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

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

INFANT NUTRITION COUNCIL AUSTRALIA NEW ZEALAND RESPONSE

13 June 2016

ESSENTIAL COMPOSITION OF FOLLOW-UP FORMULA FOR OLDER INFANTS (6-12 MONTHS)

Note: INC has commented in this section on several vitamins and minerals but would highlight that the comments concerning Zinc are of most importance.

Protein

Protein

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

Protein

Unit	**Minimum**	**Maximum**	**GUL**
g/100 kcal	[1.8] or [1.65]	[3.5] or [3.0] or [2.5]	-
g/100 kJ	[0.43] or [0.39]	[0.84] or [0.72] or [0.60]	-

Minimum

Codex Infant Formula Standard 1.8 g /100 kcal 0.43 g /100 kJ	☒ 1.65 g /100 kcal 0.39 g /100 kJ

As noted previously by INC, protein requirements have been recently estimated to be lower than previous estimates primarily as a result of changes in the reference body weights used. Additionally several dietary surveys of protein intakes in older infants (6-12 months) have identified that average protein intakes are adequate and above minimum requirements for the majority of this age group.

In addition the lower level takes into account that essential amino acids can be delivered at this protein level. The amino acid profile for 6-12 months that should be adopted is that based on the profile of amino acids in breast milk.

Based on the totality of data, and in particular new data, INC continues to support adoption of a lower minimum protein level of 1.65 g/100 kcal be adopted.

As has previously been suggested, a footnote should accompany the protein level, to ensure that low protein levels are scientifically substantiated, and, when needed, clinically evaluated.

The full justification and references were provided in the INC response to CP1 2016 in April 2016.

Maximum

☒ 3.5 g /100 kcal 0.84 g /100 kJ	Codex IF std 3.0 g /100 kcal 0.72 g /100 kJ	EFSA 2.5 g /100 kcal 0.60 g /100 kJ

INC continues to support a maximum protein level of 3.5 g/100 kcal on the basis that no new scientific evidence regarding protein requirements and upper safe protein intake levels has become available since the 37th session of CCNFSDU. We refer to previously submitted comments in support of the scientific and general substantiation of a maximum protein level of 3.5 g/100 kcal.

Footnote 3
Refers to the requirements of essential and semi-essential amino acids in follow-up formula:
[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 and the concentrations of methionine and cysteine may be added together.
At present the draft standard does not contain an Annex I, please indicate whether you support inserting Annex I of the Codex Standard for Infant Formula of if you consider that further work is required.

insert Annex I (or refer) to the Codex Standard for Infant Formula	☒ review the levels contained within the Codex Standard for Infant Formula <u>for application for FuF for older infants.</u>

Including reference to the essential and semi-essential amino acids in follow-up formula is important and defining the minimum levels for amino acids using the amino acid composition of breast milk as a reference would address this.

Annex I of Codex STAN 72-1981 describes the levels of essential and semi-essential amino acids expressed per g of nitrogen from each study and derives from this the per g of protein and per 100kcal expressions for a minimum protein level of 1.8g/100kcal. INC suggests a similar approach for follow-up formula but applying the minimum set for follow-up formula for older infants.

Footnote 6
The majority of the eWG supported retaining elements of footnote 6.
[[6)]Follow-up formula based on ~~non-hydrolysed~~ **intact** milk protein containing [~~less than 2~~ 1.65 to 1.8 g protein/100 kcal] and follow-up [formula based on hydrolysed protein [containing less than 2.25 g protein/100 kcal] should be clinically evaluated

Regarding formulas based on **hydrolysed** protein, please state whether you think that all, or only those containing less than [2.25 g/100 kcal] should be clinically evaluated.

☐ All formulas based on hydrolysed protein should be clinically evaluated	☒ Formulas based on hydrolysed protein containing less than 2.25 g/100 kcal should be clinically evaluated

If formula has already been assessed for 0-6 months then it should not need further assessment for 6-36 months.

Regarding formulas based on **intact/non-hydrolysed** protein please note that your responses to these questions do not imply that you support a minimum of 1.8 g/100 kcal or 1.65 g/100 kcal. They will be used to refine the wording in square brackets if the eWG cannot come to agreement on a minimum value.

Please state whether you support the proposal to amend the reference these types of formulas to **intact milk protein**.

☐ intact milk protein	☒ non-hydrolysed milk protein

To align with Codex STAN 71-1981 rev 2007

Regardless of the minimum protein level agreed to in Section 3.1, do you think that clinical evaluation would be required for any formulas based on intact/non-hydrolysed milk protein?

☒ Yes, all formulas containing 1.65-1.8 g/100 kcal require clinically evaluation	Yes, all formulas containing 1.65-2.0 g/100 kcal require clinically evaluation	no requirements for clinical evaluation of non-hydrolysed formulas would be required at 1.65-1.8 g/100 kcal

This is aligned with the approach taken in the Codex STAN 72-1981.

If the eWG and Committee supported adoption of a minimum of 1.65 g/100 kcal for formula based on

intact/non-hydrolysed milk protein, do you support the recommendation that the minimum protein level which requires clinical evaluation is placed in the footnote, rather than in the table? See ***Table 5*****Error! Reference source not found.** above	
☐ Yes	☒ No

Vitamin K

Vitamin K

The Chairs propose that the following drafting of vitamin K requirements for follow-up formula for older infants is recommended for adoption by the Committee:

Vitamin K

Unit	Minimum	Maximum	GUL
mg/100 kcal	4	-	27
mg/100 kJ	1	-	6.5

INC supports a minimum vitamin K level at 4 mg/100 kcal based on the totality of scientific data available to date regarding safety of use and nutritional suitability and a GUL of 27 mg/100 kcal

The nutritional suitability and safety of use of this minimum vitamin K level (4 mg/100 kcal) for follow-up formulas for older infants was most recently substantiated by the ENA proposal for the compositional requirements for follow-up formula for older infants (Koletzko, 2013).

References

Koletzko B, Bhutta ZA, Cai W, *et al.* (2013) Compositional requirements of follow-up formula for use in infancy: recommendations of an international expert group coordinated by the Early Nutrition Academy. *Annals of Nutrition and Metabolism*, 62:44–54.

Vitamin C

Vitamin C

No eWG consensus was reached on the establishment of a minimum vitamin C value. Based on the eWG responses, please provide 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 Taking a precautionary approach and aligned with the Codex Infant Formula Standard	☒ EFSA 4 mg/100 kcal 0.96 kJ/100 kcal Based on vitamin C requirement levels established by EFSA, taking into account that complementary foods are consumed from six months.

INC continues to support a minimum vitamin C level at 4 mg/100 kcal based on the totality of scientific data available to date regarding safety of use and nutritional suitability.

The nutritional suitability and safety of use of a minimum vitamin C level at 4 mg/100 kcal for follow-up formulas for older infants was most recently substantiated by the EFSA assessment of vitamin C compositional requirements for follow-on formulas in the European Union (i.e., follow-up formula for older infants) which established the minimum level at 4 mg/100 kcal (EFSA, 2014).

References:

EFSA (2014) Scientific opinion on the essential composition of infant and follow-on formulae. *EFSA Journal*, 12(7):3760.

Zinc

Zinc

Based on the views of the eWG and evidence provided, the Chairs propose the following drafting of zinc requirements for follow-up formula for older infants is recommended for adoption by the Committee

Zinc

Unit	Minimum	Maximum	GUL
mg/100 kcal	0.5	-	1.5
mg/100 kJ	0.12	-	0.36

[20)] For Follow-up formula based on soy protein isolate a minimum value of 0.75 mg/100 kcal (0.18 mg/100 kJ).

INC supports a higher GUL for zinc of 1.5 mg/100 kcal based on ISDI's final Technological Feasibility Report in relation to managing the maximum proposed zinc level supports an increase in the proposed GUL for zinc from 1.0 to 1.5 mg/100 kcal.

The final ISDI Technological Feasibility Report concerning zinc levels in follow-up formula for older infants supported an increased GUL of zinc from 1.0 to 1.5 mg/100 kcal. Setting the GUL for zinc at 1.5 mg/100 kcal is supported by data of the history of safe use and is aligned with the GUL for zinc provided for in the Codex Standard for Infant Formula (Codex STAN 72-1981).

Additionally, a GUL of 1.5 mg/100 kcal is aligned with the proposal for the nutritional composition of follow-up formula for older infants as established by the International Expert Group coordinated by the Early Nutrition Academy (Koletzko, 2013), which was based on the totality of data regarding safety and nutritional suitability for zinc in older infants.

References:

ISDI - CRD 11 (2015) Review of the standard for follow-up formula (Codex STAN 156-1987) – Comments of ISDI.

ISDI Report (2016) Technological aspects relating to the establishment of nutrient ranges in follow-up formula for older infants (6-12 months) (Codex STAN 156 – 1987). 17 February 2016.

Koletzko B, Bhutta ZA, Cai W, *et al.* (2013) Compositional requirements of follow-up formula for use in infancy: recommendations of an international expert group coordinated by the Early Nutrition Academy. *Annals of Nutrition and Metabolism*, 62:44–54.

Optional Ingredients: DHA

Docosahexaenoic acid (DHA)

No consensus was reached on the need for a minimum level, as a compromise could you accept that a statement is included in the footnote stating that national authorities can establish minimum requirements for the optional addition of DHA at their discretion.

Docosahexaenoic acid[21)]

Unit	Minimum	Maximum	GUL
% fatty acids	[-] or [0.3]	-	0.5

[21)] If docosahexaenoic acid (22:6 n-3) is added to follow-up formula, arachidonic acid (20:4 n-6) contents should reach at least the same concentration as DHA. The content of eicosapentaenoic acid (20:5 n-3), which can occur in sources of LC-PUFA, should not exceed the content of docosahexaenoic acid. Competent national and/or regional authorities may deviate from the above conditions, as appropriate for the nutritional needs.

☒ Yes	No

INC's comments for CP1 2016 recognised the reality that national authorities have established minimum levels for DHA to be added to follow-up formula for older infants when scientifically substantiated to support the nutritional needs. INC reiterates its position regarding the non-mandatory addition of ARA when DHA is added, which is to be appropriately reflected in the footnote. INC therefore supports referring

consideration of minimum levels to national authorities in a footnote.

Due to the global variability of dietary DHA intakes, it remains challenging to establish a global recommendation for a minimum DHA level in Codex STAN 156-1987 for older infants.

INC concludes that no minimum DHA level should be set and supports a footnote that consideration for a minimum level for DHA be referred to national authorities.

Optional Ingredients: L(+) lactic acid producing cultures

Optional addition L(+) lactic acid producing cultures		
[3.3.2.4 Only L(+) lactic acid producing cultures may be used]		
Several eWG members noted there are two purposes for the addition of L(+) lactic acid producing cultures referring to both the acidification of formula and supplementation with probiotics. Please indicate if you consider that the sub-Section 3.3.2.4 (Optional ingredients) should refer to one, or both types of addition.		
☒ Two purposes: acidification of formula **and** supplementation with probiotics probiotics (with clarification that the standard rather than specifically sub-section 3.3.2.4 should allow for both these purposes)	☐ For the purpose of acidification of formula **only**. Contains minimal amounts of viable bacteria.	☐ For the purpose of supplementing with probiotics **only**
Where used for acidification, L(+) lactic acid cultures are inactivated during the production process and are a food additive from a Codex perspective (or a processing aid depending on definitions applied in national legislation). So saying, given the different interpretations of the current 3.3.2.4 in Codex STAN 156-1987, and apparent from the feedback received by the eWG on this topic, it could be helpful to clarify this in section. Refer to the comments to next question. Where used for supplementation of product with viable organisms, the addition is for the purpose of conferring other outcomes that may be broadly categorised as 'for a nutritional purpose' and fits within the framework for optional ingredients.		
If you consider that standard should allow for both types of addition, please indicate if you think that this should be captured within 3.3.2.4, or as two separate clauses within the Optional Ingredients Section (Section 3.3.2).		
INC considers that the standard should allow for both types of addition: for the purpose of acidification or for other purposes following the principles for optional ingredients specified in 3.2.1 and 3.2.2. INC recommends careful consideration is given to the structure of the final standard so that it provides clarity around nutritional supplementation versus acidification functions. With respect to Codex STAN 156-1987: Section 3 of Codex STAN 156-1987 covers Essential Composition and Quality factors. Section 3.2 covering Optional Ingredients falls within this and should be limited in scope to nutritional and quality factors. Ingredients added as food additives should not be included here. Section 4 deals with Food Additives. While this section is outside the Terms of Reference for the current eWG, it should be noted that sub-section 4.3 covering pH adjusting agents lists both 4.3.10 L (+) lactic acid and 4.3.11 L (+) lactic acid producing cultures. INC considers that this provision for use of L (+) lactic acid producing cultures should be retained and that this is the most appropriate place in Codex STAN 156-1987 to cover this pH adjustment function (or the General Standard for Food Additives, Codex STAN 192-1995 if the permissions in this section are moved to this horizontal standard). INC further considers that this same food additive provision for use of L (+) lactic acid producing cultures should be added Codex STAN 72-1981 as a technical correction at the same time as the conversion factor errors detected in this Standard are corrected or alternatively added to the Codex General Standard for Food Additives STAN 192-1995, for infant formula One option is that 3.3.2.4, currently in square brackets, remains in Codex STAN 156-1987 for the sake of consistency and with Codex STAN 72-1981 clause 3.2.4. If this option is pursued INC recommends that it		

is amended as follows: "~~Only~~ L(+) producing lactic acid cultures may be used." The deletion of the word 'only' is recommended as it is not included in clause 4.3.11. An alternative option would be to amend this clause 3.3.2.4 to state that strains added must meet all the criteria set-out in 3.3.2.1 and 3.3.2.2 with the exception of cultures added for the purpose of acidification that are inactivated during production.
Based on your response above, and considering that principles for optional addition of ingredients (3.3.2.1 and 3.3.2.2) apply, do you consider that any of the following additional concepts need to be included in any proposed amended wording, please tick all that apply.
☐ The safety and suitability of the addition of strains shall be demonstrated by generally accepted scientific evidence ☐ Follow-up formula prepared ready for consumption must contain significant amounts of the viable bacteria ☐ For the purpose of producing acidified formulas ☐ Non-pathogenic lactic acid cultures may be used **OR** ☐ No additional wording is required. Alignment with the Codex Infant Formula Standard **OR** ☒The addition of [bacterial] strains must meet the criteria set-out in clauses 3.3.2.1 and 3.3.3.2. *As per alternative provided above for 3.3.2.4 offered for consideration.*
Bacterial cultures added for purposes other than acidification are Optional Ingredients and they must meet the criteria set-out that apply to all optional ingredients and recommends the addition of text that makes this clear. These criteria encapsulate the additional concepts of safety (including non-pathogenicity) and suitability, evaluated and demonstrated by generally accepted scientific evidence, without need for re-stating.

ESSENTIAL COMPOSITION OF FOLLOW-UP FORMULA FOR OLDER YOUNG CHILDREN (12-36 MONTHS)

Proposed approach

Mandatory (core) composition

Do you support the approach taken for determining the mandatory (core) composition, as well as identifying those nutrients requiring specific compositional parameters, that is :

- Evidence to support nutritional issues for young children of global concern;
- Contribution to the overall nutritional quality/integrity of the product;
- The contribution of key nutrients from cows milk for equivalence; and
- The strength of committee support for including in the core composition.

Answer: Yes, INC considers the **primary objective** for establishing compositional requirements of FUF for young children as a liquid part of the diversified diet should be to **contribute to the nutritional needs** of this age group.

This can be achieved by considering:

- Evidence to support contribution to the nutritional ~~issues for~~ needs of young children of global concern;
- Evidence to support addressing globally relevant dietary inadequacy of nutrients;
- ~~Contribution to~~ Maintenance of the overall nutritional quality/integrity of the product;
- The contribution of key nutrients from the reference beverage of a young child's diet such as cows' milk ~~for equivalence~~; and
- The strength of committee support for including in the core composition.

While each nutrient is assessed on a case by case basis, the compositional criteria should always take these principles into consideration.

Should there be a minimum number of principles that each nutrient must meet in order for it to be considered part of the mandatory (core) composition, or requiring specific compositional parameters in follow-up formula for young children? Please state what this should be.

Answer: All the principles should be met in order for a nutrient to be considered part of the mandatory (core) composition or requiring specific compositional parameters in FUF for young children.

The INC position supports **mandatory compositional criteria for the following nutrients**:
· Energy
· Protein
· Fat including minimum ALA and consideration of a maximum for TFA (for LA:ALA ratio (see comments on LA below)
· Carbohydrates (maximum total carbohydrate), including specifications for added sugars (excluding lactose)
· Vitamins and minerals: iron, calcium, vitamin A, riboflavin, vitamin B_{12}, vitamin D, vitamin C, zinc, iodine and additional consideration for folic acid.

Voluntary Nutrient Additions

Further to the mandatory (core) composition, other essential nutrients may be added to follow-up formula for young children, either as a mandated addition to the (core) composition required by national authorities, or as a voluntary addition by manufacturers. These nutrients can be chosen from the essential composition of follow-up formula for older infants. The nutrient levels must be:

- *as per the min, max, GULs stipulated for follow-up formula for older infants; or*
- *based on the min, max, GULs stipulated for follow-up formula for older infants, and amended if the nutritional needs of the local population and scientific justification warrants deviating from the level stipulated for older infants, or*
- *in conformity with the legislation of the country in which the product is sold.*

Note: all footnotes relevant to these listed essential nutrients, also apply when added to follow-up formula for young children

QUESTION:
Please comment on the proposed approach presented above for the voluntary addition of other essential nutrients. If you do not support this approach, please present an alternative approach with justification.

Answer:
INC does not support the proposed approach for the 'voluntary addition of essential nutrients'. INC supports the core principles for the inclusion of 'optional ingredients' and thus any addition must meet the general principles of safety, suitability etc.

The introduction of this proposed new category of nutrients adds unnecessary complexity to the standard. If it is considered appropriate to permit addition of nutrients mandated for 'follow-up for older infant' to 'follow-up formula for young children' where not mandated for these formula, INC would prefer these were listed as a non-exhaustive list of optional ingredients in the 'Optional Ingredient' section. This is preferred with respect to the structure of Codex STAN 156-1987 and allows appropriate limits to be specified for 'follow-up formula for young children' taking into account the applicable recommended daily intakes that apply and technical feasibility. Applying minimums, maximums or GULs as stipulated for 'follow-up formula for older infants' is an overly simplistic approach and could lead to inappropriate levels being applied.

QUESTION:
Are there any essential nutrients that are not part of the proposed mandatory (core) composition, where the levels would need to be different to that for follow-up formula for older infants, noting that the principles would allow for deviating from the level stipulated for older infants if the nutrient needs of the local population and scientific justification warrants this? Please provide justification for your answer.

Answer:
See above.

Optional Ingredients

- In addition to the [mandatory (core)] compositional requirements [and voluntary essential nutrient provisions] listed under [insert appropriate subsection] ~~to~~ [and] [insert appropriate subsection], other ingredients or substances may be added to follow-up formula for ~~older infants~~ [young children] where the safety and suitability of the optional ingredient for particular nutritional purposes, at the level of use, is evaluated and demonstrated by generally accepted scientific evidence.
- When any of these ingredients or substances is added, the formula shall contain sufficient amounts to achieve the intended effect, [taking into account levels in human milk].
- [The following substances may be added in conformity with national legislation, in which case their content per 100 kcal (100kJ) in the Follow-up Formula ready for consumption shall not exceed the levels listed below. This is not intended to be an exhaustive list, but provides a guide for competent national and/or regional authorities as to appropriate levels when these substances are added]. The Chairs propose deleting the third bullet point in preference for a principles based approach rather than inclusion of any substances in a list.

QUESTION:
Please comment on the proposed approach and principles presented above for the voluntary addition of optional ingredients and substances to follow-up formula for young children. If you do not support this approach, please present an alternative approach with justification.

Answer: INC supports the core principles for addition of optional ingredients.

QUESTION:
Please comment on whether the second principle (bullet point 2) should include the requirement that levels of optional ingredients or substances should 'take into account levels in human milk' for follow-up formula for young children. Please provide justification for your answer.

Answer: INC's view is that milk is the key reference for follow up formula for young children, because where these formula are used, they generally partially replace milk in the diet. As such INC does not support inclusion of the text in brackets in bullet point 2 above. The bullet point would then read:

> "When any of these ingredients or substances is added, the formula shall contain sufficient amounts to achieve the intended effect."

QUESTION: Do you support deletion of the third bullet point for follow-up formula for young children?
Answer: INC supports the deletion of the list of examples to apply in the 3rd bullet point as proposed by the eWG Chair even though the list is not a closed list. However, a non-exhaustive list covering the essential nutrients proposed as voluntary nutrients could be considered (refer to comments under voluntary nutrients).

Energy contribution from macronutrients

Energy contribution from macronutrients
Please provide comment and justification as to whether it is necessary to define specific macronutrient percentage contribution to overall energy.
Answer: INC supports an approach that mandates the energy range of the product and levels for macronutrients based on the key principles outlined in the mandatory composition section. The proposed levels in g/100 kcal are equivalent to using % energy from macronutrients.

Energy

Energy			
Members of the eWG have recommended that the energy density of follow-up formula for young children should be established, and the following levels proposed: **Energy**			
Unit	**Minimum**		**Maximum**
kcal/100 ml	[60]	[45]	[70]
kJ/100 ml	[250]	[188]	[293]
Should the range for the energy density of follow-up formula for young children accommodate the energy content of full fat cows' milk *and* reduced fat cows' milk, or align with the minimum energy density of follow-up formula for older infants?			
☐ FUF-older infants & full fat cows' milk 60 kcal/100ml 250 kJ/100 ml		☒ Reduced fat cows' milk (~1.5-2% fat) 45 kcal/100 ml 188 kJ/100 ml	
The minimum energy is set as the approximate energy density of reduced fat cows' milk (~1.5-2% fat), 45 kcal/100 mL.			
Do you support establishing a maximum energy density for follow-up formula for young children? If so, do you have suggestions as to how this level should be derived?			
Answer: The maximum energy is set as the approximate energy density of whole cows' milk, 70 kcal/100 mL.			

Protein

Protein
Considering the eWG's varied views, are minimum and maximum requirements necessary? If so, please state your preferred approach on how to establish protein requirements?
Answer: In establishing protein requirements, INC believes in addition to the outlined principles, specific consideration should be given to upper safe protein intake levels (noting that there is no UL defined for protein), dietary protein intake levels (including population intake distribution as well as average intakes), protein quality and history of apparent safe use. Additionally, considerations should be given to global implications of the recommendations and technical manufacturing feasibility. INC considers that a broader rather than narrower protein range for follow-up formula for young children is desirable to manage the principles outlined above. In particular, compositional requirements must be flexible enough to address both the nutritional needs / role of product of young children with different dietary habits.

In relation to feedback on the preferred approach on how to establish protein requirements, INC notes the importance of focusing on principles recommended for this purpose and that current discussions are heading towards this:

Minimum:
INC considers that minimum protein should be based on providing approximately 6% of total energy by the product.

This translates, per 100kcal unit of measure, to either:

- 1.6g/100kcal (derived from application of the WHO safe total diet protein level to the equivalent % energy in the product) OR
- 1.5g/100kcal (derived from the application of the IOM (2002) RDA of 1.05g/kg/day for children aged 1-3 years).

Maximum:
Providing the protein density of whole cows' milk (approximately 22% of energy from protein in total product) (i.e. 5.5g/100kcal)).

Note: INC recommends the inclusion of g/100kcal be included to ensure there is no confusion around conversion of the % energy to g/100kcal.

The protein levels in follow-up formula for young children will need to be varied to promote optimal nutrition of young children.

Should there be requirements for protein quality? If so how this might be achieved? Please consider both the current Follow-up formula standard, and proposals within the draft standard for older infants.

INC believes protein quality is important but this might best be considered once the protein levels have been finalised.

Total Fat

Total fat	
Based on the eWG recommendation to establish total fat requirements, please state your preferred minimum total fat value?	
☐ Current Codex FUF standard 3.0 g/100 kcal 0.7 g/100 kJ	☐ Proposed Codex FUF standard for older infants 4.4 g/100 kcal 1.1 g/100 kJ
☒ Reduced fat cows' milk 3.5 g/100 kcal 0.8 g/100 kJ	☐ Alternative value, please specify
Rationale: The minimum reflects fat content of reduced fat milk (1.5-2%).	
Based on the eWG recommendation to establish total fat requirements, please state your preferred maximum total fat value?	
☒ Proposed FUF-older infants & cows' milk 6.0 g/100 kcal 1.4 g/100 kJ	☐ Alternative value, please specify
Maximum aligned with maximum in current Codex FUF standard (i.e. maximum of 55% of total energy coming from fat).	

Essential Fatty acids

Lipids

Based on the eWG recommendation to give consideration to the fatty acid profile of follow-up formula for young children, including maximum levels for trans fat, and noting the levels in full fat and reduced fat cows' milk, please state your preferred levels (with justification) as below:

Should levels for linoleic acid, α-linolenic acid and phospholipids be established for follow-up formula for young children? Please stipulate what these levels should be; min, max, GUL.

Linoleic Acid

INC considers that it is not necessary to mandate minimum LA levels on the basis that this would not meet the key overarching principles outlined by the eWG:

- There is insufficient evidence to suggest intakes of LA are globally limited in a young child's diet. Food supply data does not indicate this is insufficient (Michaelsen, 2011). EFSA (2013) concluded intakes and status of LA were of no concern for European infants and young children.
- Follow up formula for young children will contain LA from the milkfat and/or vegetable oil fat source ingredients.

If, however, the decision is made to mandate this nutrient, INC suggests the level is no greater than that in the current Codex STAN 156-1987 of 300mg/100kcal.

ALA

INC considers that minimum ALA levels are justified in the Codex STAN 156-1987 for the following reasons:

- EFSA (2013) outlined intake data of fatty acids was scarce in the EU, and of the data available, that dietary intakes of omega 3's ALA and DHA in young children were low relative to the Adequate Intake. However, the risk of inadequate intakes of ALA and DHA in infants and young children living in Europe could not be quantified. The EFSA Panel identified follow up formula for young children as one of the means to increase the intake of these nutrients (along with iron, vitamin D and iodine).
- Minimum levels could be defined based on minimum FAO AI for 6-24 months i.e. 0.4% of total energy from ALA, which could be applied to the whole product 44mg/100kcal (i.e. 0.4% of 100kcal = 100*0.004/9).

LA: ALA Ratio

FAO (2010) concluded there was insufficient evidence to set a ratio of ALA:LA in the diet:

> "*Based on both the scientific evidence and conceptual limitations, there is no compelling scientific rationale for the recommendation of a specific ratio of n-6 to n-3 fatty acids or LA to ALA, especially if intakes of n-6 and n-3 fats lie within the recommendations established in this report*"

If however, the decision is made to mandate this ratio, INC suggests a minimum of 5:1 and a maximum of 15:1 as per Codex STAN 72-1987 could be considered.

References:

EFSA (2013). Scientific Opinion on nutrient requirements and dietary intakes of infants and young children in the European Union. EFSA Journal;11(10):3408.
https://www.efsa.europa.eu/en/efsajournal/pub/3408

FAO (2010). Fats and Fatty Acids in Human Nutrition. Report of an Expert Consultation.
Michaelsen 2011 - Food sources and intake of n-6 and n-3 fatty acids in low-income countries with emphasis on infants, young children (6–24 months), and pregnant and lactating women

<table>
<tr><td colspan="2">Should a range for the ratio of linoleic: α-Linolenic acid be established for follow-up formula for young children?</td></tr>
<tr><td>☐ Yes

Should this be a minimum of 5:1 and a maximum of 15:1 as per the Codex Infant Formula Standard, the proposed Standard for Follow-up Formula for Older Infants and the recommendations of the 2015 IEG?
☐ Yes
☐ No
☐ Alternative, please specify and provide justification for your answer.

See rationale above.</td><td>☐ No

See rationale above.</td></tr>
<tr><td colspan="2">Should a maximum percentage fat for lauric and myristic acid be established for follow-up formula for young children?</td></tr>
<tr><td>☐ Yes

Should this level be ≤20% of fat as per the Codex Infant Formula Standard, and the proposed Standard for Follow-up Formula for Older Infants, and noting this would accommodate full fat and reduced fat cows' milk?
☐ Yes
☐ No
☐ Alternative, please specify and provide justification for your answer.</td><td>☒ No

INC notes that the maximum percentage fat for lauric and myristic acid for infant formula is based on the profile of breast milk. It is more complex for young children and is difficult to justify limits.</td></tr>
<tr><td colspan="2">Should a maximum level for trans fat be established for follow-up formula for young children? If you support a maximum level, please state what percentage of fat this should be.</td></tr>
<tr><td>☒ Yes in principle but with reservations about usefulness of a maximum for total TFA in practice. INC considers that is very important to ensure that TFA levels are kept as low as possible in the diets of children but not to the point that the adequacy of intake of essential nutrients is compromised. INC considers this is best achieved by minimising the addition of industrial trans fats. In many countries the addition of industrial trans fats in the total diet has reduced significantly over recent years, such that dietary intakes of TFA pose no threat to health. As such, the pros and cons of setting a maximum for TFA within the standard need careful consideration.

Please state what the maximum level should be, and provide justification for your answer.

A TFA maximum of 3% is appropriate for infant formula and follow-up formula for older infants because the essential fatty acid requirements in these products restrict the milkfat content to approximately 50% or less of fat.</td><td>☐ No</td></tr>
</table>

Conversely, a TFA maximum of 3% is NOT appropriate for follow-up formula for young children. Follow-up formula products for young children, where used, are intended to partially replace other milks in the diet, including wholemilk. As such, setting a TFA maximum for these products, which would similarly restrict the milkfat content to 50% or less of the fat content, is out of step with dietary recommendations for milk consumption by this age group.	

Should the proposed footnote 7 for the Codex Standard for Follow-up Formula for older infants (*Commercially hydrogenated oils and fats shall not be used in follow-up formula*) also apply to follow-up formula for young children?

Yes, INC considers that footnote 7 should apply to follow-up formula for young children.

Rationale

Aranceta et al, 2012, provides the following background information:

> "Overall, recommendations for trans fatty acids intake advice to limit intake below 1 %E or to keep trans fatty acid intake as low as possible.
>
> Evidence supporting these recommendations is based on the effects of trans fatty acids on plasma lipids and cardiovascular disease…..
>
> In the USA average adult's daily ruminant trans fatty acid intake of both men and women is about 1·2g, which correspond to 0·5 %E. If similar average intake values from industrially hydrogenated fat could be anticipated, then the trans fatty acid intake from all sources should be limited to 1 %E."

The focus for public health bodies is on reducing **industrial** TFA intake (EC, 2015; FAO 2010; UAUY 2009). INC supports retaining text that restricts the addition of hydrogenated vegetable oils to follow-up formula for young children, these being the only potential sources of industrial trans fats in these formula.

Follow-up formula for young children, where used, are intended to partially replace milk, including wholemilk. Wholemilk is recommended to be consumed as part of food based dietary guidelines (FAO 2010, WHO 2005). As such, setting a maximum for TFA that is not met by wholemilk seems inappropriate in a dietary context.

EFSA (2010) noted that:

> "… dietary trans fatty acids are provided by several fats and oils that are also important sources of essential fatty acids and other nutrients. Thus, there is a limit to which the intake of trans fatty acids can be lowered without compromising adequacy of intake of essential nutrients."

The Panel concluded that trans fatty acids intake should be as low as is possible within the context of a nutritionally adequate diet.

Similarly, Hafekost et al (2014) in a review conducted for Food Standards Australia New Zealand, concluded that:

> "TFA is difficult to avoid in a nutritionally adequate diet due to the TFA contained within meat and dairy products. Therefore, recommendations to further reduce consumption of these products in Australia and New Zealand, with the aim of minimising TFA consumption, may have adverse effects on intake of other nutrients such as calcium and iron. The health risk associated with deficiencies in such nutrients may be greater than the risk associated with the small intake of TFA."

INC seeks to ensure that TFA levels are kept as low as possible in the diets of children without compromising the adequacy of intake of essential nutrients. Given that the average and range of dietary intakes of TFA vary significantly, and are sufficiently low in many countries not to pose a health risk (EFSA 2010), INC suggests that maximum TFA levels need to considered carefully. A possible approach would be to leave the setting of a TFA maximum to the discretion of national authorities in alignment with restrictions placed on the TFA levels in general purpose foods.

It is noted in CP2 by the eWG that average milk TFA levels are greater than the 3% of total fat limit defined for TFA in Codex Stand 72-1981. Precht et al (2000) summarised TFA in bovine milkfat from more than 12 countries and reported that average values from each country ranged from 1.29 to 7.31% of total fat. Briard-Bion (2008) is also useful in this context, providing additional information on the variability of levels in milkfat. Breast milk also contains TFA (2-5% of total fatty acids) (Larqué et al 2001).

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Carbohydrates

Total Available Carbohydrates	
Is a minimum available carbohydrate level required, if a consensus is reached on establishing minimum and maximum levels for energy, protein and total fat?	
Yes	☒ No
INC does not support a minimum carbohydrate level to be consistent with the provisions in section 3.2.3 of the current Codex STAN 156-1987.	

If you support establishing a minimum available carbohydrates level, what level do you support?	
Full fat cows' milk 7.5 mg/100 kcal 1.8 mg/100 kJ	IEG 2015 and proposed Codex FUF-OI 9.0 mg/100 kcal 2.2 mg/100 kJ
Not applicable	
If limits are established for sugars, is there a need to also set a maximum/GUL for total available carbohydrates?	
☒ Yes	No
INC is supportive of a total CHO maximum limited, See additional comments below.	
If you support a limit for total available carbohydrates, should a maximum level or GUL be established?	
☒ Yes, a maximum level should be established	Yes, a GUL level should be established
INC considers that a maximum level should be established to limit total available carbohydrates, but that this should not be established until the protein and fat ranges are set.	
If you support establishing a maximum/GUL, do you support 14 mg/100 kcal (3.3 mg/100 kJ)?	
Yes	☒ No (please specify your alternative).
INC is supportive of a total carbohydrate maximum limit, however, as noted above, a maximum of 14 g/100 kcal is not currently supported because the protein and fat ranges have not been set. INC is concerned that high proportions of energy from carbohydrate (higher than is typical in infant formula products) may result from protein and fat limits under discussion and that this should be carefully considered in relation to establishing a maximum for total carbohydrates and added sugars. Ingredient combinations (and resulting ingredient proportions by weight) that could be used to deliver the defined macronutrient ranges must also be considered when setting a carbohydrate cap. If careful consideration is not given to total carbohydrate levels, INC is concerned at the prospect of formula that might comprise over 50% added carbohydrate ingredients.	

Carbohydrates footnote		
Free sugars While there was widespread support for compositional requirements that limit the addition of free sugars, there was no consensus on an approach. Please select your preferred approach from the below options.		
Proposed Codex FUF-OI Standard Sucrose and/or fructose should not be added, unless needed as a carbohydrate source, and provided the sum of these does not exceed 20% of available carbohydrate.	☐ IEG 2015 Sugars other than lactose should be ≤ 10% of total carbohydrates or 5% of total energy content	☒ An alternative level (please specify)
INC considers both a restriction on both total maximum carbohydrate as well as total added sugars/free sugars (excluding lactose), is important. INC notes that direct extrapolation of the WHO (2015) recommendation for a total daily free/ added sugars intake of <10% of total energy to a maximum level of added sugars (in this context excluding lactose) to a formula product for young children that is consumed as part of a mixed diet may be too simplistic and requires further consideration. INC notes the IEG has suggested a level even lower than the WHO (2015) total daily energy from sugar is applied to a total cap in formula products for young children (i.e. 5% of total energy in the product in the		

product). INC does not support this approach, that is, reducing added sugars excluding lactose to < 5%, as this is too restrictive.
Lactose

☒ Proposed Codex FUF-OI Standard and Codex IF Standard Lactose and glucose polymers should be the preferred carbohydrates in formula based on cows' milk protein and hydrolysed protein.	IEG 2015 The main source of carbohydrates should be lactose, which should provide not less than 50% of total carbohydrates, equivalent to 4.5 g/100 kcal.
INC considers that lactose should be the preferred carbohydrate but does not consider there is a need to specify a minimum lactose content or to provide a positive list of carbohydrates that can be used. The rationale for this position is based on the absence also of such a provision in Standard 2.9.3 in the Australia New Zealand Food Standards Code.	
Other permitted carbohydrates	

Proposed Codex FUF-OI Standard Only precooked and/or gelatinised starches gluten-free by nature may be added. (NB Glucose polymers are preferred carbohydrates along with lactose).	IEG 2015 Oligosaccharides, glucose polymers, maltodextrin and pre-cooked or gelatinised starches can be added to provide energy. Non-digestible carbohydrates and fibres that proven to be safe and suitable for the age group may be added.	☒ Something else (please specify)
See response to question above.		

Iron

Iron			
While a consensus was reached on the minimum compositional requirements for iron in follow-up formula for young children, there were differing opinions on a maximum or GUL. **Iron**			
Unit	**Minimum**	**Maximum**	**GUL**
mg/100 kcal	1.0	[2.0]	[3.0]
mg/100 kJ	[0.25]	[0.3]	[0.7]
Should a maximum level or GUL be established for iron?			

☐ Yes, a maximum level should be established ☒ Yes, a GUL level should be established	No
Rationale: INC notes the wide range between the NRV for iron and the UL. On this basis INC considers a GUL may be more appropriate than a maximum.	

If you support establishing a maximum or GUL, please select your preferred value, providing scientific rationale to support your preferred choice.	
Maximum (Proposed Codex FUF-OI) 2.0 mg/100 kcal 0.5 mg/100 kJ	☒ GUL (IEG 2015) 3.0 mg/100 kcal 0.7 mg/100 kJ
Alternative value (please provide level (max/GUL))	
Rationale: See above.	

Should separate minimum and maximum/GUL levels be established for soy protein isolate formulae?	
☒ Yes	☐ No
Rationale: Separate levels should be established due to the potentially lower absorption efficiency.	

If you support establishing separate minimum and maximum/GUL levels for soy protein isolate formulae, should it be the same as the proposed Codex Standard for Follow-up Formula for older infants (a minimum of 1.5 mg/100 kcal (0.36 mg/100 kJ) and maximum of 2.5 mg/100 kcal (0.6 mg/100 kJ)?	
Yes	☒ No (please provide alternative values, with justification for your response)
Rationale: INC suggests a similar approach to that proposed by Codex STAN 156-1981 for older infants (6-12 months) For follow-up formula for older infants, the minimum and maximum levels for soy protein isolate formulae are 0.5mg/100kcal higher than the values for milk based formulae to compensate for a potential lower absorption efficiency of iron. As the levels supported for cows' milk based formulas are a minimum of 1.0mg/100kcal and a GUL of 3.0mg/100kcal, this would correspond to a: – minimum of 1.5mg/100kcal – GUL of 3.5 mg/100kcal.	

Calcium

Calcium			
No consensus was reached on the requirements for calcium in follow-up formula for young children. Noting that full fat cows' milk contributes 190 mg calcium/100 kcal (range 184 - 201 mg/100 kcal) and the average amount of calcium in reduced fat cows' milk is 259 mg/100 kcal (range 240 – 280 mg/100 kcal), Please provide comment on the below options:			
Calcium Unit mg/100 kcal mg/100 kJ	**Minimum** [50] [90] [200] [18] [22] [24] [48]	**Maximum** [N.S.]	**GUL** [180] [NS] [43]
Minimum:			
☒ Current Codex FUF standard 90 mg/100 kcal 22 mg/100 kJ		☐ Proposed Codex FUF standard for older infants 50 mg/100 kcal 12 mg/100 kJ	
☐ IEG 2015 200 mg/100 kcal		☐ Alternative value, please specify	
Rationale: Further consideration is needed before a minimum level for calcium can be determined. Minimum protein levels need to be defined before INC can suggest a specific minimum level. However, of the options listed, 90mg/100kcal is currently preferred on the basis that this is comparable to 50% of the average calcium levels in wholemilk. The proposal of 200mg/100kcal poses technical difficulties to achieve for low protein products. However, higher levels might also be considered once the minimum protein level has been confirmed. INC repeats its view that we will need to further consider this area before recommending a specific level.			

Maximum/GUL:	
☒ Current Codex FUF standard Maximum: N.S.	☐ Proposed Codex FUF standard for older infants GUL: 180 mg/100 kcal GUL: 43 mg/ 100 kJ
☐ IEG 2015 GUL: N.S.	☐ Alternative value, please specify
Rationale: INC is of the view that a maximum is not necessary and a GUL might also not be necessary may not be necessary given the low risk of toxicity and the wide range between the NRV (500mg/day) and the UL (2500mg/day). INC notes that Standard 2.9.3 in the Australia New Zealand Food Standards Code does not have either a maximum or GUL for calcium. INC further notes there is no upper limit specified in Codex STAN 156-1987, and that technical feasibility will limit excess addition of this nutrient.	

Calcium	
Should the ratio for calcium-to-phosphorous included in the Codex Standard for Infant Formula and as proposed for FUF-OI be included? Ratio calcium/phosphorus **Min** 1:1 — **Max** 2:1	
Yes	☒ No
Rationale: INC does not consider a Ca:P ratio necessary for formula for young children that is consumed in a mixed diet, if appropriate calcium minimum levels are included in the product.	

Vitamin A

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 [x)] Unit — Minimum — Maximum — GUL µg RE/100 kcal — [75] [60] [50] — [225] [180] — [200] [180] µg RE/100 kJ — [18] [14] [12] — [54] [43] — [48] [43] [x)] 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			
Current Codex FUF Std & proposed Codex FUF-OI 75 µg RE/100 kcal 18 µg RE/100 kJ	☒ IEG 2015 / Codex IF Std 60 µg RE/100 kcal 14 µg RE/100 kJ	WHO/FAO 15% of RNI 50 µg RE/100 kcal 12 µg RE/100 kJ	
Rationale: 30% of the NRV for vitamin A equates to 40ug/100mL (when calculating based on a 300mL serve/day). This translates to 57-89ug/100kcal when using the energy range of 45-70kcal/100mL. INC took the lowest figure of 57ug/100mL and suggests this level guides the minimum. This is 'close' to the ENA proposal of 60ug/100kcal and INC therefore supports this level.			

Maximum	
☒ Codex FUF std 225 µg RE/100 kcal 54 µg RE/100 kJ	Proposed Codex FUF-OI 180 µg RE/100 kcal 43 µg RE/100 kJ
Rationale: INC considers a maximum is appropriate for vitamin A. We would note, however, that it is very important that the range of vitamin A levels permitted is sufficiently wide to accommodate the variability in products. Variability is significant due to drop off that occurs during shelf-life and also due to the inherent natural levels in milkfat in these products.	
GUL	
WHO/FAO GUL of 3-5 times minimum 200 µg RE/100 kcal 54 µg RE/100 kJ	IEG 2015 180 µg RE/100 kcal 43 µg RE/100 kJ
Rationale: See above.	
Do you support the footnote below, agreed to by the Committee for follow-up formula for older infants (REP16/NFSDUE Appendix III)? [x] 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.	
☒ Yes	No

Vitamin D

Vitamin D	
Do you support that mandatory addition of vitamin D to follow-up formula for young children?	
☒ Yes	☐ No
Rationale: Vitamin D insufficiency in young children is frequently documented, even in some lower latitude countries. For this reason, a mandatory addition of vitamin D to follow-up formula for young children at a minimum of 1.5µg/100kcal, as proposed by ENA, is supported by INC.	
If you support mandatory addition, please state what the minimum level should be and provide justification for your answer.	
Minimum: 1.5µg/100kcal *Rationale:* INC considers that 30% of NRV (using a 300mL serve) is an appropriate target for a minimum level. At an energy density of 70kcal/100mL, this translates to 1.43ug/100kcal, which is comparable to that suggested by ENA.	
Please state whether vitamin D should have a maximum level or a GUL set and provide information on what this level should be with justification for your answer.	
Upper Limit: 4.5 mcg/100kcal *Rationale*: INC believes an upper limit for vitamin D is needed because of the potential toxicity of vitamin D. Similarly to follow-up formula for older infants, a maximum of 4.5 mcg/100kcal kcal, which corresponds to 3 times the minimum level, seems to be initially appropriate.	

Zinc

Zinc	
Do you support that mandatory addition of zinc to follow-up formula for young children?	
☒ Yes	☐ No
Rationale: Zinc insufficiency in young children is frequently documented. For this reason, a mandatory addition of zinc to follow-up formula for young children at a minimum of 0.6mg/100kcal, as proposed by ENA, is supported by INC.	
If you support mandatory addition, please state what the minimum level should be and provide justification for your answer.	
Minimum: 0.6 mg/100kcal *Rationale:* If 30% of the NRV is targeted (approx. 0.41mg/100mL), this is equivalent to 0.6-0.91mg/100kcal at 70 and 45kcal/respectively. The lowest value of 0.6mg is selected.	
Please state whether zinc should have a maximum level or a GUL set and provide information on what this level should be with justification for your answer.	
Maximum/GUL: *Rationale:* INC supports a maximum level for zinc but is still considering the approach to take to define this level and whether a maximum level or a GUL is the most appropriate.	

Vitamin C

Vitamin C	
Do you support that mandatory addition of vitamin C to follow-up formula for young children?	
☒ Yes	☐ No
If you support mandatory addition, please state what the minimum level should be and provide justification for your answer.	
Minimum: 4.5mg/100kcal *Rationale:* INC supports the mandatory addition of vitamin C to FUF for young children mainly due to its role in aiding iron absorption. A minimum level of **4.5mg/100kcal** as suggested by ENA, and which corresponds to 20 -30% of the FAO/WHO NRV (at 45-70kcal/100mL & a 300mL serving) seems to be appropriate.	
Please state whether vitamin C should have a maximum level or a GUL set and provide information on what this level should be with justification for your answer.	
Maximum/GUL: not specified *Rationale:* As per the rationale listed for calcium, INC does not consider setting an upper limit for vitamin C is necessary.	

Vitamin B12

Vitamin B12	
Do you support that mandatory addition of vitamin B12 to follow-up formula for young children?	
☒ Yes	☐ No
If you support mandatory addition, please state what the minimum level should be and provide justification for your answer.	

Minimum: INC considers levels in milk an important guide for this nutrient (noting milk levels are also guide for calcium and riboflavin levels). INC is further considering the approach for this nutrient before defining exact min levels.
Please state whether vitamin B12 should have a maximum level or a GUL set and provide information on what this level should be with justification for your answer.
Maximum/GUL: neither a maximum nor a GUL should be specified because no upper limit has been established for vitamin B_{12}.

Riboflavin

Riboflavin	
Do you support that mandatory addition of riboflavin to follow-up formula for young children?	
☒ Yes	☐ No
If you support mandatory addition, please state what the minimum level should be and provide justification for your answer.	
Minimum: To be advised *Rationale*: INC considers levels in milk an important guide for this nutrient (noting milk levels are also a guide for calcium and B_{12} levels). INC is further considering the approach for this nutrient before defining exact minimum levels.	
Please state whether riboflavin should have a maximum level or a GUL set and provide information on what this level should be with justification for your answer.	
Maximum/GUL: not specified *Rationale*: INC considers a maximum or GUL should not be specified as there is no safe upper limit established for riboflavin.	

Sodium

Sodium	
Should specific parameters for sodium levels in follow-up formula for young children be set?	
☒ Yes	☐ No
Should a minimum level of sodium be established? If yes, please state what this level should be and provide justification for your answer.	
Minimum: None specified. INC's view is that a minimum should not be set out.	
Please state whether sodium should have a maximum level or a GUL set and provide information on what this level should be with justification for your answer.	
Maximum: Yes, Maximum Level to be specified *Rationale:* INC recommends setting a **maximum level** for sodium of no more than 85mg/100Kcal for sodium. Considering that follow-up formula for young children should provide 15% of the daily energy intake, and taking 1000mg as the upper limit (IOM), we consider that staying with a maximum of 85 mg/100 kCal could be appropriate.	

SCOPE & LABELLING

Scope & Labelling

When answering the questions below relating to Scope and Labelling, please give consideration to whether your response covers both follow-up formula for older infants and follow-up formula for young children, or whether different approaches should be considered for these different product categories.

Do you consider that any of the current labelling provisions for follow-up formula can be adopted as is? If so, which provisions?

Yes. INC considers the labelling requirements in Section 9 of Codex STAN 156-1987 (Name of food, List of ingredients, Declaration of nutritive value, Date marking and storage instructions, Information for utilization and Additional requirements) should be retained. This section contains several references to Codex STAN 1-1985 (General standard for the labelling of prepackaged foods).

The requirement in Codex STAN 72-1981 for the text of the label and all other accompanying information to be in the appropriate language(s) would be sensible to include in Codex STAN 156-1987 as well.

Are there any labelling areas where different provisions may be required for the two age groups?

The following labelling provisions will need to be reviewed due to the split in the age groups 6-12 months and 12-36 months:

- Name of the Food
- Product Definitions
- Other Definitions
- Product Description

Are you aware of further issues and/or evidence that need to be considered to inform the review of the scope and labelling section of the Codex Standard for Follow-up Formula? Please state the specific provisions within the Scope or Labelling section which would be informed by your response.

INC is particularly concerned at the prospect of extending some of the restrictions applied to infant formula being applied to follow-up formula for older infants and young children. Our concern is based on the fact that follow-up formula is NOT suitable to satisfy by itself the nutritional requirements of normal healthy infants or young children.

To enable informed choice, sufficient information needs to be able to be provided by manufacturers for consumers for example, to aid the differentiation of products.

Do we need to make specific reference to WHA resolutions in the Codex Standard for Follow-up Formula, and if so, how and where? For example in the Scope and Labelling sections.

INC notes the relationship between WHO, FAO and Codex and the mandates, roles and purposes of each. These are all much broader for FAO and WHO than for Codex reflecting the WHO and FAO broader global roles in public health, disease and medicine and agriculture. We particularly note that the role of Codex, as set out in the statutes of Codex, is to implement the Joint FAO/WHO Food Standards Programme, which has the purpose of:

> "(a) protecting the health of the consumers and ensuring fair practices in the food trade;..." (Codex 2015).

Codex is an evidence-based organisation and the standards it promulgates are, to the greatest extent possible, reflective of current developments in science and related disciplines in order to deliver on "protecting the health of the consumers and ensuring fair practices in the food trade".

INC notes that there has been discussion over many decades, through developments and statements by WHO, FAO and WHA, that relate to food standards and practices for infants and young children. Most recently this has been in relation to non-communicable diseases and marketing of foods for infants and young children, the latter reflected in WHA69.9. Marketing of foods to infants and young children has been discussed at CCNSFDU over the same period and by its eWG on the Review of the Standard for Follow-up Formula (Codex STAN 156-1987) (the eWG) over the past two years.

In the very few Codex standards that reference WHO texts and a resolution, these are included for very

specific reasons. This is particularly the case with the Code of Marketing of Breast-milk Substitutes (1981) (the Code of Marketing) in Codex STAN 72-1981. It is worth noting that Codex STAN 72-1981 does not reference the associated WHA resolution, WHA34.22 (the resolution made at the time the Code of Marketing was finalised). This is perhaps because elements of the Code of marketing are incorporated into Codex STAN 72-1981 and the unique significance of infant formula as "a breast-milk substitute specially manufactured to satisfy, by itself, the nutritional requirements of infants during the first months of life up to the introduction of appropriate complementary feeding" (clause 2.1.1, Codex STAN 72-1981) which creates a direct parallel with many of the provisions of the Code of Marketing.

From an INC perspective, WHA69.9, and the related Guidance, falls into the category of "reflective of the broader role of the WHO and the context within which Codex operates". As with previous and multiple WHA resolutions on infant and young child nutrition, appropriate feeding practices and related questions (WHA33.32 (1980), WHA34.22 (1981), WHA35.26 (1982), WHA37.30 (1984), WHA39.28 (1986), WHA41.11 (1988), WHA43.3 (1990), WHA45.34 (1992), WHA46.7 (1993), WHA47.5 (1994), WHA49.15 (1996), WHA54.2 (2001), WHA55.25 (2002), WHA58.32 (2005), WHA59.21 (2006), WHA61.20 (2008) and WHA63.23 (2010)), only one WHA resolution and only two texts are included in Codex standards. Codex has been very selective when the number of resolutions made on related matters by parent bodies is considered. The only resolution referenced is WHA54.2 and the only WHO texts are the Code of Marketing and the Global Strategy for Infant and Young Child Feeding (the Global Strategy).

The scope of the Technical Guidance on Ending Inappropriate Promotion of Foods for Infants and Young Children (the Technical Guidance) states that the "current document does not replace any provisions in the Code [of Marketing] but clarifies the inclusion of certain products that should be covered by the Code and subsequent resolution". This clarifies that the Technical Guidance concerns clarifying the marketing of certain products for implemented by member states as they deem reasonable for their country and not the composition or safety which is within the remit of Codex to prescribe. As noted above, Codex has already appropriately adopted relevant aspects of the Code of Marketing in Codex STAN 72-1981.

The Technical Guidance and the related resolution WHA69.9 have the prospect of extending the principles of the Code of Marketing to older infants and young children beyond 6 months. Beyond 6 months, milk-based products are one of the myriad of foods consumed by older infants and young children all of which play a role in the rapidly expanding and varied diet of the developing child. However, not all milks for children up to three years are modelled on the nutrient profile of breast milk and do not serve to replace breast milk in the diet. The vast majority are modelled more closely on cows' milk. Feeding young children cows' milk is recommended in many nutrition guidelines. As well, unlike infant formula, no food beyond 6 months, other than specially formulated medical foods, is manufactured to satisfy, by itself, the nutritional requirements of infants or young children beyond 6 months. Products that function as breast-milk substitutes should not be promoted as such and member states can implement this clarification as appropriate to their environment.

INC is aware of the range of positions concerning the Codex consideration of resolution WHA69.9 and the context within which the resolution was made. Some of these are explored in the eWG's *Second Consultation Paper, 2016* especially Section 8.6, Discussions on the Inclusion of WHA Resolutions. This has been preceded by considerable discussion both within the eWG and at the plenary sessions of CCNSFDU.

The issues around full consideration versus referencing WHO texts and resolutions are likely to have been made in the past with other foods for infants and young children and other WHA resolutions but in summary the current concerns around the WHO's developments reflected in the Technical Guidance include:

- precedence has been set with some foods referring to WHO/WHA/FAO documents/resolutions;
- a reference to documents/resolutions might infer a direct link and an extension of the relevant Codex standard ;
- Codex standards are evidence based and non-evidence based inclusions in Codex standards undermine the role of Codex standards in the WTO;
- if a food is not nutritionally necessary, unlike infant formula, then it is not appropriate to reference documents/resolutions that pertain to nutritionally necessary foods;
- Codex is unique in its transparency and inclusiveness in its modus operandi and the development of standards which differs from the operations of WHO and FAO;
- Codex standards reflected in full in national legislation and which include references to other

documents/resolutions such as those of WHO, may have more far-reaching effects and could raise issues in courts of law.

The eWG asks how full consideration should be characterised. Full consideration is greater than 'consideration' so full consideration would be reflected in the degree to which consideration is given (such as read and set aside, studied assiduously, pulled apart and discussed at length, debated and argued about, the extent of acknowledgement, the reflection of intent etc). To date, all member states of WHO and at WHA have studied the matter assiduously and participated in meetings, discussions, debates and teleconferences on the matter. Many WHA member states are Codex members; CCNSFDU has debated the matter, the eWG has discussed and debated the matter and has included discussion of it in consultation documents, the CAC has considered and discussed the matter and future Codex consideration will continue. To this extent there has been and continues to be 'full consideration'.

Bearing in mind the foregoing, INC believes that is not appropriate at this time for a reference to the Technical Guidance or WHA 69.9 in Codex STAN 156-1987 to be included for the following reasons:

- multiple other texts and resolutions of WHA and FAO have not been included in Codex standards but have been given full consideration
- 'full consideration' has and continues to be given to WHO developments, texts and resolutions
- the supporting document to WHA69.9 is technical guidance that was welcomed by WHA and will be basis for continuing and further work of WHO
- member states may reflect the Technical Guidance as they deem appropriate in their country
- Codex continues to take into account the work of parent organisations, to debate the implications, considerations and impacts.

Notwithstanding the foregoing, the Codex standards setting system is increasingly evidence based and technically focussed. In part this is to reflect the role of standards within the WTO but also it is to maintain separation between policy and activities undertaken by international organisations with broader mandates (WHO, FAO, WTO, UNESCO, UNICEF etc) and a rules based, standards setting body. For these reasons, Codex must maintain a focus on factual, evidence based, technical content for standards that are made within broader policy environments. The WHA69.9 recognises the separation of the Guidance and standards setting in setting out further undertakings for the Director General of WHO. This adds further weight to the INC view that this is not appropriate at this time for a reference to be included in any Codex standard including in Codex STAN 156-1987.

Please comment on how CCNFSDU should 'give full consideration' to Resolution (A69/A/CONF./7 Rev 1) for 'Ending inappropriate promotion of foods for infants and young children' and the associated technical guidance document. Please be specific in your response and comment on what aspects of the resolution or guidance should be captured within the Standard for Follow-up Formula and within what subsection it should be reflected.

See Above.

Taking into consideration relevant WHA resolutions and accompanying documents (section 6) and the role of product in the diet, are changes required to the current drafting of Section 9.6 of the current follow-up formula standard? Please consider both follow-up formula for older infants and for young children when answering this question and comment on whether there would may need to be different approaches for the different product categories.

9.6 The products covered by this standard are not breast-milk substitutes and shall not be presented as such.

INC is reviewing this and at this time is not in a position to provide comment. However, INC will provide an addendum to this submission will be provided by Friday 15 July specifically to respond to the question relating to Section 9.6 in Codex STAN 156-1987.

ADDITIONAL COMMENT

A provision for adequate information for consumers and care-givers to make informed choice should be included in the labelling section of Codex STAN 156-1987. An approach should be considered for follow-up formula for young children, for example the percentage of NRVs for all nutrients provided by recommended daily consumption should be possible. To achieve this, NRVs for young children will need to be established as soon as possible. INC notes that NRVs are already available for young children for Australia and New Zealand.