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

SUBMISSION FROM THE INFANT NUTRITION COUNCIL

REVIEW OF THE STANDARD FOR FOLLOW-UP FORMULA

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

First Consultation Paper, March 2015

FOLLOW-UP FORMULA IN THE CONTEXT OF RELEVANT WHA RESOLUTIONS

QUESTION
WHA resolutions 39.28
Should the WHA resolution be addressed and incorporated into the standard? If so how do you propose this should be achieved. **INC is ambivalent about referencing the WHA Resolution 39.28 in a revised Codex Standard for Follow-Up Formula but believes the matter might best be considered in the labelling section.** INC notes that the WHA resolution 39.28 refers to: "a) any food or drink given before complementary feeding is nutritionally required may interfere with the initiation or maintenance of breast-feeding and therefore should neither be promoted nor encouraged for use by, infants during this period; b) the practice being introduced in some countries of providing infants with specially formulated milks (so-called "follow-up milks") is not necessary". INC considers a recommendation about "feeding practices" should more properly be included in a Guideline or a Code of Practice, but even in a Guideline/Code of Practice, its inclusion would be exceptional because Codex Guidelines and Codes of Practice are generally about technical matters (e.g. principles, inspection, risk analysis, hygiene, prevention of contamination, etc), rather than about practices.

DESCRIPTION OF FOLLOW-UP FORMULA (SECTION 2)

DEFINITION 2.1.1
2.1.1 ***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.
Should the current definition in 2.1.1 be; ☐ retained as is ☒ retained, but amended ☐ removed from the standard INC considers there is a need for a point of differentiation at the 12th month. INC suggests the definitions be separated into three groups: **2.1 Product definition** **2.2 Other definitions** **2.3 Product descriptions** The definition of follow-up formula is a product definition and would come under the first heading. INC considers further discussion around the definition is required and suggests two alternate definitions. The first is broader while the second provides for more differentiation about the role of follow up formula for older infants (6-12 months) and young children (12-36 months).

Definition 1:

2.1 ***Follow-up formula*** means a food intended for use by infants from 6 months onwards, also denominated "older infants", and by young children (12-36 months/1-3 years) constituting a significant liquid element of the diversified diet.

Definition 2:

2.1 ***Follow-up formula*** means a food intended for use by:

- Infants from 6 months and up to 12 months, also denominated "older infants", constituting the principal liquid element of the diet when appropriate complementary feeding is progressively introduced;
- Young children (12-36 months/1-3 years) constituting a significant liquid element of the diet where a diversified family diet is progressively being consumed.

DEFINITION 2.1.2

2.1.2 The term infant means a person of not more than 12 months of age.

Should the current definition in 2.1.2 be;

☒ retained within the standard ☐ removed from the standard

While the term *infant* is defined elsewhere in Codex standards, most notably in CODEX STAN 72-1981 (Rev 2007) *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants*, for completeness and because of its central importance to CODEX STAN 156-1987, INC considers the definition should be retained within the standard. This definition would appear under the heading 2.2 Other definitions and read:

2.2.1 The term infant means a person of not more than 12 months of age.

Would you support inclusion of a definition for 'older infant' in the standard?

☒ Yes ☐ No

If yes, do you support the definition proposed by the Chairs?

☒ Yes, with minor amendment ☐ No

INC supports the proposal from the Chairs that, for consistency with the Guidelines for Formulated Complementary Foods for Older Infants and Young Children (CAC/GL 8-1991, Rev. 2013), the following definition for 'older infant' should be included in CODEX STAN 156-1987

2.2.2 The term older infant means a person from the age of 6 months and not more than 12 months of age.

For completeness, the term young children should be retained:

2.2.3 The term young children means persons from the age of more than 12 months (1 year) up to the age of not more than 36 months (3 years).

DEFINITION 2.2
2.2 ***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.
Should the current definition in 2.2 be; ☐ retained as is ☒ retained, but amended ☐ removed from the standard INC suggests this product description appear in an amended form under 2.3 Product descriptions: 2.3.1 Follow-up formula is a product based on milk of cows and/or other animals and/or other ingredients which have been proven to be suitable for the feeding of older infants or for the feeding of young children.

DEFINITION 2.3
2.3 ***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.
Should the current definition in 2.3 be; ☐ retained as is ☒ retained, but amended ☐ removed from the standard INC suggests that this product description should appear under 2.3 Product descriptions and be aligned with CODEX STAN 72-1981 (Rev 2007): "2.1.2 The product 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. "

DEFINITION 2.4
2.4 ***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.
Should the current definition in 2.4 be; ☒ retained as is ☐ retained, but amended ☐ removed from the standard INC suggests this product description appear in as is under 2.3 Product description: 2.3.3 ***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.

QUESTION
Are there any additional definitions that should be included in Section 2 (Description) of the follow-up formula standard? INC does not suggest any additional definitions be included in Section 2 but rather that the definition of 'calorie' be deleted from CODEX STAN 156-1987 for consistency with CODEX STAN 72-1981 (Rev 2007).

ESSENTIAL COMPOSITION

Energy		
Should the Energy density of Follow-up Formula for older infants be;		
☐ retained as is: min 60 kcal/100 mL max 85 kcal/100 mL	☒ Amended to align with IF standard min 60 kcal/100 mL max 70 kcal/100 mL	☐ Amended

INC supports the proposal to align with CODEX STAN 72-1981 (Rev 2007) and for the range to be 60-70 kcal per 100mL

INC supports the ISDI rationale that while there is no consensus on the recommended volume of formula which should be fed to infants from six months, if the range of volumes is 450 to 750 mL per day of follow-up formula,

- at the minimum compositional limit of 60 kcal/100 ml this would contribute between 40 to 67% of energy requirements, respectively
- if the upper limit of energy density is 70 kcal, this would contribute between 47 and 78% of energy requirements
- if the current upper limit in CODEX STAN 156-1987 of 85 kcal/100 mL is used, this would contribute between 57 and 95% of energy requirements.

If we use the calculations showing a maximum formula intake between 6 and 12 months of about 650 ml, at 6 months, WHO recommends 84 kcal/kg per day; the average weight of 7.6 kg gives 638 kcal per day.

WHO considers two thirds of a child's energy at 6 to 8 months should come from (human) milk (Infant and Young child feeding model Chapter for textbooks for medical students and allied health professionals, WHO, 2009), this equals 425 kcal per day which gives (with 66 kcal/100 ml) 648 ml.

Protein		
Should the Protein requirements for Follow-up Formula for older infants be;		
☐ retained as is: min 3.0 g/100 kcal max 5.5 g/100 kcal	☐ Amended to align with IF standard min 1.8 g/100 kcal max 3.0 g/100 kcal	☒ Amended min 1.65 g/100 kcal max 3.5 g/100 kcal

Minimum level

After the age of 6 months, the protein content of human milk is significantly decreased (0.7-0.8 g/100ml or 1.08-1.2 g/100kcal, Lönnerdal 2003). A minimum protein level is to address in part infants at reduced risk of inadequacy and INC supports a proposed level of 1.65 g/100kcal.

The EFSA PRIs (2012) for protein are 10 g for a 6-month old and 12 g for a 12-month old. WHO (2007) levels for a 6-month old is 10.2 g and 11.6 g for a 12 month old. For Australia and New Zealand, the AI is 14 g (or 1.6 g/kg body weight/day, assuming a reference weight of 9 kg) but only 50% of this is expected to come from the milk source in the 6-12 month age bracket. Based on FuF intake of 500 kcal/day, a protein content of 1.65 g/100kcal will contribute 8.25 g protein per day which is approximately 60% of the Australia and New Zealand AI.

In Australia, the Melbourne InFANT Program (Lioret et al, 2013) showed that at 9 months of age, the mean protein intake was 29 g per day which is well over the 14 g AI set by the Australian National Health and Medical Research Council and by the New Zealand Ministry of Health. Therefore, infants in Australia and New Zealand have a more than adequate protein intake.

There are also benefits relating to a lower protein intake. 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. Therefore, high milk protein intakes provided with formulae for infants should be avoided” (Koletzko 2013). The ENA recommends setting the minimum content of cows’ milk protein in follow-up formula at 1.65 g/100kcal, based on a good protein quality with an adequate content of bioavailable essential amino acids.

The EFSA 2014 report,

> "considers that cows' milk protein, goats' milk protein and ISP are safe and suitable protein source for IF and FOF based on intact protein. The use of other protein sources in IF and FOF and/or the introduction of new technologies need clinical evaluation and their safety and suitability should be established in the target population prior to their general use in IF and FOF."

INC therefore proposes that cows' milk in the revised standard is replaced by cows' and goats' milk where referred to in the protein sections of the revised standard.

INC also notes that, for formula manufactured from protein hydrolysates, CODEX STAN 72-1981 (Rev 2007) requires that formulae manufactured from protein hydrolysates are clinically evaluated for safety and suitability if the protein content is less than 2.25 g/100kcal.

The EFSA 2014 report states:

> "With respect to formulae containing protein hydrolysates, the Panel reiterates the conclusions of the SCF (2003b) that those formulae are insufficiently characterized by the declared protein content even if they fulfil regulatory criteria concerning amino acid patterns and contents and that the safety and suitability of each specific IF or FOF containing protein hydrolysates has to be established by clinical evaluation."

INC supports this position in principle but suggests amending the protein footnotes at this time so that they align with the comparable footnotes in CODEX STAN 72-1981 (Rev 2007).

INC also considers that it is appropriate to set the minimum protein for soy formula to 2.25 g/100kcal as is the case for CODEX STAN 72-1981 (Rev 2007) and recommended by EFSA 2014. INC therefore seeks for this to be covered in the protein footnotes applied – refer to the next section.

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

Maximum level

A proposal for the maximum level could be based on the Upper Limit of 14% of energy coming from protein.

Based on FuF intake of 500 kcal/d

> According to the guidance max 14 percent of energy should come from protein --> 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.

INC proposes an upper limit of 3.5 g as a pragmatic response to the implementation of the revised FUF standard globally. The current lower limit for protein in CODEX STAN 156-1987 is 3.0 g/100kcal. If the protein maximum for FUF is revised to this same level, 3.0 g/100kcal, this is mutually exclusive from the current standard and represents a radical change. This may not be acceptable to all jurisdictions. It could also potentially cause significant compliance issues for manufacturers that service multiple markets on the basis that different jurisdictions will implement the revised standard partially or fully at different times.

While the Early Nutrition Academy expert panel advice supports a lowering of the maximum level of 5.5 g/100kcal in CODEX STAN 156-1987, the Chairs of the eWG conclude that there is no demonstrable negative effects from high protein intakes. It is therefore recommended that the protein maximum in the revised standard be set at 3.5 g/100kcal.

Protein		
Should the footnotes related to Protein quality for Follow-up Formula for older infants be:		
☐ retained as is: footnote 1	☐ Amended to align with IF standard Footnotes 2-6	☒ Amended Align with CODEX STAN 72-1981 (Rev 2007) footnotes 2-6 as amended.

Footnote 1

Footnote 1 in CODEX STAN 156-1987 reads

> "Protein quality shall be determined provisionally using the PER method as laid down in the section dealing with methods of analysis."

The eWG states that PER method is a bioassay in rats and is now considered out to date.

INC supports the deletion of Footnote 1.

Footnotes 2-6

The Chairs propose footnotes 2-6 from CODEX STAN 72-1981 (Rev 2007) be applied to CODEX STAN 156-1987. INC supports this proposal in principle but recommends that the word 'infant' is removed where it appears in footnotes 4-6, and amended text for footnotes 5 and 6 which takes into account the latest EFSA recommendations.

Footnote 4 would then read:

> "[4] Isolated amino acids may be added to ~~Infant F~~formula 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."

Footnotes 5 and 6 would then read:

> "[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."

and

> "[6] ~~Infant f~~Formula based on other 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."
>
> Please refer to the section above (Protein: Minimum level) for rationale.

Lipids		
Should the compositional parameters for total fat, trans fat, phospholipids and specific fatty acids (linolenic acid, α-linoleic acid, lauric and myristic acid, and erucic acid) be;		
☐ retained as is	☐ Amended to align with IF standard	☒ Amended

INC considers that the compositional parameters for total fat, trans fat, phospholipids and specific fatty acids (linolenic acid, α-linoleic acid, lauric and myristic acid, and erucic acid) in CODEX STAN 156-1987 should be aligned with parameters in CODEX STAN 72-1981 (Rev 2007).

INC recommends that the eWG considers including DHA in this section, either as a mandatory requirement with a min and GUL specified, or alternatively with a GUL specified only (as per proposed approach for manganese and phospholipids). However, INC suggests awaiting the outcomes of the consultations currently taking place in EU, on the Directive to replace Directive 2006/141 from July this year, and for these to feed into deliberations together with consideration of the relative merits of global versus regional adoption based on DHA content of complementary foods and affordability. For example, if a minimum level is specified it may be appropriate to apply a footnote, as has been applied to iron in CODEX STAN 72-1981 (Rev 2007):

> "Levels may need to be determined by national authorities.")

In addition, if a minimum DHA level is mandated for FUF for 6-12 month olds, consideration will need to be given to how best to manage the non-alignment to the DHA provisions in the CODEX STAN 72-1981 (Rev 2007). In this context, the proposed approach of non-inclusion of a positive list for optional ingredients for FUF for 6-12 months rules out listing DHA in such a list.

INC considers that exclusion of DHA from the compositional recommendations for FUF for 6-12 month olds is undesirable because the internationally accepted recommendation of ensuring that EPA content is less that the DHA content would not be documented in the standard.

Carbohydrates		
Should Codex Follow-up Formula standard compositional parameters for carbohydrates be established;		
☐ No, retained as is	☒ Yes, to align with IF standard	☐ Yes, amend
INC supports compositional parameters for carbohydrates that are aligned with CODEX STAN 72-1981 (Rev 2007), that is a minimum of 9.0 g/100kcal and a maximum of 14.0 g/100kcal.		

Carbohydrates		
Should preferred carbohydrates be specified and/or should specific compositional parameters be set sugars and starches?		
☐ No, retained as is	☒ Yes, to align with IF standard	☐ Yes, amend
Lactose should be used as the preferred carbohydrate with no minimum level required but aligned with CODEX STAN 72-1981 (Rev 2007). Sucrose, Fructose, honey should comprise [less than 20%] of carbohydrates as aligned with CODEX STAN 72-1981 (Rev 2007). INC considers that consideration be given to including a provision that states “Glucose <2g” which would be aligned with the EU Draft Delegated Act. Unrestricted addition of starches within maximum carbohydrate should be permitted as long as the additions are free of gluten.		

Vitamins and Minerals

Vitamin/Mineral	Proposed minimum level (/100kcal, /100kJ)	Proposed maximum level (/100kcal, /100kJ)	Proposed GUL (/100kcal, /100kJ)	Support proposed levels	Alternate levels for consideration	Justification for proposed or alternate levels
Vitamin A (µg RE)	60,18	225,54	-	☒ Yes ☐ No	Min: 75 Max: 225 GUL:	See note below
A minimum of 60 aligns with CODEX STAN 72-1981 (Rev 2007) and is supported by some INC members, others support maintaining the minimum requirement to 75 as contained in CODEX STAN 156-1987. All INC members support proposed maximum of 225.						

Vitamin D_3 (µg)	1, 0.25	4.5, 1.1	-	☒ Yes ☐ No	Min: 2 Max: 4.5 GUL:	See note below
A minimum of 1 aligns with CODEX STAN 72-1981 (Rev 2007) and is supported by some INC members, others support increasing the minimum requirement to 2 based on higher daily levels now recommended. All INC members support proposed maximum of 4.5.						
Vitamin E (µg)	0.5, 0.12	-	5, 1.2	☒ Yes ☐ No	Min: Max: GUL:	
Vitamin K (µg)	4, 1	-	27, 6.5	☒ Yes ☐ No	Min: Max: GUL:	
Thiamin (µg)	60, 14	-	300, 72	☒ Yes ☐ No	Min: Max: GUL:	
Riboflavin (µg)	80, 19	-	500, 119	☒ Yes ☐ No	Min: Max: GUL:	
Niacin (µg)	300, 70	-	1500, 360	☒ Yes ☐ No	Min: Max: GUL:	
Vitamin B_6 (µg)	35, 8.5	-	175, 45	☒ Yes ☐ No	Min: Max: GUL:	
Vitamin B_{12} (µg)	0.1, 0.025	-	1.5, 0.36	☒ Yes ☐ No	Min: Max: GUL:	
Pantothenic acid (µg)	400, 96	-	2000, 478	☒ Yes ☐ No	Min: Max: GUL:	
Folic acid (µg)	10, 2.5	-	50, 12	☒ Yes ☐ No	Min: Max: GUL:	
Vitamin C (mg)	10, 2.5	-	70, 17	☒ Yes ☐ No	Min: Max: GUL:	
Biotin (µg)	1.5, 0.4	-	10, 2.4	☒ Yes ☐ No	Min: Max: GUL:	
Iron (mg)	1.0, 0.25	-	-	☒ Yes ☐ No	Min: Max: GUL:	

Calcium (mg)	90, 22	-	-	☒ Yes ☐ No	Min: Max: GUL:	
Phosphorus ((mg)	60, 14	-	-	☒ Yes ☐ No	Min: Max: GUL:	
Magnesium (mg)	5, 1.2	-	15, 3.6	☒ Yes ☐ No	Min: Max: GUL:	
Sodium (mg)	20, 5	85, 21	-	☐ Yes ☒ No	Min: 20 Max: 70 GUL:	See note below.
Chloride (mg)	50, 12	160, 38	-	☐ Yes ☒ No	Min: 50 Max: 190 GUL:	See note below.
Potassium (mg)	60, 14	180, 43	-	☐ Yes ☒ No	Min: 60 Max: 210 GUL:	See note below.
It has been suggested that it may be appropriate to recommend amended maximums for sodium, chloride and potassium if accepting a maximum of 3.5 g protein/100kcal due to the natural mineral content associated with milk protein. Consideration might be given to levels of 70, 190 and 210 respectively for sodium, chloride and potassium. These are proposed based on the maximums in CODEX STAN 72-1981 (Rev 2007) and multiplied by 3.5/3. i.e. pro-rated based on higher protein maximum proposed.						
Manganese (µg)	N.S.	-	100, 24	☒ Yes ☐ No	Min: Max: GUL:	
Iodine(µg)	10, 2.5	-	60, 14	☒ Yes ☐ No	Min: Max: GUL:	
Selenium (µg)	1, 0.24	-	9, 2.2	☒ Yes ☐ No	Min: Max: GUL:	
Copper (µg)	35, 8.5	-	120, 29	☐ Yes ☒ No	Min:35 Max: GUL: 250	Min aligns with CODEX STAN 72-1981 (Rev 2007). GUL proposed based on UL of 1000 ug/d with 700 kcal FuF intake and reflects the IEG recommendation.
Zinc (mg)	0.5, 1.2	-	1.5, 0.36	☒ Yes ☐ No	Min: Max: GUL:	

Footnotes

Footnotes for vitamins and minerals
Please comment on the footnotes included in the Consultation Paper for: Vitamins A, E, niacin, B_6, and C, as well as for iron, calcium, phosphorus and copper.
Are any of the footnotes included in the Consultation Paper for the above listed vitamins and minerals applicable to follow-up formula for older infants?
Vitamin A: CODEX STAN 72-1981 (Rev 2007) footnote reads: "[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." This footnote is appropriate for CODEX STAN 156-1987.
Vitamin D: CODEX STAN 72-1981 (Rev 2007) footnote reads: "[11] Calciferol. 1 µg calciferol = 40 IU vitamin D." This footnote is appropriate for CODEX STAN 156-1987.
Vitamin E: CODEX STAN 72-1981 (Rev 2007) footnotes reads: "[12] 1 mg α-TE (alpha-tocopherol equivalent) = 1 mg d-α-tocopherol." "[13] Vitamin E content shall be at least 0.5 mg α-TE per g PUFA, using the following factors of equivalence to adapt the minimal vitamin E content to the number of fatty acid double bonds in the formula: 0.5 mg -TE/g linoleic acid (18:2 n-6); 0.75 α-TE/g α-linolenic acid (18:3 n-3); 1.0 mg α-TE/g arachidonic acid (20:4 n-6); 1.25 mg α-TE/g eicosapentaenoic acid (20:5 n-3); 1.5 mg α-TE/g docosahexaenoic acid (22:6 n-3)." These footnotes are appropriate for CODEX STAN 156-1987.
Niacin: CODEX STAN 72-1981 (Rev 2007) footnote reads: "[14] Niacin refers to preformed niacin." This footnote is appropriate for CODEX STAN 156-1987.
Vitamin B6: CODEX STAN 72-1981 (Rev 2007) does not have a footnote. The footnote in CODEX STAN 156-1987 reads: "[3] Formulas should contain a minimum of 15 µg Vitamin B6 per gramme of protein. See Section 3.2.1.1." This footnote should be removed to better align with CODEX STAN 72-1981 (Rev 2007).
Vitamin C: CODEX STAN 72-1981 (Rev 2007) footnotes read: "[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." These footnotes are appropriate for CODEX STAN 156-1987.
Calcium: The footnote in CODEX STAN 156-1987 reads: "[5] The Ca:P ratio shall be not less than 1.0 and not more than 2.0. CODEX STAN 72-1981 (Rev 2007) does not have a footnote and instead states the requirements for the ratio of calcium:phosphorus in the essential composition section below phosphorus. INC recommends the same approach be applied to CODEX STAN 156-1987 for consistency.
Phosphorous: CODEX STAN 72-1981 (Rev 2007) footnote reads: "[18] This GUL should accommodate higher needs with soy formula." The footnote in CODEX STAN 156-1987 reads: "[5] The Ca:P ratio shall be not less than 1.0 and not more than 2.0." The footnote in CODEX STAN 72-1981 (Rev 2007) is not necessary and INC recommends inclusion of the calcium:phosphorus ration in the main text as described in the above note.

Copper: CODEX STAN 72-1981 (Rev 2007) footnote reads

"[19)] Adjustment may be needed in these levels for infant formula made in regions with a high content of copper in the water supply."

INC suggests reviewing the need for this footnote if INC's recommendation to increase the GUL is accepted. INC notes that high copper intake is no longer toxic at six months of age and this may obviate the need for the footnote.

Iron: INC notes the footnote in CODEX STAN 72-1981 (Rev 2007) reads:

"[17)] Levels may need to be determined by national authorities."

INC recommends alignment with this footnote.

Are there any additional footnotes that should be considered for vitamin and mineral additions to follow-up formula for older infants?

INC does not propose additional footnotes are necessary.

Other substances

Other substances		
Should compositional parameters for choline, myo-inositol or L-Carnitine be established in the revised Codex Follow-up Formula standard;		
☒ No, retained as is	☐ Yes, to align with IF standard	☐ Yes, amend
INC supports the current compositional parameters.		

Optional ingredients

Optional ingredients
3.3.2 **Optional Ingredients** 3.3.2.1 In addition to the vitamins and minerals listed under 3.2.4 to 3.2.6, other nutrients may be added when required to ensure that the product is suitable to form part of a mixed feeding scheme intended for use from the 6th month on. 3.3.2.2 The usefulness of these nutrients shall be scientifically shown. 3.3.2.3 When any of these nutrients is added, the food shall contain significant amounts of these nutrients, based on the requirements of infants from the 6th month on and young children.
Should the current provisions and principles in 3.3.2 for the addition of optional ingredients to follow-up formula for older infants (6-12 months) be; ☐ retained as is ☒ retained, but amended ☐ removed from the standard INC supports • The permission of "optional ingredients" where their safety and suitability for the particular nutritional use in products for older infants has been evaluated and established by generally accepted scientific evidence. • That guidance from recognized scientific expert groups should be taken into consideration when ingredients are introduced into Follow-up Formulae for older infants. • The alignment of the "Optional ingredient" clause of the future Standard with Clauses 3.2.1-3.2.3 of Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981(Rev.2007)), with appropriate amendment for the target population. • That optional ingredients do not need to be present in breast milk, rather that they provide a beneficial effect as demonstrated by generally accepted scientific evidence.

- The introduction of a provision that would authorize the marketing of Follow-Up Formulae for older infants for which the composition deviates from the criteria set in the Standard, provided related scientific evaluation of safety and suitability according to the principles mentioned above has been demonstrated.
- Scientific evaluation based on the proposed established principles conducted in other countries or related prescriptive regulation should be recognized to facilitate lead times in bringing innovative products to market and reduce regulatory burden.
-

INC does not support the establishment of a positive list of optional ingredient.

The alternative draft clauses are:

3.3.2 Optional Ingredients

3.3.2.1 In addition to the compositional requirements listed under x.x.x ~~vitamins and minerals listed under 3.2.4 to 3.2.6~~, other ingredients/substances ~~nutrients~~ may be added to provide benefits similar to the outcomes of populations of breastfed babies ~~when required to ensure that~~ in ensuring the product is suitable to form part of a ~~mixed feeding scheme intended for use from the 6th month on~~ progressively diversified diet.

3.3.2.2 The suitability for the particular nutritional use in products for older infants (6-12 months) shall be scientifically demonstrated as part of a complementary feeding diet; the safety of these ingredients/substances shall be scientifically demonstrated at the level of use. ~~The usefulness of these nutrients shall be scientifically shown.~~

3.3.2.3 ~~When any of these nutrients is added,~~The ~~food~~ product shall contain a significant amount~~s~~ of these ~~nutrients~~ ingredient/ substances to achieve the intended nutritional/physiological/ functional effect, taking into account levels of follow-up formula in complementary feeding based on the ~~requirements of infants from the 6th month on and young children~~ normal intake of older infants as part of a normal feeding diet.

Rationale:

INC strongly supports harmonisation through standards that ensure a high level of consumer protection, facilitate trade, ensure fair competition, and legal certainty at national level but that also enables innovation.

INC supports the addition of optional ingredients to follow-up formula for infants and young children that result from scientific and technological progress and whose suitability for a particular nutritional use has been established by generally accepted scientific data.

INC supports that the principles in 3.3.2 are amended to align with CODEX STAN 72-1981 (Rev. 2007) with appropriate amendment for the target population. INC does not support the establishment of specific permissions for optional ingredients.

INC supports the inclusion of a principle that provides that when an optional ingredient is permitted for infant formula (such as taurine, nucleotides and L(+) lactic acid producing cultures) it should be permitted as an optional ingredient for FUF without a separate approval being required. This principle was included in the eWG consultation paper and INC seeks to have this documented in the revised standard.

Breast milk composition can provide guidance for product composition. However, since breast milk is no longer the sole source of nutrition, safety and suitability of follow-up formula for older infants should preferably be assessed based on the beneficial outcomes of feeding the relevant ingredient versus the outcome for breastfed infants. Comparison with the WHO growth curve reference is also recognised.

The safety and suitability for the intended benefit of an optional ingredient should be demonstrated through a systematic review of the available scientific data and, where necessary, appropriate studies performed following generally accepted expert guidance on the design and conduct of such studies.

Guidance on the design and conduct of appropriate studies has already been published by several eminent scientific expert groups such as the Scientific Committee on Food, the UK Committee on the Medical Aspects of Food and Nutrition Policy, the European Society for Paediatric Gastroenterology, Hepatology and Nutrition and the American Academy of Pediatrics.

Breast milk is no longer the sole source of nutrition therefore it is more appropriate to retain the principle that the product should contain a significant amount of a substance based on the nutrition requirements of older infants.

A list of specific permissions, such as those stated in CODEX STAN 72 – 1981 (Rev 2007), may lead to confusion that only these optional ingredients would be permitted. The optional Ingredient sections in CAC/GL 10 – 1979 do not identify all permissions. INC considers that the addition of optional ingredients to follow-up formula for older infants and young children should be determined on a principles and evidenced-based approach as described.

This approach is influenced by the very long process involved for the revision of any International reference. INC considers that a clear, science-based and transparent process is established at national level to allow innovation such as the addition of optional ingredients to follow-up formulas for older infants and young children to be placed rapidly in countries that base their legislation on Codex.

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

Process to review the essential composition of follow-up formula for young children (12-36 months)
See options 1 -4 in the Consultation Paper.

INC has concerns with application of Options 1-3 individually and recommends combining elements of all three:

> Focus on Option 1; use the approach outlined in Option 3 (calculated for a range of FuF intakes) as a cross-check; and, also consider the nutrient composition of cows' milk outlined in Option 2.

As a general principle, the levels of individual nutrients for which cows' milk is considered a dietary source, should be within permissible ranges specified.