of goats' milk based infant formula). It appears that this part of the sentence may have been deleted in error.

INC supports deletion of the last phrase in Footnote 3 that reads:

> "… if the ratio is less than 2.1; in the case that the ratio is between 2:1 and 3:1 the suitability of the formula has to be demonstrated by clinical testing."

The footnote would then read:

> "For an equal energy value the formula must contain an available quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast-milk as defined in Annex I); nevertheless for calculation purposes, the concentrations of tyrosine and phenylalanine may be added together. The concentrations of methionine and cysteine may be added together."

This could then be streamlined to read:

> "For an equal energy value the formula must contain an available quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast-milk as defined in Annex I); nevertheless for calculation purposes, **the sum of** concentrations of tyrosine and phenylalanine, **and the sum of** ~~may be added together. The concentrations of~~ concentrations of methionine and cysteine, may be used."

INC considers there should be no restriction regarding amino acid ratios, as complementary foods will contribute to amino acid intakes and the metabolism of older infants is more mature with respect to the capacity to convert methionine to cysteine and phenylalanine to tyrosine. For calculation purposes, both the concentrations of tyrosine and phenylalanine, as well as methionine and cysteine may be added together (IOM Dietary Reference Intakes, 2002).

Do you support the inclusion of Annex I as the reference protein for the compositional requirements for follow-up formula for older infants?
INC supports the inclusion of Annex 1, as it occurs in CODEX STAN 72-1981 (Rev 2007), for formula for older infants aged 6-12 months. Alternatively, INC could also support the inclusion of a different Annex that outlines age appropriate amino acid patterns as proposed under the recent protein quality assessment report from FAO (FAO, 2013). If Annex I is retained, it is calculated on the basis of on a minimum protein content of 1.8g/100kcal. If the protein content decreases to 1.65g/100kcal, the amino acid content and protein quality should be maintained.

Footnote 4
[4] Isolated amino acids may be added to ~~Infant F~~ **f**ormula only to improve its nutritional value for infants. Essential and semi-essential amino acids may be added to improve protein quality, only in amounts necessary for that purpose. Only L-forms of amino acids shall be used.
Do you support the inclusion of footnote 4 as amended slightly by the Chairs?
INC supports the proposal with the replacement of 'for infants' at the end of first sentence with 'for older infants'.

Footnote 5
The following wording is proposed to improve the clarity of the footnote: [5] The minimum value applies to cows' [**and/or other animals']** milk protein. ~~For infant formula based on non-cows' milk protein other minimum values may need to be applied~~. For infant formula based on soy protein isolate, a minimum value of [2.25 g/100 kcal (0.5 g/100 kJ)] applies. Do you support the modified footnote? Noting that the minimum value may change dependent on the outcome of the minimum protein content of formulas based on cows' milk protein.
INC does not support the wording proposed and instead proposes amended text for footnotes 5 and 6 which take into account the latest EFSA recommendations. INC proposes the following wording for Footnote 5: "5) The minimum value applies to cows' and goats' milk protein. For ~~infant~~ formula based on other ~~non-cows'~~ milk protein, other minimum values may need to be applied. For ~~infant~~ formula based on soy protein isolate, a minimum value of 2.25 g/100 kcal (0.54 g/100 kJ) applies." This is consistent with INC's response to the first consultation and also with the response to definition 2.2 proposals above.

Footnote 6

[6] ~~Infant~~ [Formula based on non-hydrolysed milk protein containing less than [2 g protein/100 kcal] and] ~~infant~~ [formula based on hydrolysed protein containing less than [2.25 g protein/100 kcal] should be clinically evaluated].

Do you support the inclusion of the amended footnote 6? If no, please provide rationale for the modifications proposed.

INC proposes**:**

"6) ~~Infant f~~[Formula **for older infants based on milk protein containing less than 1.8 g protein/100 kcal,** ~~**based on non-hydrolysed milk protein containing less than [2 g protein/100 kcal] and] infant**~~ **[**formula based on hydrolysed protein containing less than [2.25 g protein/100 kcal] **and formula based on milk protein of other species** should be clinically evaluated."

EFSA (2014) states: 'Based on the studies which investigated the adequacy of infant formula containing around 1.8g protein per 100kcal, the Panel considers that a minimum protein content in infant formula and follow on formula of 1.8/100kcal (0.43g/100kJ) for cow's and goat's milk-based formulae is suitable to satisfy the nutritional requirements of infants.'

INC recommends adding to footnote 6 the following:

"If the protein concerned (origin and quantity/100kcal) has been clinically assessed as suitable for infant formula it may be used in formulas for older infants without further clinical assessment."

This addition ensures that clinical assessment for the more vulnerable 0-6 month group should adequately address the needs of the older infant and the clinical assessment should not be required to be repeated.

Total Fat

The majority of the eWG members support the option to align the total fat requirements of the Codex Infant and Follow-up Formula standards. Do you support the Total fat minimum and maximum values?

Total fat[7,8]

Unit	**Minimum**	**Maximum**	**GUL**
g/100 kcal	4.4	6.0	-
g/100 kJ	1.05	1.4	-

☒ Yes	☐ No, if no please provide scientific justification

INC supports an increase in the maximum level of fat given the proposed decrease of protein

As noted in the 2014 eWG, limited intake of DHA was reported. In this context, INC recommends that the eWG considers including DHA in this section with a GUL specified only, taking into account the current status of the scientific debate and the place of follow up formula in the older infants' diet. The eWG should also consider this in the global perspective, to achieve CODEX's objectives (fair trade and consumers' protection). Furthermore, the eWG should evaluate the possible difference with the DHA provisions in the CODEX STAN 72-1981 (Rev 2007).

References:

Brenna JT, Varamini B, Jensen RG, et al. Docosahexaenoic and arachidonic acid concentrations in human breast milk worldwide. American Journal of Clinical Nutrition 2007;85:1457-1464.

Koletzko B, Lien E, Agostoni C, et al. The roles of long-chain polyunsaturated fatty acids in

pregnancy, lactation and infancy: review of current knowledge and consensus recommendations. J Perinat Med 2008; 36 (1): 5-14

The majority of the eWG members support the option to align the total fat requirements of the Codex Infant and Follow-up Formula standards. Do you support alignment of the Total fat footnotes regarding lauric and myristic acid, and erucic acid?

- Lauric acid and myristic acids are constituents of fats, but combined shall not exceed 20% of total fatty acids.
- The erucic acid content shall not exceed 1% of total fatty acids.

☒ Yes	☐ No, if no please provide scientific justification

INC supports alignment with CODEX STAN 72-1981 (Rev 2007).

The majority of the eWG members support the option to align the total fat requirements of the Codex Infant and Follow-up Formula standards. Do you support alignment of the Total fat footnotes regarding use of commercially hydrogenated fats, and trans fat?

- Commercially hydrogenated oils and fats shall not be used in ~~infant~~ **follow-up** formula
- The content of trans fatty acids shall not exceed 3% of total fatty acids. Trans fatty acids are endogenous components of milk fat. The acceptance of up to 3% of trans fatty acids is intended to allow for the use of milk fat in ~~infant~~ **follow-up** formulae.

☒ Yes	☐ No, if no please provide scientific justification

INC supports the proposal.

The majority of the eWG members support the option to align the total fat requirements of the Codex Infant and Follow-up Formula standards. Do you support alignment of the Total fat footnotes regarding phospholipids?

- The total content of phospholipids should not exceed 300 mg/100 kcal (72 mg/100 kJ).

☒ Yes	☐ No, if no please provide scientific justification

INC supports the alignment of the Total Fat footnotes relating to phospholipids.

Linoleic and α-linolenic acid

No eWG consensus was reached on the minimum and GUL requirements for LA. Please provide scientific rationale to support your preferred value:

Linoleic acid

Unit	**Minimum**	**Maximum**	**GUL**
mg/100 kcal	[300] [500]	-	[1400] [1200]
mg/100 kJ	[70] [120]	-	[330] [300]

☒ Codex IF std 300 mg/100 kcal 70 mg/100 kJ	☐ EFSA 500 mg/100 kcal 120 mg/100 kJ

INC supports alignment of the Minimum and GUL of linoleic acid with CODEX STAN 72-1981 (Rev 2007). This level has a long history of safe use.

No eWG consensus was reached on the establishment of a ratio of LA:ALA in line with the Codex Standard for Infant Formula, or the establishment of a maximum requirement for ALA.

☒ Codex IF std	☐ EFSA
Ratio linoleic/α-linolenic acid Min 5:1 Max 15:1	ALA max: 100 mg/100 kcal 24 mg/100 kJ

INC strongly supports aligning the LA and ALA requirements to those in CODEX STAN 72-1981 (Rev 2007). In any event, any upper limits applied for LA and ALA should be GULs not maximums.

INC compared the maximum levels that would apply for ALA based on the different LA and ALA options outlined in the consultation paper. This comparison is in the table below:

	Alternative proposals in Consultation Paper June 2015			Effective limits based on min and max proposals for LA and applying permissible ratios of LA/ALA
	Linoleic acid (LA)	A-linolenic acid (ALA)	LA/ALA ratio	
Min	300	50	5:1	300/15=20
	500			500/15=33
Max	*1400	N.S. Ratio	15:1	1400/5=280
	1200	100		1200/5=240

**This is stated as max in Codex IF std in CP2, but in actual fact it is a GUL in Codex IF std not a max.*

As can be seen, the maximum for ALA of 100mg/100kcal proposed by EFSA in 2014 is a significant reduction on the effective maximum that currently applies compared to specifying no maximum and managing upper limits by means of the range of permitted ratios for LA:ALA. The EFSA proposed maximum reduces the range of permissible levels of ALA as permitted in CODEX STAN 72-1981 (Rev 2007) by over 50%. This is a very significant change/reduction and compliance to this reduced range could be challenging given the natural variations that occur in the fatty acid compositions of different oils.

Further, if the proposed maximum of 100mg/100kcal is applied for ALA and the ratio requirements omitted, the range of ratios of LA:ALA that will be possible are:

- 300/100 or 3:1 if the LA minimum of 300mg/100kcal is applied; through
- 1200/100 or 12:1; to
- 1400/100 or 14:1.

If this approach was taken then it would appear to be prudent to raise the minimum requirement for LA.

Docosahexanoic acid & Arachidonic acid

Several eWG members considered that DHA and ARA compositional requirements should be included in the Standard. Do you consider that these fatty acids should be considered optional ingredients, as per the Codex Infant Formula Standard, or mandated? Please provide scientific rationale to support your preferred approach.

☐ Codex IF std X Optional addition	☐ Mandated

As noted in the 2014 eWG, limited intakes of DHA were reported. In this context, INC recommends that the eWG considers including DHA in this section either as a mandatory requirement with a minimum and GUL specified or, alternatively, with a GUL specified only, taking into account state-of the art of the scientific debate and the place of follow up formula in the older infants' diet. The current eWG should also consider this in the global perspective, to achieve the CODEX's objectives (fair trade and consumers' protection). Furthermore, the eWG should evaluate the possible difference with the DHA provisions in the CODEX STAN 72-1981.

If you support inclusion of DHA compositional requirements to the Codex Standard for follow-up formula for older infants (either as an optional or essential addition), do you support the inclusion of provisions for ARA and EPA? Please provide scientific rationale to support your preferred approach.

Irrespective of whether DHA is optional or mandated, INC has a strong view that EPA should be restricted. This is on the basis that the cheapest source of DHA is fish oils which have a relatively high content of EPA. This is evidenced by the use of such oils for DHA supplementation of adults (commonly with an EPA:DHA ratio of 1.5:1 and can be as high as 2:1).

Fish oil with an EPA content that is greater than DHA may be increasingly used in follow up formula unless a requirement is included (as is provided in CODEX STAN 72-1981 (Rev 2007)) whereby if DHA is added, the content of EPA in added LCPUFAS should not exceed the level of DHA.

INC does not support compositional requirement for ARA as dietary ARA is provided by a range of complementary foods not just formula (Koletzko, ENA 2013).

Total Carbohydrates

The majority of the eWG members support the option to align the total carbohydrate requirements of the Codex Infant and Follow-up Formula standards. However this may need to be amended if the protein requirements between the two standards differ.

Total Carbohydrates[9)]	**Minimum**	**Maximum**	**GUL**
Unit	9.0	14.0	-
g/100 kcal	2.2	3.3	-
g/100 kJ			

If consensus is reached to amend the Energy, Protein and Total Fat minimum and maximum levels to those established in the Codex Standard for Infant Formula, do you support alignment of the two standards regarding the minimum and maximum carbohydrate content?

☒ Yes	☐ No

INC supports the proposal of carbohydrate minimum and maximum levels being 9g and 14g respectively.

Lactose should be used as preferred carbohydrate with no minimum level but aligned with

CODEX STAN 72-1981 (Rev 2007))

Sucrose, fructose and honey should contribute less than 20% of total carbohydrates. This aligns with the proposal of the Chairs for glucose to be less than 2g. This also aligns with the EU Draft Delegated Act.

Unrestricted addition of starches within maximum carbohydrate amounts should be permitted. There is discussion of limiting this permission by requiring the addition to be gluten free. As noted earlier in this submission, the gluten status of starches requires further consideration.

If the Codex Standard for Infant Formula minimum and maximum values for Energy, Protein, or Total Fat are not adopted, do you support reviewing the minimum and maximum carbohydrates based on the residual energy content?	
☒ Yes	☐ No
Carbohydrate alignment with CODEX STAN 72-1981 (Rev 2007) would need to be done only if the other macronutrients changes are made.	

Carbohydrate Footnote	
In addition to stating that lactose should be a preferred carbohydrate, should a minimum lactose content of 4.5g/100 kcal be specified, unless a product is “lactose free” or more than 50% of the protein is from soy protein isolate?	
☐ Yes, support minimum lactose level	☐ No do not support minimum lactose level
INC supports lactose as the preferred carbohydrate but does not consider that a minimum level is required.	
Should glucose polymers be specified as the preferred carbohydrates in formula based on cows’ milk protein and hydrolysed protein? Or should the addition of glucose be limited only to formula made from protein hydrolysates?	
☒ Glucose polymers considered preferred carbohydrate in formula based on cows’ milk protein and hydrolysed protein	☐ Addition of glucose limited to formula made from protein hydrolysates
INC supports both lactose and glucose polymers being stated as preferred carbohydrates, in formula based on cows’ milk protein and hydrolysed protein. Many national jurisdictions categorise lactose as an animal derived ingredient and, as such, require specific sources of supply to be used. Consequently, there are potential trade issues (and also possible price impacts) if the use of glucose polymers is not permitted as an alternative to, or partial substitution for, lactose in follow up formula products. If lactose is stated as the only preferred carbohydrate ~~source~~, the ability to use glucose polymers as an alternative still needs to be retained because of this issue. Please refer to the suggested footnote text, provided for consideration, at the end of the carbohydrate questions posed.	

The eWG support that the addition of precooked and/or gelatinized starches that are gluten-free nature may be added to follow-up formula. Do you support that a limit to the percentage of total carbohydrates should be established?	
☐ addition up to 30% total carbohydrates	☒ unrestricted addition within maximum total carbohydrate limits
INC supports the unrestricted addition of starches within maximum carbohydrate amounts. In alignment with INC's comments under Definition 2.2, some members agree with the proposal from the Chairs that these are gluten free. Other members would prefer more debate on the best approach to apply. EFSA (2014) recommends levels in formulas for older infants are kept low to reduce the risk of excessive gluten levels in the overall diet of these infants but there is no need for these products to be 'gluten free'. While CODEX STAN 118-1979 (2008 revision) defines 'gluten free," different definitions and interpretations of 'gluten free' are applied by national jurisdictions and INC considers that other options, such as the establishment of a GUL, may be more appropriate.	
Some eWG members recommended that a maximum limit should be established for the addition of sucrose and fructose. Do you support the inclusion of a maximum limit for the addition of sucrose and fructose, and if so that the sum of sucrose and fructose should not exceed 20% of total carbohydrates?	
☒ Yes	☐ No
INC supports the inclusion of a maximum limit for the addition of sucrose and fructose, and that the sum of sucrose and fructose should not exceed 20% of total carbohydrates. We note that this is a high percentage.	
If your response to the above question was yes, do you think that the sum of sucrose and fructose should also include sugar from honey if treated to destroy spores of *C. botulinum*?	
☒ Yes	☐ No
INC supports the sum of sucrose and fructose including sugar from honey if treated to destroy spores of *C. botulinum.* To summarise INC proposes the following text for the carbohydrate footnote (replacing footnote 9) as in CODEX STAN 72-1981) for consideration: "Lactose should be the preferred carbohydrate but glucose polymers are an acceptable alternative which may be used without restriction. Only pre-cooked and/or gelatinised starches may be added [that are gluten free by nature]. The addition of other sugars should be avoided. If needed, sucrose, fructose or honey (the last listed treated to destroy spores of *C. botulinum*) may be added providing the sum of these does not exceed 20% of the total carbohydrates." The test in relation to gluten is included in square brackets in line with INC's comments that this requirement needs more consideration.	

Fat-soluble Vitamins

Vitamin A

No consensus was reached on the establishment of a minimum or maximum vitamin A value. Please provide scientific rationale to support your preferred value:

Vitamin A [10)]

Unit	**Minimum**	**Maximum**	**GUL**
µg RE/100 kcal	[75] [70] [60]	[225] [180] [140] [114]	-
µg RE/100 kJ	[18] [16.7] [14]	[54] [43] [33.4] [27.2]	-

[10)] expressed as retinol equivalents (RE).

1 µg RE = 3.33 IU Vitamin A= 1 µg all trans-retinol. Retinol contents shall be provided by preformed retinol, while any contents of carotenoids should not be included in the calculation and declaration of vitamin A activity.

Minimum

☒ Codex FUF std 75 µg RE/100 kcal 18 µg RE/100 kJ	☐ EFSA 70 µg RE/100 kcal 16.7 µg RE /100 kJ	☐ Codex IF std 60 µg RE/100 kcal 14 µg RE/100 kJ

INC supports aligning the Vitamin A level with the provision in CODEX STAN 156-1987.

Maximum

☒ Codex FUF std 225 µg RE/100 kcal 54 µg RE/100 kJ	☐ Codex IF std 180 µg RE/100 kcal 43 µg RE/100 kJ	☐ 140 µg RE/100 kcal 33.4 µg RE/100 kJ	☐ 114 µg RE /100 kcal 27.2 µg RE/100 kJ

INC supports aligning the Vitamin A level with the provision in CODEX STAN 156-1987

While INC prefers to retain the vitamin A requirements as per CODEX STAN 156-1987, in the interests of progressing, Australia and New Zealand should be prepared to go with the majority on Vitamin A limits providing that the permitted range allows for the maximum to be at least 3 times the minimum as currently applies for both CODEX STAN 156-1987 and CODEX STAN 72-1981.

Vitamin D

No consensus was reached on the establishment of a minimum or maximum vitamin D value. Please provide scientific rationale to support your preferred value:

Vitamin D_3 [11)]

Unit	**Minimum**	**Maximum**	**GUL**
µg/100 kcal	[1] [2]	[2.5] [3.0] [4.5]	-
µg/100 kJ	[0.25] [0.48]	[0.6] [0.75] [1.1]	-

[11)] Calciferol. 1 µg calciferol = 40 IU vitamin D

Minimum

☒ Codex IF std 1 µg /100 kcal 0.25 µg /100 kJ	☐ EFSA 2 µg /100 kcal 0.48 µg /100 kJ

A minimum of 1 µg /100 kcal aligns with CODEX STAN 72-1981 (Rev 2007) and is supported by some INC members, others support increasing the minimum requirement to 2 µg /100 kcal based on higher daily levels now recommended and vitamin D deficiency being common.

Irrespective of the minimum selected, if the higher minimum is agreed to, then the maximum must be increased to ensure an acceptable range is available for manufacturing purposes.

Maximum		
☐ Codex IF std 2.5 µg /100 kcal 0.6 µg /100 kJ	☐ Codex FUF std 3.0 µg /100 kcal 0.75 µg /100 kJ	☒ IEG 4.5 µg /100 kcal 1.1 µg /100 kJ
INC supports a maximum of 4.5 µg /100 kcal on the basis that vitamin deficiency is common and a broader range provides manufacturers some flexibility in adding this vitamin.		

Vitamin E

No consensus was reached on the establishment of a minimum vitamin E value. Please provide scientific rationale to support your preferred value:

Vitamin E

Unit	**Minimum**	**Maximum**	**GUL**
mg α-TE /100 kcal	[0.5] [0.6]	-	5
mg α-TE /100 kJ	[0.12] [0.14]	-	1.2

Minimum

☒ Codex IF std 0.5 mg α-TE /100 kcal 0.12 mg α-TE /100 kJ	☐ EFSA 0.6 mg α-TE /100 kcal 0.14 mg α-TE /100 kJ
INC supports alignment with CODEX STAN 72-1981 (Rev 2007) which is also in line with the ENA proposal. INC also supports a GUL of 5.	

Vitamin K

No consensus was reached on the establishment of a minimum vitamin K value. Please provide scientific rationale to support your preferred value:

Vitamin K

Unit	**Minimum**	**Maximum**	**GUL**
µg/100 kcal	[4] [1]	-	27
µg/100 kJ	[1] [0.24]	-	6.5

Minimum

☒ Codex IF std 4 µg /100 kcal 1 µg /100 kJ	☐ EFSA 1 µg /100 kcal 0.24 µg /100 kJ
INC supports 4 µg /100 kcal and therefore alignment with CODEX STAN 72-1981 (Rev 2007). This level is also aligned with the ENA Guideline for follow-up formula. INC supports 27 µg /100 kcal as a GUL.	

Water Soluble Vitamins

Thiamin

No consensus was reached on the establishment of a minimum thiamin value. Please provide scientific rationale to support your preferred value:

Thiamin

Unit	Minimum	Maximum	GUL
µg/100 kcal	[60] [40]	-	300
µg/100 kJ	[14] [10]	-	72

Minimum

☒ Codex IF std 60 µg /100 kcal 14 µg /100 kJ	☐ Codex FUF std/ EFSA 40 µg /100 kcal 10 µg /100 kJ

INC supports alignment with CODEX STAN 72-1981 (Rev 2007). This level is also aligned with the ENA Guideline for follow-up formula.

Riboflavin

No eWG consensus was reached on the establishment of a minimum riboflavin value. Please provide scientific rationale to support your preferred value:

Riboflavin

Unit	Minimum	Maximum	GUL
µg/100 kcal	[80] [60]	-	500
µg/100 kJ	[19] [14]	-	119

Minimum

☒ Codex IF std 80 µg /100 kcal 19 µg /100 kJ	☐ EFSA 60 µg /100 kcal 14 µg /100 kJ

INC supports alignment with CODEX STAN 72-1981 (Rev 2007). This level is also aligned with the ENA Guideline for follow-up formula.

Niacin

No eWG consensus was reached on the establishment of a minimum niacin value. Please provide scientific rationale to support your preferred value in square brackets:

Niacin*

Unit	Minimum	Maximum	GUL
µg/100 kcal	[300] [400]	-	1500
µg/100 kJ	[70] [100]	-	360

* Niacin refers to preformed niacin

Minimum

☒ Codex IF std 300 µg /100 kcal 70 µg /100 kJ	☐ Codex FUF std/ EFSA 400 µg /100 kcal 100 µg /100 kJ

INC supports alignment with CODEX STAN 72-1981 (Rev 2007). This level is also aligned with the ENA Guideline for follow-up formula.

If the minimum was increased to 400 µg /100 kcal, INC understands this could be accommodated by manufacturers but questions the need for change.

Vitamin B6

No eWG consensus was reached on the establishment of a minimum Vitamin B6 value. Please provide scientific rationale to support your preferred value in square brackets:

Vitamin B6*

Unit	**Minimum**	**Maximum**	**GUL**
µg/100 kcal	[35] [20]	-	175
µg/100 kJ	[8.5] [4.8]	-	45

[*Formulas should contain a minimum of 15 µg Vitamin B6 per gramme of protein.]*

Minimum

☒ Codex IF std 35 µg /100 kcal 8.5 µg /100 kJ	☐ Codex FUF std/ EFSA 20 µg /100 kcal 4.8 µg /100 kJ

INC supports alignment with CODEX STAN 72-1981 (Rev 2007). This level is also aligned with the ENA Guideline for follow-up formula.

Inclusion of the footnote:
Formulas should contain a minimum of 15 µg Vitamin B6 per gramme of protein

☐ Yes	☒ No

CODEX STAN 72-1981 (Rev 2007) does not have a footnote. The footnote quoted is in CODEX STAN 156-1987. This footnote should be removed to better align with CODEX STAN 72-1981 (Rev 2007).

In addition if the proposed protein levels are to be reduced (1.65-1.8 g/100 kcal) these would be lower than those currently contained in CODEX STAN 156-1987 (3.0g/100 kcal). As a consequence of the lower protein level, the minimum B6 content as proposed in this footnote would also be lower (24.8-27 ug/100 kcal). The footnote would therefore not be compatible with the minimum B6 level of 35 ug/100 kcal, when taken with the lower protein level.

Folic acid

No eWG consensus was reached on the establishment of a minimum folic acid/folate value. Please provide scientific rationale to support your preferred value in square brackets:

Folic acid

Unit	**Minimum**	**Maximum**	**GUL**
µg/100 kcal	[10]	-	[50]
µg/100 kJ	[2.5]	-	[12]

OR

Folate*

Unit	**Minimum**	**Maximum**	**GUL**
µg/100 kcal	[15]	-	[85]
µg/100 kJ	[3.6]	-	[20]

[*expressed as dietary folate equivalents (DFE)
1 µg DFE = 1 µg food folate = 0.6 µg folic acid]

Should composition be based on folate or folic acid?

☒ Folic acid	☐ Folate, expressed as dietary folate equivalents

INC supports the minimum and GUL of folic acid as proposed: 10 and 50 respectively.

The term folate refers to natural source present in, for example, vegetables. Fortification of food generally and formula in particular, is almost exclusively through the addition of synthetic folic acid.

If you support establishing compositional requirements for folate, do you support the inclusion of a footnote defining dietary folate equivalents as presented in square brackets above?
Not Applicable

Vitamin C

No eWG consensus was reached on the establishment of a minimum vitamin C value. Based on the eWG responses, please provide scientific rationale to support your preferred value in square brackets:

Vitamin C[15)]

Unit	Minimum	Maximum	GUL
mg/100 kcal	[10] [4]	-	70[16)]
mg/100 kJ	[2.5] [0.96]	-	17[16)]

[15)] expressed as ascorbic acid

[[16)] This GUL has been set to account for possible high losses over shelf-life in liquid formulas; for powdered products lower upper levels should be aimed for]

Minimum levels

☒ Codex IF Standard 10 mg/100 kcal 2.5 mg/100 kJ	☐ EFSA 4 mg/100 kcal 0.96 mg/100 kJ

INC supports alignment with CODEX STAN 72-1981 (Rev 2007). This level is also aligned with the ENA Guideline for follow-up formula.

Do you support the inclusion of footnote 16:
This GUL has been set to account for possible high losses over shelf-life in liquid formulas; for powdered products lower upper levels should be aimed for

☐ Yes	☒ No

A GUL at 70mg/100kcal should equally apply to both liquid and powder formulas because losses are still a feature over the longer shelf life of powdered products.

Biotin

No eWG consensus was reached on the establishment of a minimum biotin value. Based on the eWG responses, please provide scientific rationale to support your preferred value in square brackets:

Biotin

Unit	Minimum	Maximum	GUL
µg/100 kcal	[1.5] [1]	-	10
µg/100 kJ	[2.5] [0.24]	-	2.4

Minimum levels

☒ Codex IF Standard 1.5 µg/100 kcal 2.5 µg/100 kJ	☐ EFSA 1 µg/100 kcal 0.24 µg/100 kJ

INC supports alignment with CODEX STAN 72-1981 (Rev 2007). This level is also aligned with the ENA Guideline for follow-up formula.

On a separate issue, INC notes that conversion factor applied to convert the minimum value of 1.5 µg/100 kcal to µg/100 kJ appears to be incorrect. If a conversion factor of 4.184 was applied then the comparable minimum would be 0.36 µg/100 kJ and not 2.5 µg/100 kJ. This is an example of the importance of applying a standardised conversion factor, a matter that INC discusses at the end of this response.

Minerals & Trace Elements

Iron

No consensus was reached on the compositional requirements for iron for Follow-up Formula composition. Based on the eWG responses, please provide scientific rationale to support your preferred value in square brackets

Iron

Unit	**Minimum**	**Maximum**	**GUL**
mg/100 kcal	[0.45] [0.6] [1.0] [1.1]	[2.0] [1.9] [1.5] [2.5]	-
mg/100 kJ	[0.1] [0.14][0.25] [0.26]	[0.3] [0.45] [0.36] 0.6]	-

Minimum

☐ Codex IF	☐ EFSA	☒ Codex FUF	☐ IEG
0.45 mg/100 kcal 0.1 mg/100 kJ	0.6 mg/100 kcal 0.14 mg/100 kJ	1 mg/100 kcal 0.25 mg/100 kJ	1.1 mg/100 kcal 0.26 mg/100 kJ

INC supports alignment with CODEX STAN 156-1987. This level is also aligned with the ENA Guideline for follow-up formula.

After the age of 4-6 months, body iron stores decrease significantly and therefore the supply of iron should be greater than that in infant formula as contained in CODEX STAN 72-1981 (Rev 2007).

Should maximum levels be established?

☐ Yes	☐ No, a footnote should be added stating: "levels may be determined by National Authorities"

Some INC members support the establishment of maximums while other members do not. This in part reflects similar differences across authorities where the setting of a safety upper limit for iron is recommended by some (IOM: 40mg/day) while others, such as the ENA follow-up formula guidelines, confirm that no maximum is needed.

As a result, in the interests of progressing, INC believes Australia and New Zealand should go with the chair and the majority in relation to maximum levels for Iron.

If you support establishing a maximum level please provide scientific rationale to support your preferred value in square brackets

☐ Codex FUF	☐ IEG	☐	☐
2.0 mg/100 kcal 0.5 mg/100 kJ	1.9 mg/100 kcal 0.45 mg/100 kJ	1.5 mg/100 kcal 0.36 mg/100 kJ	2.5mg/100 kcal 0.6 mg/100 kJ

See above comments.

Should separate minimum and maximum/GUL levels be established for soy protein isolate formulas?

☒ Yes	☐ No

Soy protein isolate formulas have less efficient iron absorption and therefore higher minimum levels should be set. This approach is aligned with ENA follow-up formula guidelines and EFSA 2014. The above comments on maximum levels also apply here.

Calcium & phosphorous

No consensus was reached on the requirements for calcium for Follow-up Formula composition.

Calcium

Unit	Minimum	Maximum	GUL
mg/100 kcal	[50] [90]	-	[140] [180]
mg/100 kJ	[12] [22]	-	[35] [43]

Minimum

☐ Codex IF std 50 mg/100 kcal 12 mg/100 kJ	☒ Codex FUF std 90 mg/100 kcal 22 mg/100 kJ

INC supports alignment with CODEX STAN 156-1987 on the basis that follow up formula is the main source of calcium in the older infants' diet. As well, older infants consume lower amounts of formula than younger infants and the calcium level in follow up formula should be comparably higher than in infant formula.

Guiding upper level

☐ Codex IF std 140 mg/100 kcal 35 mg/100 kJ	☒ Codex FUF std 180 mg/100 kcal 43 mg/100 kJ

INC supports alignment with CODEX STAN 156-1987 and a GUL of 180 mg for the same reasons as set out above: that follow up formula is the main source of calcium in the older infants' diet. As well, older infants consume lower amounts of formula than younger infants and the calcium level in follow up formula should be comparably higher than in infant formula.

No consensus was reached on the requirements for phosphorous for Follow-up Formula composition.

Phosphorous

Unit	Minimum	Maximum	GUL
mg/100 kcal	[25] [60]	-	[100] [120] [N.S.]
mg/100 kJ	[6] [14]	-	[24] [29] [N.S.]

Minimum

☐ Codex IF std 25 mg/100 kcal 6 mg/100 kJ	☒ Codex FUF 60 mg/100 kcal 14 mg/100 kJ

INC supports alignment with CODEX STAN 156-1987 and a minimum of 60 mg.

Follow up formula is one of the main sources of phosphorous in the older infants' diet. As older infants consume lower amounts of formula than younger infants, the phosphorus level in follow up formula should be higher than in infant formula.

Guiding upper level

Do you consider that calcium and phosphorous ratios are taken into account when establishing a GUL? For example if the maximum calcium content is increased, should the phosphorous content also be extended?

☐ Yes	☐ No

INC does not support a GUL for phosphorus on the basis that the calcium:phosphorous ratio is the more significant aspect for phosphorous.

However, if a GUL for phosphorous is set then it would need to take account of the less efficient phosphorus absorption from soy protein isolate and the importance of maintaining the calcium:phosphorous ratio.

Should the ratio for calcium-to-phosphorous included in the Codex Standard for Infant Formula be included?
Ratio calcium/phosphorous

Min	Max
1:1	2:1

☒ Yes	☐ No

INC considers that a ratio is needed to keep a calcium-phosphorus balance in the product and would prefer that such a statement was included in the standard rather than being reflected in a footnote. Such an approach would be consistent with the treatment of the ratio in CODEX STAN 72-1981 (Rev 2007).

Should a footnote be attached to the GUL for phosphorous indicating its applicability to formula containing soy protein isolate?
[18)] This GUL should accommodate higher needs with soy formula

☒ Yes	☐ No

INC agrees a footnote would be helpful.

Sodium, chloride & potassium

No consensus was reached on the minimum or maximum requirements for sodium for Follow-up Formula composition.

Sodium

Unit	Minimum	Maximum	GUL
mg/100 kcal	[20] [25]	[60] [85]	-
mg/100 kJ	[5] [6]	[14] [21]	-

Minimum

☒ Codex IF std 20 mg/100 kcal 5 mg/100 kJ	☐ EFSA 25 mg/100 kcal 6 mg/100 kJ

INC prefers alignment with CODEX STAN 72-1981 (Rev 2007), a position that is also aligned with the ENA Guideline for follow-up formula. However, INC could support no minimum being set if this was the eWG's majority preference.

Maximum

☒ Codex IF std 60 mg/100 kcal 14 mg/100 kJ	☐ Codex FUF std 85 mg/100 kcal 21 mg/100 kJ	☐ Calculated based on max protein compositional requirement

INC supports alignment with CODEX STAN 72-1981 (Rev 2007). This level is also aligned with the ENA Guideline for follow-up formula.

No consensus was reached on the minimum requirements for chloride for Follow-up Formula composition.

Chloride

Unit	Minimum	Maximum	GUL
mg/100 kcal	[50] [60]	[160]	-
mg/100 kJ	[12] [14.3]	[38]	-

☒ Codex IF std 50 mg/100 kcal 12 mg/100 kJ	☐ EFSA 60 mg/100 kcal 14.3 mg/100 kJ

INC supports alignment with CODEX STAN 72-1981 (Rev 2007). This level is also aligned with the ENA Guideline for follow-up formula.

No consensus was reached on the minimum requirements for [potassium?] ~~chloride~~ for Follow-up Formula composition.

Potassium

Unit	Minimum	Maximum	GUL
mg/100 kcal	[60] [80]	[180]	-
mg/100 kJ	[14] [19.1]	[43]	-

☒ Codex IF std 60 mg/100 kcal 14 mg/100 kJ	☐ EFSA 80 mg/100 kcal 19.1 mg/100 kJ

INC supports alignment with CODEX STAN 72-1981 (Rev 2007). This level is also aligned with the ENA Guideline for follow-up formula.

If you propose to adapt the maximum sodium, chloride and potassium composition on the maximum protein composition, please specify how this would achieved.

INC suggests the maximums in CODEX STAN 72-1981 (Rev 2007) be multiplied by 3.5/3 based on a maximum protein level of 3.5g/100kcal.

Manganese

No consensus was reached on the minimum requirements for manganese for Follow-up Formula composition.

Manganese

Unit	Minimum	Maximum	GUL
µg/100 kcal	[1] [N.S.]	-	[100]
µg/100 kJ	[0.25] [N.S.]	-	[24]

Do you support the establishment of a minimum requirement for manganese?

☐ 1 µg /100 kcal 0.25 µg /100 kJ	☒ N.S.

INC does not support a minimum or a GUL. The technological issues that would need to be explored if a minimum was set would include whether fortification would be required to meet the minimum. While our preference is that no limits be set for manganese, INC suggests that in the interests of progressing, Australia and New Zealand go with the eWG majority in relation to limits for manganese.

Do you support the establishment of a GUL for manganese of 100 µg/100 kcal

☐ Yes	☒ No

INC does not support the setting of a GUL. As with the minimum, while our preference is that no limits be set for manganese, INC suggests that in the interests of progressing, Australia and New Zealand go with the eWG majority in relation to limits for manganese.

Iodine

No consensus was reached on the iodine requirements for Follow-up Formula composition. Please provide scientific rationale to support your preferred value:

Iodine

Unit	**Minimum**	**Maximum**	**GUL**
µg/100 kcal	[10] [15]	[29] [50] [60]	[29] [50] [60]
µg/100 kJ	[2.5] [3.6]	[7] [12] [14]	[7] [12] [14]

Minimum

☒ Codex IF std 10 µg /100 kcal 2.5 µg /100 kJ	☐ EFSA 15 µg /100 kcal 3.6 µg /100 kJ

INC supports alignment with CODEX STAN 72-1981 (Rev 2007). This level is also aligned with the ENA Guideline for follow-up formula.

Upper limit

Should a Maximum or Guiding Upper Level be established?

At what level should this be set?

☐ Maximum	☒ GUL	
☒ 60 µg /100 kcal 14 µg /100 kJ	☐ 50 µg /100 kcal 12 µg /100 kJ	☐ 29 µg /100 kcal 7 µg /100 kJ

INC supports a GUL as this provides alignment with CODEX STAN 72-1981 (Rev 2007). This level is also aligned with the ENA Guideline for follow-up formula.

Selenium

No consensus was reached on the selenium minimum requirements for Follow-up Formula composition. Please provide scientific rationale to support your preferred value:

Selenium

Unit	**Minimum**	**Maximum**	**GUL**
µg/100 kcal	[1] [3]	-	9
µg/100 kJ	[0.24] [0.72]	-	2.2

Minimum

☒ Codex IF std 1 µg /100 kcal 0.24 µg /100 kJ	☐ EFSA 3 µg /100 kcal 0.72 µg /100 kJ

INC supports alignment with CODEX STAN 72-1981 (Rev 2007). However, INC notes that the science in this area has been evolving and that higher levels could be accommodated with the minimum set at 1 µg /100 kcal.

Copper

No consensus was reached on the copper requirements for Follow-up Formula composition. Taking into account the scientific rationale of the establishment Please provide your

Copper

Unit	**Minimum**	**Maximum**	**GUL**
µg/100 kcal	[35] [60]	-	[120] [250]
µg/100 kJ	[8.5] [14.3]	-	[29] [60]

Minimum

☒ 35 µg /100 kcal 8.5 µg /100 kJ	☐ 60 µg /100 kcal 14.3 µg /100 kJ

INC supports alignment with CODEX STAN 72-1981 (Rev 2007).

Upper limit

☐ GUL 120 µg /100 kcal 29 µg /100 kJ	☒ GUL 250 µg /100 kcal 60 µg /100 kJ

INC supports a GUL of 250 µg /100 kcal on the basis that this would be the resultant intake from follow-up formula with an UL of 1000 µg /d with 700 kcal. This reflects the IEG recommendation.

Inclusion of the footnote:
Adjustment may be needed in these levels for ~~infant~~ formula made in regions with a high content of copper in the water supply

☐	Yes	☒	No

INC does not support a footnote on the basis that copper toxicity is not an issue for older infants.

Zinc

The eWG consistently supports establishing a minimum zinc content of 0.5 mg/100 kcal.
In establishing an upper limit for zinc,

Zinc

Unit	**Minimum**	**Maximum**	**GUL**
mg/100 kcal	0.5	[1.25] [1.5]	[1.25] [1.5]
mg/100 kJ	0.12	[0.3] [0.36]	[0.3] [0.36]

Should a maximum or GUL be established?

☐ Max	☒ GUL

Should the upper limit be set at 1.5 mg/100 kcal or 1.25 mg/100 kcal?

☒ 1.5 mg/100 kcal 0.36 mg/100 kJ	☐ 1.25 mg/100 kcal 0.3 mg/100 kJ

INC supports a GUL of 1.5 mg/100 kcal as this provides alignment with CODEX STAN 72-1981 (Rev 2007) and with the ENA Guideline for follow-up formula (recommendation and rationale).

Should separate minimum and maximum/GUL levels be established for soy protein isolate formulas?	
☒ Yes, for minimum but not for maximum/GUL	☐ No
Even though there may be less efficient zinc absorption from soy protein isolate formulas, higher levels of zinc intake could impact on the absorption of copper (Lonnerdal 1984) and therefore recommending a separate upper level of zinc for soy formula may not be ideal. INC considers that the proposed upper level for zinc for all follow up formulas should account for any additional needs for soy formula.	

Other substances

Choline, myo-inositol, L-carnitine			
No consensus was reached on the addition of choline to Follow-up Formula. **Choline** **Unit** / **Minimum** / **Maximum** / **GUL** mg/100 kcal: [7] [-] / - / [50] [150] mg/100 kJ: [1.7] [-] / - / [12] [36]			
Should the addition be:			
☐ Mandatory. Min: 7 mg/100 kcal 1.7 mg/100 kJ	☐ Not specified in the std	☒ Optional with GULs Min: - -	
The increasingly diversified diet of the older infant should already provide these nutrients and, unlike infant formula, follow up formula is not a sole source of nutrition. The standard should state that the addition of choline, myo-inositol and L-carnitine can be added voluntarily.			
If you support either mandatory addition or the optional addition with a specified GUL, what GUL do you support?			
☐ Codex IF std GUL: 50 mg/100 kcal 12 mg/100 kJ	☒ IEG 2013 GUL: 150 mg/100 kcal 36 mg/100 kJ		
As noted above, the standard should state that the addition of choline, myo-inositol and L-carnitine can be added voluntarily.			

No consensus was reached on the addition of myo-inositol to Follow-up Formula.

Myo-inositol

Unit	Minimum	Maximum	GUL
mg/100 kcal	[4] [-]	-	[40] [-]
mg/100 kJ	[1] [-]	-	[9.5] [-]

☐ Mandatory Min: 4 mg/100 kcal 1 mg/100 kJ GUL: 40 mg/100 kJ 9.5 mg/kJ	☐ Not Specified in the std	☒ Optional with GULs Min: - - GUL: 40 mg/100 kJ 9.5 mg/kJ

The increasingly diversified diet of the older infant should already provide these nutrients and, unlike infant formula, follow up formula is not a sole source of nutrition.

As noted above, the standard should state that the addition of choline, myo-inositol and L-carnitine can be added voluntarily.

No consensus was reached on the addition of L-carnitine to Follow-up Formula.

L-Carnitine

Unit	Minimum	Maximum	GUL
mg/100 kcal	[1.2] [-]	-	-
mg/100 kJ	[0.3] [-]	-	-

☐ Mandatory Min: 1.2 mg/100 kcal 0.3 mg/100 kJ	☐ Not Specified in the std	☒ Specified in section 3.2 Optional ingredients

The increasingly diversified diet of the older infant should already provide these nutrients and, unlike infant formula, follow up formula is not a sole source of nutrition.

As noted above, the standard should state that the addition of choline, myo-inositol and L-carnitine can be added voluntarily.

Optional ingredients

Do you support incorporating the provisions within 3.2.3 & 3.2.4 of the Infant Formula Standard into the Follow-up Formula Standard for product for older infants?

INC supports the proposal. This is on the basis that

- optional ingredients be permitted where the safety and suitability for the particular nutritional use of an ingredient in products for older infants has been evaluated and established by generally accepted scientific evidence
- guidance from recognised scientific expert groups is taken into consideration when ingredients are introduced into product for older infants.
- there is alignment of the any proposed optional ingredient clause with clauses 3.2.1-3.2.3 of CODEX STAN 72-1981(Rev.2007) with appropriate amendments as suggested above to take the specificity of the older infant target population into account
- optional ingredients need to provide a beneficial effect as demonstrated by generally accepted scientific evidence and can be, but do not need to be, present in breast milk
- scientific evaluation based on the proposed established principles conducted in other countries or related prescriptive regulation should be recognised to facilitate lead times in bringing innovative products to market and reduce regulatory burden.

While INC does not support a positive list of optional ingredients, it could support such a list if such a list was clearly preceded by a statement that "the following list is NOT an exclusive list of optional ingredients". The INC's recommendation relating to DHA was premised on there not being a positive list. This position would need reconsideration if a positive list was to proceed. The same would be required in relation to the recommendations relating to Choline, myo-inositol and L-carnitine.

The revised CODEX STAN 156-1987 should also state that if ingredients and substances are scientifically assessed and approved for use in infant formula for more vulnerable infants (0-6 months), these same ingredients and substances do not require separate assessment and approval for use in follow up formula for older infants and young children.

If yes, should the same minimum, maximum and GULs be aligned with the Infant Formula Standard for product for older infants, or should these be reviewed?

INC only supports a list that is clearly preceded by the statement that the list is NOT an exhaustive list.

Maximum, minimum or GULs should be aligned with CODEX STAN 72-1981(Rev.2007).

Based on eWG responses the Chairs propose the following for your consideration. Please comment on the following for the addition of optional ingredients to follow-up formula for older infants and provide justification and rationale for your responses:

Taking into account eWG responses to include the reference not only to vitamins and minerals, but other ingredients; and to take into consideration wording drafted in Section 2 Description.

3.3.2.1 In addition to the **[compositional requirements]** ~~vitamins and minerals~~ listed under 3.2.4 to 3.2.6, other ~~nutrients~~ [**ingredients]** may be added when required to ensure that the product is suitable to form part of [a mixed feeding scheme] OR [**progressively diversified diet**] OR [**complementary diet**] intended for use from ~~the~~ 6th month**s** on.

Please comment on all wording in square brackets

INC supports some of the proposed amendments as follows:

> "3.3.2.1 In addition to the compositional requirements ~~listed~~ under 3.2.4 to 3.2.6, other ingredients **or substances** may be added ~~**when required**~~ to ensure that the product is suitable to form part of **an increasingly** diversified diet.

The inclusion of the term 'substances' ensures a breadth of coverage that would otherwise be limited. The deletion of 'when required' would seem to require additional justification where this is not necessary. The term 'increasingly' is consistent with the INC's recommendations earlier in this submission.

Taking into account eWG responses to align with the principles contained within the Codex Infant Formula standard 3.2.2, and that concept that the ingredient does not necessarily need to be present in breast milk, the following wording is proposed in square brackets:

3.2.2.2 [The suitability for the particular nutritional uses of [older] infants and the safety of these substances shall be scientifically demonstrated. The formula shall contain sufficient amounts of these substances to achieve the intended effect~~, taking into account levels in human milk~~.]

Please comment on all wording in square brackets

INC supports the proposed text with the following amendment to streamline :

> "3.3.2.2 The suitability **and safety** for the particular nutritional **use in products for** older infants **(> 6-12 months)** ~~and the safety of these substances~~ shall be scientifically demonstrated as part of an **increasingly diversified**~~complementary feeding diet; the safety of these ingredients/ substances shall be scientifically demonstrated~~ at the level of use."

As noted above, the revised CODEX STAN 156-1987 should also state that if ingredients and substances are scientifically assessed and approved for use in infant formula for more vulnerable infants (0-6 months), these same ingredients and substances do not require separate assessment and approval for use in follow up formula for older infants and young children.

PROCESS TO REVIEW THE ESSENTIAL COMPOSITION OF FOLLOW-UP FORMULA FOR YOUNG CHILDREN (12-36 MONTHS)

Flexibility

Several eWG members stated that flexibility in the composition of products for young children was important due to the increased contribution of complementary foods to the diversified diet of young children.
Do you support an approach where not all nutrients or substances that have compositional requirements established for older infants are mandated for addition to follow-up formula for young children?

☒ Yes	☐ No

INC supports the proposal where not all nutrients or substances that have compositional requirements established for older infants are mandated for addition to follow-up formula for young children.

Young children start having an increasingly diversified diet and consume a wider variety of food groups as their key source of nutrition. As a result, the composition of follow up formula for young children can safely be less prescriptive than the composition for follow up formula for older infants. This increased flexibility reflects the different roles that such products play in the diet of the developing older infant/young child.

Do you support an approach that can encompass the views of the majority of the eWG in that the compositional requirements established for older infants can be used as a basis for the composition of product for young children, in addition to ensuring that milk based drinks can be considered within the compositional requirements for this age group? Please provide your comments.

☒ Yes	☐ No

INC supports the compositional requirements of follow up formula for older infants serving as a basis for the compositional requirements of follow up formula for younger children, but most importantly, with the necessary adjustments to further adapt it to the different nutritional requirements of the child as the child grows up and consumes an increasingly diversified family diet.

As follow up formula is often used as a substitute for cows' milk for young children (Ghisolfi 2012, Alexy & Kersting, 2003), the beneficial nutrients that are part of cows' milk should be considered. Compositional requirements must be flexible enough to include both highly formulated products and those that are predominately based on cows' milk with addition of the key nutrients.

Are there other elements of flexibility that should be considered in the development of compositional requirements for follow-up formula for young children?

INC considers that the compositional requirements for follow up formula for young children should be flexible enough to address the nutrients that are key in the young child's diet and that is not otherwise provided by solid food. Moreover, the composition has to take into account the nutrients that are provided by cows' milk such as Ca, A, B6, B2 and B12 D.

There must also be flexibility in energy for the follow up formula for young children compared to the energy levels required for the follow up formula for older infants.

Key nutrients

Several eWG members referred to the findings of the 2014 eWG report on key nutrients for which there is evidence of inadequate intakes/status in the target population. Globally, iron and the quality of dietary fat were consistently found to be inadequate in sub-groups of the target population.

Do you consider that minimum compositional requirements for iron and fat quality will be required for product targeted to young children?

INC considers that scientifically based minimum compositional requirements for iron and fat quality (in particular unsaturated fat) are required for a product targeted to young children.

Studies have shown that young children might have insufficient intakes of some nutrients such as iron and fatty acids etc. Therefore, follow up formula for young children should have specific minimum requirements for iron and fat quality.

Several eWG members referred to the findings of the 2014 eWG report and stated that the requirements should be flexible enough to provide a source of the nutrients identified to be lacking in several countries internationally: α-linolenic acid (ALA), docosahexanoic acid (DHA), vitamin A and D, calcium, zinc and iodine.

Do you consider that minimum compositional requirements for these nutrients should be required to ensure the nutritional integrity of product targeted to young children?

INC considers that minimum compositional requirements in intakes for unsaturated fatty acids (LA, ALA), some vitamins (vitamin A and D), zinc, iodine and iron etc are important.

Calcium (contained in cows' milk) should have a minimum in follow up formula for young children.
INC does not consider it necessary to set minimum mandatory compositional requirements for DHA and ARA. The addition of ARA should not be linked to DHA. Please see our earlier comments on DHA and the importance of restrictions on EPA as the same applies for young children.

Do you consider that maximum compositional requirements for these nutrients should be required to ensure the nutritional integrity of product targeted to young children?
INC considers that scientifically based upper limits (maximums or GULs) for these nutrients could be established for follow up formula for young children in order to avoid safety risks related to high intakes of certain nutrients. These can be based on an acceptable macronutrient distribution range for fatty acids or a tolerable safety limit for micronutrients. Where a tolerable safety limit is set for this group, then this needs to be taken into account for any upper limits.

Nutritional integrity
At a global level, what compositional parameters are considered important to mandate to ensure the nutritional integrity of product for the young child age group? (Consideration could be given to macronutrient and/or micronutrient requirements)
INC considers that the balance of protein, carbohydrate and fat in the context of total energy needs to be carefully considered with regard to the dietary intake of young children. Limits applied should provide sufficient flexibility that the balance of these components in cows' milk falls within the permitted ranges. In particular, it is important to take account of the inadequate intakes that are already reported of unsaturated fatty acids, vitamins A and D, and minerals Zinc, Iodine, Iron etc. In relation to Iron, account would need to be taken of vitamin C intakes. It is also important to consider that cows' milk, is the main source for calcium, phosphorus and vitamins B6, B2, and B12 in the young child's diet and should be taken as a reference for this composition parameter. Cows' milk protein quality can also be taken as a reference for this age group.
Do you consider that nutritional equivalence to products that follow-up formula may replace is required? If so, please specify, what nutrients should be equivalent, and comment whether their addition should be mandatory or voluntary?
We believe that follow up formula for young children should seek nutritional equivalence to certain nutrients in products it might replace. In this respect, reference should be made to the particular nutritional properties of cows' milk that are important contributors to intake of such nutrients in the young child's diet, particularly levels of calcium, riboflavin (vitamin B2), vitamin B12, vitamins A, D, zinc, and the quality of dairy protein. As follow up formula for young children may be used to replace cow's milk, it is important that mandatory minimums of certain nutrients present in cow's milk are included in the revised standard.
The eWG highlighted that consideration of the safety and suitability of nutrients and other substances, added to follow-up formula for young children is necessary and several proposed that the essential composition of follow-up formula for older infants should be used as a starting point. If a nutrient or other substance is added to follow-up formula (whether mandatory or voluntary), what are your views on the minimum and maximum levels of addition being consistent with the levels in follow-up formula for older infants?
The minimum and upper levels of follow up formula for young children should be based on the levels used for older infants, adapted to the reference daily intake and the safety limits required for follow up formula for young children (which sometimes differs from the ones in older infants). They should also respect the safe maximum levels and the standards for follow up formula for young children.

OTHER ISSUES TO BE CONSIDERED

INC suggests that the following two issues warrant further consideration by the eWG in addition to those matters identified in the consultation paper.

Conversion factors

INC has undertaken a review of the requirements specified per 100kcal and per 100kJ for major macronutrients and a range of vitamins in minerals in CODEX STAN 156-1987, and in relevant standards from the US FDA and EU, and in the Australia New Zealand Food Standards Code. This review identified that there is significant inconsistency in the energy conversion factor calculated by dividing the per kJ requirement specified by the per 100kcal requirement specified. INC suggests that this inconsistency could be reduced by stating the conversion factor that is applied directly within the standard, for example,

> 'The conversion factors for joules and calories are: 1 kJ = 0.239 kcal; and 1 kcal = 4.184 kJ'.

We note that the provision in CODEX STAN 156-1987 at clause 2.1.4 states (in relation to the definition of calorie) that:

> "…1 kilojoule (kJ) is equivalent to 0.239 calories (kcal)."

A similar provision is included in CODEX STAN 73-1981 for canned baby food at clause 2.3.

Some of the inconsistencies observed may be due to other factors such as inconsistent rounding of values or inconsistencies regarding the number of significant places used. INC would like to draw attention to this issue and suggests that strategies are developed and implemented within the revised CODEX STAN 156-1987 which provide leadership in this area to promote greater global harmonisation in the future.

Trade, ingredient supply and technical issues

Industry has a responsibility to identify and inform the consultation process regarding trade, ingredient supply and technical issues that have the potential to impact on the implementation and/or technical viability of new standards. INC has raised a number of issues of this nature within this submission including:

- Trade issues which will arise if the permitted range for protein for follow up formula for older infants is set such that it is mutually exclusive from the current permitted protein range for follow up formula. INC seeks recognition of the significance of this issue and strongly advocates that it is included in the considerations for setting the maximum protein level for follow up formula for older infants.
- Alternative sources of DHA. Since the cheapest source of supply of DHA is fish oil with EPA levels significantly higher than DHA (as used in adult supplements), INC recommends that there is a restriction placed on the level of EPA where DHA is added.
- Also from a trade/supply perspective, it is important that there is an acceptable alternative to lactose as the preferred carbohydrate for follow up formula for older infants. This is reflected in INC's responses in the carbohydrate section. Glucose polymers, if not stated as a preferred carbohydrate, still need to be accepted as an alternative and to be able to be used without restriction.
- The technical feasibility of compliance with specified limits especially within minimum-upper level ranges, must be taken into account.

These types of issues need to be considered alongside scientific and nutritional considerations to ensure that revised provisions of the follow up formula standard can be practically implemented and to minimise the risk of unintended consequences once implemented.